Unattended sleep studies in the diagnosis and reassessment of obstructive sleep apnoea

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Rationale for assessment

A rigorous assessment of evidence is the basis of decision-making when funding is sought under Medicare. A team from Adelaide Health Technology Assessment (AHTA), The University of Adelaide, was commissioned by the Department of Health and Ageing to conduct a systematic review of the literature and an economic evaluation of unattended sleep studies in the diagnosis and reassessment of obstructive sleep apnoea (OSA). An advisory panel with expertise in this area provided advice to AHTA to assist with the evaluation of the safety, effectiveness and cost-effectiveness of unattended sleep studies.

This assessment report is provided to the Medical Services Advisory Committee (MSAC). The MSAC advises the Minister for Health and Ageing on the evidence relating to the safety, effectiveness and cost-effectiveness of new and existing medical technologies and procedures and under what circumstances public funding should be supported.

The procedure

OSA occurs when an upper airway blockage is experienced by a person during sleep, usually as a consequence of relaxation of the tongue and soft tissues that occlude an abnormally narrow upper airway. This narrowing is often associated with obesity in adults or developmental or congenital abnormalities in children. The affected person can suffer a repeating cycle of sleep, obstructive choking and a gasping arousal from sleep. Different types of studies are used to identify whether sleep apnoea is occurring, and to what extent, in persons presenting with symptoms of excessive daytime sleepiness, snoring, and choking or gasping during sleep as reported by the individual or an observer.

Sleep studies are categorised into four types. The Level 1 sleep study, which is also called laboratory-based polysomnography (PSG), is the gold standard in the diagnosis and reassessment of OSA. It is an 'attended' sleep study involving a laboratory technician monitoring the patient and the environment during testing. As such, it is a resource- and time-intensive procedure that results in long waiting lists. Level 2, 3 and 4 sleep studies are all 'unattended' and are usually carried out in the home.

The amount of information recorded in a sleep study reduces as the level of the sleep study increases. Both Level 1 and Level 2 sleep studies record signals that allow the reliable identification of body position, sound and arousals from sleep (eg electrooculogram, electroencephalogram, electromyography). Whereas a Level 1 sleep study routinely involves 12 to 13 recording channels, an unattended Level 2 sleep study usually maintains a minimum of seven recording channels. In contrast, a Level 3 sleep study measures four or more parameters, including at least two respiratory channels (eg one airflow channel plus one respiratory effort channel or two airflow channels). A Level 4 sleep study is a sleep investigation where either the number or the type of cardiorespiratory signals fails to fulfil criteria for a Level 3 sleep study. A large number of

sleep study devices have obtained Therapeutic Goods Administration (TGA) marketing approval and are currently used in clinical practice in Australia.

Assessment of unattended sleep studies

Clinical need

OSA has been associated with an increased risk of hypertension and cardiac abnormalities, both of which are risk factors for cardiovascular events such as stroke and myocardial infarction. Available literature suggests that moderate to severe OSA in men is associated with an elevated risk of all-cause mortality, as well as death related to coronary artery disease. The OSA symptoms of excessive daytime sleepiness, headache, depression, fatigue, and difficulty in thinking and functioning due to sleep deprivation have also been associated with motor vehicle accidents and work-related accidents, as patients are prone to falling asleep while sitting down.

OSA prevalence in adult males has been reported internationally in the ranges 24–26%, 15–19% and 9–14% at apnoea–hypopnoea severity index (AHI) thresholds ≥5, 10 and 15, respectively. In adult women the ranges are 9–28%, 5–15% and 4–7% at the same cut-off points. In Australia the best available information of OSA presence and severity—although of limited quality—suggests that mild OSA (respiratory disturbance index (RDI) 5 to <15) is present in 20% of individuals, while moderate to severe OSA (RDI ≥15) occurs in 5% of individuals. Prevalence in males is 15% for mild OSA and 3% for moderate to severe OSA, while in females it is 5% for mild OSA and 1% for moderate to severe OSA. OSA in childhood is also common, with approximately 1–3% of children affected to different degrees. These estimates of OSA prevalence vary due to the different diagnostic thresholds, populations studied (ambulatory vs clinic, ages, symptoms), body position and tools used in the epidemiological studies. There are also limitations associated with defining and measuring OSA by apnoea thresholds or indexes that do not necessarily correlate well with clinically meaningful OSA symptoms.

The clinical need for sleep studies in the *referral setting* and the *paediatric setting* in Australia is considerable. ICD-10-AM coding for OSA as the principal diagnosis indicates that there were 35 896 hospital separations for OSA in Australia in 2006–07. These data appear to relate to a confirmatory diagnostic sleep study and not the following continuous positive airway pressure (CPAP) treatment titration activity. There has been a linear increase in sleep apnoea over the period 1998–2007, presumably as a consequence of an ageing and increasingly overweight population—age and obesity being two known risk factors for OSA. The majority of people who are hospitalised for OSA are those aged 45–64 years, with peak hospitalisation occurring in the 55–59 years age group. A large cluster of hospitalisations for OSA also occurs in children aged 1–4 years.

Estimates of the number of patients presenting to primary care or a *non-specialised unit setting* with suspected sleep apnoea are more difficult to ascertain. The information on diagnostic yield from the evidence-base was collated and used in conjunction with the known number of OSA cases (from ICD-10-AM coding) in 2006–07 to estimate the number of people that could be clinically suspected of OSA in Australia. Using these data, two base-case scenarios were developed assuming that 80% of adults / 100% of children (using AHI thresholds ≥5 / ≥1 respectively) and 53% of adults / 42% of children (using AHI threshold ≥15 / ≥5 respectively) with suspicion of OSA would have

their OSA confirmed using laboratory-based PSG. Therefore, in the base-case clinical need scenarios the total number of adults presenting to a medical practitioner with suspected OSA was estimated to range from 37 911 to 57 225, according to the accepted AHI threshold; while 5567 to 13 255 children would visit a clinician with suspected OSA. Reassessment with a sleep study following OSA treatment was estimated to be required for 25% of adults and children (7582 and 1392, respectively).

Safety

Only one uncontrolled case series provided weak evidence on the safety of unattended sleep studies for the diagnosis of OSA. Minor adverse events, such as skin redness and itching resulting from sleep device attachment, occurred in a small proportion of patients. In general, unattended sleep studies are considered safe diagnostic technologies. However, for theoretical safety reasons, caution should be used when considering unattended sleep studies for patients with neurocognitive disorders or for very young children.

No comparative data regarding the safety of home-based sleep studies relative to an attended Level 1 sleep study were identified. As patients with suspected OSA are primarily triaged for an attended sleep study according to symptom severity, true positive or false negative OSA results from an unattended sleep study would be unlikely to have a clinically significant impact on the patient's health outcomes, despite the associated earlier or later diagnostic waiting times relative to current practice. Adverse consequences associated with unnecessary treatment following a false positive unattended sleep study result are also likely to be uncommon. Therefore, it is reasonable to assume that unattended Level 2, 3 and 4 sleep studies are no worse than attended Level 1 sleep studies in terms of safety.

Effectiveness

The effectiveness of unattended sleep studies for the diagnosis of OSA was assessed in a non-specialised unit setting, a referral setting and a paediatric setting.

Diagnosis in a non-specialised unit setting

Two uncontrolled case series of poor quality reported on the impact of unattended sleep studies on patients' health outcomes in a non-specialised unit setting. This evidence suggested that the diagnosis of OSA and subsequent treatment resulted in resolved symptoms, reduced apnoea events and an impact on comorbid hypertension. However, patients' quality of life did not appear to improve.

At AHI ≥5, Level 3 sleep studies had moderate to high test performance relative to attended Level 1 sleep studies in a non-specialised unit setting, with area under the curve, sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV) greater than 82%. The use of higher AHI thresholds (eg ≥15) as indicative of OSA results in a loss of sensitivity and poorer NPV, and makes these studies inappropriate to rule out false negatives. Level 4 sleep studies, which involve fewer cardiorespiratory channels, were, not unexpectedly, less accurate than Level 3 sleep studies. Average sensitivity and NPV of these studies at AHI ≥15 highlights the importance of clinical judgment in identifying possible false negative test results. A lower

AHI cut-off point (eg ≥5) might result in better diagnostic accuracy for Level 4 sleep studies in this setting, but no evidence is currently available.

The proportions of patients with negative results from an unattended Level 4 study in this setting who would be referred or receive an additional Level 1 sleep study were 24% and 14%, respectively. These findings reinforce the role of referral and confirmatory laboratory-based PSG in the process of OSA diagnosis, especially in patients with moderate to severe OSA-related symptoms but 'normal' results from an unattended sleep study.

No comparative studies were identified that could inform an assessment of the impact on health outcomes of unattended sleep studies relative to referral ± an attended Level 1 sleep study in a non-specialised unit setting. However, expert opinion from the Advisory Panel indicated that the use of unattended sleep studies is unlikely to change the range, or clinically significant timing, of the available treatment options. Therefore, it appears that in this setting patient health outcomes following unattended sleep studies could be similar to those obtained in current practice, if unattended sleep studies have reasonable diagnostic accuracy, the results are interpreted in the context of patient symptom severity and the patient is treated as a consequence of an abnormal test result.

Diagnosis in a referral setting

Three controlled studies of moderate to poor quality, one randomised controlled trial and two prospective cohort studies were identified that reported on a change in health outcomes in patients with OSA, diagnosed with the aid of unattended sleep studies, in a referral setting. Level 2 and Level 4 sleep studies provided a benefit in terms of reducing excessive daytime sleepiness and controlling apnoea–hypopnoea episodes. Comparative evidence indicated that patients' health outcomes following Level 2 or 4 sleep studies were neither clinically nor statistically significantly different from those achieved following diagnosis with laboratory-based PSG. No controlled studies provided direct evidence of the effectiveness of Level 3 sleep studies in a referral setting.

Despite assessing different sleep devices at various AHI thresholds, data from a number of cross-classification studies suggest that the test performance of Level 2 and Level 3 sleep studies is generally accurate, with moderate to good sensitivity and fair but variable specificity. The false negative rates ranged from 15% to 20% for Level 2 sleep studies and from 19% to 35% for Level 3 sleep studies. Due to the fewer cardiorespiratory signals recorded during testing, Level 4 sleep studies were not as accurate as Level 2 or Level 3 studies in diagnosing OSA in a referral setting. The diagnostic accuracy of Level 4 sleep studies could be acceptable, but test performance largely depends on the type of sleep devices used and the clinical value of the AHI cut-off points.

Evidence from a controlled study indicated that, in this setting, about 39% of patients would receive a further Level 1 sleep study following a Level 3 sleep study, but did not indicate what proportion of these patients had positive or negative Level 3 sleep study results. The use of these unattended sleep studies also saved 1 month of time to diagnosis when compared with the current practice of receiving a laboratory-based PSG. This time difference is unlikely to be clinically important, given the current system of triaging patients for PSG according to symptom severity, but may be important from a patient's perspective.

Diagnosis in a paediatric setting

Extremely weak evidence from a case report suggests that unattended sleep studies and subsequent OSA treatment may improve children's neuropsychologic functioning and reduce the occurrence of respiratory episodes. Higher level evidence on a change in children's health outcomes following the use of Level 2, 3 or 4 unattended sleep studies was not available.

In a paediatric setting the accuracy of Level 3 or 4 sleep studies was reported at various AHI cut-off points (>1, >3 and >5), which are generally lower than those used for diagnosing OSA in adults (AHI ≥5 and ≥15). These Level 3 and 4 sleep studies demonstrated perfect sensitivity, PPV and NPV at AHI >1. However, nearly one-third of healthy subjects could not be identified by unattended sleep studies at this AHI threshold (specificity: 63%), indicating a high false positive rate. The test performance of Level 3 and 4 sleep studies was acceptable at AHI >5, with sensitivity, specificity, PPV and NPV of 60% or above. Extraordinary results were reported by one study (Zucconi et al 2003), whose authors observed null specificity and NPV at AHI >5. The extreme findings in this study might be attributable to the small sample size (n=12), the patients being at higher risk of OSA (eg severe symptoms) or a relatively low AHI threshold.

Data were not available on the impact of unattended sleep study results on subsequent patient management in the paediatric setting.

Reassessment of treatment efficacy

No studies were identified that provided data on the effectiveness of unattended sleep studies at reassessing treatment efficacy.

Economic considerations

This evaluation determined that the use of unattended sleep studies in the diagnosis of OSA appears to be no worse than attended Level 1 sleep studies in improving patients' health outcomes. Therefore, a cost comparison analysis of the proposed diagnostic approach (use of unattended sleep studies) relative to the current clinical pathway (use of laboratory-based PSG) was undertaken and subjected to sensitivity analysis. The economic evaluation costed the whole OSA diagnostic process, from a patient's visit to a doctor's office until determination of a correct OSA diagnosis. It included all non-trivial cost items during the process, including additional attended sleep studies as a consequence of technical failure, false negative or uncertain unattended sleep study test results, as well as unnecessary treatment for patients receiving a false positive diagnosis. Due to an absolute lack of evidence, no economic analysis of unattended sleep studies for the reassessment of treatment efficacy was warranted.

The cost comparison analysis indicated that the proposed clinical pathway with unattended sleep studies would cost $691, $754 and $525 per capita in a non-specialised unit setting, a referral setting and a paediatric setting, respectively. Although the use of unattended sleep studies can incur additional costs for further confirmatory laboratory-based PSG or potential unnecessary treatment, the total costs of the whole proposed adult diagnostic pathway would be $144 *lower* per capita in a non-specialised unit setting and $16 *lower* in a referral setting compared with the current clinical pathway, due to the cost savings from having the test in the home. However, the high cost of an adenotonsillectomy procedure in *children* with false positive results from an unattended

sleep study would result in an *additional cost* of $53 per capita in the paediatric setting when compared with the current clinical pathway. The sensitivity analyses demonstrated that the results of the cost comparison between the proposed and current diagnostic pathways is robust for most of the varying but plausible variables in the economic analysis, with the exception of the likely uptake of laboratory-based PSG once unattended sleep studies are available, and the rates of true positives (correct diagnoses) for both Level 2 and Level 4 sleep studies in a referral setting.

Given that the target population for unattended sleep studies was estimated to range from 37 911 to 57 225 in a non-specialised unit setting, from 13 269 to 20 029 in a referral setting and from 5567 to 13 225 in a paediatric setting, the total costs to society for the proposed diagnostic pathway were estimated to range between $39 124 128 and $61 602 452 if unattended sleep studies are used in all healthcare settings. The cost implications of unattended sleep studies to society would be a cost *saving* of $5 459 220 to $8 240 332 in a non-specialised unit setting and $212 303 to $320 457 in a referral setting when compared with current clinical practice, where an attended Level 1 sleep study is the only type of sleep study available. However, *additional costs* of $295 051 to $702 502 would be incurred by society for the use of unattended sleep studies in a paediatric setting. Should all unattended sleep studies be listed on the MBS, the Australian Federal Government alone would spend between $27 478 883 and $43 284 633 per annum on diagnosing OSA. Compared with current clinical practice, however, the use of unattended sleep studies in a non-specialised unit setting and a referral setting would result in an overall cost *saving* of $4 217 181 to $6 365 556 and $225 595 to $340 521, respectively, to the Federal Government. An *additional cost* of $176 209 to $419 545 would be borne by the government if unattended sleep studies are used for the diagnosis of paediatric OSA.

The process of reassessment was costed from when a patient consults a doctor for altered or unresolved OSA symptoms until the first sleep study undertaken. Costs, such as those for a further confirmatory Level 1 sleep study and for unnecessary treatment, were not included due to lack of evidence. The proposed reassessment pathway with the use of unattended sleep studies would cost Australian society $5 549 532. A cost *saving* to the healthcare system overall of $1 029 905 would be incurred by unattended sleep studies. The cost implications of home-based sleep studies to the Federal Government are estimated at $3 989 422, which is $724 993 *less* than that of the current reassessment pathway. However, owing to the exclusion of downstream costs, the actual cost impact of unattended sleep studies for reassessing treatment efficacy are a likely underestimate.

It is noted that the above results were obtained under the assumption that laboratory-based PSG is the only sleep study available in current clinical practice. However, in reality, Level 2 sleep studies have been subsidised by the Australian Government since October 2008 as an interim funding measure. Therefore, the cost implications as indicated by the economic and financial analyses in this assessment are likely to be an overestimate of the actual cost impact of unattended sleep studies.

Other relevant considerations

One of the major reasons that the diagnostic option of unattended sleep studies is being considered is the long waiting list for laboratory-based PSG. The timely diagnosis of OSA with the aid of unattended sleep studies, although unlikely to incrementally improve current health outcomes, could have a significant impact on patients and their partners'

quality of life and relationship, especially for those patients with mild OSA who are currently at the bottom of the waiting list for an attended sleep study. In addition, the use of unattended sleep studies in clinical practice provides a potential benefit in terms of improving equitable access to sleep studies for those patients living in rural or remote areas where a sleep laboratory or centre is not available.

Besides the diagnosis and reassessment of OSA, unattended sleep studies might have clinical value in diagnosing work-related or environment-related sleep problems as well as other sleep disorders that require prolonged or repetitive monitoring.

Due to the unattended nature of the investigation, home-based sleep studies have a higher rate of technical failure. This is mainly caused by unnoticed sensor dislodgement and battery failure during recording. Other limitations of unattended sleep studies include movement artefacts and inadequate cardiorespiratory parameter availability. These technical considerations on the use of unattended sleep studies in clinical practice, along with the existence of inter-/intra-reader variability, indicate the importance of having unattended sleep studies ordered, scored and interpreted by appropriately trained and credentialed medical professionals.

Glossary and abbreviations

AASM	American Academy of Sleep Medicine
AHI	Apnoea–hypopnoea index
AHTA	Adelaide Health Technology Assessment
AIHW	Australian Institute of Health and Welfare
APAP	Auto-adjusting positive airway pressure
AR-DRG	Australian Refined Diagnosis Related Groups
ArI	Arousal index
ARTG	Australian Register of Therapeutic Goods
ASA	Australasian Sleep Association
AUC	Area under the curve: calculated as the area under an ROC curve, the AUC provides a numerical description of the accuracy of a diagnostic test
BMI	Body mass index
CAD	Coronary artery disease
CER	Cost-effectiveness ratio
CHF	Congestive heart failure
CI	Confidence interval
Cleveland Questionnaire	An instrument that measures daytime sleepiness in patients, especially in adolescents, with OSA
COPD	Chronic obstructive pulmonary disease
CPAP	Continuous positive airway pressure
CVD	Cardiovascular disease such as hypertension, coronary artery disease, ischaemic heart disease
DALY	Disability-adjusted life year
DRG	Diagnosis related group
ECG	Electrocardiogram
EEG	Electroencephalogram
EMG	Electromyogram
ENT	Ear, nose and throat
EOG	Electrooculogram
ESS	Epworth Sleepiness Scale: a self-administered questionnaire to measure daytime sleepiness
Executive Maze Task	An instrument to test subjects' executive neurocognitive function

FOSQ	Functional Outcomes of Sleep Questionnaire: a specific self-reported questionnaire to assess the functional impairment in patients with sleep disorders
GERD	Gastro-(o)esophageal reflux disease
HR	Hazard ratio
ICER	Incremental cost-effectiveness ratio
LR	Likelihood ratio
LR+	How much the odds of the disease increase when a test is positive
LR–	How much the odds of the disease decrease when a test is negative
LYG	Life-years gained
LVEF	Left ventricular ejection fraction
MAD	Mandibular advancement device
MBS	Medicare Benefits Schedule
MLWHF Questionnaire	Minnesota Living with Heart Failure Questionnaire: an instrument that measures the clinical signs and symptoms of heart failure, physical and emotional conditions, as well as work, social and sexual activities
MSAC	Medical Services Advisory Committee
MWT	Maintenance of Wakefulness Test: a test to evaluate daytime sleepiness/wakefulness
NHMRC	National Health and Medical Research Council
Nottingham Health Profile	A generic instrument that measures ill health on various dimensions of quality of life
NPV	Negative predictive value: the proportion of patients with negative test results who are correctly diagnosed as not having the disease
ODI	Oxygen desaturation index
OSA	Obstructive sleep apnoea
PAT	Peripheral arterial tone
Power	The ability of a statistical test to reject a false null hypothesis
PPV	Positive predictive value: the proportion of patients with positive test results who are correctly diagnosed as having the disease
PSG	Polysomnography
PVD	Peripheral vascular disease

QALY	Quality-adjusted life year
QoL	Quality of life
QUADAS	Quality Assessment of Diagnostic Accuracy Studies
RACP	Royal Australasian College of Physicians
RCT	Randomised controlled trial
RDI	Respiratory disturbance index
REM	Rapid eye movement: a stage of sleep characterised by rapid movements of eyes, and during which dreams mostly occur
RIP	Respiratory inductive plethysmography
ROC curve	Receiver–operator characteristic curve
SAQLI	Sleep Apnea Quality of Life Index: a quality of life instrument that measures sleep apnoea-specific impairment
SDB	Sleep-disordered breathing
Sensitivity	The proportion of people with a disease who test positive
SF-36	MOS 36-item Short-Form Health Survey: a self-administered questionnaire that measures generic health status
Sleep Apnea Questionnaire	A questionnaire focusing on sleep apnoea syndrome
Specificity	The proportion of people without a disease who test negative
SROC	Summary receiver operator characteristic (curve)
TGA	Therapeutic Goods Administration
TSANZ	Thoracic Society of Australia and New Zealand
UPPP	Uvulopalatopharyngoplasty

Introduction

Adelaide Health Technology Assessment (AHTA), with input and advice from an appropriately constituted Advisory Panel of experts (Appendix A), have reviewed the use of unattended sleep studies, which are tests used in the diagnosis and reassessment of obstructive sleep apnoea (OSA) in three broadly construed settings—referral, paediatric and non-specialised unit.

This assessment report is intended for the Medical Services Advisory Committee (MSAC). The MSAC evaluates new and existing health technologies and procedures for which funding is sought under the Medicare Benefits Scheme in terms of their safety, effectiveness and cost-effectiveness, while taking into account other issues such as access and equity. The MSAC adopts an evidence-based approach to its assessments, based on reviews of the scientific literature and other information sources, including clinical expertise.

This report summarises the assessment of current evidence on unattended sleep studies in the diagnosis and reassessment of obstructive sleep apnoea in a non-specialised unit setting, a referral setting and a paediatric setting.

Rationale for assessment

Two separate applications have been made to the MSAC to have the use of unattended sleep studies—in the diagnosis and reassessment of OSA—receive continued funding on the Medicare Benefits Schedule (MBS). Currently, a narrow range of unattended sleep studies receive interim funding on the MBS. This assessment is evaluating whether this interim funding should continue and perhaps be extended to other types of unattended sleep studies.

The two applicants sponsoring this request for MBS funding are: (1) the Australasian Sleep Association in conjunction with the Thoracic Society of Australia and New Zealand, and (2) Healthy Workplace Solutions Pty Ltd trading as Healthy Sleep Solutions.

Background

Unattended sleep studies

According to Australasian Guidelines (Hensley et al 2005) there are three main functions of respiratory sleep studies:

1. Diagnostic studies: to assist a clinician to make a diagnosis

2. Intervention studies: to commence and titrate treatment (predominantly continuous positive airway pressure (CPAP) therapy), or confirm the effectiveness of a new treatment

3. Follow-up studies: to follow up and reassess the progress of a patient.

This assessment report is primarily concerned with the use of unattended sleep studies at points 1 and 3, ie in the diagnosis of obstructive sleep apnoea (OSA) and as a follow-up study to reassess the patient.

Respiratory sleep studies are usually categorised into four types, ranging from the 'gold' standard Level 1 (laboratory-based polysomnography, PSG) study, which records the most amount of information on the patient's sleeping respiratory status, to Level 4 studies, where minimal data are obtained (Collop et al 2007; Hensley et al 2005) (Table 1).

Table 1 Types of sleep study

Sleep study type	Description
Level 1	PSG is considered the reference standard against which other respiratory sleep monitors are evaluated. Recordings are made in a sleep laboratory with trained sleep laboratory staff **in *attendance***. 12–13 recording channels are routinely recorded: 2 EEG, 2 EOG, submental EMG, ECG, bilateral leg movements, arterial oxygen saturation, sound, respiratory thoraco-abdominal movements, airflow (nasal pressure and oronasal thermocouples) and body position.
Level 2	A minimum of seven channels are recorded, including EEG, EOG, chin EMG, ECG or heart rate, airflow, respiratory effort, oxygen saturation. This type of monitor allows for sleep staging and therefore calculation of an AHI. It is configured in a fashion that allows studies to be performed in the home. *These are **unattended** by trained sleep laboratory staff.*
Level 3	A minimum of four channels are monitored, including ventilation or airflow (at least two channels of respiratory movement, or respiratory movement and airflow), heart rate or ECG and oxygen saturation. *These are **unattended** by trained sleep laboratory staff.*
Level 4	Monitors of this type measure a single parameter or two parameters, eg oxygen saturation or airflow. *These are **unattended** by trained sleep laboratory staff.*

Source: Modified from Hensley et al (2005)

AHI = apnoea–hypopnoea index; ECG = electrocardiogram; EEG = electroencephalography; EMG = electromyogram; EOG = electrooculogram; PSG = polysomnography.

Recently, the American Academy of Sleep Medicine (AASM), who originally promulgated a similar categorisation as given in Table 1, have suggested that, given the proliferation of portable unattended sleep study devices, the validity of a scheme based mainly on the number of recording channels is less certain. They have a preference now for focusing on the *types* of signals rather than the *number* of channels. At minimum they

suggest that an unattended sleep study should record airflow, respiratory effort and blood oxygenation (Collop et al 2007).

For consistency with the latest (2005) Australasian Sleep Association (ASA) Guidelines, however, and for ease of interpretation, this report has categorised the unattended sleep study literature according to the scheme in Table 1. ASA recommends all Level 1 to 4 studies be done under the guidance of an ASA-accredited laboratory and reported by an accredited sleep physician.

Apart from the amount of data obtained on the patient, one other important variable distinguishes between types of sleep studies, ie whether the studies are attended or unattended by a trained sleep laboratory technician. Unattended studies are usually conducted in the home, while attended sleep studies (Level 1 or PSG) are performed in a sleep laboratory. The ASA Guidelines define 'attended' and 'unattended' sleep studies as follows (Hensley et al 2005):

Attended: a study continuously attended by medical, scientific/technical or nursing staff specifically trained in the performance of sleep studies.

Unattended: a study where staff with such training are absent during the recording period. These studies are usually undertaken using portable equipment and are located in the home.

The above definitions have been used when applying the criteria to include studies in the systematic literature review that underpins this assessment report.

Intended purpose

This assessment report is concerned with the use of unattended sleep studies in the diagnosis and reassessment of OSA, which occurs when an upper airway blockage is experienced by a person, regardless of airflow drive or respiratory effort (Figure 1). Upper airway narrowing (often associated with obesity in adults or developmental or congenital abnormalities in children) leads to obstruction during sleep. These apnoea episodes last at least 10 seconds in adult patients, but in infants and young children they may be shorter than 10 seconds. The affected person can suffer a repeating cycle of sleep, obstructive choking and a gasping arousal from sleep. Clinically, this can manifest in cardiac abnormalities, hypertension, excessive daytime sleepiness, headache, depression, fatigue, and difficulty in thinking and functioning due to sleep deprivation (particularly of rapid eye movement (REM)[1] or slow wave sleep). Patients are prone to falling asleep while sitting down. Snoring, nocturnal diuresis and gastro-oesophageal reflux are other common associated symptoms (Beers & Berkow 1999; Franklin et al 2007). Snoring and daytime sleepiness are the usual reasons that prompt people to seek medical attention (Franklin et al 2007).

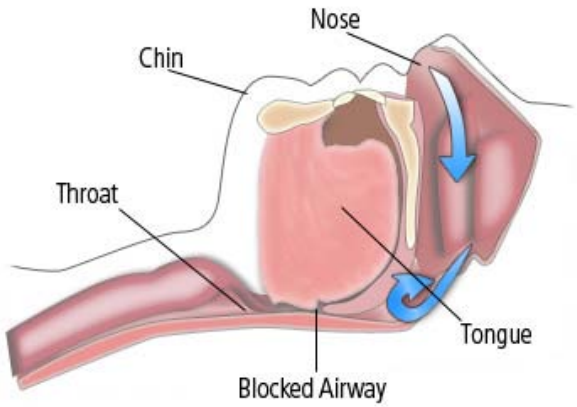
OSA is commonly diagnosed on the basis of (Collop et al 2007):

[1] Rapid eye movement (REM) sleep is a portion of sleep characterised by rapid eye movements. Dreams mostly occur during REM sleep. Slow wave sleep is often referred to as deep sleep and is made up of stage 3 and stage 4 non-REM sleep (Kryger et al 2000).

- occurrence of daytime sleepiness
- loud snoring
- witnessed breathing interruptions
- awakenings due to gasping or choking in the presence of at least five obstructive respiratory events (apnoeas, hypopnoeas or arousals related to respiratory effort) per hour of sleep.

The presence of 15 or more obstructive respiratory events per hour of sleep, in the absence of sleep-related symptoms, is also sufficient for the diagnosis of OSA, and is considered clinically important due to the greater association of this severity of obstruction with important consequences such as increased risk of cardiovascular disease (Collop et al 2007).

Figure 1 Depiction of OSA



Source: MySleepTest.com. Available at: https://www.mysleeptest.com/user_files/image/the_nose_diagram.jpg [accessed February 2010]

Suspected OSA

Patients in whom OSA is suspected usually fall into one of three categories (Hensley et al 2005):

1) Patients with a history of habitual loud snoring and excessive daytime sleepiness and in whom apnoeas may have been witnessed. The ASA Guidelines recommend a sleep study for these patients, as there is a high probability that they have OSA.

2) Patients in whom the history is less clear-cut; for example, where snoring may be related to sleeping position and associated with weight gain and mild daytime sleepiness. The ASA Guidelines suggest that, for these patients, it is reasonable to defer a sleep study pending response to measures to relieve nasal obstruction or modify lifestyle factors (eg reduce weight or alcohol consumption). Where a sleep study has been deferred, a formal follow-up is recommended. If there has been an inadequate symptomatic response to these measures, a sleep study is suggested.

   However, those patients who are occupational drivers, have a history of accident or 'near miss' accident at work or while driving that could be related to sleepiness, or

have coexisting vascular disease (eg ischaemic heart disease, cerebrovascular disease, or poorly controlled hypertension) are recommended to receive a sleep study.

3) Patients who snore but have no evidence of excessive daytime sleepiness or cardiorespiratory dysfunction, and where occasional apnoeas may have been observed. The ASA Guidelines consider that a sleep study is unlikely to be clinically useful for these patients and the test should therefore not be performed routinely, except where upper airway surgery is being contemplated. Such patients should be advised of the importance of recognising and reporting the occurrence of symptoms of sleep disruption, suggesting that sleep apnoea may have become clinically important.

For this assessment report, suspected OSA was defined in:

- Adults as suspected on the basis of excessive daytime sleepiness, snoring, choking or gasping during sleep, witnessed apnoea or nocturia.

- Children as suspected on the basis of snoring, behavioural change and learning difficulties.

Diagnosis of OSA

In order to diagnose OSA and measure the progress of a patient, or compare treatments between patients, it is important to have common criteria for scoring sleep-related respiratory events and symptoms.

Excessive daytime sleepiness is a symptom of OSA but is a highly subjective measure. In order to objectify its assessment, the Epworth Sleepiness Scale (ESS) was developed, and has become of the most common methods of assessing daytime sleepiness. In patients with OSA, ESS scores have been found to significantly correlate with the respiratory disturbance index (RDI) and minimum oxygen saturation recorded during sleep (Johns 1991). Other measures include the Maintenance of Wakefulness Test (MWT) and the Cleveland Sleep Questionnaire. The Cleveland Questionnaire is an instrument measuring daytime sleepiness in patients, especially adolescents, with OSA. It consists of 16 items, with a score ranging from 1 to 5 on each item. A higher score suggests more severe daytime sleepiness (Kump et al 1994). The MWT also evaluates excessive daytime sleepiness/wakefulness. It assesses how well a subject is able to stay awake while resisting the stress to fall asleep in a somnolent setting. The MWT is used clinically to examine the response to treatment in patients with disorders that cause daytime sleepiness, and is also helpful to judge whether subjects have the ability to stay awake for safety or employment purposes. A longer period of sleep latency in MWT suggests less daytime sleepiness (Banks et al 2004). The Brouillette OSA scoring system was developed specifically to measure sleepiness in children. It used discriminant stepwise analysis to identify three factors that were highly predictive of paediatric OSA, namely difficulty in breathing during sleep, apnoea observed during sleep and snoring. Brouilette scores can range from –4 to 4. A score >3.5 is considered diagnostic of OSA; a score <–1 indicates an absence of OSA; and scores between –1 and 3.5 may or may not indicate OSA and thus require confirmatory sleep studies (Brouilette et al 1984).

Standardised criteria for scoring sleep-related respiratory events (apnoea and hypopnoea episodes) are listed in Table 2. The apnoea–hypopnoea index (AHI), defined as the

number of apnoea and hypopnoea events per hour of sleep, has been widely used to classify patients as either having OSA or being normal, as well as to classify the severity of OSA. Lower AHI cut-off points are used for paediatric than for adult OSA (Table 2).

Table 2 Definition of respiratory events and classification of OSA severity

	Adults	Children
Definition of respiratory events		
Apnoea[a]	Cessation of breathing; and the event lasts for 10 seconds or longer	Cessation of airflow at nose and mouth, as measured using oronasal thermistor or end-tidal PCO_2 recording
Hypopnoea	(1) A decrease (>50%) from baseline in the amplitude of breathing during sleep, as measured using pneumotachography, nasal pressure, thoraco-abdominal movement or oronasal flow; and the event lasts for 10 seconds or longer OR (2) A clear amplitude reduction in breathing during sleep that does not reach the above criterion but is associated with either oxygen desaturation ≥3% or arousal; and the event lasts for 10 seconds or longer	A decrease (>50%) from baseline in the amplitude of airflow as measured using oronasal thermistor or end-tidal PCO_2 recording; with or without a reduction in oxygen saturation or arousal
Classification of OSA severity		
Normal	AHI < 5	AHI ≤ 1
Mild OSA	5 ≤ AHI < 15	1 < AHI ≤ 5
Moderate OSA	15 ≤ AHI < 30	5 < AHI ≤ 15
Severe OSA	AHI ≥ 30	AHI > 15

Source: modified from American Thoracic Society (1996); Hensley et al (2005)

[a] There are three types of apnoea: obstructive, central and mixed. Obstructive apnoea is associated with evidence of persistent respiratory effort; central apnoea is associated with cessation of breathing effort; and mixed apnoea has features of both central and obstructive apnoea (American Academy of Sleep Medicine Task Force 1999).

AHI = apnoea–hypopnoea index; OSA = obstructive sleep apnoea.

In adults mild OSA is defined as a minimum of five respiratory events per hour, as epidemiological studies suggest that at this threshold there may be measurable health effects such as sleepiness, motor vehicle accidents and hypertension. Moderate OSA, at 30 respiratory events per hour of sleep, has a clear association with hypertension, a known risk factor for cardiovascular events (Young et al 1997a, 1997b). Characteristics associated with increasing severity of adult OSA include older age, male sex, minority race, body mass index (BMI) and central adiposity (Punjabi et al 2009). Laboratory sleep studies these days are generally scored with higher AHI values, as the technology used to measure respiratory events and oxygen desaturation has changed since the original OSA thresholds were determined (Hensley et al 2005).

Based on normative data (eg at the 97.5th percentile in general, asymptomatic population), paediatric OSA is usually diagnosed at AHI >1. However, this cut-off point does not necessarily reflect the clinical significance of the AHI value. It has been suggested that children are most likely to be at increased risk of adverse outcomes with an AHI >5 (moderate to severe paediatric OSA) (Kirk et al 2003; Schechter 2002).

Attended or Level 1 sleep studies (PSG) classify OSA using the AHI. *Unattended* sleep studies (Level 2, 3 and 4 studies) classify OSA using similar, albeit simpler, respiratory indices, namely the RDI and the oxygen desaturation index (ODI). The RDI is defined as

the number of apnoea/hypopnoea events per hour of recording time in most unattended sleep studies; whereas the ODI is the number of times that oxygen saturation drops by a certain percentage per hour of recording time (Trikalinos et al 2007).

Current treatment options

OSA is currently treated using a range of therapies, including continuous positive airway pressure (CPAP), ear, nose and throat (ENT) surgery, oral appliances and weight loss (Abad & Guilleminault 2009). Adult and paediatric OSA patients usually require different treatment approaches. CPAP is recognised as the standard treatment for OSA in adults, while ENT surgery is the mainstay initial treatment for paediatric OSA (Abad & Guilleminault 2009; Australasian Sleep Association 2009; Praud & Dorion 2008).

CPAP is nearly 100% effective in adult patients who use it regularly, and has been recommended by the ASA as the first-line treatment for moderate to severe OSA in adults (Australasian Sleep Association 2009). However, the efficacy of CPAP depends heavily on patients' compliance with the therapy (Australasian Sleep Association 2009). The non-adherence[2] rate, which ranges from 46% to 83% according to the literature, suggests that poor compliance is a limitation of CPAP treatment (Weaver & Grunstein 2008). Supportive intervention and cognitive behavioural therapy have resulted in higher rates of CPAP use (Smith et al 2009). Before CPAP is undertaken, a laboratory-based or a home-based CPAP titration trial is carried out to determine the minimum pressure level needed to eliminate apnoea episodes. CPAP works by pushing air through the airway passage at a certain pressure to keep the airway open. During CPAP treatment the patient wears a mask or other interface devices over, or in, his/her nose and/or mouth. Pressurised air is delivered from a CPAP machine through a flexible tube (American Sleep Apnea Association 2005; Hirshkowitz & Sharafkhaneh 2005). Since there are no CPAP machines designed specifically for children, attention should be paid in choosing the appropriate mask for paediatric patients (Praud & Dorion 2008). OSA can be controlled under constant airway pressure (fixed CPAP) or auto-adjusting positive airway pressure (APAP) as needed. Patients' compliance and treatment response can be recorded by some CPAP machines. This facilitates the treating clinician's evaluation of treatment efficacy, and the need for adjustment of the air pressure level or a change in treatment modality, as required (American Sleep Apnea Association 2005; Australasian Sleep Association 2009; Hirshkowitz & Sharafkhaneh 2005).

Since most paediatric OSA is attributable to the anatomic structure or relatively small size of the airway passage, adenotonsillectomy is the mainstay treatment option in children with OSA (Abad & Guilleminault 2009; Praud & Dorion 2008). Other surgical treatment options in the management of paediatric OSA include surgery to rectify craniofacial anomalies and a lip–tongue adhesion procedure.

The most commonly performed surgery for adult OSA is the uvulopalatopharyngoplasty (UPPP) procedure, during which the upper airway is enlarged by suturing of the lateral pharyngeal walls and, sometimes, by removal of the tonsils, adenoids or part of the uvula and soft palate (Abad & Guilleminault 2009; Sundaram et al 2005). Other surgeries to

[2] CPAP adherence is defined as more than 4 hours nightly use of a CPAP machine (Weaver & Grunstein 2008).

treat patients with OSA include nasal reconstruction, laser midline glossectomy, mandibular osteotomy and uvulopalatal flap (Abad & Guilleminault 2009; Sundaram et al 2005). A tracheotomy, by creating a hole in the trachea, is the treatment of last resort and is used in cases of extremely serious sleep apnoea when other treatment has failed or when there is significant urgency. Tracheotomy is associated with a high rate of complications and so is seldom performed (Abad & Guilleminault 2009).

