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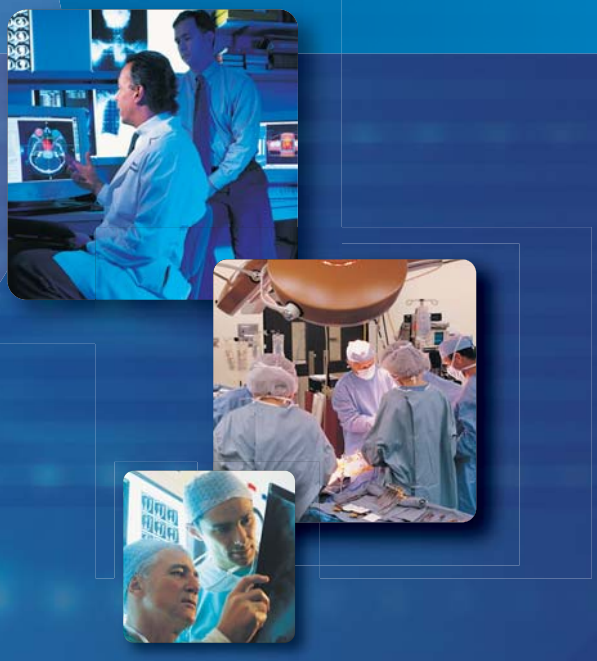
Portable Monitoring Devices for Diagnosis of Obstructive Sleep Apnea at Home: Review of Accuracy, Cost-Effectiveness, Guidelines, and Coverage in Canada



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Portable Monitoring Devices for Diagnosis of Obstructive Sleep Apnea at Home: Review of Accuracy, Cost-Effectiveness, Guidelines, and Coverage in Canada

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December 2009

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Health technology assessment agencies face the challenge of providing quality assessments of medical technologies in a timely manner to support decision-making. Ideally, all important deliberations would be supported by comprehensive health technology assessment reports, but the urgency of some decisions often requires a more immediate response.

The Health Technology Inquiry Service (HTIS) provides Canadian health care decision-makers with health technology assessment information, based on the best available evidence, in a quick and efficient manner. Inquiries related to the assessment of health care technologies (drugs, devices, diagnostic tests, and surgical procedures) are accepted by the service. Information provided by the HTIS is tailored to meet the needs of decision-makers, taking into account the urgency, importance, and potential impact of the request.

Consultations with the requestor of this HTIS assessment indicated that a review of the literature would be beneficial. The research question and selection criteria were developed in consultation with the requestor. The literature search was carried out by an information specialist using a standardized search strategy. The review of evidence was conducted by one internal HTIS reviewer. The draft report was internally reviewed and externally peer-reviewed by two or more peer reviewers. All comments were reviewed internally to ensure that they were addressed appropriately.

Reviewers

These individuals kindly provided comments on this report.

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Industry: The following manufacturers were provided with an opportunity to comment on an earlier version of this report: Covidien Canada and SagaTech Electronics Inc. All comments that were received were considered when preparing the final report.

Conflicts of Interest: Dr. Debra Morrison has conducted sleep studies for VitalAire.

ACRONYMS AND ABBREVIATIONS

AASM	American Academy of Sleep Medicine
AHI	apnea-hypopnea index
APAP	automatic positive airway pressure
CI	confidence interval
CMS	US Centers for Medicare & Medicaid Services
CPAP	continuous positive airway pressure
ESS	Epworth Sleepiness Scale
HTA	health technology assessment
OR	odds ratio
OSA	obstructive sleep apnea
PM-APAP	portable monitoring followed by automatic positive airway pressure
PSG	polysomnography
QALYs	quality-adjusted life-years
RCT	randomized controlled trial
RDI	respiratory disturbance index

GLOSSARY

Accuracy: the proportion of patients who have been correctly diagnosed.

Apnea: the cessation of airflow.

Apnea-hypopnea index (AHI): the total number of apneas and hypopneas per hour of sleep.

Hypopnea: a reduction in airflow relative to baseline airflow.

Negative likelihood ratio: ratio of the proportion of patients with disease who have a negative test result (false-negative rate) to the proportion of people without disease who have a negative test result (true-negative rate or specificity).

Positive likelihood ratio: ratio of the proportion of patients with disease who have a positive test result (true-positive rate or sensitivity) to the proportion of people without the disease who have a positive test result (false-positive rate).

Respiratory disturbance index (RDI): the total number of apneas and hypopneas per total monitoring time.

Sensitivity: the proportion of patients with disease who have a positive test result (true-positive).

Specificity: the proportion of patients without disease who have a negative result (true-negative).

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TITLE: Portable Monitoring Devices for Diagnosis of Obstructive Sleep Apnea at Home: Review of Accuracy, Cost-Effectiveness, Guidelines, and Coverage in Canada

DATE: December 2009

EXECUTIVE SUMMARY

Context and Policy Issues

Obstructive sleep apnea (OSA) is a syndrome that is characterized by recurrent episodes of partial (hypopnea) or complete (apnea) upper airway obstruction during sleep despite ongoing respiratory efforts. The symptoms include excessive daytime sleepiness, impaired concentration, and snoring. OSA has been linked to an increased risk of motor vehicle accidents, hypertension, cardiovascular disease, neurocognitive changes, and stroke. Approximately 4% of men and 2% of women have OSA. Polysomnography (PSG) is the gold-standard investigation used in the diagnosis of OSA. The costs of using PSG in a sleep laboratory are high because of the cost of the examination time, the need for a qualified technician and sleep specialist, and equipment costs. Furthermore, OSA is often undiagnosed because of long wait times to see a sleep physician and receive a diagnosis. As a result, the requirement of using laboratory PSG to obtain an accurate diagnosis of OSA has been debated for years, and the use of portable monitoring devices has been proposed. This report reviews the evidence on the accuracy and cost-effectiveness of using portable monitoring devices for the diagnosis of OSA at home and in the laboratory when compared with laboratory PSG. Current guidelines, information on the portable monitoring devices available in Canada, coverage of devices by private and public health plans in Canada, and the level of patient compliance with continuous positive airway pressure (CPAP) treatment when OSA is diagnosed are reviewed.

Research Questions

1. Which portable monitoring devices for the diagnosis of obstructive sleep apnea at home are available in Canada?
2. What is the accuracy of using portable monitoring devices for the diagnosis of obstructive sleep apnea at home compared with laboratory-based testing? Which patient populations are most suitable for home diagnosis using portable monitoring devices? Is there evidence for the use of portable monitoring devices in a supervised setting?
3. What is the cost-effectiveness of using portable monitoring devices compared with laboratory-based testing for the diagnosis of obstructive sleep apnea?
4. What are the guidelines for using portable monitoring devices for the diagnosis of obstructive sleep apnea at home?
5. What is the level of patient compliance with continuous positive airway pressure treatment of obstructive sleep apnea?
6. What jurisdictions provide coverage for devices that are used for the diagnosis and treatment of obstructive sleep apnea at home? How much coverage is provided and under what conditions?

Methods

Published literature was obtained by searching databases between 2003 and October 2008. Filters were applied to limit the retrieval to health technology assessments (HTAs), systematic reviews, meta-analyses, economic analyses, and guidelines. A randomized controlled trial (RCT) filter was applied to retrieve RCTs from 2007 to January 2009. The websites of regulatory agencies, HTA organizations, and related agencies were also searched. The Google search engine was used to search for information on the Internet. These searches were supplemented by hand-searching the bibliographies of selected papers. Two reviewers screened and selected articles for inclusion in this report.

Summary of Findings

Several portable monitoring devices are available in Canada for use in the diagnosis of OSA. Most machines measure respiration and oxygenation directly. Several evolving technologies measure these variables indirectly through peripheral arterial tone and actigraphy.

Two HTAs published in 2007 were retrieved in the search. One of the key findings of the first HTA report was that for those with a high pretest probability of moderate-to-severe OSA (based on medical history, reported daytime sleepiness, and other measures), initial management using laboratory PSG does not result in better outcomes than an ambulatory approach in terms of diagnosis, CPAP titration, or response to CPAP therapy. Level 2 and 3 portable monitors produced accurate results in the diagnostic assessment of OSA when laboratory PSG was used as the reference. Accurate results were also achieved using level 4 portable monitors measuring at least three parameters. Diagnostic accuracy decreased for level 4 monitors measuring two or fewer parameters. The accuracy of portable monitors seemed to be better in studies that were conducted in sleep laboratories compared with studies that were conducted at home. In the second HTA report, results obtained from modelling different strategies showed a trade-off for time to diagnosis and CPAP therapy versus test accuracy. After the release of these assessments, the US Centers for Medicare & Medicaid Services (CMS) decided to cover CPAP therapy for adults who were diagnosed using PSG or home testing.

