CENTERS FOR MEDICARE AND MEDICAID SERVICES
Medicare Evidence Development & Coverage Advisory Committee

September 12, 2007

Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, Maryland

Panelists

Vice-Chair
Steven Pearson, M.D., M.Sc.

Voting Members
Gregory L. Barkley, M.D.
Karl E. Becker, M.D., M.B.A.
Mark V. Boswell, M.D., Ph.D.
Gregory J. Dehmer, M.D.
Marion Danis, M.D.
Saty Satya-Murti, M.D., F.A.N.N.
Mercedes K.C. Dullum, M.D.
Loren Hiratzka, M.D.
Marvin Konstam, M.D.

CMS Liaison
Louis Jacques, M.D.

Consumer Representative
Randel Richner, B.S.N., M.P.H.

Industry Representative
Peter Juhn, M.D., M.P.H.

Panelists (Continued)

Guest Expert Panelists
Doran Edwards, M.D.
Barry L. Whites, M.D., F.C.C.P.

Executive Secretaries
Maria Ellis
Michelle Atkinson

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PANEL PROCEEDINGS

(The meeting was called to order at 8:08 a.m., Wednesday, September 12, 2007.)

MS. ELLIS: Good morning and welcome, committee chairperson, members and guests. I am Maria Ellis, an executive secretary with the Medicare Evidence Development and Coverage Advisory Committee.

The committee is here today to discuss the

evidence, hear presentations and public comment, and make recommendations concerning, one, the diagnosis and treatment of obstructive sleep apnea in Medicare beneficiaries who may be candidates for continuous positive airway pressure therapy. Two, alternatives to facility-based polysomnography in the diagnosis of OSA, including home sleep testing devices and clinical diagnosis without the use of sleep testing.
The following announcement addresses conflicts of interest issues associated with this meeting and is made part of the record. The conflict of interest statutes prohibit special government employees from participating in matters that could affect their or their employers' financial interests. Each member will be asked to disclose any financial conflicts of interest during their introduction.
We ask, in the interest of fairness, that all persons making statements or presentations also disclose any current or previous financial involvement in a company that

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manufactures or provides devices or other tools for the diagnosis and treatment of obstructive sleep apnea. This includes direct financial investment, consulting fees, and significant institutional support. If you haven't already received a disclosure statement, they are available on the table outside of this room.
We ask that all presenters please adhere to their time limits. We have numerous presenters to hear from today and a very tight agenda, and therefore, cannot allow extra time. There is a timer at the podium that you should follow. The light will begin flashing when there are two minutes remaining and then turn red when your time is up. Please note that there is a chair for the next speaker and please proceed to that chair when it is your turn.
For the record, voting members present for today's meeting are Dr. Karl Becker, Dr. Mark Boswell, Dr. Gregory Dehmer, Dr. Marion Danis, Dr. Saty Satya-Murti, Dr. Mercedes Dullum, Dr. Loren Hiratzka, Dr. Marvin Konstam, and Dr. Gregory Barkley. A quorum is present and no one has been recused because of conflicts of interest.
The entire panel, including nonvoting members, will participate in the voting. The voting scores will be available on our web site following the meeting. Two averages will be calculated, one for the voting members and one for the entire panel.

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I ask that all panel members please speak directly into the mikes and you may have to move the mikes since we have to share.
And lastly, please remember to discard your trash in the trash cans located outside this room.
And now I would like to turn the meeting over to Dr. Louis Jacques.
DR. JACQUES: Good morning. My name is Louis Jacques, I'm the director of the division of items and devices here in the Coverage and Analysis Group. I would like to thank you all for coming, and we certainly appreciate

the interest in this particular issue. As you can tell by the number of people in the room, many of you probably already know each other, this is a topic for which there is quite a bit of interest.
Just one reminder. The context of this discussion is OSA diagnosis or the qualification of Medicare coverage for CPAP devices. I realize OSA is a fascinating topic and this could turn into a three-day meeting if we don't sort of keep in mind the context. Thank you.
Now I'll turn things over to Dr. Steve Pearson.
DR. PEARSON: Thank you, Louis. I'm chairing this meeting, but it's also my first meeting as a MedCAC member, so I just want to say a brief welcome to everybody also, and also thank the staff within the Coverage and Analysis Group

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for the work they've put in to working with us already on the questions, helping us understand the issues, because obviously we want to try to provide a discussion that will benefit them in forming their decisions. I also want to thank all the members of the panel who are here today for the work that they already did and for what we will do today.
I believe that the first order of business is for us to introduce each of ourselves and to declare our conflicts of interest, so I will start.
I am the president of the Institute for Clinical and Economic Review at Harvard Medical School. My conflicts of interest would include the fact that I'm a paid consultant to America's health insurance plans, and I think that covers it.
DR. BECKER: I'm Karl Becker, recently retired from the University of Kansas in Kansas City, I'm an anesthesiologist. I have no conflicts of interest.
DR. BOSWELL: My name is Mark Boswell, I'm an anesthesiologist from Texas Tech University.
DR. DEHMER: My name is Greg Dehmer, I'm a professor of medicine at Texas A&M College of Medicine and director of the cardiology division in the Scott & White Clinic. I'm an interventional cardiologist and have no conflicts of interest.
DR. DANIS: My name is Marion Danis. I'm in the

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section of ethics and health policy in the department of bioethics at the National Institutes of Health, I run the ethics consultation service there and I have no conflicts.
DR. SATYA-MURTI: I am Saty Satya-Murti. I am a clinical neurologist and an independent health policy consultant. I used to be a Medicare medical director for several years. I have no conflict of interest.
DR. DULLUM: Mercedes Dullum, cardiac surgeon, Cleveland Clinic Florida. I have no conflicts of interest.
DR. HIRATZKA: Loren Hiratzka, a community cardiac surgeon from Cincinnati, Ohio, and I'm also medical director for Tri-Health Hospitals' cardiac surgery programs. I have no conflicts of interest.
DR. KONSTAM: Mark Konstam, chief of cardiology at

Tufts New England Medical Center, and I have no conflicts of interest to declare.
DR. BARKLEY: I'm Greg Barkley, I'm a neurologist at Henry Ford Hospital in Detroit and have no conflicts of interest.
DR. JUHN: I'm Peter Juhn, vice president, evidence and regulatory policy at Johnson & Johnson, and I am the industry rep. No conflicts of interest to report.
MS. RICHNER: I'm Randel Richner, a private consultant, and I have no conflicts of interest.
DR. EDWARDS: Doran Edwards, medical director of

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the Statistical Analysis DMERC and I have no conflicts of interest.
DR. WHITES: My name is Barry Whites, I practice pulmonary critical care, and am also medical director for TriSpan, which is a Part A intermediary. No conflicts.
DR. PEARSON: Thank you, and just a quick word of housekeeping. You may note, we do have a very full agenda today, but I cannot envision any of us being able to sit from eight until noon without at least some break. So we're going to try to squeeze a five-minute break in around, sometime in between 10 and 10:30, we'll see how the flow of the morning goes, but it's just to remind the panel members as well that we'll have a chance to get a drink of water and to stand up.
So, I'm going to now ask Francina Spencer to, if she would please, to present the voting questions so that we can have that as a framework as we discuss the questions.
MS. SPENCER: Once again, good morning, and welcome to today's MedCAC on OSA, the diagnosis of OSA for CPAP.
First -- I will wait for the slides.
I would like to introduce to you the members of our CMS team, and when I call your name, would you please stand, some of whom you have already met. Miss Michelle Atkinson, executive secretary. Miss Maria Ellis, executive secretary. Dr. Ross Brechner, lead medical officer. Miss Jean Stiller, analyst. Dr. Louis Jacques, director of the division of

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items and devices. Dr. Steve Phurrough, director of coverage and analysis, who is not here today. And I am Francina Spencer.
In the interest of time, this is the purpose of the meeting.
The Medicare coverage criteria for CPAP therapy requires among other things, a diagnosis of moderate or severe OSA; surgery must be a likely alternative; an AHI greater than 15, or between five and 14 with symptoms. The AHI must be based on a minimum of two hours of sleep recorded by PSG using actual recorded hours of sleep.
Our current policy specifically states that the PSG must be performed in a facility-based sleep study laboratory and not in the home or in a mobile facility. In 2004 CMS reconsidered the policy to include the use of unattended portable home sleep devices to diagnose OSA for CPAP devices. At that time CMS found insufficient evidence to conclude that

unattended portable multichannel sleep study testing is reasonable and necessary in the diagnosis of OSA for CPAP therapy. The test remains non-covered for this purpose. In January of 2007, CMS received a request from the American Academy of Otolaryngology, Head and Neck Surgery, to modify this decision to include the use of unattended portable multichannel home sleep testing devices as an alternative to facility-based PSG in the evaluation of

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OSA.
In addition, CMS has received numerous requests concerning the criteria for determining the AHI, more specifically the requirement that the AHI must be based on a minimum of two hours of sleep recorded by PSG using actual hours of sleep. It has been suggested that this requirement be changed to a minimum of two hours of sleep or less if the actual number of AHI episodes reported is 30 or more in less than two hours.
These devices have been approved or cleared by the FDA for use in the home or portable setting by the 510(k) clearance process, which means that they are substantially equivalent to devices already on the market.
The CPAP MedCAC questions to be addressed today are:
One, how confident are you that there is sufficient evidence to determine that each of the following strategies can in routine use produce an accurate diagnosis of OSA for the prescription of CPAP?
Two, for each OSA diagnostic strategy for which there is enough evidence in question one, how confident are you about the sensitivity, ability to minimize false negatives, and specificity, ability to minimize false positives?
Three, should each of the following be weighed as a

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criterion for the prescription of CPAP for the diagnosis of OSA?
Four, CPAP is currently a standard treatment for OSA. Defining successful treatment as combined subjective improvement of OSA clinical signs or symptoms and continued patient use of CPAP for two or more months, how confident are you that there is sufficient evidence to determine the ability of each of the following diagnostic strategies to accurately predict successful treatment of OSA with CPAP?
Five, how confident are you that each of the following diagnostic strategies will accurately predict successful treatment of OSA with CPAP?
Six, how confident are you that no clinically meaningful harm to patients will be caused by a trial by CPAP strategy as an alternative to strategies that require a positive prior PSG or home sleep test before CPAP.
And finally, how confident are you that your conclusions can be generalized to, A, the Medicare population, and B, providers in community practice?
Thank very much and continue to enjoy the remainder

of the meeting.
DR. PEARSON: Thank you, Francina. The panel has had a chance for one conversation about, to clarify questions about the questions themselves, but because we have just a few minutes, I just want to make sure if there are any

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specific clarifying questions that anyone on the panel thinks that they should ask now, so that everybody will try to have the same perception of these questions going forward. Yes?
DR. SATYA-MURTI: One of the questions, I think five, it says other. So we can assume anything other than type two, four -- in question three, other types? Because some of the presenters have put in footnotes as to what they believe others to be.
DR. PEARSON: That's a good question. Louis, can you clarify that for us?
DR. JACQUES: Sure. In the context of question three, other was simply, are there any other factors in line with the various clinical factors, either symptoms or signs noted above, that the committee would think ought to be included in this particular question. Although we tried to cast the net fairly broadly from everything from snoring to various more formal measurements of scoring, certainly we're not claiming to have exhausted every possible option there. So that's simply, if the committee identifies something else that they thought ought to be weighed as a criteria, we're leaving that as a possibility for the question.
DR. PEARSON: Yes.
DR. KONSTAM: You know, I just have a general question. With regards to many of or all of these questions we're going to be asked, can this or that strategy do this or

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that, or be used for this or that purpose. I guess when answering those, you know, will there be a presumption that, you know, additional criteria can be established, or certain patient processes or standards that be developed, you know, to make that can be reasonable? Or is it going to be necessary for us to find those in answering each one of those questions?
DR. JACQUES: We don't have a specific question about certification of particular providers or technicians or others, although certainly we've heard a lot of interest on that particular issue. If the committee feels that there is strong evidence to support particular qualifications, we are certainly happy to hear that from the committee. But we did realize that even in these particular questions, absent that additional discussion, was likely to take the whole day. There are other things that Francina has mentioned in terms of some of the secondary questions or requests that did come up in addition to the formal requestor of record, and not all of those are reflected in the committee questions here. CMS can certainly deal with those ourselves. If the committee wants to provide us some input, it certainly could, and we would be happy to receive it. But we felt that if we asked the questions for every sort of possible nuance

in this, then we would probably be pressed for time.
DR. KONSTAM: Well, I guess as a follow-up to that,

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if we come to do that, I mean, I'm thinking it might be important for us to state the qualifications that we have in our minds about the questions.
DR. JACQUES: We certainly could. The last question, which is how confident are you that your conclusions can be generalized to, and then subsection B of that was providers in community practice. And that would be the place, if you had any particular reservations that the trials were only done in certain types of facilities or by certain providers with particular qualifications, that would be the place to sort of opine on that.
DR. PEARSON: Peter, one more quick question and then we will move to the presentations. Peter.
DR. JUHN: Yeah. I wanted to (inaudible).
DR. PEARSON: The question was whether there is a distinct difference between question four and five.
DR. JACQUES: Yes. This is one of the ways in which the Coverage and Analysis Group sometimes likes to split the issue, which is, is there sufficient evidence with which to make judgments and then in the judgments, you know, how much confidence do you have in its performance. So in the first they're just asking, is there enough evidence for you to have a reasonable consideration, if you will.
DR. PEARSON: We will make sure that that's clear again, because that's true for some of the other questions.

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All right. Why don't we move forward, and we will have time again after the presentations, other issues or thoughts may come up about the questions, but why don't we move forward with the first presentation, which is from Dr. Eric Mair.
DR. MAIR: Good morning. Panel members and esteemed colleagues, it's a great honor to speak with you this morning. The American Academy of Otolaryngology has funded my travel for this meeting and I have absolutely no financial involvement with any manufacturers of any product for home sleep studies. However, I do have financial involvement with in-lab polysomnography sleep centers, so today you'll see that I'll actually speak against my personal financial interests, so please listen closely.
There are 18 million Americans who suffer from apnea. We know it can be markedly debilitating. There are negative impacts of unmanaged apnea, specifically higher healthcare expenditures and a lower quality of life. The existing diagnostic capacity is lacking since the home studies are really not yet recognized by CMS for reimbursement. Most apnea patients don't even know from what they suffer and the patients many times incur hardships and high costs of in-lab PSG tests. What I would like to state today is that there is sufficient data that exists to support decisive action for the approval of home sleep studies.
So what about this diagnostics at home stuff? It

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seems logical, we've been talking amongst everyone and it's inevitable, it's coming, it's down the pipeline, but yet despite its promise, we continue years upon years to debate whether or not we're going to adopt it. Why not? Well, home studies are less expensive, they're accurate, they're safe, they're definitely more patient-friendly than the in-lab studies that I'm used to too. Well, the problem is there are political influences that have played a major role in the debate.

Let's back up a little bit. The Holter monitor, which is an ambulatory electrocardiography device, it was developed by Dr. Norman Holter about 50 years ago and initially it was about a 75-pound device, it was a backpack actually that went onto the patients and the patients were allowed to walk around their room and stay in the hospital only, supervised by hospital staff only, to get the recordings for the Holter monitor, to see if they had an arrhythmia or not. Fewer patients were treated for many years with the Holter monitor because it was a greater expense and there were many undiagnosed patients who had significant arrhythmias.

Well, now we know that the Holter monitor is about as heavy as a paperback book and we can, it's very technologically advanced, and it can do tracings for up to a month for a patient at a time. That didn't come overnight

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and it met with much opposition. Now, we still do have the 75-pound Holters; they're the hospital telemetry units that we have. They're needed. And if we take a step back now and say what about in-lab polysomnography, definitely we need this. There's no question that we need this. But I think that in light of these lightweight Holters, these home studies, we can really make the diagnosis of obstructive sleep apnea much quicker, much more effectively, safer, and in a home environment. Can you imagine today what it would be like if we still had attended Holter monitoring, this would be abysmal. But just years ago we had the same type of meetings where people were very much against having unattended Holters. Technology has come a long way and I think what we need to do is to evaluate it very closely and to embrace what we can.

Industry politics abound. Everyone's rooting for their favorite horse. The horse up front, the front runner is by far the in-lab PSG. All the sleep centers vote yes, let's do this and let's keep this. The home testing is running a distant second or third, and it's supported by the non-sleep centers. The clinical impression for the folks that say let's just treat patients who potentially have obstructive sleep apnea with CPAP, they're just starting to emerge in this race. Unfortunately, the problem is that the patients seem to be the big losers in this scenario.

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Let's answer some questions: Is there enough evidence that analysis based on recordings done using

portable recording devices, home studies, do they provide reliable scientific data which is as good or even better than polysomnography. A recent comprehensive meta-analysis specifically looked at this question with 18 prospective cohort studies of taking tests where you have both home sleep studies and in-lab polysomnography done together on the same group of patients. There were very positive meta-analyses saying that home studies definitely have a role now. However, the negative comment, the only negative comment really that was made is that there's a 10 percent difference approximately between the AHIs and the RDIs between polysomnography in facility and home testing. But what about this 10 percent? Is this going to make us say we shouldn't fund or recognize home studies? How accurate does it need to be? Does it need to be within five percent between home studies and in-lab polysomnography? Maybe two percent, maybe .2 percent. Well, how do we make this decision? The way we make this decision, how close is close enough, is we need to find out, does clinical intervention change? Does the test result make me want to change my clinical practice from home lab versus in-lab polysomnography? Let's look at that. First of all, you see on your

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left-hand side is the in-lab PSG RDIs ranging between a hundred down to five. Let's take that 10 percent difference in home RDIs on either end. With an RDI of a hundred in lab, that would be 90 to 110 on home sleep studies; would that change anything that we do clinically for the patient? Absolutely not. Follow this all the way down to an RDI of five and it's still, a 10 percent difference is not a clinically important difference. So we're looking at more than just numbers, we're looking at patients and how we treat the patients. And the conclusion is there's no difference, there's no treatment differences in any RDI range. Well, what about this gold standard? The gold standard we know, we say is polysomnography in lab, this is what we base everything on. If we take it back a little bit, I served 20 years in the military and recently retired, and one of my best tours was over in Europe. I spent four years in Europe and got a great love for renaissance clocks. Now here's a renaissance clock from outside of London, and the people in those days, in the renaissance days they would look up and say what time is it? They would look right up on the clock and say I know what time it is, because that's the gold standard, that anyone knows what time it is by looking at the town's renaissance clock. And then there's this other little pesky thing that comes on years later called the atomic clock.

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Well, we know that the accuracy of the renaissance clock is a few seconds off per day, versus an atomic clock which is a partial second off in over ten million years. There's a big difference. However, if we study the gold standard, the renaissance, and compare it to the atomic

clock, the sensitivity and specificity is going to be off on the atomic clock. And assuming that the renaissance clock is the gold standard, we'll come up with a definition to say this atomic clock is not worth it, it's 10 percent off, we shouldn't use it.
Well, let's take a look at some other clocks.
France, here's one from Italy and one from Sweden. Now our studies says let's compare this atomic clock, let's say the home study, to polysomnography in different sleep centers.
The same thing we're going to find out is that it's not accurate. And the problem is not that the atomic clock is not accurate, but the problem is many of our studies do the wrong comparisons. Specifically what we need to do is to compare each of the renaissance clocks to each other; only when you compare each renaissance clock to another renaissance clock, you're going to find out that there may be variability and there may be problems associated with the gold standard. The gold standard may be tarnished. A device can only be as valid as the standard used for its comparison.
Well, our gold standard, we know from good studies

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now that it really doesn't stand up to inspection. The variance is a major source of problems with today's polysomnography. Specifically, the results of a PSG for AHI between technicians, different technicians, will vary between 15 to 35 percent. Between centers will vary between 20 to 38 percent. And night to night variance may be between 12 and 35 percent. I'm sure everyone here in the room has been involved somewhat with in-lab polysomnography and knows what it's like. Maybe you don't personally, but to know what it's like to be hooked up to EEGs, EKGs, weights, and to lay on a bed that you don't know where it's located, have a video look at you, this is not quite the testing that we want to really find what apnea's about. So there's notable variances.
Well, new studies? I think that we might need new studies. That's what's going to be the help for us right now. Well, a meta-analysis has recently looked at the current literature and it very positively supports home studies. Then we have the American academies of we want to own the sleep centers and we don't want home sleep studies, we have those studies that are sponsored by those societies. And on the other hand we have the medical industry studies, they're sponsored by the deep pockets of the medical industry, and each wants to promote their own cause. It's important that we know that there are studies out there that aren't sponsored by certain societies or by certain agencies,

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and these studies I think we should bring our attention to. One of them I was very fortunate to be involved with and it involved more of a cooperative effort with sleep medicine doctors working with sleep surgeons and other sleep types of doctors. Where we took patients and just did other studies that had already been done, supported by other companies or supported by sleep societies, now we're doing the studies, and very interestingly doing double line

analysis, looking at ROC curves and Bland-Altman curves, we found that when you do a PSG and a home study together, you take that data, you send it to other PSG labs in your community, the same data, the raw data, and you have those folks decide what is the AHI, does this patient have apnea or not? It's very interesting when we looked at that data versus the home study data that was sent also, to other computer system data, that the variance was greater between the PSG labs themselves than between the home studies and the PSG labs.

I had the honor of speaking here three years ago and I spoke to some of the panel members afterwards after the voting, it was a close vote, and sharing a little bit of this data. It's much more developed now over these last three years. One of the comments from the board members was, man, if the PSG were up here at CMS for whether or not it was going to be approved, it might not be approved with how

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strict the criteria is today. But we're looking at, just as the previous talk showed, a substantial equivalence. There's definitely substantial equivalence between the polysomnography and the in-lab sleep studies.

But we know that obstructive sleep apnea is more than a test. We're treating patients, we aren't treating numbers. This is a multidimensional process involving history, physical exam, subjective and objective metrics which the polysomnography tests, whether it be the home studies or the in-lab multichannel polysomnography, is only one of the tests. We're guided by more than just one test alone, especially in the elderly Medicare population where a high AHI may not be associated with obstructive sleep apnea as a symptom.

Another question I would like to address in my time is, is a CPAP trial alone an adequate diagnostic method? A CPAP trial unfortunately does not measure the severity of obstructive sleep apnea. So these are the patients that I think may have apnea, they're going to get a CPAP machine. Severity of obstructive sleep apnea is important from a mortality statistics point of view, and almost always the patients with severe apnea will have a much better compliance because they know they need to from a medical point of view. This CPAP trial alone doesn't give us that information. Testing a patient under manipulated conditions will also

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alter the outcome. Compliance with CPAP is not great. Patient motivation is needed to maybe improve, if they know that my AHI is over 20 and my mortality statistics are higher. CPAP trials alone without testing can result in unnecessary treatment in non-apnea patients. And it's definitely a more expensive outcome option than home studies. It does not allow for the alternate treatment considerations either. And the bottom line is, we really can do better.

Clinical impressions of obstructive sleep apnea are seen as many things to many people. Even at the time of Shakespeare, in Henry IV, Pato says, look over there at

Falstaff. He's asleep behind the arris and snorting like a horse. He's snoring, he picks up the snoring aspect of it. And the prince looks by and says, hark, how hard he fetches breath, noting the apnea part specifically.
So that leads to the next question, is clinical impression alone adequate for the diagnosis of apnea? And I think the data is strongly out in our literature published that says that clinical impression alone is not a reliable indicator of the presence or absence or level of severity of the apnea. Clinical evaluation can serve merely or in helping as a screening tool to determine which patients should be referred for definitive diagnostic sleep tests. It's almost a flip of a coin if you have a patient who you think may have apnea and you look at a PSG or a detailed

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subjective metrics, that it's very difficult to tell on a clinical impression alone.
And in summary, undiagnosed obstructive sleep apnea is a substantial healthcare problem. This is something that is going to worsen unless we do something about it. There's a definite political bias that has negatively impacted patient care. Think Holter. We don't want to go down that same route that we went. The bottom line with Holter now is great, but it took years to come across with this stuff. Home study sleep testing is an excellent and an accurate tool for diagnosis of obstructive sleep apnea symptoms as shown in meta-analyses. Clinical impression is only useful for the determination of who needs a sleep study. An obstructive sleep apnea diagnosis from CPAP trials presents problems, and the problems may be with misdiagnosis and with substantially higher costs. Sufficient data now exists to support the immediate decisive action on allowing home testing.
Thank you for your time.
DR. PEARSON: Thank you very much. Both literary and punctual, much appreciated. I hope the panel members will write questions if they have them for the presenters down. We will have some time after lunch to pose questions to the presenters.
We would like to move ahead, though, to the next presentation, which is from Thomas Trikalinos, who is

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assistant director of the Tufts New England Medical Center Evidence-Based Practice Center, and he's going to address the technology assessment.
DR. TRIKALINOS: Hello. I'm going to discuss the technology assessment on the home diagnosis of obstructive sleep apnea. This was done by the Tufts New England Medical Center Evidence-Based Practice Center.
There were several key questions and we simplified them so that we can read them quickly. Does the baseline severity of the condition predict response to CPAP or clinical outcomes? How do portable monitors compare with facility-based polysomnography in diagnosing the condition? What effects do technologist support and automated scoring have on the diagnostic abilities of portable monitors? What

are the complications, harms and adverse events pertinent to sleep studies? And what are the errors and data loss rates that are associated with facility-based PSG and portable monitors?
I believe that the panel members already have seen a draft of the report; there's an updated draft of the report and I hope that you have seen the updated one.
We undertook a systematic review of the literature to address these key questions. We did MEDLINE searches and we produced the reference lists from relevant papers to identify studies that would be possibly eligible. We also

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searched the database of the FDA to identify reports of adverse events secondary to medical device use.
Because we have many different key questions, they are addressed by different research designs. Therefore, I do not list the exact eligibility criteria here. Generally we included prospective studies. There is a comprehensive list of criteria in the report, details are in there. However, if you would like, I could elaborate.
There are many different sleep monitors as you will see and as you know, and we decided that we needed a scheme to classify them. We therefore modified a scheme that had been proposed by the then ASDA, now it's the American Academy of Sleep Medicine, to classify these different monitors.
This is an operational classification and it has been modified because there are newer monitors that have emerged, that have been developed, and they use newer channels that were not, that had not been proposed when the original specification was introduced.
Let me guide you very quickly through this slide.
We want to estimate the apnea-hypopnea index as the portion of the number of respirator events over total sleep time, total actual sleep time, not total recorded sleep time. The ASDA classification used an operational criteria to decide whether information on airflow that quantifies the respiratory disturbances was adequate or not, and the