Oral appliances such as mandibular advancement devices are indicated for mild to moderate OSA. They treat OSA by moving the jaw and tongue forward to keep the throat open. Oral appliances are often prescribed to patients who are not suitable for, or fail, CPAP treatment. Follow-up visits in a dental clinic are suggested in order to assess the treatment efficacy, monitor patients' compliance and check the deterioration of the devices (Ballard 2008; Kushida et al 2006).

Given the relationship between obesity and OSA (an increase in fat around the throat can cause narrowing of the airway), obese adult patients are often encouraged to lose weight through a change in lifestyle or other measures (which may include bariatric surgery). Excessive weight is less commonly a cause of OSA in children. However, if obesity contributes to a case of paediatric OSA, weight reduction is advised along with other treatment (Abad & Guilleminault 2009; Ballard 2008; Praud & Dorion 2008).

Reassessment of OSA

In those patients who have been diagnosed and treated for their OSA and have experienced symptom relief and are clinically stable, routine follow-up sleep studies are not necessary. However, if symptoms such as snoring or daytime sleepiness recur despite ongoing treatment with CPAP or a mandibular advancement splint, repeat diagnostic and/or therapeutic unattended or attended sleep studies may be required. This may be done to confirm satisfactory adherence to treatment, re-titrate CPAP, establish objectively the level of daytime sleepiness, or rule out alternative causes of daytime sleepiness. Follow-up sleep studies may also be required to assess disease progression in patients initially judged to have a mild abnormality but in whom symptoms have progressed (Hensley et al 2005).

Because childhood growth can impact on OSA treatment efficacy, reassessment occurs often in children. Sleep studies have a role in that reassessment. In adults reassessment occurs less frequently and is usually only indicated when there is a change in symptoms or symptoms are unresolved. The OSA patient may be assessed with a sleep study while receiving treatment (eg CPAP) or after treatment (eg surgery). Reassessment may also be required due to major weight loss or surgical correction to the cause of OSA in adults; or when symptoms reappear despite treatment in both adults and children.

Clinical need

Health risks associated with OSA

The relationship between OSA and health risks has been examined by a number of studies. Caution should be exercised in directly comparing the results from these studies

because of the different control groups (comparators), varying methods of adjusting for covariates, and different types of sleep study and AHI cut-off points across these studies.

OSA has been associated with an increased risk of hypertension and cardiac abnormalities, both of which are risk factors for cardiovascular events such as stroke and myocardial infarction. Health risks appear to be more common in men than women. Punjabi et al (2009) studied 6441 men and women participating in the Sleep Heart Health Study—a prospective cohort study of the cardiovascular consequences of sleep-disordered breathing undertaken in the USA. Sleep-disordered breathing was assessed on the basis of an AHI determined by an in-home Level 2 sleep study. Survival analysis and proportional hazards regression models were used to calculate hazard ratios for mortality after adjusting for age, sex, race, smoking status, BMI and prevalent medical conditions. The average follow-up period for the cohort was 8.2 years. Stratified analyses by sex indicated that AHI was associated with mortality in men but not in women. When the model was fully adjusted for potential confounders, the hazard ratios for mild, moderate and severe sleep-disordered breathing were 1.24 [95% CI 0.90, 1.71], 1.45 [95% CI 0.98, 2.14] and 2.09 [95% CI 1.31, 3.33], respectively, in men younger than 70 years. There was no association between sleep-disordered breathing and mortality in men older than 70 years. An AHI ≥15 had a fully adjusted hazard ratio of 1.69 [95% CI 1.13, 2.52] for male death caused by coronary artery disease (CAD). In women there was no association between sleep-disordered breathing and CAD-related death (Punjabi et al 2009).

An Australian prospective cohort study in Busselton has also suggested that OSA is an independent risk factor for all-cause mortality (Marshall et al 2008). Moderate to severe OSA (RDI ≥15/hour), as determined with the use of a Level 4 home-based sleep study, was independently associated with a greater risk of all-cause mortality (adjusted hazard ratio [HR] = 6.24, 95% CI 2.01, 19.39) than non-OSA (n = 285, 22 deaths). Mild OSA (RDI 5 to <15/hour) did not appear to be an independent risk factor for higher mortality, although the width of the confidence interval suggests a lack of statistical power (HR = 0.47, 95% CI 0.17, 1.29). There was also limited statistical power to detect potential effect modification (eg by gender). Unlike the study by Punjabi et al, this analysis was hampered by the use of a Level 4 sleep study as the diagnostic tool.

The OSA symptoms of excessive daytime sleepiness, headache, depression, fatigue, and difficulty in thinking and functioning due to sleep deprivation (particularly of REM or slow wave sleep) have also been associated with motor vehicle accidents and work-related accidents, as patients are prone to falling asleep while sitting down. A 2007 systematic review identified four studies of medium quality that investigated the effect of OSA on traffic accidents (Franklin et al 2007). All four reported an increased frequency of traffic accidents, independent of driving exposure (kilometres driven), in subjects with OSA. At an AHI >20, the odds of an accident resulting in personal injury or property damage >US$500 were 2.6 times higher [95% CI 1.1, 6.4] in a sleep clinic population compared with healthy controls, regardless of driving exposure or alcohol consumption (Barbé et al 1998). This contrasts with Teran-Santos et al (1999) who reported that, at an AHI ≥5, the adjusted odds were 11 times higher that a subject would require emergency care after a highway accident [95% CI 4.0, 30] compared with controls without a traffic accident in the previous 2 months, regardless of alcohol consumption, visual refraction disorders, BMI, years of driving, kilometres of driving per year, work schedule and similar ESS scores (Teran-Santos et al 1999).

Prevalence of OSA

A health technology assessment that systematically reviewed the prevalence of OSA identified three population studies (random sampling) that reported the prevalence of undiagnosed OSA by age (populations ranging in age from approximately 30 to 70 years) and gender (Franklin et al 2007). Two of these studies were from the USA and one from Spain, and they used similar measurement methods and definitions of AHI thresholds. Results suggested that OSA prevalences in males were in the ranges 24–26%, 15–19% and 9–14% at AHI ≥5, 10 and 15, respectively. In women the range were 9–28%, 5–15% and 4–7% at the same cut-off points (Franklin et al 2007).

The prospective cohort study undertaken in Busselton, Australia, provides the best available information of OSA presence and severity in an Australian community-based setting, although it is limited by the use of a Level 4 sleep study to estimate AHI thresholds. Mild OSA (RDI 5 to <15) was present in 20% of individuals, while moderate to severe OSA (RDI ≥15) occurred in 5% of individuals. Prevalence in males was 15% for mild OSA and 3% for moderate to severe OSA, while in females it was 5% for mild OSA and 1% for moderate to severe OSA.

A recent study from New Zealand that compared the prevalence of OSA in Maori and non-Maori people found that, in a non-Maori population, the prevalence of at least mild OSA (RDI ≥5 and ESS > 10) was conservatively estimated to be 4.1% for men and 0.7% for women. For a Maori population, using the same criteria, the prevalence was estimated at 4.4% for Maori men and 2.0% for Maori women. After controlling for sex and age, Maori were 4.3 times more likely to have moderate–severe OSA at an RDI ≥15 [95% CI 1.3, 13.9] than non-Maori. Ethnicity, however, was not an independent risk factor for OSA after controlling for BMI and neck circumference. It would be reasonable to suggest, therefore, that population subgroups at risk of obesity in Australia would have a similarly higher prevalence of clinically meaningful OSA (Mihaere et al 2009).

OSA in childhood is relatively common, with approximately 1–3% of children affected to different degrees (Anuntaseree et al 2001; Brunetti et al 2001).

These varying estimates of OSA prevalence are probably due to the different diagnostic thresholds and tools used in the epidemiological studies. There are also limitations associated with defining and measuring OSA by apnoea thresholds or indexes that do not necessarily correlate well with clinically meaningful symptoms (Stradling & Davies 2004).

Impact of OSA on the health system

Public and private sector hospital separations, estimated from Australian Refined Diagnosis Related Groups (AR-DRG) data for sleep apnoea, have doubled in just under a decade in Australia—from 17 315 in 1998–99 to 38 662 in 2006–07[3] (Figure 2). The sleep apnoea diagnosis related group (DRG) was ranked 14th in the top 20 highest volume Australian DRGs in the private sector in 2006–07, with 30 764 separations and

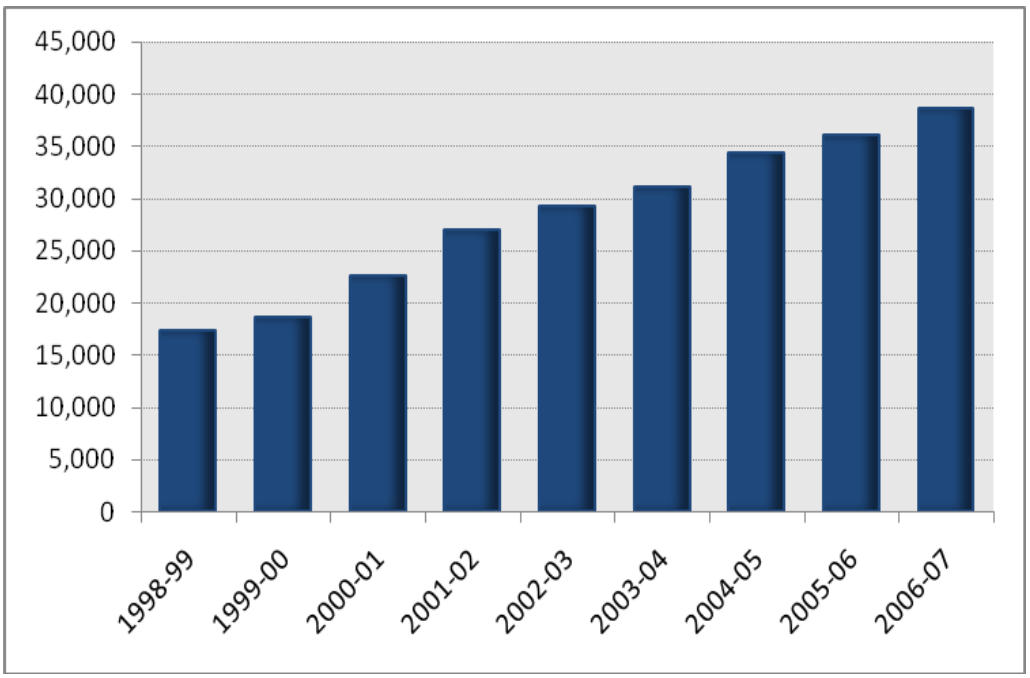
[3] Source: AIHW National Hospital Morbidity Database, AR-DRG (version 5.0/5.1) E63Z Sleep Apnoea. Available at: http://d01.aihw.gov.au/cognos/cgi-bin/ppdscgi.exe?DC=Q&E=/ahs/drgv5_9899-0607. [accessed August 2009].

an average length of stay of 1.01 days.[4] Hospital separations for sleep apnoea for this DRG appear, therefore, to be driven by overnight private sector hospital separations (mainly from sleep centres) and would relate to the sleep study diagnosis of sleep apnoea and titration of CPAP treatment.

Similar results are seen using ICD-10-AM coding for sleep apnoea as the principal diagnosis, with 16 766 separations in 1998–99, increasing to 44 334 in 2006–07. Twice as many males (30 512) as females (13 820) were separated from hospital with this condition. The average length of stay for hospitalisation related to sleep apnoea in that year was 1.2 days. The vast majority of all sleep apnoea separations relate to OSA—35 896 in 2006–07[5].

Presumably, the linear increase in sleep apnoea, as demonstrated in Figure 2, is a function of an ageing and increasingly overweight population—age and obesity being two known risk factors for OSA (Marshall et al 2007; Thornburn 2005).

Figure 2 Hospital separations for sleep apnoea, Australia, 1998–99 to 2006–07



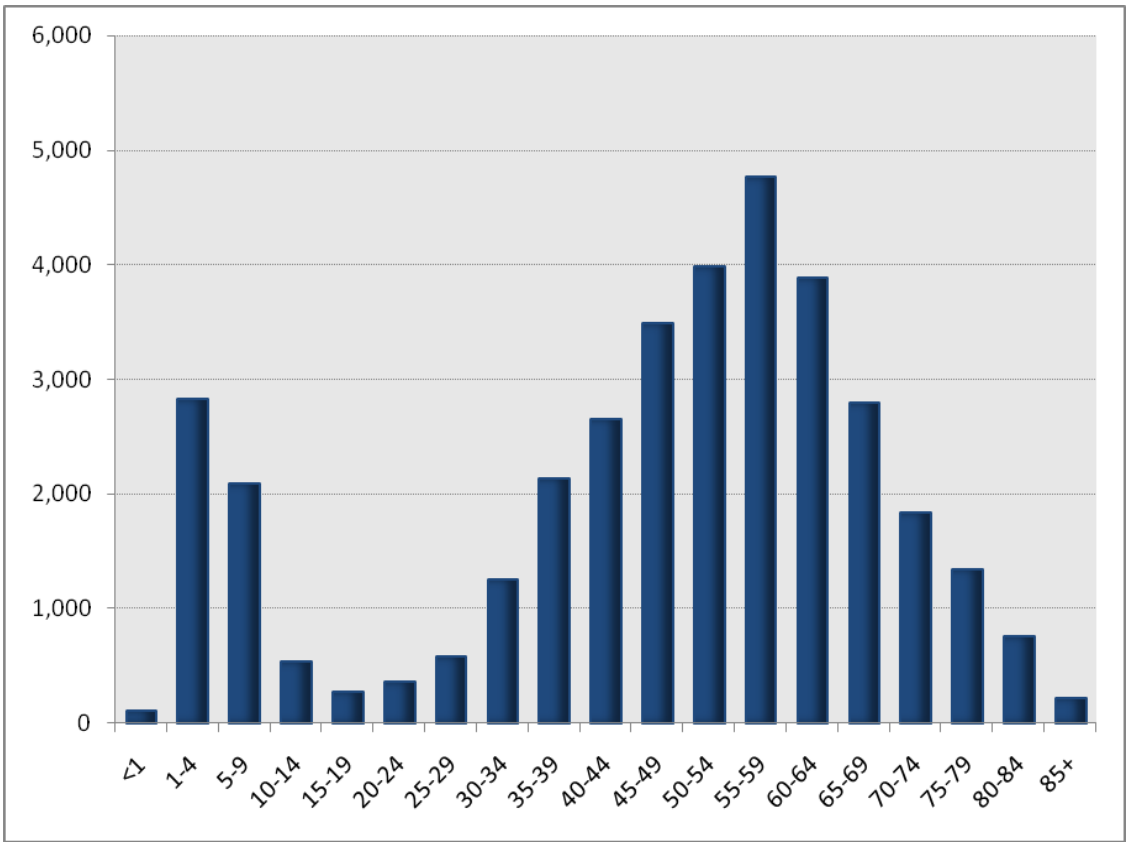
Source: AIHW National Hospital Morbidity Database for AR-DRG E63Z Sleep apnoea (version 5.0/5.1)

The majority of people who are hospitalised for OSA are aged 45–64 years, with peak hospitalisation occurring in the 55–59 years age group, as can be seen in the 2006–07 ICD-10-AM data presented in Figure 3. A large cluster of hospitalisations for OSA also occurs in children aged 1–4 years.

[4] Source: Department of Health and Ageing. National Hospital Cost Data Collection. Round 11 (2006-07) Cost Report - public version 5.1, private version 4.2 and 5.1, page 43. Available at: http://www.health.gov.au/internet/main/publishing.nsf/Content/Round_11-cost-reports [accessed December 2009].

[5] Source: AIHW National Hospital Morbidity Database, ICD-10-AM (version 5.0/5.1) G47.3 Sleep Apnoea. Available at: http://d01.aihw.gov.au/cognos/cgi-bin/ppdscgi.exe?DC=Q&E=/ahs/pdx0607. [accessed August 2009].

Figure 3 Hospital separations for OSA by age group, Australia, 2006–07



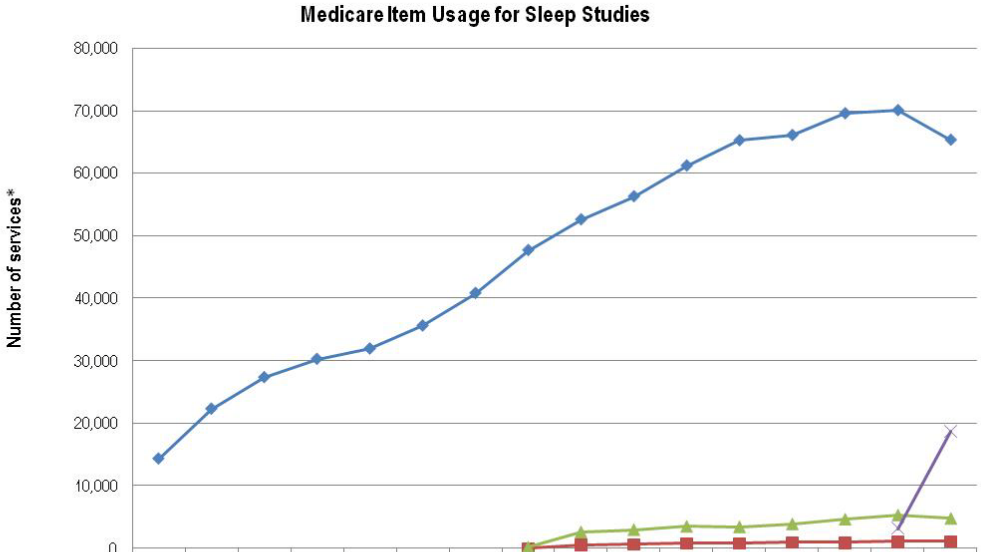
Source: AIHW National Hospital Morbidity Database, ICD-10-AM, G47.32 Obstructive sleep apnoea

The clinical need for sleep studies in the *referral setting* or the *paediatric setting* in Australia would therefore appear to be considerable.

There was a potential problem with the ICD-10 data, however, as it was unknown whether it related only to the *diagnosis* of OSA or included hospital separations associated with *titrating CPAP* or *reassessing OSA* status. A comparison was therefore made between the 2006–07 ICD-10 data for all sleep apnoea principal diagnoses and the data derived from Medicare item number sleep study claims over the same period. The Medicare data (estimated to cover 85–90% of all sleep study usage for suspected sleep apnoea (Marshall et al 2007)) included services for all persons receiving up to three Level 1 sleep studies in a 12-month period (item numbers 12203, 12213, 12210). The total Medicare services numbered 71 968, while the ICD-10 public and private sleep apnoea principal diagnosis separations numbered 44 334 during the 2006–07 financial year. This suggests that the ICD-10 data only relate to the first diagnostic sleep study and not the following titration activity.

Figure 4 gives a breakdown of Medicare item number usage for sleep studies since 1994. Item numbers 12203, 12213 and 12210 are Level 1 sleep studies (PSG), while item number 12250 is a Level 2 study that has only recently been listed (interim funding). The trend in Medicare claims suggests that the proportion of adult Level 1 studies has dropped over the period of Level 2 study listing on the MBS, while paediatric Level 1 studies appear relatively stable.

Figure 4 Medicare item number usage for sleep studies in Australia (1994–2009)



	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	YTD 2009
Item 12203 (>18 years)	14,308	22,299	27,347	30,272	31,934	35,618	40,828	47,701	52,619	56,314	61,240	65,289	66,134	69,608	70,107	65,372
Item 12213 (12-18 years)								26	535	626	813	770	922	907	1,061	1,081
Item 12210 (0-12 years)								178	2,588	2,953	3,481	3,414	3,881	4,617	5,290	4,739
Item 12250 (Level 2)															3,142	18,746

The clinical need for sleep studies on patients presenting to primary care or a *non-specialised unit setting* with suspected sleep apnoea is more difficult to estimate.

For the purposes of estimating the number of unattended diagnostic sleep studies in this setting, the information on diagnostic yield from the evidence-base was collated (Appendix E, Tables 52–54) and used in conjunction with the known number of OSA cases in 2006–07 to estimate the number of people that would be clinically suspected of OSA in Australia.

As mentioned previously, using ICD-10-AM coding, 35 896 patients had a principal diagnosis of OSA in Australia in 2006–07. Of these, 30 329 (84.5%) patients were 14 years old or above. It is assumed that the remaining 5567 were treated in a paediatric setting. The articles identified by this assessment indicated that the prevalence of OSA in the adult target population (adults with suspected OSA) ranged between 53% and 100%, and between 25% and 82%, when the diagnosis of OSA was established at PSG AHI ≥5 and ≥15, respectively; whereas between 62% and 100%, and between 29% and 75%, of paediatric patients with suspected OSA had AHI results of ≥1 and ≥5, respectively (Table 36). In order to estimate the clinical need for unattended sleep studies, two base-case scenarios were chosen, assuming that 80% of adults / 100% of children (using AHI thresholds of ≥5 / ≥1) and 53% of adults / 42% of children (using AHI thresholds of ≥15 / ≥5) with suspicion of OSA would have their OSA confirmed using laboratory-based PSG. Therefore, in the base-case clinical need scenarios, the total numbers of adults presenting to a medical practitioner with suspected OSA is estimated to range from 37 911 (30 329 ÷ 80%[6]) to 57 225 (30 329 ÷ 53%) according to which AHI

[6] The number of patients with suspected OSA x diagnostic yield = the number of patients with confirmed OSA; therefore, the number of patients with suspected OSA = the number of patients with confirmed OSA ÷ diagnostic yield.

threshold is accepted; while 5567 (5567 ÷ 100%) to 13 255 (5567 ÷ 42%) children would visit a clinician with suspected OSA. Reassessment with a sleep study following OSA treatment was estimated to be required for 25% of adults and children (7582 adults and 1392 children) on the basis of expert opinion.

Existing sleep studies

Unattended sleep studies are widely available in the Australian community (Table 3) but are not currently permanently publicly reimbursed. Level 2 sleep studies are currently receiving interim public funding, dependent on the outcome of the current MSAC review. The other type of sleep study that is both widely available and publicly funded is PSG (Level 1 sleep studies).

PSG is considered the gold standard against which other sleep assessment devices or monitors are evaluated. Recordings are made in a sleep laboratory with trained sleep laboratory staff in attendance. Of the 12–13 recording channels routinely recorded, there are usually two electroencephalogram (EEG) channels, two electrooculogram (EOG) channels, a submental electromyogram (EMG) and an electrocardiogram (ECG); as well as assessments of bilateral leg movements, arterial oxygen saturation, respiratory thoraco-abdominal movements, airflow (nasal pressure and oronasal thermocouples), and sound and body position via infra-red camera and body position sensors (Hensley et al 2005). The aim is to assess all relevant physiological parameters of a patient during sleep in order to diagnose and quantify the severity of sleep-disordered breathing, including OSA.

The provision of PSG in Australia has been steadily growing since public funding was granted in 1990. Marshall et al (2007), in their analysis of Australian Medicare figures, noted that the growth in PSG usage has been higher than overall population growth, and higher than usage for other diagnostic procedures and classes of medical interventions. Per capita data from 1995–2004 indicate that PSG usage increased from 123 to 308 per 100,000 Medicare-eligible people.

Marketing status of device / technology

A large number and wide variety of sleep assessment devices have been registered on the Australian Register of Therapeutic Goods (Table 3). These devices are primarily for recording physiological parameters during sleep, although the extent of measurement will depend on the device. Some of these devices can be used in multiple settings, eg the home, sleep clinic/laboratory, hospital.

Table 3 Sleep studies listed on the Australian Register of Therapeutic Goods (ARTG)

Product name[a]	Category	Level of sleep study	ARTG #	Product #	Sponsor
S-Series Sleep Monitoring System	Sleep assessment device	Level 1	33843	147226	Compumedics Limited
Alice Sleep System	Sleep assessment device	Level 1 or Level 2	33843	133795	Respironics Australia Pty Ltd
Compumedics Siesta System	Sleep assessment device	Level 1 or Level 2	33843	147227	Compumedics Limited
P-Series Sleep Monitoring System	Sleep assessment device	Level 1 or Level 2	33843	146221	Compumedics Limited
Somté	Sleep assessment device	Level 1 or Level 2	33843	147228	Compumedics Limited
	Sleep assessment device	Level 1 or Level 2	33843	156949	CareFusion Australia 316 Pty Ltd
E-Series PSG System	Sleep assessment device	Level 2	33843	147229	Compumedics Limited
Sandman Pocket	Sleep assessment device	Level 2	33843	141190	Mallinckrodt A Division of Tyco Healthcare Pty Ltd
	Sleep assessment device	Level 2	33843	124009	Bird Healthcare Pty Ltd
Somnea	Sleep assessment device	Level 3	33843	146222	Compumedics Limited
MicroMESAM (ApneaLink)	Sleep assessment device	Level 4	33843	100101	Resmed Limited
Masima SET pulse oximetry (Rad-5, Rad-8)	Oximeter, pulse	Level 4	17148	138873 or 153897	Masimo Australia Pty Ltd
Watch_PAT	Sleep assessment device	Level 4	33843	164315	Naol Australia Pty Ltd
	Oximeter, pulse	Level 4	17148	134826	Cardiac Agencies Pty Ltd
	Oximeter, pulse	Level 4	17148	150247	Cardioscan Pty Ltd
	Sleep assessment device	Level 4	33843	152338	The Critical Group Pty Ltd
Compumedics Sleep System	Sleep assessment device	Unknown	33843	146223	Compumedics Limited
	Regulator, vacuum	Unknown	33483	109583	Australian Centre for Advanced Medical Technology Pty Ltd
	Sleep assessment device	Unknown	33843	122870	Five Star Conference Planning Pty Ltd T/A Body Logic Resources
	Sleep assessment device	Unknown	33843	147509	Respironics Australia Pty Ltd
	Sleep assessment device	Unknown	33843	159460	Medtel Pty Ltd
Safiro System	Sleep assessment device	Ambulatory EEG recorder, used with other cardiorespiratory devices	33843	146224	Compumedics Limited
	Sleep assessment device, software	A data program, used with cardiorespiratory monitor	42238	156998	CareFusion Australia 316 Pty Ltd
	Sleep assessment device, software	A data program, used with cardiorespiratory	42238	99720	Central Neurophysiology

monitor	Supplies Pty Ltd

Source: https://www.ebs.tga.gov.au/ebs/ANZTPAR/PublicWeb.nsf/cuDevices?OpenView
[a] If provided on the ARTG.

Current reimbursement arrangements

It is estimated that Medicare funds 85–90% of the total number of sleep studies performed in Australia (Marshall et al 2007).

Eight items are currently listed on the MBS to reimburse medical services associated with sleep study investigation of sleep apnoea (Table 4). Currently, Level 2 sleep studies are the only unattended sleep studies to receive funding, albeit interim funding, on the MBS (item number 12250). This item number was listed on the MBS on 1 October 2008. The Schedule notes that no other Category 2 MBS items—Diagnostic Procedures and Investigations—may be billed for home-based sleep studies, other than item number 12250.

Table 4 Current listings of sleep study items on the Medicare Benefits Schedule (January 2010)

MBS item No	Services
12250	OVERNIGHT INVESTIGATION FOR SLEEP APNOEA FOR A PERIOD OF AT LEAST 8 HOURS' DURATION, WHERE: (a) the patient is referred for the investigation by a medical practitioner; (b) the necessity for the investigation is determined by a qualified sleep medicine practitioner (as defined in explanatory note D1.25) prior to the investigation; (c) a qualified sleep medicine practitioner has: (i) established quality assurance procedures for the data acquisition; and (ii) personally analysed the data and written the report; (d) the investigation must include, during a period of sleep, a continuous recording of an electrocardiograph (ECG); a continuous recording of an electroencephalograph (EEG); and respiratory function testing (including oro-nasal airflow, rib cage/abdominal movement, body position, oximetry); (e) interpretation and report of the investigation (with analysis of sleep stage, arousals, respiratory events and assessment of clinically significant alterations in heart rate) are provided by a qualified sleep medicine practitioner based on reviewing the parameters recorded under (d) above. - payable only once in a 12-month period. Fee: $316.90 Benefit: 75% = $237.70, 85% = $269.40
12203	OVERNIGHT INVESTIGATION FOR SLEEP APNOEA FOR A PERIOD OF AT LEAST 8 HOURS DURATION, FOR AN ADULT AGED 18 YEARS AND OVER WHERE: a) continuous monitoring of oxygen saturation and breathing using a multi-channel polygraph, and recording of EEG, EOG, submental EMG, anterior tibial EMG, respiratory movement, airflow, oxygen saturation and ECG are performed; b) a technician is in continuous attendance under the supervision of a qualified sleep medicine practitioner; c) the patient is referred by a medical practitioner; d) the necessity for the investigation is determined by a qualified adult sleep medicine practitioner prior to the investigation; e) polygraphic records are analysed (for assessment of sleep stage, arousals, respiratory events and assessment of clinically significant alterations in heart rate and limb movement) with manual scoring, or manual correction of computerised scoring in epochs of not more than 1 minute, and stored for interpretation and preparation of report ; and f) interpretation and report are provided by a qualified adult sleep medicine practitioner based on reviewing

	the direct original recording of polygraphic data from the patient - payable only in relation to each of the first 3 occasions the investigation is performed in any 12-month period. Fee: $555.75 Benefit: 75% = $416.85, 85% = $486.65
12207	OVERNIGHT INVESTIGATION FOR SLEEP APNOEA FOR A PERIOD OF AT LEAST 8 HOURS DURATION, FOR AN ADULT AGED 18 YEARS AND OVER WHERE: a) continuous monitoring of oxygen saturation and breathing using a multi-channel polygraph, and recordings of EEG, EOG, submental EMG, anterior tibial EMG, respiratory movement, airflow, oxygen saturation and ECG are performed; b) a technician is in continuous attendance under the supervision of a qualified sleep medicine practitioner; c) the patient is referred by a medical practitioner; d) the necessity for the investigation is determined by a qualified adult sleep medicine practitioner prior to the investigation; e) polygraphic records are analysed (for assessment of sleep stage, arousals, respiratory events and assessment of clinically significant alterations in heart rate and limb movement) with manual scoring, or manual correction of computerised scoring in epochs of not more than 1 minute, and stored for interpretation and preparation of report; and f) interpretation and report are provided by a qualified adult sleep medicine practitioner based on reviewing the direct original recording of polygraphic data from the patient *- where it can be demonstrated that a further investigation is indicated in the same 12-month period to which item 12203 applies* for the adjustment and/or testing of the effectiveness of a *positive pressure ventilatory support device* (other than nasal continuous positive airway pressure) in sleep, in a *patient with severe cardio-respiratory failure,* and where previous studies have demonstrated failure of continuous positive airway pressure or oxygen - each additional investigation Fee: $555.75 Benefit: 75% = $416.85, 85% = $486.65
12210	OVERNIGHT PAEDIATRIC INVESTIGATION FOR A PERIOD OF AT LEAST 8 HOURS DURATION FOR A CHILD AGED 0–12 YEARS, WHERE: a) continuous monitoring of oxygen saturation and breathing using a multi-channel polygraph, and recording of EEG (minimum of 4 EEG leads with facility to increase to 6 in selected investigations), EOG, EMG submental +/- diaphragm, respiratory movement must include rib and abdomen (+/- sum) airflow detection, measurement of CO_2 either end-tidal or transcutaneous, oxygen saturation and ECG are performed; b) a technician or registered nurse with sleep technology training is in continuous attendance under the supervision of a qualified paediatric sleep medicine practitioner; c) the patient is referred by a medical practitioner; d) the necessity for the investigation is determined by a qualified paediatric sleep medicine practitioner prior to the investigation; e) polygraphic records are analysed (for assessment of sleep stage, and maturation of sleep indices, arousals, respiratory events and the assessment of clinically significant alterations in heart rate and body movement) with manual scoring, or manual correction of computerised scoring in epochs of not more than 1 minute, and stored for interpretation and preparation of report; f) the interpretation and report to be provided by a qualified paediatric sleep medicine practitioner based on reviewing the direct original recording of polygraphic data from the patient. - payable only in relation to the first 3 occasions the investigation is performed in a 12-month period. Fee: $663.30 Benefit: 75% = $497.50, 85% = $594.20

12213	OVERNIGHT PAEDIATRIC INVESTIGATION FOR A PERIOD OF AT LEAST 8 HOURS DURATION FOR A CHILD AGED BETWEEN 12 AND 18 YEARS, WHERE: a) continuous monitoring of oxygen saturation and breathing using a multi-channel polygraph, and recording of EEG (minimum of 4 EEG leads with facility to increase to 6 in selected investigations), EOG, EMG submental +/- diaphragm, respiratory movement must include rib and abdomen (+/- sum) airflow detection, measurement of CO_2 either end-tidal or transcutaneous, oxygen saturation and ECG are performed; b) a technician or registered nurse with sleep technology training is in continuous attendance under the supervision of a qualified sleep medicine practitioner; c) the patient is referred by a medical practitioner; d) the necessity for the investigation is determined by a qualified sleep medicine practitioner prior to the investigation; e) polygraphic records are analysed (for assessment of sleep stage, and maturation of sleep indices, arousals, respiratory events and the assessment of clinically significant alterations in heart rate and body movement) with manual scoring, or manual correction of computerised scoring in epochs of not more than 1 minute, and stored for interpretation and preparation of report; f) the interpretation and report to be provided by a qualified sleep medicine practitioner based on reviewing the direct original recording of polygraphic data from the patient. - payable only in relation to the first 3 occasions the investigation is performed in a 12-month period. Fee: $597.60 Benefit: 75% = $448.20, 85% = $528.50
12215	OVERNIGHT PAEDIATRIC INVESTIGATION FOR A PERIOD OF AT LEAST 8 HOURS DURATION FOR CHILDREN AGED 0–12 YEARS, WHERE: a) continuous monitoring of oxygen saturation and breathing using a multi-channel polygraph, and recording of EEG (minimum of 4 EEG leads with facility to increase to 6 in selected investigations), EOG, EMG submental +/- diaphragm, respiratory movement must include rib and abdomen (+/- sum) airflow detection, measurement of CO_2 either end-tidal or transcutaneous, oxygen saturation and ECG are performed; b) a technician or registered nurse with sleep technology training is in continuous attendance under the supervision of a qualified paediatric sleep medicine practitioner; c) the patient is referred by a medical practitioner; d) the necessity for the investigation is determined by a qualified paediatric sleep medicine practitioner prior to the investigation; e) polygraphic records are analysed (for assessment of sleep stage, and maturation of sleep indices, arousals, respiratory events and the assessment of clinically significant alterations in heart rate and body movement) with manual scoring, or manual correction of computerised scoring in epochs of not more than 1 minute, and stored for interpretation and preparation of report; f) the interpretation and report to be provided by a qualified paediatric sleep medicine practitioner based on reviewing the direct original recording of polygraphic data from the patient. - where it can be demonstrated that a further investigation is indicated in the same 12-month period to which item 12210 applies, for therapy with Continuous Positive Airway Pressure (CPAP), bilevel pressure support and/or ventilation is instigated or in the presence of recurring hypoxia and supplemental oxygen is required - each additional investigation. Fee: $663.30 Benefit: 75% = $97.50, 85% = $594.20
12217	OVERNIGHT PAEDIATRIC INVESTIGATION FOR A PERIOD OF AT LEAST 8 HOURS DURATION FOR CHILDREN AGED BETWEEN 12 AND 18 YEARS, WHERE: a) continuous monitoring of oxygen saturation and breathing using a multi-channel polygraph, and recording of EEG (minimum of 4 EEG leads with facility to increase to 6 in selected investigations), EOG, EMG submental +/- diaphragm, respiratory movement must include rib and abdomen (+/- sum) airflow detection, measurement of CO_2 either end-tidal or transcutaneous, oxygen saturation and ECG are performed; b) a technician or registered nurse with sleep technology training is in continuous attendance under the supervision of a qualified sleep medicine practitioner; c) the patient is referred by a medical practitioner; d) the necessity for the investigation is determined by a qualified sleep medicine practitioner prior to the investigation;

	e) polygraphic records are analysed (for assessment of sleep stage, and maturation of sleep indices, arousals, respiratory events and the assessment of clinically significant alterations in heart rate and body movement) with manual scoring, or manual correction of computerised scoring in epochs of not more than 1 minute, and stored for interpretation and preparation of report; f) the interpretation and report to be provided by a qualified sleep medicine practitioner based on reviewing the direct original recording of polygraphic data from the patient. - where it can be demonstrated that a further investigation is indicated in the same 12-month period to which item 12213 applies, for therapy with Continuous Positive Airway Pressure (CPAP), bilevel pressure support and/or ventilation is instigated or in the presence of recurring hypoxia and supplemental oxygen is required - each additional investigation. Fee: $597.60 Benefit: 75% = $448.20, 85% = $528.50
11503	MEASUREMENT OF THE MECHANICAL OR GAS EXCHANGE FUNCTION OF THE RESPIRATORY SYSTEM, OR OF RESPIRATORY MUSCLE FUNCTION, OR OF VENTILATORY CONTROL MECHANISMS, using measurements of various parameters including pressures, volumes, flow, gas concentrations in inspired or expired air, alveolar gas or blood, electrical activity of muscles (the tests being performed under the supervision of a specialist or consultant physician or in the respiratory laboratory of a hospital) - each occasion at which 1 or more such tests are performed, not being a service associated with a service to which item 22018 applies Fee: $131.05 Benefit: 75% = $98.30, 85% = $111.40

Sourced: Medicare Australia (2010)

Box 1 outlines the description given in the MBS explanatory notes concerning the definition of a 'qualified sleep medicine practitioner' for the sleep study MBS items.

Box 1 MBS explanatory notes defining 'qualified sleep medicine practitioner'

A 'qualified adult sleep medicine practitioner' as described in item numbers 12203, 12207 and 12250, a 'qualified paediatric sleep medicine practitioner' as described in item numbers 12210 and 12213, and a 'qualified sleep medicine practitioner' as described in item numbers 12215 and 12217 means:

For practitioners who commenced providing sleep studies before 1 March 1999:

(a) the person has been assessed by the Credentialling Subcommittee or the Appeal Committee of the Specialist Advisory Committee in Respiratory and Sleep Medicine of the Royal Australasian College of Physicians as having had, before 1 March 1999, sufficient training and experience in the relevant field of sleep medicine (ie either adult or paediatric sleep medicine, for which there are separate items) to be competent in independent clinical assessment and management of patients with respiratory sleep disorders and in reporting sleep studies; or

(b) the person has been assessed by the Credentialling Subcommittee or the Appeal Committee as having had, before 1 March 1999, substantial training or experience in either adult or paediatric sleep medicine (for which separate items exist), but requires further specified training or experience in sleep medicine to be competent in independent clinical assessment and management of patients with respiratory sleep disorders and in reporting sleep studies, and either:

(i) the period of 2 years immediately following that assessment has not expired; or

(ii) the person has been assessed by the Credentialling Subcommittee as having satisfactorily finished the further training or gained the further experience specified for that person;

OR

For practitioners who commenced providing sleep studies on or after 1 March 1999:

(c) the person has attained Level I or Level II of the relevant Advanced Training Program (in Adult or Paediatric Sleep Medicine) of the Thoracic Society of Australia and New Zealand and the

Australasian Sleep Association, after having completed at least 12 months core training, including clinical practice in the relevant field of sleep medicine and in reporting sleep studies; or

(d) the Specialist Advisory Committee in Respiratory and Sleep Medicine of the Royal Australasian College of Physicians has recognised the person, in writing, as having training equivalent to the training mentioned in paragraph (c).

In relation to paragraph (d) of item numbers 12203 to 12217, and paragraph (b) of item number 12250, the patient should be seen in consultation by a qualified sleep medicine practitioner to determine the necessity for the investigation, unless the necessity has been clearly established by other means.