Two systematic reviews and one meta-analysis not included in the identified HTAs were reviewed. The results from a 2007 systematic review showed that diagnostic accuracy increases with manual scoring compared with automatic scoring. The low sensitivity that was demonstrated with the use of pulse oximetry alone indicated that it is insufficient for the diagnostic assessment of OSA. Findings from a 2006 meta-analysis suggested that home sleep studies provided similar diagnostic information when compared with laboratory PSG but may underestimate the severity of OSA. Portable sleep studies were also significantly more likely to give a poor recording when compared with laboratory PSG. A 2003 systematic review found that sensitivities and specificities were generally higher for level 2 and level 3 portable monitors than for level 4 portable monitors. The percentage of portable monitoring studies that did not collect adequate data was generally higher when not attended by a sleep technician. There was limited evidence on the use of portable monitors in an unattended setting. Based on these findings, the research group recommended against the use of portable monitoring devices for the diagnosis of OSA at home.

Two RCTs not included in the identified HTAs or systematic reviews were retrieved. One RCT (n = 106) assessed whether CPAP compliance and clinical outcomes differed between patients who were randomly assigned to home diagnosis and CPAP autotitration or conventional laboratory PSG. At a six-week follow-up clinic visit, CPAP compliance and the clinical outcomes evaluated did not differ between the two groups. Another RCT (n = 62) compared the utility and reliability of a portable monitoring device in patients who were randomly assigned to receive portable monitoring simultaneously with PSG or portable monitoring at home. The results indicated that portable monitoring at home is less sensitive for the diagnosis of OSA when compared with portable monitoring conducted in the laboratory. The use of wrist actigraphy tended to overestimate sleep time and did not significantly improve the accuracy of portable monitoring at home.

One cost-utility analysis and one informal cost comparison were identified. The cost-utility analysis indicated that portable monitoring followed by CPAP autotitration or split-night PSG may be cost-effective alternatives to full-night PSG for diagnosis and treatment initiation for OSA. The informal cost comparison showed that in the USA, Spain, UK, and France, portable sleep studies were 35% to 88% less costly than laboratory sleep studies.

Four clinical practice guidelines outlining the use of portable monitoring devices for the diagnosis of OSA were retrieved. Three of these guidelines recommend limiting the use of portable monitoring devices to those patients with a high pretest probability of moderate-to-severe OSA and without other potentially confounding medical conditions or sleep disorders. In addition, they recommend the maintenance of the same high technical standards during home testing as those that would be found in an accredited sleep centre. A fourth guideline recommends the use of actigraphy as a method to estimate total sleep time when PSG is unavailable.

Limitations

Most studies evaluating portable monitoring devices have been conducted on Caucasian male patients with no comorbidities and a high pretest probability of OSA. Consequently, the results of these studies may not be generalizable to other groups of patients. Most studies assessing portable monitors for diagnostic accuracy were conducted simultaneously with the use of PSG in a laboratory. Hence, it is difficult to assess the utility of portable monitoring devices for use at home. Studies examining long-term, clinically important outcomes in patients who receive a diagnosis after the use of portable monitoring devices are yet to be performed.

CPAP Compliance

Although CPAP is the cornerstone of therapy for OSA, compliance is often poor. Several factors may influence treatment initiation and compliance with CPAP, including severity of symptoms, cost to the patient, frequency of follow-up, satisfaction with mode of therapy, education about the health consequences of OSA, and level of discomfort including claustrophobia and upper airway side effects.

Coverage

A survey was conducted to assess which Canadian jurisdictions provide coverage for devices that are used in the diagnosis and treatment of OSA at home. Responses were received from all jurisdictions except Quebec, Northwest Territories, and Nunavut. Public funding of CPAP equipment is available in Ontario, Alberta, Manitoba, New Brunswick, Saskatchewan, Newfoundland, and the Yukon. The only jurisdiction that funds private testing at home using a portable monitoring device for oximetry is the Yukon. British Columbia, Prince Edward Island, and Nova Scotia do not provide coverage for devices that are used at home for the diagnosis or treatment of OSA. Several private medical insurance policies cover CPAP equipment, but the amount of aid varies between insurers, and there may be variations in benefits between individual and group policies at the same firm.

Conclusions and Implications for Decision- or Policy-Making

Although laboratory PSG is the standard test used in the diagnosis of OSA, there is evidence that among patients with a high pretest probability of moderate-to-severe OSA with no comorbidities, portable monitoring devices may be useful for the diagnostic evaluation of patients when there is limited access to laboratory sleep studies and sleep specialists. Pulse oximetry that is used alone is not recommended for the diagnostic evaluation of OSA. Canadian jurisdictions should take local needs and resources into account when considering reimbursement of portable monitoring at home.

1 CONTEXT AND POLICY ISSUES

Obstructive sleep apnea (OSA) is a syndrome that is characterized by recurrent episodes of partial (hypopnea) or complete (apnea) upper airway obstruction during sleep despite ongoing respiratory efforts.[1] The symptoms include excessive daytime sleepiness, impaired concentration, and snoring.[1] OSA has been linked to an increased risk of motor vehicle accidents,[2,3] hypertension,[4-6] cardiovascular disease,[7-9] neurocognitive changes,[10,11] and stroke.[12,13] Information on the Canadian prevalence of OSA is lacking, but population-based studies across geographical regions and ethnic groups indicate a prevalence of approximately 4% among men and 2% among women.[14,15] The prevalence among children is poorly established, but an estimated 1% to 4% of school-age children have OSA.[16]

The accurate diagnosis and monitoring of OSA are important in its management, especially among patients with severe disease.[17] Polysomnography (PSG) is the gold-standard investigation used in the diagnosis of OSA.[17] PSG is performed in a hospital or sleep centre that is equipped with specialized equipment and personnel.[18] Patients stay overnight in the sleep laboratory and are continually monitored by a technician so that adjustments are made in the event of faulty equipment or artifacts.[18] The test measures sleep cycles and stages through the continuous recordings of brain waves, eye movement, respiratory effort, airflow, blood oxygen saturation, heart rate and rhythm, limb movement, body position, and direct observation of the person during sleep.[19] These data are interpreted by a sleep specialist and collated to calculate the apnea-hypopnea index (AHI), which is the sum of apneas and hypopneas per hour of sleep.[20] Higher AHI values imply more severe sleep disturbances, and specific cut-offs are used to establish a diagnosis of OSA.[20]

The costs that are associated with PSG investigations in a sleep laboratory are high because of the examination time required, the need for a qualified technician and sleep specialist, and equipment costs.[21] A 2003 estimate of the cost per study in Alberta for the diagnosis of OSA and continuous positive airway pressure (CPAP) titration is C$1,500.[22] Furthermore, OSA is often undiagnosed because of long wait times to see a sleep physician and receive a diagnosis.[23] Most sleep specialists in Canada practice in urban centres.[13] The number of sleep laboratories and sleep study rates vary among Canadian jurisdictions.[23] The results from a 2004 study indicated that the annual number of PSG investigations for OSA per 100,000 people ranged from 28 in Newfoundland to 776 in Ontario.[23] Furthermore, the study showed that the demand for sleep laboratory services is increasing in eastern and western Canada. Time waiting to see a sleep specialist averaged from four to six months, the completion of PSG ranged from eight to 30 months, and the average total wait time was 24 months (range eight to 36 months).[23] Wait times have likely increased in subsequent years. As a result, the requirement of using laboratory PSG to obtain an accurate diagnosis of OSA has been debated for years, and the use of portable monitoring devices has been proposed.[19,21,24]

The American Academy of Sleep Medicine (AASM) has four classifications of diagnostic sleep equipment (Table 1).[25,26] Portable monitoring systems are generally designed to be used in the patient's home without the presence of a sleep technician. The potential benefits of portable monitoring include increased access to care, lower costs, and test results that are more representative of the severity of symptoms in the home setting.[24] Apneas, hypopneas, and episodes of desaturation can be identified, classified, and quantified using portable monitoring systems.[18] However, the parameters that are measured using level 3 and level 4 portable monitors cannot be used for sleep staging.[18] This inability does not allow for the computation of the AHI, because total sleep time cannot be calculated. Therefore, portable monitoring devices calculate the respiratory disturbance index (RDI) by dividing the sum of apneas and hypopneas by the total monitoring time.[20,27] There is some confusion surrounding the RDI because alternative definitions[28,29] are

used, and some sleep specialists do not distinguish between AHI and RDI.[30] The RDI that is derived using portable monitoring tends to be lower than the AHI that is obtained by using PSG, increasing the likelihood of a false-negative result.[18] Therefore, portable monitoring devices are often used for patients with a high pretest probability (clinical suspicion) of OSA.[19]