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operational criteria was at least two airflow channels or one airflow channel and one respiratory effort channel.
Depending on whether the different monitors have two airflow or effort channels and whether they identified or distinguished actual sleep from total recording time, they are classified in these categories.
As I said before, there are several newer monitors that would be classified in category IV; that means that they do not have at least two airflow channels and they do not identify sleep/wake. The major criteria that throws them into category IV is that they do not have two airflow channels. To do them justice, we split category IV into two sub-categories, into two subgroups, subgroups that have portable monitors that have at least three channels, monitors that gather at least three different bioparameters, versus the old category IV which is portable monitors that gather only one or two bioparameters. And in this category IV class

are where most of these newer monitors fall.
So we did a systematic review of the literature.
We examined 3,500 plus abstracts that came out of our searches, and finally we included 95 publications.
I will be naming the key questions as they are named in the technology assessment to facilitate cross-referencing for those who want to do it.
So the question was, what is the ability of

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apnea-hypopnea index at baseline to predict outcomes after a CPAP treatment period? We did not identify any studies that associated baseline apnea-hypopnea index with response to CPAP with respect to mortality, cardiovascular outcomes, and outcomes of any sort. However, we identified three RCTs, or two RCTs and three prospective cohorts that associated baseline apnea-hypopnea index with response to CPAP and CPAP compliance. Two RCTs assert associations with changes in quality of life scores. And changes in physiological measurements like changes in objective wakefulness tests, the effort sleepness score, changes in blood pressure ranges, were described in four cohorts.
The synopsis of all this is that baseline apnea-hypopnea index or RDI, depending on how it's measured by facility-based PSG or portable monitors, is modestly associated with response to CPAP use or CPAP adherence, quality of life scores and physiological measurements. Of note is that all the studies that were eligible focused on very selective populations, and people who had severe sleep apnea or high apnea-hypopnea indices on average. Therefore, these data cannot be used to describe or answer the question of whether facility-based PSG is generally useful in the management of people who are suspected of the disease.
Question two pertains to the comparison of portable monitors with facility-based PSG. There were 75 studies that

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were eligible here and there were studies that assessed measurements with facility-based PSG and portable monitors in the same patients, prospective studies without overt verification bias. In these studies we assessed how well the monitors, the measurements from the portable monitors agreed with the corresponding measurements from facility-based PSG, and how well the measurements of the portable monitors were able to predict apnea-hypopnea index and facility-based PSG was sufficiently high to be suggestive of the disease. And the definition of sufficiently high to be suggestive of the disease was more than 15 events per hour, although alternative categories of more than 10 or more than 20 events per hour were also assessed.
I will just make some methodological comments.
When we assessed the agreement between two measurements, we usually had this kind of scatter plots, where the measurement with the portable monitor, for example, is on the vertical axis and the measurement with the other monitor, with the facility-based PSG, the reference standard, is on the horizontal axis. Were the two measurements identical, all

points would align across the red dashed line, which is the line of identity. This scatter plot is informative but is not as informative as a different kind of plot. This is a difference versus average plot, a so-called Bland-Altman plot. Here on the vertical axis

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you've got the difference between the two measurements, and on the horizontal axis you've got the estimate of how large this difference is, how large the true value is. Here it's very easy to appreciate that individual patients, individual measurements may vary greatly. For example, we had several points that where the difference is more than 14 events per hour for a specific patient, although the average difference, which is denoted by the line that says bias, this is the average difference between the two measurements, and it signifies a systematic error, a systematic -- sorry -- a systematic difference between the two measurements. Bias is a technical term. It's approximately minus ten. Now, we can use Bland-Altman plots to summarize these views by only three lines; this is the mean bias, and the upper and lower limits of agreement. The limits of agreement denote the region in which the mean bias is expected to find itself 95 percent of the time. Broad limits of agreement mean that the individual measurements are not interchangeable. Assessing concordance is different from assessing the ability to predict apnea-hypopnea index suggestive of the disease. We can consider portable monitors as diagnostic tests and we can assess their sensitivity, their ability to minimize the false negatives, and their specificity, their ability to minimize false positives. It's informative to

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plot sensitivity and specificity variance in plots like this. Studies that have perfect sensitivity and specificity, 100 percent sensitivity and 100 percent specificity, would find themselves in the upper left corner of the graph. Studies that are completely noninformative would line themselves across the major diagonal at the top, they would be no better than chance there. As I said, portable monitors are diagnostic tests, and one can assess the information that's conveyed by a diagnostic test to identify people with a disease with a quantity that's called the positive likelihood ratio. Also, someone can assess the information conveyed by a portable monitor to truly rule out the presence of disease by a quantity that's called the negative likelihood ratio. Negative and positive likelihood ratios of one have no diagnostic ability, have no information. Studies, tests that are good by convention are said to have positive likelihood ratios of more than ten and negative likelihood ratios of less than .1, and these are easily identified on the plot. The shaded triangle that's on the vertical axis on the left denotes the region where studies with high positive likelihood ratios would fall. The upper shaded region denotes where studies with very low negative likelihood

ratios would fall, and the cross-section, the polygon in the upper left corner is studies with both high and low

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likelihood ratios would fall. So whenever I refer to studies of diagnostic ability, of studies of portable monitors as having high diagnostic ability, I would say that the studies lie on or very, very near these shaded areas.
There were many portable monitors and we organized the presentation according to the operational specification scheme. Most studies pertained to type IV monitors, either type IV with three or more bioparameters or type IV with less than two bioparameters, two or less bioparameters.
This is, I'm going to show you only two graphs and then I'm only going to summarize, because there are many, many different subanalysis and subgroups. This is a graph that tries to summarize together, a Bland-Altman type of analysis across several studies. It has to do with home testing type III studies. On the vertical axis is, as in the Bland-Altman plot, the difference between the two measurements. Forget the small letters below at the bottom of the graph, they're just the monitors and the studies from which they come from. Each study, here we have one, two, three, four, five, six, seven studies, each study is denoted by three lines, which is the mean bias and the limits of agreement. And I have drawn gray shaded areas to group together where all the mean biases range, and upper and lower gray areas to group together where all the upper and lower limits of agreement range.

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So as we see for this specific example, mean bias may range from plus five to minus, I don't remember, seven or eight. You can take the whole message that the limits of agreement across most studies are not big, are not broad, that they cannot exclude differences of 20 or even 40, which means that the two monitors do not give measurements that are interchangeable.
Here is an example of the analysis that assessed the ability of portable monitors to classify people to predict apnea-hypopnea index that's more than 15 in facility-based polysomnography. In the left panel we have different cutoffs shown. We see that for example in the right picture, studies cluster close to the areas that signify high diagnostic ability. So I'm going to proceed with the synopsis for all monitor types, difference versus average analysis suggests that the measurements are not interchangeable. However, the discrepancies between the measurements are more pronounced for larger values of apnea-hypopnea index or RDI. Therefore, a classification to high and low apnea-hypopnea index or RDI can still be good. That is, both measurements may be discrepant and they may differ by a lot, but they are both sufficiently high, let's say above 15 percent, sorry, 15 events per hour.
For type II monitors, based on limited data, type II monitors may identify apnea-hypopnea index more than 15

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events per hour with high diagnostic ability. The same is true for type III monitors, they may identify apnea-hypopnea index suggestive for the disease, more than 15 events per hour. This is true also for more than 10 and more than 20 events per hour, with more limited data for high diagnostic ability.

Overall, the diagnostic ability appears to be higher for studies that are conducted in the lab setting. This is no surprise; these are usually studies that are conducted similar in time and space so there's not that variability, but there are other factors also.

And for studies with manual scoring of the portable monitor recordings, studies of type IV monitors with three or more bioparameters showed high diagnostic ability to identify the condition as defined, actually to identify apnea-hypopnea index suggestive of the condition. And the same was true for studies with type IV monitors that assess one or two bioparameters, but here the presentation of the individual studies was selective, selective dates, and tended to present the cutoffs with portable monitoring that maximized sensitivity and the cutoffs that maximized specificity, so we have the extreme cutoffs on the ROC curve, and these usually fall into the shaded areas that are suggestive of high diagnostic ability.

Some comments on how applicable are these results

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from these studies to the Medicare population. All the studies focused on people who were young, average age ranged from 50 to 52 on median. They are predominantly male, predominantly obese, and in most of the studies comorbidities that may affect sleep have been excluded. Moreover, they're conducted by specialists who are very familiar with the disease and its treatment, and its differential diagnosis.

So in the Medicare population, if anything, I believe that we would expect lower specificity of portable monitors, relatively more false positives. This is because in the Medicare population you have comorbidities like cardiac failure, atrial flutters, strokes, comorbidities where you have Cheyne-Stokes breathing patterns, and perhaps certain portable monitors are not able to differentiate them from obstructive sleep apnea, they need additional information.

In addition, widespread use of this technology by health providers who are not familiar with the disease would probably result in worse overall diagnostic ability. This is very well known from clinical trials and one might speculate it for diagnostic studies too.

What is the role of technologist support and patient education, specifically in the home setting? For studies in the home setting, there is no data that allows us to answer this question.

Comparison of manual and automated scoring, in

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studies that assessed both manual and automated scoring in the same patients, manual scoring or manual editing of

automated scoring seems to be superior to automated scoring alone to identify apnea-hypopnea index more than 15 events per hour in facility-based PSG. However, in considering this, you should keep in mind that different monitors have different scoring algorithms and different algorithms evolve with software versions, so this is a finding that pertains to these specific studies rather than a readily generalizable finding.

What are the errors that are related to automated scoring and manual scoring? There are no detailed data on specify types of errors that are specifically related to automatic scoring or manual scoring. No robust conclusions can be drawn.

For studies of portable monitors in the home setting, what errors are related to unattended use? There are no studies that directly relate unattended usage in the home setting with specific errors. However, there are several studies with indirect data that are compatible with the notion that there is a reduced error rate when you have some kind of feedback teaching alerts that alert the user when something goes wrong, or when data were remotely sent to a technologist in the lab who was monitoring and calling people at home.

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Comparison of complications, harms and adverse events. As I said, we searched the FDA database. There were a variety of adverse events that were reported there, and they had mainly to do with electrical burns, chemical burns, thermal burns, possible allergic reaction and eye irritations after showering. There is a very large study of more than 16,000 facility-based PSG studies in 17 centers in a prospective study, and there was only one death after two weeks, probably unrelated to the facility-based PSG. As commented in the study, 28 events during these studies were prompting immediate attention; they were usually cardiac events, arrhythmias. And there were 28 potentially alarming events that were identified post hoc by the team that was doing the scoring across all these 16,000-plus polysomnographies.

Rates of data loss in sleep studies. We reported the proportion of sleep studies that showed data loss or bad quality recordings and this has, this follows the definition that was used in the study. The left, you can see that the small amount has been added to facilitate visibility. The Xs are the portable monitors and the empty circles are the facility-based PSG, and a breakdown for reporting portable monitor at home versus studies where portable monitor was in the lab. I have to say that there are five studies for portable monitors that show very high event rates. Otherwise

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if you exclude those studies, the view is probably more or less the same; however, there are these five studies that show high data loss.

There is no study that directly compared several possible strategies for the diagnosis of the condition and

the initiation of CPAP treatment. One measured decision analytic techniques to compare different strategies. We had a follow-on project on the technology assessment that was given to the MedCAC panel. This follow-on project has now been dropped and is going to go on to a peer review. However, I will share with you some outline of this model. We did not perform a full decision analysis, this is utility and patient preference. This is not incorporated in the model but this model is a probability profile of various strategies.
Here are -- here is a description of the various strategies that we assessed. Strategy one is no one gets a diagnosis and no one is ever started on CPAP, which is one extreme. Strategy six is that no one gets a diagnosis if we facilitate PSG or with portable monitor, but they're all started on empirical CPAP. And the other strategies are a combination of diagnosis with the facility-based PSG and CPAP level titration in the lab, or diagnosis at home and impression in the lab, or management completely outside the lab.

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Here we assess the proportion of people who started CPAP treatment. We do not feel that CPAP compliance just starts, so there's mean time to diagnosis and mean time to CPAP initiation.
This was modeled, some technical details as Markov processes, a hypothetical cohort of a hundred thousand people, because among people who are 50 years old or around that age, the main analysis was data from this cohort. But we have a sensitivity analysis and we also have a scenario from people who would be 70-year-olds that would be approximately Medicare beneficiaries.
There are some global assumptions that the severity of the disease remains stable over the two years which is the time horizon for this analysis. The risk of death is not modeled. Comorbidities, co-existing disorders or health conditions other than obstructive sleep apnea are not explicitly modeled.
Because we did not assess patient preferences and utilities we have some implicit assumptions. That is, that benefits of treatment will be assumed for those with a true positive diagnosis. Avoidance of unnecessary treatments and potentially unnecessary costs would be avoided, or would be possible for those with true negative diagnosis. Potential harms and unnecessary costs are found for those with false positive and false negative diagnosis.

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As said before, it's challenging to estimate transition probabilities for this model for people who are older than the typical participant of these studies and for people who have comorbidities.
I'm only to give you some comments on two of our reports that are very important in this model. One is the prevalence of the condition, the prevalence of apnea-hypopnea index more than 15 events per hour among people who are

suspected for the condition on clinical grounds, and from a meta-analysis, it established that this prevalence was about 54 percent. Because the confidence of the meta-analysis is very, very narrow, we did a large range of sensitive analysis, from 25 to 75 percent. We have absolutely no clue what the corresponding number is among older Medicare beneficiaries. There are several reasons of why it would be lower and we believe that the presence of conditions that would present, false positives is a major thing.
In this analysis we also say that there is an association of clinical symptoms and the presence of high apnea-hypopnea index a lot in older adults, so this also introduces considerations. So, we set the prevalence lower to older adults to 27 percent.
Here is the sensitivity and specificity of a portable monitor to identify apnea-hypopnea index smaller than 15 in facility-based polysomnography. This is not a

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specific monitor, this is a hypothetical prototype monitor, and this data found from type III monitors or type IV monitors with three or more bioparameters. Because of the potential for false positives with some monitors, we penalized the specificity for older adults, lowered it from 84 percent to 70 percent.
Now the main analysis for middle aged people is like the analysis on the sensitivity cohort of older adults is with great -- the first strategy was no one starting on CPAP, the last strategy is everyone starting on CPAP, you see why it's zero to 100 percent, all the other strategies are in between. Let's just focus on the gray, because here we discuss about Medicare beneficiaries. Strategies, what you will see is that strategy five, which is management completely outside the sleep labs, diagnosis at home and titration with auto-titrating devices at home has a larger proportion of people who are starting on CPAP.
This is the proportion started on CPAP among patients with the disease, so among patients who truly have apnea-hypopnea index more than 15, this is the operational definition of the disease for the modeling.
And this is -- the previous one was the, if you like, the true positives to start on CPAP. This is the false positives, and we see that strategy five is the strategy that manages people outside the sleep labs, has that higher

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proportion of false positives, and that's why it has higher counts.
This is the time that elapses from entering the cohort to the first apnea-hypopnea index or respiratory distress index measurements, and I expressed it as a percentage of the two-year follow-up instead of giving numbers. So because of the queue in the sleep labs and the limited capacity of the sleep labs, there is approximately in our model a 27-week delay. We did not assume any delay for portable monitors. This is a non-realistic assumption but it's subjected to sensitivity analysis.

This is the time to CPAP initiation. The previous was time to CPAP, or to diagnosis, this is the time to CPAP initiation. Lower numbers mean that the initiation is faster and as you see, strategy one never started CPAP, so they spent all their time without ever starting CPAP. Strategy five, which is management completely at home with portable monitors, has a quick initiation of CPAP. Strategy four is a mixed strategy that screens with portable monitors and then a very fast screening and titrating CPAP in the lab, and it has also a time to initiate that is fairly, around the same ballpark with the other strategies.
I just summarized the previous findings in words.
For middle aged people, the proportion of people who are expected to initiate CPAP treatment is roughly similar across

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the four strategies that employ some kind of testing for obstructive sleep apnea, plus or minus 10 percent. What this means has to be assessed with utility analysis or with patient preferences, but this is an analysis that we did not do, for good reasons.
This seems to be a fairly robust sensitivity analysis. For older adults, diagnosis of CPAP titration at home, which is strategy five, has more false positives and is expected to result in 30 percent false positive diagnosis among people who have the disease, and therefore among people who do not have the disease, and therefore increase the whole numbers in the whole cohort.
For both cohorts, time to first measurement is practically negligible for strategies where home monitoring is used in the diagnostic part, hut this has to do with the assumption that it did not penalize, there is nothing post-time delays for portable monitors. When the diagnostic part is done in the lab, the mean time to first measurement is approximately 26 weeks, and this means the delay is very sensitive to the corresponding sensitivity analysis that assesses the ability of sleep labs to see patients and their capacity.
Time to CPAP treatment initiation among people who have the disease is approximately 27 weeks when all people are diagnosed in lab, approximately 15 weeks when screening

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with home monitors is done, and is negligible when a home-based approach is used. This analysis is, again, sensitive to the various assumptions that were done in this model.
That would be the end of the technology assessment.
DR. PEARSON: Thank you very much. Since you finished ahead of time, Ross, do you mind if we have some questions first?
Any questions for Dr. Trikalinos?
DR. HIRATZKA: I'm just curious if there was a similar technology assessment done for the previous assessment whenever it was, and what the differences might be now compared to that particular technology assessment.
DR. TRIKALINOS: So if I understand your question,

there was a previous technology assessment several years ago?
DR. HIRATZKA: I'm just asking if there was one and if so, what are the differences between then and now.
DR. TRIKALINOS: There was a previous technology assessment and qualitatively the findings are very similar. The diagnostic abilities of type III and type IV monitors are qualitatively similar. The current technology assessment did extensive sensitivity analysis and we also identified those, we also restricted at-home monitors in the different categories. One sees that the numbers, the findings are qualitatively similar, I would say.

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DR. KONSTAM: First of all, I just want to congratulate you for this analysis. It's a very complicated set of literature. You know, just getting into this unknown of the Medicare population, and you started looking at the 70-year-old patients and assumed for at least specificity, I guess, but there was not much specific data, but just a presumption.
DR. TRIKALINOS: It's completely an assumption.
DR. KONSTAM: Right. But of course the specificity of facility-based PSG might be lower also in that population.
DR. TRIKALINOS: This is a good point. So what we need is, the rationale behind generalizing the specificity of portable monitors is the one that I mentioned briefly before, and it is that several monitors, they don't have the ability to distinguish between conditions that affect sleep, and they will be misdiagnosed for obstructive sleep apnea. Based on discussions with our technical expert, she said that the ability of the facility-based polysomnography to differentiate these conditions would be unimpeded, so we did not penalize the diagnostic ability of the facility-based PSG in these specific populations.
Moreover, for technical reasons, there has to be a reference strategy that is the appropriate strategy, and given the operational distinction of the difference in apnea-hypopnea index in the model design, it's logical to use

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the facility-based PSG as our perfect parameter.
DR. BECKER: If you look at your analysis of the various types of monitoring devices, type II, III and IV specifically, could you comment on whether or not you think that type III and IV can really be used for diagnosis, or are they better for screening?
DR. TRIKALINOS: So this would be -- could you repeat your question? I'm sorry.
DR. BECKER: Well, I guess I'm a little confused when you talk about type III and type IV, especially type IV, whether your overall impression is that is a screening device for determining OSA, or can you also consider them a diagnostic device? Especially when you go through your various models, really you looked at, say model four, you're sort of using the home monitoring as a screening device and then going to a study in a PSG lab. Could you comment on the differences between types II, III and IV?

DR. TRIKALINOS: So, direct comparisons between the three different types of monitors were not done. These are indirect comparisons and they can be done only qualitatively. As for the -- so I will not do any comparative comparisons across II, III and IV. But what I can say is that the summary sensitivity and specificity as outlined in the meta-analysis, all of which were type III and IV was, it showed that these monitors have high sensitivity, so they

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could be used for screening purposes.
DR. BECKER: Thank you.
DR. SATYA-MURTI: You talked about data loss in portable recording. In facility-based recording, data loss I assume would be recognized real time or very soon, but in home recordings, would the fidelity of the data collection depend on recording how much data was lost and how much was not reported?
DR. TRIKALINOS: So, the definition of this particular part with data losses is a bit tricky. The definition of data loss varies with different studies. Data loss could be considered as recorded unreadable, or if a minimum quality standard was not reached. This is at what range for definition of error rates. As you said, for a facility-based polysomnography, because it's an attended examination, the technologist would intervene and correct the testing if a lead was detached or something. All these numbers that I showed you, data loss, are what the individual study said that was not good quality or not acceptable, but they do have different definitions. So it's something that should not be taken without looking at each definition of that loss.
DR. SATYA-MURTI: Okay. If one hour of good data was collected in a portable monitor and the rest of the data for the rest of the study was lost, it depends on how they

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report that, is that data lost or is one hour of collection good enough that I'm going to call it data collected.
DR. TRIKALINOS: Correct, but most studies had the minimum criteria of two or three hours of sleep, of recording of good quality to accept it. But in principle, what you say is correct.
DR. PEARSON: Yes?
DR. JUHN: Just to follow up on the data loss discussion, the actual identification of data loss is an inadequacy of the study. So, were there any studies that you looked at that tried to capture the need to repeat a study, especially when they had a data loss?
DR. TRIKALINOS: So the question is how many studies repeated studies.
DR. JUHN: Yeah, because of the purported data loss.
DR. TRIKALINOS: There are studies that assess the need to repeat studies. However, these were not data for studies in the home setting specifically. I don't recall the specific answer to this question.

DR. PEARSON: Let me ask one last question before we move on. I understand why you had to use the AHI or RDI or some kind of reference standard, but if you back up, I'm very interested in the varied ability of AHI to predict clinical success with CPAP. So I want to ask you, given your

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understanding of the literature, if the physician had a high prior probability for a patient who had an obstructive airway that would be responsive to CPAP, what's the positive likelihood ratio of getting an AHI over 15 versus just starting that patient on CPAP?
DR. TRIKALINOS: So, we did not assess the diagnostic ability of clinical examination, we did not assess clinical examination alone.
DR. PEARSON: But just as a higher probability, how reliant are you that you have a higher probability?
DR. TRIKALINOS: So, when you have a higher prior probability, just for the prevalence in the model, it would be 54 percent. This is based on the following calculation. We took all the studies that had referral issues relating to clinical symptoms and signs, and among these studies the percentage, from the meta-analysis, the prevalence was 54 percent of the patients.
DR. PEARSON: But you don't know how many of those responded to CPAP?
DR. TRIKALINOS: We did not assess the specific topic. And as for the CPAP question, I should again note that these were studies that assessed people who already had very severe disease, so baseline AHI among people who have very, very advanced disease, very severe disease, does not necessarily predict differences in compliance.

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DR. PEARSON: Okay. There may be other questions, but I want to move ahead with Dr. Brechner. You'll have another chance to ask questions after lunch.
DR. BRECHNER: They say you can't teach an old dog new tricks, but I just learned that if I don't want to be subject to a bunch of questions, I should finish right on time.
(Laughter.)
We have been here an hour and a half. If everybody would, why don't you all stand up for like 30 seconds, because I don't want you to fall asleep while I'm talking. That's good. Okay, let's get started.
You just heard from Dr. Trikalinos and one of the things, he talked about models, modeling different kinds of situations, one of them, number six was left all alone standing in the corner, and my talk will give some information that might affect how we think about number six, which is that everybody goes to a CPAP trial directly. The outline for this talk is, I will be giving a brief outline of the referral pattern to CPAP, CPAP treatment, and then providing some data for the modeling of clinical diagnosis for OSA, and some information on the harms and benefits of CPAP, some considerations and some

conclusions.
Now when a PSG is performed and read, given right

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now at a diagnostic level of AHI greater than 15, what is the sensitivity and specificity for an absolutely correct diagnosis in the world of correct diagnoses? Well, the answer is we don't know that, it's the gold standard, maybe not based on gold, and it's the best maybe that we have, but it's not really clear that it's sensitive and specific a hundred percent.
In fact, we got some data from Dr. Mair that showed there are different ways of reading these things, et cetera, et cetera. If the test is positive, however, the patient goes to CPAP. When a home monitor test is performed, and once again, at a diagnostic level of RDI/AHI greater than 15, the sensitivity of the test and specificity are variable, and I see all kinds of values ranging between 50 and 100 percent for all of these, and that's just an approximate thing for the sake of this talk. Put if the test is positive, the patient goes to CPAP.
If we base the diagnosis of OSA on clinical diagnosis alone, I will be giving you some information on what the sensitivity and specificity is following, immediately following this, and if the test is positive, the clinical diagnosis and we decide to do something on the basis of clinical only, the patient goes to CPAP.
I searched around looking at clinical diagnosis of OSA and models and different kinds of things in HomeMed, and

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I read a couple thousand abstracts looking for information. Now when I present this data, I'm presenting nine of the 15 or 16 or so studies that I really looked at that I thought would make sense in the talk here, because I don't want to put too much information out in 20 minutes. And on each one of these slides at the bottom, you will notice that I have an average age in the study and what the AHI was, the cutoff point in this study.
Crocker, et al., 1990, aimed at determining if the number of PSGs required could be reduced in the population when you're diagnosing for OSA. It took a hundred consecutive patients, screened, and these patients were given a PSG, a model was created, and then it was found that the model correctly classified 33 of 36 patients with OSA and 35 of 69 patients with an AHI of less than 15. Significant factors are on the screen. The sensitivity of this model for, as compared to PSG for correctly diagnosing OSA was 92 percent and the specificity was 51 percent. They concluded that you reduce the need for PSG by a third with clinical observation.
In 1996, Deegan, et al., aimed at answering the question, what is a predictive value for the clinical feature for the diagnosis of OSA? 250 consecutive patients who were pre-screened by an MD and has a clinical assessment. A PSG and a questionnaire was administered. Using the clinical

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features and oximetry, 32.4 percent of the patients could be confidently categorized as having a diagnosis or not having a diagnosis of OSA, as compared to PSG. They concluded, again, that reduced the need for PSG by about a third with clinical observations.

In 1984, Haponik, et al, aimed to answer the question, is PSG necessary to assess the presence and severity of sleep-disordered breathing? In 37 patients clinically suspected of a diagnosis of OSA, they were given PSG and a questionnaire was administered. They had a sensitivity of 64 percent for the correct diagnosis of OSA as compared to PSG, and a specificity of 100 percent, but they concluded that a single observation alone, clinical observation was an ineffective screening procedure for detecting OSA.

Julia-Serda, in '84, aimed to answer the question, is cephalometry useful in sparing PSG? 225 consecutive referrals with suspected OSA had a clinical assessment, questionnaire, physical exam, history, spirometry, cephalometry and PSG. A statistical model was built, and the sensitivity of the model for a correct diagnosis of OSA as compared to PSG was 93 percent and the specificity was 83 percent. And they concluded that cephalometry, oximetry and physical exam and history could help in sparing the need for PSG.

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In 1997, Dixon, et al., aimed at answering the question, can we predict OSA diagnosis from a clinical model? They took 99 patients who were pre-op for bariatric surgery, and they went ahead and did a thorough sleep history, physical exam, an ESS was given, the Epworth sleep test, and all the patients had PSG that was hand-scored. They created a model with some independent predictors and they created a score pattern for that model, and if the score was greater than three, then the model had a sensitivity of 89 percent for correct diagnosis of OSA, once again compared to PSG, and a specificity of 81 percent, and this is for moderate to severe OSA. They concluded that there was a simple method here of predicting OSA in severely obese symptomatic subjects, and this could assist in limiting the use of PSG.