Approach to assessment

Objective

To carry out a structured evaluation of the safety, effectiveness and cost-effectiveness of unattended sleep studies for (1) diagnosis of adult OSA in both referral and non-specialised unit settings, (2) diagnosis of paediatric OSA in a referral setting and (3) reassessment of treatment efficacy in adults and children diagnosed with OSA. The basis of this structured evaluation was a systematic literature review.

Clinical pathways

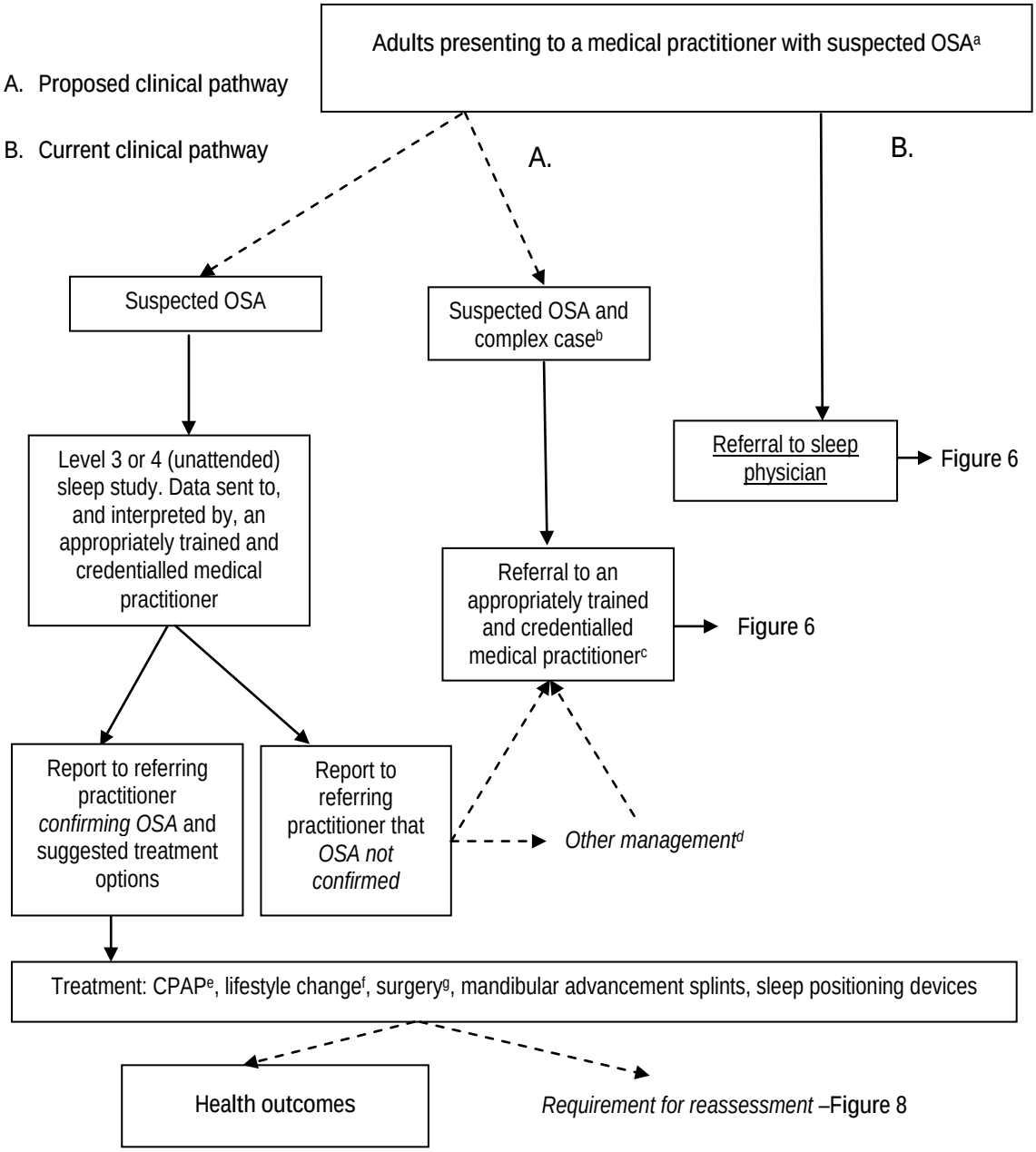
Flowcharts help define the place of an intervention in the clinical management of a patient. This includes whether the new intervention will be used incrementally or will replace a current intervention. The placement of an intervention in a clinical pathway assists with identifying the correct comparator for the new intervention, against which safety, effectiveness and cost-effectiveness will be measured. The suggested flowcharts provided below are clinical pathways based on information contained in the applications to MSAC, as well as background reading and clinical advice from the Advisory Panel.

Three clinical pathways have been suggested to encompass the proposed use of unattended sleep studies in the *diagnosis* of OSA: (1) in a non-specialised unit setting (Figure 5), (2) in a referral setting (Figure 6) and (3) in a paediatric setting (Figure 7).

Reassessment of patients diagnosed with OSA is captured by Figure 7 in the paediatric setting and by Figure 8 for adults.

It should be noted that one of the four clinical pathways not only describes the likely ordering of unattended sleep studies by medical practitioners but also indicates a shift in clinical practice. Figure 5 may reduce the pool of eligible patients for Figure 6. Thus, unattended sleep studies would partially replace referral to a sleep physician in Figure 5, although the physician—as an appropriately trained and credentialed medical practitioner—would probably still be interpreting the test results from Figure 5. Similarly, the necessity for ordering a sleep study would not need pre-approval by a qualified sleep medicine practitioner. Thus, should unattended sleep studies receive permanent Medicare reimbursement, there may be a broadening of eligibility for 'appropriately trained and credentialed medical practitioners' to receive reimbursement for unattended sleep study interpretation, as opposed to (currently) 'qualified sleep medicine practitioners'. The actual determination or definition of what is considered appropriate training/credentialing would be discussed by the relevant craft groups and the Department of Health and Ageing. In Figure 6 and Figure 7 *unattended* sleep studies would partially replace *attended* sleep studies.

Figure 5 Clinical pathway for use of unattended sleep studies by a medical practitioner in the diagnosis of adult OSA in a non-specialised unit setting



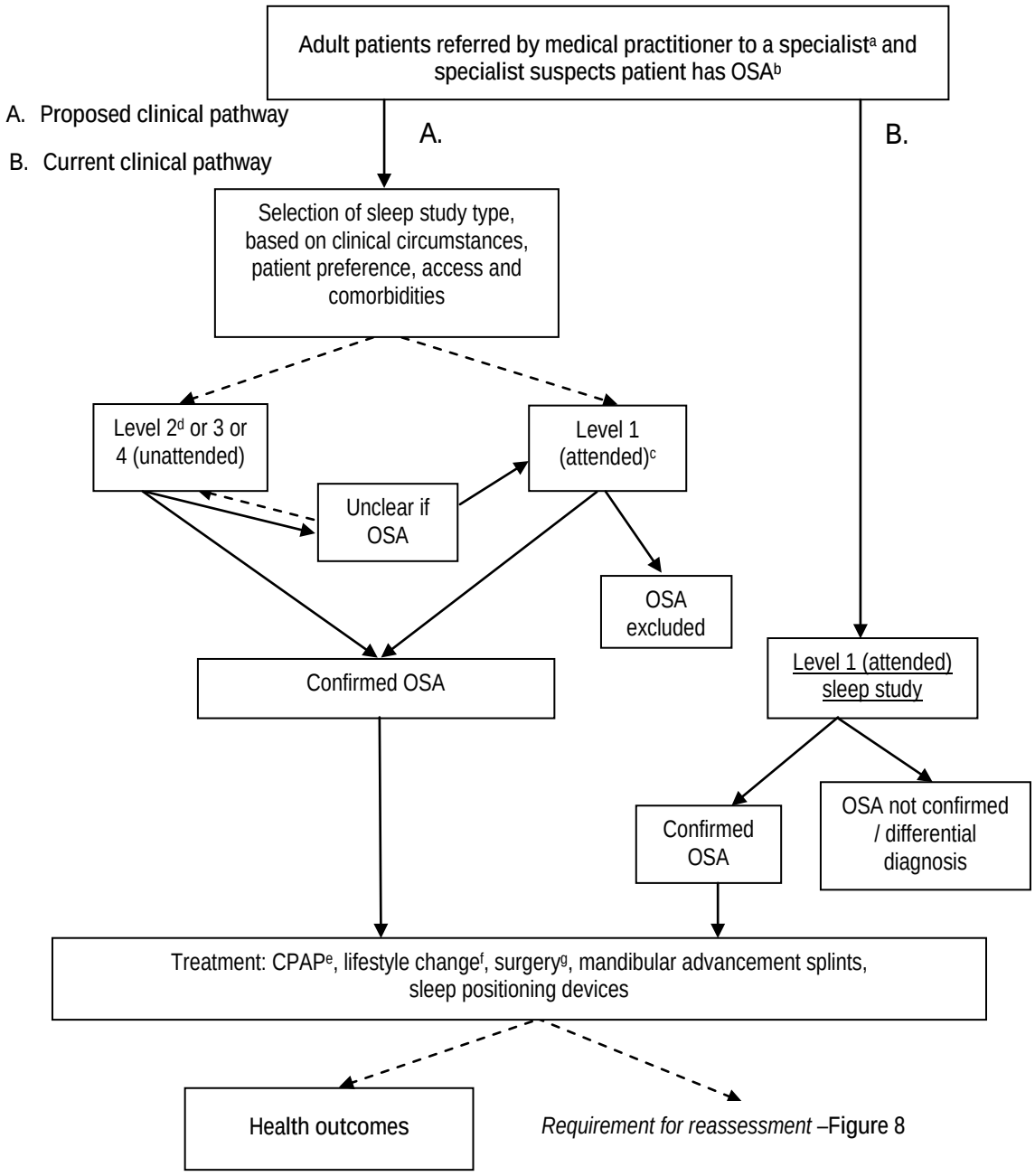
Note: Relevant comparator is underlined

[a] Suspected on the basis of excessive daytime sleepiness, snoring, choking or gasping during sleep, witnessed apnoea, nocturia and exclusion of other upper airway pathology; [b] Subtle and/or difficult cases (eg complex sleep apnoea, sleep hypoventilation) or patient factors require a supervised study (eg age, frailty, anxiety, intellectual impairment); [c] Appropriately trained and credentialed medical practitioner for interpreting sleep studies; [d] Including re-testing with Level 3 or 4 sleep studies or referral to an ear, nose and throat (ENT) surgeon to assess possible nasal obstruction; [e] Patient would initially require a CPAP titration study in a laboratory or auto-titration in the home before long-term use commences; [f] Including weight management, behavioural change; [g] Including nasal, tonsil or adenoid surgery, corrective surgery for mandible or palate, tracheostomy, uvulopalatopharyngoplasty.

OSA = obstructive sleep apnoea; CPAP = continuous positive airway pressure

The depicted pathway provides a population-level generic overview of how OSA is diagnosed in Australia, as well as the likely use of unattended sleep studies in clinical practice. This pathway is not proscriptive as there will always be variations in practice, depending on the characteristics of the presenting patient as well as the skills and experience of the attending medical practitioner. The purpose of this pathway is simply to inform the inclusion/exclusion criteria for the systematic review and the subsequent economic analysis.

Figure 6 Clinical pathway for use of unattended sleep studies in the diagnosis of adult OSA in a referral setting



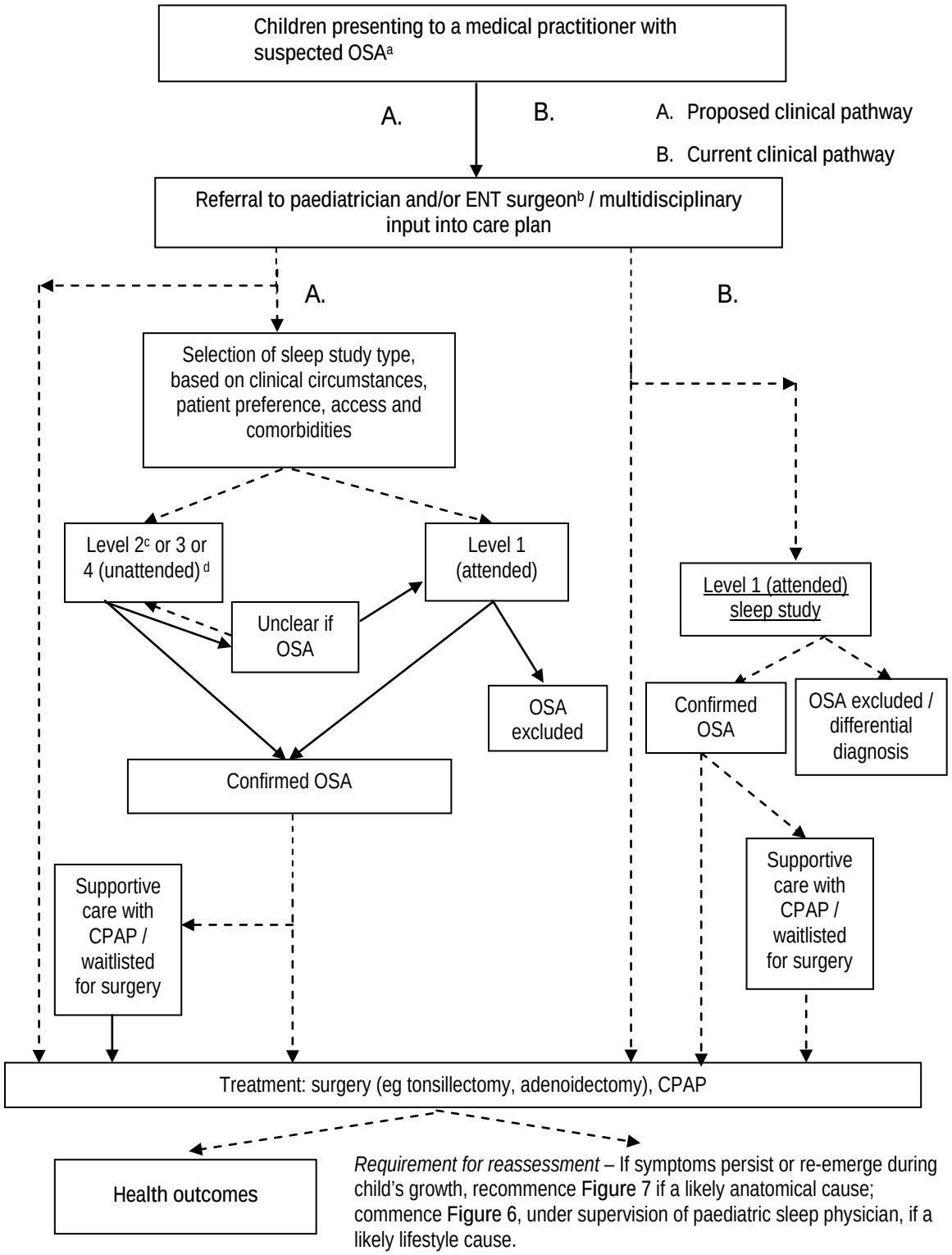
Note: Relevant comparator is underlined

[a] Appropriately trained and credentialled medical practitioner for interpreting sleep studies; [b] Suspected on the basis of excessive daytime sleepiness, snoring, choking or gasping during sleep, witnessed apnoea, nocturia; [c] Subtle and/or difficult cases (eg complex sleep apnoea, sleep hypoventilation) or patient factors require a supervised study (eg age, frailty, anxiety, intellectual impairment); [d] It is possible that Level 2 studies may replace Level 1 studies in rural/remote areas where access to Level 1 studies is problematic; [e] Patient would require a CPAP titration study in a laboratory or auto-titration in the home before long-term use commences; [f] Including weight management, behavioural change; [g] Including nasal, tonsil or adenoid surgery, corrective surgery for mandible or palate, tracheostomy, uvulopalatopharyngoplasty.

OSA = obstructive sleep apnoea; CPAP = continuous positive airway pressure

The depicted pathway provides a population-level generic overview of how OSA is diagnosed in Australia, as well as the likely use of unattended sleep studies in clinical practice. This pathway is not proscriptive as there will always be variations in practice, depending on the characteristics of the presenting patient as well as the skills and experience of the attending medical practitioner. The purpose of this pathway is simply to inform the inclusion/exclusion criteria for the systematic review and the subsequent economic analysis.

Figure 7 Clinical pathway for use of unattended sleep studies in the diagnosis and reassessment of OSA in a paediatric setting

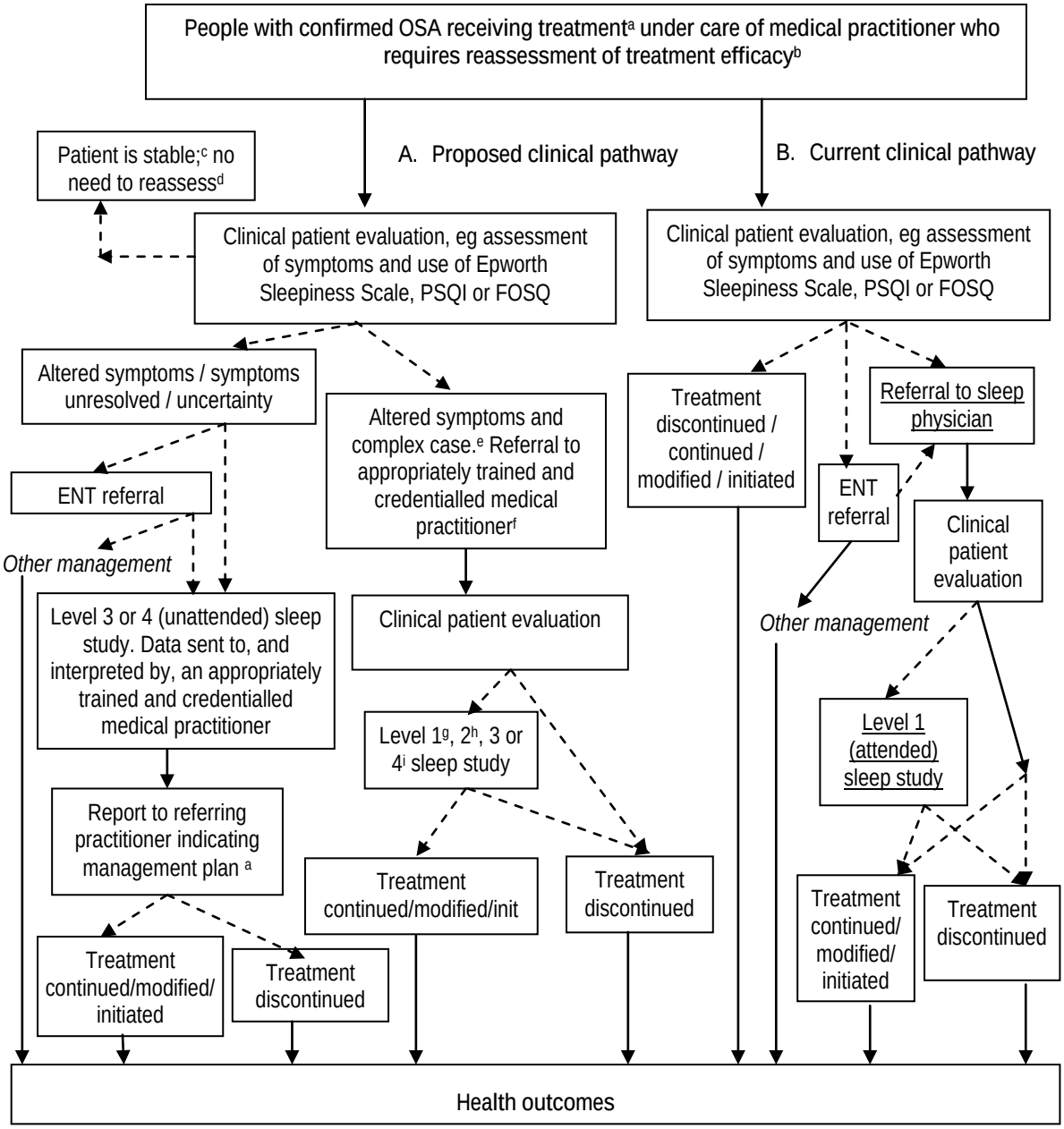


Note: Relevant comparators are underlined

[a] Suspected on the basis of snoring, behavioural change, learning difficulties, secondary enuresis; [b] Some children (particularly those aged 14–18 years) may follow the pathways in Figure 5 or Figure 6 if the cause of the OSA is suspected to be lifestyle-related, rather than due to anatomic factors; [c] It is possible that Level 2 studies may replace Level 1 studies in rural/remote areas where access to Level 1 studies is problematic; [d] Level 3 or 4 studies would likely be rarely done in very young children due to compliance issues.

OSA = obstructive sleep apnoea; CPAP = continuous positive airway pressure

Figure 8 Clinical pathway for use of unattended sleep studies to reassess treatment efficacy in adults diagnosed with OSA



Note: Relevant comparators are underlined

[a] GPs cannot currently prescribe continuous positive airway pressure (CPAP) treatment unless they also meet specific training and credentialing requirements; [b] Approximately 40–50% of adults with treated OSA. For example, reassessment due to patient weight loss, lifestyle change, after surgery, return of symptoms in patient previously controlled on CPAP, or medico-legal reasons; [c] Approximately 50% of these patients; [d] Only receive further reassessment if a legislative requirement, eg for patients at high occupational risk; [e] Approximately 25% of these patients; [f] Appropriately trained and credentialed medical practitioner for interpreting sleep studies; [g] Approximately 80% of these patients would receive Level 1 study; [h] It is possible that Level 2 studies may replace Level 1 studies in rural/remote areas where access to Level 1 studies is problematic; [i] Approximately 20% of these patients would receive level 3 or 4 studies

PSQI = Pittsburgh Sleep Quality Index; FOSQ = Functionality of Sleep Questionnaire; OSA = obstructive sleep apnoea; ENT = ear, nose and throat surgeon

The depicted pathways in Figure 7 and Figure 8 provide a population-level generic overview of how OSA is diagnosed in Australia, as well as the likely use of unattended sleep studies in clinical practice. These pathways are not proscriptive as there will always be variations in practice, depending on the characteristics of the presenting patient as well as the skills and experience of the attending medical practitioner. The purpose of these pathways is simply to inform the inclusion/exclusion criteria for the systematic review and the subsequent economic analysis.

Comparators

The relevant comparators for this assessment depended on the likely use and setting of use of unattended sleep studies. Figure 5 to Figure 8 all provide proposed clinical pathways for use of unattended sleep studies, and compare these to the current clinical pathways. In all these figures the comparator(s), against which the safety, effectiveness and cost-effectiveness of unattended sleep studies was measured, has/have been underlined.

Accordingly, in this assessment report the use of unattended sleep studies to diagnose OSA in adults in the non-specialised unit setting was compared with that of referral to a sleep physician (specialist) for a diagnosis. The performance of unattended sleep studies as part of the diagnostic strategy for adults referred to a specialist was compared with that of a Level 1 sleep study. The relevant comparators to use of unattended sleep studies in a paediatric setting were Level 1 sleep studies or surgery. When reassessing OSA or the efficacy of treatment in patients with OSA using unattended sleep studies, the relevant comparator was referral to a sleep physician and a Level 1 sleep study.

Comparators are important in the context of *directly* assessing the effectiveness of unattended sleep studies on patient health outcomes. Diagnostic accuracy studies alone may assist in determining the utility of a new portable sleep study in terms of its precision at predicting OSA at predefined cut-off based on a PSG apnoea–hypopnoea index (AHI), typically AHI ≥15. However, as stated in the ASA Guidelines, 'achieving a high degree of precision in terms of sensitivity and specificity around a particular AHI cut-off may be less important than how the use of a portable diagnostic device (compared with traditional attended PSG) affects clinical decision-making and patient outcomes' (Hensley et al 2005).

The reference standard

Unattended sleep studies are tests to diagnose OSA. In this assessment the accuracy of unattended sleep studies at predicting OSA was benchmarked against the reference standard (and 'gold standard')—the Level 1 attended sleep study, also known as polysomnography (PSG).

Research questions

In the event that **direct evidence**[7] was available to assess the safety, effectiveness and cost-effectiveness of unattended sleep studies, the following research questions were to be addressed by this evaluation.

[7] For a description of direct evidence see section on Diagnostic Assessment Framework (page 32)

Diagnosis in non-specialised unit setting

1. Are Level 3 and/or 4 unattended sleep studies (plus or minus referral to an appropriately trained and credentialed medical practitioner) as safe as, or safer than, referral to a sleep physician for adults with suspected obstructive sleep apnoea?

2. Are Level 3 and/or 4 unattended sleep studies (plus or minus referral to an appropriately trained and credentialed medical practitioner) as, or more, effective than referral to a sleep physician for improving the health outcomes of adults with suspected obstructive sleep apnoea?

3. If there is evidence of net clinical benefit from Questions 1 and 2, are Level 3 and/or 4 unattended sleep studies (plus or minus referral to an appropriately trained and credentialed medical practitioner) cost-effective compared with referral to a sleep physician for adults with suspected obstructive sleep apnoea?

Diagnosis in referral setting

4. Are Level 2, 3 or 4 unattended sleep studies (plus or minus Level 1 studies) as safe as, or safer than, Level 1 laboratory-based (attended) sleep studies alone for adults with suspected obstructive sleep apnoea referred to a specialist?

5. Are Level 2, 3 or 4 unattended sleep studies (plus or minus Level 1 studies) as, or more, effective than Level 1 laboratory-based (attended) sleep studies alone at improving the health outcomes of adults with suspected obstructive sleep apnoea referred to a specialist?

6. If there is evidence of net clinical benefit from Questions 4 and 5, are Level 2, 3 or 4 unattended sleep studies (plus or minus Level 1 studies) cost-effective compared with Level 1 laboratory-based (attended) sleep studies alone when used for adults with suspected obstructive sleep apnoea referred to a specialist?

Diagnosis in paediatric setting

7. Are Level 2, 3 or 4 unattended sleep studies (plus or minus Level 1 studies) as safe as, or safer than: (1) Level 1 laboratory-based (attended) sleep studies alone or (2) surgery without use of a prior sleep study for children with suspected or previously diagnosed obstructive sleep apnoea referred to a specialist paediatric multidisciplinary team?

8. Are Level 2, 3 or 4 unattended sleep studies (plus or minus Level 1 studies) as, or more, effective than: (1) Level 1 laboratory-based (attended) sleep studies alone or (2) surgery without use of a prior sleep study at improving the health outcomes of children with suspected or previously diagnosed obstructive sleep apnoea referred to a specialist paediatric multidisciplinary team?

9. If there is evidence of net clinical benefit from Questions 7 and 8, are Level 2, 3 or 4 unattended sleep studies (plus or minus Level 1 studies) cost-effective compared with: (1) Level 1 laboratory-based (attended) sleep studies alone or (2) surgery without use of a prior sleep study when used for children with suspected or

previously diagnosed obstructive sleep apnoea referred to a specialist paediatric multidisciplinary team?

Reassessment of treatment efficacy

10.

a. Are Level 3 or 4 unattended sleep studies (plus or minus Level 1 studies) as safe as, or safer than, referral to a sleep physician plus Level 1 laboratory-based (attended) sleep studies when reassessing treatment efficacy in adults with obstructive sleep apnoea who have had an alteration in OSA symptoms?

b. Is referral to an appropriately trained and credentialed medical practitioner plus Level 2, 3 or 4 unattended sleep studies (plus or minus Level 1 studies) as safe as, or safer than, referral to a sleep physician plus Level 1 laboratory-based (attended) sleep studies when reassessing treatment efficacy in adults with obstructive sleep apnoea who have had an alteration in OSA symptoms and are a complex case?

11.

a. Are Level 3 or 4 unattended sleep studies (plus or minus Level 1 studies) as, or more, effective than referral to a sleep physician plus Level 1 laboratory-based (attended) sleep studies when reassessing treatment efficacy in adults with obstructive sleep apnoea who have had an alteration in OSA symptoms?

b. Is referral to an appropriately trained and credentialed medical practitioner plus Level 2, 3 or 4 unattended sleep studies (plus or minus Level 1 studies) as, or more, effective than referral to a sleep physician plus Level 1 laboratory-based (attended) sleep studies when reassessing treatment efficacy in adults with obstructive sleep apnoea who have had an alteration in OSA symptoms and are a complex case?

12.

a. If there is evidence of net clinical benefit from Questions 10a and 11a, are Level 3 or 4 unattended sleep studies (plus or minus Level 1 studies) cost-effective compared with referral to a sleep physician plus Level 1 laboratory-based (attended) sleep studies when reassessing treatment efficacy in adults with obstructive sleep apnoea who have had an alteration in OSA symptoms?

b. If there is evidence of net clinical benefit from Questions 10b and 11b is referral to an appropriately trained and credentialed medical practitioner plus Level 2, 3 or 4 unattended sleep studies (plus or minus Level 1 studies) cost-effective compared with referral to a sleep physician plus Level 1 laboratory-based (attended) sleep studies when reassessing treatment efficacy in adults with obstructive sleep apnoea who have had an alteration in OSA symptoms and are a complex case?

In the event that **linked evidence**[8] was the only evidence available to assess the safety, effectiveness and cost-effectiveness of unattended sleep studies, the following research questions were to be addressed by this evaluation.

Linkage 1 – Test accuracy

1. In adults with suspected OSA or confirmed (with symptoms altered/unresolved) OSA, are Level 3 and/or 4 unattended sleep studies as accurate as Level 1 laboratory-based (attended) sleep studies at diagnosing or reassessing OSA?

2. In referred cases of adults with suspected or confirmed (with symptoms altered/unresolved) OSA, or children with suspected or previously diagnosed OSA, are Level 2 or 3 or 4 unattended sleep studies as accurate as Level 1 laboratory-based (attended) sleep studies at diagnosing or reassessing OSA?

Linkage 2 – Change in patient management

3. Does the use of Level 3 and/or 4 unattended sleep studies (plus or minus referral to an appropriately trained and credentialed medical practitioner, plus or minus use of a Level 1 study) in the diagnosis of adult OSA, or reassessment of confirmed OSA, impact on patient management differently compared with the referral of a patient to a sleep physician with or without the use of a Level 1 laboratory-based (attended) sleep study?

4. Does the use of Level 2, 3 or 4 unattended sleep studies (plus or minus use of a Level 1 study) in the diagnosis of referred cases of suspected adult OSA, or reassessment of confirmed OSA, impact on patient management differently compared with the use of a Level 1 laboratory-based (attended) sleep study alone?

5. Does the use of Level 2, 3 or 4 unattended sleep studies (plus or minus use of a Level 1 study) in the diagnosis or reassessment of paediatric OSA impact on patient management differently compared with: (1) the use of Level 1 laboratory-based (attended) sleep studies alone or (2) surgical treatment without use of a prior sleep study?

Linkage 3 – Likely impact of unattended sleep studies on patient health outcomes

Do unattended sleep studies detect the same target condition for which treatment has proven effective?

The linkage between test results and treatment decisions can be assumed when the new test will be used to replace an existing test, and standard treatment for the target condition is well established. Thus, if unattended sleep studies are proposed as an **alternative** to attended sleep studies (ie may be a replacement test in some cases, an additional test in other cases, or not an option) for the diagnosis of OSA and

[8] For a description of linked evidence see section on Diagnostic Assessment Framework (page 32)

reassessment of treatment efficacy in patients with the same spectrum of disease as currently receiving attended sleep studies, it is proposed that there would not be a broad change in management. Although individual patients may receive a different form of treatment, depending on the method of diagnosis, the same range of treatment options would be available for both diagnostic modalities. It is proposed, therefore, that the treatment would be given to the same population in whom treatment effectiveness has already been established, and so no further assessment of treatment effectiveness is necessary.

The Advisory Panel indicated that different treatments would not be used if unattended sleep studies were the norm and diagnosis occurred *earlier than currently* (with attended sleep studies), because any difference between the two technologies in terms of the time to OSA diagnosis and management would not be clinically important. Patients are currently triaged for sleep tests according to the clinical severity of their symptoms. Therefore, a full linked evidence approach was not required, as the spectrum of clinically relevant disease in the population receiving **unattended** sleep studies is likely to be similar as in those currently receiving **attended** sleep studies. A separate literature search and assessment of likely treatment effectiveness in the population receiving unattended sleep studies was therefore not undertaken.[9]

Diagnostic assessment framework

This assessment of unattended sleep studies is based on the framework outlined in the MSAC *Guidelines for the Assessment of Diagnostic Technologies* (MSAC 2005).

To assess the effectiveness of unattended sleep studies, we need to consider their diagnostic accuracy (in comparison with a reference standard), their impact on the clinical management of people with suspected OSA and their ultimate impact on the health outcomes of patients needs. The first goal of this assessment was therefore to find **direct evidence** of the effectiveness of unattended sleep studies on patient health outcomes, ie primary research where one group of people with suspected (or confirmed) OSA would receive unattended sleep studies ± subsequent testing, treatment and follow-up, and would be compared with another group receiving the current testing, treatment and follow-up (minus unattended sleep studies) for suspected (or confirmed) OSA. The comparison would occur over a period of time until the impact on health outcomes (eg survival, resolution of symptoms) could be evaluated.

There was limited, low-quality direct evidence available assessing the health impact of unattended sleep studies, so in this assessment the available direct evidence was supplemented with a **linked evidence** approach.

This means that evidence from studies that report on:

- diagnostic test performance (diagnostic accuracy)—sensitivity, specificity and accuracy

[9] This assumption that treatment options and treatment effectiveness would be the same regardless of whether unattended or attended sleep studies were used to diagnose OSA was confirmed by the limited *direct evidence* that was found comparing the impact of the two types of sleep studies on the health outcomes of patients.

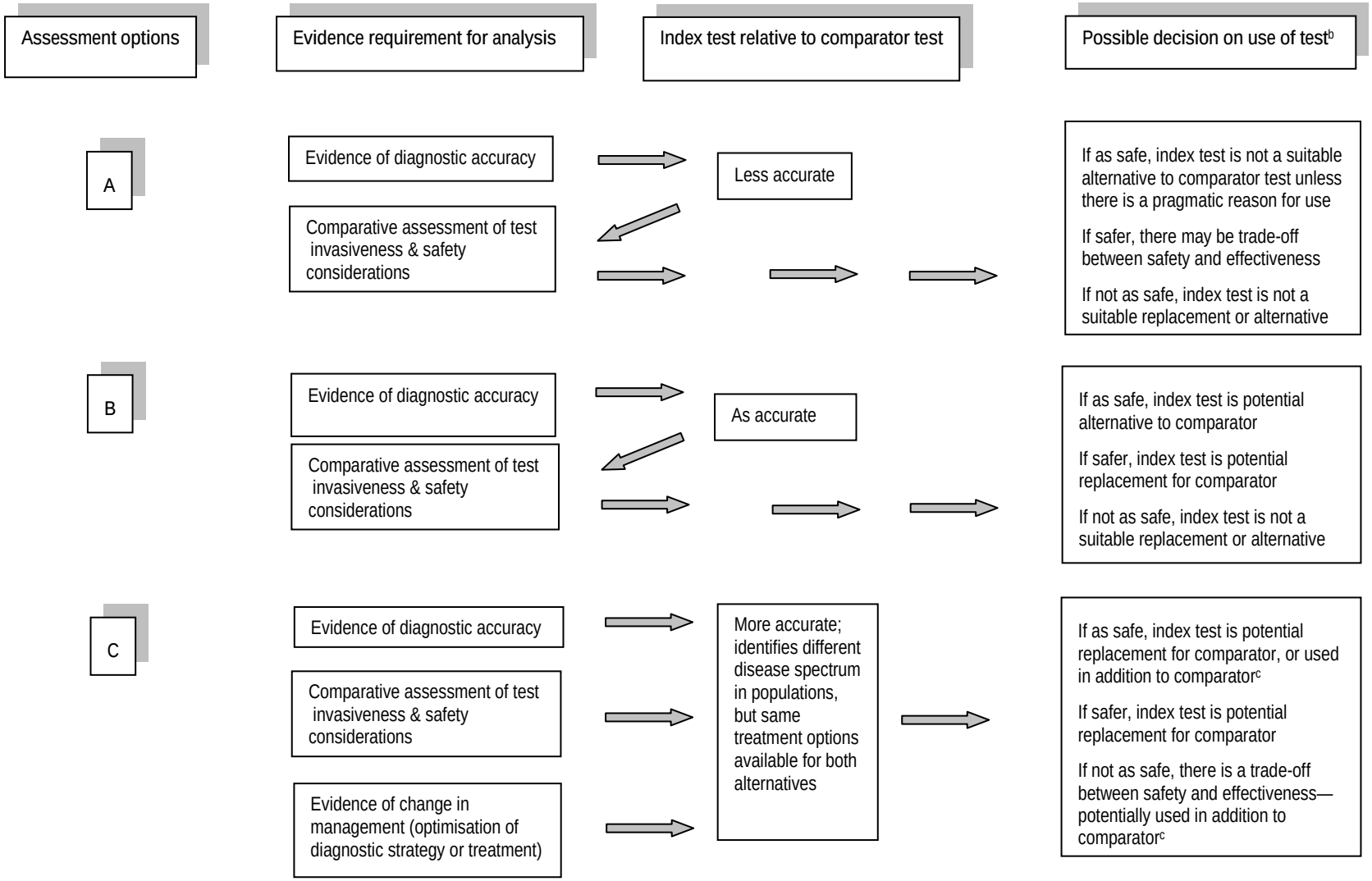
- the impact on clinical decision-making—does clinical decision-making (patient management) change as a result of the test?

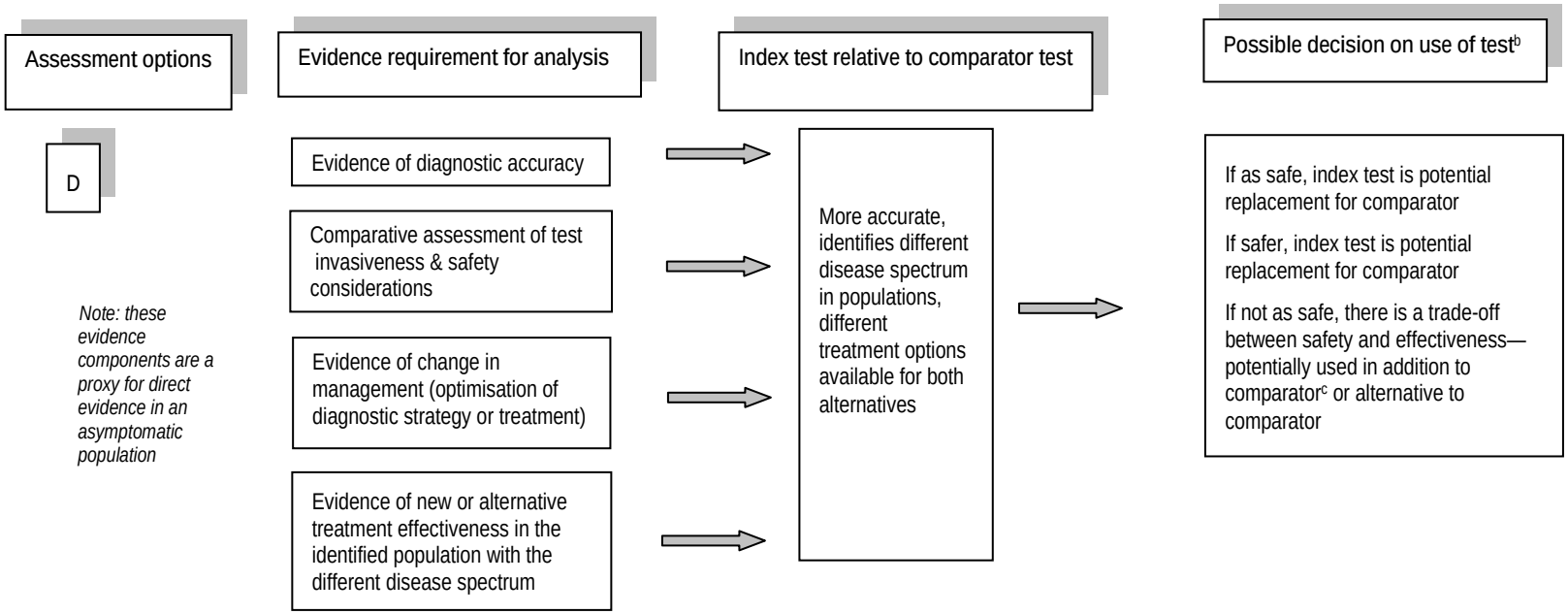
- the impact of the treatment of diagnosed patients on health outcomes—do patients receiving a change in management benefit in terms of health outcomes?

was narratively linked in order to infer the effect of the diagnostic test on patient health outcomes.