The pretest probability may be identified using the medical history,[1] reported daytime sleepiness (based on the Epworth Sleepiness Scale [ESS] score),[31] Sleep Apnea Clinical Score,[32] and Berlin Questionnaire.[33] Although clinical prediction formulas[34-36] have been developed to assess the pretest probability of OSA, none has yet been widely adopted in clinical practice.[17]

Table 1: American Academy of Sleep Medicine Classification for Sleep Studies[25]

	Level 1	Level 2	Level 3	Level 4
Description	Sleep technician attended polysomnography in sleep centre or hospital laboratory	Unattended portable polysomnography at home	Unattended cardiorespiratory testing at home	Unattended single or dual bioparameter recording at home
Parameters measured	Minimum of 7 including brain waves, eye movements, chin muscle movements, respiratory effort, oxygen saturation, airflow, heart rate, or rhythm	Minimum of 7 including brain waves, eye movements, chin muscle movements, respiratory effort, oxygen saturation, airflow, heart rate, or rhythm	Minimum of 4 including at least 2 respiratory variables (e.g., respiratory movement and airflow), a cardiac variable (e.g. heart rate or rhythm), and oxygen saturation	Minimum of 1 including oxygen saturation, airflow, or chest movement (Newer devices measure at least 3 variables including peripheral arterial tonometry and actigraphy)
Parameters recorded can determine sleep stages or sleep disruption	Yes	Yes	No	No
Body position	Documented or objectively measured	Possible	Possible	No
Leg movement	EMG or motion sensor desirable but optional	Optional	Optional	No
Interventions during study	Possible	No	No	No

EMG = electromyography.

The treatment of choice for moderate-to-severe OSA is CPAP.[37] The CPAP device is used to reduce airway obstruction when pressurized air is blown through the upper airways through a nose mask or a face mask while the patient is asleep.[38] CPAP has been shown to improve respiratory function, daytime alertness, and quality of life.[37,39,40] Full-night PSG and CPAP titration (the adjustment of settings for optimal treatment) have traditionally been performed during two overnight stays in a sleep laboratory.[17] To improve efficiency and reduce the time spent in the laboratory, split-night studies are commonly used so that diagnosis and CPAP titration occur on the same night.[41-43] Split night studies have been shown to be effective for CPAP titration.[44] Furthermore, portable monitoring followed by CPAP titration using an autotitrating device (CPAP autotitration) has been used for the diagnosis and initial management of OSA at home.[45,46]

High health care expenditures associated with patients before diagnosis of OSA have been shown to decrease on initiation of CPAP therapy.[47,48] Economic evaluations conducted in the UK,[49] US,[50] and Canada[51] have indicated that the treatment of OSA with CPAP is a cost-effective use of health care resources when compared with no treatment. Because home sleep studies do not incur the costs that are associated with the use of the laboratory or the need for the continuous presence of a technician, they may be a cost-effective approach in the diagnosis of sleep disorders. Early economic evaluations, however, have favoured the use of laboratory PSG over that of portable monitoring testing[52,53] or overnight oximetry alone[54] for diagnosing OSA.

The number of patients who have not been diagnosed with OSA yet present with symptoms suggestive of OSA is a challenge because of the cost and scarcity of laboratory PSG testing. This report reviews the evidence on the accuracy and cost-effectiveness of using portable monitoring devices for the diagnosis of OSA at home and in the laboratory when compared with laboratory PSG. Current guidelines, information on the portable monitoring devices available in Canada, coverage of devices by private and public health plans in Canada, and the level of patient compliance with CPAP treatment when OSA is diagnosed are reviewed.

2 RESEARCH QUESTIONS

1. Which portable monitoring devices for the diagnosis of obstructive sleep apnea at home are available in Canada?
2. What is the accuracy of using portable monitoring devices for the diagnosis of obstructive sleep apnea at home compared with laboratory-based testing? Which patient populations are most suitable for home diagnosis using portable monitoring devices? Is there evidence for the use of portable monitoring devices in a supervised setting?
3. What is the cost-effectiveness of using portable monitoring devices compared with laboratory-based testing for the diagnosis of obstructive sleep apnea?
4. What are the guidelines for using portable monitoring devices for the diagnosis of obstructive sleep apnea at home?
5. What is the level of patient compliance with continuous positive airway pressure treatment of obstructive sleep apnea?
6. What jurisdictions provide coverage for devices that are used for the diagnosis and treatment of obstructive sleep apnea at home? How much coverage is provided and under what conditions?

3 METHODS

Published literature was obtained by cross-searching EMBASE, MEDLINE, and CINAHL databases on the OVID search system between 2003 and October 2008. Regular alerts were established on EMBASE, MEDLINE, and CINAHL, and information retrieved through alerts is current to January 15, 2009. Parallel searches were performed on PubMed and the Cochrane Library (Issue 4, 2008) databases. English language publication limits were applied. Filters were applied to limit the retrieval to health technology assessments (HTAs),

systematic reviews, meta-analyses, economic analyses, and guidelines. A randomized controlled trial (RCT) filter was applied to retrieve RCTs from 2007 to January 2009.

The websites of regulatory agencies, HTAs, and related agencies were searched, as were specialized databases such as those of the University of York Centre for Reviews and Dissemination. The Google search engine was used to search for information on the Internet. These searches were supplemented by hand-searching the bibliographies of selected papers to include relevant information from economic analyses and observational studies not originally retrieved in the literature search. Two reviewers screened and selected articles for inclusion in this report.

4 SUMMARY OF FINDINGS

Which portable monitoring devices for the diagnosis of obstructive sleep apnea at home are available in Canada?

4.1 Portable Monitoring Devices Available in Canada

Several portable monitoring devices are available to be used in the diagnostic evaluation of OSA.[24,55,56] Table 2 shows some of the portable devices that are licensed for sale in Canada. Most machines measure respiration and oxygenation directly. Evolving technologies measure these variables indirectly. The Watch-PAT 100 measures peripheral arterial tone, which is thought to correlate with respiratory obstruction and actigraphy (a measure of movement usually in the wrist) and which is used to estimate total sleep time.

The Canadian price of the Remmers Sleep Recorder (SagaTech, Calgary, AB, Canada) including analysis software is approximately C$7,200. The cost per study is approximately C$6; costs for interpretation of the sleep study vary but are generally less than C$100 (Ron Platt, VP Research & Development, SagaTech Electronics Inc., Calgary: personal communication, 2008 November 20).

Table 2: Examples of Portable Monitoring Devices That Are Licensed in Canada[57]

Device and Level	Manufacturer	Parameters Measured for Diagnosis
Trex Home Sleep[58] Level 2	Natus Medical Incorporated DBA Excel-Tech Ltd (XLTEK) (Oakville, ON, Canada)	• Parameters measured include oxygen saturation and EEG
Alice PDx Diagnostic System[59] Level 2, 3, 4	Philips Respironics (Murrysville, PA, USA)	• Pressure based (with snore) • Thermal airflow • Body position • Thoracic/abdominal respiratory effort • Oxygen saturation • Heart rate • EEG, EMG, EOG
Easy II PSG[60] Level 2	Cadwell (Kennewick, WA, USA)	• EEG • Airflow • Respiratory effort • Oxygen saturation • Snoring • Body position

Table 2: Examples of Portable Monitoring Devices That Are Licensed in Canada[57]		
Device and Level	**Manufacturer**	**Parameters Measured for Diagnosis**
Trackit Sleep Walker[61] Level 2	G&B Electronic Designs Ltd. (Bordon, United Kingdom)	• EEG, EOG, EMG, ECG • Airflow • Respiratory effort • Abdominal effort • Chest effort • Body position • Oxygen saturation • Pulse wave • Heart rate • PLM
Remmers Sleep Recorder[62] (formerly SnoreSat) Level 3	SagaTech (Calgary, AB, Canada)	• Oxygen saturation • Heart rate • Pulse amplitude • Nasal airflow (through nasal cannula pressure) • Snoring sounds • Body position • Respiratory efforts • Leg EMG
Stardust II Sleep Recorder[63] Level 3	Philips Respironics (Murrysville, PA, USA)	• Oxygen saturation • Heart rate • Nasal airflow pressure • Chest or abdominal effort • Supine or non-supine sleep positioning • Patient event monitor tracks bathroom visits and lights out
MediPalm[56,64] Level 2, 3, 4	Braebon Medical Corporation (Kanata, ON, Canada)	• EEG, EOG, EMG, ECG • Oxygen saturation • Heart rate • Pressure flow • Snore • Thermal flow • Chest effort • Abdominal effort • Body position • Event marker
MediByte[64] Level 3	Braebon Medical Corporation (Kanata, ON, Canada)	• ECG, EMG • Airflow (through nasal cannula pressure) • Snore • Oxygen saturation • Heart rate • Body position • Event marker • Chest effort (from respiratory effort belt) • Abdominal effort (from respiratory effort belt) • Thermal flow