This year, 2007, Mulgrew et al., and Dr. Ryan is here with us today, he's the senior author on the paper, he will be talking. Aimed to answer the question, what is the utility of a diagnostic algorithm in conjunction with ambulatory CPAP titration in initial management of obstructive sleep apnea? This was an open-labeled randomized control trial that compared PSG with ambulatory CPAP titration in high risk patients who were identifiable by a diagnostic algorithm. The patients were randomly assigned to PSG or ambulatory titration using a combination of oral CPAP and overnight oximetry, and were observed for three months.

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After the three months, there were no differences in the primary outcome, that is AHI on CPAP, between the PSG and the

ambulatory groups, or in the secondary outcomes. And of note was that adherence to CPAP therapy was better in the ambulatory group than in the PSG group.
The authors concluded among other things that PSG confers no advantage over the ambulatory approach in terms of diagnosis and CPAP titration in initial management of patients with a high probability of OSA. And they stated that when access to PSG is inadequate, the ambulatory approach can certainly expedite the treatment.
2006, Lim, et al., aimed at answering the question, can we develop a model to predict the diagnosis of OSA from clinical diagnosis only? They took 71 snorers who were consecutively referred for an OSA diagnosis, and they assessed the status by clinical assessment using certain symptoms, Epworth test, BMI, and also gave the patients a PSG. They developed a clinical assessment model which had cutoff points for an ESS score of greater than 15, a BMI of greater than 28, and the presence of symptoms that are listed on the board. The sensitivity of this model for predicting a correct diagnosis of OSA compared to PSG was 93.4 percent, and the specificity was 60 percent. The authors concluded that identifying non-apnoeic snorers in whom PSG could be avoided can be correctly accomplished by a clinical

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assessment relying on the absence of at least two of the three clinical features listed, that is, the ESS, BMI, and presence of symptoms.
Hoffstein, et al., in 2006, aimed at answering the question, can we develop a model to predict OSA diagnosis from clinical diagnosis only? And they had 594 patients referred to a sleep clinic on suspicion of sleep apnea, and they all had a questionnaire and PSG. On the basis of their model, the sensitivity of the subjective clinical impression was 63 percent for a correct diagnosis of OSA as compared to PSG, and a specificity of 60 percent. And they concluded that the subjective impression alone is not enough to reliably identify patients with or without OSA.
In 2006, Guylay, et al., aimed at comparing the clinical assessment with home oximetry in the diagnosis of OSA, and they had 98 non-consecutive patients referred to a sleep clinic with suspicion of sleep apnea. All the patients answered a questionnaire, had a physical exam and history, and the physicians also independently just estimated their likelihood of the patient having obstructive sleep apnea. Compared to the PSG, the physician assessment had a sensitivity of 79 percent for a correct diagnosis of OSA and a 50 percent specificity versus, PSG oximetry had a sensitivity of 65 percent for a correct diagnosis of OSA and a specificity of 74 percent desaturations of two percent.

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With regard to the percent of time spent at a saturation of greater than or equal to one percent, the sensitivity was 93 percent and the specificity was 51 percent. So the authors concluded that home oximetry with less than one percent practically excluded OSA.

In 2006 Senn, et al., aimed at answering the question, is a CPAP trial viable for a diagnosis of OSA? 76 sleepy snorers were consecutively referred for OSA diagnosis and were included in the study, and they defined the positive CPAP trial as the patient was, at the time of checkup was using CPAP for greater or equal to two hours per night and the patient chose to continue therapy with CPAP. They were asking themselves the questions, could the trial predict an AHI of greater than or equal to 10 on PSG, and how successfully were OSA patients treated over a period of four months or more.
Significantly, the CPAP trial predicted sleep apnea with a sensitivity of 80 percent as compared to PSG and a specificity of 97 percent. And they concluded that in a selected population, the CPAP trial would help to diagnose OSA and to ID patients who would benefit from CPAP, and reduce the need for polysomnography, and that long-term CPAP therapy could be established without the need.
The final data slide is from Pillar, et al., in 1994, who were interested in the question of a clinical

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prediction of an OSA diagnosis. 86 patients referred to a sleep clinic for suspicion of sleep apnea had a questionnaire, physical exam and PSG. Versus PSG, the clinical assessment had a sensitivity of 79 percent for a correct diagnosis of OSA as compared to PSG, and a specificity of 55 percent. And the model which they created with these factors as listed on the board was able to predict OSA with a sensitivity of 92 percent, but the specificity was only 18 percent. They also concluded that a CPAP trial might help to diagnose OSA, ID patients who benefit from CPAP, and reduce the need for PSG.
I have listed here briefly just some other studies that I had, and I have the information on these studies if anybody's interested.
Now coming to CPAP benefits and harms, this is one of the places where I read a thousand abstracts looking for something on CPAP benefits and harms. This chart lists a number of outcomes that were observed in different kinds of studies for CPAP benefits or harms. In every one of these, CPAP either was equal to the control or it was better, and so there was no harm that I found here. I did find one study from Germany where they reported that the titration, oral titration wasn't done well enough in some cardiovascular patients with OSA and they recommend being careful about titrating with CPAP cardiovascular patients. Otherwise, I

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could not find much in the way of harms and it would be nice if people have this information, to share it.
Now, some considerations. The gold standard is PSG, but as Dr. Mair represented, it may not be a gold standard, and as I mentioned earlier. For an AHI cutoff of 15, I found in my papers that for a clinical diagnosis only, sensitivity was 51 to 93 percent, that's the range overall, this is not a 95 percent confidence interval, it was just the

range of the papers. Specificity, 51 to 100 percent. PSG, I don't know what the sensitivity and specificity is, and the others are compared to PSG. Home monitoring, sensitivity of 50 to 90 percent, specificity 50 to 100 percent, that's the range as compared to PSG.
Now, note that they all miss cases, for some reason or another they all miss cases. But all of them, from what I gather, all the studies, PSG, home apparatus, and giving it, there's some stimulus from a clinician to send them in. I don't know how many people are from outside the system. They come in, they get a home apparatus, they test it, they have to see a physician, or a PSG who haven't seen a physician. So really, clinical referrals cover all 100 percent of people who we may see that have home apnea, unless they haven't gone to a clinician.
Current wait time right now for treatment with PSG is approximately two to ten months, and I'm basing that on

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some of the work of Dr. Trikalinos. And once again, there are no harms from CPAP.
So what are the take home messages? We have sensitivity and specificity ranges that are widely variable for the three possible modalities, and one option is that everyone goes to CPAP, in which case we find a lot of how we normally look, approximately 100 percent of the cases, for sensitivity. And there are no harms from CPAP. There are lots of other little factors that are involved here that I'm sure we'll have some chatting about, but that's an interesting point. The wait time for treatment goes to a few weeks although Dr. Trikalinos's model estimated that was zero. And one of the interesting things is that if you're doing a CPAP trial, there is no harm in it, and the wait time for PSG is two months to ten months -- I might have said weeks before -- then what you have is they can go to a CPAP trial quickly and still get back in time for their PSG, depending on what the harm was. It's just an interesting thought, you know, about how this mechanism is working. But if the CPAP is not working, it would make sense that if you put somebody on a CPAP trial, you watch them as a clinician afterwards, and check and see how they're doing, and they can still be sent for further workup as I just suggested, and there would be no time lost.
That's all I have to say. Thank you very much.

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(Applause.)
DR. PEARSON: I'm sure we have some questions, but in the interest of time, I'm afraid we're going to have to move ahead with introducing Dr. Frank Ryan, who is a professor of medicine at the University of British Columbia and the senior author on a study that is in the packet that the panel has. Dr. Ryan.
DR. RYAN: Good morning, Mr. Chairman, members of the committee, ladies and gentlemen, and thank you to Dr. Brechner, who invited me to talk at this meeting and discuss the study that we did recently.

I'm a professor of medicine at the University of British Columbia in Canada. I'm a respiratory physician with a particular interest in the management of sleep apnea. And rather than discussing in detail our study, I will discuss it briefly, but I thought what I would do is put it in context of what our thought processes were when we embarked on this study, and perhaps make some comments about why or how it might be relevant to the deliberations that are taking place this morning.
These are data on wait times in various countries, wait times for polysomnography, and numbers of studies performed per year per 100,000 of population. The bottom line shows the figures for Canada, and if you look at the last column from the right, the number of studies per year

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per 100,000, in Canada it's about 370, which is not dissimilar from the figure for the United States which is the line above it, 427.
However, that figure disguises wide disparities in the availability of polysomnography in Canada. I don't have a pointer, but if you look at Ontario, the figure is 776, which is luxurious and in fact is a cause for some concern at the provincial government level and they're looking into that. But there are parts of Canada where there's no access to polysomnography, so in British Columbia, for instance, you know, we get quite a number of patients from Yukon Territories, Northern Territories, because they don't have any PSGs up there. And on the east coast also, the availability of polysomnography is limited. We don't do too badly in BC but we still have quite long wait times for polysomnography.
So the American Academy of Sleep Medicine, American Thoracic Society and the Canadian Thoracic Society all recommend polysomnography for the diagnosis of obstructive sleep apnea and also for the titration of sleep pressure. Unfortunately this approach, the conventional approach inevitably leads to discrepancies between the demand for the services and the capacity of sleep laboratories, and this results in inevitable delays. And this is of particular concern for patients who have severe obstructive sleep apnea.

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And everybody here will be aware of the various potential solutions that are being offered to deal with this problem, and I listed some of them here. The one I'm going to talk a little bit more about is medical decision analysis or medical decision-making, which would be probably a better way to term it. And if you think of the probability of disease, you can start with a baseline probability which could be the prevalence, for example, and that can be adjusted upwards or downwards by clinical features from the history or the physical examination to give a clinical index of suspicion, which could be further modified by the results of a preliminary test, for example, which can give information about sensitivity and specificity, and an ability to calculate likelihood ratios to give a probability of

disease.
And then if one plots the probability of disease on a continuum from zero to one, one can set thresholds for various types of management. So for example, the test threshold here would be the threshold at which there's no difference between the value of not treating the condition or of doing the diagnostic test, or another threshold here is the test treatment threshold which is the value at which there is no difference in the value between doing the diagnostic test and treating empirically. So if you have a condition where there's a high pretest probability, you may

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elect to proceed directly to the empiric treatment as opposed to doing the test.
So that was the intellectual basis, if you like, for the study which we did and was published earlier this year in the Annals of Internal Medicine. And our hypothesis was that polysomnography was not required for effective diagnosis and treatment titration in patients who have a high probability of obstructive sleep apnea, and that in those patients with a high probability, an ambulatory clinical algorithm could be safely used for both diagnosis and CPAP titration.
So the first step obviously was a diagnostic algorithm to identify patients with a high probability of moderate to severe obstructive sleep apnea. Based on a retrospective case series, we knew that among patients referred to our sleep clinic, in those who had an Epworth sleepiness score of 10 or greater, the prevalence of moderate to severe obstructive sleep apnea was approximately 50 percent. So starting with that baseline prevalence and then basically using a strategy of sequential likelihood ratios, we then went on to administer a clinical prediction rule called the sleep apnea clinical score, which is basically a four-variable linear regression model based on snoring, witnessed apnea, neck size, and the presence or absence of systemic hypertension. Then following that, patients

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underwent a home monitoring device which essentially was an overnight oximetry, I could give you a little more detail than that but it's basically an overnight oximetry, and these lead to a probability of disease.
This is the Remmers sleep recorder, which is a multichannel portable device. However, the respiratory disturbance index is based solely on the measurement of the overnight oximetry. It does, however, give useful qualitative data in terms of printouts of tracings of oxygen saturation, respiratory effort, airflow, and so on, which is useful for corroborating the diagnosis.
So we started with our baseline prevalence of 50 percent of moderate to severe apnea among patients referred to us who were sleeping. And if we administer the sleep apnea, or perform the sleep apnea clinical score on those patients, if the score was greater that or equal to 15, that has a positive likelihood ratio of 4.45, which converted the

probability to 80 percent. And those patients then went on to have the Remmers sleep recorder, and an RDI or respiratory disturbance index of greater than or equal to 15 had a positive likelihood ratio of 8.1, which converted the pre to a post-test probability of 95 percent. So that's how we selected the patients for our clinical trial.
One of the comments about the study was that the number of patients who were eligible was a very small

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fraction of the number of patients assessed, although that's a little bit misleading, because the figure here actually represents all of the patients who were referred to our sleep clinic during the 18-month period of the trial, but in fact the majority of them were not even assessed for the study, so it's a little bit artificial. However, patients were excluded for a whole variety of clinical reasons. Much of this was driven by safety considerations as this was an approach that hadn't been formally tested before.
In any event, we randomly assigned 68 patients, and patients were assigned either to the conventional approach which involved a diagnostic polysomnography followed the next night by a CPAP titration polysomnogram, and they were treated, they were set at a fixed CPAP pressure and treated at a fixed pressure for three months and then outcomes were assessed. The ambulatory group received one week of auto-CPAP using a machine that gave information about the pressure that was administered and gave an index called the 95th percentile pressure, which is basically the CPAP pressure at or below which the patient spent 95 percent of the time during the previous recording period. And we used that figure and adjusted it upwards or downwards, mainly upwards, in a proportion of the patients based on the results of an overnight oximetry which indicated any residual sleep disorder reading. And then after two weeks of that process,

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they were put on a fixed CPAP pressure and continued on that fixed pressure for three months and then outcomes were assessed.
The primary outcome was the apnea-hypopnea index on CPAP therapy after three months of treatment, so a measure of the effectiveness of the treatment strategy in eliminating the sleep disorder breathing. The secondary outcomes were sleepiness, a disease-specific quality of life index called the sleep apnea quality of life index, objective compliance which is recorded and measured by the CPAP machine, and we also looked at CPAP pressure.
The baseline values for the patients were comparable between the two groups. They were your typical group of patients whom we enter into these studies, they were middle aged, predominantly male. They were quite obese, they were sleepy, Epworth scores of four 14. They had high sleep apnea clinical scores and had high respiratory disturbance indices on the home monitoring, and impaired quality of life.
Just looking at the performance of the diagnostic algorithm first, these are the figures for the true

positives. So we had 41 patients that we could evaluate for this part of the study. The majority of those, of course, were those who had been randomly assigned to the polysomnography limb of the study, but there were others who either exited early, or there were patients who didn't meet

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the criteria of the diagnostic algorithm. So there were, true positives 34, false positives two, two false negatives and three true negatives. And looking at the sensitivity and specificity, this gave us a sensitivity of 94.4 percent and a specificity of 60 percent for the diagnostic algorithm, with the likelihood ratio of positive 2.36 and negative of 0.09. And so I borrowed one of Dr. Trikalinos's slides from his paper and tried to superimpose where our study would lie on this. So I think this, so it has high sensitivity but not particularly high specificity, but fell within the critical gray area.

Looking at the outcomes of the randomized trial, the primary outcome was apnea-hypopnea index, and basically there was no difference between the two groups.

Interestingly, neither approach was perfect in terms of eliminating sleep disorder breathing. One of the patients in the ambulatory group turned out to be a misclassification and had in fact changed those readings. We had picked this up early in the study because that person didn't respond well to CPAP therapy, and it was quite a struggle to keep him in the trial. So he didn't like the therapy, it wasn't doing him any good. But there were also patients in the polysomnogram group who had significant residual sleep apnea. Some of these would be what would now be characterized as complex sleep apnea patients who have a mixture of central and

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obstructive apneas.

In terms of the secondary outcomes, there was no difference between the two groups in the Epworth sleepiness scale or in the sleep apnea quality of life index. I actually put the data up here for the final values, because there was no difference either in the change from baseline in either Epworth score or the sleep apnea quality of life index. The CPAP pressures were also not significantly different, and in terms of adherence to CPAP, the ambulatory group had significantly better compliance.

Another thing that we looked at, although didn't examine statistically, was that patients preferred the ambulatory approach when we asked them. Patients in the ambulatory group, only six percent would prefer to have been assessed in the other limb, whereas 63, I think, percent of the patients who had been studied in the polysomnogram limbs would have preferred to have been studied in the ambulatory treatment.

So we concluded that expedited ambulatory diagnosis with CPAP titration could be safely offered to patients with a high pretest probability of moderate to severe obstructive sleep apnea, and in that group of patients we could identify no advantage to polysomnography over auto-CPAP for titration,

auto-CPAP pressure. And there was potentially better treatment compliance with use of the ambulatory algorithm.

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Patients preferred the ambulatory approach. But another element of this was that there is a small risk of diagnosis obviously with the ambulatory approach, so you need some sort of backup strategy to deal with patients who don't meet the criteria of the algorithm or who don't respond appropriately to treatment. That led us to recommend this clinical algorithm which, this part of the slide basically just describes the protocol for the study so that if patients are coming, they're referred with a suspected diagnosis of sleep apnea.
If they meet the criteria for the diagnostic algorithm and there are no contraindications such as a suspicion of another significant sleep disorder, then they have a high probability of moderate to severe sleep apnea and will go on to have a trial of CPAP therapy. And if after two weeks they are improved symptomatically and they are adhering to therapy, and there is no significant residual sleep-disordered breathing, then they can continue CPAP without any further testing. However, if they don't meet the criteria for the algorithm or if they don't respond appropriately to CPAP, then these indicate that there are significant diagnostic uncertainty and these patients should go on to polysomnography.
And there are various scenarios where this algorithm might not be appropriate. So for instance, if

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there is significant diagnostic uncertainty, if the probability is less than the test frequent threshold, if there's significant comorbid respiratory or cardiac disease that can cause diagnostic confusion, or if there's a safety critical occupation where it's absolutely essential that a correct diagnosis is made quickly, if there's a suspicion about other sleep disorders, for example Cheyne-Stokes breathing or central sleep apnea or hypoventilation symptoms, patients like that we feel would not be appropriate for use of the algorithm, or if for logistical reasons it's not possible to do home testing.
The other group of patients who we feel need polysomnography are those who respond unfavorably to the trial of CPAP therapy. And I would also say that patients who are considering other treatments, because there are other treatments for sleep apnea other than CPAP, specifically oral appliances and corrective upper airway surgery, because of the fact that these treatments are not as predictably effective as CPAP, it's important to have a very firm baseline in terms of the severity of diagnosis for comparison with follow-up studies, and obviously other sleep disorders like narcolepsy and parasomnia that might cause diagnostic confusion.
Now there are some important caveats to our study. Firstly, I would describe this as a narrow validation study

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conducted in a single academic center, so that speaks to how generalizable the results are. Our entry criteria were very stringent and so that speaks to, again, the generalizability to the larger population of patients who need sleep testing. And clearly, this is a type of study that needs to be replicated in a larger multicenter design, and include impact analyses including economic analyses.

There are some studies already in progress and we recently applied for a multicenter trial using less rigorous criteria, using a non-inferiority design, and incorporating an economic analysis.

Some general comments about the study. We used oximetry as one component of the diagnostic strategy, so we used the approach of sequential likelihood ratios based on a high baseline prevalence, clinical features strongly suspicious for sleep apnea and an ambulatory test. We found the strategy to be useful in identifying patients with moderate to severe obstructive sleep apnea for whom a trial of CPAP is appropriate. And in patients identified by the diagnostic strategy, a successful trial of CPAP helps to corroborate the diagnosis, or perhaps to put it the other way around, failure to respond to a trial of CPAP draws the diagnosis into question.

The applicability of our algorithm is highly dependent on the characteristics of the referral population,

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including its baseline prevalence. So that is probably relevant to the patients who would be served by Medicare.

And also, I would say that we used portable monitoring as part of an integrated management model delivered by clinicians who have expertise in sleep medicine and who understand the limitations of these approaches, and have strategies to deal with the exceptions.

So, we feel that access to polysomnography is essential to all of those patients who don't meet the criteria for the algorithm or who don't respond favorably to treatment.

And just by way of disclosure, our study was funded by a grant in aid from ResMed Corp., which manufactures CPAP equipment, and Vitalaire, which is a provider of CPAP equipment in Canada. However, that grant in aid was negotiated on our behalf by UBC and these companies had no role whatsoever in the conduct or reporting of the study.

And also by way of counterbalancing, I happen to derive significant clinical income from reporting polysomnograms.

So I leave it at that. I don't know whether we have time for questions, but thank you very much.

(Applause.)

DR. PEARSON: Thank you very much. We do have time for questions and then we will also have time for a break. So I turn to the panel. Yes?

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Oh, can I make sure that everybody is clear? The Remmers sleep recorder is a type III?

DR. RYAN: Well, it's a little confusing because -- we used it because there were published data on likelihood ratios. It derives the respiratory disturbance index purely based on overnight oximetry, so from that point of view we used it as a type IV device. However, it could perhaps be classified as a type III device because it does provide information about airflow and respiratory effort, and snoring and body position and so on.
DR. PEARSON: But the information you used was type IV?
DR. RYAN: Yes.
DR. PEARSON: Yes?
DR. DULLUM: Actually that was kind of my question. Just for clarification, when you say ambulatory monitoring, I kind of understood you were talking about CPAP treatment, but you're talking about a portable test device as well as CPAP trial.
DR. RYAN: Yes. So the ambulatory arm basically conducted the diagnosis and the treatment trials entirely outside of the sleep laboratory.
DR. DULLUM: But I mean using CPAP, or are you basing your ambulatory on the Remmers?
DR. RYAN: Well, both, because the alternative

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strategy requires a polysomnogram firstly for the diagnosis and then secondly to titrate the optimal CPAP pressure.
DR. DULLUM: So you're not advocating just CPAP? Because that's one of the questions, do you need to do portable testing or can you just do a CPAP trial?
DR. RYAN: Well, obviously on the basis of how we did it, I think an empirical trial of CPAP seems like a reasonable thing to do in patients who have a high pretest probability of the diagnosis of moderate to severe obstructive sleep apnea. In our experience you need a clinical assessment and portable monitoring to identify patients who have a sufficiently high pretest probability.
DR. PEARSON: Can I ask, did you go back to your data and look at that subpopulation of patients who did qualify as having high pretest probability, and look at only those who would have qualified on the basis of their Epworth sleep scale and see if the other predictive values were the same for those patients?
DR. RYAN: Well, I was going to address that. Actually if we look at one of my slides which showed that the pretest probability based purely on the clinical assessment went from the baseline prevalence of 50 percent to 80 after the clinical assessment. It then went from 80 percent to greater than 95 percent on the home monitoring. But you know, that's a big difference in terms of clinical confidence

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in the diagnosis, so I'm comfortable in applying an empiric treatment to somebody who has a greater than 95 percent probability of having the diagnosis; I would be less confident in somebody who is only an 80 percent probability of the diagnosis.

DR. KONSTAM: This clarifies, you know, in the limited randomized PSG, was that data used just for titrating CPAP or was it also used to confirm the diagnosis?
DR. RYAN: Yes. Basically that group had a diagnostic, a full overnight in-laboratory polysomnogram which established the diagnosis.
DR. KONSTAM: So what did you -- I'm assuming there must have been some patients for whom the diagnosis was not confirmed.
DR. RYAN: There were some false positives but interestingly, the false positives, the vast majority had obstructive sleep apnea but not of a significance greater than an apnea-hypopnea index of --
DR. KONSTAM: What did you do with those patients, did you treat them anyway?
DR. RYAN: We treated them anyway, so those patients went on to have their CPAP treatment, yes.
DR. KONSTAM: So in the primary endpoint analysis, all of those patients were in, even those who didn't meet the diagnosis by PSG.

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DR. RYAN: That's right.
DR. KONSTAM: And how, just to be curious, how could you tell they benefitted? I mean, I guess the diagnosis in those patients was still, I guess up in question.
DR. RYAN: That's right.
DR. KONSTAM: So how would you know that they benefitted, because maybe they didn't really have obstructive sleep apnea?
DR. RYAN: Well, as I stated, the majority, and I'm working from recollection here, the majority of false positives had obstructive sleep apnea but it was a minor obstructive sleep apnea, and in typical practice those patients would still merit a trial of CPAP.
DR. KONSTAM: I'm not sure how you knew they had obstructive sleep apnea if they had a negative PSG test, I'm not clear about that.
DR. RYAN: Yeah. Well, they were randomized to that management algorithm based upon the criteria of the diagnostic algorithm, so they were treated regardless of what their diagnosis was. And their outcomes were assessed accordingly.
DR. PEARSON: Yes?
DR. SATYA-MURTI: The CPAP trial duration before you consider someone in a binary fashion to have failed or

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not will become crucial, because one of the questions subsequently is the CPAP trial. So you chose three months. I agree you have to start at some point, but why three months? And were these patients given CPAP with, say, with biofeedback and other exercise measures that are dependent on patients' own motivation? Were they given encouragement to stay with it, or it's just there for them occasionally? So the question is time duration and what did you use as the

definitive hard index to say that they failed.
DR. RYAN: That they failed therapy? Okay.
Well, your first question is why did we choose three months as the duration of the trials; is that right?
DR. SATYA-MURTI: Yeah.
DR. RYAN: Well, it was a somewhat arbitrary number. But if you look at CPAP compliance, it tends to drop off over time, but most of the dropouts have occurred within three months, so that's partly our rationale. But to be honest, it was more an issue of practicality and completing the study in a reasonable time frame.
In terms of -- all of the patients were managed in the same way in terms of CPAP orientation and encouragement. They were managed fairly intensively in the first couple of weeks of the study, but there was no difference in that approach between the polysomnography group and the ambulatory group.