An algorithm for decision-making regarding the possible use of unattended sleep studies was applied after the evidence had been evaluated (Figure 9). It was considered at the commencement of this assessment that unattended sleep studies were likely to fall into rows A, B or C.

Figure 9 Decision algorithm for interpretation of linked evidence in the assessment of diagnostic tests [a]





[a] Decision algorithm developed by T. Merlin (2007) and modified (2009); [b] Cost-effectiveness is another consideration once the decision on safety and effectiveness is made; [c] In those patients who tested negative on comparator test.

Review of literature

The medical literature was systematically searched to identify relevant studies and reviews for the period from 1980 (or, if inception of the database was later, from that date) until April 2009. Search alerts were maintained over the duration of the review to identify any key research published and indexed in the major databases since the completion of the search. In such an event the full search would have been updated. Appendix B describes the electronic databases that were used for this search and other sources of evidence that were investigated. Grey literature[10] was included in the search strategy. Unpublished literature, however, was not canvassed as it is difficult to search for this literature exhaustively and systematically, and trials that are difficult to locate are often smaller and of lower methodological quality (Egger et al 2003). It is, however, possible that these unpublished data could alter the results of this assessment.

The search terms, presented in Appendix B, were used to identify literature on the safety, effectiveness and cost-effectiveness of using unattended sleep studies in the diagnosis and reassessment of OSA.

Selection of studies

The criteria for including studies in this report are presented in the relevant areas of the 'Results' section. The eligibility criteria for research on the safety of unattended sleep studies in the four scenarios of usage are presented in Box 14, Box 2, Box 6 and Box 10. The criteria for including studies relevant to determining the **direct** effectiveness of unattended sleep studies on health outcomes are presented in Box 3, Box 7 and Box 11. The criteria for selecting the **linked** evidence components in this assessment of the value of unattended sleep studies as a diagnostic tool are presented in Box 4, Box 5, Box 8, Box 9, Box 12 and Box 13. Similarly, the criteria are given in Box 14 for selecting primary research on the use of unattended sleep studies to reassess OSA.

In general, studies were excluded if they:

- did not address the research question;
- did not provide information on the pre-specified target population;
- did not include one of the pre-specified interventions;
- did not compare results with the pre-specified comparators;
- did not address one of the pre-specified outcomes or provided inadequate data on these outcomes (in some instances, a study was included to assess one or more outcomes but had to be excluded for other outcomes owing to data inadequacies);

[10] Literature that is difficult to find, including published government reports, theses, technical reports and non-peer-reviewed literature.

- were written in other languages and gave a lower level of evidence than that available in English; or
- did not have the appropriate study design.

Where two or more papers reported on different aspects of the same study, such as the methodology in one and the findings in the other, they were treated as one study. Similarly, if the same data were presented in multiple articles, results from the most comprehensive or most recent article only were included.

Search results

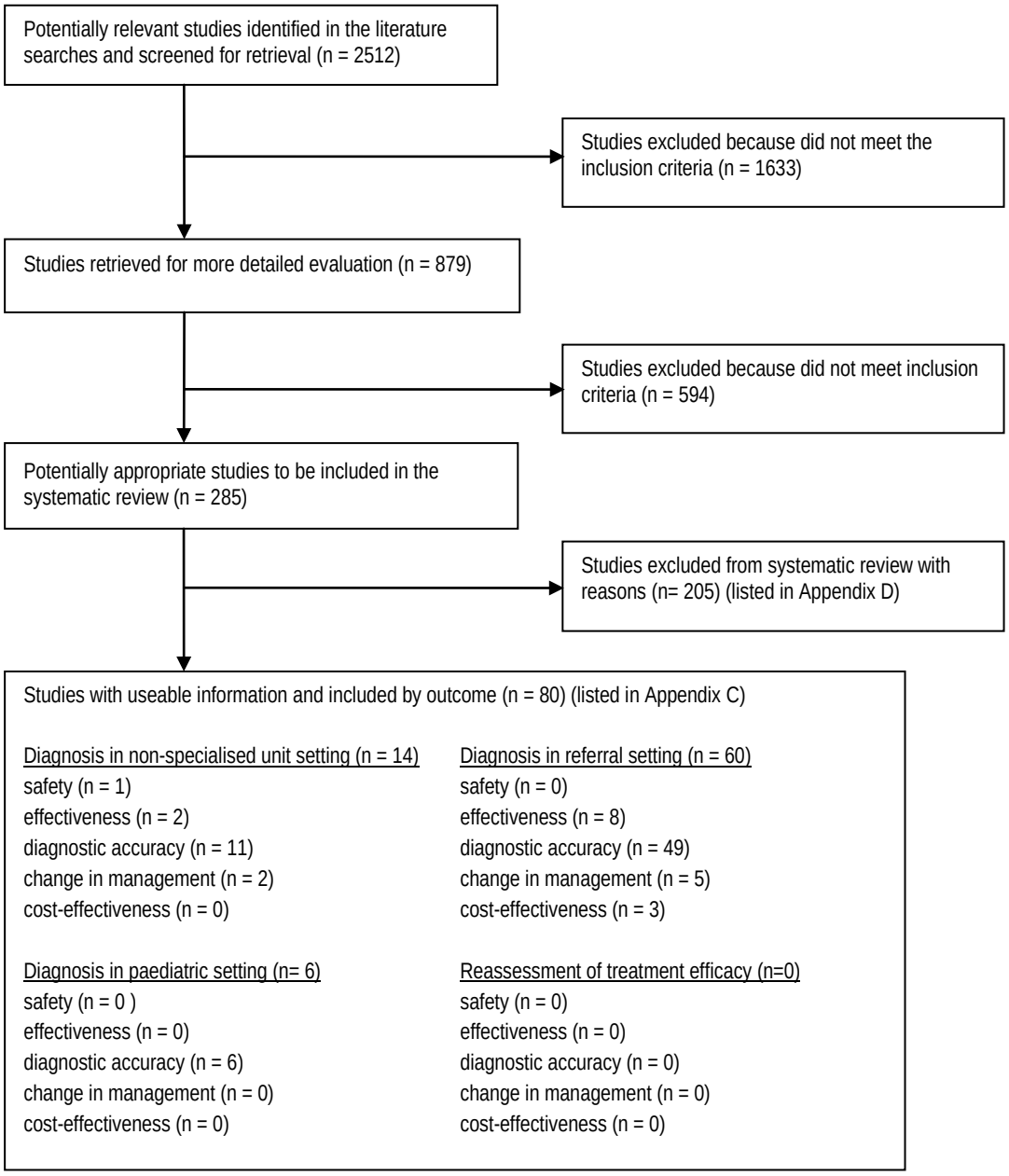
The process of study selection for this report went through five phases:

1. All reference citations from all literature sources were collated into an Endnote X.1 database.
2. Duplicate references were removed.
3. Studies were excluded on the basis of the citation information if it was obvious that they did not meet the inclusion criteria. Studies marked as requiring further evaluation were retrieved for full-text assessment.
4. Studies formed part of the evidence-base if they met the selection criteria. The remainder provided background information.
5. The reference lists of the included studies were pearled for additional relevant literature. These were retrieved and assessed according to phase 4.

The evidence-base consisted of studies from phases 4 and 5 that met the inclusion criteria.

Any doubt concerning inclusions at phase 4 was resolved by consensus by two reviewers. A third reviewer was included to arbitrate where necessary. The results of the process of study selection are provided in Figure 10.

Figure 10 Summary of the process used to identify and select literature on unattended sleep studies



Adapted from Moher et al (1999)

Data extraction and analysis

A profile of key characteristics was developed for each included study (Appendix C). Each study profile described the level of evidence, design and quality of the study, authors, publication year, location, study period, criteria for including/excluding patients, study population characteristics, type of intervention (ie type of sleep study), comparator intervention and/or reference standard (where relevant), outcomes assessed and definition of OSA or respiratory events used in the study.

Studies that could not be retrieved or that met the inclusion criteria but contained insufficient or inadequate data for inclusion are listed in Appendix D. Definitions of all technical terms and abbreviations are provided in the Glossary. Descriptive statistics were extracted or calculated for all safety and effectiveness outcomes in the individual studies.

Assessing diagnostic accuracy

To assess the diagnostic accuracy of each of the unattended sleep studies, where possible the sensitivity, specificity, negative and positive predictive values (NPV, PPV) and likelihood ratios of the tests were calculated with corresponding 95% confidence intervals (CIs). Data were extracted into a classic 2 × 2 table, in which the results of the index diagnostic test were cross-classified against the results of the reference standard (Armitage et al 2002; Deeks 2001), and Bayes' Theorem was applied:

		OSA status (based on reference standard: Level 1 PSG)		
		Disease +	*Disease –*	
Index test *(Level 2, 3, 4 sleep study)*	*Test +*	true positive	false positive	Total test positive
	Test –	false negative	true negative	Total test negative
		Total with OSA	Total without OSA	

Primary measures

Test sensitivity was reported as the proportion of people with OSA (as determined by a Level 1 PSG) who had a positive test result on the unattended sleep study:

Sensitivity (true positive rate) = true positive / total with OSA

Test specificity was reported as the proportion of people without OSA (as determined by a Level 1 PSG) who had a normal test result on the unattended sleep study:

Specificity (true negative rate) = true negative / total without OSA

The obverse of these rates were also provided where relevant, ie 1–sensitivity (false negative rate) and 1–specificity (false positive rate).

False positive rate = false positive / total without OSA

False negative rate = false negative / total with OSA

When a 95% CI was not provided, it was calculated by exact binomial methods.

Summary measures

Positive and negative likelihood ratios were reported if available. These ratios measure the probability of the test result in patients with OSA compared with those without OSA.

LR+ = sensitivity/1–specificity

LR– = 1–sensitivity/specificity

A likelihood ratio of 1 means that the test does not provide any useful diagnostic information, whereas LR+ >5 and LR– <0.2 can suggest strong diagnostic ability (MSAC 2005).

The summary receiver–operator characteristic curve (SROC) plots the estimated sensitivity versus 1–specificity from different studies to produce a global measure of test accuracy.

Meta-analysis was not conducted owing to the heterogeneous nature of the available evidence-base assessing the diagnostic accuracy of unattended sleep studies, specifically the different definition and thresholds for respiratory events. A narrative meta-synthesis of the data was therefore undertaken.

All statistical calculations were undertaken using the biostatistical computer package Stata version 10.0 (Stata Corporation 2007).

Appraisal of the evidence

Appraisal of the evidence was conducted at three stages:

Stage 1: Appraisal of the applicability and quality of individual studies included in the review (strength of the evidence).

Stage 2: Appraisal of the precision, size of effect and clinical importance of the results for primary outcomes in individual studies—used to determine the safety and effectiveness of the intervention.

Stage 3: Integration of the body of evidence for conclusions about the net clinical benefit of the intervention in the context of Australian clinical practice.

Stage 1: Strength of the evidence

The evidence presented in the selected studies was assessed and classified using the dimensions of evidence defined by the National Health and Medical Research Council (MSAC 2000).

These dimensions (Table 5) consider important aspects of the evidence supporting a particular intervention and include three main domains: strength of the evidence, size of the effect and relevance of the evidence. The first domain is derived directly from the literature identified as informing a particular intervention; the last two each requires expert clinical input as part of its determination.

Table 5 Evidence dimensions

Type of evidence	Definition
Strength of the evidence:	
Level	The study design used, as an indicator of the degree to which bias has been eliminated by design[a]
Quality	The methods used by investigators to minimise bias within a study design
Statistical precision	The p-value or, alternatively, the precision of the estimate of the effect. It reflects the degree of certainty about the existence of a true effect
Size of effect	The distance of the study estimate from the 'null' value and the inclusion of only clinically important effects in the confidence interval
Relevance of evidence	The usefulness of the evidence in clinical practice, particularly the appropriateness of the outcome measures used

[a] See Table 6

The three sub-domains (level, quality and statistical precision) are collectively a measure of the strength of the evidence. The 'level of evidence' reflects the effectiveness of a study design to answer a particular research question (Table 6).

Table 6 Designations of levels of evidence according to type of research question (including table notes)

Level	Intervention[a]	Diagnostic accuracy[b]
I[c]	A systematic review of level II studies	A systematic review of level II studies
II	A randomised controlled trial	A study of test accuracy with: an independent, blinded comparison with a valid reference standard[d], among consecutive persons with a defined clinical presentation[e]
III-1	A pseudorandomised controlled trial (ie alternate allocation or some other method)	A study of test accuracy with: an independent, blinded comparison with a valid reference standard[e], among non-consecutive persons with a defined clinical presentation[e]
III-2	A comparative study with concurrent controls: • Non-randomised, experimental trial[f] • Cohort study • Case-control study • Interrupted time series with a control group	A comparison with reference standard that does not meet the criteria required for level II and III-1 evidence
III-3	A comparative study without concurrent controls: • Historical control study • Two or more single-arm studies[g] • Interrupted time series without a parallel control group	Diagnostic case-control study[e]
IV	Case series with either post-test or pre-test/post-test outcomes	Study of diagnostic yield (no reference standard)[h]

Sources: Merlin et al (2009); hierarchies adapted and modified from: Bandolier (1999); Lijmer et al (1999); NHMRC (1999); Phillips et al (2001)

[a] Definitions of these study designs are provided in NHMRC (2000b), pp 7–8, and in the accompanying Glossary.

[b] These levels of evidence apply only to studies of assessing the *accuracy* of diagnostic or screening tests. To assess the overall *effectiveness* of a diagnostic test, there also needs to be a consideration of the impact of the test on patient management and health outcomes (MSAC 2005; Sackett & Haynes 2002). The evidence hierarchy given in the 'Intervention' column should be used when assessing the impact of a diagnostic test on health outcomes relative to an existing method of diagnosis/comparator test(s). The evidence hierarchy given in the 'Screening' column should be used when assessing the impact of a screening test on health outcomes relative to no screening or alternative screening methods.

[c] A systematic review will only be assigned a level of evidence as high as the studies it contains, excepting where those

studies are of level II evidence. Systematic reviews of level II evidence provide more data than the individual studies and any meta-analyses will increase the precision of the overall results, reducing the likelihood that the results are affected by chance. Systematic reviews of lower level evidence present results of likely poor internal validity, and thus are rated on the likelihood that the results have been affected by bias, rather than whether the systematic review itself is of good quality. Systematic review *quality* should be assessed separately. A systematic review should consist of at least two studies. In systematic reviews that include different study designs, the overall level of evidence should relate to each individual outcome/result, as different studies (and study designs) might contribute to each different outcome.

[d] The validity of the reference standard should be determined in the context of the disease under review. Criteria for determining the validity of the reference standard should be pre-specified. This can include the choice of the reference standard(s) and its timing in relation to the index test. The validity of the reference standard can be determined through quality appraisal of the study (Whiting et al 2003).

[e] Well-designed population-based case-control studies (eg population based screening studies where test accuracy is assessed on all cases, with a random sample of controls) do capture a population with a representative spectrum of disease and thus fulfil the requirements for a valid assembly of patients. However, in some cases the population assembled is not representative of the use of the test in practice. In diagnostic case-control studies a selected sample of patients already known to have the disease are compared with a separate group of normal/healthy people known to be free of the disease. In this situation patients with borderline or mild expressions of the disease, and conditions mimicking the disease, are excluded, which can lead to exaggeration of both sensitivity and specificity. This is called spectrum bias or spectrum effect because the spectrum of study participants will not be representative of patients seen in practice (Mulherin & Miller 2002).

[f] This also includes controlled before-and-after (pre-test/post-test) studies, as well as adjusted indirect comparisons (ie using A vs B and B vs C to determine A vs C, with statistical adjustment for B).

[g] Comparing single arm studies, ie case series from two studies. This would also include unadjusted indirect comparisons (ie using A vs B and B vs C to determine A vs C, but where there is no statistical adjustment for B).

[h] Studies of diagnostic yield provide the yield of diagnosed patients, as determined by an index test, without confirmation of the accuracy of this diagnosis by a reference standard. These may be the only alternative when there is no reliable reference standard.

Note A: Assessment of comparative harms/safety should occur according to the hierarchy presented for each of the research questions, with the proviso that this assessment occurs within the context of the topic being assessed. Some harms (and other outcomes) are rare and cannot feasibly be captured within randomised controlled trials, in which case lower levels of evidence may be the only type of evidence that is practically achievable; physical harms and psychological harms may need to be addressed by different study designs; harms from diagnostic testing include the likelihood of false positive and false negative results; harms from screening include the likelihood of false alarm and false reassurance results.

Note B: When a level of evidence is attributed in the text of a document, it should also be framed according to its corresponding research question, eg level II intervention evidence; level IV diagnostic evidence; level III-2 prognostic evidence.

Note C: Each individual study that is attributed a 'level of evidence' should be rigorously appraised using validated or commonly used checklists or appraisal tools to ensure that factors other than study design have not affected the validity of the results.

Effectiveness is based on the probability that the design of the study has reduced or eliminated the impact of bias on the results. The NHMRC evidence hierarchy provides a ranking of various study designs ('levels of evidence') by the type of research question being addressed. Of interest to this assessment were the hierarchies concerned with (1) diagnostic accuracy and (2) interventions—for any **direct** evidence of safety or effectiveness, evidence on change in management as part of **linked** evidence, and evidence on unattended sleep studies for reassessment.

With specific regard to diagnostic evidence, the individual studies assessing diagnostic effectiveness were graded according to the quality and applicability criteria (MSAC 2005) shown in Table 7.

Table 7 Grading system used to rank included diagnostic studies

Validity criteria	Description	Grading system
Appropriate comparison	Did the study evaluate a direct comparison of the index test strategy versus the comparator test strategy?	C1 direct comparison CX other comparison
Applicable population	Did the study evaluate the index test in a population that is representative of the subject characteristics (age and sex) and clinical setting (disease prevalence, disease severity, referral filter and sequence of tests) for the clinical indication of interest?	P1 applicable P2 limited P3 different population
Quality of study	Was the study designed to avoid bias? High quality = no potential for bias based on predefined key quality criteria Medium quality = some potential for bias in areas other than those pre-specified as key criteria Poor quality = poor reference standard and/or potential for bias based on key pre-specified criteria	Study design: NHMRC level of evidence (Table 6) Study quality (QUADAS checklist): Q1 high quality (≥12/14) Q2 medium (10–11/14) Q3 poor reference standard, poor quality (<10/14) or insufficient information

The appraisal of intervention studies was undertaken using a checklist developed by the NHMRC (2000a). This checklist was used for trials and cohort studies. Uncontrolled before-and-after case series are a poorer level of evidence with which to assess effectiveness. The quality of this type of study design was assessed according to a checklist developed by the UK National Health Service (NHS) Centre for Reviews and Dissemination (Khan et al 2001). Studies of diagnostic accuracy were assessed using the QUADAS quality assessment tool (Whiting et al 2003).

Stage 2: Precision, size of effect and clinical importance

Statistical precision was determined using statistical principles. Small CIs and p-values give an indication as to the probability that the reported effect is real and not attributable to chance (NHMRC 2000b). Studies need to be appropriately powered to ensure that a real difference between groups will be detected in the statistical analysis.

For intervention studies it was important to assess whether statistically significant differences between the groups being compared were also clinically important. The size of the effect needed to be determined, as well as whether the 95% CI included only clinically important effects.

The outcomes being measured in this report also needed to be assessed as to whether they were appropriate and clinically relevant. Inadequately validated (predictive) surrogate measures of a clinically relevant outcome should be avoided (NHMRC 2000b).

Stage 3: Assessment of the body of evidence

Appraisal of the body of evidence was conducted along the lines suggested by the NHMRC in their guidance on clinical practice guideline development (NHMRC 2008c). Five components are considered essential by the NHMRC when judging the body of evidence:

- the evidence-base—which includes the number of studies sorted by their methodological quality and relevance to patients

- the consistency of the study results—whether the better quality studies had results of a similar magnitude and in the same direction, ie homogeneous or heterogeneous findings

- the potential clinical impact—appraisal of the precision, size and clinical importance or relevance of the primary outcomes used to determine the safety and effectiveness of the test

- the generalisability of the evidence to the target population

- the applicability of the evidence—integration of this evidence for conclusions about the net clinical benefit of the intervention in the context of Australian clinical practice.

A matrix for assessing the body of evidence for each research question, according to the components above, was used for this assessment (Table 8) (NHMRC 2008a).

Table 8 Body of evidence matrix

Component	A	B	C	D
	Excellent	Good	Satisfactory	Poor
Evidence-base[a]	Several[b] level I or II studies with low risk of bias	One or two level II studies with low risk of bias or a systematic review / multiple level III studies with low risk of bias	Level III studies with low risk of bias, or level I or II studies with moderate risk of bias	Level IV studies, or level I to III studies with high risk of bias
Consistency[c]	All studies consistent	Most studies consistent, and inconsistency may be explained	Some inconsistency reflecting genuine uncertainty around clinical question	Evidence is inconsistent
Clinical impact	Very large	Substantial	Moderate	Slight or restricted
Generalisability	Population(s) studied in body of evidence are the same as the target population	Population(s) studied in body of evidence are similar to the target population	Population(s) studied in body of evidence differ to target population, but it is clinically sensible to apply this evidence to target population	Population(s) studied in body of evidence different to target population, and it is hard to judge whether it is sensible to generalise to target population
Applicability	Directly applicable to Australian healthcare context	Applicable to Australian healthcare context with few caveats	Probably applicable to Australian healthcare context with some caveats	Not applicable to Australian healthcare context

Adapted from NHMRC (2008a)

[a] Level of evidence determined from the NHMRC evidence hierarchy (Table 6); [b] Several: more than two studies; [c] If there is only one study, rank this component as 'not applicable'.

SR = systematic review

Expert advice

An advisory panel was established to provide guidance to the health technology assessors to ensure that the assessment was clinically relevant and to take into account consumer interests. Membership of the Advisory Panel is provided at Appendix A.

Results of assessment

The results of the assessment of unattended sleep studies for the diagnosis of OSA are presented under the following three subtitles: diagnosis in a non-specialised unit setting; diagnosis in a referral setting; and diagnosis in a paediatric setting—which correspond to the clinical pathways outlining the likely use of unattended sleep studies (Figure 5 to Figure 7).

Diagnosis in a non-specialised unit setting

Is it safe?

Use of unattended sleep studies by a medical practitioner in the diagnosis of adult OSA was assessed in terms of possible patient harms that may result from testing. Box 2 outlines the inclusion criteria determined a priori for including studies that assessed the safety of unattended sleep studies.

Box 2 Criteria for selecting studies to assess the safety of unattended sleep studies in a non-specialised unit setting

Selection criteria	Inclusion criteria
Population	Adults with suspected OSA[a] – Subgroups: age range, BMI range, comorbid conditions (eg COPD, depressive symptoms, diabetes, CVD, GERD), occupation
Index test / intervention	*Level 3* unattended sleep study involving the assessment of two or more cardiopulmonary parameters (eg detection of airflow, respiratory movement, arterial oxygen saturation, ECG), and subsequent data analysis and interpretation by an appropriately trained and credentialled medical practitioner OR *Level 4* unattended sleep study involving the assessment of one cardiopulmonary parameter (usually oximetry), and subsequent data analysis and interpretation by an appropriately trained and credentialled medical practitioner ± *Referral to an appropriately trained and credentialled medical practitioner* ± *Level 1 study*
Comparator(s)	*Referral to sleep physician* ± *Level 1* laboratory-based, overnight, attended (by sleep technician) sleep study / polysomnography that includes assessments of: sleep staging (EEG, EOG, EMG), detection of airflow (quantitative or semi-quantitative nasal transducers), respiratory movement (via transducers on chest or abdominal walls, or via RIP), arterial oxygen saturation (via a pulse oximeter), ECG, leg movement, snoring, body positioning, and subsequent data analysis and interpretation
Outcomes	Physical harms from testing, eg allergy to electrode adhesive
Publication type	Randomised or non-randomised controlled trials, cohort studies, registers, case series, case reports or systematic reviews of these study designs. Non-systematic reviews, non-research letters, editorials; and animal, in-vitro and laboratory studies, were excluded.
Search period	1980 – April 2009
Language	Non-English language articles were excluded unless they provided a higher level of evidence than the English language articles identified.

[a] Suspected on the basis of snoring/gasping/choking while asleep, excessive daytime sleepiness, witnessed apnoea, nocturia

BMI = body mass index; COPD = chronic obstructive pulmonary disease; CVD = cardiovascular disease such as hypertension, coronary artery disease, ischaemic heart disease; ECG = electrocardiogram; EEG = electroencephalogram; EMG = electromyogram; EOG = electrooculogram; GERD = gastro-oesophageal reflux disease; OSA = obstructive sleep apnoea; RIP = respiratory inductive plethysmography

One study was identified that reported on safety outcomes associated with the use of an unattended sleep study in the diagnosis of adult OSA in a non-specialised unit setting. Abraham et al (2006) investigated a Level 4 portable device, ClearPath System Nx-301 (Nexan Inc, USA), in a total of 50 patients with stable heart failure. In this moderate-quality level III-2 diagnostic study, no significant adverse events were observed. Post-examination skin redness was complained of by 19 (38.0%) patients, with significant redness occurring in one (2.0%) patient. Mild itching from the sensor and the sender of the device was reported by 12.0% and 6.0%, respectively, of patients after the Level 4 sleep study (Table 9) (Abraham et al 2006).

Table 9 Adverse events from an unattended sleep study in a non-specialised unit setting

Study	Evidence level and quality	Population	Index test	Adverse events
Level 4 sleep study				
(Abraham et al 2006)	Cross-classification study Level III-2 diagnostic evidence C1, P1 Q2 [QUADAS: 10/14]	50 patients with stable heart failure	Home-based ClearPath System Nx-301	Redness: 19/50 (38.0%) Significant redness: 1/50 (2.0%) Moderate redness: 8/50 (16.0%) Slight redness: 10/50 (20.0%) Mild itching: 9/50 (18.0%) From sensor: 6/50 (12.0%) From sender: 3/5 (6.0%)

Summary — Are Level 3 and/or 4 unattended sleep studies (± referral to an appropriately trained and credentialed medical practitioner ± Level 1 study) as safe as, or safer than, referral to a sleep physician ± Level 1 study for adults with suspected OSA?

Minor adverse events from the use of unattended sleep studies by a medical practitioner in the diagnosis of adult OSA were reported by Abraham et al (2006). Significant skin redness after a Level 4 sleep study using the ClearPath System Nx-301 was complained of by one patient (2.0%). An additional 18 patients (36.0%) developed mild to moderate redness resulting from the sleep study. Mild itching, either from the sensor or the sender, was reported as an adverse event in 18.0% (9 out of 50) patients. No other studies were identified that reported physical harms associated with unattended sleep studies in a non-specialised unit setting. Level 1 sleep studies are only performed in a referral setting, so the absence of data against this comparator is not unexpected.

Is it effective?

Direct evidence

Studies were included to assess the diagnostic effectiveness of unattended sleep studies in a non-specialised unit setting according to the criteria outlined in Box 3.

Box 3 Criteria for selecting studies to assess the diagnostic effectiveness of unattended sleep studies in a non-specialised unit setting

Selection criteria	Inclusion criteria
Population	Adults with suspected OSA[a] – Subgroups: age range, BMI range, comorbid conditions (eg COPD, depressive symptoms, diabetes, CVD, GERD), occupation
Index test / intervention	*Level 3* unattended sleep study involving the assessment of two or more cardiopulmonary parameters (eg detection of airflow, respiratory movement, arterial oxygen saturation, ECG), and subsequent data analysis and interpretation by an appropriately trained and credentialed medical practitioner OR *Level 4* unattended sleep study involving the assessment of one cardiopulmonary parameter (usually oximetry), and subsequent data analysis and interpretation by an appropriately trained and credentialled medical practitioner ± *Referral to an appropriately trained and credentialed medical practitioner* ± *Level 1 study*
Comparator(s)	*Referral to sleep physician* ± *Level 1* laboratory-based, overnight, attended (by sleep technician) sleep study / polysomnography that includes assessments of: sleep staging (EEG, EOG, EMG), detection of airflow (quantitative or semi-quantitative nasal transducers), respiratory movement (via transducers on chest or abdominal walls, or via RIP), arterial oxygen saturation (via a pulse oximeter), ECG, leg movement, snoring, body positioning, and subsequent data analysis and interpretation
Outcomes	Primary: 1) *patient-relevant:* survival/mortality rate, resolution/reduction of symptoms (eg snoring, excessive daytime sleepiness, witnessed apnoea), disease-specific quality of life; *2) surrogate:* respiratory events / number of apnoeas or hypopnoeas (eg AHI, RDI), oxygen saturation (eg ODI), sleep time and efficiency (eg sleep stage duration/quality, ArI), control of comorbidities (eg hypertension, HbA_{1C} control, heart failure outcomes) Secondary: additional sleep studies (by type), referral to sleep physician / credentialed medical practitioner, time to diagnosis, time to commencement of treatment, treatment type
Publication type	Randomised or non-randomised controlled trials or cohort studies or uncontrolled pre-test/post-test case series or systematic reviews of these study designs. Non-systematic reviews, letters, editorials; and animal, in-vitro and laboratory studies, were excluded.
Search period	1980 – April 2009
Language	Non-English language articles were excluded unless they appeared to provide a higher level of evidence than the English language articles identified.

[a] Suspected on the basis of snoring/gasping/choking while asleep, excessive daytime sleepiness, witnessed apnoea, nocturia

AHI = apnoea–hypopnoea index; ArI = arousal index; BMI = body mass index; COPD = chronic obstructive pulmonary disease; CVD = cardiovascular disease such as hypertension, coronary artery disease, ischaemic heart disease; ECG = electrocardiogram; EEG = electroencephalogram; EMG = electromyogram; EOG = electrooculogram; GERD = gastro-oesophageal reflux disease; ODI = oxygen desaturation index; OSA = obstructive sleep apnoea; RDI = respiratory disturbance index; RIP = respiratory inductive plethysmography

Evidence of a change in the health outcomes of adult patients with OSA, diagnosed with the aid of unattended sleep studies in a non-specialised unit setting, was reported by two prospective case series of low evidentiary level (level IV interventional evidence) and poor quality (Eskafi et al 2006; Patel & Davidson 2007).

Eskafi et al (2006) assessed a Level 3 portable device, EdenTrace II Plus Multirecording System (EdenTech Corporation, USA), in 58 patients with stable mild to moderate congestive heart failure. This device recorded the following signals: oronasal airflow, thoracic movement, oxygen saturation, body position and snoring sound. A respiratory event was defined as a reduction of 50% or more in airflow for at least 10 seconds, accompanied by oxygen desaturation of no less than 4%. A total of 17 (29.3%) patients with respiratory events ≥10 per hour (RDI ≥10) were treated by a mandibular advancement device (MAD). Post-treatment health outcomes reported by this study were health-related quality of life (QoL) and changes in sleep apnoea syndromes and respiratory events. In 11 patients who used MAD for more than 6 months, the score on individual domains in the two QoL questionnaires did not change significantly after 6 months of treatment when compared with corresponding baseline scores ($p>0.05$). This suggested that the diagnosis of sleep apnoea by a Level 3 sleep study and subsequent treatment did not improve patients' health-related QoL. However, the sleep apnoea symptoms, such as excessive daytime sleepiness and snoring, were significantly controlled by the MADs, with scores on the Sleep Apnea Questionnaire[11] reducing by an average of 7 points at 6 months after treatment, a clinically important and statistically significant ($p=0.003$) change. The mean RDI, as measured by EdenTrace II Plus Multirecording System, decreased by approximately one-third, from 25.4±10.3 pre-treatment to 16.5±10.0 after 6 months of use of a MAD ($p=0.04$) (Table 10).

Table 10 Patient health outcomes before and after diagnosis of OSA by an unattended sleep study and subsequent treatment in a non-specialised unit setting

Item	Baseline	Post-treatment (6 months)	p-value
Health-related quality of life			
Nottingham Health Profile[12]			
Overall	12.9±15.8	12.1±16.9	p>0.05
Emotion	3.2±5.7	3.3±8.7	p>0.05
Sleep	17.4±16.5	12.2±10.5	p>0.05
Energy	27.0±41.2	25.9±41.1	p>0.05
Emotion	3.2±5.7	3.3±8.7	p>0.05
Mobility	13.6±19.2	15.4±25.2	p>0.05
Social isolation	6.4±21.4	5.5±18.3	p>0.05
Minnesota Living with Heart Failure Questionnaire[13]			
Overall	26.5±23.2	24.9±21.5	p>0.05
Physical dimension	11.8±2.1	11.5±11.8	p>0.05
Emotion	3.6±4.5	2.8±4.6	p>0.05

[11] The Sleep Apnea Questionnaire consists of 15 questions on a 5-point scale focusing on sleep apnoea syndromes, eg excessive daytime sleepiness. A higher overall score indicates more severe sleep apnoea symptoms (Eskafi et al 2006).

[12] The Nottingham Health Profile is a generic instrument that measures ill health on various dimensions of QoL. It consists of 38 questions, with scores varying from 0 to 100 in each domain. A higher score suggests poorer QoL (Eskafi et al 2006).

[13] The Minnesota Living with Heart Failure Questionnaire measures the clinical signs and symptoms of heart failure; physical and emotional conditions; and work, social and sexual activities. It consists of 21 questions, with scores varying from 0 to 5 for each question. A higher score indicates lower QoL (Eskafi et al 2006).

Item	Baseline	Post-treatment (6 months)	Difference
Sleep apnoea syndrome			
Sleep Apnea Questionnaire	22.5±5.1	15.5±7.5	p=0.003
Number of respiratory events			
Respiratory disturbance index	25.4±10.3	16.5±10.0	p=0.04

Source: Eskafi et al (2006)

Note: Results presented as mean ± standard deviation

In the other case series, Patel et al (2007) investigated another Level 3 portable monitor, Embletta PDS (Embla, USA), in a total of four patients (three adults and one 8-year-old boy) with suspected OSA in the home setting. Each of the three adults were found to have greater than five apnoea and hypopnoea episodes per hour (RDI >5); and were therefore diagnosed with OSA. APAP treatment was recommended for the three adult patients: two accepted and the third patient declined and instead opted to proceed with a palatal implant. Of the two patients managed by APAP, one patient reported better sleep quality and an absence of daytime sleepiness after 2 weeks of treatment. In addition, his blood pressure rapidly returned to normal level after the OSA treatment, whereas his hypertension had been poorly controlled previously. The other patient was lost to follow-up during APAP treatment. The patient who received a palatal implant reported a dramatic reduction in snoring at 6 weeks after the surgery.

Linked evidence

The limited nature of the direct evidence presented above, including the lack of comparison against the usual workup and treatment of OSA, and the very small patient numbers, made it appropriate to pursue a linked evidence approach. Evidence of the diagnostic accuracy of unattended sleep studies and their impact on patient management were assessed and reported. The criteria for selecting such studies are outlined in Box 4 and Box 5.

Box 4 Criteria for selecting studies to assess the diagnostic accuracy of unattended sleep studies in a non-specialised unit setting

Selection criteria	Inclusion criteria
Population	Adults with suspected OSA[a] – Subgroups: age range, BMI range, comorbid conditions (eg COPD, depressive symptoms, diabetes, CVD, GERD), occupation
Index test / intervention	*Level 3* unattended sleep study involving the assessment of two or more cardiopulmonary parameters (eg detection of airflow, respiratory movement, arterial oxygen saturation, ECG), and subsequent data analysis and interpretation by an appropriately trained and credentialed medical practitioner OR *Level 4* unattended sleep study involving the assessment of one cardiopulmonary parameter (usually oximetry), and subsequent data analysis and interpretation by an appropriately trained and credentialed medical practitioner
Comparator(s)	*Level 1* laboratory-based, overnight, attended (by sleep technician) sleep study / polysomnography that includes assessments of: sleep staging (EEG, EOG, EMG), detection of airflow (quantitative or semi-quantitative nasal transducers), respiratory movement (via transducers on chest or abdominal walls, or via RIP), arterial oxygen saturation (via a pulse oximeter), ECG, leg movement, snoring, body positioning, and subsequent data analysis and interpretation
Outcomes	Sensitivity, specificity, accuracy, negative predictive value, positive predictive value, area under the curve, positive likelihood ratio, negative likelihood ratio, level of agreement Summary measures: diagnostic odds ratio, summary receiver operator characteristic curve

Publication type	Cross-sectional studies where patients were cross-classified on the index test and comparator and/or reference standard. Case-control diagnostic studies were acceptable only if cross-sectional studies were not available. Systematic reviews of cross-sectional studies. Non-systematic reviews, non-research letters, editorials; and animal, in-vitro and laboratory studies were excluded.
Search period	1980 – April 2009
Language	Non-English language articles were excluded unless they provided a higher level of evidence than the English language articles identified.

[a] Suspected on the basis of snoring/gasping/choking while asleep, excessive daytime sleepiness, witnessed apnoea, nocturia

BMI = body mass index; COPD = chronic obstructive pulmonary disease; CVD = cardiovascular disease such as hypertension, coronary artery disease, ischaemic heart disease; ECG = electrocardiogram; EEG = electroencephalogram; EMG = electromyogram; EOG = electrooculogram; GERD = gastro-oesophageal reflux disease; OSA = obstructive sleep apnoea; RIP = respiratory inductive plethysmography

Box 5 Criteria for selecting studies to assess the change in management following the use of unattended sleep studies in a non-specialised unit setting

Selection criteria	Inclusion criteria
Population	Adults with suspected OSA[a] – Subgroups: age range, BMI range, comorbid conditions (eg COPD, depressive symptoms, diabetes, CVD, GERD), occupation
Index test / intervention	*Level 3* unattended sleep study involving the assessment of two or more cardiopulmonary parameters (eg detection of airflow, respiratory movement, arterial oxygen saturation, ECG), and subsequent data analysis and interpretation by an appropriately trained and credentialled medical practitioner OR *Level 4* unattended sleep study involving the assessment of one cardiopulmonary parameter (usually oximetry), and subsequent data analysis and interpretation by an appropriately trained and credentialed medical practitioner ± *Referral to an appropriately trained and credentialed medical practitioner* ± *Level 1 study*
Comparator(s)	*Referral to sleep a sleep physician* ± *Level 1* laboratory-based, overnight, attended (by sleep technician) sleep study / polysomnography that includes assessments of: sleep staging (EEG, EOG, EMG), detection of airflow (quantitative or semi-quantitative nasal transducers), respiratory movement (via transducers on chest or abdominal walls, or via RIP), arterial oxygen saturation (via a pulse oximeter), ECG, leg movement, snoring, body positioning, and subsequent data analysis and interpretation
Outcomes	Additional sleep studies (by type), referral to sleep medicine physician / credentialed medical practitioner, time to diagnosis, time to commencement of treatment, alteration in treatment, treatment type
Publication type	Randomised or non-randomised controlled trials (including before-and-after studies) or cohort studies or uncontrolled pre-test/post-test case series or systematic reviews of these study designs. Non-systematic reviews, non-research letters, editorials; and animal, in-vitro and laboratory studies, were excluded.
Search period	1980 – April 2009
Language	Non-English language articles were excluded unless they provided a higher level of evidence than the English language articles identified.