Table 2: Examples of Portable Monitoring Devices That Are Licensed in Canada[57]		
Device and Level	**Manufacturer**	**Parameters Measured for Diagnosis**
MediByte Jr[64] Level 4 (can be upgraded to level 3 by adding one respiratory effort belt)	Braebon Medical Corporation (Kanata, ON, Canada)	• Airflow (through nasal cannula pressure) • Snore • Oxygen saturation • Heart rate • Body position • Event marker • Chest effort (optional from respiratory effort belt)
ApneaLink[65] Level 4	ResMed (Bella Vista, Australia)	• Oxygen saturation • Heart rate • Breathing sounds • Respiratory flow
ApneaLink Plus[66] Level 3	ResMed (Bella Vista, Australia)	• Oxygen saturation • Heart rate • Breathing sounds • Respiratory flow • Respiratory effort
Embletta[67] Level 3	Embla Systems (Broomfield, CO, USA)	• Flow pressure (through nasal cannula) • Oral flow (thermistor) • Snore • Abdominal movement • Thoracic movement • Oxygen saturation • Heart rate • Pulse waveform • Body position and activity • Event button • Limb movement, ECG, EEG, EOG (on some models)
Embletta GOLD [68] Level 3	Embla Systems (Broomfield, CO, USA)	• ECG, EEG, EOG • Flow pressure (through nasal cannula) • Oral flow (thermistor) • Derived flow (from respiratory effort belts) • Snore • Differential pressure • Abdominal movement • Thoracic movement • Oxygen saturation • Heart rate • Pulse waveform • Body position and activity • Event button
Apnea Risk Evaluation System (ARES)[69] Level 3	Advanced Brain Monitoring, Inc. (Carlsbad, CA, USA)	• Oxygen saturation • Heart rate • Respiratory effort • Airflow (nasal pressure) • Snoring sounds • Head position • Head movement

Table 2: Examples of Portable Monitoring Devices That Are Licensed in Canada[57]		
Device and Level	**Manufacturer**	**Parameters Measured for Diagnosis**
Sandman Pocket Portable Sleep Recorder[70] Level 3	Nellcor Puritan Bennett (Melville) (Kanata, ON, Canada)	• Pressure transducer airflow • BreathSensor thermistor airflow • Snore • ECG • Chest effort • Abdominal effort • Body position • Oxygen saturation • Heart rate (derived) • Patient ground • Pulse transit time • 2 channels (for optional EOG, EEG, EMG, PLM, pH, $_{ET}C0_2$)
Somté[71] Level 3	Compemedics Limited (Abbotsford, Australia)	• Pressure • Nasal airflow (pressure transducer) • Snore • Thoracic effort • Abdominal effort • Limb movement • Body position • Oxygen saturation • Heart rate • Pulse waveform • Oximeter signal quality • 2 channels (for optional EOG, EEG, ECG)
ApnoeScreen Pro[72] Level 3	Cardinal Health (Hoechberg, Germany)	• Nasal and oral flow (thermistor) • Snoring sounds • Oxygen saturation • Heart rate • Sleep position • Activity sensor • Light sensor
SleepTrek 3[73] Level 3	Astro-Med Inc. (West Warwick, RI, USA)	• Airflow • Snore • Respiratory effort • Body position • Heart rate • Oxygen saturation
SleepStrip Disposable Sleep Apnea Screener[74] Level 4	S.L.P. Ltd. (Tel-Aviv, Israel)	• Nasal flow (thermal sensor) • Oral flow (thermal sensor)
Watch-PAT 100[75] Level 4	Itamar Medical (Caesarea, Israel)	• PAT • Heart rate (derived from PAT signal) • Actigraphy (to measure sleep-wake patterns) • Oxygen saturation

Table 2: Examples of Portable Monitoring Devices That Are Licensed in Canada[57]		
Device and Level	**Manufacturer**	**Parameters Measured for Diagnosis**
Actiwatch[76] To be used with other portable monitoring devices	Philips Respironics (Murrysville, PA, USA)	• Actigraphy (to measure sleep-wake patterns)

ECG = electrocardiography; EEG = electroencephalography; EMG = electromyography; EOG = electrooculography; $_{ET}C0_2$ = end-tidal carbon dioxide; PAT = peripheral arterial tone; PLM = periodic limb movement.

What is the accuracy of using portable monitoring devices for the diagnosis of obstructive sleep apnea at home compared with laboratory-based testing? Which patient populations are most suitable for home diagnosis using portable monitoring devices? Is there evidence for the use of portable monitoring devices in a supervised setting?

4.2 Health Technology Assessments

Two HTAs that were commissioned by the Agency for Healthcare Research and Quality[77,78] were identified in the search. Both were published in 2007 at the request of the US Centers for Medicare & Medicaid Services (CMS) to help support the decision that portable monitoring devices could be used to accurately diagnose OSA for CPAP coverage.

One HTA[77] examined whether portable monitoring could be used to accurately identify patients with OSA who would benefit from CPAP therapy when compared with laboratory PSG. A systematic literature review was used to identify 95 studies that assessed the ability of sleep studies to predict the response to CPAP treatment or CPAP use by adults. None of these studies assessed hard clinical outcomes such as mortality or cardiovascular events. In general, the included studies evaluated predominantly male, middle-aged populations with no comorbidities and a high likelihood of OSA. This report found that for those with a high pretest probability of moderate-to-severe OSA, initial management with laboratory PSG does not result in better outcomes compared with an ambulatory approach in terms of diagnosis, CPAP titration, or response to CPAP therapy.

One RCT[45] compared the utility of home diagnosis using the Remmers Sleep Recorder portable monitor (SagaTech, Calgary, AB, Canada) and home CPAP autotitration with laboratory-based PSG diagnosis and CPAP titration in 68 patients with a high pretest probability of moderate-to-severe OSA. After three months, there was no statistically significant difference between the PSG and ambulatory groups in the primary outcome of median AHI/RDI on CPAP (3.2/h versus 2.5/h; difference 0.8/h [95% confidence interval (CI), −0.9/h to 2.3/h]) (p = 0.31). There were also no differences in secondary outcomes including the ESS score and the Sleep Apnea Quality of Life Index. Furthermore, adherence to CPAP therapy was statistically significantly better in the ambulatory group (median 5.4 h/night versus 6.0 h/night; difference −1.12 h/night [CI −2.0 h/night to 0.2 h/night]) (p = 0.021).

Evidence from the included studies indicated that level 2 and level 3 portable monitors may have the capability to detect AHI/RDI suggestive of OSA with high positive likelihood ratios (greater than 10) and low negative likelihood ratios (less than 0.1) when laboratory PSG was used as a reference. Level 4 portable monitors measuring at least three parameters also showed high positive likelihood ratios and low negative likelihood ratios, but the evidence for level 4 devices that measure one or two parameters was weaker for diagnostic accuracy. The accuracy of portable monitors seemed to be better in studies that were conducted in sleep laboratories compared with those conducted at home. Furthermore, the rates of unsatisfactory sleep studies and data corruption were higher for portable monitoring in the home setting compared with portable monitoring or PSG

conducted in a laboratory. For the studies conducted in the home setting, the authors did not find any data regarding whether and to what extent technologist support and patient education affected the accuracy of the results. Manual scoring or manual editing of automated scoring improved diagnostic accuracy compared with automated scoring alone.

Another HTA[78] examined the potential access to OSA diagnosis and CPAP therapy using strategies other than laboratory-based PSG. Mathematical models using Markov processes were used to simulate seven strategies for diagnosing OSA and CPAP treatment. The modelling approaches used estimates that were derived from focused systematic reviews and meta-analyses of the literature. Hypothetical cohorts of patients with suspected OSA were followed for a time horizon of two years or until they had technically adequate CPAP titration. The strategies included no testing and no CPAP therapy, laboratory-based PSG and CPAP titration, laboratory-based split-night PSG, home diagnosis using a portable monitor with laboratory-based split-night PSG to verify positive cases, home diagnosis and laboratory-based split-night PSG in all negative cases, home diagnosis using a portable monitor and home CPAP autotitration, and empirical CPAP therapy without testing for all patients. The models were stratified based on middle-aged (approximately 50 years old) and Medicare-aged (approximately 70 years old) populations.