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DR. SATYA-MURTI: If they failed this trial, then they go on to PSG, so that, the quality of tagging someone as having failed would really depend on the treating physician, so you could say the patient failed and therefore they move on to PSG.
DR. RYAN: Yeah. Well, you know, we recommended an algorithm based on the results of our study but we haven't actually formally tested that algorithm. I mean, that would require a completely different validation.
DR. PEARSON: I think we'll let Peter jump in.
DR. JUHN: I think you alluded to this in your presentation, but I just wondered if you could talk a little bit about the challenges that you perceive in extending the trial results outside the trial population, so how to implement it in the community and what particular type of context the community would have to adopt in practice in order to achieve similar results.
DR. RYAN: That's a very good question. I mean, our first step to try to broaden the applicability of this is to conduct a multicenter trial across Canada using less rigorous entry criteria. So we would take patients who had an Epworth score of 10, a sleep apnea clinical score of 10 as opposed to 15, and an apnea-hypopnea index of 10 as opposed to 15. So we would look at it in six or seven different centers using a greater number of physicians and a broader

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sample of patients. However, at the end of that study, assuming the results are positive, one is still left with the question, well, can this be applied in community hospitals, could this be applied in general practice. I think it will be very important to do those studies and to do impact analysis in terms of waiting times and costs to validate this approach.
DR. KONSTAM: You know, I just wanted to come back to what I was asking you earlier and personally, I think this is a very well done trial with a good endpoint, better than a lot of the other endpoints in some other trials, so I think

it's valuable. I just want to sort of nail down exactly, you know, what we learned from this.
It seems that, you know, what your trial is looking at is, is home auto-titration CPAP versus in-facility titration of CPAP in a population who is going in with a presumptive diagnosis based on clinical assessment plus ambulatory diagnostics. It doesn't seem as though it bears any clear answer to the question of what is the relative diagnostic ability of ambulatory testing versus in-facility PSG; is that a fair summary?
DR. RYAN: That's a fair comment, but I think, you know, I think Dr. Trikalinos addresses that issue in his systematic review because there are two ways of looking at it, how closely do the measurements agree or how useful is an

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ambulatory approach within a clinical strategy.
DR. KONSTAM: No, I was just wondering in terms of what your study showed.
DR. RYAN: Absolutely.
DR. PEARSON: Yes?
DR. DULLUM: I guess one of my concerns is both in your presentation about the presence of cardiovascular patients with cardiovascular disease, and what we're looking at is the Medicare population, so the majority of them will have it. So in your group, it's my understanding you didn't feel it was safe to take this approach in people with cardiovascular disease?
DR. RYAN: Well, again, within the context of a clinical trial, you know, we thought it was important to minimize any risk to patients who might have been misdiagnosed, so we excluded patients with significant cardiovascular disease or any suspicion that they might have Cheyne-Stokes breathing. We also excluded patients with severe respiratory disease. Again, we don't know how useful or how safe it would be in patients like that, but clearly it would be a more difficult algorithm to apply in patients in a more heterogeneous population. So again, you know, it goes back to the earlier question. We were dealing with patients who virtually had a diagnosis of obstructive sleep apnea on their pretest probability. Patients with cardiovascular

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disease are complicated because they have complex forms of sleep-disordered breathing, some of which may be appropriately managed with sleep apnea, or with CPAP, and others which are not. And it's often very difficult without a definitive study such as polysomnography to tease those two out.
DR. PEARSON: I know we're very thankful for you to come. I hope you're going to be here for the afternoon; are you going to be here for a while?
DR. RYAN: I have to fly home.
DR. PEARSON: You have to fly home. Thank you very much again, Dr. Ryan, thank you.
(Applause.)
And we will definitely have time for all of the

scheduled public comments, but it's 10:20. I would like to take a five-minute break which, as you know, means that we will start to get back in here in about five minutes and probably get started in about seven to eight. But please try to make it very brief so we can give everybody their chance to have a break.
(Recess.)
DR. PEARSON: All right. We have a long list of public speakers, they each get five minutes. They will introduce themselves, starting with Tom Kehoe.
DR. KEHOE: Good morning. I'm Dr. Tom Kehoe, I'm a

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pulmonologist intensivist. I have been interested in and participated in sleep medicine for 20-some years. I'm also the medical director of SNAP Laboratories, which is a salaried position. SNAP Laboratories provides a portable home level III device for the diagnosis of obstructive sleep apnea, actually for all sleep apnea, and we assess habitual loud snoring. The SNAP device is, as I said, a level III device. It measures oral and nasal airflow, oral and nasal sounds, pulse rate, oximetry, it has an effort channel, and we have been in business for ten-plus years.
Polysomnography is the crowned and still accepted gold standard for diagnosing sleep apnea. All alternate diagnostic methods must be compared to polysomnography for validation. Unfortunately, polysomnography results are a moving target, which makes it somewhat difficult to adequately compare alternate diagnostic methods. Dr. Mair in his presentation mentioned the variability inherent in polysomnography data in terms of inter-reader variation and night-to-night variation. The best way, then, to assess new alternative diagnostic methods would be to do it simultaneously with polysomnography.
Since the last MedCAC meeting on this subject, there have been a number of validation studies that have been performed. I'm going to mention two that were done, one was mentioned by Dr. Mair, with a unique twist.

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In the first study by Stephanie Su from the University of Chicago, 60 patients were compared simultaneously with polysomnography and SNAP testing. There was good sensitivity, specificity, negative and positive predictive value in the results, in comparison results.
A similar study done by Dr. Michaelson and Dr. Mair from Wilford Hall Army Air Force Hospital was done in the same way and showed similar results.
The twists in these two studies is that two blinded readers looked at the polysomnography data and two blinded readers looked at the SNAP data. It was found in both studies that inter-reader variability was less with the home study, the SNAP study, than it was with polysomnography. So the conclusions were that SNAP analysis, i.e., level III home testing was a viable accurate alternative to polysomnography in diagnosing sleep apnea, and intervariability at least in SNAP analysis was less than with polysomnography.

The next study I want to talk about, if home testing and polysomnography are equally accurate in diagnosing obstructive sleep apnea, what about the use of CPAP, what about getting the accurate CPAP levels for treatment? The idea is out there that only polysomnography titration will give you an accurate CPAP level for treatment. However, a study by Juan Mesa and his group in Spain in the American, or the Journal of Respiratory and

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Critical Care Medicine in 2004 looked at 360 patients with diagnosed obstructive sleep apnea. They divided the 360 patients randomly into three groups, the first group being polysomnography titration for CPAP, the second group being auto-titration for CPAP, and the third group was formula-derived CPAP. The last two groups were done in the home.
Patients were followed for three months and the results looked at, showed that there were no significant differences in the reduction in AHI, there was improvement in subjective symptoms of sleepiness that were similar in all three studies, and the compliance after three months with the CPAP treatment was the same in all three studies. So maybe we don't need polysomnography or PSG titrated CPAP.
DR. PEARSON: Dr. Kehoe, I'm sorry, the time is up. We can give you another minute to wrap up.
DR. KEHOE: All right. I want to comment a bit on the last study that Dr. Brechner talked about, the question of whether CPAP alone is able to diagnose obstructive sleep apnea. A paper by Senn in Chest, 2006, suggested this might be the case. However, the question, one of the questions on the question the group has asked, could this be clinically harmful? It can be clinically harmful in my opinion, because it does not give you severity of the obstructive sleep apnea, which would modulate the compliance of the patient. If he

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doesn't think that he has sleep apnea or that it's severe, he might be less apt to use the CPAP.
Also, it does not provide for alternate treatments for CPAP, and the facts state that 50 to 80 percent of patients with proven sleep apnea do not tolerate CPAP. So there would be a large false negative group that would need polysomnography testing.
DR. PEARSON: Dr. Kehoe, thank you.
DR. KEHOE: Okay. Thank you very much.
DR. PEARSON: Thank you. Next is Michael Coppola.
DR. COPPOLA: Thank you. I'm here today as the medical director of a million bed sleep lab. Five of those are traditional attended polysomnography and the rest are the homes of the people that I care for. I'll give you some considerations today from someone who has done thousands of sleep studies, both in home and in the attended traditional setting, and give you some thoughts, some things to think about pertaining to this.
I have no ongoing financial issues. I was formerly involved as the medical advisory board of ResMed Corporation.

That relationship terminated in June of 2006. I'm on the board of directors of the American Sleep Apnea Association but I'm not speaking on their behalf this morning. I would like to share some lessons learned. We have been using a medical management model involving portable

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testing in Massachusetts since 1988 with over 10,000 studies to date. I have also helped a managed care organization in the Pacific Northwest, Group Health, when they initiated their program, and have followed up carefully with them their results with over 20,000 studies. These mature programs, not the initial 20 patients somebody decided to publish, but these are mature, sophisticated programs with quality control, have shown that 80 to 95 percent of patients can be served with a home testing medical management model. This is one of our patients. He's been on CPAP since 1988. We have a type III recorder here showing severe obstructive sleep apnea. This diagnosis is irrefutable. This is the patient after self-titration with nasal CPAP therapy. He has been on therapy since 1988, he is now a Medicare patient, and we have him scheduled for a polysomnography to justify a renewal of the CPAP. Under current CMS guidelines, not only to get the CPAP but even the supplies for CPAP, he must undergo an expensive polysomnogram, in a patient who has been happily benefitting from CPAP for 19 years, and this is not -- he is not alone. All successful models of portable testing have addressed the continuum of care. It's silly to talk about these, testing as if they isolate, if they existed in isolation. Emphasis must be placed on successful outcomes and the strategies for implementation of the technology

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rather than the technology is the key to success. Outcomes need to be measured. In facility-based studies an evaluation by a sleep expert for negative studies or poor outcomes is necessary. I think using the portable studies with a continuum of a traditional sleep program is critical. What is the best model? I think having a sleep expert, however you define that, would be the best person to decide which modality would be best. Having both tools, I have both tools, I actually earn more of my income from breathing facilities, like many of your other speakers from facility-based studies. But I'm here to tell you, I don't mind giving up some of that revenue. I have thousands of patients left untreated and I would like to be able to access them quickly. Diagnostic criteria, obviously witnessed apneas, excessive daytime sleepiness and morning headaches are those symptoms which I think correlate best. However, I don't, I'm not a proponent of history alone as sufficient to initiate CPAP therapy. Type III recordings have accumulated the most real world experience and published results, and they translate best to terminology we currently use for polysomnography. However, there are numerous type IV devices, I think, that are probably clinically equally as

good that deserve a careful evaluation.
Currently, I think the channels should measure

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effort, airflow, preferably pressure as we find that's much more sensitive, heart rate and oxygen level, because I'm a respiratory physician and I like to know what the oxygen level is.
I think response to therapy is confirmatory, but as a single diagnostic modality it has been insufficiently tested to generalize to a large population. There are real clinical problems. CPAP needs to be done right the first time. If you have an attended CPAP titration or an outpatient CPAP event that is not done correctly, you've lost the patient to CPAP probably forever; it's very difficult to rescue those patients.
DR. PEARSON: Dr. Coppola, can you move to your last slide, please?
DR. COPPOLA: The advantages to the Medicare population, for home testing it's accessible. We have problems with night driving and safety. We also have Medicaid patients, many of whom are single parents who have to get child care, they cannot come to the laboratory.
Disadvantages, you've heard about comorbidities. I share that concern, Cheyne-Stokes or class III or IV heart failure patients should not be studied in the home.
Thank you very much.
DR. PEARSON: Thank you very much. Dr. Dement?
DR. FREUDMAN: My name is Jon Freudman, and I'm

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here on behalf of the Home Sleep Testing Coalition, which is comprised of clinicians, including sleep medicine specialists, companies that manufacture and distribute home sleep testing devices, and providers of sleep services. I'm pleased to have with me today Dr. William Dement to provide testimony to you on behalf of the coalition.
As you know, Dr. Dement is a pioneering sleep researcher. However, you may not be aware that he was the founder of the world's first sleep clinic and laboratory at Stanford University. So as we speak about polysomnography today, he defined it. Dr. Dement is the author of over 500 scientific research articles and books, including the first sleep medicine textbooks. If you are to listen to anyone today, it should be Dr. Dement. In 1975, Dr. Dement launched the American Sleep Disorder Association, which is now the American Academy of Sleep Medicine, and he was its president for 12 years.
It's truly an honor to present from Stanford University the person who may be the strongest and most respected authority in sleep medicine during the last 30 years, Dr. William Dement.
DR. DEMENT: Thank you, Jon. If I had thought 40 years ago -- anyway, I'm here today on behalf of the Sleep Coalition and this coalition is reimbursing me for my airfare and hotel accommodations, and I have a financial interest in

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Sleep Quest and the ResMed Corporation.
I would like to comment briefly at the outset on the recently published AHRQ report, which we understand the committee has received. The coalition agrees with the report's conclusion that a home sleep study performed with an FDA-approved device that provides an apnea-hypopnea index is a reasonable option to confirm the diagnosis of clinically suspected obstructive sleep apnea. The coalition further agrees with the report's conclusion that home sleep testing may identify apnea-hypopnea indices suggestive of obstructive sleep apnea with high positive likelihood ratios and low negative likelihood ratios. We caution, however, that the report includes certain caveats and other statements that detract from those evidence-based conclusions.
For example, the report refers to polysomnography as a reference standard but does not mention that there is not an anatomic reference standard for the diagnosis of obstructive sleep apnea. PSG may characterize the syndrome but it has never been a definitive diagnostic tool.
When I started the world's first sleep disorder clinic and laboratory at Stanford 37 years ago, we certainly had no idea about the high prevalence of obstructive sleep apnea. Back then we needed to study every physiological parameter at our disposal in an attended setting because we knew so little about sleep disorders and their potential

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negative consequences. We now have enough research to support in-home testing. That a cheaper and more convenient test is not readily available to so many sufferers is unconscionable.
Not all parameters measured during polysomnography are needed to diagnose obstructive sleep apnea. However, those parameters that are required can be reliably measured in the home. Scores of studies, as we have heard, published over the years have supported home testing. While polysomnography remains the study of choice for patients with certain rare neurologically based sleep disorders, it has no advantage over home sleep testing when managing obstructive sleep apnea, at least for the majority of patients. In fact, it is well recognized that home testing may provide for a better reflection of patient's normal sleep and that for many patients, especially the aging like me, a home test frankly is much more desirable than going to my own sleep clinic and spending one or two nights in the lab, for a variety of reasons.
The published evidence and years of experience in many countries has documented that home studies are neither new nor experimental. They are well proven and demonstrate a high degree of sensitivity and specificity, reliability and consistency. Sleep testing devices have become very reliable and home testing is practiced today routinely in numerous

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settings with minimal failure rates.
This committee has an opportunity to favorably

affect the care of numerous Medicare beneficiaries who have undiagnosed obstructive sleep apnea, many of whom are at imminent risk of being involved in car accidents, developing heart failure or having strokes, or simply suffering a very poor quality of life. The only diagnostic modality currently available to these patients is polysomnography, the most complex and expensive study. The call for expanding the use of simplistic studies is shared by the Institute of Medicine, the National Sleep Foundation, the American Sleep Apnea Association, and of course patients.
Although access to polysomnography has improved somewhat in recent years, the option of a home study is still desperately needed. All of us who practice sleep medicine know that many patients, for reasons including inconvenience, fear, physical limitations, or medical condition, will not present to a sleep laboratory. In addition, home studies are certainly the optimal methodology for follow-up when it is indicated, and many times the only practical situation when the need for a diagnosis is more urgent.
DR. PEARSON: Dr. Dement, I'm sorry; could you please conclude?
DR. DEMENT: Yeah, I have one more sentence.
DR. PEARSON: Thank you.

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DR. DEMENT: I urge the members of the committee to vote in favor of expanding coverage for home sleep testing. Thank you very much.
(Applause.)
DR. PEARSON: Thank you. I'm just going to say, I love this job of chairing this meeting, but I hate having to remind everybody to please watch the lights up there so you can keep within five minutes. I know it's hard, but it will help us all.
DR. FREUDMAN: I'm not going to use five. My background is internal medicine. I'm an independent consultant and one of my clients is Sleep Solutions, who makes a diagnostic device. When I was in charge of Blue Shield of California's technology assessment program, we too invited outside testimony. I found that those who were most motivated to attend the meetings were those who had the most financial skin in the game. I'd like to remind the MCAC that the testimony you may hear later and some of the input you have received off-line includes those with a vested interest in maintaining a very lucrative status quo for sleep labs. Please remember, there are more sleep labs than manufacturers of approved and validated home sleep testing devices. There are more of them than us.
I would like to remind the panel of a few issues. We are not debating a new biomarker or test. As you've heard

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from Dr. Dement, the parameters that confirm the diagnosis of OSA are those that pertain to airway obstruction, and these are the same either in PSG or home testing venues.
The AHRQ analysis supports our position that a home sleep study performed on an FDA cleared portable device that

provides an AHI is a reasonable option to confirm the diagnosis of clinically suspected OSA. However, the report includes wording that is nuanced and at times detracts from the core evidence message. CMS and the MCAC members should be aware that one of the report's authors, Dr. Ambrosio, is the AASM section chair on sleep-related breathing disorders. The potential for bias here is I think obvious. The limitations of PSG, as Dr. Mair so well described this morning, are not discussed in the report. When reviewing a literature that compares PSG and home test performed on successive nights, this variation is germane. Included in the report summary are cautionary remarks regarding the Medicare age group. True, in general the validation studies involved younger patients. However, the pathophysiology of intermittent air wave obstruction does not change at age 65. There was speculation in the report that there may be patients over the age of 65 who will be misdiagnosed by portable studies. However, there is nothing in the body of the report to substantiate this speculation, not one sentence.

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The AHRQ report mentions restless leg syndrome, these patients have symptoms in their extremities. They can be managed clinically and receive sleep medicine consultation or PSG as needed. The AHRQ report contains no studies regarding heart failure masquerading as obstructive sleep apnea. Certainly patients with severe COPD or heart failure can be studied in a lab if appropriate. However, identifying coexistent unrecognizable OSA and heart failure is very important for these patients and home sleep testing could be of enormous value to the Medicare program. Patients on lasix don't want to spend the night in a sleep lab. Dr. Bill Abraham from Ohio State University uses home sleep testing extensively in a heart failure program, and his comments to CMS last spring are part of the record. Given that the core data and the AHRQ report indicate that home sleep testing can identify patients suggestive of OSA, I urge the MCAC and CMS to focus on the evidence conclusion and not the speculations in the AHRQ report. I would like to conclude with a few comments pertaining to the AASM's position on this matter. Increased sleep lab capacity, this does not change the fact that home sleep testing is an evidence validated, less expensive

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alternative, and not all patients can be tested in a lab. The AASM has mentioned a study they are sponsoring that will assess both polysomnography and portable studies. What isn't commonly known is that in this study, patients who have an AHI of less than 15 on portables will then need to go to get a PSG. Patients who have an AHI of less than 15 on PSG will not need a portable study. So there's an asymmetric design in this study that will clearly have the potential to

alter the outcome.
The AASM has cited some modeling studies to show that portable studies will increase costs. You know, we don't need modeling here, we have in vivo evidence, Kaiser Permanente and the Veterans Administration, who are at risk for costs of sleep testing, repeat sleep testing, sleep apnea, or the consequences of missing sleep apnea, have piloted the use of portables and continue a decade later to continue to use portables. This is not a modeling exercise. This is not needed.
DR. PEARSON: Dr. Freudman --
DR. FREUDMAN: Yes, I'll finish. It's clear the AASM's goal on home sleep testing is to limit sleep testing to a venue they control. I urge the MCAC and CMS to think about more clinical issues, the evidence, what is best for patients in the Medicare program. Thank you.
DR. PEARSON: Dr. Atwood.

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(Applause.)
DR. ATWOOD: Good morning. Thank you for allowing me to speak today. I'm speaking on behalf of the American College of Chest Physicians. I am a pulmonary and sleep medicine physician at the University of Pittsburgh. My disclosures are that I have received grant support from Respironics, ResMed and MedCare, and have served as a consultant in the past to Respironics and ResMed, as well as the Sleep Manufacturers Alliance. The American College of Chest Physicians paid my way today. I do not have slides.
The American College of Chest Physicians is a leading professional society of pulmonary, critical care, sleep medicine physicians, cardiologists and cardiothoracic surgeons, and other allied health professionals. We have a long history of involvement in the sleep medicine field through a variety of venues, including professional development, education and research. We do appreciate the opportunity to comment on proposed changes for the payment of portable sleep apnea testing that CMS is currently considering.
Sleep apnea, obviously, is presently a large and rapidly growing part of contemporary pulmonary sleep medicine, or pulmonary medicine. This is true both for pulmonary physicians who subspecialize in sleep medicine and for pulmonologists who treat sleep apnea patients without

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additional sleep medicine training. While the practice of sleep medicine is definitely multidisciplinary and becoming more so, the largest primary specialty of sleep medicine practitioners is, consists of pulmonary medicine specialists. The future of sleep apnea diagnosis and management is of keen interest to our members and their patients.
The technology available to clinicians in diagnosing sleep apnea is one of the fastest growing aspects of this field. High quality small and easily portable monitors that can accurately detect sleep apnea are now available and FDA-approved. The traditional approach to

diagnosing sleep apnea in a sleep laboratory alone is undergoing revision, as we've heard. Our position is that portable sleep apnea testing is a legitimate means of making a diagnosis of sleep apnea. This is not to say that it should replace full sleep laboratory facility testing. Rather, we view non-facility-based sleep apnea testing as one of several different tools that should be available to practitioners evaluating patients for suspicion of sleep apnea. We believe CMS should support adoption of portable sleep apnea testing in some circumstances, and these circumstances are clearly evolving. However, we caution against using portable sleep apnea testing for the diagnosis of any other sleep disorder other than adult obstructive

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sleep apnea, and specifically not pediatric sleep apnea. The key to successfully using any diagnostic tool or strategy is to understand its strengths and limitations, and portable sleep apnea testing is no different. Its benefits are simplicity of use, flexibility in allowing testing to occur in the patient's own familiar surroundings, and possibly lower cost. The use of portable sleep apnea monitors also allows for more rapid diagnosis of high risk patients where there may not be a traditional sleep laboratory available, or lengthy waiting times exist. Its limitations are recording a smaller number of signals, technically inadequate recordings because of bad sensors or signals that cannot be replaced or corrected during the recording, and false negative studies. These limitations mean that portable sleep apnea testing will not work for every patient, and we acknowledge that there is still much to be worked out about how best to use these tests and which subgroups may benefit most from them. There is still relatively little published scientific data on the age group of Medicare beneficiaries, for example. There may be subgroups of patients who are more or less likely to benefit from such an approach. Not everything is known. But we do know enough about portable sleep apnea testing in our opinion to recommend that CMS adopt it in some circumstances.

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As we've heard, a growing number of clinicians are successfully using portable sleep apnea testing in their practices and manage sleep apnea patients with it, including patients who are Medicare beneficiaries. These are practitioners in private practice, those who work for the VA system, those who work for other HMOs. The spectrum of practice that is using this is already fairly broad and is becoming even broader. The importance of giving sleep apnea patients appropriate care by qualified clinicians cannot be overstated. It's not so much the tool we believe is the most crucial aspect of the care, but the relationship that the patient has with a qualified physician. We conclude with just a few practical suggestions.

Portable sleep apnea testing should be used by knowledgeable physicians trained in its use and in its interpretation. We do not recommend the unthinking adoption of portable sleep apnea testing by any or all physicians. Our goal is not to turn every bedroom in America into a sleep laboratory. Neither is our intent to restrict appropriate use to facility-based testing for sleep apnea. One way that this could be accomplished is through accredited sleep laboratories, but there are perhaps others as well. Patients should undergo full sleep laboratory evaluation if the portable sleep apnea testing is not

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diagnosed, it is not diagnostic and sleep apnea is still suspected. Payment for portable testing should be appropriate to its cost and physician training required interpreting it.
And finally, we recommend CMS consider partnering with other federal grant making or research agencies to sponsor additional research in this field.
Thank you.
DR. PEARSON: Thank you very much.
(Applause.)
DR. PEARSON: David Gourley.
MR. GOURLEY: Good morning. My name is David Gourley, I'm a registered respiratory therapist licensed to practice in the state of New Jersey and New York. I currently am the vice president of regulatory affairs at Chilton Memorial Hospital in Pompton Plains, New Jersey. I'm here representing the American Association for Respiratory Care, or AARC, which is a 43,000-member organization, a professional organization of respiratory therapists. My travel here was funded by the AARC, and I have no conflicts of interest.
Sleep diagnostics and therapeutics have been an integral part of the respiratory therapist scope of practice for decades. Patients with sleep-disordered breathing, in particular OSA, are afflicted with additional comorbidities

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which we've heard about this morning here, like hypertension, diabetes, obesity and heart failure. The acuity of these patients varies widely but is especially true among the Medicare beneficiary.
The AARC submitted extensive written comments in April of this year on the proposed national coverage policy decision memo regarding the proposed revisions to Medicare coverage extending it to home testing. Our key point to share with you today is focused on the recommendation the AARC made to CMS to revise the currently revised policy to mandate specific personnel qualifications of both physicians and polysomnographic personnel.
Physicians who have no certification or specialization in sleep disorders are opening sleep disorder centers around the country. Personnel must be hired to staff these centers and unfortunately, the demand for employees to staff these centers exceeds the supply of competency-tested

healthcare professionals who are qualified to prepare the patient, set up the testing equipment, run the polysomnograms while monitoring the patient's clinical status. The result is that on-the-job trainees are hired with no prior training and no competency testing to provide these clinical services. Untrained and untested personnel simply do not have the skills required to assure that the test is being performed correctly and that the patient is responding

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appropriately. Inaccurately or poorly executed testing can result in false positives, false negatives, or inconclusive testing. We believe that it is important for Medicare to set a high standard in terms of personnel qualifications to help assure a high quality of service to the Medicare beneficiary. The key point that the AARC would like to make to this committee today is with regards to amending the coverage under Medicare as follows: Polysomnography must be performed by qualified personnel, such as registered polysomnographic technologists, licensed and credentialed respiratory therapists, specially trained nurses or other healthcare professionals who have been competency-tested by nationally recognized accreditation entities, and under the supervision or oversight of a board certified physician holding a sleep specialty credential.
Thank you very much.
DR. PEARSON: Thank you. Next is Kelly Garber.
MS. GARBER: Good morning. I appreciate the opportunity to address the group. It's a bit of a daunting task following so many world renowned physicians. You'll notice right away I'm not a physician as I begin to speak, the upside of which is that you'll probably nod off a bit and still get the point of my comments.
I'm division clinical manager of Apria Health Respiratory Services and Apria Healthcare. To give you a

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little bit of background, and I will only give the high points in the interest of time, we are a full service home care company specializing in respiratory services and respiratory equipment, home medical equipment, home infusion services and home diabetic supplies, serving patients in all 50 states, including over a million Medicare beneficiaries this years. We do employ respiratory clinicians, 850 of which are respiratory therapists.
Dr. Mair spoke earlier of the inevitability of home sleep testing. To take that one step further, I can tell you that in certain areas of the private sector it is in practice today. Others have mentioned Kaiser Permanente, the VA and the Navy as examples. Kaiser Permanente of Colorado, their Colorado region uses 90 percent or takes 90 percent of their members who are referred for home sleep testing, and they are used in that manner, including our senior population, there is no distinction that is made. They're using this primarily in order to service the ongoing stream and the ever-growing stream of patients referred to their sleep apnea clinics.
Other managed care organizations in other parts of the

country are also using it successfully.
We can state that home-based testing, we don't believe is appropriate for all patients, and in fact, definitely screening criteria needs to be put in place to address the patients who are perhaps recurring or suspected

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central sleep apnea, complex sleep apnea, and other clinical situations.
Key considerations, we just want to remind the group that it is not experimental, and others have supported this. An infrastructure actually already exists in the home care community, and therefore that the logical solution would be the home care companies currently employing respiratory clinicians already specializing in obstructive sleep apnea treatments to perform these tests in the home.
In addressing one of the key questions posed by the group, the ability of the testing to determine applicability and success with CPAP therapy, it is our feeling that the type of diagnostics does not have a direct reflection on compliance. Rather, patient education, mask comfort, the ability to offer heated humidification, and troubleshooting and other on-board support offered to the patient is more reflective of success with CPAP therapy.
Our recommendations include the approval of type II testing for home diagnostics testing, revising the criteria for AHI to be based on a minimum of two hours sleep or less if the actual number of AHI episodes recorded is 30 or more in less than two hours.
And we want to also be very cautious about the development of a policy related to direct-to-CPAP models, not so much in light of risks and other things associated with