[a] Suspected on the basis of snoring/gasping/choking while asleep, excessive daytime sleepiness, witnessed apnoea, nocturia

BMI = body mass index; COPD = chronic obstructive pulmonary disease; CVD = cardiovascular disease such as hypertension, coronary artery disease, ischaemic heart disease; ECG = electrocardiogram; EEG = electroencephalogram; EMG = electromyogram; EOG = electrooculogram; GERD = gastro-oesophageal reflux disease; OSA = obstructive sleep apnoea; RIP = respiratory inductive plethysmography

Several studies included in this assessment report did not specifically state that the patient population was suspected of OSA (Abraham et al 2006; Quintana-Gallego et al 2004; Sériès et al 2005; Smith et al 2007). These studies primarily included patients with heart failure. Given that patients with comorbidities were pre-specified as subgroups of interest in the target population (those suspected of OSA) for this assessment, these studies on heart failure patients have been included on the assumption that a sleep study was being performed to rule out comorbid OSA in these patients.

Is it accurate?

Receiver–operator characteristic (ROC) curve analysis was performed in one moderate-quality study reporting the diagnostic accuracy of unattended sleep studies in a non-specialised unit setting (level III-2 diagnostic evidence) (Quintana-Gallego et al 2004) (Table 11).

Quintana-Gallego et al (2004) investigated the accuracy of a Level 3 portable device, Apnoescreen II (Erich Jaeger Gmbh & CoKg, Germany), in the home setting to diagnose OSA in a group of 75 patients with stable heart failure. This device identified respiratory events by the amplitude of airflow and oxygen saturation signals. Level 1 laboratory-based PSG was used as the reference standard. This Level 3 monitor demonstrated high accuracy in this population to diagnose OSA, with area under the curve (AUC) values of 0.896, 0.907 and 0.862 at PSG AHI thresholds of 5, 10 and 15, respectively.

Table 11 Area under the curve of an unattended sleep study in a non-specialised unit setting

Study	Evidence level and quality	Population	Respiratory event definition	*Reference standard* Cut-off point	AUC of index test [95% CI] ±SD
Level 3 studies					
(Quintana-Gallego et al 2004)	Cross-classification study Level III-2 diagnostic evidence CX, P1 Q2 [QUADAS: 10.5/14]	68/75 patients with stable heart failure	Apnoea: no airflow, ≥10 s Hypopnoea: ↓ airflow ≥50%, ≥10 s, accompanied by oxygen desaturation ≥4% (or arousal)	*Level 1 laboratory-based PSG* AHI ≥5	*Home-based Apnoescreen II* 0.896 [0.815, 0.977]
				AHI ≥10	0.907 [0.817, 0.998]
				AHI ≥15	0.862 [0.730, 0.994]

AHI = apnoea–hypopnoea index; AUC = area under the curve; CI = confidence interval; n/a = not applicable; PSG = polysomnography; s = seconds

The diagnostic accuracy of unattended sleep studies in a non-specialised unit setting was reported in terms of the sensitivity, specificity, PPV, NPV, LR+ and LR– in seven studies of moderate to good quality (level III-1 or III-2 diagnostic evidence) (Table 12). Level 1 laboratory-based PSG was used as reference standard in all seven studies.

The sensitivity and specificity of four Level 3 portable monitors, namely Apnoescreen II, Stardust II (Respironics Inc, USA), Embletta (Flaga, Iceland) and LifeShirt system (Vivometrics Inc, USA), were investigated in four cohorts of patients with suspected OSA or with stable heart failure (Carter et al 2004; Quintana-Gallego et al 2004; Smith et al 2007; Yin et al 2006). The respiratory event definition varied across studies, including a reduction in airflow of 25% or 50%, accompanied or not accompanied by oxygen desaturation ≥3% or 4%. However, consistency in the definition of apnoea/hypopnoea

episodes was observed between the index test and the reference standard in the same study. Using a threshold RDI ≥ 5 for unattended sleep studies and PSG AHI ≥5, the sensitivity and specificity of Level 3 sleep studies ranged from 82.5% to 100% and from 88.6% to 100%, respectively. If RDI or AHI ≥15 was used as the diagnostic cut-off point for OSA, the sensitivity and specificity ranged from 68.4% to 93.8% and 25.0% to 100%, respectively. Level 3 sleep studies showed a relatively high PPV of 76.0% to 100% in patients with suspected OSA, whereas the NPV ranged between 60.0% and 100%, when varying cut-off points for the number of respiratory events per hour were used. The PPV and NPV in patients with stable heart failure were 70.0% and 50.0%, respectively, at an RDI threshold of 10; and 75.0% and 43.8%, respectively, at an RDI cut-off point of 20. Carter et al (2004) reported infinity for LR+ and 0 for LR– in their study, which might be attributable to its small population group (10 patients). The LR+ and LR– in the other two cohorts with larger study sample sizes (44 patients in Yin et al's study and 20 patients in Smith et al's study) ranged from 1.0 to 2.6 and from 0.2 to 0.9 (weak to moderate diagnostic ability), respectively, using RDI/AHI thresholds of between 5 and 30.

Of the three cohort studies investigating Level 4 sleep studies, Gergely et al's (2009) paper provided the highest level of evidence (level III-1 diagnostic evidence) and, at the same time, involved the largest patient group. This good-quality study examined two Level 4 portable devices, SleepStrip (S.L.P. Ltd, Israel) and Pulsox-M24 (Konica-Minolta, Japan), in a home setting in 83 patients with OSA symptoms. The SleepStrip recorded the signal of nasal flow. A reduction in airflow of ≥50%, lasting ≥10 seconds, was marked as a respiratory event. The highest sensitivity (71.9%) and PPV (85.4%) were obtained at a threshold RDI/AHI of 15. The corresponding specificity, NPV, LR+ and LR– were 73.1%, 54.3%, 2.7 and 0.4, respectively, at this cut-off point, indicating moderate diagnostic ability. The best specificity (87.3%) and NPV (80.0%), as well as the highest LR+ (4.5) and LR– (0.5), were observed when a RDI/AHI ≥40 was used in the diagnosis of OSA.

The Pulsox-M24 had superior specificity (>92%), PPV (>91%) and a higher LR+ (8.2 to 21.6) when compared with SleepStrip. However, the sensitivity of this home-based Pulsox-M24 study (39.3% to 63.2%) was not as good as that of the home-based SleepStrip study. No significant differences in NPV and LR– between the two Level 4 devices were observed. The highest sensitivity of 63.1% was reached when the lowest cut-off point for RDI/AHI (≥15) was used. At this threshold the Pulsox-M24 also demonstrated fair, although not perfect, specificity (94.7%) and PPV (94.7%) in patients with suspected OSA. The NPV, LR+ and LR– were 53.3%, 8.2 and 0.4, respectively, using a RDI/AHI ≥15 as indicative of OSA.

Two further articles were identified that reported the sensitivity of other Level 4 portable monitors, namely the Stardust® Sleep Recorder (Respironics Inc, USA) and ClearPath System Nx-301. In general, these devices had higher test sensitivity (84.8% for the Stardust® Sleep Recorder and 73% for the ClearPath System Nx-301) than both SleepStrip and Pulsox-M24 (Abraham et al 2006; Sériès et al 2005). Using 10 and 15 as the cut-off points for RDI and PSG AHI, respectively, the Stardust® Sleep Recorder had a high specificity of 92.9% in the diagnosis of adult OSA. The PPV, NPV, LR+ and LR– of this Level 4 portable monitor were 96.6%, 72.2%, 11.9 and 0.2, respectively, in patients with stable heart failure, suggesting strong diagnostic ability.

Table 12 Test characteristics of unattended sleep studies in a non-specialised unit setting

Study	Evidence level and quality	Population	Respiratory event definition	*Index test* Cut-off point	*Reference standard* Cut-off point	Sensitivity % [95% CI]	Specificity % [95% CI]	PPV % [95% CI]	NPV % [95% CI]	LR+ [95% CI]	LR– [95% CI]
Level 3 sleep study											
(Quintana-Gallego et al 2004)	Cross-classification study Level III-2 diagnostic evidence CX, P1 Q2 [QUADAS: 10.5/14]	68/75 patients with heart failure	Apnoea: no airflow, ≥10 s Hypopnoea: ↓ airflow ≥50%, ≥10 s, accompanied by oxygen desaturation ≥4% (or arousal)	*Home-based Apnoescreen II*	*Laboratory-based PSG*						
				RDI ≥5	AHI ≥5	82.5 [70.7, 94.2]	88.6 [74.1, 97.3]				
				RDI ≥10	AHI ≥10	79.3 [64.5, 94.0]	97.8 [93.7, 100.0]				
				RDI ≥15	AHI ≥15	68.4 [47.5, 89.0]	94.6 [86.1, 99.0]				
(Yin et al 2006)	Cross-classification study Level III-2 diagnostic evidence CX, P1 Q2 [QUADAS: 10.5/14]	44/90 patients with suspected OSA	↓ airflow >50%, ≥10 s, accompanied by oxygen desaturation ≥3%	*Home-based Stardust II*	*Laboratory-based PSG*						
				RDI ≥5	AHI ≥5	100.0	—	93.2	—	1.0	—
				RDI ≥15	AHI ≥15	93.8	25.0	76.9	60.0	1.3	0.2
				RDI ≥30	AHI ≥30	79.2	70.0	76.0	73.7	2.6	0.3
				RDI ≥50	AHI ≥50	90.0	97.1	90.0	97.1	31.0	0.1
(Smith et al 2007)	Cross-classification study Level III-2 diagnostic evidence CX, P1 Q2 [QUADAS: 10/14]	20 patients with stable heart failure	Apnoea: no airflow ≥10 s Hypopnoea: ↓ airflow or thoraco-abdominal movement ≥50%, ≥10 s	*Home-based Embletta*	*Laboratory-based PSG*						
				RDI ≥10	AHI ≥15	58.3 [28.6, 83.5]	62.5 [25.9, 89.8]	70.0 [35.4, 91.9]	50.0 [20.1, 79.9]	1.6 [0.6, 4.3]	0.7 [0.3, 1.5]
				RDI >20	AHI ≥15	25.0 [6.7, 57.2]	87.5 [46.7, 99.3]	75.0 [21.9, 98.7]	43.8 [20.8, 69.4]	2.0 [0.3, 16.0]	0.9 [0.6, 1.2]
(Carter et al 2004)	Cross-classification study Level III-2 diagnostic evidence CX, P1 Q2 [QUADAS: 10/14]	10 patients with suspected OSA	Apnoea: ↓ airflow >75%, ≥10 s; or a less significant ↓ airflow accompanied by oxygen desaturation ≥3% Hypopnoea: ↓ airflow >25%	*Home-based LifeShirt system*	*Laboratory-based PSG*						
				RDI >5	AHI >5	100.0 [59.8, 100.0]	100.0 [19.8, 100.0]	100.0 [59.8, 100.0]	100.0 [19.8, 100.0]	∞	0
				RDI >15	AHI >15	85.7 [42.0, 99.2]	100.0 [31.0, 100.0]	100.0 [51.7, 100.0]	75.0 [21.9, 98.7]	∞	0.1 [0.0, 0.9]

Study	Evidence level and quality	Population	Respiratory event definition	*Index test* Cut-off point	*Reference standard* Cut-off point	Sensitivity % [95% CI]	Specificity % [95% CI]	PPV % [95% CI]	NPV % [95% CI]	LR+ [95% CI]	LR– [95% CI]
Level 4 sleep study											
(Gergely et al 2009)	Cross-classification study Level III-1 diagnostic evidence CX, P1 Q1 [QUADAS: 12/14]	83 patients with suspected OSA	Apnoea: ↓ airflow ≥88%, >10 s Hypopnoea: ↓ airflow ≥50%, >10 s	*Home-based SleepStrip*	*Laboratory-based PSG*						
				RDI ≥15	AHI ≥15	71.9 [58.3, 82.6]	73.1 [51.9, 87.6]	85.4 [71.6, 93.5]	54.3 [36.9, 70.8]	2.7 [1.4, 5.1]	0.4 [0.2, 0.6]
				RDI ≥25	AHI ≥25	68.3 [51.8, 81.4]	81.0 [65.3, 90.9]	77.8 [60.4, 89.3]	72.3 [57.1, 83.9]	3.6 [1.9, 6.9]	0.4 [0.2, 0.6]
				RDI ≥40	AHI ≥40	57.1 [37.4, 75.0]	87.3 [74.9, 94.3]	69.6 [47.0, 85.9]	80.0 [67.3, 88.8]	4.5 [2.1, 9.6]	0.5 [0.3, 0.8]
			Unattended sleep study: oxygen desaturation ≥3% Laboratory-based PSG: apnoea: ↓ airflow ≥88%, time >10 s; hypopnoea: ↓ airflow ≥50%, >10 s	*Home-based Pulsox-M24*	*Laboratory-based PSG*						
				ODI ≥15	AHI ≥15	63.2 [49.3, 75.2]	92.3 [73.4, 98.7]	94.7 [80.9, 99.1]	53.3 [38.0, 68.1]	8.2 [2.1, 31.6]	0.4 [0.3, 0.6]
				ODI ≥25	AHI ≥25	61.0 [44.5, 75.4]	100.0 [89.6, 100.0]	100.0 [83.4, 100.0]	72.4 [58.9, 83.0]	∞	0.4 [0.3, 0.6]
				ODI ≥40	AHI ≥40	39.3 [22.1, 59.3]	98.2 [89.0, 99.9]	91.7 [59.8, 99.6]	76.1 [64.2, 85.1]	21.6 [2.9, 159.0]	0.6 [0.5, 0.8]
(Sériès et al 2005)	Cross-classification study Level III-2 diagnostic evidence CX, P1 Q1 [QUADAS: 12.5/14]	47/50 patients with stable heart failure	Unattended sleep study: oxygen desaturation ≥2% followed by a rise in oxygen saturation Laboratory-based PSG: apnoea: no airflow ≥10 s; hypopnoea: ↓ airflow or respiratory ≥50%, ≥10 s	*Home-based Stardust® Sleep Recorder*	*Laboratory-based PSG*						
				ODI >10	AHI >15	84.8 [67.3, 94.3]	92.9 [64.2, 99.6]	96.6 [80.4, 99.8]	72.2 [46.4, 89.3]	11.9 [1.8, 79.0]	0.2 [0.1, 0.4]

Study	Evidence level and quality	Population	Respiratory event definition	*Index test*	*Reference standard*	Sensitivity	Specificity	PPV	NPV	LR+	LR–
				Cut-off point	Cut-off point	% [95% CI]	% [95% CI]	% [95% CI]	% [95% CI]	[95% CI]	[95% CI]
(Abraham et al 2006)	Cross-classification study Level III-2 diagnostic evidence CX, P1 Q2 [QUADAS: 10/14]	30/50 patients with stable heart failure	Unattended sleep study: oxygen desaturation ≥3 Laboratory-based PSG: apnoea: no airflow ≥10 s; hypopnoea: ↓ airflow ≥50%, ≥10 s	*Home-based ClearPath System Nx-301*	*Laboratory-based PSG*						
				ODI ≥5	AHI ≥15	73					
				ODI ≥10	AHI ≥10	80					
				ODI ≥15	AHI ≥15	77					

AHI = apnoea–hypopnoea index; CI = confidence interval; LR = likelihood ratio; NPV = negative predictive value; ODI = oxygen desaturation index; OSA = obstructive sleep apnoea; PPV = positive predictive value; PSG = polysomnography; RDI = respiratory disturbance index; s = seconds

Apart from test accuracy characteristics, there are other methods for evaluating the extent of agreement between the index test and reference standard in measuring the same medical condition. These include the mean difference and limits of agreement determined by Bland and Altman plot analysis; the Inter-rater agreement as measured by Cohen's Kappa coefficient; and correlation measures such as the Spearman rank correlation coefficient and Pearson correlation coefficient (Flemons et al 2003). Although correlation measures can assess whether two tests are measuring a similar parameter, they cannot assess the level of agreement between the two tests (Bland & Altman 1987). Thus, in terms of assessing whether unattended sleep studies are producing similar results to PSG, the Bland and Altman plots and Cohen's Kappa coefficient are the more useful measures.

The agreement between unattended sleep studies and laboratory-based PSG in measuring OSA, using the above methods, in a non-specialised unit setting was reported by a total of five studies (level III-1 or level III-2 diagnostic evidence): three investigated Level 3 sleep studies and two examined Level 4 sleep studies (Table 13).

Yin et al (2006) evaluated the home-based Stardust II device in measuring RDI in 40 out of 44 patients with suspected OSA. Using Bland and Altman plot analysis, the authors found that the RDI (the number of events where there was a reduction in airflow >50% accompanied by oxygen desaturation ≥3% per hour) obtained from Stardust II was higher than the PSG AHI, with a mean difference of 3.7±13.1. The limits of agreement between this Level 3 sleep study and laboratory-based PSG ranged between –22.5 and 29.9. This means that results from the Stardust II device could range between being lower than PSG by AHI 22.5 up to higher than PSG by AHI 29.9. This lack of agreement is unacceptable for the diagnosis of mild to moderate OSA, despite the linear correlation observed between the tests (Pearson correlation coefficient of 0.845 ($p<0.01$)). Smith et al (2004) tested the diagnostic agreement between a Level 3 device, Embletta, and laboratory-based PSG in 20 patients with stable heart failure. The home-based Embletta device showed a poor agreement with PSG in the diagnosis of OSA (Kappa coefficient=0.27, $p=0.06$). However, the other moderate-quality study by Cater et al (2004) suggested good diagnostic agreement between the LifeShirt system and laboratory-based PSG in a small group of 10 patients, with a Spearman correlation coefficient of 0.97 ($p<0.05$). Taken together, these results are largely inconclusive, given the small sample sizes, patient selection bias, variation in cut-off points and devices.

Gergely et al (2009) evaluated the performance of two Level 4 sleep studies in the diagnosis of OSA in 83 patients with suspected OSA. In this high-quality cohort study, a moderate overall agreement between the SleepStrip and laboratory-based PSG (Kappa coefficient=0.457, $p<0.01$) and between home-based Pulsox-M24 and laboratory-based PSG (Kappa coefficient=0.509, $p<0.01$) was determined, using 15, 25 and 40 as the cut-off points for RDI, ODI and AHI, respectively. In the study by Sériès et al (2005) the authors observed a relatively lower ODI from the Stardust® Sleep Recorder, when compared with PSG AHI, with a mean difference of –6.4 between the two results. The agreement limits of the two diagnostic tests ranged roughly from –25 to 15 in the Bland and Altman plot (meaning the Stardust® Sleep Recorder results could range somewhere between lower than PSG by AHI 25 up to higher than PSG by AHI 15), suggesting that use of this Level 4 study could result in inappropriate diagnosis and treatment and, therefore, is not an acceptable alternative to a Level 1 study.

Table 13 Other agreement measures of unattended sleep studies in a non-specialised unit setting

Study	Evidence level and quality	Population	Respiratory event definition	*Index test*	*Reference standard*	Agreement measure
				Cut-off point	Cut-off point	
Level 3 sleep study						
(Yin et al 2006)	Cross-classification study Level III-2 diagnostic evidence CX, P1 Q2 [QUADAS: 10.5/14]	44/90 patients with suspected OSA	↓ airflow >50%, ≥10 s, accompanied by oxygen desaturation ≥3%	*Home-based Stardust II* n/a	*Laboratory-based PSG* n/a	Mean difference (RDI–AHI): 3.7±13.1 Limits of agreement: [–22.5, 29.9] (Bland and Altman plot analysis) r=0.845 (p<0.001) (Pearson χ^2 test)
(Smith et al 2007)	Cross-classification study Level III-2 diagnostic evidence C1, P1 Q2 [QUADAS: 10/14]	20 patients with stable heart failure	Apnoea: no airflow ≥10 s Hypopnoea: ↓ airflow or respiratory movement ≥50%, ≥10 s	*Home-based Embletta* RDI ≥10 RDI >20	*Laboratory-based PSG* AHI ≥15 AHI ≥15	k=0.27 (*p*=0.06) (analysis of Inter-rater agreement)
(Carter et al 2004)	Cross-classification study Level III-2 diagnostic evidence CX, P1 Q2 [QUADAS: 10/14]	10 patients with suspected OSA	Apnoea: ↓ airflow >75%, ≥10 s; or a less significant ↓ airflow accompanied by oxygen desaturation ≥3% Hypopnoea: ↓ airflow >25%	*Home-based LifeShirt system* ODI >5 ODI >15	*Laboratory-based PSG* AHI >5 AHI >15	ρ=0.97 (p<0.05) (Spearman rank correlation) r=0.96 (p<0.05) (Pearson χ^2 test)
Level 4 sleep study						
(Gergely et al 2009)	Cross-classification study Level III-1 diagnostic evidence CX, P1 Q1 [QUADAS: 12/14]	83 patients with suspected OSA	Apnoea: ↓ airflow ≥88%, >10 s Hypopnoea: ↓ airflow ≥50%, >10 s	*Home-based-SleepStrip* RDI ≥15 RDI ≥25 RDI ≥40	*Laboratory-based PSG* AHI ≥15 AHI ≥25 AHI ≥40	k=0.457 (p<0.01) (analysis of Inter-rater agreement)
			Unattended sleep study: oxygen desaturation ≥3% Laboratory-based PSG: apnoea: ↓ airflow ≥88%, >10 s; hypopnoea: ↓ airflow ≥50%, >10 s	*Home-based Pulsox-M24* ODI ≥15 ODI ≥25 ODI ≥40	*Laboratory-based PSG* AHI ≥15 AHI ≥25 AHI ≥40	k=0.509 (p<0.01) (analysis of Inter-rater agreement)

Study	Evidence level and quality	Population	Respiratory event definition	*Index test*	*Reference standard*	Agreement measure
				Cut-off point	Cut-off point	
(Sériès et al 2005)	Cross-classification study Level III-2 diagnostic evidence CX, P1 Q1 [QUADAS: 12.5/14]	47/50 patients with stable heart failure	Unattended sleep study: oxygen desaturation ≥2% followed by a rise in oxygen saturation Laboratory-based PSG: apnoea: no airflow ≥10 s; hypopnoea: ↓ airflow or respiratory movement ≥50%, ≥10 s	*Home-based Stardust® Sleep Recorder* n/a	*Laboratory-based PSG* n/a	Mean difference (ODI–AHI): –6.4 Limits of agreement: [–25, 15] (roughly) (Bland and Altman plot analysis)

AHI = apnoea–hypopnoea index; n/a = not applicable; ODI = oxygen desaturation index; OSA = obstructive sleep apnoea; PSG = polysomnography; RDI = respiratory disturbance index; s = seconds

Four case series were identified that reported the diagnostic yield of Level 3 or Level 4 sleep studies without providing the results of diagnostic agreement (level IV diagnostic evidence). Since diagnostic yield provides inferior evidence of the diagnostic accuracy of an index test, and evidence has already been presented on the AUC, sensitivity, specificity, PPV, NPV, LR+, LR– and other agreement measures concerning unattended sleep studies' performance in diagnosis of adult OSA, the results of the three studies have been tabulated in Appendix E but are not reported in detail.

Do unattended sleep studies change patient management?

Two case series were identified that reported the impact on patient management of unattended sleep studies in a non-specialised unit setting (level IV interventional evidence) (Martinez et al 2005; West et al 2001) (Table 14).

The moderate-quality study by Martinez et al (2005) reported the likelihood of additional referrals as a consequence of diagnosis with an unattended sleep study. Abnormal findings on a Level 4 sleep study resulted in a moderate increase in the likelihood of referral (LR 2.7, 95% CI 1.2, 6.0) compared with a normal finding. Not all patients with abnormal results were referred, while nearly one-quarter of patients with normal results were still referred. It appears that, in both situations, the referring medical practitioner may be substituting clinical judgment over the results of the test, integrating the results of the test with other diagnostic information, or using the test as a triage tool to determine the urgency of further treatment. Of note was the fact that only half of the recommended additional specialist consultations were completed by patients with an abnormal Level 4 sleep study result.

In addition, Martinez et al (2005) observed that there was half the rate of additional PSG testing in those with a normal (3/21, 14.3%) as opposed to abnormal (22/79, 28.8%) result from a home-based oximetry. Although this study did not provide any comparative data, it noted that time to diagnosis with the unattended study was approximately 3 weeks (22.5 days) for patients with an ODI of 11–15 but only 8 days for patients with an ODI >15. This suggests that the severity of the condition, as quantified by the sleep study and/or the associated clinical symptoms, may play a role in the triaging process and thus impact on the waiting time experienced until a confirmatory PSG and diagnosis is received. Furthermore, Martinez et al's (2005) study reported on the change in patient management associated with the use of a Level 4 study. CPAP treatment was the

mainstay option for those with moderate to severe OSA diagnosed on the basis of this unattended study (100%), with approximately 60% (57.9%) also recommended to losing weight. Of those with mild OSA according to the unattended study, 20% were recommended CPAP while 60% were recommended positional therapy.

The other poor-quality case series investigated patient referral and management with the use of home-based oximetry in a total of 100 patients in a primary practice setting (West et al 2001). All patients were assessed by standard Epworth sleepiness scale (ESS) prior to the oximetry study. Ten of the 100 patients were referred to an ENT specialist before the Level 4 sleep study was carried out because, based on clinical assessment, they suffered from snoring uncomplicated by sleep apnoea. Another nine patients with no significant snoring and no risk of sleep apnoea were followed up by a general practitioner. The remaining 81 patients underwent a Level 4 sleep study. One patient with a normal result on oximetry was referred to an ENT specialist. Forty-nine out of 81 (60.5%) patients who received the Level 4 sleep study had an ODI of above 20 on oximetry. They were referred to a respiratory physician and underwent a trial of CPAP, with the average length of period from sleep study to respiratory outpatient appointment, and from respiratory outpatient appointment to CPAP trial, being 2 months (60.0±35.0 days) and 1 month (33.7±34.2 days), respectively. Three of the patients were referred to an ENT specialist after a trial of CPAP due to the diagnosis of unilateral nasal obstruction and the need to assess the feasibility of tonsillectomy. The remaining 31 (38.3%) patients were followed up by the general practitioner. Later, ENT referral was suggested in two of these patients. In total, six patients (7.4%) were referred to an ENT specialist after the Level 4 sleep study, with an average waiting time between sleep study and an ENT specialist outpatient appointment of about 4 months (125.3±99.6 days). The lack of control arm in this study means that conclusions cannot be drawn as to whether the use of Level 4 sleep studies changes patient management relative to current clinical practice.

Table 14 Change in management of unattended sleep studies in a non-specialised unit setting

Study	Evidence level and quality	Population	Index test	Additional referrals
Level 4 sleep study				
(Martinez et al 2005)	Retrospective case series Level IV interventional evidence CX, P1 Q2 [NHS CRD: 4/6]	100 patients with suspected OSA referred to general internist, randomly selected from 325 medical records	Home-based Pulse oximeter - 2500 PalmSAT	(1) Patient referral: Sleep consultation recommended in those with abnormal results: 51/79 (64.6%), 24/79 (30.4%) completed Abnormal finding resulted in a moderate increase in likelihood of referral (LR 2.7, 95% CI 1.2, 6.0] Sleep consultation recommended in those with normal results: 5/21(23.8%), 4/21 (19.0%) completed (2) Additional Level 1 study: Additional Level 1 study in those with abnormal results: 22/79 (27.8%) Additional Level 1 study in those with normal results: 3/21(14.3%) (3) Time to diagnosis:

				ODI 11–15: median 22.5 days ODI >15: median 8 days (4) Management alteration: Treatment of those with moderate to severe OSA: 19/19 (100%) CPAP + 11/19 (57.9%) weight reduction recommended Treatment of those with mild OSA: 1/5 (20.0%) CPAP recommended, 3/5 (60.0%) positional therapy recommended
(West et al 2001)	Prospective case series Level IV interventional evidence CX, P1 Q3 [NHS CRD: 3.5/6]	100 patients with suspected OSA	Home-based oximetry or home-based video oximetry	ENT referral before the unattended sleep study: 10/100 (10.0%) ENT referral after the unattended sleep study: 6/81 (7.4%) (waiting time: 60.0±35.0 days) Respiratory physician referral after the unattended sleep study: 49/81 (60.5%) (waiting time: 125.3±99.6 days

ENT = ear, nose and throat; LR = likelihood ratio; OSA = obstructive sleep apnoea; CPAP = continuous positive airway pressure

Direct evidence

Summary — Are Level 3 and/or 4 unattended sleep studies (± referral to an appropriately trained and credentialled medical practitioner ± Level 1 study) as, or more, effective than referral to a sleep physician ± Level 1 study at improving the health outcomes of adults with suspected OSA?

Direct evidence of the effectiveness of unattended sleep studies in the diagnosis of adult OSA in a non-specialised unit setting was reported by two case series of poor quality (level IV interventional evidence) (Eskafi et al 2006; Patel & Davidson 2007).

Both of these studies investigated Level 3 sleep devices in patients with stable heart failure and suspected OSA. Treatment after the diagnosis of OSA with these unattended sleep studies included CPAP, MAD and palatal implant. Patients' sleep-apnoea-related symptoms, such as snoring and excessive daytime sleepiness, were reduced after treatment. In addition, patients had higher sleep quality and their comorbidities, eg hypertension, were better controlled. However, patients' health-related QoL was not improved by the diagnosis and treatment of OSA, and it is unknown whether the Level 3 study would perform as well as a Level 1 study.

Linked evidence

Summary — In adults with suspected OSA, are Level 3 and/or 4 unattended sleep studies as accurate as Level 1 laboratory-based (attended) sleep studies at diagnosing OSA?

Eleven studies met the inclusion criteria for this review and provided evidence on the accuracy of unattended sleep studies in the diagnosis of adult OSA in a non-specialised unit setting. The Level 3 or Level 4 sleep studies were investigated in a variety of study

populations, including patients with suspected OSA based on their clinical symptoms, and those with comorbid stable heart failure, a cardiac pacemaker or acromegaly. There were seven moderate- or good-quality studies comparing unattended sleep studies with laboratory-based PSG (level III-1 or III-2 diagnostic evidence). Also included in this assessment were four case series that reported diagnostic yield from unattended sleep studies (level IV diagnostic evidence).

A moderate-quality study by Quintana-Gallego et al (2004) reported that the AUC values for a Level 3 portable monitor, Apnoescreen II, were 0.896, 0.907 and 0.862 at PSG AHI thresholds of 5, 10 and 15, respectively. The corresponding sensitivity and specificity of this device in the diagnosis of OSA were 82.5% and 88.6% at AHI ≥5, 79.3% and 97.8% at AHI ≥10, and 68.4% and 94.6% at AHI ≥15, respectively. Other Level 3 devices, such as Stardust II, Embletta and the LifeShirt system, were examined in three studies, with test sensitivity and specificity ranging between 25.0% and 100% at different thresholds for RDI/AHI (Carter et al 2004; Smith et al 2007; Yin et al 2006). The PPV and NPV for Level 3 portable monitors ranged from 76.0% to 100% and from 60.0% to 100%, respectively, in patients with suspected OSA. In patients with stable heart failure, both the PPV (70.0% to 75.0%) and the NPV (43.8% to 50.0%) were lower than those in patients with symptoms suggestive of OSA. A large difference in both LR+ (1 to infinity) and LR– (0 to 0.9) was observed among various RDI/AHI cut-off points and across different studies. Yin et al (2006) observed a mean difference of 3.7±13.1 in RDI/AHI between Stardust II and laboratory-based PSG, with agreement limits of between –22.5 and 29.9, which is unacceptable in diagnosing mild to moderate OSA. The agreement between another Level 3 portable monitor, Embletta, and the reference standard was also poor, with a Kappa coefficient of 0.27 (p=0.06) (Smith et al 2007). However, a high level of agreement in the diagnosis of OSA was suggested between the home-based LifeShirt system study and laboratory-based PSG (ρ=0.97, p<0.05) (Carter et al 2004), albeit the study sample was small (n=10).

The performance of Level 4 sleep studies in the diagnosis of OSA on four portable monitors, SleepStrip, Pulsox-M24, Stardust® Sleep Recorder and ClearPath System Nx-301, were evaluated by three studies (Abraham et al 2006; Gergely et al 2009; Sériès et al 2005). The sensitivity and specificity of these Level 4 devices ranged from 39.3% to 84.8% and from 73.1% to 100%, respectively, at PSG AHI cut-off points of 5, 10, 15, 20, 25 and 40. PPV of 69.6% to 100% and NPV of 53.3% to 80.0% were reported by these studies. The ranges of LR+ and LR– were from 2.7 to 11.9 and from 0.2 to 0.6, respectively. A moderate overall agreement was suggested between the home-based SleepStrip and laboratory-based PSG (k=0.457, p<0.01) and between unattended Pulsox-M24 and attended PSG (k=0.509, p<0.01) (Gergely et al 2009). The mean difference between ODIs from Stardust® Sleep Recorder and PSG AHIs were reported as –6.4, with agreement limits –25 to 15, suggesting that the use of this Level 4 study could result in inappropriate diagnosis and treatment.

Summary — Does the use of Level 3 and/or 4 unattended sleep studies (± referral to an appropriately trained and credentialled medical practitioner ± Level 1 study) in the diagnosis of adult OSA impact on patient management differently compared with the referral of a patient to a sleep physician ± the use of a Level 1 laboratory-based (attended) sleep study?

Two case series that reported a change in patient management following diagnosis of adult OSA using unattended sleep studies in a non-specialised unit setting were identified. In

West et al's (2001) poor-quality study, 81 out of 100 patients with suspected OSA received home-based oximetry. Forty-nine patients (60.5%) were referred to a respiratory physician and underwent a trial of CPAP, based on ODI >20. The mean length of period between unattended oximetry study and CPAP trial was around 3 months. Another 31 (38.3%) patients were followed up in a primary healthcare setting. ENT referral was recommended to a total of six patients (7.4%), including one with a normal oximetry result, three after a trial of CPAP and two during follow-up by a general practitioner. The average waiting time from Level 4 sleep study to ENT outpatient appointment was around 4 months. No data were available comparing Level 3 or 4 unattended sleep studies with referral to a specialist with or without testing with an attended Level 1 sleep study.

Martinez et al (2005), in his retrospective case series of moderate quality, determined that not all patients with abnormal results on a Level 4 study were referred, while nearly one-quarter of patients with normal results were still referred. They also observed that there was half the rate of additional PSG testing in those with a normal (14%), as opposed to abnormal (28%), result from a Level 4 sleep study. CPAP was prescribed to all patients with severe OSA, whereas positional therapy was the major treatment for mild OSA.

Diagnosis in a referral setting

Is it safe?

Studies were included to assess the safety of unattended sleep studies in a referral setting according to the criteria outlined in Box 6.

Box 6 Criteria for selecting studies to assess the safety of unattended sleep studies in a referral setting

Selection criteria	Inclusion criteria
Population	Adults with suspected OSA[a] and referred to a specialist – Subgroups: age range, BMI range, comorbid conditions (eg COPD, depressive symptoms, diabetes, CVD, GERD), occupation
Index test / intervention	*Level 2* unattended sleep study / polysomnography that includes assessments of: sleep staging (EEG), detection of airflow, respiratory movement, arterial oxygen saturation, electrocardiogram (ECG), and subsequent data analysis and interpretation OR *Level 3* unattended sleep study involving the assessment of two or more cardiopulmonary parameters (eg detection of airflow, respiratory movement, arterial oxygen saturation, ECG), and subsequent data analysis and interpretation by an appropriately trained and credentialed medical practitioner *OR* *Level 4* unattended sleep study involving the assessment of one cardiopulmonary parameter (usually oximetry), and subsequent data analysis and interpretation by an appropriately trained and credentialed medical practitioner ± *Level 1 study*
Comparator(s)	*Level 1* laboratory-based, overnight, attended (by sleep technician) sleep study / polysomnography that includes assessments of: sleep staging (EEG, EOG, EMG), detection of airflow (quantitative or semi-quantitative nasal transducers), respiratory movement (via transducers on chest or abdominal walls, or via RIP), arterial oxygen saturation (via a pulse oximeter), ECG, leg movement, snoring, body positioning, and subsequent data analysis and interpretation
Outcomes	Physical harms from testing, eg allergy to electrode adhesive
Publication type	Randomised or non-randomised controlled trials, cohort studies, registers, case series, case reports or systematic reviews of these study designs. Non-systematic reviews, non-research letters, editorials; and animal, in-vitro and laboratory studies, were excluded.
Search period	1980 – April 2009
Language	Non-English language articles were excluded unless they provided a higher level of evidence than the English language articles identified

[a] Suspected on the basis of snoring/gasping/choking while asleep, excessive daytime sleepiness, witnessed apnoea, nocturia

BMI = body mass index; COPD = chronic obstructive pulmonary disease; CVD = cardiovascular disease such as hypertension, coronary artery disease, ischaemic heart disease; ECG = electrocardiogram; EEG = electroencephalogram; EMG = electromyogram; EOG = electrooculogram; GERD = gastro-oesophageal reflux disease; OSA = obstructive sleep apnoea; RIP = respiratory inductive plethysmography

There were no studies that met the selection criteria that reported safety outcomes concerning unattended sleep studies in a referral setting.

An examination of possible adverse consequences associated with unattended sleep studies in adults, such as the psychological and physical harms caused by a false positive result and subsequent unnecessary treatment, is provided in the 'Discussion' section of the report (see page 152).

Summary — Are Level 2, 3 or 4 unattended sleep studies (± Level 1 studies) as safe as, or safer than, Level 1 laboratory-based (attended) sleep studies alone for adults with suspected OSA referred to a specialist?

No studies were identified that could inform an assessment of the safety of unattended sleep studies to diagnose OSA in adults referred to a specialist.

Is it effective?

Direct evidence

In this assessment report direct evidence is used to evaluate whether there is a change to patient health outcomes following the use of unattended sleep studies in adult patients suspected of OSA in a referral setting. The selection criteria to identify this evidence are outlined in Box 7.