Using their model, the authors estimated that in the middle-aged population, the use of laboratory-based PSG and CPAP titration would result in the longest wait times (13.6 weeks for diagnosis and 27.3 weeks to be offered CPAP therapy). The model estimated that using portable monitoring and home CPAP autotitration would result in the shortest wait times (2.1 weeks for OSA to be diagnosed and 4.8 weeks to be offered CPAP treatment). Shorter wait times were obtained in the elderly cohort. However, strategies that used portable monitors as the first (or only) test increased the numbers of false-positives or false-negatives compared with laboratory-based PSG. These findings show that there is a trade-off between time to diagnosis and CPAP therapy versus test accuracy.

After the release of these HTA reports and a subsequent public forum, CMS approved the use of portable monitoring devices for diagnosing OSA in March 2008.[79] As part of this decision, CMS de-emphasized the diagnostic accuracy of portable monitoring in lieu of strategies that are more apt to predict favourable outcomes with CPAP treatment. CMS will cover CPAP therapy for a trial period of 12 weeks for adults who are diagnosed using PSG or home testing (based on level 2, 3, or 4 devices measuring at least three parameters). CPAP therapy will subsequently be covered for those who benefit from therapy during the 12-week trial.

4.3 Systematic Reviews and Meta-analyses

Two systematic reviews[80,81] and one meta-analysis[82] were identified in the search.

A systematic review[80] that was completed in 2007 as a joint Nordic project of HTA agencies examined the sensitivity and specificity of portable monitoring devices compared with PSG for diagnosing OSA. Only studies comparing portable monitoring or pulse oximetry with overnight laboratory PSG during the same night were included in the analysis. A total of 435 patients (8% to 26% women) were included in the eight studies comparing portable monitoring with PSG. Scoring was done manually in six studies and automatically in three studies (one study reported the results of both automatic and manual scoring). All patients were referred for an investigation based on suspicion of OSA. The review also included seven studies that compared diagnostic assessment using pulse oximetry alone to PSG in a total of 1,735 patients (20% women). Automatic analysis was done in five studies, and manual scoring was used in two studies. The authors noted that the cut-offs for a diagnostic AHI differed between studies. The results showed that manually scored portable monitoring devices had a high pooled sensitivity (0.93; 95% CI 0.89 to 0.97) and a high pooled

specificity (0.92; 95% CI 0.87 to 0.96) to identify a pathologic AHI using PSG as a reference. Portable monitoring devices using automatic scoring of results had a high pooled sensitivity (0.92; 95% CI 0.83 to 0.97) and most patients with a pathologic AHI were identified. However, the pooled specificity was lower (0.85; 95% CI 0.73 to 0.93). Pulse oximetry alone (using oxygen desaturation as a surrogate for AHI) had a low pooled sensitivity (0.69; 95% CI 0.66 to 0.72) and a high pooled specificity (0.93; 95% CI 0.91 to 0.95). These findings show that diagnostic accuracy increases with manual scoring and suggest that pulse oximetry alone is insufficient in the diagnostic assessment of OSA.

Ghegan et al. published a meta-analysis in 2006 comparing the accuracy of home sleep studies using laboratory PSG for the diagnosis of OSA.[82] Eligible studies included prospective cohort studies of portable and laboratory sleep studies on the same groups of patients simultaneously or sequentially. Of the 18 included studies (n = 1,331), 11 provided sufficient data for a comparison of the primary outcome measure (AHI/RDI derived from the sleep study), and seven studies provided data on one or more of the secondary outcome variables including mean low oxygen saturation, recorded sleep time, rate of inadequate recordings, and cost. Of the 18 included studies, four were conducted in a laboratory. When portable monitoring and PSG were performed in the laboratory simultaneously, a technician was present to ensure the quality of the study. The remaining studies were sequentially performed with the same set of participants in the laboratory and then in an unmonitored home setting. No information was provided on the demographics or clinical history of the included patients. After pooling data from 11 studies (n = 743), RDI values that were derived from portable sleep studies were found to be 10% lower compared with AHI values that were derived using laboratory PSG (odds ratio [OR] 0.90; 95% CI 0.87 to 0.92). This trend was unchanged when studies that were performed only in a laboratory setting were excluded from the analysis. Based on data from three studies (n = 100), there was no statistically significant difference in the mean low oxygen saturation between laboratory PSG and portable sleep studies (OR 1.0; 95% CI 0.94 to 1.10). Across eight studies (n = 405), recorded sleep time was found to be statistically significantly higher when laboratory PSG was compared with portable sleep studies (OR 0.87; 95% CI 0.86 to 0.89). Portable sleep studies were statistically significantly more likely to give a poor recording when compared with laboratory PSG (14.6% versus 6.2%; p = 0.0001). The rate of poor recordings was not found to be related to the complexity of the portable device including the number of leads. The authors concluded that home sleep studies provide similar diagnostic information compared with laboratory PSG, but they may underestimate the severity of OSA.
In 2003, a joint task force of the AASM, the American College of Chest Physicians, and the American Thoracic Society published a systematic review[81] evaluating the accuracy of portable monitoring devices for detecting OSA. Studies in children, studies in languages other than English, reviews, meta-analyses, case reports, abstracts, letters, and editorials were excluded from the review. Thirteen of the 51 included studies that were published between 1990 and 2001 were conducted at home. The majority of the studies were performed predominantly with male Caucasian patients having a high pretest probability of moderate-to-severe OSA and no comorbidities. The included studies evaluated level 4 monitors (n = 35), level 3 monitors (n = 12), and level 2 monitors (n = 4). Sensitivities and specificities using laboratory PSG as a reference were calculated in 49 studies. Although there was a range of reported values, the sensitivities and specificities were generally higher with level 2 and level 3 portable monitors than with level 4 portable monitors. The percentage of portable monitoring studies that did not collect adequate data was generally higher in unattended studies. Overall, the most consistent, high-quality data came from level 3 portable monitors used in the presence of a technician. The data on level 2 and level 4 portable monitors were inadequate to support their clinical use. There was limited evidence on the use of portable monitors in an unattended setting. Based on these findings, the research group recommended against the use of portable

monitoring devices for the diagnosis of OSA at home. These results were used to generate a practice parameter[83] that has since been updated.[84]

4.4 Randomized Controlled Trials

We considered the available HTAs and systematic reviews to be a reliable estimate of the literature on the clinical accuracy of portable monitoring devices compared with laboratory PSG for the diagnosis of OSA. Two RCTs[46,85] were published subsequent to these reports.

Berry et al. assessed if CPAP compliance and various clinical outcomes differed when home diagnosis and CPAP autotitration were used instead of conventional laboratory PSG.[46] A total of 106 patients from a veterans administration medical centre were selected based on severity of daytime sleepiness (ESS score of 12 or more) and the presence of more than two of the following: loud habitual snoring, witnessed apnea or gasping, or treatment of hypertension. Patients with comorbidities were excluded from the trial. Included participants were predominantly male (88%) and obese (average body mass index of 34.2 ± 0.64 kg/m^2). Patients were randomly assigned to one of two study groups. The PSG group (n = 53) underwent laboratory PSG for diagnosis and CPAP titration. The portable monitoring followed by automatic positive airway pressure (PM-APAP) group (n = 53) used a portable monitoring device (Watch-PAT 100, Itamar Medical, Israel) for diagnosis followed by autotitration CPAP at home. The demographic characteristics of the two groups did not differ at randomization. Patients were trained on how to use the portable monitoring device and the autotitrating equipment. Automated analysis was used to score results for portable monitoring, and a physician reviewed the tracings for accuracy. Of the 53 patients who were assigned to each group, 51 were diagnosed with OSA in the PM-APAP group, and 48 were diagnosed with OSA in the PSG group. After CPAP titration, patients were offered treatment with CPAP. Those accepting CPAP treatment (45 in the PM-APAP group and 43 in the PSG group) started therapy using identical devices. At a six-week follow-up clinic visit, 40 patients in the PM-APAP group (78.4% of those with OSA and 88.8% of those starting CPAP therapy) and 39 in the PSG group (81.2% of those with OSA and 90.6% of those starting CPAP therapy) were still using CPAP. The differences between the two groups in CPAP adherence were not statistically significant. Furthermore, the mean nightly compliance (PM-APAP 5.20 ± 0.28 h/night versus PSG 5.25 ± 0.38 h/night), decrease in ESS score (−6.50 ± 0.71 versus −6.97 ± 0.73), improvement in the global Functional Outcome of Sleep Questionnaire score (3.10 ± 0.05 versus 3.31 ± 0.52), and CPAP satisfaction did not differ between the groups. The authors were unable to identify any predictive factors for CPAP adherence that were unique to the portable monitoring pathway. These findings suggest that a clinical pathway using portable monitoring and unattended autotitration may result in similar CPAP treatment compliance and clinical outcomes compared with a pathway using laboratory PSG. This trial is limited by the short follow-up of six weeks after the start of CPAP treatment. Furthermore, this trial may have been insufficiently powered to detect a difference between the two treatment strategies.