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CPAP therapy, but in light of utilization controls and other things to avoid any type of fraud or abuse.
A definite benefit of home sleep testing would be the cost savings that could be realized. Knowing that testing costs can be slightly varied from region to region, an average of 40 percent savings can be realized for home sleep testing. If you extrapolate that out over ten years, the savings would exceed a billion dollars, just factoring in the current growth of the Medicare population.
We did include a patient's perspective. This is a patient who is a Medicare beneficiary but also a VA patient who went through the process of home sleep testing and was extremely satisfied with that process, and does recommend it for all Medicare beneficiaries.
In summary, this proven technology has been adopted by Medicare's largest Medicare advantage plan, the Veterans Administration and the U.S. Navy. And we would like to have you consider that in light of the other high technological advances that have allowed certain things to be done in the home, for example, the more advanced ventilators that provide pressure support, very high mobility for patients who are in the home who might have previously been in an acute care setting for extended periods of time. Home infusion therapy

made possible by more advanced pumps. Apnea monitors and then the ever-growing CPAP and BiPAP technology with

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downloadable and other features that continue to hit the market.
So we're suggesting that we implement this as quickly as possible in order to reap the saving that can be realized, and that's all I have.
Thank you.
(Applause.)
DR. PEARSON: Thank you very much. Stephen Burton.
DR. BURTON: Thank you. I'm the president of Ion Healthcare, and we're a disease management company that specializes in management of sleep apnea patients. We do not manufacture sleep therapy devices, we do not manufacture home diagnostic tests, and we do not operate a sleep center, but insurance payers reimburse us to use all of those technologies to manage sleep apnea patients.
This is the life they lead. I want to remind people of the patient perspective today. In our model we follow largely Dr. Ryan's results in a clinical example, where we identify at-risk patients with clinical impressions, self-report questionnaires and physical findings. We then confirm the diagnosis with a test, a sleep diagnostic test; 25 percent of the time that ends up being in a sleep lab, 75 percent of our patients end up doing it at home. Medicare patients, a hundred percent have to do it today in the sleep lab, so they suffer a different level of care in our

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organization. And one of the things that underscores that, I want to emphasize, two entire communities, one being Europe and one being Japan, their standard of care today is ambulatory and has been for almost a decade. Millions of patients are properly managed and care in both those environments. We stand behind the ball in terms of that delivery of care.
In our U.S. home testing, the patient that does do a home test typically within two days is tested and within one further day receives a report and pays an average of $295. The patients that are referred to the sleep center within our patient base typically waits eight weeks, but that can go anywhere up from one week to 18 weeks, and typically two weeks later receive a report and pay on average $1,200. Medicare patients all experience the bottom line for that.
Unmanaged apnea has a tremendous impact on the cost that patients pay. An unmanaged apnea patient pays twice as much healthcare dollars as the patient who goes in and is finally managed; that's been well studied, well proven. So finding the patients, reducing the hurdle to enable someone to be diagnosed is an important step.
Apnea impacts surgical outcomes to such a degree that in this one study they show that complications that come from a surgical caseload with apnea patients who are unmanaged versus managed, complications are twice as high

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once the apnea has been identified and recognized, post the study they can identify that apnea was one of the contributors to the complications, and in severe complications it's as often as three times the level of complications when it's unmanaged apnea playing in the mix. This has resulted also in liability that's coming through from post-surgical reactions of cases, it's also led the ASA to generate a practice guideline last year suggesting an apnea management process needs to be in place for anyone suspected of sleep apnea if they're going to undergo anesthesia. JHACO also put it as a potential safety initiative for next year, and they expanded it to any patient that will be anesthesia or analgesic. That's a tremendous body of patients that now need to be managed and recognized whether they have sleep apnea of not. We need to develop a model of care that can tolerate that group of patients. One of the things that was I believe passed out to you shortly ago was a picture like this, and I apologize to the audience here not to have this, it wasn't in the original slides, but people began talking about level II maybe being a test that we recommended. And I wanted people to just appreciate real patient impact. Some people talk about it as PSG in the home, but the problem is, this is what you will require the patient to go through to achieve that, so I hope it's a standard that will not be suggested or realized as a

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practical standard. Level III home testing is surely sufficient to be able to be applied to someone who presents as at risk for apnea.

Clinical impressions in our patient base of thousands, one-third of the time our patients, if it went only with referring physician's clinical impressions, one-third of the time we would have applied treatment unnecessarily. So it's important that we have some ability to do that.

Thank you very much.

DR. PEARSON: Thank you.

(Applause.)

DR. PEARSON: Alex Chediak.

DR. CHEDIAK: Thank you. I'm Alex Chediak, president of the American Academy of Sleep Medicine. I am the owner of a private sleep laboratory in South Miami, Florida, chief of the sleep disorder center at Mount Sinai Medical Center, and associate professor of medicine at the University of Mount Sinai, excuse me, University of Miami at Mount Sinai. In these roles I diagnose and treat patients with a whole variety of sleep disorders, I teach house officers and fellows, and I conduct clinical research. I'm here today at the request of the American Academy of Sleep Medicine and my travel has been sponsored by the academy. The AASM appreciates the opportunity to comment on the

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MedCAC's view of National Coverage Determination 240.4. Proponents of portable monitoring contend that the

diagnosis of OSA is limited because facility-based polysomnography is not widely available. While this might be the case in some countries, this statement is inconsistent with data in the United States. A study based on 2001 data estimated that 427 polysomnograms were performed per year for 100,000 in the population. Since then the number of accredited AASM facilities has more than doubled to 1,256, and 259 applications have been received in the first six months of 2007. An independent survey by SRI estimated that there are more than 2,500 accredited and nonaccredited sleep disorder facilities in the United States in 2004, with an average wait time then of two to three weeks for facility-based polysomnography. A 2005 survey of U.S. sleep centers by Wachovia reported a percent increase in sleep center bed capacity over the previous year, and an approximate three-week wait time was reported by an AASM survey in 2004.
Most recently in 2007, AASM surveyed its accredited sleep disorder facilities and found a decrease in PSG and consultation wait times to a median of 12 and 14 days respectively. Considering that not all sleep facilities are accredited by the AASM, this survey data likely overestimates the wait time for PSG and sleep physician consultations in

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2007.
We conclude that in the United States as a whole, patients do not have unacceptable delays in assessing sleep consultations for facility-based polysomnography. Furthermore, the number of accredited sleep centers continues to grow and current data suggests that increasing demand will be met by appropriate increased supply.
In 2003 the AASM in association with the American College of Chest Physicians and the American Thoracic Society published practice parameters for the use of portable monitoring in the investigation of obstructive sleep apnea in adults. The practice parameters did not recommend unattended portable monitoring for OSA. The manuscript was updated September 1st, 2004, by a report of the Agency for Healthcare Research and Quality found in Europe, but did not materialize to change the earlier conclusions.
In his request letter, Dr. Nielsen of the American Academy of Otolaryngology cites four recently conducted investigations in support of the use of ambulatory portable monitoring to diagnose OSA. These have been previously reviewed. All four of these studies were performed outside of the United States, and in two of the four they did not directly address the use of portable monitoring to diagnose OSA. All four of those were carried out by sleep medicine specialists in academic sleep centers and in a population not

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representative of Medicare beneficiaries.
The August 8, 2007 Agency for Healthcare Research and Quality technology assessment report reviewed earlier today similarly noted that one could not necessarily extrapolate such findings to circumstances where healthcare

providers with less training and experience might use these devices.
In summary, two recent studies provide some evidence in support of portable monitoring for the diagnosis of OSA in selected patient groups with high pretest probability for OSA who are managed intensively in academic centers by sleep specialists. Medicare demographics were not well represented in these studies and their results cannot be extrapolated to primary care or surgical practice. Further studies are needed to confirm these results to determine whether these approaches are cost effective compared to facility-based polysomnography. They do not warrant a change in NCD 240.4.
The academy believes that obstructive sleep apnea should be diagnosed by a combination of clinical history, physical examination, and recording of breathing while asleep. Such a comprehensive approach by physicians trained and expert in sleep medicine is necessary to avoid overdiagnosis of the condition and also to avoid unnecessary treatment.

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MedCAC should be aware of two ongoing studies aimed at elucidating the role of portable monitoring in the diagnosis and management of OSA. An American Sleep Medicine Foundation grant has funded Drs. Cheryl Rosen and Susan Redline at Case Western Reserve for a large multicenter trial that will compare ambulatory strategies for both the diagnosis of OSA and CPAP against the facility-based protocol. Following a paradigm designed to mimic actual practice in our area, the study deems to examine both clinical and economic outcomes. The results from this grant are expected by June 2009.
DR. PEARSON: I'm sorry, Mr. Chediak, we'll have to stop there. Thank you.
DR. CHEDIAK: Can I have one sentence?
DR. PEARSON: Yes.
DR. CHEDIAK: In closing, the AASM is not opposed to the development and application of new technologies that would be of benefit to our patients. We acknowledge the limited new evidence that supports portable monitoring. However, we think that we should wait for the results from the grants of the Veterans Administration and the American Sleep Medicine Foundation trials to provide evidence for making rational decisions regarding home-based portable monitoring in the management of adult obstructive sleep apnea. Thank you.

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DR. PEARSON: Thank you.
(Applause.)
DR. PEARSON: Dr. Philip Westbrook.
DR. WESTBROOK: Alex is the current president of the American Academy of Sleep Medicine, I was the third president, I guess that's progress. My name is Philip Westbrook, I'm a pulmonary physician and a physiologist with an over 30-year focus on breathing during sleep. I am chief

medical officer of Advanced Brain Monitoring, Incorporated, which has developed based on my specifications a portable system, the ARES, for evaluation and quantification of sleep disorder breathing. I am also chief medical officer of Adventist Medical, Incorporated, a company developing treatment for obstructive sleep apnea. Finally, most of my current income derives from an investor-owned company which provides laboratory polysomnography for sleep apnea. From a financial point of view, I truly have conflicts of interest, but I'm not conflicted about patient care.

I believe that our current approach to the diagnosis and treatment of sleep apnea allocates too much time and money to diagnosis and too little to treatment and follow-up. Validation studies of our systems and others have shown that portable studies contain measure of AHI similar to traditional attended laboratory polysomnography. The AHRQ report concludes that portable monitors can identify AHIs

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suggestive of, their term, the sleep apnea syndrome with high positive likelihood ratios and low negative likelihood ratios.

Simply put, a validated portable recording and analysis system can be as useful as polysomnography when making treatment decisions for patients with sleep apnea. However, not all portable recording devices are equivalent. I believe that portable systems should provide multiple channels and full disclosure recording required to identify all types of abnormal breathing during sleep, including complex sleep apnea and central sleep apnea. But at the same time, they have to be very easy for patients to use. The monitor must have a low failure rate when self-applied in the real world.

A portable diagnostic system should include analysis of patient information that gives a risk of disease assessment. Using patient history and other measures it is possible, as we know, to predict those in need of a diagnostic home sleep study. Examining a person's breathing over a couple of nights while he or she sleeps relatively unencumbered at home can give a larger and more accurate snapshot of that person's usual state than a short stay in a laboratory.

Our initial study with the ARES was rated A by the most recent review. The methodologies were fully described

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as was both the PSG and portable scoring. Sensitivities and specificities, as shown here, were high.

In this large study where the recorder was mailed to the subjects and they had to put it on using simple printed instructions on each of two nights, the failure rate was only two percent. Healthy controls were included, and 10 percent were in the Medicare age range. Most of the difference in severity classification between the lab PSG and the portable system at home could be accounted for by the positional differences and by the known night-to-night variability in apnea-hypopnea index, which is true of any

system studied anywhere.
Subsequently an independent validation study of the area was carried out at New York University, this time with the ARES recorder that included airflow by a nasal cannula pressure transducer system that allows detection of flow limitation. The report of this study has been accepted for publication in the Journal of Clinical Sleep Medicine. There is, however, an error on this slide, I apologize for it. The failure rate recorded and found was six percent, not two percent. The author's conclusion, the present data again confirmed that it is possible to obtain sleep disorder breathing indices comparable to those obtained by full laboratory polysomnography from data acquired by an unattended limited diagnostic device, at least in subjects

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suspected of sleep-disordered breathing or of having no sleep disorder.
I must tell you I sort of object to the author's use of the term limited, at least as applied to our current monitor from the others. Our current version provides a full disclosure recording of airflow, respiratory effort, pulse, oxygen inflow and saturation, head position, movement, quantitative snoring and sleep staging, and continuously evaluates signal quality and tells the wearer if adjustments need to be made. I submit this is not limited monitoring. However, what is limited is my time, so I'm going to skip the next three slides, which really you don't need to see, and I'll go directly to my conclusions. My summary recommendations are as follows: I think CMS should approve portable systems which acquire the signals rated by experts as necessary or highly desirable and that have met rigorous validation standards. The systems must provide full disclosure recordings and these must be reviewed and interpreted by experts, reviewed and interpreted by experts, as must all diagnostic services. The system should incorporate historical and anthropomorphic information and should be capable of obtaining more than one night of data, in other words, a full sample of sleep.
I thank you very much for the opportunity to present my views.

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(Applause.)
DR. PEARSON: Thank you. Next, Dr. Kuna.
DR. KUNA: My name is Sam Kuna, I work at the University of Pennsylvania and the Philadelphia VA Medical Center, and I'm representing the American Thoracic Society.
I receive grant support from Respironics.
In 2003 the American Thoracic Society participated in an evidence-based review of portable monitor testing in the diagnosis of sleep apnea. The resulting report concluded there was insufficient evidence to support the use of portable monitors in an unattended setting, but some evidence that type III monitors appear to have a limited role in an attended setting. There has been no change in that official position since that report.

The ATS recognizes, however, that obstructive sleep apnea is a major public health issue. The outstanding 2007 AHRQ evidence-based review details the important medical consequences of sleep apnea, and we know this is a prevalent disorder. The commonly quoted estimates of nine percent of men and four percent of women have sleep apnea is based on an epidemiological study that was published 15 years ago. We know that obesity is the strongest predictor of sleep apnea, and that over the past 15 years there has been an alarming increase in obesity in the United States. It is therefore very likely that the prevalence of sleep apnea has risen

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precipitously over that time and will continue to do so until the obesity epidemic has abated. This trend will only exacerbate the limited access to polysomnogram testing that already exists for many patients.
Despite the current lack of evidence supporting the role of portable monitor testing, many healthcare providers confronted with growing patient demand and limited access to polysomnogram testing are increasingly using portable monitors to diagnose their patients with sleep apnea. The clinical experience of physicians with training and expertise in the management of sleep disorder breathing is that under certain conditions, type III portable monitors can play a helpful role in improving access to diagnosis and treatment of sleep apnea and in reducing costs.
Confronted with increasing patient needs and growing use of those monitors in the absence of evidence-based guidelines, the ATS firmly believes that additional research is urgently needed to determine the appropriate role of portable monitors in clinical practice. The controversy surrounding portable monitor testing is due to a lack of evidence, not the presence of strong evidence against its use.
To help obtain the needed evidence, the ATS is helping to organize a workshop on the research priorities in ambulatory management of sleep apnea that is being held next

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month, October 15th and 16th, in Arlington, Virginia. The workshop is bringing together a select group of diverse stakeholders to identify the gaps in our knowledge regarding portable monitor testing and determine the research required to provide the needed evidence.
As commented earlier by Dr. Mair and others, although portable monitor testing is the focus of today's forum, the ATS acknowledges the significant limitations of polysomnogram testing. Polysomnography has been assigned a gold standard status through accustomed use. It was never subjected to the rigorous evaluation process that is being applied to the emerging portable monitor technology. It is ironical that our gold standard test failed to meet the requirement that are currently being demanded of portable monitors.
Our current method of diagnosing sleep apnea using polysomnography is too reliant on just one number, the

apnea-hypopnea index. The ATS advocates a clinical research initiative that leads to a more holistic approach to the management of sleep apnea. We need prospective research studies comparing complete clinical management pathways in diverse patient populations. CTSA is a practice safe network that could potentially serve as a platform for such research. CMS can play a critical role in promoting this initiative through its coverage of evidence development, approving the

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use of portable monitor testing for CPAP but limiting this coverage to patients participating in the clinical research designed to obtain the needed evidence.
The unrestricted approval of CPAP coverage based on portable monitor testing in the absence of evidence-based medical guidelines for this emerging technology will likely lead to its indiscriminate use. While the time may be appropriate for limited approval of portable monitor testing under special clinical circumstances, the ATS advocates that more evidence-based medicine from adequately powered, high quality clinical research studies is needed before widespread application of portable monitor testing in the management of sleep apnea is warranted. CMS approval of CPAP coverage with evidence development would provide critical support for this needed research.
Thank you for your time.
(Applause.)
DR. PEARSON: Dr. Parish.
DR. PARISH: I'm Dr. James Parish, I'm associate professor of medicine at Mayo Clinic, Mayo Clinic Arizona. I'm here today representing, however, NAMDRC, the National Association of Medical Direction of Respiratory Care, and my expenses were supported by NAMDRC. In terms of a conflict of interest, I have received in the past a research grant from ResMed, but apart from that I have no other conflicts of

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interest.
Recognize that because of limited time I just want to address a couple of issues here. One issue that hasn't been addressed yet that was part of the questions I understood for this hearing was the so-called two-hour rule, and I wanted to address the committee and advocates on behalf of our members that we would advocate a change in the so-called two-hour rule. The current rule is that to diagnose obstructive sleep apnea, two hours of sleep is required to create an AHI. However, many patients who have severe sleep apnea or have disruptive sleep fail to achieve the two-hour rule, and it often requires patients to go back for follow-up studies in order to achieve the two hours of sleep, which is a burden to the patients and to the taxpayer. So we advocate changing the two-hour of sleep parameter to two hours of recording time.
The second issue is the issue of portable monitoring, and the organization believes that there was a major study in 2003 looking at the issue of portable monitoring devices, and believes that not much has changed in

the medical literature since that time. However, we recognize that many experienced clinicians recognize that there are a group of high probability or high risk patients who can be accurately diagnosed with portable monitors. However, while OSA is the most common sleep-related

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breathing disorder, it's not the only one. In my practice I see many patients with congestive heart failure or other cardiovascular disease; they have central sleep apnea or Cheyne-Stokes respirations. I see patients with neuromuscular diseases like Parkinson's disease that are referred to the sleep laboratory. These patients often have central apnea or Cheyne-Stokes. These patients would actually worsen if treated with CPAP; central sleep apnea often will worsen or at least not be effectively treated with CPAP. They often require high level positive airway pressure, supplemental oxygen, or other respiratory devices for effective treatment. So these would not be good patients for portable monitoring but do require facility-based type I studies. So all is not just obstructive sleep apnea.
We believe strongly that any of these diagnostic studies that are considered should be interpreted only by experts who are adequately trained in sleep and/or pulmonary medicine, and that these are not suitable for widespread use in the community, as there is a certain skill to interpreting these.
The third, or the last issue I wanted to stress is chronic disease management. We believe that OSA, a new emphasis should be placed upon the total management of the patient, not just a diagnostic modality of diagnosing patients. Sleep apnea needs to be recognized as a chronic

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disease under the supervision of trained physicians who can guide the patient through the entire process of diagnosis and a wide variety of treatment options, not just CPAP, that are available for patients with obstructive sleep apnea.
So again, NAMDRC appreciates an opportunity to offer our comments here today and we thank you very much for your consideration. Thank you very much.
(Applause.)
DR. PEARSON: Thank you. Mark Goetting.
DR. GOETTING: I'm not David White, David couldn't make it, I'm his pinch hitter. I'm associate clinical professor of neurology medicine pediatrics at Michigan State University and a member of the AASM, and practice full-time sleep medicine. I'm pleased to share with you my views, which are based on familiarity with the body of published evidence, and my own experience as a practitioner in the field of sleep medicine and medical director of fully accredited centers.
I'm going to just skip to the summary, to make sure I get all my slides in. At the outset, I want to state my opinion that there is ample evidence and clinical experience to condone, to recommend that home sleep testing be an alternative to laboratory testing for the diagnosis of sleep

apnea and the initiation of CPAP. Despite a few reservations, the AHRQ report supports my conclusion.

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The committee should recognize that we are not dealing here with a theoretical issue, that home studies go back more than 20 years. Major providers, as have been mentioned, have been using these in clinical algorithms, and my own sleep center has embraced home testing. We put into practice evidence-based protocols using both tests, laboratory and home, as an advantage to our patients. By supporting coverage for home studies the committee will favorably respond to the well publicized calls by the Institute of Medicine, National Sleep Foundation, American Sleep Apnea Association, as well as other organizations, calling for the expansion of diagnostic testing. The reasons why these organizations and others are calling for coverage of home studies are obvious to many sleep physicians. We need to deploy multiple testing modalities to meet growing requirements as we are now understanding the relationship between sleep apnea and cardiovascular disease, diabetes, obesity and more. And we also need to address new indications, new thoughts such as patients undergoing sedation and general anesthesia who may be at risk for sleep apnea.
Furthermore, while the number of sleep labs have grown to about 3,000 in America, there are still many patients who do not have reasonable access to these centers in the more than 10,000 cities and towns in America. Even

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when a sleep lab is available, we still need a simpler home test as an alternative to polysomnography when the patient's situation calls for an immediate evaluation, to which sleep labs often cannot respond to well, as well as a solution to the numerous patients, many of them being elderly, who for one reason or another cannot come to the laboratory or cannot sleep there. We recognize that polysomnography will remain the test of choice for many patients. However, restricting us to only PSG handicaps us as physicians.
Home studies are already well recognized and supported in the literature. We know with very high confidence that for most patients, home studies are clinically appropriate and effective as an alternative to PSG. It affects the largest ongoing NIH-funded study on apnea, the Sleep Heart Health Study, with over 6,500 subjects, and the more recently launched Hispanic health study, including over 15,000 subjects, relying entirely on data generated from unattended home studies.
Physicians managing sleep disorders are fortunate to have access to many devices cleared by the FDA specifically for diagnosing sleep apnea in the home setting. Unfortunately I don't have time to go through the categorization, but I will state that there is ample evidence to conclude that type II, type III, and other devices that measure three or more parameters offer clinical acceptability

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for sensitivity and specificity when used with clinical assessment. The four-category classification system is dated going back to 1994 and is probably now obsolete. A number of newer technologies provide excellent clinical performance, although these devices do not fall squarely into the old definitions.

One of the better examples of technology that performs extremely well in the home setting, although it does not fit the traditional categorization, is the Watchpad, which has been in clinical use for over four years in the United States. This not only accurately diagnoses sleep apnea, it also measures sleep time, sleep fragmentation and amount of REM sleep. Does that mean it's a type II device? Not really. Since it measures the AHI by tracking reactions of the autonomic nervous system, it's not exactly a type III device. So what type is this technology, is it even relevant to ask today? What matters most is the fact that Watchpad has evidence supporting its use, some of it addressed in the AHRQ report, concerning efficacy, sensitivity, specificity, and reproducibility.

DR. PEARSON: Dr. Goetting, you're short on time.

DR. GOETTING: I'm sorry. There is no evidence that the sensitivity or specificity of home testing ought to be different in the geriatric population. Since the AHRQ report, there's one study of 2,900 elderly patients, average

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age of 76, by Susan Redline, showing home study in 96 percent of patients provided a technically adequate result. Thank you.

(Applause.)

DR. PEARSON: Dr. Kuhlmann.

DR. KUHLMANN: Thank you for having me. My name is David Kuhlmann and I have no paying affiliations or conflicts of interest. I'm a member of the American Academy of Sleep Medicine and I'm a board certified sleep specialist. I'm one of the guys in the trenches. I'm first going to comment on home-based studies and then I'm going to talk about referring people for lab-based studies.

Now, I don't know whether or not it would be wise to begin ambulatory monitoring as a diagnostic option for sleep apnea, but if we go with home-based studies, we need to make sure that we're doing it for the right reasons. Certainly cost and convenience are important, but the most important thing when it comes to treating a person with sleep apnea is to make sure that our Medicare and Medicaid patients are using their CPAP machines. It's not that the severity of sleep apnea motivates people to use CPAP; the people most excited to use CPAP are the ones who understand the etiology and treatment of their disease, who have the worst symptoms and who derive the most benefits from using their machines. It has been shown that referral to a sleep

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specialist increases the knowledge of the patients and better compliance with CPAP. Sleep specialists are familiar with

many problems such as mask leak and pressure changes that need to be done in order for a patient to adhere to CPAP. So if the ambulatory monitoring is approved, then it should be done through accredited sleep centers, because sleep specialists are the people who have the best interests of the people at heart.

Now quickly to go through my presentation, request for uniformity. We recently came out with, AASM came out with a scoring criteria to replace R&K Manual. The new scoring manual gave both a recommended and an alternate definition for hypopnea. Recommended was a drop in nasal pressure by 30 percent and a four percent desat. The alternative, a drop in nasal pressure by 50 percent with a three percent or arousal.

The respiratory committee actually ended up going with the definition that was in line with the current reimbursement for CPAP, which is that four percent desat with a 30 percent decrement in nasal pressure. But the committee initially recommended the alternative definition to utilize as a standard. The American Academy of Sleep Apnea currently recommends that all research be done using the alternative definition.

Sleep laboratories are allowed to use either

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definition of scoring so long as they label which one is being used when they're scoring their studies. But there's a concern that with this alternative definition of hypopneas, it won't be reimbursed for CPAP because it's a different formula for hypopnea rather than the recommended definition, it's the alternative definition.

I would think there are two problems with the dual definition of hypopnea. One is that future research is getting cloudy because there's two different definitions of hypopnea. I think that a solution would be to make the recommended definition of hypopnea be the apnea-hypopnea index, and that if you use the alternative definition of hypopnea, you just label it the respiratory disturbance index. Both definitions would then get the same criteria for reimbursement by CMS, an AHI or RDI greater than 15, or an AHI or RDI greater than five with symptoms that I'm sure you're already aware of.

The second problem is that the current guidelines for sleep are discriminatory towards women inadvertently. And that is while in my clinical practice, a lot more women can have arousal rather than oxygen desaturations associated with their events. Upper airway resistance syndrome, which is actually most common in women, about 60 percent of the women, so basically a lot of women aren't able to qualify for CPAP by going with the recommended definition of

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apnea-hypopnea index, and that's really what brought me here today.