Box 7 Criteria for selecting studies to assess the diagnostic effectiveness of unattended sleep studies in a referral setting

Selection criteria	Inclusion criteria
Population	Adults with suspected OSA[a] and referred to a specialist – Subgroups: age range, BMI range, comorbid conditions (eg COPD, depressive symptoms, diabetes, CVD, GERD), occupation
Index test / intervention	*Level 2* unattended sleep study / polysomnography that includes assessments of: sleep staging (EEG), detection of airflow, respiratory movement, arterial oxygen saturation, electrocardiogram (ECG), and subsequent data analysis and interpretation by an appropriately trained and credentialed medical practitioner OR *Level 3* unattended sleep study involving the assessment of two or more cardiopulmonary parameters (eg detection of airflow, respiratory movement, arterial oxygen saturation, ECG), and subsequent data analysis and interpretation by an appropriately trained and credentialed medical practitioner *OR* *Level 4* unattended sleep study involving the assessment of one cardiopulmonary parameter (usually oximetry), and subsequent data analysis and interpretation by an appropriately trained and credentialed medical practitioner ± *Level 1 study*
Comparator(s)	*Level 1* laboratory-based, overnight, attended (by sleep technician) sleep study / polysomnography that includes assessments of: sleep staging (EEG, EOG, EMG), detection of airflow (quantitative or semi-quantitative nasal transducers), respiratory movement (via transducers on chest or abdominal walls, or via RIP), arterial oxygen saturation (via a pulse oximeter), ECG, leg movement, snoring, body positioning, and subsequent data analysis and interpretation
Outcomes	Primary: 1) *patient-relevant*: survival/mortality rate, resolution/reduction of symptoms (eg snoring, excessive daytime sleepiness, witnessed apnoea episodes), disease-specific quality of life; 2) *surrogate*: respiratory events / number of apnoeas or hypopnoeas (eg AHI, RDI), oxygen saturation (eg ODI), sleep time and efficiency (eg sleep stage duration/quality, ArI) Secondary: additional sleep studies (by type), referral to sleep physician / qualified sleep medicine practitioner, time to diagnosis, time to commencement of treatment, treatment type
Publication type	Randomised or non-randomised controlled trials or cohort studies or uncontrolled pre-test/post-test case series or systematic reviews of these study designs. Non-systematic reviews, letters, editorials; and animal, in-vitro and laboratory studies, were excluded.
Search period	1980 – April 2009
Language	Non-English language articles were excluded unless they provided a higher level of evidence than the English language articles identified

[a] Suspected on the basis of snoring, behavioural change, learning difficulties, secondary enuresis

AHI = apnoea–hypopnoea index; ArI = arousal index; BMI = body mass index; COPD = chronic obstructive pulmonary disease; CVD = cardiovascular disease such as hypertension, coronary artery disease, ischaemic heart disease; ECG = electrocardiogram; EEG = electroencephalogram; EMG = electromyogram; EOG = electrooculogram; GERD = gastro-oesophageal reflux disease; ODI = oxygen desaturation index; OSA = obstructive sleep apnoea; RDI = respiratory disturbance index; RIP = respiratory inductive plethysmography

Primary effectiveness outcomes

Evidence of a change in the symptoms, QoL and number of respiratory events in adult patients with OSA, diagnosed using unattended sleep studies in a referral setting, was reported by eight studies: one randomised controlled trial (RCT) (level II interventional evidence) (Whitelaw et al 2005), two cohort studies (level III-2 interventional evidence) (Berry et al 2008; White & Gibb 1998) and five case series (level IV interventional evidence) (Antic et al 2009; Coppola & Lawee 1993; Fletcher et al 2000; Nader et al 2006; Tomlinson & John Gibson 2006).

In Whitelaw et al's (2005) RCT of poor quality, a total of 307 patients who were referred to a sleep centre for suspicion of symptomatic OSA were randomised to receive a Level 4 home-based SnoreSat study (intervention group) or a laboratory-based PSG (control group). Nineteen patients (6.2%) refused to receive a sleep study or withdrew from the trial after learning the results from the sleep study. Of the remaining 288 patients, 156 underwent the Level 4 sleep study and 132 had laboratory-based PSG. Patients in the intervention group and those in the control group had comparable mean ages (46.9 years in both groups), average BMIs (31.8 kg/m^2 vs 32.1 kg/m^2), mean neck circumferences (40.9 cm vs 41.0 cm), mean baseline ESS scores (11.6 in both groups), mean baseline Sleep Apnea Quality of Life Index (SAQLI) [14] scores (4.02 vs 4.17) and mean baseline scores on the MOS 36-item Short-Form (SF-36) Health Survey[15] domains (SF-36 Vitality: 37.1 vs 39.0; SF-36 Mental health: 68.8 vs 70.0). APAP treatment was prescribed to patients in both groups. Patients' health outcomes were measured 4 weeks after the treatment.

In Berry et al's (2008) cohort of 106 patients at high risk of moderate to severe OSA, subjects were initially randomised to receive a Level 4 home-based Watch_PAT100 study or a laboratory-based PSG. OSA diagnosis was established when peripheral arterial tone (PAT) index or AHI ≥5. Six patients with negative PSG results transferred to the unattended sleep study group for confirmation of absence of OSA, while four patients with PAT index <5 received additional PSG to rule out OSA. Patients were either treated by APAP (home-based titration) for OSA, diagnosed with the aid of the unattended Watch_PAT100 study, or managed with CPAP (laboratory-based titration) at PSG AHI ≥5. A comparison of patient outcomes was performed at 6 weeks after the treatment between the APAP group (n=40) and the CPAP group (n=39). Patients in the two groups were matched for demographic parameters, such as gender, age, BMI and baseline ESS score.

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[14] The SAQLI is a QoL instrument that measures sleep-apnoea-specific impairment on four dimensions: daily functioning, social interactions, emotional functioning and symptoms. It is composed of 35 questions, with a scale ranging from 1 (maximal impairment) to 7 (no impairment) on each question. The dimension score is averaged over questions in each dimension. A total SAQLI score is the average score across four dimensions. A high score indicates poor QoL. A fifth dimension, treatment-related symptoms, can be included in the SAQLI to record possible adverse events from the sleep apnoea treatment (Flemons & Reimer 2002).

[15] The SF-36 Health Survey is a self-administered questionnaire that measures generic health status on eight domains: vitality, mental health, pain, physical functioning, social functioning, role limitations (physical problems), role limitations (emotional problems), and general health perception and health change. It consists of 36 multi-scale (2-scale, 3-scale or 6-scale) items. The item scores on each domain are coded, added and transformed to a 0 (worst health) to 100 (best health) scale (Brazier et al 1992).

Another moderate-quality observational cohort study by White and Gibb involved 30 patients who had positive results using a Level 2 home-based Healthdyne NightWatch System™ study (NightWatch AHI >30) and were treated by APAP (home-based titration). An additional 30 patients received CPAP (laboratory-based titration) treatment for severe OSA, diagnosed with the aid of attended PSG (PSG AHI >30). The two groups were similar in gender, age, neck size and, in most cases, BMI. The sleep study (unattended or attended) was repeated at 6–8 weeks after the treatment to evaluate the treatment efficacy.

In the five moderate-quality case series that provided direct evidence of the effectiveness of unattended sleep studies in a referral setting, patients were diagnosed with OSA by Level 3 or Level 4 sleep studies and treated by home-based-titration CPAP or laboratory-based-titration CPAP for a certain period (2 weeks to 3 months). Three case series had sample sizes of more than 100 subjects, whereas the other two reported the health outcomes in relatively small populations of no more than 30 patients.

Change in symptoms

Evidence of a change in symptoms in patients at risk of (predominantly) moderate to severe OSA was reported in six of these studies (Table 15). Symptoms were either measured using various questionnaires/tests (eg the ESS, the Cleveland Questionnaire[16] and the Maintenance of Wakefulness Test (MWT)[17]) or reported by patients' bed partners.

In Whitelaw et al's (2005) RCT, excessive daytime sleepiness was improved after the diagnosis of OSA by the Level 4 home-based SnoreSat study and following 4-week APAP treatment, with scores on the ESS reducing by an average of 3.4 points (from 11.6 to 8.2). This figure was not different from the mean ESS decrease of 3.4 in the group of patients who had their diagnosis of OSA confirmed by laboratory-based PSG and who likewise underwent APAP treatment for 4 weeks (p=0.27). Similar results were reported by Berry et al (2008). In this cohort study of poor quality, the mean changes in ESS scores were –6.5 in the intervention group (Level 4 home-based Watch_PAT100 study + APAP treatment) and –7.0 in the control group (laboratory-based PSG + CPAP treatment), with no statistically or clinically important difference between the two groups (p>0.05). Both of the above studies indicated that OSA patients' symptoms were controlled regardless of whether they had been diagnosed by unattended sleep studies or through laboratory-based PSG. The two types of test appeared to be equally effective in those patients referred to a specialist with suspicion of symptomatic or clinically important OSA.

Of the remaining four case series of moderate quality, three demonstrated a beneficial impact of home-based sleep studies on patients' symptoms, such as excessive daytime

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[16] The Cleveland Questionnaire is an instrument measuring daytime sleepiness in patients, especially adolescents, with OSA. It consists of 16 items, with a score ranging from 1 to 5 on each item. A higher Cleveland Questionnaire score suggests more severe daytime sleepiness (Kump et al 1994).

[17] The MWT is a test to evaluate excessive daytime sleepiness/wakefulness. It assesses how well a subject is able to stay awake while resisting the stress to fall asleep in a somnolent setting. The MWT is used clinically to examine the response to treatment for patients with disorders that cause daytime sleepiness, and is also helpful in judging whether subjects have the ability to stay awake for safety or for employment purposes. A longer period of sleep latency in MWT suggests less daytime sleepiness (Banks et al 2004).

sleepiness and snoring (Coppola & Lawee 1993; Fletcher et al 2000; Tomlinson & John Gibson 2006). The case series by Antic et al (2009) was the only study that was carried out in an Australian setting. In this series of 195 patients with ODI greater than 27 on a Level 4 home-based Masimo Radical Oximeter, all subjects either underwent 3 months of APAP (home-based titration) treatment (nurse-led care) or received additional laboratory-based PSG and 3 months of CPAP (laboratory-based titration) treatment (physician-directed care). It was determined that there was no difference between the nurse-led-care pathway and the physician-directed-care pathway in terms of a change in patients' ESS scores (mean change in the nurse-led-care group 4.0 ± 4.9 vs mean change in the physician-directed-care group 4.2±4.3). The MWT revealed an increase in the sleep latency time after the home-based sleep study plus APAP treatment (mean change 30.2 ± 10.0 minutes) and after the unattended sleep study plus additional attended PSG plus CPAP treatment (mean change 31.7±8.4 minutes), although no statistically significant or clinically important difference between the two groups (mean difference: –1.5 minutes, 95% CI –4.8 minutes, 1.8 minutes). A comparison of the ESS and MWT results between the two models of care suggested that the use of laboratory-based PSG as a supplementary test in the diagnosis of OSA did not influence the impact of unattended sleep studies on patients' symptom control.

Table 15 Change in symptoms after diagnosis of OSA using unattended sleep studies and subsequent treatment in a referral setting

Study	Evidence level and quality	Population	Index test / comparator + treatment	Respiratory event definition	Symptom measure
Level 3 sleep study					
(Tomlinson & John Gibson 2006)	Retrospective case series Level IV interventional evidence CX, P1 Q2 [NHS CRD: 4/6]	118 patients with OSA (RDI ≥5)	Home-based AutoSet Portable II Plus + CPAP	Apnoea: no airflow, ≥10 s Hypopnoea: ↓ airflow >50%	ESS score[a]: Baseline: mean = 15.4 (range: 6–24) 2 weeks after treatment: mean = 5.9 (range: 0–16) Mean change: –9.5 (p<0.0001) 3 months after treatment: mean = 5.5 (range: 1–12) Mean change: –9.9 (p<0.0001)
(Coppola & Lawee 1993)	Retrospective case series Level IV interventional evidence CX, P1 Q2 [NHS CRD: 4/6]	11 patients with moderate to severe OSA (RDI ≥20)	Home-based Edentrace Recording System + APAP	Not reported	Cessation of snoring (reported by bed partners): Post-treatment: 10/10 (100%)
Level 4 sleep study					
(Whitelaw et al 2005)	Randomised controlled trial Level II interventional	156 patients with suspected OSA	Home-based SnoreSat + APAP	Oxygen desaturation ≥4%, ≥10 s	ESS score[a]: Baseline: mean = 11.6±4.4 4 weeks after treatment: mean = 8.2 Mean change: –3.4

Study	Evidence level and quality	Population	Index test / comparator + treatment	Respiratory event definition	Symptom measure
	evidence C1, P1 Q3 [NHMRC: 1/3]	132 patients with suspected OSA	Laboratory-based PSG + APAP	Apnoea: no airflow, ≥10 s Hypopnoea: ↓ respiratory movement >30%, ≥10 s, associated with oxygen desaturation ≥4%	ESS score[a]: Baseline: mean = 11.6±4.8 (p=1.00 between the two groups) 4 weeks after treatment: mean = 7.6 Mean change: –4 (p=0.27 between the two groups)
(Berry et al 2008)	Prospective cohort study Level III-2 interventional evidence C1, P1 Q3 [NHMRC: 3.5/6]	40 patients with high risk of moderate to severe OSA	Home-based Watch_PAT 100 + APAP	↓ PAT accompanied by ↑heart rate and changes in oxygen saturation (using a specific algorithm)	ESS score[a]: Baseline: mean = 16.4±4.4 6 weeks after treatment: mean = 9.9 Mean change: –6.5±4.9
		39 patients with high risk of moderate to severe OSA	Laboratory-based PSG + CPAP	Apnoea: no airflow, ≥10 s Hypopnoea: ↓ airflow, accompanied by arousal or ↓ oxygen saturation ≥3%	ESS score[a]: Baseline: 16.6±3.7 (p>0.05 between the two groups) 6 weeks after treatment: mean = 9.6 Mean change: –7.0 ±4.6 (p>0.05 between the two groups)
(Antic et al 2009)	Prospective case series Level IV interventional evidence CX, P1 Q2 [NHS CRD: 4.5/6]	100 patients with moderate to severe OSA (ODI >27)	Home-based Masimo Radical Oximeter + APAP	Oxygen desaturation >2%	ESS score[a] (n=90): Mean change (3 months after treatment): 4.0±4.9 MWT score (n=65): Mean change (3 months after treatment): 30.2±10.0 minutes
		95 patients with moderate to severe OSA (ODI >27)	Home-based Masimo Radical oximeter + Laboratory-based PSG + CPAP	Oxygen desaturation >2%	ESS score[a] (n=84): Mean change (3 months after treatment): 4.2±4.3 Mean difference between the two groups [95% CI]: –0.1 [–1.5, 1.3] MWT[b] (n=61): Mean change (3 months after treatment): 31.7±8.4 minutes Mean difference between the two groups [95% CI]: –1.5 minutes [–4.8 minutes, 1.8 minutes]
(Fletcher et al 2000)	Prospective case series Level IV interventional evidence CX, P1 Q2 [NHS CRD: 4/6]	30[c]/63 with suspected OSA	Home-based CPAP nasal mask + APAP	Apnoea: ↓ airflow >85%, ≥10 s Hypopnoea: ↓ airflow >40%	ESS score[a]: Baseline: mean = 16.8±0.6 3 weeks after treatment: mean = 10.5±0.9 Mean change: –6.3 (p<0.01) Cleveland Questionnaire score[d]: Baseline: mean = 39.5 ±1.6 3 weeks after treatment: mean = 24.3±1.6 Mean change: –15.2 (p<0.01)

Note: Results presented as mean ± SD

[a] ESS score ranges from 0 to 24. A higher ESS score indicates more daytime sleepiness; [b] A longer period of latency in MWT indicates less daytime sleepiness; [c] OSA patients, diagnosed with the aid of unattended sleep study, who were treated by APAP longer than 3 months; [d] Cleveland Questionnaire score ranges from 16 to 80. A higher score indicates more daytime sleepiness.

CI = confidence interval; CPAP = continuous positive airway pressure; ESS = Epworth Sleepiness Scale; MWT = Maintenance of Wakefulness Test; ODI = oxygen desaturation index; OSA = obstructive sleep apnoea; PAT = peripheral arterial tone; PSG = polysomnography; RDI = respiratory disturbance index; s = seconds.

Change in QoL

Three studies, including one RCT, one cohort study and one case series, were identified that reported a change in patient's QoL resulting from the diagnosis of OSA (Table 16). Various instruments were used by these studies to measure QoL, including the SAQLI, SF-36, Functional Outcomes of Sleep Questionnaire (FOSQ)[18] and Executive Maze Task[19].

In the RCT by Whitelaw et al (2005) less severe sleep-apnoea-specific impairment on patients' QoL was observed after the home-based SnoreSat study and 4-week APAP treatment, with a mean increase in SAQLI score of 0.82. In addition, the higher post-treatment scores on various SF-36 domains suggested that patients had better general QoL after the diagnosis of OSA. The increasing scores on the SAQLI and the SF-36 in the intervention group were not significantly different from those in the control group ($p>0.05$), which indicated that the home-based sleep study was as good as the laboratory-based PSG at improving patients' QoL. This conclusion was confirmed by Berry et al's (2008) cohort study, in which patients' everyday activities were less impaired by excessive sleepiness (higher FOSQ scores were reported) after the unattended sleep study or the laboratory-based PSG. No statistically significant or clinically important difference in the mean increase of FOSQ score was discovered between the intervention group (home-based Watch_PAT100 + APAP) and the control group (laboratory-based PSG + CPAP) (3.1 vs 3.3, $p>0.05$).

In a lower level study by Antic et al (2009), there was no beneficial effect of diagnosis with the home-based Masimo Radical Oximeter and subsequent APAP on patients' QoL, as measured by FOSQ, SF-36 and Executive Maze Task, in either of the nurse-led or physician-directed clinical pathways. The use of attended PSG and laboratory-based CPAP titration after the home-based sleep study did not yield any better results on patients' QoL when compared with the unattended oximetry study and home-based CPAP titration (95% CIs of the mean differences between the two clinical pathways included 0 for all three QoL measures).

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[18] The FOSQ is a specific self-reported questionnaire to assess functional impairment in patients with sleep disorders. It is composed of 35 items within five domains: activity level, vigilance, general productivity, intimacy and sexual relationships, and social outcome. Subjects are required to rate their difficulty in performing a given activity on a 4-point scale (from extreme difficulty to no difficulty). The mean-weighted item score for each domain ranges from 0 to 4. The total FOSQ scores are the sum of the scores from various domains. Higher FOSQ scores suggest less severe functional impairment (Weaver et al 1997).

[19] The Executive Maze Task is an instrument to test subjects' executive neurocognitive function. It provides a profile of five domains: sensory-motor, attention, memory, language and executive function. In this test the numbers of maze tasks (Integneuro test battery) successfully completed and maze errors made in an 8-minute period are calculated. More completed maze tasks and fewer errors indicate better neurocognitive function (Antic et al 2009).

Table 16 Change in quality of life after diagnosis of OSA using unattended sleep studies and subsequent treatment in a referral setting

Study	Evidence level and quality	Population	Index test / comparator + treatment	Respiratory event definition	Quality of life measure
Level 4 sleep study					
(Whitelaw et al 2005)	Randomised controlled trial Level II interventional evidence C1, P1 Q3 [NHMRC: 1/3]	156 patients with suspected OSA	Home-based SnoreSat + APAP	Oxygen desaturation ≥4%, ≥10 s	SAQLI score[a]: Mean change (4 weeks after treatment): 0.82 SF-36 score[b]: Increases in scores on SF-36 domains between the two groups: p>0.05
		132 patients with suspected OSA	Laboratory-based PSG + APAP	Apnoea: no airflow, ≥10 s Hypopnoea: ↓ respiratory movement >30%, ≥10 s, associated with oxygen desaturation ≥4%	SAQLI score[a]: Mean change (4 weeks after treatment): 0.92 (p=0.50 between the two groups) SF-36 score[b]: Increases in scores on SF-36 domains between the two groups: p>0.05
(Berry et al 2008)	Prospective cohort study Level III-2 interventional evidence C1, P1 Q3 [NHMRC: 3.5/6]	40 patients with high risk of moderate to severe OSA	Home-based Watch_PAT 100 + APAP	↓ PAT accompanied by ↑ heart rate and changes in oxygen saturation (using a specific algorithm)	FOSQ score[c]: Mean change (6 weeks after treatment): 3.1±0.3
		39 patients with high risk of moderate to severe OSA	Laboratory-based PSG + CPAP	Apnoea: no airflow, ≥10 s Hypopnoea: ↓ airflow, accompanied by arousal or ↓ oxygen saturation ≥3%	FOSQ score[c]: Mean change (6 weeks after treatment): 3.3±3.2 (p>0.05 between the two groups)
(Antic et al 2009)	Prospective case series Level IV intervention evidence CX, P1 Q2 [NHS CRD: 4.5/6]	100 patients with moderate to severe OSA (ODI >27)	Home-based Masimo Radical Oximeter + APAP	Oxygen desaturation >2%	FOSQ score[c] (n=89): Mean change (3 months after treatment): –13.6±19.1 SF-36 Vitality score[b] (n=89): Mean change (3 months after treatment): –16.1±20.5 SF-36 Mental Health score[b] (n=89): Mean change (3 months after treatment): –4.8±13.8 Executive Maze Task[d] (n=73): Successfully completed maze task: Mean change (3 months after treatment): –2.1±5.2 Errors made: Mean change (3 months after treatment): –17.6±39.6
		95 patients with	Home-based Masimo	Oxygen desaturation	FOSQ change[c] (n=81): Mean change (3 months after

Study	Evidence level and quality	Population	Index test / comparator + treatment	Respiratory event definition	Quality of life measure
		moderate to severe OSA (ODI >27)	Radical oximeter + Laboratory-based PSG + CPAP	>2%	treatment): –13.2±17.6 Mean difference between the two groups [95% CI]: –0.4 [–6.0, 5.2] SF-36 Vitality score[b] (n=81): Mean change (3 months after treatment): –15.3±18.5 Mean difference between the two groups [95% CI]: –0.8 [–6.8, 5.1] SF-36 Mental Health score[b] (n=81): Mean change (3 months after treatment): –5.1±19.0 Mean difference between the two groups [95% CI]: 0.3 [–4.7, 5.3] Executive Maze Task[d] (n=68): Successfully completed maze task: Mean change (3 months after treatment): –1.2±4.6 Mean difference between the two groups [95% CI]: –0.9 [–2.6, 0.7] Errors made: Mean change (3 months after treatment): –16.9±50.1 Mean difference between the two groups [95% CI]: –0.7 [–15.7, 14.3]

Note: Results presented as mean ± SD

[a] SAQLI score ranges from 1 to 7. A higher SAQLI score indicates less apnoea-specific impairment; [b] SF-36 score ranges from 0 to 100. A higher SF-36 score indicates better generic health status; [c] FOSQ score ranges from 0 to 20. A higher FOSQ score indicates less severe functional impairment in patients with sleep disorders; [d] More completed maze tasks and fewer errors indicate better neurocognitive function.

CI = confidence interval; CPAP = continuous positive airway pressure; FOSQ = Functional Outcomes of Sleep Questionnaire; ODI = oxygen desaturation index; OSA = obstructive sleep apnoea; PAT = peripheral arterial tone; PSG = polysomnography; s = seconds; SAQLI = Sleep Apnea Quality of Life Index; SF-36 = Short-form 36 Health Survey

Change in respiratory events

Data on the change in the number of respiratory events after diagnosis of OSA using unattended sleep studies and with subsequent treatment were provided by six studies (Table 17).

The RCT by Whitelaw et al (2005) and the two cohort studies by White and Gibb (1998) and Berry et al (2008) demonstrated that diagnosis of OSA with the aid of home-based sleep studies and subsequent CPAP treatment resulted in substantially fewer apnoea/hypopnoea episodes, with a reduction in the number of respiratory events per hour ranging from 12.4 to 60.1. This reduction is clinically meaningful. The extent of the reduction margin depended on the baseline AHI/ODI/PAT index—no matter how severe the patients' OSA was at diagnosis, the AHI/ODI/PAT index decreased uniformly to less than 7.5 after treatment. In the two cohort studies the mean changes in AHI/PAT index were not significantly different between the home-based sleep study groups and the laboratory-based PSG groups. However, in Whitelaw et al's RCT, the AHI decrease of 20.3 in the PSG group was significantly greater than the ODI reduction of 12.4 in the home-based SnoreSat group. This difference was attributable to the higher

baseline AHI in the control group (mean AHI 26.0) than the ODI in the intervention group (mean = 16.6, p<0.05). Given the size of the trial, it is unusual that randomisation did not guarantee equal distribution of confounding factors (such as baseline AHI) between trial arms. Lack of concealment of allocation may have been a factor. The post-treatment AHI/ODI did not differ between the two groups (5.7 vs 4.2, p=0.06).

The impact of unattended sleep studies and subsequent CPAP treatment on reducing patients' respiratory events was also reported in three case series (Coppola & Lawee 1993; Fletcher et al 2000; Nader et al 2006).

Table 17 Change in respiratory events after diagnosis of OSA using unattended sleep studies and subsequent treatment in a referral setting

Study	Evidence level and quality	Population	Index test / comparator + treatment	Respiratory event definition	Respiratory event /hour
Level 2 sleep study					
(White & Gibb 1998)	Prospective cohort study Level III-2 interventional evidence C1, P1 Q2 [NHMRC: 4/6]	30 patients with severe OSA (AHI >30)	Home-based NightWatch System™ + APAP	Apnoea: no airflow, ≥10 s Hypopnoea: ↓ airflow >50%, associated with oxygen desaturation >4% or arousal	AHI: Baseline: mean = 67.5±27.9 6–8 weeks after treatment: mean = 7.4±7.7 Mean change: –60.1
		30 patients with severe OSA (AHI >30)	Laboratory-based PSG + CPAP	Apnoea: no airflow, ≥10 s Hypopnoea: ↓ airflow >50%, associated with oxygen desaturation >4% or arousal	AHI: Baseline: mean = 66.8±27.4 (p=0.922 between the two groups) 6–8 weeks after treatment: mean = 7.6±7.7 (p=0.948 between the two groups) Mean change: –59.2
Level 3 sleep study					
(Coppola & Lawee 1993)	Retrospective case series Level IV interventional evidence CX, P1 Q2 [NHS CRD: 4/6]	11 patients with moderate to severe OSA (RDI ≥20)	Home-based Edentrace Recording System + CPAP	Not reported	RDI: Baseline: mean = 40.9±17.5 Post-treatment: mean = 2.4±1.7 Mean change: –38.5 (p<0.01)
Level 4 sleep study					
(Whitelaw et al 2005)	Randomised controlled trial Level II interventional evidence C1, P1 Q3 [NHMRC: 1/3]	156 patients with suspected OSA	Home-based SnoreSat + APAP	Oxygen desaturation ≥4%, ≥10 s	ODI: Baseline: mean = 16.6 4 weeks after treatment: mean = 4.2 Mean change: –12.4
		132 patients with suspected OSA	Laboratory-based PSG + APAP	Apnoea: no airflow, ≥10 s Hypopnoea: ↓ respiratory movement >30%, ≥10 s, associated with oxygen desaturation ≥4%	AHI: Baseline: mean = 26.0 (p<0.05 between the two groups) 4 weeks after treatment: mean = 5.7 (p=0.06 between the two groups) Mean change: –20.3

Study	Evidence level and quality	Population	Index test / comparator + treatment	Respiratory event definition	Respiratory event /hour
(Berry et al 2008)	Prospective cohort study Level III-2 interventional evidence C1, P1 Q3 [NHMRC: 3.5/6]	40 patients with high risk of moderate to severe OSA	Home-based Watch_PAT100 + APAP	↓ PAT accompanied by ↑ heart rate and changes in oxygen saturation (using a specific algorithm)	PAT index: Baseline: mean = 33.3±24.0 6 weeks after treatment: mean = 3.5±1.9 Mean change: –29.8
		39 patients with high risk of moderate to severe OSA	Laboratory-based PSG + CPAP	Apnoea: no airflow, ≥10 s Hypopnoea: ↓ airflow, accompanied by arousal or ↓ oxygen saturation ≥3%	AHI: Baseline: mean = 39.8±28.7 (p>0.05 between the two groups) 6 weeks after treatment: mean = 5.3±4.4 (p >0.05 between the two groups) Mean change: –34.5
(Nader et al 2006)	Retrospective case series Level IV interventional evidence CX, P1 Q2 [NHS CRD: 4/6]	62 patients with OSA (ODI ≥10)	Hospital-based portable pulse oximetry +APAP	Oxygen saturation <90%, and/ or oxygen desaturation ≥3%, ≥10 s	ODI: Baseline: 30.7 ±14.2 After treatment: 12.5 ±9.4 Mean change: –18.2 (p<0.001)
(Fletcher et al 2000)	Prospective case series Level IV interventional evidence CX, P1 Q2 [NHS CRD: 4/6]	30[a] /63 patients with suspected OSA	Home-based CPAP nasal mask +APAP	Apnoea: ↓ airflow >85%, ≥10 s Hypopnoea: ↓ airflow >40%	RDI (manual scoring): Baseline: 34.1±4.0 3 weeks after treatment: 8.6±0.8 Mean change: –25.5 (p<0.01) RDI (auto scoring) Baseline: 21.2±3.2 3 weeks after treatment: 6.0±0.6 Mean change: –15.2 (p<0.01)

Note: Results presented as mean ± SD

[a] OSA patients, diagnosed with the aid of unattended sleep study, who received APAP for longer than 3 weeks

AHI = apnoea–hypopnoea index; APAP = auto-adjusting positive airway pressure; CPAP = continuous positive airway pressure; ODI = oxygen desaturation index; OSA = obstructive sleep apnoea; PAT = peripheral arterial tone; RDI = respiratory disturbance index; s = seconds

Sleep time and efficiency

White and Gibb (1998) compared sleep variables in a cohort of 60 patients receiving either unattended sleep studies or laboratory-based PSG. In this study of moderate quality 30 patients were diagnosed as OSA by home-based NightWatch System™ and received APAP (home-based titration) treatment for 6–8 weeks; and another 30 patients with OSA confirmed by attended PSG underwent a laboratory-based CPAP titration trial and subsequent CPAP treatment. After treatment no statistically significant difference in any measure of sleep was observed between the two groups (Table 18). Given the small sample size, it is possible that clinically important differences may have occurred between the groups despite the lack of a statistically significant difference. The laboratory-based PSG group experienced approximately 20 minutes' extra sleep. With the expectation of sleep time, however, the differences between groups were minimal. Since the corresponding baseline sleep variables were not reported by the authors, the change in sleep time and efficiency after the diagnosis of OSA by the unattended sleep study or

laboratory-based PSG could not be determined. It is also unclear whether this was a factor that influenced the results.

Table 18 Sleep variables after diagnosis of OSA using an unattended sleep study and subsequent treatment in a referral setting

Item	Home-based NightWatch System™ + APAP	Laboratory-based PSG + CPAP	p-value
Sleep time	366.8±51.5 minutes	384.7±67.9 minutes	0.249
Sleep latency	7.5±9.3 minutes	10.8±10.4 minutes	0.216
Sleep efficiency	86.9±8.2%	84.9±10.4%	0.418
Sleep stage 1	10.1±5.5%	9.5±7.1%	0.706
Sleep stage 2	58.3±7.1%	58.0±11.0%	0.906
Sleep stage 3	5.8±3.3%	7.7±5.5%	0.202
Sleep stage 4	1.9±2.7%	3.7±5.5%	0.105
REM	23.8±7.1%	20.9±9.1%	0.179
REM latency	80.7±42.7 minutes	95.8±55.9 minutes	0.245

Source: White & Gibb (1998)

Note: Results presented as mean ± SD

CPAP = continuous positive airway pressure; REM = rapid eye movement

Secondary effectiveness outcomes

Secondary effectiveness outcomes, such as time to commencement of treatment and additional sleep studies, of unattended sleep studies in a referral setting were reported by one cohort study (level III-2 interventional evidence) (White & Gibb 1998) and one case series (level IV interventional evidence) (Fletcher et al 2000).

White and Gibb's (1998) cohort study reported no significant difference in the time to commencement of treatment between the home-based NightWatch System™ group and the laboratory-based PSG group, although a trend for less waiting time for APAP (home-based titration) treatment was observed in the unattended sleep study group (34.3 days vs 47.9 days, p=0.59). In Fletcher et al's (2000) case series of moderate quality, nine out of 63 (14.3%) patients who underwent a Level 4 sleep study did not have satisfactory home study results to establish or rule out a diagnosis of OSA. Of these nine patients, seven (11.1%) received additional laboratory-based PSG, and the other two refused to have further diagnostic testing.

Linked evidence

Linked evidence of diagnostic accuracy and change in management were assessed, due to insufficient direct evidence of a change in the health outcomes of patients diagnosed with OSA by unattended sleep studies in a referral setting. The criteria for selecting studies are outlined in Box 8 and Box 9.

Box 8 Criteria for selecting studies to assess the diagnostic accuracy of unattended sleep studies in a referral setting

Selection criteria	Inclusion criteria
Population	Adults with suspected OSA[a] and referred to a specialist – Subgroups: age range, BMI range, comorbid conditions (eg COPD, depressive symptoms, diabetes, CVD, GERD), occupation
Index test / intervention	*Level 2* unattended sleep study / polysomnography that includes assessments of: sleep staging (EEG), detection of airflow, respiratory movement, arterial oxygen saturation, electrocardiogram (ECG), and subsequent data analysis and interpretation by an appropriately trained and credentialed medical practitioner OR *Level 3* unattended sleep study involving the assessment of two or more cardiopulmonary parameters (eg detection of airflow, respiratory movement, arterial oxygen saturation, ECG), and subsequent data analysis and interpretation by an appropriately trained and credentialed medical practitioner OR *Level 4* unattended sleep study involving the assessment of one cardiopulmonary parameter (usually oximetry), and subsequent data analysis and interpretation by an appropriately trained and credentialed medical practitioner
Comparator(s)	*Level 1* laboratory-based, overnight, attended (by sleep technician) sleep study / polysomnography that includes assessments of: sleep staging (EEG, EOG, EMG), detection of airflow (quantitative or semi-quantitative nasal transducers), respiratory movement (via transducers on chest or abdominal walls, or via RIP), arterial oxygen saturation (via a pulse oximeter), ECG, leg movement, snoring, body positioning, and subsequent data analysis and interpretation
Outcomes	Sensitivity, specificity, accuracy, negative predictive value, positive predictive value, area under the curve, positive likelihood ratio, negative likelihood ratio, level of agreement Summary measures: diagnostic odds ratio, summary receiver operator characteristic curve
Publication type	Cross-sectional studies where patients were cross-classified on the index test and comparator and/or reference standard. Case-control diagnostic studies were acceptable only if cross-sectional studies were not available. Systematic reviews of cross-sectional studies. Non-systematic reviews, non-research letters, editorials; and animal, in-vitro and laboratory studies, were excluded.
Search period	1980 – April 2009
Language	Non-English language articles were excluded unless they provided a higher level of evidence than the English language articles identified.

[a] Suspected on the basis of snoring/gasping/choking while asleep, excessive daytime sleepiness, witnessed apnoea, nocturia

BMI = body mass index; COPD = chronic obstructive pulmonary disease; CVD = cardiovascular disease such as hypertension, coronary artery disease, ischaemic heart disease; GERD = gastro-oesophageal reflux disease; ECG = electrocardiogram; EEG = electroencephalogram; EMG = electromyogram; EOG = electrooculogram; OSA = obstructive sleep apnoea; RIP = respiratory inductive plethysmography

Box 9 Criteria for selecting studies to assess the change in management following the use of unattended sleep studies in a referral setting

Selection criteria	Inclusion criteria
Population	Adults with suspected OSA[a] and referred to a specialist – Subgroups: age range, BMI range, comorbid conditions (eg COPD, depressive symptoms, diabetes, CVD, GERD), occupation
Index test / intervention	*Level 2* unattended sleep study / polysomnography that includes assessments of: sleep staging (EEG), detection of airflow, respiratory movement, arterial oxygen saturation, electrocardiogram (ECG), and subsequent data analysis and interpretation by an appropriately trained and credentialed medical practitioner OR *Level 3* unattended sleep study involving the assessment of two or more cardiopulmonary parameters (eg detection of airflow, respiratory movement, arterial oxygen saturation, ECG), and subsequent data analysis and interpretation by an appropriately trained and credentialed medical practitioner OR *Level 4* unattended sleep study involving the assessment of one cardiopulmonary parameter (usually oximetry), and subsequent data analysis and interpretation by an appropriately trained and credentialed medical practitioner ± *Level 1 study*
Comparator(s)	*Level 1* laboratory-based, overnight, attended (by sleep technician) sleep study / polysomnography that includes assessments of: sleep staging (EEG, EOG, EMG), detection of airflow (quantitative or semi-quantitative nasal transducers), respiratory movement (via transducers on chest or abdominal walls, or via RIP), arterial oxygen saturation (via a pulse oximeter), ECG, leg movement, snoring, body positioning, and subsequent data analysis and interpretation
Outcomes	Additional sleep studies (by type), referral to sleep medicine physician / credentialed medical practitioner, time to diagnosis, time to commencement of treatment, alteration in treatment, treatment type
Publication type	Randomised or non-randomised controlled trials (including before-and-after studies) or cohort studies or uncontrolled pre-test/post-test case series or systematic reviews of these study designs. Non-systematic reviews, non-research letters, editorials; and animal, in-vitro and laboratory studies, were excluded.
Search period	1980 – April 2009
Language	Non-English language articles were excluded unless they provided a higher level of evidence than the English language articles identified.

[a] Suspected on the basis of snoring/gasping/choking while asleep, excessive daytime sleepiness, witnessed apnoea, nocturia

BMI = body mass index; COPD = chronic obstructive pulmonary disease; CVD = cardiovascular disease such as hypertension, coronary artery disease, ischaemic heart disease; GERD = gastro-oesophageal reflux disease; ECG = electrocardiogram; EEG = electroencephalogram; EMG = electromyogram; EOG = electrooculogram; OSA = obstructive sleep apnoea; RIP = respiratory inductive plethysmography

Is it accurate?

Eight studies assessed the accuracy of Level 3 and 4 unattended sleep studies, as measured by area under the ROC curve, in comparison with the reference standard Level 1 studies (laboratory-based PSG) (Table 19). There were no studies that assessed the accuracy of Level 2 studies using this measure (AUC).

The highest quality study available (level II diagnostic evidence) indicated that a Level 3 ApnoeScreen II sleep study conducted in the home and manually scored had good overall diagnostic accuracy in comparison with a laboratory-based PSG at an AHI ≥5 threshold (0.89–0.91), which only improved at the higher AHI thresholds for OSA severity (AHI ≥30: AUC 0.99, 95% CI 0.96, 1.00). Results were consistent when scored by two different individuals. Similarly high diagnostic accuracy relative to laboratory-

based PSG was reported by two other lower quality studies assessing the SomnoCheck and MERLIN Level 3 studies.

The test accuracy of Level 4 studies was assessed in five studies, relative to the reference standard of laboratory-based PSG (Table 19). The accuracy of these studies was lower than that observed for the Level 3 studies—which is not surprising, given the reduced number of physiological parameters measured. The highest level of evidence available (good-quality level III-1 diagnostic evidence) in the correct population (suspected OSA) reported AUCs in the range 0.71–0.89, suggesting moderate accuracy of the home-based ApnoeScreen I and Oxiflow (Baltzan et al 2000; Golpe et al 2002). The results of a similar quality study on a broader population (sleep disordered breathing) indicated variability in measurements when taken over one night or three nights (Wong et al 2008).