Garcia-Diaz et al. compared the utility and reliability of a portable monitoring device (Apnoescreen II, Erich Jaeger GmbH & CoKg, Germany) used in the laboratory and at home with laboratory PSG for the diagnosis of OSA.[85] The Apnoescreen II portable monitoring device measures cardiorespiratory variables and wrist actigraphy. A total of 62 patients were randomly assigned to receive portable monitoring simultaneously with PSG or portable monitoring at home. Most of the included patients were male (87%), and all patients had a high pretest probability of OSA. A total of 14.5% of the included patients had a cardiovascular comorbidity (defined as a history of ischemic heart disease or stroke). A technician set up the equipment for patients receiving portable monitoring at home. All recordings were analyzed manually by a technician. To study inter-observer reliability of portable monitoring,

two manual analyses were carried out by two researchers. For portable monitoring, RDI was calculated using the total sleep time as estimated by actigraphy or by using the total recording time for different cut-off points of AHI. For patients who received portable monitoring with PSG in the laboratory, the sensitivity and specificity were similar using wrist actigraphy versus total recording time (range 94.6% to 100% versus 91.6% to 96.9% for sensitivity respectively; range 88% to 96.7% versus 92% to 96.7%, for specificity respectively). For patients who received portable monitoring at home, the sensitivity and specificity using wrist actigraphy versus total recording time were similar (83.8% to 95.8% versus 83.8% to 87.5%; 92% to 100% versus 94.7% to 100% respectively). Although the diagnostic accuracy of home portable monitoring was only slightly lower than that obtained using laboratory monitoring, home studies had to be repeated in one case because of a technical failure and in another case because of the poor quality of the airflow signal. The results showed that the inter-observer reliability of the portable monitoring studies was very high (intraclass correlation coefficient for RDI = 0.99). The authors concluded that portable monitoring at home is effective and reliable for the diagnosis of OSA but is less sensitive compared with portable monitoring in the laboratory. The authors noted that as wrist actigraphy tends to overestimate sleep time, it did not significantly improve the accuracy of portable monitoring at home. This trial is limited by the small sample size in a specific patient population.

The results from these RCTs may not be generalizable to a population of patients with a low likelihood of OSA. Larger, long-term trials looking at clinically significant outcomes and CPAP compliance are needed to capture the utility of diagnosis and treatment initiation at home for patients with OSA.

What is the cost-effectiveness of using portable monitoring devices compared with laboratory-based testing for the diagnosis of obstructive sleep apnea?

4.5 Economic Analyses and Cost Information

One cost-utility analysis,[86] and one informal cost comparison[82] were identified.

Deutsch et al. compared two potentially cost-saving strategies with conventional full-night PSG for diagnosing and treating OSA in the USA.[86] The first strategy involved split-night PSG with laboratory monitoring during the first two hours of sleep followed by CPAP titration for the remainder of the night if the diagnostic criteria for OSA were met. Patients with insufficient CPAP titration returned to the laboratory for a second full-night CPAP titration. The second strategy consisted of portable monitoring at home for a night followed by a night of home CPAP autotitration if the diagnostic criteria for OSA were met. If home testing was inadequate (as a result of equipment or human error), if the results were negative, or if CPAP autotitration failed, patients received the conventional full-night PSG strategy. The conventional strategy was full-night laboratory PSG followed by laboratory CPAP titration on the second night with diagnostic results for OSA. A decision tree model was used for each diagnostic strategy followed by CPAP titration in a hypothetical cohort of individuals aged between 30 and 64 years with a moderate-to-high risk of OSA. The time horizon of the model was five years. A third-party payer perspective was adopted in the economic analysis. The estimates for clinical effectiveness and resource use were derived from published studies. The inclusion criteria for the selection of these studies were not specified. The methods that were used to select the estimates were neither reported nor discussed. The data that were used to estimate direct costs (sleep testing, CPAP titration, office visits, and CPAP equipment rental) to the third-party payer came from the 2004 Medicare Fee Schedule. Direct health care costs due to the complications of untreated OSA were omitted from the analysis. Effectiveness was measured as quality-adjusted life-years (QALYs).

The mean expected total costs were US$4,886 for full-night PSG, US$4,565 for split-night PSG, and US$4,096 for home diagnosis. The QALYs for full-night PSG, split-night PSG, and home studies were 2.33, 2.31, and 2.23 respectively. When compared with home studies, split-night PSG resulted in an incremental cost of US$5,932 per QALY gained, and the full-night PSG strategy resulted in an incremental cost of US$7,383 per QALY gained. When full-night PSG was compared with split-night PSG, the incremental cost was US$11,586 per QALY gained. Sensitivity analyses showed that the results were affected only by variations in the rate of CPAP acceptance. The authors concluded that the home study and split-night PSG strategies were cost-effective alternatives to full-night PSG for diagnosis and treatment initiation in OSA.
The limitations of this evaluation include an absence of indirect costs (including health care and non-health care costs arising from the complications of untreated OSA) in the analysis. The authors of this evaluation did not report search methods or inclusion criteria nor did they justify their selection of estimates. Given the limited information reported, it is not possible to judge the quality of the evidence used to derive input model parameters or the generalizability of the estimates. In addition, these results may not reflect the costs in a Canadian setting. Future economic evaluations estimating indirect costs from a societal perspective in various patient populations could provide a more comprehensive perspective on the cost-effectiveness of home diagnosis and treatment initiation relative to other OSA management strategies.

Ghegan et al. conducted an informal cost comparison of portable sleep studies versus laboratory sleep studies.[82] The authors did not describe what was included in each cost calculation. The results showed that in the USA, Spain, UK, and France, portable sleep studies were 35% to 88% less costly than laboratory sleep studies. The authors noted that this difference would probably be less in a formal cost analysis because of a greater number of portable sleep studies that would need to be repeated as a result of poor recordings.

What are the guidelines for using portable monitoring devices for the diagnosis of obstructive sleep apnea at home?

4.6 Guidelines

Four clinical practice guidelines outlining the use of portable monitoring devices for the diagnosis of OSA were retrieved.

A 2008 update[87] of the *Canadian Thoracic Society guidelines: Diagnosis and treatment of sleep disordered breathing in adults*[88] (2006) makes recommendations to address the limited availability of sleep specialists and diagnostic investigations in most regions of Canada. The guidelines state that medical specialist assessment or access to laboratory PSG should be triaged based on medical need and be completed within two to four weeks in the most urgent cases or within two to six months in all other cases depending on comorbid diseases, occupation, and severity of daytime sleepiness (level of evidence D; based on case series, case reports, or expert opinion). The guidelines refer to level 1 (complete laboratory PSG) testing as the accepted standard for the diagnosis of OSA (level of evidence C; based on case-control studies or cohort studies with a risk of bias). The guidelines state that level 2 testing (full ambulatory PSG) or level 3 testing (multi-channel cardio-respiratory recording) can be used to confirm the diagnosis in patients with a moderate-to-high pretest probability of OSA. Neither level 2 testing nor level 3 testing is recommended for use by patients with comorbid disease (for example, ischemic heart disease, cerebrovascular disease, congestive heart failure, refractory systemic hypertension, obstructive or restrictive lung disease, pulmonary hypertension) and in the diagnosis of other forms of sleep-disordered breathing (for example, central sleep apnea, complex sleep apnea, and sleep-hypoventilation) (level of evidence C). Pulse oximetry alone is not recommended in the diagnostic evaluation of suspected OSA. It may have a role in the initial assessment of OSA (level of evidence C). The guidelines state that all sleep monitoring should be conducted based on quality assurance and be interpreted by a physician who is trained in the

diagnosis of sleep-disordered breathing (level of evidence D). Clinical prediction formulas are not recommended to establish a diagnosis of OSA but may be used to assess the pretest probability (level of evidence C). These recommendations are based on a review of the literature and consensus.

A 2008 Institute for Clinical Systems Improvement guideline[89] states that PSG is the accepted standard test for the diagnosis of OSA. Among patients with a high pretest probability of OSA, the use of portable monitoring devices at home can be used for the diagnostic assessment of OSA with a comprehensive sleep evaluation and interpretation of results by physicians who have received training in sleep medicine and in interpreting sleep studies. Other criteria outlined in the guidelines for the use of portable monitoring devices at home include cases where treatment initiation is urgent and PSG is not readily available, patients who cannot be studied in the sleep laboratory, and the absence of comorbid conditions including significant pulmonary, cardiac, or neurologic disease. The guideline states that non-diagnostic results in patients with a high suspicion of OSA must be followed by laboratory PSG. This guideline is based on a literature review by a multidisciplinary work group.