And so it came out, basically when there were no changes in oxygen saturation but changes in EMG tone, there's such an arousal, so basically there are episodes with when

there is no oxygen desaturation but this is a hypopnea. I mean, it's apparent because of the arousal associated with the decrement and nasal pressure, and that's probably close to 50 percent.
So, my conclusions. CMS should reimburse for CPAP for both the recommended and alternative definitions of hypopnea, the AHI should be distinguished from the respiratory disturbance index, and the same criteria for reimbursement should be used for both RDI and AHI.
Thank you.
DR. PEARSON: Thank you.
(Applause.)
The last of the prepared speakers is Dr. Davidson.
DR. DAVIDSON: While I worked in the past for ResMed, so they let me go, I'm apparently not a very good negotiator, so I didn't get anybody to pay my way, but I will be selling some Girl Scout cookies which I bought on the way to help defray my costs.
(Laughter.)
So, I want to talk for a moment about

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evidence-based medicine, knowing this panel knows much more about it than I do. There are problems with evidence-based medicine; you've got to look at the levels, but you've got to look at the strength of the science and you've got to look at the strength of the recommendations, and that is going to be very important in our decision process today. If I ever jump from an airplane, skip the evidence-based medicine, I'm taking the chute.
Now we don't have absolute anatomic, I like that term, objective measurements of SDB. I wish we did, like we do for some other diseases. The AHI is what we have, thank you, Dr. Dement and your buddies. It may not be the world's greatest, but it's what we've used for 40 or 50 years, and I've actually gotten to like it.
Now what I want to tell you is that there's variability, there's slope in this system. So if you're looking for something that's going to make statistical sense down to .000 whatever, it just simply doesn't exist. Man is not perfect in his nighttime sleep. And this slope is 10 percent, night-to-night variability, first night effect, and the AHI change with age anyway. And then we're dealing with this thing called the gold standard which you've heard questioned here, and now even with that question we're saying well, maybe two hours is fine, and I don't see that at all.
The questions, the validity of home tests, in my

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review there's 21 studies, 1,200 patients, ten countries, you have it hopefully attached. Here is the unweighted and the weighted averages. And unweighted, the difference between PSG and home was 25 versus 24 one event, or four percent, and weighted was two percent, I mean two events, or eight percent. And I don't think that's very much, because the first night effect, people just don't sleep the same in a laboratory, you've heard that addressed.

You've heard the Bland-Altman plot, and this is an example of one in an article on night-to-night variability. And any time you look at sleep research, and sleep research is great stuff, you only see Bland-Altman plots, they always look like this. This is the slope in the system. This is the difference in how we sleep tonight versus last night. It's just what's built in. You can't get a tighter fit than this.
And then there's interscore variability, and even in the sleep community doing their own analysis of this, they found very substantial differences and it speaks for itself. This was just different people reading the same test, another Bland-Altman plot. It's the slope in the system. These tests are basically the same tests measuring the same thing, and the inconsistencies and variabilities, if you wish to argue them for the rest of your life, are in the patients, the scoring, the first night effect, not in the value of the

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tests.
Now I did for just a moment want to address the second question, and that was an alternative mechanism for diagnosing sleep apnea. So I developed this algorithm, I'm sure many others have, I don't take credit for it, but basically snoring is the premier symptom. If somebody comes in that snores every night, that's serious snoring. And this was developed for the geriatric patients, one or more comorbidities, and I think they can go to an APAP trial, versus no comorbidities. These are the comorbidities, they're in your handouts with the references. But if they are highly suspect, they can go straight to APAP. I have yet to meet a person who uses CPAP to sleep with at night for the fun of it. It doesn't happen.
And there aren't complications to it. We haven't blown anybody up yet. We haven't even gotten a good pneumothorax and it hasn't even dropped on someone's head and given them a head injury. So the complications are few, or none, and the risks are none. If they use a CPAP machine they have the disease, no question in my mind. If they don't like CPAP, I don't know what they have any more than you do. Then they need to go to a sleep test. For garden variety, it's a home sleep test. If you want to take somebody with heart failure or Parkinson's, I'm not really a sleep doctor, I'm just a head and neck surgeon, but I can tell when they're

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demented.
(Laughter.)
They need to see a real sleep doctor, they need to get PSG. PSG is great, but you don't need it for garden variety home sleep testing. Thank you.
DR. PEARSON: Thank you very much.
(Applause.)
DR. PEARSON: We're doing pretty well. Thank you again to all the speakers for trying to deal with five minutes. We do have three open public speakers who will get two minutes each and then we'll break for lunch. I'd like to

invite Edward Grandi, if that's the correct pronunciation, to come up, and please announce your affiliations.
MR. GRANDI: Thank you. My name is Edward Grandi. I'm the executive director of American Sleep Apnea. I paid my way to get here. American Sleep Apnea is supported through funds, unrestricted grants from the manufacturers of CPAP devices.
The American Sleep Apnea Association is the only national nonprofit organization dedicated to the public and public and patient education about sleep apnea and to supporting patients. The ASAA is here today specifically to speak on behalf of the millions of Americans who have sleep apnea but remain undiagnosed and untreated. The millions of Americans at risk of developing sleep apnea is on the rise.

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This is due in part to the aging of the baby boom generation, as well as the ever increasing prevalence of obesity among adults and, sadly, children as well. The consequence of not addressing this major public health issue impacts not only the individual with increased risk of debilitating disease and death, but society as a whole.
There is a pressing need to use diagnostic technology currently available for unattended sleep studies. This will not only accommodate the testing of more people who learned about sleep apnea through the ASAA outreach, but helps the sleep medicine community better respond to the needs of Medicare patients, the uninsured, and the traditionally underserved populations of our country who would otherwise not receive appropriate diagnosis and treatment they desperately need.
It's worth noting that this illness, unlike many others, cuts across racial, ethnic, religious, cultural, demographic and economic lines. No one is immune.
The ASAA is not asking you to provide ambulatory sleep diagnostic service on a carte blanche basis. A more rational approach to extending the current standard in-lab attended polysomnography to a less expensive and more accessible environment is to recognize that ambulatory studies can become, given the present technology, an integrated part, an integrated element of a system of care.

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The ASAA feels, however, that this can only happen successfully if it is overseen by a licensed qualified sleep professional who will then be able to use the latest technology to reach the most people in need.
DR. PEARSON: Mr. Grandi, I'm going to have to ask you to wrap up.
MR. GRANDI: We do not wish to replace the standard of attended sleep studies, but merely to argue the capabilities of trained sleep specialists to use all available options for the diagnosis, and we urge that you do provide adequate funding to support CPAP use under the conditions that I've described. Thank you very much.
DR. PEARSON: Thank you very much. Michael Thomas.
MR. THOMAS: My name is Michael Thomas, I'm the

president and CEO of Sleep Solutions. We are a manufacturer of sleep apnea products.
I just have three points I wanted to proffer to the committee. Number one is that there is a little bit of evidence that has been published in regards to patients who do not want to show up or do not want to be studied in a sleep lab. There's a study by Dr. Elso and Dr. Grant at the University of Buffalo that showed that anywhere between 22 and 27 percent of patients decide to no-show when they have a scheduled sleep study.
There's another study that was published by the

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Minnesota VA, it was Rice, et al., and I believe you have that information in your packet. That was a very good study showing two different things, that there was a significant increase in utilization in terms of the number of studies, but the impact that had on the overall budget was 60 percent, with about a 600 percent increase in the number of sleep studies that were done over a five-year period, again resulting in a 60 percent increase in budget, so it was a very cost effective approach in terms of diagnosis.
The other part that they had in that particular study was to show the patient outcomes as measured by the Epworth sleepiness scale and also by a validated tool, the function option sleep questionnaire, which also was similar to polysomnography.
And then the third and final point I just want to make, again, there was another published study by Peary, et al., that showed -- it was actually done at Walter Reed Medical Center, that showed that as many as 30 percent of the patients done in a tertiary care center with polysomnography had needed their studies to be redone again.
So again, the literature does have examples of the flawed standard, so to speak, and that there are uses for portable studies, and I hope you will consider that. Thank you.
DR. PEARSON: Thank you. Two more. David

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Kuhlmann.
DR. KUHLMANN: I got a lot of what I needed to say out up there, and I appreciate the time to further comment on the fact that really as far as being, I mean, all this home monitoring is fine if that's what you feel is best. I don't know, I'm not an expert. But we really need to make sure that if we're doing this, we're doing it for the right reasons.
You know, you talk about cost effectiveness of diagnosis, whatever, but really what's important is the cost effectiveness of the management. And it's, there are studies showing that sleep specialists are the best to manage this stuff. The problem a lot of times when people have problems with CPAP, it's because they don't have a mask that fits right. I just would hate to see the day where, you know, you have home portable (inaudible) and you have a home health company for the management, because you don't have a

physician taking care of that patient, and that's what we're here for.
And that's, you know, to take us out of the equation, I mean, it's not cost effective, because we're the ones who, you know, manage them, and that's what's cost effective, not -- the diagnosis is certainly important, but we need to make sure that it's cost effective if he's (inaudible) by a specialist.

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The field is booming, it's a new field, and we have to kind of fight for our own little space in things, but it could be a big problem if people who don't have the best interests of people with sleep apnea and other sleep diseases in mind being the ones treating these patients.
DR. PEARSON: And Mr. Kingsbury.
MR. KINGSBURY: I know everybody's hungry so I'll be very quick. My name is Robert Kingsbury, I'm president and founder of Sleep Quest. We're a disease management company that takes care of sleep apnea sufferers, and I've done this for a long time. We've done over 10,000 studies. Our compliance rate really focuses on outcomes and treatment. We use board certified sleep physicians like Dr. Dement to interpret our studies. We had a study funded by ResMed called Square study.
I would like to take a step further on Dr. Ryan's great speech this morning and say that we went a step further and did psychomotor (inaudible) testing. What we did, we checked people's reaction time 30 days after they, 30 days on initial diagnosis, and we showed -- and we also did SF-36 measures. We showed off-the-chart results with, as far as emotional vitality and alertness. This was done on a small sample, it was published as an abstract. It was at the AASM meeting in Utah.
We work complementary with sleep labs. We have a

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great relationship with labs like Stanford. We're not trying to obviate sleep labs, we're trying to work in conjunction with them.
And finally, I think there needs to be a new code for in-home titrations that we haven't talked about. Thanks.
DR. PEARSON: Thank you very much.
I think we could all use some extra motivation, alertness, et cetera, after lunch. I would like to also thank, again, Dr. Trikalinos and the people who put months and months of work into this culminating with today's conversations, and all of the prepared speakers who traveled here, some from as far as Canada.
What we will do since we're running 15 minutes late, we do want to have plenty of time this afternoon, I would like to reconvene at one o'clock. That gives us 45 minutes for lunch. One o'clock we will start on the dot with questions to presenters, that's a very important part of the afternoon, and we hope to see you back after lunch.
(Lunch recess.)
DR. PEARSON: We will start our afternoon session,

which is a little bit more free-form, but we will start with an opportunity for the panel to ask questions of the presenters, and that can include both prepared presenters as well as public presenters. So we're going to spend approximately 30 minutes with questions and then move to the

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important questions since some panelists have to leave at three o'clock. So with that, if we can, I'll just open it up to the panel and to anyone who would like to offer a framing statement, or just start the questions. Marion. And when questions are asked of the presenters, would you please come up to the microphone to answer so that we can all benefit from it.

DR. DANIS: I would just like to ask, among the presenters there was some varied comments about how the categories of types I through IV are perhaps out of date, and that the current criteria for, or the number of channels needed is the sort of thing we need to be paying more attention to. I was wondering if we could hear some comments from the presenters about how up to date the categories are and how we might think about any need to revise our thinking with that.

DR. BRECHNER: That would be an easy problem for me because if you go directly to CPAP, you don't have to worry about channels. But as to the rest of it, you know, I'll leave it up to others.

MS. RICHNER: Could I ask one follow-up to that? I thought the CPAP machines now also have diagnostic capabilities. How many of them are available in the home and are they classified in the other category or type IV or whatever?

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SPEAKER: If I might take a stab at that, Dr. Kuhlmann and I were on the panel that created those levels based on what we had available. Our thinking at the time was type I is probably somnography, type IV was simple oximetry, type III was most of the studies which measured basically the non-EEG component of the PSG, which was respiratory effort, heart rate, oximetry, and type II was a type III with some EEG, limited EEG recording. So that's basically the way it played out.

We now have technology that doesn't fit well into any of those. We have some that are type IV that don't meet the criteria for a type III, but have several channels that they monitor. We have a Watchpad which basically looks at pulse transit time and makes, drives data about its autonomic function and it infers, actually correlates pretty well, so that's what the state of the art is right now.

MS. RICHNER: Another important follow-up to that is the differentiation between manual and automatic reading. So, it seems to me that a lot of studies, that to me is a pretty critical point in terms of quality of the study ultimately, whether it was manual or automatic.

SPEAKER: Yeah. I didn't answer the CPAP question. There are CPAP machines now, particularly of the automatic

variety, that do provoke feedbacks of information that is, again, secondarily may have some diagnostic value. More

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importantly, they allow us a lot more flexibility in the management model, are less reliant on what happens in the sleep lab in terms of CPAP titration when we can get a 90-day printout of what actually happens with this patient. So all that is incorporated into these what are now involving fairly complex treatment algorithms that don't fit neatly into our prior view of the way it had to be done.
In terms of full disclosure, automation, all PSG today almost is electronic. We talk about full lab polysomnography and even those have some capability of doing some scoring, some grading of events, which is then reviewed by a clinician and altered hopefully, and that is full disclosure, they're able to review the data. I think most people in the field think that whatever the recording device is, it should have full disclosurability to look at the raw data to make sure that the diagnosis was correct.
DR. GOETTING: Mark Goetting. Just let me make a comment. Like many of the speakers, I ran out of time. The classification system, as I mentioned in my talk, it's probably not germane anymore, but in the type IV there's two types, there's a subtype of two channel or one or two channels, and then those that go beyond that.
And, you know, in our particular lab we use the Watchpad. We've done over 500 studies. It's a different way of looking at sleep-disordered breathing without actually

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attaching anything to the face. We can use it while people are on CPAP without interfering with their therapy. It does give a measure of whether the patient's awake or asleep, whether the sleep is fragmented, and to some degree what stage of sleep the patient is in. But it doesn't fit neatly into a category, so I would echo what the previous speaker said, that the categorization probably is not as clean as it was in 1994 because of the new technologies.
DR. RYAN: Frank Ryan, Vancouver. I just wanted to address your question about the diagnostic information available from the CPAP machine. These are unpublished data, but we did have an opportunity to look at that issue and we were looking specifically at patients who had residual sleep apnea, and despite treatment with CPAP, and actually that was as common with polysomnography as with the ambulatory approaches, which was interesting. We found that if you took the apnea-hypopnea index of 10 as the cutoff for residual sleep apnea, that the residual sleep apnea identified by the CPAP machine had about a 90 percent sensitivity and about a 46 percent specificity for that diagnosis.
So it has some utility and we felt it was clinically important, because when we looked at those patients, the patients who had significant residual sleep apnea weren't as compliant with therapy and their improvements in quality of life and sleepiness were not as

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impressive as the group as a whole. So it may be that these machines had the ability to identify patients who were not adequately treated with CPAP and they were appropriate for further investigation.
DR. WHITES: If I could ask one other question, when said failed, were these a failure because of the apnea event, or in particular the apnea, was it associated with significant desaturation, was that looked at as a separate item or would you just say failure?
DR. RYAN: No. Well, we didn't call them failures, we just categorized them as residual sleep apnea. In other words, when we downloaded their data from the CPAP machine, it showed evidence of residual sleep apnea.
DR. WHITES: You defined that as --
DR. RYAN: An apnea-hypopnea index of 10.
DR. WHITES: But no relationship to oxygen saturation?
DR. RYAN: That wasn't specifically looked at, no.
DR. CHEDIAK: Alex Chediak, American Academy of Sleep Medicine. I'd like to comment also about the automatic CPAP devices' ability to accurately record AHI. These devices use different algorithms for detecting events and distinct algorithms for how they respond. And if you look at all models for different devices, there's clear differences. There's not been a published study of, and if it's

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unpublished I'm not aware of it, regarding how good they are at actually reproducing AHI compared to portable monitoring and in-laboratory polysomnography. I use the information when I have it, but I'm not quite sure what it means.
SPEAKER: One thing about it, the whole thing started with a desire to find out whether a person is breathing, and there are many channels. The effect of the breathing is going to be seen in EEG, oximetry, pulse rate, but I think there's one thing that's very important to remember. Those other parameters can also be affected by other means. So whatever happens, the point I'm going to make, the airflow is extremely important, the only channel that's really related to the air going in and going out. Everything else is giving a little bit more information that might be important, might be very important, but that one channel is the key to the whole thing. And as long as that channel is there, I think, also the airflow and the sound that comes out of it, gives much more information about breathing problems than pulse rate, than EEG, than other channels.
If you go today to any engineer and ask him how would you measure sleep apnea, how would you measure if somebody is breathing, the last thing he would do is say I'll look at oximetry. The one thing is to measure directly the airflow going in or coming out. Thank you.

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DR. PEARSON: Yes, Peter.
DR. JUHN: A related question to this, and this is

linked to a question I asked when we did the technology assessment earlier, which is, the portable devices have a significant loss of data, so my question is going to be two. One is, is there a difference in the level of lost data depending on the type of portable monitoring device, and then secondly, how much or how often does the loss of data lead to an incomplete study so that the study has to actually be repeated?
SPEAKER: Unfortunately our literature is fairly flawed, and therefore the meta-analysis of our literature comes out with a fairly negative view. There are a number of published studies, small studies reporting people's maintenance periods with this technology that are included in the meta-analysis, 20 to 25 patients, and the data loss there, you know, we saw a slide with data loss of 30 or 40 percent, which is ridiculous. In the clinical world we're talking data loss in the order of one to four percent in large studies done on a variety of different technologies. The Sleep Heart Health Study did full polysomnography in the home, and I think Dr. Rappaport is here. He can comment on properly designed studies with studies applied by professionals with very low data loss, even when we're talking about 16 channel home

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polysomnography.
SPEAKER: Just for clarification, the Sleep Heart Health, I suspect everybody knows, is a large NIH-funded study were we did home polysomnography. It was full but it was unintended, so it included EEG, and the data loss statistics were all reported. It was quite low for the respiratory signals. The highest data loss was for the EEG and, as predicted, was more difficult to apply monitors. But there was around a five to six percent signal loss for the respiratory channels, five to 10 percent, I don't remember the exact number.
And the important point also is that when you look at the quality of the study in terms of giving a satisfactory interpretation, these were actually not patients, these were normal subjects or community dwelling subjects, so we had very low counts overall, as well as a small number of severe apneas that were undetected. So it was not a clinic population at all.
The downside, of course, was that it was an intensively difficult job to train the technicians who applied these so we could get the numbers as good as they were, and there were a lot of quality assurance issues. So although this would qualify as level II testing, it was extraordinarily labor-intensive although not necessarily intended.

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DR. DULLUM: So there is a lot of variability, because I heard somebody present earlier today, well, we'll just mail the packet to the patient and they'll stick it on. I mean, to me, I don't think I could do that.
SPEAKER: That's a completely different approach.

In other words, you can't do that with full polysomnography, you can't have people apply EEG electrodes when you just mail them a test. There are people who have attempted to come up with technologies to do that but to my knowledge there is no level II device out there, meaning one that gets EEG and all the channels that is self-applied. All of them are applied by a technician.
But what was referred to as the kind of thing you mailed is usually a level III or a III-like device, which bypasses the difficult-to-apply sensors and comes up with surrogates for it. It turns out the breathing channels, for the most part, are the easiest to self-apply. So once you decide that you're going to go with the surrogates for sleep, motion detectors, other things that don't have to be applied at all beyond being attached to the equipment, the breathing channels are relatively easy to self apply.
And we just finished a study that was referred to by Dr. Westbrook as being a home use study, looking at the particular device which can be mailed and self-applied, and the failure rate was on the order of six percent. So again,

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it depends what you're trying to measure, what your failure will be. The more you ask for, the more you fail.
DR. CHEDIAK: One more time, Alex Chediak from the American Academy of Sleep Medicine. The Sleep Heart Health Study, as already stated by Dr. Rappaport, was with normal people, and they don't thrash around in bed as much as our sleep apnea patients do, so the sensor loss there may not apply to severe sleep apnea patients at home.
When you mail the device to the patient's house, it's clear that they have a higher sensor loss, regardless of how simple it is to apply. I can tell you from personal experience testing a device that I was involved in, the additional deployment which was sort of a mask you wear during sleep and an oximeter, and I have been doing this for 20 years now, and mine failed, my oximeter fell off, and the alarm wasn't loud enough to wake me up. So things happen. When you send it home there's more likely to be a failure than it is if you do it in a laboratory with a technologist to apply it for you.
DR. GOETTING: One quick final comment, Mark Goetting. The device that we use, we've looked at our data and we've had a two percent failure rate, technical failure rate. Some of those were reckless use, we just pulled the device off, and others were people who had mental compromise. So you know, it's pretty good, and the device we use is

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Watchpad. And I agree, the fewer the signals you get, the better the signals you choose, the better technical results you're going to get from that.
And I'd also agree that you want to be able to have physicians looking at raw data to edit it, and we can do that with Watchpad, which is one of the other types of IV with three-plus channels. I just ask you to consider that. This technology doesn't involve putting something on the face, so

patient acceptance is pretty high. There's been published success rates of getting a technically adequate study that go up to about 99 percent, so it is something to consider. Patients toss around. Even in the Sleep Heart Health Study at age 60, 20 percent of the patients for the sample there had moderate or severe sleep apnea. The vast majority still with type III recording had technically adequate studies. The hook-up time for type II studies is published in the literature, it's about 45 to 60 minutes of tech time to put the electrodes on to get adequate EEG data to mimic, or for full polysomnography at home. So it's not a minimal task, you cannot mail it out. There are better choices for the average patient with sleep apnea.
DR. FREUDMAN: Since we're discussing real world experience with portable studies, our experience with the NoteSom, a type III study, first of all, the device does include warnings if leads come off, and video if you're using

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it, and the failure rate or data loss rate, I believe, Mike, it's what, about three or four percent? And that's with a largely Veterans Administration patient population, and that's with an analysis of what, about 10,000?
SPEAKER: 20,000.
DR. FREUDMAN: 20,000 patients.
DR. PEARSON: I think we can move on to another question.
DR. SATYA-MURTI: Minus a more proximal level, we found on the technology assessment that AHI is neither the best index nor does it correlate with improvement in function. And then we also heard that the upper respiratory areas is essential. And yet another facet is that it need not be an oxygen desaturation, but simply respiratory distress without desat. So this makes me wonder if OSA is starting to lose its definition, its type definition, and the more we look at it, the more diluted it's getting. Depending on how intensively we look at it, OSA may really lack a very precise clinical or laboratory definition, and we're working from that point.
DR. WHITES: If I can make a comment, we have looked at over the years, when it comes to sleep apnea, its major consequence was not the obstruction of the airway but what happens when that occurs over a long period of time, and that leads to cardiovascular complications, your sudden

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death, your arrhythmias. And the other could lead certainly to obstruction of sleep, sleep fragmentation, but the major consequences of what we're trying to prevent, at least from the health aspect, is not the nuisance of the apnea that causes the sleep fragmentation, because snoring does that, too, and we don't cover that if that's all you have.
So what we're really interested in, I think, and what we need to be concentrating on is the clinical scenario of someone with significant obstructive sleep apnea that does desaturate, that has symptoms from that, and the health consequences that do occur. The reason I asked the question

before concerning the lack of ability to monitor the desaturation in some of these patients and in correlating that with the need for extra CPAP, which may do nothing more than increase sleep, cause more hardships and less utilization. So again, that's something else we see in these patients. We kind of diluted, I think, the obstructive sleep apnea and its consequences in looking at that, and we want to make sure these patients don't have, instead of treating the snoring, sleep fragmentation, and we need to concentrate, I think, and at least have that information available to us as far as severity's concerned.
DR. GOETTING: Mark Goetting. As far as the spectrum of sleep apnea, it's probably no different than if you're going to talk about hypertension, glucose intolerance,

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depression or many other conditions. There are some obvious cases and there are some beneficial therapies, and then there is the spectrum that blends into normal. So we end up in sleep medicine of course drawing a line in the sand or in some cases at least of saying yes or no, and then often there is this gray area where the therapy is used.
But that's not really the issue with portable testing, that's an issue of defining what's abnormal physiology, then getting at how do you record that. I think we have the recording techniques, it's the blur with how a human tolerates these disturbances in physiology and whether that creates disease.
DR. KUHLMANN: As far as arousal versus oxygen saturations, probably the highest correlation with -- you know, sleep's a brand new field, like I said, and as far as studies go, what's probably most correlated with high blood pressure, if you believe that certain sleep apnea or hypopnea can cause high blood pressure, is arousal in oxygen saturation. There have been a couple of studies, unfortunately I don't have them here, to demonstrate that it's the arousals that are -- basically what happens is you have, you also find some (inaudible) partial closure of the airway, and what happens is that normally during the day the airway is kept open, but at night you lose a lot of that intervention into the airway and as a result it can collapse,

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and one of two things happens. If it's partially closed you can have a hypopnea, a partial closure of your airway, which can lead to snoring.
If you have a full closure of the airway, then one of two things is going to happen. Either you'll have an oxygen desaturation because you're not breathing, or you'll have an arousal, and the reason you have arousal is like I said, when we're awake we don't have a problem with sleep apnea, because we have chronic interventions to our airway to keep it open.
So actually if oxygen saturations are bad, you know, all these studies on strokes and partial hypoxia of the brain, that's very important from an oxygen saturation standpoint. But when it comes to symptomatology, there's

been a study showing that increased fragmentation and arousal is more associated with daytime sleepiness than oxygen saturation.
More importantly from a medical comorbidity standpoint, it's the, you know, the time of respiration. And what's happening is you have these episodes where we have sleep fragmentations, and they act like surges, so they might translate to a baseline level of high blood pressure, and once again I'm not going to say that sleep apnea causes high blood pressure, there's no studies out there that say that. Do studies strongly support this, yes, but it's not the

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oxygen saturations that are associated with the high blood pressure, it's the arousals.
DR. GOETTING: I just want to address the comment regarding oxygen desaturation and apnea as it relates to cardiovascular endpoints. There is that conventional wisdom, and before I became a sleep doctor I was a pulmonologist, so I obviously think of oxygen as very, very important for everything, but I've come to think of it a little different now. The best data we have that CPAP alters cardiovascular endpoints leading to mortality came from a veterinarian in, I think it was 2005, 2006 that it was published, and there he showed that patients with an AHI greater than 30 who were treated with CPAP had better outcomes than both non-patients with fatal cardiovascular (inaudible). In that particular study, they don't use oxygen desaturation as an indicator of hypopnea necessarily, so they could or could not have been desaturated.
If you look at the test tube data and you take it away from the humans, and it's hard to do, but if you look at the test tube data, sleep recognition has been shown to produce much of the same sort of changes at the cellular level and at the level of low blood vessel responses to stimuli as sleep apnea, so it just seems that we have the ability to do it. Whether we've done it or not, I don't really know yet, but the ability is there.