Table 19 Area under the curve of unattended sleep studies in a referral setting

Study	Evidence level and quality	Population	Respiratory event definition	*Reference standard* Cut-off point	AUC of Index test [95% CI] ±SD
Level 3 studies					
(García-Díaz et al 2007)	Cross-classification study Level II diagnostic evidence CX, P1 Q1 [QUADAS: 13/14]	62 consecutive patients with suspected sleep apnoea/hypopnoea syndrome referred to sleep laboratory	Apnoea: no oronasal airflow, ≥10 s Hypopnoea: ↓ airflow ≥50% associated with either an oxygen desaturation ≥4% (and/or EEG arousal in PSG study), ≥10 s	*Laboratory-based PSG* AHI ≥5	*Home-based Apnoescreen II* Observer A: 0.89 [0.81, 0.97] Observer B: 0.91 [0.83, 0.98]
				AHI ≥10	Observer A: 0.97 [0.93, 1.00] Observer B: 0.98 [0.95, 1.00]
				AHI ≥15	Observer A: 0.97 [0.94, 1.00] Observer B: 0.98 [0.94, 1.00]
				AHI ≥30	Observer A: 0.99 [0.96, 1.00] Observer B: 0.99 [0.96, 1.00]
(Tonelli de Oliveira et al 2009)	Cross-classification study Level III-1 diagnostic evidence CX, P2 Q1 [QUADAS: 13/14]	121 patients with suspected OSA	Apnoea: no airflow, ≥10 s Hypopnoea: ↓ airflow ≥50% or any discernable ↓ airflow associated with arousal oxygen desaturation ≥3%	*Laboratory-based PSG* AHI ≥5	*Home-based Somnocheck* 0.96 [0.91, 0.99]
				AHI ≥10	0.92 [0.85, 0.96]
				AHI ≥15	0.91 [0.85, 0.96]
				AHI ≥30	0.92 [0.86, 0.96]

Study	Evidence level and quality	Population	Respiratory event definition	*Reference standard* Cut-off point	AUC of Index test [95% CI] ±SD
(Calleja et al 2002)	Cross-classification study Level III-2 diagnostic evidence CX, P1 Q2 [QUADAS: 10/14]	79 patients with clinically suspected sleep apnoea/hypopnoea syndrome	Apnoea: no airflow ≥10 s Hypopnoea: ↓ airflow ≥50% ≥10 s + ≥3% in oxygen desaturation and/or arousal	*Laboratory-based PSG* [a]	*Cardiorespiratory polygraphy – MERLIN*[b]
				AHI ≥ 5	0.98 [0.95, 1.01]
				AHI ≥ 10	0.96 [0.91, 1.00]
				AHI ≥ 15	0.95 [0.91, 1.00]
				AHI ≥ 20	0.93 [0.88, 0.99]
				AHI ≥ 30	0.93 [0.86, 1.00]
Level 4 studies					
(Golpe et al 2002)	Cross-classification study Level III-1 diagnostic evidence CX, P1 Q1 [QUADAS: 14/14]	55 patients with suspected sleep apnoea/hypopnoea syndrome referred to sleep unit	Apnoea: no airflow, ≥10 s Hypopnoea: discernible ↓ airflow ≥10 s accompanied by oxygen desaturation ≥4% and/or arousal	*Laboratory-based PSG*	*Home-based Apnoescreen I* [b]
				AHI ≥ 10	0.89±0.19
(Baltzan et al 2000)	Cross-classification study Level III-1 diagnostic evidence CX, P1 Q1 [QUADAS: 12/14]	66 patients with suspected OSA	Unattended sleep study: apnoea: no airflow, ≥10 s; hypopnoea: ↓ airflow ≥50% accompanied by oxygen desaturation ≥4% Laboratory-based PSG: apnoea: ↓ airflow >90%, ≥10 s; hypopnoea: ↓ airflow ≥50% accompanied by oxygen desaturation ≥4%	*Laboratory-based PSG*	*Home-based OxiFlow*
				AHI >15	0.77 [0.65, 0.89]
			Unattended sleep study: apnoea: no airflow, ≥10 s; hypopnoea: ↓ airflow ≥25% accompanied by oxygen desaturation ≥4% Laboratory-based PSG: as in the above row	AHI >15	0.72 [0.60, 0.84]
			Unattended sleep study: apnoea: no airflow, ≥10 s; hypopnoea: ↓ airflow ≥20% accompanied by oxygen desaturation ≥4% Laboratory-based PSG: as in the above row	AHI >15	0.71 [0.58, 0.83]

Study	Evidence level and quality	Population	Respiratory event definition	*Reference standard* Cut-off point	AUC of Index test [95% CI] ±SD
			Unattended sleep study: apnoea: no airflow, ≥10 s; hypopnoea: ↓ airflow Not applicable ≥50% accompanied by oxygen desaturation ≥2% Laboratory-based PSG: as in the above row	AHI >15	0.77 [0.65, 0.88]
			Unattended sleep study: apnoea: no airflow, ≥10 s; hypopnoea: ↓ airflow ≥25% accompanied by oxygen desaturation ≥2% Laboratory-based PSG: as in the above row	AHI >15	0.71 [0.58, 0.83]
(Wong et al 2008)	Cross-classification study Level III-1 diagnostic evidence CX, P1 Q1 [QUADAS: 12/14]	31/34 patients with suspected sleep disordered breathing	Unattended sleep study: apnoea: no airflow, ≥10 s; hypopnoea: ↓ airflow ≥50%, ≥10 s Laboratory-based PSG: apnoea: no airflow, ≥10 s; hypopnoea: ↓ airflow ≥50%, ≥10 s, accompanied by oxygen desaturation ≥3% or arousal	*Laboratory-based PSG*	*Home-based Flow Wizard*
				AHI ≥10 [c]	0.96
				AHI ≥10 [d]	0.92
				AHI ≥30 [c]	0.85
				AHI ≥30 [d]	0.89
(Golpe et al 1999)	Retrospective cohort study—cross-classified Level III-2 diagnostic evidence CX, P1 Q1 [QUADAS: 12/14]	116 patients with suspected OSA	Unattended sleep study: oxygen desaturation ≥4%, ≥10 s Laboratory-based PSG: apnoea: no airflow through either the mouth or nose, ≥10 s; hypopnoea: ↓ oronasal airflow >50%, associated with either oxygen desaturation ≥4% or by arousal	*Laboratory-based PSG*	*Home-based finger oximeter, AVL-Minolta Pulsox 7*
				AHI ≥10	0.76±0.10
			Unattended sleep study: oxygen resaturation ≥3%, ≥10 s Laboratory-based PSG: as in the above row	AHI ≥10	0.74±0.10
			Unattended sleep study: oxygen saturation <90% Laboratory-based PSG: as in the above row	AHI ≥10	0.72±0.10
(Pittman et al 2004)	Cross-classification study Level III-2 diagnostic evidence CX, P1 Q2 [QUADAS: 11.5/14]	29 patients with suspected OSA	Unattended sleep study: ↓ arterial pulse wave volume, associated with ↑ heart rate or wrist activity; ↓ arterial pulse wave volume, associated with oxygen desaturation ≥3%; or oxygen desaturation ≥4% Laboratory-based PSG: apnoea: no airflow, ≥10 s; hypopnoea: ↓ airflow >50%, or lesser extent (noticeable change) in association with oxygen desaturation ≥3%	*Laboratory-based PSG*	*Home-based Watch_PAT + Nonin 8000J pulse oximeter*
				AHI ≥10	0.82
				AHI ≥15	0.97
				AHI ≥20	0.92
				AHI ≥30	0.89

Study	Evidence level and quality	Population	Respiratory event definition	*Reference standard*	AUC of Index test [95% CI] ±SD
				Cut-off point	
			Unattended sleep study: as in the above row Laboratory-based PSG: apnoea: no airflow, ≥10 s; hypopnoea: ↓ airflow or thoraco-abdominal movement ≥30%, associated with oxygen desaturation ≥4%	AHI ≥5	1.00
				AHI ≥10	0.99
				AHI ≥15	0.90
				AHI ≥20	0.86
				AHI ≥30	0.87

[a] Unclear if attended or unattended; [b] Manual scoring only (automatic scoring also provided in the study results); [c] 3-night data; [d] 1st night data

AHI = apnoea–hypopnoea index; CI = confidence interval; n/a = not applicable; OSA = obstructive sleep apnoea; PSG = polysomnography; s = seconds; SD = standard deviation

Other common methods of measuring test accuracy were reported in the evidence-base assessing the performance of unattended versus attended sleep studies (Table 20). Two of the three studies assessing the accuracy of Level 2 studies were conducted on the target population for this assessment, and found uniformly high sensitivity at two AHI thresholds (81–84% at AHI ≥10 and 15, respectively). Specificity, however, varied in the range 63–98%, whether as a consequence of the different thresholds or the study characteristics is unclear. The NPV was high in both studies (80–85%), although not high enough to rule out OSA, as between 15% and 20% of patients would have a negative test on a Level 2 sleep study that was positive on a Level 1 sleep study.

Seven studies reported measures of test sensitivity, specificity, NPV, PPV and likelihood ratios for Level 3 unattended sleep assessment devices (Table 20). Once again, sensitivity (and thus NPV) was high but specificity varied considerably. At a PSG threshold for mild OSA (AHI ≥5), sensitivity was in the range 96–97%, with specificity 65–91%. At AHI ≥10 sensitivity was in the range 73–91%, with specificity 80–100%, while at AHI ≥15 the rates were 75–91% and 56–98%, respectively. For moderate to severe OSA at a PSG threshold of AHI ≥30, sensitivity was 78–96% and specificity 48–95%. It should be noted that the lower end of these ranges in accuracy estimates were predominantly reported by the lowest quality study in the evidence-base assessing Level 3 sleep studies (Whittle et al 1997). NPVs were in the range 65–91% and varied according to the diagnostic threshold chosen.

The evidence-base was more substantive for assessing the accuracy of Level 4 unattended sleep assessment devices, with 17 studies reporting on their performance relative to laboratory-based PSG (Table 20). The highest quality level II and III-1 diagnostic evidence found that sensitivity at an AHI ≥10 was in the range 92–98% when taking into account the trade-off with specificity (see italics in table), and specificity was lower, at 48–86%. At AHI ≥15 the trade-off in sensitivity and specificity peaked at 55% and 88%, respectively (Baltzan et al 2000), while at AHI ≥30, the trade-off in sensitivity and specificity occurred at an RDI ≥28, with 91% sensitivity and 75% specificity (Wong et al 2008). NPVs were moderate to high, ranging across thresholds to between 75% and 95%.

Table 20 Test characteristics of unattended sleep studies in a referral setting

Study	Evidence level and quality	Population	Respiratory event definition	*Index test*	*Reference standard*	Sensitivity % [95% CI]	Specificity % [95% CI]	PPV % [95% CI]	NPV % [95% CI]	LR+ [95% CI]	LR– [95% CI]
				Cut-off point	Cut-off point						
Level 2 study											
(Iber et al 2004)	Cross-classification study Level III-1 diagnostic evidence CX, P1 Q2 [QUADAS: 11.5/14]	64 patients with suspected OSA	Apnoea: no or almost no airflow, ≥10 s Hypopnoea: ↓ airflow or respiratory movement ≥30%, ≥10 s, accompanied by oxygen desaturation ≥3%	*Home-based Compumedics PS-2 system*	*Laboratory-based PSG*						
				AHI ≥10	AHI ≥10	84.4 [66.5, 94.1]	62.5 [43.7, 78.3]	69.2 [52.2, 82.5]	80.0 [58.7, 92.4]	2.3 [1.4, 3.6]	0.3 [0.1, 0.6]
(Portier et al 2000)	Cross-classification study Level III-2 diagnostic evidence CX, P1 Q1 [QUADAS: 12/14]	78/103 patients with suspected sleep apnoea	Apnoea: ↓ airflow ≥75%, ≥10 s Hypopnoea: ↓ airflow ≥25%, ≥10 s	*Home-based Minisomno*	*Laboratory-based PSG*						
				AHI ≥15	AHI ≥15	81.1 [64.3, 91.4]	97.6 [85.6, 99.9]	96.8 [81.5, 99.8]	85.1 [71.1, 93.3]	33.2 [4.8, 231.8]	0.2 [0.1, 0.4]
(Ancoli-Israel et al 1997)	Cross-classification study Level III-2 diagnostic evidence CX, P1 Q2 [QUADAS: 11/14]	34 patients with suspected sleep apnoea or healthy people	Apnoea: no airflow, ≥10 s Hypopnoea: ↓ airflow ≥50%	*Home-based NightWatch System™*	*Laboratory-based PSG*						
				AHI ≥10	AHI ≥10	100.0 [83.4, 100.0]	66.7 [30.9, 91.0]	89.3 [70.6, 97.2]	100.0 [51.7, 100.0]	3.0 [1.2, 7.6]	0.0

Study	Evidence level and quality	Population	Respiratory event definition	*Index test*	*Reference standard*	Sensitivity % [95% CI]	Specificity % [95% CI]	PPV % [95% CI]	NPV % [95% CI]	LR+ [95% CI]	LR– [95% CI]
				Cut-off point	Cut-off point						
Level 3 study											
(García-Díaz et al 2007)	Cross-classification study Level II diagnostic evidence CX, P1 Q1 [QUADAS: 13/14]	62 consecutive patients with suspected sleep apnoea/hypopnoea syndrome referred to sleep laboratory	Apnoea: no oronasal airflow, ≥10 s Hypopnoea: ↓ airflow ≥50% associated with either an oxygen desaturation ≥4% (and/or EEG arousal in PSG study), ≥10 s	*Home-based Apnoescreen II*	*Laboratory-based PSG*						
				RDI ≥10	AHI ≥10	Observer A: 86.4 [75.4, 97.5] Observer B: 83.8 [71.9, 95.6]	Observer A: 100.0 Observer B: 92 [81.3, 100]			Observer A: ∞ Observer B: 10.47 [2.75, 39.9]	Observer A: 0.14 [0.06, 0.31] Observer B: 0.18 [0.08, 0.37]
				RDI ≥15	AHI ≥15	Observer A: 87.5 [76, 98.9] Observer B: 84.4 [71.8, 96.9]	Observer A: 96.7 [90.2, 100] Observer B: 96.7 [90.2, 100]			Observer A: 26.2 [3.8, 181.1] Observer B: 25.3 [3.7, 174.9]	Observer A: 0.13 [0.05, 0.32] Observer B: 0.16 [0.17, 0.36]
				RDI ≥30	AHI ≥30	Observer A: 91.7 [80.6, 100] Observer B: 95.8 [87.8, 100]	Observer A: 94.7 [87.6, 100] Observer B: 94.7 [87.6, 100]			Observer A: 17.4 [4.5, 67] Observer B: 18.2 [4.7, 70.3]	Observer A: 0.09 [0.02, 0.33] Observer B: 0.04 [0.01, 0.3]
(Parra et al 1997)	Cross-classification study Level II diagnostic evidence CX, P1 Q1 [QUADAS: 12/14]	89 patients with suspected sleep apnoea	Apnoea: no airflow, ≥10 s Hypopnoea: ↓ airflow or thoracic movement, ≥10 s, associated with oxygen desaturation ≥2% (or arousal)	*Home-based Edentrace II, Model 3711*	*Laboratory-based PSG*						
				RDI >8	AHI >10	95	33				
				RDI >18	AHI >10	73	80				
				RDI >23	AHI >10	63	93				

Study	Evidence level and quality	Population	Respiratory event definition	*Index test* Cut-off point	*Reference standard* Cut-off point	Sensitivity % [95% CI]	Specificity % [95% CI]	PPV % [95% CI]	NPV % [95% CI]	LR+ [95% CI]	LR– [95% CI]
(Tonelli de Oliveira et al 2009)	Cross-classification study Level III-1 diagnostic evidence CX, P2 Q1 [QUADAS: 13/14]	121 patients with suspected OSA	Apnoea: no airflow, ≥10 s Hypopnoea: ↓ airflow ≥50% or any discernable ↓ airflow associated with arousal oxygen desaturation ≥3%	*Home-based Somnocheck*	*Laboratory-based PSG*						
				RDI ≥5	AHI ≥5	96.2 [92.5, 99.8]	64.7 [42.0, 87.4]	94.3 [89.9, 98.7]	73.3 [51.0, 95.7]	2.7	0.1
				RDI ≥10	AHI ≥10	90.7 [82.7, 95.2]	82.9 [67.3, 91.9]	92.9 [85.3, 96.7]	68.4 [62.8, 88.6]	5.2	0.1
				RDI ≥15	AHI ≥15	81.3 [71.1, 88.5]	82.6 [69.3, 90.9]	88.4 [78.8, 94.0]	73.1 [59.7, 83.2]	4.6	0.2
				RDI ≥30	AHI ≥30	80.0 [68.3, 91.7]	92.1 [86.0, 98.2]	85.7 [75.1, 96.3]	88.6 [81.6, 95.6]	10.1	0.2
(Reichert et al 2003)	Cross-classification study Level III-1 diagnostic evidence CX, P1 Q2 [QUADAS: 11.5/14]	45/51 patients with suspected OSA	Apnoea: no airflow, ≥10 s Hypopnoea: ↓ airflow ≥50%, ≥10 s, accompanied by oxygen desaturation ≥2%	*Home-based NovaSom QSG™*	*Laboratory-based PSG*						
				RDI ≥15	AHI ≥15	91 SE: 6%	83 SE: 8%	83 SE: 8%	91 SE: 6%		
(Calleja et al 2002)	Cross-classification study Level III-2 diagnostic evidence CX, P1 Q2 [QUADAS: 10/14]	79 patients with clinically suspected sleep apnoea/hypopnoea syndrome	Apnoea: no airflow ≥10 s Hypopnoea: ↓ airflow ≥50% ≥10 s + ≥3% in oxygen desaturation and/or arousal	*Cardiorespiratory polygraphy – MERLIN*[d]	*Laboratory-based PSG*[e]						
				RDI ≥6.7	AHI ≥ 5	97.1 [93, 100]	90.9 [74, 100]		83.3		
				RDI ≥15.8	AHI ≥ 15	90.6 [83, 98]	80.8 [66, 96]				
				RDI ≥21.1	AHI ≥ 20	91.1 [83, 99]	85.3 [73, 79]				
				RDI ≥27.6	AHI ≥ 30	88.6 [78, 99]	90.9 [82, 99]	88.6			

Study	Evidence level and quality	Population	Respiratory event definition	*Index test*	*Reference standard*	Sensitivity % [95% CI]	Specificity % [95% CI]	PPV % [95% CI]	NPV % [95% CI]	LR+ [95% CI]	LR– [95% CI]
				Cut-off point	Cut-off point						
(Ancoli-Israel et al 1981)	Cross-classification study Level III-1 diagnostic evidence CX, P1 Q3 [QUADAS: 9.5/14]	27/36 patients with suspected sleep apnoea or nocturnal myoclonus	Apnoea: no airflow ≥10 s Hypopnoea: ↓ airflow ≥50%, ≥10 s	*Home-based Medilog portable analog recorder*	*Laboratory-based PSG*						
				RDI ≥30	AHI ≥30	78					
(Whittle et al 1997)	Cross-classification study Level III-2 diagnostic evidence CX, P1 Q2 [QUADAS: 11/14]	58[a]/150 patients with suspected sleep apnoea	Apnoea: no airflow, >10 s Hypopnoea: ↓ respiratory movement >50%, >10 s	*Home-based Edentrace system, Model 3711*	*Laboratory-based PSG*						
				RDI ≥10	AHI ≥15	93.8 [77.8, 98.9]	34.6 [17.9, 55.6]	63.8 [48.5, 76.9]	81.8 [47.8, 96.8]	1.4 [1.1, 1.9]	0.2 [0.0, 0.8]
				RDI ≥15	AHI ≥15	75.0 [56.2, 87.9]	57.7 [37.2, 76.0]	68.6 [50.6, 82.6]	65.2 [42.8, 82.8]	1.8 [1.1, 2.9]	0.4 [0.2, 0.8]
				RDI ≥15	AHI ≥30	77.8 [51.9, 92.6]	47.5 [31.8, 63.7]	40.0 [24.4, 57.8]	82.6 [60.5, 94.3]	1.5 [1.0, 2.2]	0.5 [0.2, 1.2]
				RDI ≥20	AHI ≥30	44.4 [22.4, 68.7]	82.5 [66.6, 92.1]	53.3 [27.4, 77.7]	76.7 [61.0, 87.7]	2.5 [1.1, 5.9]	0.7 [0.4, 1.0]
Level 4 sleep study											
(Sériès et al 1993)	Cross-classification study Level II diagnostic evidence CX, P1 Q1 [QUADAS: 12/14]	240 patients with suspected OSA	Unattended sleep study: oxygen desaturation followed by a rapid return to the baseline oxygen saturation Laboratory-based PSG: apnoea: no airflow, >10 s; hypopnoea: ↓ respiratory movement >50%, associated with oxygen desaturation ≥4%	*Home-based Biox IVA oximeter*	*Laboratory-based PSG*						
				ODI >10	*AHI >10*	*98.2 [92.9, 99.7]*	*47.7 [38.9, 56.6]*	*61.4 [53.7, 68.5]*	*96.9 [88.2, 99.5]*	*1.9 [1.6, 2.2]*	*0.0*
				ODI >20	AHI >20	100.0 [93.9, 100.0]	38.8 [31.4, 46.7]	42.6 [35.3, 50.3]	100.0 [92.9, 100.0]	1.6 [1.4, 1.8]	0.0

Study	Evidence level and quality	Population	Respiratory event definition	*Index test*	*Reference standard*	Sensitivity % [95% CI]	Specificity % [95% CI]	PPV % [95% CI]	NPV % [95% CI]	LR+ [95% CI]	LR– [95% CI]
				Cut-off point	Cut-off point						
(Baltzan et al 2000)	Cross-classification study Level III-1 diagnostic evidence CX, P1 Q1 [QUADAS: 12/14]	66 patients with suspected OSA	Unattended sleep study: apnoea: no airflow, ≥10 s; hypopnoea: ↓ airflow ≥50% accompanied by oxygen desaturation ≥4% Laboratory-based PSG: apnoea: ↓ airflow >90%, ≥10 s; hypopnoea: ↓ airflow ≥50% accompanied by oxygen desaturation ≥4%	*Home-based OxiFlow*	*Laboratory-based PSG*						
				RDI >2	AHI >15	90	32				
				RDI >10	AHI >15	55	88				
				RDI >15	AHI >15	34	94				
				RDI >20	AHI >15	31	97				
				RDI >30	AHI >15	7	100				
(Ayappa et al 2004)	Cross-classification study Level III-1 diagnostic evidence CX, P1 Q1 [QUADAS: 12/14]	56/59 patients with suspected OSA or healthy people	Unattended sleep study: apnoea: ↓ airflow >90%, ≥10 s; hypopnoea: ↓ airflow >50%, ≥10 s, or ↓ airflow > 20–50%, ≥10 s followed by sudden resolution of the flow limitation shape and/or by oxygen desaturation >4% Laboratory-based PSG: apnoea: ↓ airflow >90%, ≥10 s; hypopnoea: ↓ airflow >50%, ≥10 s, or ↓ airflow 20–50%, ≥10 s followed oxygen desaturation >4% or by arousal	*Hospital/home-based portable Sleep Data Recorder or Compumedics P2 System*[b]	*Laboratory-based PSG*						
				RDI ≥18	AHI ≥18	88.4 [74, 96]	92.3 [62, 100]	97.4 [85, 100]	70.6 [44, 89]	11.5 [1.7, 75.8]	0.1 [0.1, 0.3]
(Wong et al 2008)	Cross-classification study Level III-1 diagnostic evidence CX, P1 Q1 [QUADAS: 12/14]	31/34 patients with suspected sleep disordered breathing	Unattended sleep study: apnoea: no airflow, ≥10 s; hypopnoea: ↓ airflow ≥50%, ≥10 s Laboratory-based PSG: apnoea: no airflow, ≥10 s; hypopnoea: ↓ airflow ≥50%, ≥10 s, accompanied by oxygen desaturation ≥3% or arousal	*Home-based Flow Wizard*	*Laboratory-based PSG*						
				RDI ≥8	AHI ≥10	100	43	86	100	1.8	0.0
				RDI ≥12	AHI ≥10	96	71	92	83	3.4	0.1
				RDI ≥18	*AHI ≥10*	*92*	*86*	*96*	*75*	*6.4*	*0.1*
				RDI ≥21	AHI ≥10	88	100	100	70	—	0.1
				RDI ≥21	AHI ≥30	100	50	52	100	2.0	0.0
				RDI ≥28	AHI ≥30	91	75	67	94	3.6	0.1
				RDI ≥45	AHI ≥30	36	90	67	72	3.6	0.7

Study	Evidence level and quality	Population	Respiratory event definition	*Index test*	*Reference standard*	Sensitivity % [95% CI]	Specificity % [95% CI]	PPV % [95% CI]	NPV % [95% CI]	LR+ [95% CI]	LR– [95% CI]
				Cut-off point	Cut-off point						
(Schafer et al 1997)	Cross-classification study Level III-1 diagnostic evidence CX, P1 Q2 [QUADAS: 11/14]	114 patients with suspected OSA	Unattended sleep study: oxygen desaturation ≥4% or 2%, accompanied by a visible change in heart rate Laboratory-based PSG: ↓ airflow ≥50%, followed by oxygen desaturation ≥4% or by arousal	*Home-based MESAM IV device*	*Laboratory-based PSG*						
				ODI ≥5	AHI ≥10	96	15	73	63		
				ODI ≥10	AHI ≥10	95	41	79	78		
				ODI ≥15	AHI ≥10	83	62	84	60		
				ODI ≥20	AHI ≥10	68	74	86	49		
				ODI ≥25	AHI ≥10	60	85	91	48		
(Gyulay et al 1993)	Cross-classification study Level III-1 diagnostic evidence CX, P1 Q2 [QUADAS: 11/14]	98 patients with suspected OSA	Unattended sleep study: oxygen desaturation ≥2% Laboratory-based PSG: apnoea: no airflow ≥10 s; hypopnoea: ↓ airflow ≥50%, ≥10 s	*Home-based pulse oximeters, Model Biox 3700*	*Laboratory-based PSG*						
				ODI ≥15	AHI ≥15	65	74				
			Unattended sleep study: oxygen desaturation ≥3% Laboratory-based PSG: as in the above row	ODI ≥15	AHI ≥15	51	90				
			Unattended sleep study: oxygen desaturation ≥4% Laboratory-based PSG: as in the above row	ODI ≥15	AHI ≥15	40	98				
			Unattended sleep study: oxygen saturation <90% Laboratory-based PSG: as in the above row	CT_{90} ≥1%	AHI ≥15	93	51				

Study	Evidence level and quality	Population	Respiratory event definition	*Index test*	*Reference standard*	Sensitivity % [95% CI]	Specificity % [95% CI]	PPV % [95% CI]	NPV % [95% CI]	LR+ [95% CI]	LR– [95% CI]
				Cut-off point	Cut-off point						
(Fietze et al 2004)	Cross-classification study Level III-1 diagnostic evidence CX, P1 Q2 [QUADAS: 10.5/14]	18[c]/35 patients with suspected OSA	Unattended sleep study: oxygen desaturation ≥3% with absence of moving artefacts and irrespective of co-existing changes in snoring or heart rate Laboratory-based PSG: apnoea: no airflow ≥10 s; hypopnoea: ↓ airflow ≥50%, ≥10 s, associated with either oxygen desaturation of ≥3 or an arousal	*Home-based portable MESAM IV device (MAP)*	*Laboratory-based PSG*						
				ODI ≥5	AHI ≥5	100.0 [77.1, 100.0]	0.0 [0.0, 94.5]	94.4 [70.6, 99.7]	—	1.0 [1.0, 1.0]	—
				ODI >15	AHI >15	57.1 [20.2, 88.2]	90.9 [57.1, 99.5]	80.0 [29.9, 98.9]	76.9 [46.0, 93.8]	6.3 [0.9, 45.3]	0.5 [0.2, 1.1]
(Golpe et al 1999)	Cross-classification study Level III-2 diagnostic evidence CX, P1 Q1 [QUADAS: 12/14]	116 patients with suspected OSA	Unattended sleep study: oxygen desaturation ≥4%, ≥10 s Laboratory-based PSG: apnoea: no airflow, ≥10 s; hypopnoea: ↓ airflow >50%, associated with either oxygen desaturation ≥4% or by arousal	*Home-based AVL-Minolta Pulsox 7*	*Laboratory-based PSG*						
				ODI ≥31	AHI ≥10	32	97	95	47		
			Unattended sleep study: oxygen resaturation ≥3%, ≥10 s Laboratory-based PSG: as in the above row	ORI ≥40	AHI ≥10	29	97	95	46		
			Unattended sleep study: oxygen saturation <90% Laboratory-based PSG: as in the above row	CT_{90}% ≥0.8%	AHI ≥10	84	48	72	66		
(Ayappa et al 2008)	Cross-classification study Level III-2 diagnostic evidence CX, P1 Q2	67/77 patients with suspected sleep disordered breathing	Unattended sleep study: apnoea: no airflow, ≥10 s; hypopnoea: ↓ airflow >50%, accompanied by oxygen desaturation ≥3.5% and resaturation Laboratory-based PSG: apnoea: ↓ airflow >90%; hypopnoea: ↓	*Home-based ARES™ Unicorder*	*Laboratory-based PSG*						
				RDI ≥5	AHI ≥5	92 [80, 97]	67 [41, 86]			2.8	0.1

Study	Evidence level and quality	Population	Respiratory event definition	*Index test* Cut-off point	*Reference standard* Cut-off point	Sensitivity % [95% CI]	Specificity % [95% CI]	PPV % [95% CI]	NPV % [95% CI]	LR+ [95% CI]	LR– [95% CI]
	[QUADAS: 11.5/14]		airflow ≥30%, accompanied by oxygen desaturation ≥4%	RDI ≥10	AHI ≥10	89 [72,96]	72 [53, 86]			3.2	0.2
				RDI ≥15	AHI ≥15	76 [57, 88]	82 [65, 93]			4.3	0.3
			Unattended sleep study: apnoea: no airflow, ≥10 s; hypopnoea: ↓airflow >50%, accompanied by oxygen desaturation and resaturation ≥1% and ≥1 surrogate arousal indicator Laboratory-based PSG: apnoea: ↓ airflow >90%; hypopnoea: ↓ airflow >50%, or ↓ airflow 20–50%, accompanied by oxygen desaturation ≥4%	RDI ≥10	AHI ≥10	90 [78, 96]	78 [40, 96]			4.0	0.1
				RDI ≥15	AHI ≥15	84 [71, 93]	81 [54, 95]			4.5	0.2
(Pang et al 2006)	Cross-classification study Level III-2 diagnostic evidence CX, P1 Q2 [QUADAS: 11.5/14]	32/37 patients with suspected sleep disordered breathing	Unattended sleep study: apnoea: ↓ airflow >88%, ≥10 s; hypopnoea: ↓ airflow >50%, ≥10 s Laboratory-based PSG: apnoea: no airflow, ≥10 s; hypopnoea: ↓ airflow or thoraco-abdominal movement ≥30%, ≥10 s, associated with oxygen desaturation ≥4% or arousal	*Home-based SleepStrip*	*Laboratory-based PSG*						
				RDI ≥15	AHI ≥15	54.5 [32.7, 74.9]	70.0 [35.4, 91.9]	80.0 [51.4, 94.7]	41.2 [19.4, 66.5]	1.8 [0.7, 5.0]	0.6 [0.4, 1.1]
				RDI ≥25	AHI ≥25	43.8 [20.8, 69.4]	81.3 [53.7, 95.0]	70.0 [35.4, 91.9]	59.1 [36.7, 78.5]	2.3 [0.7, 7.5]	0.7 [0.4, 1.1]
				RDI ≥40	AHI ≥40	33.3 [11.3, 64.6]	95.0 [73.1, 99.7]	80.0 [29.9, 98.9]	70.4 [49.7, 85.5]	6.7 [0.8, 52.9],	0.7 [0.5, 1.1]
(Pittman et al 2004)	Cross-classification study Level III-2 diagnostic evidence	29 patients with suspected OSA	Unattended sleep study: 1) ↓ PAT, associated with ↑ heart rate or wrist activity; 2) ↓ PAT, associated with oxygen desaturation ≥3%; or 3) oxygen desaturation ≥4%	*Home-based Watch_PAT + Nonin 8000J pulse oximeter*	*Laboratory-based PSG*						
				PAT index ≥5	AHI ≥5	96.6 [80.3, 99.8]	—	100.0 [85.0, 100.0]	0.0 [0.0, 94.5]	—	—

Study	Evidence level and quality	Population	Respiratory event definition	*Index test* Cut-off point	*Reference standard* Cut-off point	Sensitivity % [95% CI]	Specificity % [95% CI]	PPV % [95% CI]	NPV % [95% CI]	LR+ [95% CI]	LR– [95% CI]
	CX, P1 Q2		Laboratory-based PSG: apnoea: no airflow, ≥10 s; hypopnoea: ↓	PAT index ≥10	AHI ≥10	89.3 [70.6, 97.2]	0.0 [0.0, 94.5]	96.2 [78.4, 99.8]	0.0 [0.0, 69.0]	0.9 [0.8, 1.0]	∞
	[QUADAS: 11.5/14]		airflow >50%, or a noticeable change in airflow accompanied by oxygen desaturation ≥3%	PAT index ≥15	AHI ≥15	95.5 [75.1, 100.0]	100.0 [56.1, 100.0]	100.0 [80.8, 100.0]	87.5 [46.7, 99.3]	∞	0.0
				PAT index ≥20	AHI ≥20	80.0 [55.7, 93.4]	88.9 [50.7, 99.4]	94.1 [69.2, 99.7]	66.7 [35.4, 88.7]	7.2 [1.1, 46.3]	0.2 [0.1, 0.6]
				PAT index ≥30	AHI ≥30	83.3 [50.9, 97.1]	82.4 [55.8, 95.3]	76.9 [46.0, 93.8]	87.5 [60.4, 97.8]	4.7 [1.6, 13.6]	0.2 [0.1, 0.7]
			Unattended sleep study: as in the above row Laboratory-based PSG: apnoea: no airflow, ≥10 s; hypopnoea: ↓ airflow or thoraco-abdominal movement ≥30%, associated with oxygen desaturation ≥4%	PAT index ≥5	AHI ≥5	100.0 [75.9, 100.0]	7.7 [0.0, 37.9]	57.1 [37.4, 74.9]	100.0 [5.5, 100.0]	1.1 [0.9, 1.3]	0.0
				PAT index ≥10	AHI ≥10	100.0 [73.2, 100.0]	20.0 [5.3, 48.6]	53.8 [33.7, 72.9]	100.0 [31.0, 100.0]	1.3 [1.0, 1.6]	0.0
				PAT index ≥15	AHI ≥15	100.0 [62.9, 100.0]	40.0 [20.0, 63.6]	42.9 [22.6, 65.6]	100.0 [59.8, 100.0]	1.7 [1.2, 2.4]	0.0
				PAT index ≥20	AHI ≥20	88.9 [50.7, 99.4]	55.0 [32.0, 76.2]	47.1 [23.9, 71.5]	91.7 [59.8, 99.6]	2.0 [1.2, 3.4]	0.2 [0.0, 1.4]
				PAT index ≥30	AHI ≥30	100.0 [46.3, 100.0]	66.7 [44.7, 83.6]	38.5 [15.1, 67.7]	100.0 [75.9, 100.0]	3.0 [1.7, 5.3]	0.0
(Westbrook et al 2005)	Cross-classification study Level III-2 diagnostic evidence CX, P1 Q2 [QUADAS: 11/14]	187 patients with suspected sleep disordered breathing, with comorbidities or healthy people	Unattended sleep study: oxygen desaturation/resaturation of 2.5%/2.5%, 3.0%/2.7%, 3.5%/3.0%, 4.0%/3.2%, or 2.2%/2.2% accompanied by arousal Laboratory-based PSG: NR	*Home-based ARES Unicorder*	*Laboratory-based PSG*						
				ODI ≥5	AHI ≥5	95.7	57.9				
				ODI ≥10	AHI ≥10	91.5 [87.3, 94.4]	85.7 [78.8, 90.6]	91.5 [87.3, 94.4]	85.7 [78.8, 90.6]		
				ODI ≥15	AHI ≥15	86.1	83.7				
				ODI ≥20	AHI ≥20	86.9	85.4				
				ODI ≥30	AHI ≥30	79.4	100.0				

Study	Evidence level and quality	Population	Respiratory event definition	*Index test*	*Reference standard*	Sensitivity % [95% CI]	Specificity % [95% CI]	PPV % [95% CI]	NPV % [95% CI]	LR+ [95% CI]	LR– [95% CI]
				Cut-off point	Cut-off point						
(Williams et al 1991)	Cross-classification study Level III-2 diagnostic evidence CX, P2 Q2 [QUADAS: 10/14]	36 patients referred to a sleep disorders clinic with suspected sleep apnoea	Apnoea defined as no airflow, ≥10 s	*Home-based pulse oximetry Omeda Biox 3700 IV or Nellcor N100*	*Laboratory-based PSG*						
				Oxygen desaturation ≥4% and saturation to a value of ≤90%	AI >10	75.0 [50.6, 90.4]	100.0 [71.7, 100.0]	100.0 [74.7, 100.0]	72.2 [46.4, 89.3]	∞	0.25 [0.1, 0.5]
(Wiltshire et al 2001)	Cross-classification study Level III-2 diagnostic evidence CX, P1 Q3 [QUADAS: 9.5/14]	84 patients with suspected sleep apnoea	Oxygen desaturation ≥4%	*Home-based Ohmeda Biox3740*	*Laboratory-based PSG*						
				ODI ≥10	ODI ≥10	40.6 [24.2, 59.2]	100.0 [91.4, 100.0]	100.0 [71.7, 100.0]	73.2 [61.2, 82.7]	∞	0.6 [0.4, 0.8]
				ODI ≥15	ODI ≥15	34.8 [17.2, 57.2]	100.0 [92.6, 100.0]	100.0 [59.8, 100.0]	80.3 [69.2, 88.2]	∞	0.7 [0.5, 0.9]
(Ryan et al 1995)	Cross-classification study Level III-2 diagnostic evidence CX, P1 Q3 [QUADAS: 9.5/14]	69 patients with suspected sleep apnoea	Unattended sleep study: oxygen desaturation ≥4% Laboratory-based PSG: apnoea: no airflow, ≥10 s; hypopnoea: ↓ thoracic movement >25%, ↓ abdominal movement >15%, or paradoxical movement with ↓ airflow >25%	*Home-based Minolta Pulsox-7*	*Laboratory-based PSG*						
				ODI >15	AHI >15	31.3 [16.7, 50.1]	100.0 [88.3, 100.0]	100.0 [65.5, 100.0]	62.7 [49.1, 74.7]	∞	0.7 [0.5, 0.9]

Study	Evidence level and quality	Population	Respiratory event definition	*Index test* Cut-off point	*Reference standard* Cut-off point	Sensitivity % [95% CI]	Specificity % [95% CI]	PPV % [95% CI]	NPV % [95% CI]	LR+ [95% CI]	LR– [95% CI]
(Takeda et al 2006)	Cross-classification study Level III-2 diagnostic evidence CX, P1 Q3 [QUADAS: 8.5/14]	135 patients suffering from sleep disturbance	Unattended sleep study: oxygen desaturation ≥3% Laboratory-based PSG: apnoea: no airflow, ≥10 s; hypopnoea: ↓ airflow >25%, ≥10 s, accompanied by oxygen desaturation ≥3% or arousal	*Home-based Apnomonitor III*	*Laboratory-based PSG*						
				ODI ≥5	AHI ≥20	86.9 [78.2, 92.5]	33.3 [19.1, 51.1]	78.2 [69.1, 85.3]	48.0 [28.3, 68.2]	1.3 [1.0, 1.7]	0.4 [0.2, 0.7]
				ODI ≥10	AHI ≥20	78.8 [69.2, 86.1]	58.3 [40.9, 74.0]	83.9 [74.5, 90.4]	50.0 [34.4, 65.6]	1.9 [1.3, 2.8]	0.4 [0.2, 0.6]
				ODI ≥15	AHI ≥20	74.7 [64.8, 82.7]	77.8 [60.4, 89.3]	90.2 [81.2, 95.4]	52.8 [38.8, 66.5]	3.4 [1.8, 6.3]	0.3 [0.2, 0.5]
				ODI ≥20	AHI ≥20	73.3 [64.9, 80.4]	88.9 [73.0, 96.4]	93.9 [84.4, 98.0]	46.4 [34.4, 58.7]	5.6 [2.2, 14.4]	0.4 [0.3, 0.5]
(Olson et al 1999)	Cross-classification study—retrospective Level III-2 diagnostic evidence CX, P2 Q3 [QUADAS: 7/14]	793 patients suspected of OSA receiving home oximetry who also had a PSG	Apnoea and hypopnoea not defined Relationship between (1) arterial oxygen saturation <90% greater than 1% of recording time (CT_{90}), and (2) Δ Index (saturation variability criteria), and AHI investigated	*Home-based Pulse oximetry (Biox 4700)*	*Laboratory-based PSG*						
				CT_{90} 1.0	AHI ≥5	69.9	54.7			1.55	0.52
				Δ Index 0.4	AHI ≥5	82.7	54.2			1.80	0.32
				CT_{90} 1.0	AHI ≥15	75.3	46.1			1.39	0.54
				Δ Index 0.4	AHI ≥15	88.5	39.6			1.48	0.29
				CT_{90} 1.0	AHI ≥30	84.3	44.0			1.50	0.36
				Δ Index 0.4	AHI ≥30	92.6	34.1			1.40	0.22

[a] Patients with ODI<30; [b] Hospital-based: n=52; home-based: n=7; portable Sleep Data Recorder: n=56; Compumedics P2 System: n=3; [c] Patients with ODI between 5 and 30; [d] Manual scoring only (automatic scoring also provided in the study results); [e] Unclear if attended or unattended.