The Portable Monitoring Task Force of the AASM published *Clinical Guidelines for the Use of Unattended Portable Monitors in the Diagnosis of Obstructive Sleep Apnea in Adult Patients*[84] in 2007. The recommendations include the use of portable monitoring devices for diagnosis at home only in conjunction with a comprehensive clinical evaluation supervised by a trained sleep specialist in an accredited sleep centre. A follow-up visit to review the test results is recommended for all patients who have been diagnosed using portable monitoring devices at home. Portable monitoring devices are recommended as an alternative to laboratory PSG only in patients with a high pretest probability of moderate-to-severe OSA. They may also be used by patients for whom laboratory PSG is not possible as a result of immobility, safety, or critical illness. The guidelines do not recommend using portable monitoring devices in the diagnostic evaluation of patients with significant comorbid medical conditions that may degrade accuracy (for example, moderate-to-severe pulmonary disease, neuromuscular disease, or congestive heart failure), patients suspected of having comorbid sleep disorders (for example, central sleep apnea, periodic limb movement disorder, insomnia, parasomnias, circadian rhythm disorders, or narcolepsy), or for asymptomatic populations undergoing general screening. The guideline recommends that when using portable monitoring devices at home, an experienced sleep technician, sleep technologist, or appropriately trained health care practitioner should apply the sensors or educate the patient about the correct application of sensors. To ensure the accuracy of results, the guidelines recommend that the portable monitoring device chosen should display raw data for manual scoring or editing of automated scoring by a qualified sleep technician or technologist. When negative or technically inadequate results from portable monitoring at home occur in patients with a high suspicion of moderate-to-severe OSA, the guidelines recommend that follow-up laboratory PSG should be done. Pulse oximetry alone is not recommended for the diagnostic evaluation of suspected OSA. These recommendations are an update to previous guidelines[83] and are based on a literature review and consensus.

The AASM published *Practice Parameters for the Use of Actigraphy in the Assessment of Sleep and Sleep Disorders*[90] in 2007. Actigraphy is indicated as a method to estimate total sleep time in patients with OSA when PSG is unavailable. The guidelines state that "combined with a validated method to monitor respiratory events, use of actigraphy may improve accuracy in assessing the severity of obstructive sleep apnea." This recommendation is based on a review of the evidence and was rated as a generally accepted standard of practice based on a high degree of clinical certainty that was obtained from blind prospective comparative trials.

4.7 Limitations

Most studies evaluating portable monitoring devices were conducted on Caucasian male patients having no comorbidities and a high pretest probability of OSA. Consequently, the results of these studies may not be generalizable to other groups of patients including women, children, patients of different ethnicities, and those with significant comorbid conditions. Furthermore, it is unknown if portable monitoring may be useful for general screening of asymptomatic patients.

Interpretations of the HTA, systematic review, and meta-analysis reports comparing portable monitoring devices with laboratory PSG are limited by variations in the devices used, setting (home, sleep clinic, laboratory), scoring (manual or automated), definition of hypopnea, and the threshold AHI to define OSA. There is also a lack of consensus among investigators about how the RDI that is generated from portable monitoring devices can be compared statistically with the AHI because of a lack of direct equivalency between the two ratios.[27]

Most studies assessing portable monitors for diagnostic accuracy were conducted simultaneously with the use of PSG in a laboratory. Hence, it is difficult to assess the utility of portable monitoring devices for use at home. No studies have directly compared portable monitors head to head. For most devices, there is a lack of adequate validation data in larger samples of patients. Studies prospectively examining patients who test negative for OSA with portable monitoring for long-term clinically significant outcomes (including mortality due to cardiovascular events or motor vehicle accidents) are yet to be performed.

In one economic evaluation that was published in the last five years, the costs were computed on the basis of US Medicare reimbursement rates. This may limit generalizability to the technologies that are available in Canada. Studies evaluating the cost-effectiveness of portable monitoring devices in different populations from a societal perspective are yet to be performed.

Although there are several evidence-based guidelines for the use of portable monitoring devices in the diagnostic evaluation of OSA, there are no published standards for scoring or interpretation of portable monitoring results.

What is the level of patient compliance with continuous positive airway pressure treatment of obstructive sleep apnea?

4.8 Continuous Positive Airway Pressure Treatment Compliance

Although CPAP is the cornerstone therapy for OSA, compliance with treatment is often poor, with reported use ranging from 65% to 80% and between 8% and 15% of patients refusing to accept treatment after one night's use.[37] Non-compliance with CPAP therapy may lead to ongoing symptoms of sleep disruption, daytime sleepiness, and poor cognitive function.[37] One study reported that 46% of people with OSA used CPAP for at least four hours per day on more than 70% of days.[91] There is no consensus on the duration of nightly use that is needed for optimal benefit, but it has been shown that greater than six hours per night leads to clinically significant improvements in self-reported daytime sleepiness.[92] A survey conducted in Quebec assessed the long-term compliance of CPAP therapy in 80 patients.[93] The results showed that 54% of patients were using CPAP four or more years after diagnosis and most reported an improvement in symptoms. However, 15% had stopped using CPAP after an average of 10 months, and 31% had never started therapy after diagnosis and CPAP titration.

Several factors may influence treatment initiation and compliance with CPAP, including severity of symptoms, cost to the patient, frequent follow-up, satisfaction with mode of therapy, education about the health consequences of OSA, and discomfort including claustrophobia and upper airway side effects (such as nasal congestion, dryness, rhinitis, and nose bleeds).[94,95] It has been shown that the pattern of compliance with CPAP therapy is

established during the first week of treatment and is predictive of long-term use.[94] Guidelines developed by the AASM[96] recommend that CPAP should be monitored during the first weeks of treatment to help troubleshoot factors interfering with compliance. Many manufacturers have developed software that enables patient-specific compliance data to be obtained by the clinician.[38] Other recommendations included routine patient education, heated humidification, and maintenance of long-term follow-up with at least yearly visits.[94]

A 2004 systematic review assessed the efficacy of interventions designed to increase compliance with CPAP.[37] According to the limited available evidence, none of the interventions that were aimed at modifying the mode of delivery (for example, fixed, autotitrating, or bi-level) led to clinically important increases in hours of CPAP use. There was evidence, however, to suggest that psychological or educational interventions may improve compliance with CPAP therapy. Further assessments may show which interventions are cost-effective in the long term and can be incorporated into clinical practice.

What jurisdictions provide coverage for devices that are used for the diagnosis and treatment of obstructive sleep apnea at home? How much coverage is provided and under what conditions?

4.9 Coverage

4.9.1 Public Funding for Devices Used in the Diagnosis and Treatment of Obstructive Sleep Apnea at Home

The findings of a survey that was conducted across Canadian jurisdictions appear in Table 3. Responses were received from all jurisdictions except Quebec, Northwest Territories, and Nunavut. Public funding for OSA treatment (CPAP, APAP, or bi-level positive airway pressure [BiPAP] equipment) is available in Ontario, Alberta, Manitoba, New Brunswick, Saskatchewan, Newfoundland, and the Yukon. The only jurisdiction that funds private testing at home using a portable monitoring device for oximetry is the Yukon. British Columbia, Prince Edward Island, and Nova Scotia do not provide coverage for devices that are used at home for the diagnosis or treatment of OSA.

Table 3: Survey Results for Public Funding of Devices Used in the Diagnosis and Treatment of Obstructive Sleep Apnea at Home			
Jurisdiction	**Public Funding Source**	**Eligibility Criteria**	**Coverage**
New Brunswick (Zeljko Bolesnikov and Robert Vautier, Department of Health, Fredericton: personal communication, 2008 September 26)	New Brunswick Medicare New Brunswick Department of Social Development Health Service Convalescent/Rehabilitation Program	N/A Assists with purchase of equipment not covered by New Brunswick Medicare or private health plans. Patient must be client of Social Development and complete application form outlining equipment needed and medical information from diagnosing physician.	No funding or coverage of devices used in diagnosis or treatment of OSA at home. **Diagnosis:** Not covered **Treatment:** CPAP or BiPAP equipment including mask, headgear, and humidifier
Prince Edward Island (Arlene Powers, Medical Programs, PEI Department of Health, Charlottetown: personal communication, 2008 October 15)	None	N/A	No funding
Newfoundland and Labrador (Tanweer Azher, Respirologist/Internal Medicine Specialist, St. John's: personal communication, 2008 November 10)	Social Services Assistance	Must meet eligibility criteria of program	**Diagnosis:** Not covered **Treatment:** Full coverage of CPAP equipment
Nova Scotia (Anne Tweed, Medical Consultant, NS Department of Health, Halifax: personal communication, 2008 October 3)	None	N/A	Nova Scotia provincial medical system does not fund devices used for the diagnosis or treatment of OSA at home.