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DR. DULLUM: I just wanted a clarification on the access to in-lab PSG available to patients. I've heard a lot about that's the reason to have portable monitors, is because patients do not have access to these tests. I just want to know if that really is the percentage or not and has this been accurately looked at, or is this just a number that we're pulling out of the air.
DR. PEARSON: Could we have one pro and one con?
DR. KUHLMANN: I just want to say, the wait time in my lab is two weeks, and in general in order to be a competitive lab, you know, you want to have a minimum wait time, and a wait time of two months I think is rare. I'm sure there are places that have ten-month waits, I've never seen such a thing. What would have been more helpful rather than having a range of two to ten months, which would probably have been inaccurate to begin with, but it would be better to have a mean in different service areas of the wait

time. I'm sure there are places that have longer wait times, but I think in general probably not.
SPEAKER: I work at a hospital in New York and we serve a predominantly indigent and underinsured population, not directly relevant to Medicare, but it impacts heavily on the answer to the question. And the answer is that currently those people have no access through PSG because it's not adequately reimbursible. In fact, Medicaid criteria say that

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you have to have a PSG to get CPAP but then refuse to pay for it essentially. And most of the labs until recently, at least in New York City, just simply would not take Medicaid patients. They all usually surreptitiously would refer them to us, we've always done them but essentially we don't even bother billing them, we do it for free. So access is very poor in my kid's bus driver and the city, you know, subway drivers and the other people that we rely on who are in this group of underinsured and indigent.
It's much better if you're able to pay for PSG.
There's no question that the data that shows things aren't as bad as they might be, if you look only at the insured population, and Medicare is actually doing pretty well in that regard, yes, the PSGs have grown in availability to match the number of patients, but if you project that curve according to what we think is the number of people who have not come to medical attention yet, it's a huge number and it's likely we will have to open an awful lot more sleep labs to serve them.
DR. FREUDMAN: John Freudman, Sleep Solutions. I just want to echo, the access statistics are going to reflect populations you're looking at and they're not going to reflect the patient who either lives too far away to either call to get an appointment or refuses to spend the night in a lab. So yes, access has improved but the numbers don't

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clarify the patients who are unwilling to go, and it also isn't necessarily the issue that there is an evidence-based alternative as well, but it ought to be an option.
DR. TRIKALINOS: I just want to say that we had a difficult time to find out what was the mean time, the mean time delay for a person to get facility-based PSG. So Dr. Ryan showed a slide from 2004, a study from Australia where they called centers in the United States and did a survey, and the ranges were from two months up to 12 months, if I recall correctly. They note that this is very variable depending on the region, depending on whether it is in a rural area or an urban area, whether this is a university hospital or not. But I don't feel that we have established data that's reliable on how long the average delay is.
DR. CHEDIAK: Two different issues. I noticed that my name was on that chair reserved, and I wondered if you guys knew something I didn't know.
First, with respect to Dr. Rappaport's point about indigent patients, I have the same problem in Miami, and definitely Medicaid requires polysomnography for CPAP, and so

it's a healthcare issue, not a polysomnography access issue. The fact of the matter is that when we polled our 1,200-and-some-odd accredited facilities, we got back nearly 1,000 responses in April, we had about a 12-day wait time, excuse me, 14-day median wait time for polysomnography and 12

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days for consultation, and those are the facts. Now if you want to look at it geographically, Wisconsin has no accredited lab so I don't know what's going on in Wisconsin. So to find out what's going on in Wisconsin, make it necessary to have your test done in an accredited facility and they'll all get accredited by next year.

DR. PEARSON: We're going to end it there. Yes?

DR. BARKLEY: I have a question about the portable monitors and video. Do they all have video that comes with it, do none of them have video, how is that taken into account with those portable monitors?

DR. GOETTING: None that I'm aware of have video. There's probably some out there that have it, but none of the commonly used ones have video.

And let me, if I can, take one or two sentences to mention a patient group who has not been discussed, and those are inpatients, those who are in rehabilitation facilities. You cannot get them into a laboratory by ambulance and there are people who have, my patients who will be on a rehab floor for stroke with clinical sleep apnea as noted by the nurses. We can't get them tested in the facility, you know, so a portable test would be ideal. There are other examples where laboratory polysomnography is just not practical.

DR. PEARSON: Let me ask a question, actually Dr.

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Trikalinos in particular, if you would come up and answer. I feel that with all of the comments about PSG, we are also going to be asked to look at home testing and clinical titration, and we should be equally worried about false negatives, perhaps even more so than false positives. Personally I'm a little bit less worried about false negatives because I figure the patient may end up getting a PSG ultimately if they have a negative home test and they're still not doing well.

But from your view of the evidence, can you help us understand what you think the risk is for a significant increase in false positives with the use of home testing as opposed to PSGs? I know you commented on the possibility that an older population would raise that, but can you first do what you know from the evidence and then your speculation?

DR. TRIKALINOS: We did not specifically assess this specific question, so whatever I'm going to tell you is whatever I have learned through my research. I don't think that there is any data that documents any health harm from false positives that would lead to a CPAP trial. I do not know whether there are adverse health events associated with a false positive of diagnosis of sleep apnea that would then lead to a CPAP trial. There could be cost considerations,

though.
DR. PEARSON: I'm just concerned with the actual

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evidence on the rate of false positives. Is it your understanding that home testing would lead to an increase in the rate of false positives?
DR. TRIKALINOS: Okay. I think -- well, it all depends very much on how you treat the gold standard, the reference standard of facility-based polysomnography. In our analysis we treat the lab-based polysomnography as a reference standard that has representative specificity, so according to this benchmark you would expect more false positives.
DR. PEARSON: Can you help me gain some estimate of the magnitude of that increase?
DR. TRIKALINOS: Okay. In the modeled strategies that focused on the 50-year-old cohort, based on the evidence that's out there, approximately 15 percent of false positive diagnoses are expected, and this has to do with the specificity of being approximately 84 percent. In our sensitivity analysis for 70-year-olds, we analyzed this to 70 percent, so this would be a 30 percent false positive, crudely speaking, but this is an example.
DR. PEARSON: Thank you. Do you have just a short specific question about that?
SPEAKER: To directly answer your question, there's several published studies and I'm not aware of a single one that reports a higher number on the ambulatory study than on

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either a simultaneous or a non-simultaneous PSG, and the reason for that should be obvious mathematically. The problem with calculating an AHI is that you need both numbers of events which you can argue about whether you get exactly the same number, but it usually is, and the denominator which is the amount of sleep time. Since almost all the monitors we're talking about don't measure sleep, they make the assumption that either the total recording time is always longer than the amount of sleep, or some subset of that based on bad signal is what you divide by, and so they tend to lower the AHI. So the raising of it artifactually is really only due to having a very poor respiratory signal, and that's not usually published, or it can be also due to something else.
We do it in studies that we've done looking at the AHI in a home study and then sending out the data to different sleep centers and having them read the same data. Some of them will be higher, some of them will be lower. So it could be a false positive and a false negative on the home sleep study with the same exam, depending on how you read the PSG. So that makes it a very difficult question to answer.
DR. PEARSON: One more, and then we've got to move on.
SPEAKER: I would like to comment on the possibility of a false positive. Sleeping in a hospital

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laboratory is not a native environment, sleep efficiency in a sleep laboratory is not great, and it's quite possible that someone could have more REM sleep in their bed at home, which is a familiar environment, which will drive up the AHI. I can't recall ever seeing a false positive type III recording for obstructive sleep apnea. The only concern is the misdiagnosis of Cheyne-Stokes ventilation defense in a type III recording with OSA, and that's something we talked about earlier.

DR. PEARSON: This is a process time for us. If we want to start to move towards our own internal conversations, it's about that time. So if you have any specific questions of perhaps specific folks, that's still certainly fine, but then I think we'll move to more internal conversations.

DR. DEHMER: I have a question that probably relates more to the individual than it does to the equipment. We've heard all this information this morning about PSG and whether it's a gold standard or a flawed standard, we've heard all the technical information about the home studies, but it really seems like it boils down, and several people have emphasized this, it's the importance of the individuals who are interpreting the studies, is at least equal to all the fancy whistles and bells in this equipment.

So this is probably going to generate a long line at the microphone but I would like to know what it takes, if

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I wanted to go home when I get home tomorrow and hang my shingle up and say I'm a sleep specialist, what kind of training would I need in order to do that? Now that being said, I'm not going to that, I'm a cardiologist, and I'd like to say that all EKGs need to be read by a cardiologist, but in fact there are many physicians that can diagnose atrial fibrillation on an EKG and they don't need to be a cardiologist. So what are the criteria for becoming a sleep specialist and what are the minimum among the criteria that one really needs to know to interpret those studies.

DR. CHEDIAK: Well, the American Academy of Sleep Medicine, which accredits facilities and sets standards of care for a variety of sleep disorders, has been very interested in that problem and spearheaded now what in April is going to be the first ACGME-sponsored sleep certification examination. That's a credential that doesn't necessarily, it's not sort of required for payment, so if you're a Medicare beneficiary in Florida where I'm from and you want a sleep test, any physician can open an office right there and say that they're doing sleep testing. You can do it in your office or you can have an independent diagnostic testing facility. I personally think that's unfortunate and hopefully we will be able to change that.

In some other states like in Alabama they require AASM accreditation for the center or laboratory in order to

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be paid for doing the tests, and in the AASM accreditation standards, you have to be a board certified sleep doctor

overseeing all the studies and reviewing all the interpretations.
Now to get to that point, to get board certification as it stands today in a five-year window to get in there, where you either have one, have already received certification from the American Board of Sleep Medicine, which has been around for a number of years now, and you're allowed to take the examination. Two, have completed a year of fellowship training in sleep disorders medicine by an ACGME-accredited program, or what used to be an AASM-accredited program before ACGME took over the accreditation process. Or three, have at least one year of accumulated experience in sleep medicine by self-validation over the previous five years, and then you can take the exam. So if it ever becomes necessary to have board certification in sleep medicine in order to be reimbursed by Medicare, these are the steps for you to get there.
In order to get there you could be an internist, you don't have to be a pulmonology internist, so you're eligible. You can be an otolaryngologist, you can be a pediatrician, psychiatrist or a neurologist, those are the pathways.
Now having said that, there are some other caveats

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about how one can do testing but they're very much state-specific, and the variance is so huge from one state to the other, it's impossible for me to predict except in those states where I know the law for reasons of convenience or reasons of problems I'm addressing.
MS. RICHNER: In terms of the home monitoring and having someone read that report, who would be certified to read it, wouldn't the management change from the things that we have now in terms of access, if you're thinking that a certified physician would have to read the report, would there in turn be some change in home monitoring or diagnostic reading?
DR. CHEDIAK: The question pertains to what is the minimum credential to allow for a primary reading of home studies?
MS. RICHNER: That's right.
DR. CHEDIAK: And I don't think that's been clearly established. From the American Academy of Sleep Medicine point of view, I think you have to be a sleep doctor, board certified in sleep medicine. I think it's part of the curriculum and the training that we go through, how to look at and interpret portable recording. Now, is there another credential out there at the moment, not that I'm aware of.
MS. RICHNER: So what will be the cost? I mean, if home diagnostics are available, then the certification of the

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reading, and then the therapeutic treatment options after that would have to be determined, so it seems that there's going to be an issue here among all of you here with different societies, respiratory therapists, sleep physicians, the home health, everyone's going to have to do

Kumbaya to come up with --
DR. CHEDIAK: Well, the Kumbaya is already going on. You'll recall that Dr. Sam Kuna mentioned that there's already in Washington, I think it's going to be the 15th or 16th, and I will be back in Washington for that meeting, there's going to be a joint meeting to look at research issues in portable monitoring. The American Academy of Sleep Medicine approximately a year and a half ago formed a task force to look specifically at if portable monitoring is going to be used, what are the sensors, what's sensible, how is it going to be monitored, what's the minimum disclosure we're going to have, and then develop some guidelines for qualifications for interpreting and reading. That report was presented to the board of directors of the American Academy of Sleep Medicine about two months ago. It's undergoing revisions and so forth, so I don't want to speak to it directly, but it is in the pipeline.
MS. RICHNER: Right now there's an issue of self-referral in some sense, isn't there, because it seems to me that the physician orders the test, the sleep -- I'm

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trying to follow the pathway here, because, you know, given that we're going to have -- well, you know, that the home diagnostics will be available some day, that there's going to have to be some kind of process for who reads it and who gets paid for that.
DR. CHEDIAK: And we agree, and we're in the process of developing this. But there are other developments. We need to know what sensors and what types of monitors are going to be widely used and approved, so we're in a catch-22 a little bit, but we are in that process and we are very aggressively working towards coming up with guidelines for use of portable monitors that would be used through our AASM-accredited facilities, and would deal with training board certified sleep doctors.
DR. PEARSON: Gentlemen, I'm sorry, we're going to have to keep going with the other questions. We are going to move very soon into the phase where the panel has discussion. I know we have three people who need to leave at three o'clock, so we're going to get through our phase of internal discussion and be able to have at least part, if not all, of the voting by three o'clock.
DR. SATYA-MURTI: Well, anyway, we heard that your anticipated completion of study in June 2009, and then we also heard this morning, I don't remember if it was referring to the same issue, that they are likely to be asymmetries,

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and I wonder if it's design flaws. Now that we have two years ahead of the study, is it possible at this time for the advocate groups and minds to meet and address these design flaws?
DR. CHEDIAK: We've already given them money, and the actual design of the study was not purposely made to exclude anything, it was trying to reproduce what clinicians are likely to do, which is in moderate or severe sleep apnea,

either have a full out-of-the-laboratory evaluation managed by a sleep expert, or a split policy, and then look at the primary outcomes properly powered of number of hours of use, of acceptance of therapy, and there's one other which escapes me right now, and a few secondary outcomes. The importance of it is that in contrast to what you've heard from other studies today, this study will be powered to actually answer that. In order to show CPAP compliance at three months, we calculated we would need 180 subjects each month. So this study has about 390 subjects that are going to be recruited for it. It's going to take a while, but the money's gone and I'm not sure we can do anything about it.
SPEAKER: The problem with the asymmetry, very quickly, has been brought up before the deadline even before this protocol was submitted. There are some problems and I think there are some political type issues that really need

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to be ironed out, and it was brought up before that there was some significant problems that may need to be addressed at this level. I don't think this study is yet ready for prime time.
DR. PEARSON: Marion?
DR. DANIS: A quick question for Dr. Ryan. You used just the oximetry despite the fact that your device had other things. And could you just tell us, we were thinking about, but because we're hearing airflow is --
DR. RYAN: Well, the justification for that is we wanted something simple and we could have gone with oximetry. The particular instrument had published data on likelihood ratios and that was very important to us in developing the study. So, my comment about the other channels that we weren't going to use was that it was useful for corroborating. We didn't actually use those data to select our patients, but in clinical practice they are useful. My own preference would be to have something that measures other respiratory data, particularly airflow, as well as oximetry. But from the point of view of the study, we interpret the data as one would interpret an oximetry, which is a type IV device.
DR. PEARSON: This will be the last question.
DR. JUHN: Just a very quick question about, it has been raised a couple times today about false positives, as

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well as tertiary trials of CPAP therapy and the harms that come from CPAP therapy. And I think with Ross's presentation, there really aren't any clinically documented harms, but there may be some harms regarding management of that patient. And I think in some of your letters several of you commented, and I'm wondering if anyone would like to talk about what harms they foresee in actually managing someone if they are falsely put on a CPAP therapy.
DR. GOETTING: Let me make a quick comment on that. It's very difficult to get patients to adhere to CPAP and that's an issue of you need the right patient, but you also

need the right physician, someone who is confident that this person is likely to benefit from therapy. If you don't know if the person has sleep apnea or not and you're just going to put the mask on and ask them to sleep and then see if they feel better, clearly there's a placebo effect. This has been done with at least one medication study for an intervention for sleep apnea. Some people will feel better, and those people who use CPAP are emotionally invested in its success, and I don't think you can absolutely judge by a response that way. But on the other side of it, it's very difficult for someone who even needs to use CPAP in some cases to use it. So it's a confusing issue that way. Is there harm? It's difficult to get enthusiastic prescribing a therapy that

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is hard to use, that you're not even confident is going to be beneficial. And let me just make a quick other point. You don't necessarily have to use airflow to look at sleep fragmentations with sleep apnea. This is a very robust correlation that when sleep apnea occurs, at the resolution of it there's a sympathetic discharge that can be measured with other devices, one of them is the Watchpad. You don't have to put something on their face to have a good idea if they're having sleep-disordered breathing.

DR. BURTON: Steve Burton, Ion Healthcare. There's many things that happen if you go straight to CPAP. One of them is, putting pressure on a person's face changes their airway, so you will not be monitoring exactly what they are in the absence of treatment. The other is a lot of times people have such a negative reaction to this device, and even if they have trouble tolerating it, they won't be back for the sleep study, and that applies to thousands of patients that we've managed, and most of our referrals come from surgical centers. And they have, you know, they might post a case that's two days away, and so they'll say let's do a CPAP trial. The challenge we have is they may carry them through the postoperative week. The bill that Medicare gets for setting that up is two times the home diagnostic bill, so it's very cost

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ineffective to go straight to a CPAP trial, because you have so many one-time charges that you're incurring about a 4 or $500 bill for starting the CPAP, where you could have $220 for a reliable home test. So I would suggest it's very cost ineffective to go straight to CPAP. And then you've got a patient who says oh, my gosh, this is the experience I'm going to have, then you have a hard time getting them to go to the lab or even take a home test, because they say well, if I learn I've got it, I've got to start using this device. So it's almost cart before the horse, and it can be for us in managing patients. Like I said, I've really got no dog in the hunt whether to use a home test or sleep lab, the insurance company is paying me to manage the patient. But I can tell you the process we have

today is, given the flexibility of allowing them to take it home allows us much greater compliance and getting that patient to determine if they're going to use something, than if we go straight to the end game and try to use it.
DR. PEARSON: Last comment.
DR. KUNA: Sam Kuna. Like any medical intervention, about 50 percent of the patients adhere adequately to CPAP, so that it's very useful as a physician managing that patient to know why you started him on the treatment in the first place and how far you should push to get them back on that treatment to manage their care.

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The other point I want to make is we really don't know why people do adhere to CPAP. The literature is not consistent tying it to any of the potential symptoms, Epworth sleepiness scale, apnea-hypopnea index. And we know the patients make their decision to use CPAP or not in the first several days use, perhaps even before they have experienced any clinical benefit from that treatment. So that it's very problematic relying on CPAP to decide whether or not you're adequately treating a patient with sleep apnea.
DR. PEARSON: All right. So, thank you. So, we have, what I would like to spend is about 30 minutes before we move towards discussing formal voting and during that time is for us to have back and forth conversation. We can certainly look at the questions that we're pointing to now, start to ask specific questions about what they mean, and if we have comments about certain elements of the data that you feel are particularly important in considering some of these, but this is the time for us to start to chew on this. Yes?
DR. HIRATZKA: Question Number 3 here, explicitly it means physical examination in this respect, and I assume you mean by the presentations about this particular subject, because even if the evidence base is poor, there is no financial incentive, but I find it very difficult to judge any of these particular categories for Question 3.
DR. PEARSON: Yeah, but this is a question, I will

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invite Ross if he's here, or Louis to comment, because I am really not sure that we as a group will give value added voting on the clinical criteria.
DR. JACQUES: One of the reasons why this question is here is that clearly we can't anticipate in advance what things the public or others might say at this particular meeting. And if the sense of the committee is that there is not enough evidence about any of these things to reasonably answer the question, then the committee can certainly choose not to.
MS. RICHNER: I have a question. I always, you know, being a health researcher for many years, if you can look at any particular environment that would reflect sort of the lack of restrictions of payment, and then you go into an area that's a laboratory of sorts, and I know there's been studies at Kaiser, I know there's been a study at VA. Is there some type of treatment guidelines they put in place at

some point that I didn't really see that would define clinical criteria, to have a home diagnostic versus an in-lab facility diagnostic? Was there anything in, was there anything published in anything that has been published at Kaiser or the VA from that perspective?
DR. PEARSON: Dr. Trikalinos, did you run across anything published during your research?
DR. TRIKALINOS: Unfortunately, these were mainly

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retrospective studies and were excluded.
MS. RICHNER: They're retrospective?
DR. TRIKALINOS: I think there's a couple of studies from Kaiser that were retrospective and we excluded them. I mean, I obviously remember that.
DR. DANIS: It seems to me that the VA study really had some very good criteria and it seems like the Canadian studies did, and it seems to me also that we're going to be, I think that the fact that prior probability influences your interpretation of what you're planning here, it's very important for us to think about some of these factors. And it seems like things like the Epworth sleep score do have a very useful value, which is to say that we ought to try hard to think about these things. And I was struck among others that there is not type of tension in --
DR. PEARSON: We're not going to take public comments. Thanks anyway. If you want to ask a specific question for a clinician, you can still do that, but I'd like to try to keep it among us now.
I also -- this issue -- I mean, I'm torn too, because the study that Dr. Ryan spoke of, clearly, you know, is among the better if not the best study in which we would want to see the Epworth sleep clinical score perhaps used as some kind of method for clinicians to judge high prior probability in conjunction with home tests or going to CPAP.

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I'm not sure if it's our goal to help Medicare to do this. It's clear that the literature is full of different kinds of algorithms and decision rules to decide who is a high prior probability. So it really would be helpful for us to indicate which of these you feel the literature currently says are among the most important.
DR. JACQUES: Yes. I mean, the committee could also decide that there might be too much precision implied in the question the way things are sort of outlined, and you know, the committee might choose in answering this question simply to comment on a particular topic or to question generally about physical diagnosis signs or clinical symptoms presented by the patient, or something along those lines. This question was in the context of, if someone were going to do a trial of CPAP based on clinical diagnosis alone, i.e., in-lab strategy using PSG or home testing, would there be some constellation of those sort of other clinical symptoms that one would require to meet some threshold in lieu of testing in order to qualify for CPAP. But if the committee feels that there is not enough evidence to answer

that particular question or that the whole question in light of the discussion today really can't be taken in that context, then the committee can certainly decide to change it.
DR. PEARSON: Let me just ask the committee perhaps

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for some direction. We'll start with, the importance of that as Louis said, is whether we believe that clinical evaluation going straight to a trial of CPAP is a strategy that we would recommend. I would like to invite comments on that before we move to the question perhaps of home testing versus PSG. So what about clinical evaluation straight to a trial of CPAP?
DR. WHITES: Well, I think it has been shown as a general comment, based on clinical evaluation alone without specifying what part of the clinical evaluation, this question couldn't be answered. I think it must be very specific, and who's doing the evaluation. If we're talking about, I think a nurse practitioner, which is the CNP that we have today, or a physician's assistant who has that ability to order the test and be paid for by Medicare, are we going to go by that clinical evaluation alone with no more expertise? And I think that's a very easy question to answer.
On the other hand, if we're talking about a boarded sleep physician who has clinical experience, then the answer may be a four or a five in that extreme circumstance. If you're looking at BMI, you look at witnessed apnea, you look at nocturnal oxygen monitoring which shows desaturation, I think you'd probably feel fairly comfortable. So again, I think the question, at least when I look at it, is much too general and not specific enough to give an answer.

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DR. PEARSON: I don't get another comment but just to be clear, are we considering overnight oximetry as part of clinical evaluation or as part of home testing?
DR. WHITES: Again, I think that's something we have to decide. I would hope we would consider that as part of the clinical evaluation and not home testing. Again, we've got a lot of definition when we talk about home testing devices in question C. We don't design those home testing devices and so it would be yes but, or no but, but I think in the general questions, I think it's the only one that's specific in here that has reference to a PSG. So when we talk about the PSG as a type I, I gather what they're talking about is it could be a type I or type II, but it doesn't say that in the question we have here. So I think that we must be more specific and I think we're going to have to, when we answer the questions, clarify those questions and I don't think we can generalize them.
I think the other question that comes to mind right now is that it's deciding whether or not we need to open the dam without knowing what's downstream. And we are looking as far as I'm concerned without those regulations and without the clarification of who's going to be reading and who's going to order, that's really a major concern that I have.

DR. PEARSON: Yes.
DR. KONSTAM: I guess I would be very reluctant to

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condone a trial on the basis of clinical evaluation alone. I mean, if there's one thing that I have learned during the course of the meeting today is, first of all, it's a very confusing area. There is, you know, contradictory evidence in the literature. You know, I don't know how we know that we know how to make the diagnosis, but I think we agree that there is no absolute gold standard to cite other than the fact that PSG was PSG. I think in terms of dangers, I think, you know, the risk, if you want to talk about risk, I guess there's always a risk, you know, when you are uncertain or you don't really have a correct diagnosis.
Now, you know, I think there probably are people who are much better at it than most of the rest of us, but how is anybody going to decide who that is? And if you believe at all that, you know, there is the ability to do it, do we know anything about the ability to do it in the Medicare population, where we know even less, you know. So, you know, I think what's clear is that these different pieces of information are complementary, the clinical evaluation provides complementary information to the testing. And you know, from my gestalt, you know, I want some confirmational information before sending a patient to a CPAP trial knowing that they're very likely to reject that from the comments that have been made that, you know, you need to sort of reinforce that they really have this diagnosis, and to bank

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on them without that, I see problems with it.
DR. PEARSON: Yes?
DR. SATYA-MURTI: On Question 3, the last row is others types of testing. Now maybe consider just plain oximetry, because that seems to have been crucial at least in some of the studies, along with clinical scores. Therefore, the VA does use that as a threshold to even make an approach to CPAP. So if you believe in the strength and merits of the preceding clinical symptomatology, maybe that other could be broken down to just plain oximetry, in which case like the Senn paper that speaks to, only requires clinical trials of tolerating and using the CPAP for more than two hours per night, and they found 76 patients -- 31 were truly (inaudible) and they used somewhat similar criteria.
DR. PEARSON: Yes?
DR. BARKLEY: The other problem I have with the clinical decision scale is that we have almost 10 or 12 different items, and if we all end up giving each one of them a high score, does that mean you're going to have to have all 10 or 12 of them in order to qualify for the diagnosis, or is it going to be something like the DSM-IV where you have to have four out of six or something of that sort? I really don't think that our panel is really qualified to make a valid judgment on this question.
DR. PEARSON: The reason I brought it up is for

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those who find the Ryan paper influential, if you were to wish to consider that home testing and clinical evaluation, or just clinical evaluation, we kind of need to know how to categorize it if we're going to use that as a basis for our voting.

So let me ask Dr. Ryan, was that home testing or was that clinical evaluation?

DR. RYAN: Absolutely it's home testing, because as far as I'm concerned, oximetry is a test that requires a lot of sophistication for interpretation, particularly to minimize the risk for false negatives and false positives, so it's definitely home monitoring.

DR. PEARSON: With that clarification, is there anyone who would want to say anything positive about clinical evaluation for an initial trial of CPAP, or should we move to the next threshold?

DR. EDWARDS: Well, you have at least one surgeon here and we tend to cut to the chase. I think if you have a physician who is sufficiently skilled in his craft, in sleep studies, and the documentation we've seen here has numbers up around 80 percent or better on clinical evaluation with a skilled observer, taking into consideration all these items on Number 3 and perhaps other parameters, and the lack of harm from the CPAP trials, I would say that at least given the stratification of the patients that we've seen here from

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AHIs of 5 up to 30, that somewhere in there there is a subcomponent that a physician could very clearly put on a CPAP trial without any problems whatsoever.

DR. PEARSON: Any other comments? Yes?

DR. BECKER: I would just like to comment. If we are going to say that clinical impression is good enough for putting somebody on CPAP, we need to know what the clinical impression is. It needs to have some sort of criteria like it has in Number 3, some sort of check-off list or an algorithm, so that you just don't say, well, he has obstructive sleep apnea and I'm sure he does, and there needs to be some foundation, some thought process going into this. And so I actually think that, well, I don't know whether all of these 10 or 12 criteria here are what you really need, or whether you need five of them or four of them or three of them. But you certainly need to have some list that people can look at so that they can make a reasonable impression.

DR. PEARSON: We'll go to Marion and then to the next question.

DR. DANIS: I think if you look at the Canadian study where the O2 sats really took you from 80 percent to 95 percent, it seems to me that to call that home testing really adds something to the clinical impression, and I would think it's important to fit it in.

DR. PEARSON: My guess is that the slope they're on

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in their research is they're starting with a very stringent criteria and as mentioned, the multicenter trial will loosen

that a bit, and we'll start to find out whether or not perhaps even about home testing producing harm, the study will be able to look at. But this issue of whether CPAP is out on home oximetry will be good enough for us (inaudible). Yes?
DR. BARKLEY: I'm unaware of any diagnoses that Medicare allows that some physicians can make and not others, so I think that if we say that clinical impression alone is significant to be able to order CPAP, that means that any provider, physician, nurse practitioner, P.A., should be able to do this across the country. So that yes, there probably are clinicians that do have that ability, but I don't think that the Medicare rules apply in that critical circumstance.
DR. WHITES: I think that's my concern, is that the data that we have, and I think from some of the studies from Canada, I think again, was a very selective group of patients reviewed, seen, evaluated by subspecialists in a very controlled environment who said you could wean down how many you ended up with out of the total number of patients. I think until we have such regulations that Medicare is about to do so, that we are opening a can of worms and are going to be in trouble to make a recommendation to go by clinical basis alone. I don't think we have the structure there to

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safeguard the trust fund and safeguard the patients in this area.
DR. SATYA-MURTI: You know, while I agree with that approach, there's ample situations in medicine where anyone can order MRIs to stress tests, cardiac stress tests. So to single out this clinical entity as deserving more of a higher standard would be setting a precedent, while I do agree.
DR. EDWARDS: Let me just say, I don't think we would be setting a precedent. In the DME world, durable medical equipment, CMS has already said in certain incidents that only certain specialists may do the examination to order a particular piece of equipment. So this would be a piece of durable medical equipment and it would be possible to restrict the purchase or ordering of this particular DME to that subset of physicians, and that would of course then subsequently restrict those who could order the test and interpret it. But there is a precedent for that.
DR. PEARSON: I think we're in very important territory but it's probably a bit upfield from our role. These are things that Medicare will think about carefully, I'm sure, and it's impossible for us to think about that in the absence of thinking about these conceptual issues. Looking at the clock again, let's move to the next one labeled at the next level. If Medicare is going to continue to pay for CPAP following PSG, let's talk about home

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testing levels II, III and IV. You're going to be asked to vote on whether you think the sensitivity and specificity of these are up to snuff, or if they are to ask a global question about home testing, but let's start to tease that issue apart, where it talks about the evidence, the use,

utility and accuracy of home testing.
DR. BARKLEY: I have a general concern about home testing where you have inpatient and outpatient monitoring, and like if you don't have video you don't know what's going on. So I just have a general concern if we're looking at people who by nature are thrashing around in bed, have lots of motion and artifactual movements that may or may not be related to sleep apnea, are we able to diagnose and treat that properly without some sort of independent correlation of, by some other means to know exactly what the movement is. And that actually applies to the set of more simplified testing where you are relying on one measure or a couple of measures where you have more redundancy to be able to say well, this could be the basic problem, but let's look at these other factors to see if there's a correlation.
DR. PEARSON: Other thoughts in particular about the II, III, IV distinction? Yes, I'm sorry.
DR. BARKLEY: And if you look at the technical assessment that was presented, the conclusion was that there was a difference in facility versus out of facility, and I'm

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not sure that we have the data at this point in time to make a firm recommendation for change. I think the process is there and hopefully it will be here shortly, but if you look at individuals who gave us these reports, that the statistical analysis that was done in the technical assessment, I think if I read it correctly, was talking in terms of home testing versus non-home testing, and I don't think the conclusion was that there was significant data that a lot of times you could make the determination.
DR. PEARSON: Yeah.
DR. KONSTAM: I didn't read it quite that way. I mean I, you know, I thought it was a great analysis and I think, you know, obviously there's a lot of variability in the absolute metrics for AHI, particularly IN, it really got big, you know, the variability increase got very high numbers, which probably reduces clinical relevance because he got the diagnosis anyway. I think the most relevant part of the analysis was sensitivities and specificities, and, you know, my conclusion from reading their results was, there was pretty reasonable sensitivity/specificity for the home testing, you know, relative to a facility-based analogy. Now, you know, they weren't perfect, but then again, you know, the facility-based analogies are certainly not perfect either. So I mean, I came away from that really feeling pretty favorably, and that I really couldn't say that

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based on a good combination of good clinical assessment and home-based testing that you weren't going to achieve reasonable indications.
DR. PEARSON: Peter?
DR. JUHN: I think in the TA it was stated that the interchangeability may not be there, but as far as categorization, and maybe looking at home monitoring as really categorizing someone into a high risk or low risk, I

think it was a valid assumption.
DR. PEARSON: One of the things that worried me was that the risk of publication bias in this kind of field is extremely high. Most of these trials are going to be funded by the companies making the home testing devices or with some link to them. And I'm not sure we saw any studies that, and maybe that's because they really do work very well, but I was struck by this publication bias.
I think with this level IV testing, it's kind of like level II is, you know, basically like the in-lab at home. Level III seems to be a pretty robust body of evidence. And I think if anything, the TA raises some question about type IV, and yet one of the best studies used type IV with various clinical evaluations, et cetera, et cetera. I don't know if others are wrestling with this issue about type IV, whether it's low evidence or whether we have very good evidence for type IV.

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DR. BECKER: I had one question about type IV and then I had marked difficulty determining exactly what is being monitored. Is it pulse oximetry in all the cases, is it upper respiratory breathing, efficient sleep, is it an EKG? I mean, we really don't see in these studies exactly which monitors are being opined. And I know from my work as an anesthesiologist just having a pulse oximeter on somebody for five or six hours even under anesthetic, a lot of times they're bouncing all over the place and it isn't due to the anesthesia. And so a person at home at night wrestling around, I think you need at least three or four different monitors on there to try to distinguish what's real and what's not.
DR. KONSTAM: Now, you know, I guess what I get out of all this is that this is a test, you know. Whether it's facility PSG or home testing, this is a test, you know, as opposed to thinking of PSG as the diagnosis, there really is in medicine almost nothing like that, you know, where the test is the diagnosis. The test is the facilitator for the diagnosis in conjunction with clinical assessment, you know. And to me, I mean, to me I think the testing, whether it be facility PSG or home testing, really should be viewed in that light. And I think viewed in that light, you know, you might say okay, well, maybe there's some degradation of information from the home-based testing, you know, there's evidence for

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that.
But you know, we've also heard a great deal of value to the clinical assessment, and I guess I can't get away from the fact that there are at least large numbers of patients who could be diagnosed with a combination of, you know, clinical diagnosis plus the home-based testing. And maybe that's not everybody, there may be people who there's still uncertainty based on that combination and they can go to facility-based PSG. But to say that, you know, it will never work, you know, to have home plus clinical assessment, you need the PSG, to me that's elevating the facility-based

testing to a level which I don't think is really accurate.
DR. PEARSON: Marion.
DR. DANIS: I really agree with that, and I think what it means is that I'm inclined to say the approaches done at home are acceptable depending upon other, you know, whether there are comorbidities, whether the prior probability is high. And so for us to answer these questions without the caveat being in there would make me nervous. I would want to say we, it seems like a reasonable approach for a test that can lead to a diagnosis if we can have those conditions on them.
MS. RICHNER: I'm agreeing again. I think that the issue is no longer whether a home diagnostic test is at least as good as the sleep lab diagnostic test. I don't think

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that's the issue anymore. It's whether and how the patient, you know, the whole algorithm and what it looks like, and how we clearly, you know, identify the patient population that it's most needed.
I'm going to fall back again on the Case Western study, I know the background (inaudible) and it's an opportunity to really track to see how they stratify the patient population that are really going to benefit from CPAP and how that all comes together with the clinical parameters as well as the level of the diagnostic tests. So all that I think is important. As a panel, what are we supposed to do about that? I think our responsibility first of all is to look at the evidence about whether or not this diagnostic in the home is as good as in a facility. To me it's obvious, it's good, it's there, so now we have other problems that CMS is going to have to address.
DR. PEARSON: And we are being asked also to help judge the evidence in the context of how generalizable it is to community physicians and to other patient populations. But this issue of type IV and who, as Marion was saying, in what context is it, the context of a well skilled clinician with a high prior probability. You know, I am a bit concerned that we don't have very much evidence of what may be a higher risk for false positives with primary care physicians or others who have snoring patients send them for

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a type IV. I just don't know what evidence there is right now to suggest that that's going to turn up a lot of false positives.
DR. BECKER: I guess I have a question. I think we should probably be considering this in view of a typical patient rather than the outlier patient, the one who is way, way out on the fifth percentile or the 95th percentile. Shouldn't we be looking to answer these questions on how we think the typical patient with OSA, how we can best analyze him and treat him?
DR. JACQUES: Well, I think the major task for this particular committee specifically, you know, what is the evidence and what conclusions can be drawn from the evidence. To the extent that there may be some qualitative discussions

about particular patient populations or particular providers, we certainly do listen to that. But it would not be up to the committee to write an algorithm, we've heard plenty of algorithms before, including everyone who's ever written on mobility assistive equipment, which I expect most of you are familiar with. So I think that it would be helpful for the committee to focus on is the evidence adequate to, you know, make some conclusions, and then we would wrestle with the issues of provider certification, safe scope of practice, all the other things that would impact on that.
So if the evidence is only adequate for a standard

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patient, then the committee could say the adequacy for a standard patient. If the evidence is not sort of sliced and diced in a way that one could, you know, do that, then I think the committee would simply make a statement on the adequacy of the evidence as a whole. And to the extent that there were other comments about specifics, then Miss Spencer and Dr. Brechner will be tasked in sorting all that out.
DR. SATYA-MURTI: Actually, I was hoping Question 7 would be Question 1. That makes it so much each easier.
DR. PEARSON: Yes?
DR. WHITES: The one comment in looking at the overview and the technical analysis, it says the ability of a portable monitor to predict (inaudible, off microphone) to be worse in home-based versus those in a specialized sleep lab. That was the overview. Again, the data we're looking at to answer the questions says, you know, specificity, sensitivity, but we're trying to apply this to an overall patient population, and we're saying that the information is not as good to predict the AHI, then you go back and say that the AHI is the item that we all really need to be looking at. What we really have is another bungled vignette that we need to be looking at as far as the history's concerned, what was the cutoff. And as I get information from 2004 to 2007, there was not a lot of additional information that answered those kinds of questions. And that was just a comment, thank

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you.
DR. EDWARDS: Just to follow along with that, again with reference to the home testing device type IV, I was under the impression from the literature that I read that it doesn't measure AHI as the others do, it measures something called the respiratory disturbance index, which can be restlessness, leg movement, a number of other things. And my concern is in a generalized population that those might be interpreted as respiratory events when they have absolutely nothing to do with that and may give too many false positives.
So I was concerned, first of all, if indeed it is an RDI, we haven't defined what RDI qualifies for CPAP.
DR. PEARSON: Right. Yes?
DR. DULLUM: I guess that I just feel that we have a system that works for Medicare patients now. I don't know whether we have a problem with access, it doesn't seem like

it from the presentations, and I'm just concerned that we will get home monitoring, the patients will not be in an attended situation. Medicare patients tend to have more or other comorbidities and can be at more risk. So there will be a mad rush to monitor a lot of Medicare patients because they're actually going to get paid for the test, as opposed to what it really boils down to, will we really be able to look at the comorbidities, find the problems, and

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appropriately treat the Medicare population instead of testing everybody.
DR. WHITES: One other comment, being from Mississippi, I hope you're all aware that we now lead the nation in obesity, we have now accomplished the greater than 30 percent threshold, but we also have the lowest birth weight, so think about that.
(Laughter.)
DR. PEARSON: I just want to pick up on a minor note that I hope the committee will consider and that is, we heard some comment about the fact that the AHI rises naturally as people age, I don't think there were any specific numbers on that, but if that's true, it's something where we look at international studies using cutoffs of 40 to 50, we have 15, but if it rises in the 60s and 70s, then we need to know a lot more about that before we start to pay for certain numbers.
We still have about 30 minutes before some people have to leave, so we have some time for conversation and time to do the voting and then wrap up early today. Any other specific comments, questions? All right. Marion, yes.
DR. DANIS: There was a time (inaudible, off microphone) children, and I just for my own educational purposes, are there data out there on sleep studies on kids who are getting more and more obese? And I wonder if, you

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said the Medicaid population, and I just wanted to hear something, do we have any concern about that?
DR. JACQUES: There would be very, very few children in the Medicare patient population, especially children who qualify for Medicare on the basis of some sort of disability specifically related to obstructive sleep apnea. We could from a policy point of view determine if the evidence were more in one test than another, to create some sort of other process for children, but I'm not aware that this has actually come up in terms of claims adjudication. I've never heard from contractors that they were having any specific problems or issues specifically related to children. And if there is no evidence about this particular therapy or diagnosis in children, then I think it might be more efficient for the committee to just sort of leave that issue.
DR. PEARSON: Yes?
DR. HIRATZKA: I would like to hear from the anesthesia colleagues on the panel a little bit more about this inference that was made for the risk of anesthesia in the diagnosis of sleep apnea, and the contribution or

treatment for reducing that risk.
DR. BOSWELL: As an anesthesiologist, my concern after anesthesia is related to postoperative complications generally related to a specific reaction to a specific type of anesthetic or anesthesia. The anesthesia literature now

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supports the high risk of sleep apnea (inaudible, off microphone) so while we don't know the exact incidence, it may be 15 to 20 percent in a postoperative patient, but we don't have good numbers on that.
But on a related question, I'm more concerned that, in a situation like that, I'm going to go ahead and treat irrespective of whether I know the patient has sleep apnea. I'll put pulse ox on, probably supplemental oxygen (inaudible, off microphone) that kind of thinking doesn't justify using CPAP without a diagnosis, because the risks are entirely different. So that's from an anesthesiology standpoint. I would like to have a way of knowing our priority.
DR. BECKER: The American Society of Anesthesiology has actually looked at this and published a practice guideline for the perioperative management of patients with obstructive sleep apnea. In fact I have a copy of it right here if you would like it. Basically we realize it exists, that it's becoming more and more prevalent. The incidence of obstructive sleep apnea in surgical patients is probably higher than that of the general population because some of the patients we're taking to surgery are actually having procedures for obstructive sleep apnea, such as a uvulopalatoplasty and so forth. Whether or not they work, I'm not sure, but we don't want to get into that.

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The other problem is that it is a real problem in a postoperative patient, especially on people who are having intravenous DCA analgesia with a continuous infusion of opioids, people do get opioids as a routine post-op, and there's a lot of guidelines out there that we actually try to limit the doses of opioids, if not eliminate them altogether, in people with obstructive sleep apnea because of the frequent instances of post-op hypoxia and sometimes respiratory arrest.
DR. PEARSON: I know we're trying to continue a full conversation, but since some of our colleagues have to leave at three o'clock, let's try to keep our comments as short as we can.
DR. WHITES: One quick comment. One of the problems that we end up with in the Medicare population the most is that there's no reimbursement for the inpatient sleep study type II, III or IV as an inpatient. It has to go as a DRG so a patient who is discharged could come back to have the study, even if, for example, the anesthesiologist witnesses apnea, they desaturated. That is a true problem and it may be something that we might recommend, that those inpatients who have a history that's compatible and are having a procedure done, that could be an avenue of having

those people tested there by whatever mechanism. Since the data says it's more reliable in a facility for type II, III

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or IV, we could get that type of monitoring as an inpatient.
DR. PEARSON: Yes?
DR. KONSTAM: You know, I guess I just sort of want to turn back to the technology assessment, just sort of okay, you know, what is the final word or what is the summary view of the technology assessment, because that's I guess my strongest guide. And to me the statement here that I think speaks to our issues the most clearly is, you know, type III monitors may have the ability to predict AHI suggestive of obstructive sleep apnea with high positive likelihood ratios and low negative likelihood ratios compared to high cutoffs in laboratory-based PSG, especially where manual scoring is employed.
Now the sentence that follows relates to type IV monitors, I won't read it, but it's a little bit more wishy-washy than that and makes me a little bit more concerned.
But focusing on the type III testing, I mean, you know, you can read that as a negative sort of statement, if you want to. I read it as a positive statement in the sense that, you know, we have a gold standard that's imperfect, and you know, if you come into the test with a high probability, you come into a test that has, you know, may have high positive likelihood issues or low negative, especially when manual scoring is employed. You know, I'd say, boy, I mean,

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I'm hard pressed to arrive at a qualification of the therapy in that circumstance. So I'm just not sure how we can turn around from that and say you know what, we've got to stick with PSG. I'm having trouble with that.
DR. WHITES: One of them would be then, is there such a difference statistically negative that you would do the type II, III or IV in a hospital-based area, since they seem to do better there than it does in a home base?
DR. KONSTAM: I'm not following the question. I mean, most of the studies actually come from a --
DR. WHITES: Looking at the studies and the way it's reported, it would appear that there was better correlation of data, less variance if it was done in a sleep area, a designated sleep area in the facility, and not necessarily in a home-based area.
DR. KONSTAM: Maybe --
(Inaudible colloquy, panelists speaking at the same time.)
DR. KONSTAM: As I read through the review, the majority of the data came from home-based testing and I took this statement to sort of incorporate that setting.
DR. TRIKALINOS: There seems to be lower diagnostic ability for the home setting. Now, there are quite a few reasons that might explain this. I think that one of the major reasons is that when you test, in this specific study,

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the two sleep studies were performed on different nights, so the night-to-night variability might explain much of this. However, this is not something that was formally submitted to testing. In this technology assessment we did not perform an analysis, only for the -- we did our analysis only for the modeling part because we needed some numbers. We did not do a meta-analysis because there's a lot of heterogeneity in the way that the actual reference standard was defined, the apnea-hypopnea index and the respiratory events, so with different monitors there was quite a bit of heterogeneity. I think the focus was not to try to give a summary of all types of monitors or all type IV monitors, given that there are also caveats about how these things get classified.

DR. PEARSON: We will now move towards voting, all right?

MS. ATKINSON: There are ballots in your folders with your names on them. And what we'll do is if you could fill out the ballots and then once Dr. Pearson reads off the questions, you have cards in front of you, numbered cards. You'll have to show the number that you've chosen so we can put it into a spreadsheet, and then Maria will come around and collect your sheets with the questions, okay?

DR. PEARSON: All right. So, we are going to start with number one, and I will just preface it by saying some of the questions are asking whether there is enough or

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sufficient evidence to determine, and then sometimes the follow-on question will be if there is sufficient evidence, how good is it.

So Number 1: How confident are you that there is sufficient evidence to determine if each of the following strategies can, in routine use, produce an accurate diagnosis of OSA for the prescription of CPAP?

1.A. Diagnosis based on clinical evaluation alone, ranking from no confidence, one, to very confident, five?

DR. EDWARDS: Your question specifically is, is there enough evidence?

DR. PEARSON: Is there enough evidence to judge whether it can produce.

(Panelists voted and votes were recorded by staff.)

MS. ATKINSON: All the scores will be posted on the web site as soon as the meeting's over, so you don't need to scurry around, we'll get it up there.

DR. PEARSON: 1.B, how confident are you that there is sufficient evidence to determine ... for diagnosis based on clinical evaluation plus PSG?

(Panelists voted and votes were recorded by staff.)

DR. PEARSON: 1.C, sufficient evidence for diagnosis based on clinical evaluation plus home testing device?

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DR. SATYA-MURTI: This is across the board, all home testing devices, right?

DR. PEARSON: Yes. I know we're about to split them out, but right now it is.
DR. KONSTAM: Well, can I understand that? Wouldn't it be any home? We can't vote on every single one, can we?
DR. JACQUES: The next one breaks it down into classes. We can't get into specific brand names and things like that, but if the committee were to decide that there were inadequate evidence to deal with some test --
DR. KONSTAM: So it's not all, it's any.
DR. PEARSON: Let's do any.
(Panelists voted and votes were recorded by staff.)
DR. PEARSON: Thank you. Moving to Question 2. All right. For each OSA diagnostic strategy for which there is enough evidence in Question 1, and I'll just pause to say that that means that you may opt out if you don't wish to vote on this one, even if you voted two or one, if you wish to vote on this, you may, but if you wish to opt out because you do not feel there was enough evidence, you may. So, for each one that you did think there was enough evidence on, how confident are you about the sensitivity and specificity ranging from one, no confidence, to five, very confident?

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We'll start with 2.A, the sensitivity, I'm sorry, specificity, the ability to identify persons who have OSA, clinical evaluation only.
(Panelists voted and votes were recorded by staff.)
DR. PEARSON: Thank you. How about the ability to exclude persons who do not have OSA, sensitivity, for clinical evaluation only?
(Panelists voted and votes were recorded by staff.)
DR. PEARSON: Going to 2.B, same question, specificity, the diagnosis is based on clinical evaluation plus PSG, the ability to identify persons who have OSA.
(Panelists voted and votes were recorded by staff.)
DR. PEARSON: Okay. 2.B, the second part, persons who do not have OSA.
(Panelists voted and votes were recorded by staff.)
MS. RICHNER: I got mine mixed up, I wanted five for the second one and four for the first.
DR. BOSWELL: Where are we?
DR. PEARSON: 2.B, to exclude.
DR. KONSTAM: Could we vote on 2.B.1 again, because somehow I missed that.
DR. PEARSON: So looking at testing specificity.
(Panelists voted and votes were recorded by staff.)
DR. PEARSON: Okay. Do we need to redo 2.B.2 or are we okay? We're okay. All right.

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2.C.1, 2.C, the first question. Diagnosis based on clinical evaluation plus home testing device type II, for specificity, persons who have OSA.
(Panelists voted and votes were recorded by staff.)
DR. PEARSON: Okay. 2.C, part two. Specificity.

(Panelists voted and votes were recorded by staff.)
DR. PEARSON: Okay. Moving to D, I think we're getting the hang of this, diagnosis based on clinical evaluation plus home testing device type III, specificity.
(Panelists voted and votes were recorded by staff.)
DR. PEARSON: All right 2.D, part two, specificity, persons who do not have OSA.
(Panelists voted and votes were recorded by staff.)
DR. PEARSON: All right. Moving to 2.E, we're up to device type IV, the first element is ability to identify persons who have OSA, 2.E, part one.
(Panelists voted and votes were recorded by staff.)
DR. PEARSON: 2.E, part two, ability to exclude persons who do not have OSA.
(Panelists voted and votes were recorded by staff.)
DR. PEARSON: Actually, we didn't query each other what we want to do with 2.F, just oximetry. Why don't we go ahead and do it that way. Shall we talk about whether we wanted home testing other devices, or just pulse oximetry?
DR. SATYA-MURTI: May we pass on that?

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DR. PEARSON: Let's pass on that.
I would like to ask the committee's consent to not, you don't want to go through each of these clinical criteria. Any strong opposition? Now we can come back and talk about it otherwise, but is there opposition to that, finishing the votes and then coming back? Okay.
Question 4. Now this is another one that we talked about earlier. In the middle of the question it's how confident are you that there's sufficient evidence, so here we're talking about sufficiency of evidence to determine, not whether it actually is good, bad or indifferent, okay? CPAP is currently a standard treatment of OSA. Defining successful treatment as combined subjective improvement of OSA clinical signs and symptoms and continued patient use of CPAP for two or more months, how confident are you that there is sufficient evidence to determine the ability of each of the following diagnostic strategies to accurately predict successful treatment of OSA with CPAP? I'll let you think about that for a second. All right. Let's have a vote on sufficiency of evidence for PSG plus clinical evaluation.
(Panelists voted and votes were recorded by staff.)
DR. PEARSON: The next one is home testing plus clinical evaluation.
(Panelists voted and votes were recorded by staff.)

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DR. SATYA-MURTI: Any home testing?
DR. PEARSON: Yes, any home testing. All right. Sufficiency of evidence for clinical evaluation plus trial by CPAP.
(Panelists voted and votes were recorded by staff.)
DR. PEARSON: And clinical evaluation alone.
(Panelists voted and votes were recorded by staff.)
DR. PEARSON: All right. Thank you. Let's move

over to Question Number 5, getting more serious, perhaps. Let's just think for a second. Now we're going to be asked, how confident are you that each of the following diagnostic strategies will accurately predict successful treatment of OSA with CPAP? One is no confidence, five is high confidence.
We'll start with 5.A, if you will, PSG plus clinical evaluation.
(Panelists voted and votes were recorded by staff.)
DR. PEARSON: All right. Part two, thank you.
Home testing plus clinical evaluation? Now here it is tough not to have them split out.
DR. JACQUES: But they all managed to vote.
DR. PEARSON: All right, thank you.
(Panelists voted and votes were recorded by staff.)
DR. PEARSON: Clinical evaluation plus trial by CPAP.

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(Panelists voted and votes were recorded by staff.)
DR. PEARSON: And last, clinical evaluation alone.
(Panelists voted and votes were recorded by staff.)
DR. PEARSON: Thank you. Turn the page to Number 6, a single question. How confident are you that no clinically meaningful harm to patients will be caused by a trial by CPAP strategy as an alternative to strategies that require prior positive PSG or home sleep test before CPAP? It ranges from one, no confidence that there will be no clinical harm, sorry for the double negative, to five, high confidence that there is no clinical harm.
(Panelists voted and votes were recorded by staff.)
DR. PEARSON: Another kind of gestalt question, Question Number 7 on the last page, how confident are you that your conclusions can be generalized to, the first part is the Medicare population, ranging from one, no confidence, to five, high confidence.
(Panelists voted and votes were recorded by staff.)
DR. PEARSON: Thank you. And can be generalized to providers in community practice.
(Panelists voted and votes were recorded by staff.)
DR. PEARSON: Thank you. All right. Now that we have several members who need to leave, I'm sure that there are folks who have come a long way who would have just given anything for one more second in front of that microphone as

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we were wrestling with things in our toddler short pants here. I know that the committee spent time wrestling with this and I appreciate your input to this group's additional input. I thank you for your participation and I thank the panel members for their time, and I think we will adjourn. Thank you very much.
(Whereupon, the meeting adjourned at 3:00 p.m.)