Table 3: Survey Results for Public Funding of Devices Used in the Diagnosis and Treatment of Obstructive Sleep Apnea at Home			
Jurisdiction	**Public Funding Source**	**Eligibility Criteria**	**Coverage**
Ontario[97]	Ministry of Health and Long-Term Care, ADP	Diagnosis of OSA by sleep physician using Level 1 test. Patients must be referred to registered ADP sleep clinic by family physician for diagnosis. Equipment unavailable under Workplace Safety & Insurance Board or to Group "A" veterans for pensioned conditions.	**Diagnosis:** Not covered **Treatment:** CPAP or APAP system (including CPAP or APAP device, heated humidifier, basic mask and headgear, carrying case, tubing, caps, filters). Specialized masks and headgear must be purchased by patient. ADP pays 75% of ADP-approved price. Patients pay remaining 25%. If patients are receiving social assistance benefits from Ontario Works, Ontario Disability Support Program, ADP pays 100% of ADP-approved price. ADP contributes toward the cost of replacement every 5 years if equipment cannot be repaired.
Manitoba (Roxie Eyer, Program Consultant, Manitoba Health, Winnipeg: personal communication, 2008 September 24)	Manitoba Sleep Disorders Centre	Diagnosis using Level 1 sleep study. Level 3 sleep studies not accepted in diagnosis of OSA. Diagnosis and treatment plan following assessment by the Sleep Disorders Centre.	**Diagnosis:** Not covered **Treatment:** Fixed pressure CPAP machines for long-term treatment. APAP machines not covered. Equipment and supplies funded with no additional charges incurred by patient.
Saskatchewan (Keith Hopkin, Policy & Program Consultant, Saskatchewan Health, Saskatoon: personal communication, 2008 October 8)	Saskatchewan Health SAIL (Saskatchewan Aids to Independent Living) Program	Residents with valid Saskatchewan Health coverage ineligible to receive service from other government agencies such as First Nations and Inuit Health (Health Canada), Workers' Compensation Board, Saskatchewan Government Insurance, or Veterans Affairs Canada. CPAP and BiPAP machines must be ordered by Saskatchewan respirologist.	**Diagnosis:** Not covered **Treatment:** CPAP or BiPAP machines provided on loan subject to continued eligibility for Saskatchewan Health coverage. Patient responsible for cost of masks, tubing, humidifier, and other supplies as needed.

Table 3: Survey Results for Public Funding of Devices Used in the Diagnosis and Treatment of Obstructive Sleep Apnea at Home			
Jurisdiction	**Public Funding Source**	**Eligibility Criteria**	**Coverage**
Alberta[98-101]	Lung Association – Alberta and NWT CPAP Assistance Program	Must be member of Lung Association and have medical prescription for CPAP therapy (including CPAP titration report). Level 1 and Level 3 sleep studies with interpretation by respirologist or sleep specialist acceptable for diagnosis. Coverage provided when medical insurance and other sources of funding declined and there is proof of financial need (low-income families).	**Diagnosis:** Not covered **Treatment:** CPAP equipment (from used or donated machine pool). Provides up to $300 towards CPAP supplies (mask, tubing, heated humidifier, filters). If CPAP equipment malfunctions within 90 days, it is replaced with another machine from program because costs to cover repairs not covered.
	Alberta Government Plan under the Income Supports Health and Training Benefits Regulation (Schedule 3, Section 15)	Patient needs equipment not covered by other program or resource including Alberta Aids to Daily Living. Physician must provide written opinion that item is essential for medical management of individual's condition. Approved by Director, Strategic Policy and Supports. Level 1 sleep assessment and interpretation by pulmonary specialist and results of CPAP titration required. Level 3 sleep studies not accepted for diagnosis of OSA.	**Diagnosis:** Not covered **Treatment:** CPAP equipment covered to maximum of $2,000
	Alberta Social Services, Assured Income for the Severely Handicapped, Department of Veterans' Affairs	Patients meet eligibility criteria of programs.	**Diagnosis:** Not covered **Treatment:** May provide financial aid for individuals not covered by private medical insurance

Table 3: Survey Results for Public Funding of Devices Used in the Diagnosis and Treatment of Obstructive Sleep Apnea at Home			
Jurisdiction	**Public Funding Source**	**Eligibility Criteria**	**Coverage**
British Columbia (Laural Blake, Medical Services Branch, Ministry of Health Services, Victoria: personal communication, 2008 October 22)	None	N/A	Ministry does not fund devices used at home for the diagnosis or treatment of OSA.
Yukon (Dianne Tait, Manager, Extended Benefits and Pharmaceutical Programs, Government of Yukon, Whitehorse: personal communication, 2008 October 22)	Yukon Pharmacare Program for Seniors	Physician diagnosed OSA, and prescription written for CPAP. Results from overnight PSG or overnight oximetry read by respirologist. Program does not include First Nations residents who are covered by Non-Insured Health Benefits program.	**Diagnosis:** Overnight oximetry (Respironics Oximeter) supplied by local oxygen vendor. Fee is charged to Pharmacare program **Treatment:** CPAP equipment including replacement masks; only pays balance of what private insurance (if available) will not cover

ADP = Assistive Devices Program; APAP = autotitrating positive airway pressure; BiPAP = bi-level positive airway pressure; CPAP = continuous positive airway pressure; N/A = non-applicable; OSA = obstructive sleep apnea.

4.9.2 Private Coverage for Continuous Positive Airway Pressure Equipment

The Lung Association conducted a survey of private insurance companies in Canada to determine which companies and types of policies provide aid for access to CPAP equipment after a diagnosis of OSA[100] (Table 4). The survey indicates that many group medical insurance policies cover CPAP equipment, that the amount of aid varies between insurers, and that there may be variations in benefits between individual and group policies at the same firm.

Table 4: Private Coverage for Continuous Positive Airway Pressure Devices[100]	
Private Insurer	**Coverage Provided**
Blue Cross	Non-standard benefit for groups of more than 100
Canada Life	Consideration based on medical condition
Great-West Life	Standard coverage when required for chronic condition
London Life	Standard coverage
Manufacturers Life	Provided under Medical Equipment Benefit
Maritime Life	Standard under Supplementary Health Coverage
Mutual Life	Standard under Medical Equipment Benefit
Sun Life	Must be medically necessary for treatment of OSA

OSA = obstructive sleep apnea.

5 CONCLUSIONS AND IMPLICATIONS FOR DECISION- OR POLICY-MAKING

Although laboratory PSG is the standard test used in the diagnosis of OSA, there is evidence that, among patients with a high pretest probability of moderate-to-severe OSA, portable monitoring devices can be used at home for diagnosis when there is limited access to laboratory sleep studies and sleep specialists. Current evidence indicates that the results that are obtained from the use of portable monitoring devices at home may be less accurate compared with portable monitoring conducted in a laboratory or laboratory PSG. Some studies, however, show no difference in short-term compliance and response to CPAP therapy when portable monitoring and CPAP autotitration at home are compared with laboratory-based PSG diagnosis and CPAP titration.

Current guidelines recommend limiting the use of portable monitoring devices to those patients with a high pretest probability of moderate-to-severe OSA and no other potentially confounding medical conditions or sleep disorders. In addition, they recommend that the same high standards be maintained in home testing as in an accredited sleep centre. Ideally, portable monitoring devices should be used as part of a comprehensive sleep evaluation program that includes access to sleep specialists, PSG facilities, and therapists who are experienced in fitting and troubleshooting CPAP devices. CPAP therapy should be monitored during the first weeks of treatment to help ensure patient compliance. No standards for scoring or interpretation of portable monitoring devices have been published, but a review of the raw data should be the basis for deciding the adequate quality and final interpretation of the sleep study. Pulse oximetry when used alone is not recommended in the diagnostic evaluation of OSA. The role of portable monitoring devices for widespread screening and diagnosis of OSA in patients with a lower likelihood of OSA is controversial. More economic evaluations assessing the cost-effectiveness of portable monitoring for the diagnostic evaluation of different patient populations will be of interest.

Several portable monitoring devices are available in Canada for the diagnostic evaluation of OSA. Canadian jurisdictions should account for local needs and resources when considering the reimbursement of portable monitoring devices for the diagnosis of OSA at home.

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