AHI = apnoea–hypopnoea index; CI = confidence interval; CT = cumulative percentage time; LR = likelihood ratio; NPV = negative predictive value; NR = not reported; ODI = oxygen desaturation index; ORI = oxygen resaturation index; OSA = obstructive sleep apnoea; PAT = peripheral arterial tone; PPV = positive predictive value; PSG = polysomnography; RDI = respiratory disturbance index; s = seconds; SE = standard error

Twenty-two studies reported on the agreement and/or correlation between unattended and attended sleep studies (Table 21). The agreement measures such as Bland and Altman plots and Kappa statistics are stronger measures of effect than the correlation measures and so greater weight is given to the studies reporting these results.

Four studies of moderate quality reported on the agreement between Level 2 and Level 1 studies. The results were heterogeneous. Moderate levels of agreement between a home-based Compumedics PS-2 system and laboratory-based PSG were observed by Iber et al (2004), while the Minisomno® Level 2 system performed poorly against the same reference standard in two studies (limits of agreement allowed clinically important differences between the two tests) (Gagnadoux et al 2002; Portier et al 2000).

Six studies reported on the agreement between Level 3 studies and laboratory-based PSG, three studies of which were of very high quality (Dingli et al 2003; García-Díaz et al 2007; Parra et al 1997). All three studies showed good agreement between Level 1 studies and the Embletta, Apneoscreen II and Edentrace II devices. The lower quality studies showed that the levels of agreement between the Level 3 devices and laboratory-based PSG were often clinically unacceptable. Whether this is a fault of the conduct and design of the study or a reflection on the performance of the device itself is unclear.

Twelve studies assessed the performance of Level 4 studies in terms of their agreement with the results of Level 1 studies. The level and quality of evidence was poorer than that of the Level 3 studies, and the results were heterogeneous. Only two studies showed reasonable levels of agreement between Level 4 studies and laboratory-based PSG using a portable Sleep Data Recorder or Compumedics P2 System, or a finger oximeter AVL-Minolta Pulsox 7 device (Ayappa et al 2004; Golpe et al 1999).

Table 21 Other agreement measures of unattended sleep studies in a referral setting

Study	Evidence level and quality	Population	Respiratory event definition	*Index test*	*Reference standard*	Agreement measure
				Cut-off point	Cut-off point	
Level 2 study						
(Iber et al 2004)	Cross-classification study Level III-1 diagnostic evidence CX, P1 Q2 [QUADAS: 11.5/14]	64 patients with suspected OSA	Apnoea: no or almost no airflow, ≥10 s Hypopnoea: ↓ airflow or respiratory movement ≥30%, ≥10 s, accompanied by oxygen desaturation ≥3%	*Home-based Compumedics PS-2 system*	*Laboratory-based PSG*	Weighted k: 0.57 [95% CI: 0.42, 0.71] (analysis of Inter-rater agreement)
				AHI ≥4.2	AHI ≥4.2	
				AHI ≥9.5	AHI ≥9.5	
				AHI ≥23.1	AHI ≥23.1	
			Apnoea: no or almost no airflow, ≥10 s Hypopnoea: ↓ airflow or respiratory movement ≥30%, ≥10 s, accompanied by oxygen desaturation ≥4%	AHI: 0–1.1	AHI: 0–1.1	Weighted k: 0.46 [95% CI: 0.31, 0.61] (analysis of Inter-rater Agreement)
				AHI: 1.1–4.4	AHI: 1.1–4.4	
				AHI: 4.4–13.8	AHI: 4.4–13.8	
				AHI: >13.8	AHI: >13.8	
			Apnoea: no or almost no airflow, ≥10 s Hypopnoea: ↓ airflow or respiratory movement ≥30%, ≥10 s	AHI: 0–26.7	AHI: 0–26.7	Weighted k: 0.59 [95% CI: 0.45, 0.73] (analysis of Inter-rater agreement)
				AHI: 26.7–37.9	AHI: 26.7–37.9	
				AHI: 37.9–51.2	AHI: 37.9–51.2	
				AHI >51.2	AHI >51.2	

Study	Evidence level and quality	Population	Respiratory event definition	*Index test*	*Reference standard*	Agreement measure
				Cut-off point	Cut-off point	
(Gagnadoux et al 2002)	Cross-classification study Level III-2 diagnostic evidence CX, P1 Q1 [QUADAS: 13.5/14]	65/99 patients with suspected sleep apnoea	Apnoea: no airflow, ≥10 s Hypopnoea: ↓ respiratory movement ≥50%, ≥10 s	*Home-based Minisomno®* n/a	*Hospital-based PSG* n/a	Mean difference (AHI): –0.75 Limits of agreement: [–28, 26.5] (Bland and Altman plot analysis)
(Portier et al 2000)	Cross-classification study Level III-2 diagnostic evidence CX, P1 Q1 [QUADAS: 12/14]	78/103 patients with suspected sleep apnoea	Apnoea: ↓ airflow ≥75%, ≥10 s Hypopnoea: ↓ airflow ≥25%, ≥10 s	*Home-based Minisomno®* n/a	*Laboratory-based PSG* n/a	Mean difference (AHI): –2.9 Limits of agreement: [–30, 36] (p=0.13) (Bland and Altman plot analysis)
(Ancoli-Israel et al 1997)	Cross-classification study Level III-2 diagnostic evidence CX, P1 Q2 [QUADAS: 11/14]	34 patients with sleep apnoea or healthy people	Apnoea: no airflow, ≥10 s Hypopnoea: ↓ airflow ≥50%	*Home-based NightWatch System™* AHI ≥10	*Laboratory-based PSG* AHI ≥10	ρ=0.63 (p<0.003) (Spearman rank correlation)
Level 3 sleep study						
(Dingli et al 2003)	Cross-classification study Level II diagnostic evidence CX, P1 Q1 [QUADAS: 14/14]	50/61 consecutive patients referred to the sleep centre with possible obstructive sleep apnoea–hypopnoea syndrome	Apnoea: no airflow ≥10 s Hypopnoea: ↓ thoraco-abdominal movement ≥50% ≥10 s	*Unattended home-based Embletta device* n/a	*Laboratory-based full channel PSG* n/a	k=0.54 (p<0.001) (analysis of Inter-rater agreement)

Study	Evidence level and quality	Population	Respiratory event definition	*Index test*	*Reference standard*	Agreement measure
				Cut-off point	Cut-off point	
(García-Díaz et al 2007)	Cross-classification study Level II diagnostic evidence CX, P1 Q1 [QUADAS: 13/14]	62 consecutive patients with suspected sleep apnoea–hypopnoea syndrome referred to sleep laboratory	Apnoea: no oronasal airflow, ≥10 s Hypopnoea: ↓ airflow ≥50% associated with either an oxygen desaturation ≥4% (and/or EEG arousal in PSG study), ≥10 s	*Home-based Apnoescreen II* n/a	*Laboratory-based PSG* n/a	Observer A: Mean difference (RDI–AHI): 3.1±17 [95% CI –1.1, 7.5] Observer B: Mean difference: 1.6±16.4 [95% CI –2.5, 5.8] Limits of agreement: reported graphically (Bland and Altman plot analysis)
(Parra et al 1997)	Cross-classification study Level II diagnostic evidence CX, P1 Q1 [QUADAS: 12/14]	89 patients with suspected sleep apnoea	Unattended sleep study: apnoea: no airflow, ≥10 s; hypopnoea: ↓ airflow or thoracic movement, ≥10 s, associated with oxygen desaturation ≥2% Laboratory-based PSG: apnoea: no airflow, ≥10 s; hypopnoea: ↓ airflow or thoraco-abdominal movement, ≥10 s, associated with oxygen desaturation or arousal	*Home-based Edentrace II, Model 3711* n/a	*Laboratory-based PSG* n/a	Mean difference (RDI–AHI): –2.5 Limits of agreement: [–5.8, 0.7] (Bland and Altman plot analysis)
(Tonelli de Oliveira et al 2009)	Cross-classification study Level III-1 diagnostic evidence CX, P2 Q1 [QUADAS: 13/14	121 patients with suspected OSA	Apnoea: no airflow, ≥10 s Hypopnoea: ↓ airflow ≥50% or any discernable ↓ airflow associated with arousal oxygen desaturation ≥3%	*Home-based Somno-check* n/a	*Laboratory-based PSG* n/a	Mean difference (RDI–AHI): 2.6 Limits of agreement: [–17.7, 22.6] (Bland and Altman plot analysis)
(Whittle et al 1997)	Cross-classification study Level III-2 diagnostic evidence CX, P1 Q2 [QUADAS: 10/14]	20/23 patients with suspected sleep apnoea	Apnoea: no airflow, >10 s Hypopnoea: ↓ respiratory movement >50%, >10 s	*Home-based Edentrace system, Model 3711* n/a	*Laboratory-based PSG* n/a	Mean difference (RDI–AHI): –8 Limits of agreement: [–32, 16] (Bland and Altman plot analysis) r=0.8 ($p<0.001$) (Pearson χ^2 test)

Study	Evidence level and quality	Population	Respiratory event definition	*Index test*	*Reference standard*	Agreement measure
				Cut-off point	Cut-off point	
	Cross-classification study Level III-2 diagnostic evidence CX, P1 Q2 [QUADAS: 11/14]	58[a]/150 patients with suspected sleep apnoea	Apnoea: no airflow, >10 s Hypopnoea: ↓respiratory movement >50%, >10 s	*Home-based Edentrace system, Model 3711* n/a	*Laboratory-based PSG* n/a	r=0.38 (p<0.01) (p<0.001) (Pearson χ^2 test)
(Miyata et al 2007)	Cross-classification study Level III-2 diagnostic evidence CX, P1 Q3 [QUADAS: 8/14]	18 patients with OSA	Apnoea: no airflow, ≥10 s Hypopnoea: ↓ airflow associated with either an oxygen desaturation >3%, ≥10 s, or arousal	*Home-based LT-200* n/a	*Laboratory-based PSG* n/a	Mean difference (RDI–AHI): –4.3 Limits of agreement: [–13.1, 4.4] (Bland and Altman plot analysis) r=0.94 (p<0.0001) (Pearson χ^2 test)
Level 4 sleep study						
(Golpe et al 2002)	Cross-classification study Level III-1 diagnostic evidence CX, P1 Q1 [QUADAS: 14/14]	55 patients with suspected sleep apnoea–hypopnoea syndrome referred to sleep unit	Apnoea: no airflow, ≥10 s Hypopnoea: discernible ↓ airflow ≥10 s accompanied by oxygen desaturation ≥4% and/or arousal	*Laboratory-based PSG* n/a	*Home-based Apnoescreen I* [b] n/a	Mean difference (ODI–AHI): –4.2 Limits of agreement: [–34.3, 25.9] (Bland and Altman plot analysis)
(Baltzan et al 2000)	Cross-classification study Level III-1 diagnostic evidence CX, P1 Q1 [QUADAS: 12/14]	66 patients with suspected OSA	Apnoea: ↓ airflow >90%, ≥10 s Hypopnoea: ↓ airflow ≥50% accompanied by oxygen desaturation ≥4%	*Home-based OxiFlow* n/a	*Laboratory-based PSG* n/a	r=0.58 (Pearson χ^2 test)
(Ayappa et al 2004)	Cross-classification study Level III-1 diagnostic evidence CX, P1 Q1 [QUADAS: 12/14]	56/59 patients with suspected OSA or healthy people	Apnoea: ↓airflow >90%, ≥10 s Hypopnoea: ↓ airflow >50%, ≥10 s, or ↓ airflow 20–50%, ≥10 s followed by sudden resolution of the flow limitation shape and/or followed by oxygen desaturation >4%	*Hospital/ home-based portable Sleep Data Recorder or Compumedics P2 System*[b] n/a	*Laboratory-based PSG* n/a	Mean difference (ODI–AHI): –10.9 Limits of agreement: [–14.6, –7.2] (Bland and Altman plot analysis)

Study	Evidence level and quality	Population	Respiratory event definition	*Index test*	*Reference standard*	Agreement measure
				Cut-off point	Cut-off point	
(Wong et al 2008)	Cross-classification study Level III-1 diagnostic evidence CX, P1 Q1 [QUADAS: 12/14]	31/34 patients with suspected sleep disordered breathing	Unattended sleep study: apnoea: no airflow, ≥10 s; hypopnoea: ↓ airflow ≥50%, ≥10 s Laboratory-based PSG: apnoea: no airflow, ≥10 s; hypopnoea: ↓ airflow ≥50%, ≥10 s, accompanied by oxygen desaturation ≥3% or arousal	*Home-based Flow Wizard* n/a	*Laboratory-based PSG* n/a	Mean difference (ODI–AHI): 1.8 Limit of agreement: [–32.4, 36.0] (Bland and Altman plot analysis)
(Fietze et al 2004)	Cross-classification study Level III-1 diagnostic evidence CX, P1 Q2 [QUADAS: 10.5/14]	18[c]/35 patients with suspected OSA	Unattended sleep study: oxygen desaturation ≥3% with absence of moving artefacts and irrespective of co-existing changes in snoring or heart rate Laboratory-based PSG: apnoea: no airflow ≥10 s; hypopnoea: ↓ airflow ≥50%, ≥10 s, associated with either oxygen desaturation of ≥3 or an arousal	*Home-based portable MESAM IV device (MAP)* ODI ≥5 ODI >15	*Laboratory-based PSG* AHI ≥5 AHI >15	ρ=0.78, p<0.0001 (Spearman rank correlation test)
(Golpe et al 1999)	Cross-classification study Level III-2 diagnostic evidence CX, P1 Q1 [QUADAS: 12/14]	116 patients with suspected OSA	Unattended sleep study: oxygen desaturation ≥4%, ≥10 s Laboratory-based PSG: apnoea: no airflow, ≥10 s; hypopnoea: ↓airflow >50%, associated with either oxygen desaturation ≥4% or by arousal	*Home-based finger oximeter, AVL-Minolta Pulsox 7* n/a	*Laboratory-based PSG* AHI ≥10	Mean difference (ODI–AHI): –3.19 Limits of agreement: [–6.9, 0.59] (Bland and Altman plot analysis) r=0.60, p<0.01 (Pearson χ^2 test)
			Unattended sleep study: oxygen resaturation ≥3%, ≥10 s Laboratory-based PSG: as in the above row	n/a	AHI ≥10	Mean difference (ODI–AHI): 2.2 Limits of agreement: [–1.6, 6.1] (Bland and Altman plot analysis) r=0.58, p>0.05 (Pearson χ^2 test)
			Unattended sleep study: oxygen saturation <90% Laboratory-based PSG: as in the above row	n/a	AHI ≥10	r=0.50, p<0.01 (Pearson χ^2 test)

Study	Evidence level and quality	Population	Respiratory event definition	*Index test*	*Reference standard*	Agreement measure
				Cut-off point	Cut-off point	
(Pang et al 2006)	Cross-classification study Level III-2 diagnostic evidence CX, P1 Q2 [QUADAS: 11.5/14]	32/37 patients with suspected sleep disordered breathing	Unattended sleep study: apnoea: ↓ airflow >88%, ≥10 s; hypopnoea: ↓ airflow >50%, ≥10 s Laboratory-based PSG: apnoea: no airflow, ≥10 s; hypopnoea: ↓ airflow or thoraco-abdominal movement ≥30%, ≥10 s, associated with oxygen desaturation ≥4% or arousal	*Home-based SleepStrip*	*Laboratory-based PSG*	k=0.139 (p=0.190) (analysis of Inter-rater agreement)
				RDI ≥15	AHI ≥15	
				RDI ≥25	AHI ≥25	
				RDI ≥40	AHI ≥40	
(Pittman et al 2004)	Cross-classification study Level III-2 diagnostic evidence CX, P1 Q2 [QUADAS: 11.5/14]	29 patients with suspected OSA	Unattended sleep study: 1) ↓ PAT, associated with ↑ heart rate or wrist activity; 2) ↓ PAT, associated with oxygen desaturation ≥3%; or 3) oxygen desaturation ≥4% Laboratory-based PSG: apnoea: no airflow, ≥10 s; hypopnoea: ↓ airflow >50%, or lesser extent (noticeable change) in association with oxygen desaturation ≥3%	*Home-based Watch_PAT + Nonin 8000J pulse oximeter*	*Laboratory-based PSG*	Mean difference (ODI–AHI): –1.4 Limits of agreement: [–31.5, 28.7] (Bland and Altman plot analysis) k=0.72 (p<0.0001) (analysis of Inter-rater agreement)
				PAT index ≥5	AHI ≥5	
				PAT index ≥10	AHI ≥10	
				PAT index ≥15	AHI ≥15	
				PAT index ≥20	AHI ≥20	
				PAT index ≥30	AHI ≥30	
			Unattended sleep study: as in the above row Laboratory-based PSG: apnoea: no airflow, ≥10 s; hypopnoea: ↓ airflow or thoraco-abdominal movement ≥30%, associated with oxygen desaturation ≥4%	PAT index ≥5	AHI ≥5	Mean difference (ODI–AHI): –1.6 Limits of agreement: [–28.0, 24.8] (Bland and Altman plot analysis) k=0.80 (p<0.0001) (analysis of Inter-rater agreement)
				PAT index ≥10	AHI ≥10	
				PAT index ≥15	AHI ≥15	
				PAT index ≥20	AHI ≥20	
				PAT index ≥30	AHI ≥30	
(Westbrook et al 2005)	Cross-classification study Level III-2 diagnostic evidence CX, P1 Q2 [QUADAS: 11/14]	187 patients with suspected sleep-disordered breathing, with comorbidities or healthy people	Unattended sleep study: oxygen desaturation/resaturation of 2.5%/2.5%, 3.0%/2.7%, 3.5%/3.0%, 4.0%/3.2%, or 2.2%/2.2% accompanied by arousal Laboratory-based PSG: NR	*Home-based ARES Unicorder*	*Laboratory-based PSG*	Mean difference (ODI–AHI): –1.9 Limits of agreement: [–29.9, 26.1] (Bland and Altman plot analysis) r=0.88 (p<0.01) (Pearson χ^2 test)
				n/a	n/a	

Study	Evidence level and quality	Population	Respiratory event definition	*Index test*	*Reference standard*	Agreement measure
				Cut-off point	Cut-off point	
(Wiltshire et al 2001)	Cross-classification study Level III-2 diagnostic evidence CX, P1 Q3 [QUADAS: 9.5/14]	84 patients with suspected sleep apnoea	Oxygen desaturation ≥4%	*Home-based Ohmeda Biox3740*	*Laboratory-based PSG*	Mean difference (ODI): –8.4 Limits of agreement: [–33.1, 16.3] (Bland and Altman plot analysis) r=0.08 (p<0.001) (Pearson χ^2 test)
				n/a	n/a	
(Takeda et al 2006)	Cross-classification study Level III-2 diagnostic evidence CX, P1 Q3 [QUADAS: 8.5/14]	135 patients suffering from sleep disturbance	Unattended sleep study: oxygen desaturation ≥3% Laboratory-based PSG: apnoea: no airflow, ≥10 s; hypopnoea: ↓ airflow >25%, ≥10 s, accompanied by oxygen desaturation ≥3% or arousal	*Home-based Apno-monitor III*	*Laboratory-based PSG*	r=0.54 (p<0.001) (Pearson χ^2 test)
				n/a	n/a	
(Olson et al 1999)	Cross-classification study—retrospective Level III-2 diagnostic evidence CX, P2 Q3 [QUADAS: 7/14]	793 patients suspected of OSA receiving home oximetry who also had a PSG	Apnoea and hypopnoea not defined. Relationship between (1) arterial oxygen saturation <90% greater than 1% of recording time (CT_{90}) and (2) Δ Index (saturation variability criteria), and AHI investigated	*Home-based Pulse oximetry (Biox 4700)*	*Laboratory-based PSG*	ρ=0.36 (*p*<0.0001) (Spearman rank correlation test
				CT_{90} 1.0	AHI ≥15	
				Δ index 0.4	AHI ≥15	ρ=0.59 (*p*<0.0001) (Spearman rank correlation test

[a] Patients with ODI between 5-30; [b] Hospital-based: n=52; home-based: n=7; portable Sleep Data Recorder: n=56; Compumedics P2 System: n=3; [c] Patients with ODI <30.

AHI = apnoea–hypopnoea index; CI = confidence interval; CT = cumulative percentage time; n/a = not applicable; NR = not reported; ODI = oxygen desaturation index; ORI = oxygen resaturation index; OSA = obstructive sleep apnoea; PAT = peripheral arterial tone; PSG = polysomnography; RDI = respiratory disturbance index; s = seconds

Nineteen case series (level IV diagnostic evidence) were identified that reported on the diagnostic yield of unattended Level 2, 3 or 4 sleep studies in a referral setting. These results are presented in Appendix E. Four Level 2 studies identified a mean AHI of 22–46 in their study populations. Eleven studies reported on the severity of OSA identified in patients receiving Level 3 sleep studies, with the average AHI/RDI in the range 12.9–60.8. At an AHI/RDI threshold of 5, 86–100% of patients were positive, 84–100% were positive at a cut-off point of 10, 71–93% at a cut-off point of 15, and 13–73% with severe OSA at a threshold of 30. Five studies reported on the diagnostic yield from Level 4 sleep devices, with a mean RDI in the range 7.8–45.1.

Does it change patient management?

One study reported on the proportion of patients receiving unattended sleep studies that went on to complete an additional Level 1 sleep study. Whittle et al (1997) found that 38.7% of patients went on to further testing after a Level 3 study, but they did not distinguish between those patients who had received a positive or negative OSA result

from the unattended sleep study. Whittle et al (1997) observed that the median time to diagnosis with a Level 3 sleep study was 18 days, compared with 47 days with laboratory-based PSG (Table 22). Although statistically significant ($p<0.001$), the difference in the time diagnosis between unattended and attended sleep studies was not clinically relevant (expert opinion from the Advisory Panel).

Three studies provided data on the change in patient management as a consequence of use of a Level 3 study for diagnosis. Two of these studies provided hypothetical analyses, ie the treatment decision was recorded after receiving the diagnostic result from two studies—index test and reference standard—on the same patient (Golpe et al 2002; Parra et al 1997). The third study was a cohort study, where the treatment decision was actually acted upon (Whittle et al 1997) (Table 22).

The two hypothetical studies provided identical results in that the therapeutic decision agreement, on the basis of a Level 3 sleep study in comparison with laboratory-based PSG, was 89%. In these two studies the proportion of patients treated with CPAP according to the Level 1 study who would not be treated according to the Level 3 study (false negatives) ranged from 6.7% to 9.1%. The reverse situation—the proportion of patients treated with CPAP according to the Level 3 study who would not be treated according to PSG (false positives)—ranged from 4.5% to 13.6%. Similarly, there was little difference between actual patient management on the basis of a Level 3 study compared with a Level 1 study. Whittle et al (1997) determined that 61% of patients were offered CPAP after a Level 3 study, compared with 67% after PSG. Compliance with CPAP was slightly higher after the unattended study (88%) compared with the attended study (80%), and rates of CPAP usage were very similar.

Table 22 Management of adults in a referral setting

Study	Evidence level and quality	Population	*Index test comparator*		Management alteration
			Respiratory event definition	Treatment decision	
Level 3 sleep study					
(Parra et al 1997)	Cross-classification study Level III-2 interventional evidence CX, P1 Q1 [NHMRC: 4/6]	89 patients with suspected sleep apnoea	*Home-based Edentrace II, Model 3711*		*Hypothetical treatment decision:* Therapeutic decision agreement between the two groups: 79/89 (88.8%) Patients treated with CPAP according to PSG who would not be treated according to index test: 6 (6.7%) Patients treated with CPAP according to index test who would not be treated according to PSG: 4 (4.5%)
			Apnoea: no airflow, ≥10 s Hypopnoea: ↓ airflow or thoracic movement, ≥10 s, associated with oxygen desaturation ≥2%	Treated with CPAP if RDI >30 with clear clinical impairment; or RDI >30 without moderate clinical impairment	
			Laboratory-based PSG		
			Apnoea: no airflow, ≥10 s Hypopnoea: ↓ airflow or thoraco-abdominal movement, ≥10 s, associated with oxygen desaturation or arousal	Treated with CPAP if AHI >30 with clear clinical impairment; or AHI >30 without moderate clinical impairment	

Study	Evidence level and quality	Population	*Index test comparator*		Management alteration
			Respiratory event definition	Treatment decision	
(Golpe et al 2002)	Cross-classification study Level III-2 interventional evidence CX, P1 Q2 [NHMRC: 4/6]	55 patients with suspected sleep apnoea/ hypopnoea syndrome referred to sleep unit	*Home-based Apnoescreen I*		*Hypothetical treatment decision:* Therapeutic decision agreement between the two groups: 33/37 (89%) *[excluding 7 uninterpretable studies]* Patients treated with CPAP according to PSG who would not be treated according to index test: 4/44 (9.1%) Patients treated with CPAP according to index test who would not be treated according to PSG: 6/44 (13.6%)
			Apnoea: no airflow, ≥10 s Hypopnoea: discernible ↓ airflow ≥10 s accompanied by oxygen desaturation ≥4% and/or arousal	Treated with CPAP if RDI ≥10	
			Laboratory-based PSG		
			Apnoea: no airflow, ≥10 s Hypopnoea: discernible ↓ airflow ≥10 s accompanied by oxygen desaturation ≥4% and/or arousal	Treated with CPAP if AHI ≥10	
(Whittle et al 1997)	Prospective cohort study Level III-2 interventional evidence CX, P1 Q2 [NHMRC: 4/6]	150 patients with suspected sleep apnoea	*Home-based Edentrace system, Model 3711*		CPAP offered: 92/150(61%) Continuing CPAP: 81/92 (88%) CPAP usage: 4.7±2.4 hours/night Referred to ENT for tonsillectomy: 2/150 (1.3%)
			Apnoea: no airflow, >10 s Hypopnoea: ↓ respiratory movement >50%, >10 s	Treated with CPAP if RDI >30	
		75 patients with suspected sleep apnoea	*Laboratory-based PSG*		CPAP offered: 50/75 (67%) (p>0.5) Continuing CPAP: 40/50 (80%) (p=0.4) CPAP usage: 5.0±2.4 hours/night (p>0.5)
			Apnoea: no airflow, >10 s Hypopnoea: ↓ respiratory movement >50%, >10 s	Treated with CPAP if RDI >30	

AHI = apnoea–hypopnoea index; CPAP = continuous positive airway pressure; OSA = obstructive sleep apnoea; PSG = polysomnography; RDI = respiratory disturbance index

Direct evidence

Summary — Are Level 2, 3 or 4 unattended sleep studies (± Level 1 studies) as, or more, effective than Level 1 laboratory-based (attended) sleep studies alone at improving the health outcomes of adults with suspected OSA referred to a specialist?

Evidence of a change in the symptoms, QoL and the number of respiratory events in adult patients with OSA, diagnosed using unattended sleep studies in a referral setting, was reported by eight studies. The evidence was largely of poor quality despite the availability of comparative studies (including level II interventional evidence).

The two highest level studies provided direct evidence of the clinical effectiveness of Level 4 studies. In Whitelaw et al's (2005) RCT, excessive daytime sleepiness was improved after the diagnosis of OSA with the aid of the home-based SnoreSat study and following 4-week APAP treatment, with scores on the ESS reducing by an average of 3.4 points (from 11.6 to 8.2). This figure was identical to the mean ESS decrease of 3.4 in the group of patients who

had their diagnosis of OSA confirmed by laboratory-based PSG and who likewise underwent APAP treatment for 4 weeks (p=0.27). Similar results were reported in the cohort study by Berry et al (2008). These studies indicated that OSA patients' symptoms were controlled regardless of whether they had been diagnosed by Level 4 unattended sleep studies or through laboratory-based PSG. A flow-on effect on patient QoL was apparent—with better QoL reported after the unattended sleep study diagnosis and subsequent treatment in these two studies, which was consistent with the results observed after laboratory-based PSG diagnosis and subsequent treatment.

The case series by Antic et al (2009) was the only study carried out in an Australian setting that assessed the effectiveness of a Level 4 home-based sleep study. All subjects receiving this test either underwent 3 months of APAP (home-based titration) treatment (nurse-led care) or received additional laboratory-based PSG and 3 months of CPAP (laboratory-based titration) treatment (physician-directed care). A comparison of the ESS and MWT results between the two models of care suggested that the use of laboratory-based PSG as a supplementary test in the diagnosis of OSA did not influence the impact of unattended sleep studies on patients' symptom control. In this study the impact of symptom control on patients' QoL was not apparent.

Direct evidence of the effect of unattended sleep studies on the secondary outcomes of respiratory events and commencement of treatment were supportive of the results on the impact on patient clinical symptoms (primary outcomes). The poor-quality cohort study by White & Gibb (1998) reported a reduced AHI after a diagnostic Level 2 sleep study and subsequent CPAP treatment. However, the mean change in AHI in the unattended sleep study group was not significantly different from that in the laboratory-based PSG group (–60.1 vs –59.2). In addition, a Level 2 sleep study did not result in clinically significantly less waiting time for CPAP treatment or more sleep time when compared with a Level 1 sleep study.

The evidence on Level 3 studies was non-comparative, and so comparative effectiveness cannot be directly assessed.

Linked evidence

Summary — In referred cases of suspected adult OSA, are Level 2, 3 or 4 unattended sleep studies as accurate as Level 1 laboratory-based (attended) sleep studies at diagnosing OSA?

Linked evidence in the report found that selected Level 2 and 3 unattended studies have moderate to high test performance, on a range of diagnostic accuracy measures, relative to laboratory-based PSG. Sensitivity was generally high, although specificity was variable. NPVs were also high, although the likelihood of incorrect negative results (false negatives) was in the range 15–20% for the highest quality Level 2 studies and 19–35% across Level 3 studies that varied in quality.

Four studies of moderate quality reported on the agreement between Level 2 and Level 1 studies, and the results were heterogeneous. Moderate levels of agreement between a home-based Compumedics PS-2 system and laboratory-based PSG was observed by Iber et al (2004), while the Minisomno® Level 2 system performed poorly against the same reference standard in two studies (limits of agreement allowed clinically important differences between the two tests). Three studies of very high quality showed good

agreement between Level 1 studies and the Level 3 Embletta, Apneoscreen II and Edentrace II devices. Lower quality studies indicated that the agreement between the Level 3 devices and laboratory-based PSG was often clinically unacceptable.

A general trend in the evidence-base was that manually scored unattended sleep studies had better congruence with laboratory-based PSG than did automated scoring techniques.

The test accuracy of Level 4 studies was lower than that observed for the Level 3 studies. The highest level of evidence available (good-quality level III-1 diagnostic evidence) in the correct population (suspected OSA) reported moderate to good diagnostic accuracy overall, with AUCs in the range 0.71–0.89. The highest quality level II and III-1 diagnostic evidence found that test sensitivity ranged more widely for the Level 4 studies across various diagnostic thresholds (55–92%), with specificity more constrained (75–98%). NPVs were moderate to high—75–95% across different diagnostic thresholds. In terms of the agreement in OSA diagnoses between Level 4 and Level 1 studies, the level and quality of evidence was poorer than that of the Level 3 studies, and the results were heterogeneous. Only two studies showed reasonable levels of agreement between Level 4 studies and laboratory-based PSG.

Summary — Does the use of Level 2, 3 or 4 unattended sleep studies (± Level 1 study) in the diagnosis of referred cases of suspected adult OSA impact on patient management differently compared with the use of a Level 1 laboratory-based (attended) sleep study alone?

The only comparative data available to answer this question did not report on the difference in additional referrals or sleep tests between patients in the unattended and attended sleep study groups. Whittle et al (1997) reported that nearly 39% of patients went on to further testing after a Level 3 study, but did not distinguish between those patients who had received a positive or negative OSA result from that unattended sleep study. In addition, the authors observed that the median time to diagnosis with a Level 3 sleep study was 18 days, compared with 47 days with laboratory-based PSG—the difference was statistically significant.

Diagnosis in a paediatric setting

Is it safe?

Studies were included to assess the safety of unattended sleep studies in a paediatric setting according to the criteria outlined in Box 10.

Box 10 Criteria for selecting studies to assess the safety of unattended sleep studies in a paediatric setting

Selection criteria	Inclusion criteria
Population	Children with suspected[a] or previously diagnosed OSA – Subgroups: age range, BMI range, comorbid conditions (eg Downs syndrome, cleft palate, developmental delay)
Index test / intervention	*Level 2* unattended sleep study / polysomnography that includes assessments of: sleep staging (EEG), detection of airflow, respiratory movement, arterial oxygen saturation, electrocardiogram (ECG), and subsequent data analysis and interpretation by an appropriately trained and credentialed medical practitioner OR *Level 3* unattended sleep study involving the assessment of two or more cardiopulmonary parameters (eg detection of airflow, respiratory movement, arterial oxygen saturation, ECG), and subsequent data analysis and interpretation by an appropriately trained and credentialed medical practitioner *OR* *Level 4* unattended sleep study involving the assessment of one cardiopulmonary parameter (usually oximetry), and subsequent data analysis and interpretation by an appropriately trained and credentialed medical practitioner ± *Level 1 study*
Comparator(s)	*Level 1* laboratory-based, overnight, attended (by sleep technician) sleep study / polysomnography that includes assessments of: sleep staging (EEG, EOG, EMG), detection of airflow (quantitative or semi-quantitative nasal transducers), respiratory movement (via transducers on chest or abdominal walls, or via RIP), arterial oxygen saturation (via a pulse oximeter), ECG, leg movement, snoring, body positioning, and subsequent data analysis and interpretation OR *Surgery without use of a prior sleep study*[b]
Outcomes	Physical harms from testing, eg allergy to electrode adhesive
Publication type	Randomised or non-randomised controlled trials, cohort studies, registers, case series, case reports or systematic reviews of these study designs. Non-systematic reviews, non-research letters, editorials; and animal, in-vitro and laboratory studies, were excluded.
Search period	1980 – April 2009
Language	Non-English language articles were excluded unless they provided a higher level of evidence than the English language articles identified

[a] Suspected on the basis of snoring, behavioural change, learning difficulties, secondary enuresis; [b] There is no guarantee that those patients that would currently proceed to surgical treatment without a (Level 1) sleep study—perhaps because of access issues—would not have an unattended sleep study prior to surgical treatment should these unattended sleep studies be publicly funded.

BMI = body mass index; ECG = electrocardiogram; EEG = electroencephalogram; EMG = electromyogram; EOG = electrooculogram; OSA = obstructive sleep apnoea; RIP = respiratory inductive plethysmography

No paediatric studies were identified that reported safety outcomes related to the use of unattended sleep studies in the diagnosis of OSA or for the reassessment of treatment efficacy.

Potential harms associated with using unattended sleep studies in young children, such as untoward accidents and allergy to electrode adhesives, are addressed in the 'Discussion' section of the report (see page 152).

Summary — Are Level 2, 3 or 4 unattended sleep studies (± Level 1 studies) as safe as, or safer than, Level 1 laboratory-based (attended) sleep studies alone, or surgery without use of a prior sleep study, for children with suspected or previously diagnosed OSA referred to a specialist paediatric multidisciplinary team?

No studies reported on the safety of unattended sleep studies in children with suspected or previously diagnosed OSA.

Is it effective?

Direct evidence

Box 11 outlines the criteria determined a priori for including studies that assessed the effectiveness of unattended sleep studies in a paediatric setting.

Box 11 Criteria for selecting studies to assess the diagnostic effectiveness of unattended sleep studies in a paediatric setting

Selection criteria	Inclusion criteria
Population	Children with suspected[a] or previously diagnosed OSA – Subgroups: age range, BMI range, comorbid conditions (eg Downs syndrome, cleft palate, developmental delay)
Index test / intervention	*Level 2* unattended sleep study / polysomnography that includes assessments of: sleep staging (EEG), detection of airflow, respiratory movement, arterial oxygen saturation, electrocardiogram (ECG), and subsequent data analysis and interpretation by an appropriately trained and credentialed medical practitioner OR *Level 3* unattended sleep study involving the assessment of two or more cardiopulmonary parameters (eg detection of airflow, respiratory movement, arterial oxygen saturation, ECG), and subsequent data analysis and interpretation by an appropriately trained and credentialed medical practitioner *OR* *Level 4* unattended sleep study involving the assessment of one cardiopulmonary parameter (usually oximetry), and subsequent data analysis and interpretation by an appropriately trained and credentialed medical practitioner ± *Level 1 study*
Comparator(s)	*Level 1* laboratory-based, overnight, attended (by sleep technician) sleep study / polysomnography that includes assessments of: sleep staging (EEG, EOG, EMG), detection of airflow (quantitative or semi-quantitative nasal transducers), respiratory movement (via transducers on chest or abdominal walls, or via RIP), arterial oxygen saturation (via a pulse oximeter), ECG, leg movement, snoring, body positioning, and subsequent data analysis and interpretation OR *Surgery without use of a prior sleep study*[b]
Outcomes	Primary: 1) *patient-relevant*: survival/mortality rate, resolution/reduction of symptoms (eg snoring, excessive daytime sleepiness, witnessed apnoea episodes), disease-specific quality of life; 2) *surrogate*: respiratory events / number of apnoeas or hypopnoeas (eg AHI, RDI), oxygen saturation (eg ODI), sleep time and efficiency (eg sleep stage duration/quality, ArI) Secondary: additional sleep studies (by type), referral to sleep physician / qualified sleep medicine practitioner, time to diagnosis, time to commencement of treatment, treatment type
Publication type	Randomised or non-randomised controlled trials or cohort studies or pre-test/post-test case series, or systematic reviews of these study designs. Non-systematic reviews, letters, editorials; and animal, in-vitro and laboratory studies, were excluded.
Search period	1980 – April 2009
Language	Non-English language articles were excluded unless they provided a higher level of evidence than the English language articles identified

[a] Suspected on the basis of snoring, behavioural change, learning difficulties, secondary enuresis; [b] There is no guarantee that those patients that would currently proceed to surgical treatment without a (Level 1) sleep study—perhaps because of access issues—would not have an unattended sleep study prior to surgical treatment should these unattended sleep studies be publicly funded.

AHI = apnoea–hypopnoea index; ArI = arousal index; BMI = body mass index; ECG = electrocardiogram; EEG = electroencephalogram; EMG = electromyogram; EOG = electrooculogram; ODI = oxygen desaturation index; OSA = obstructive sleep apnoea; RDI = respiratory disturbance index; RIP = respiratory inductive plethysmography

One study was identified that provided evidence regarding a change in the health outcomes of children with OSA, diagnosed by unattended sleep studies (Patel &

Davidson 2007). This is actually a case report because it involved only one child whilst the other three were adult patients. Therefore, the study would only be eligible for assessing the safety rather than, strictly speaking, the effectiveness of unattended sleep studies for paediatric OSA. However, since no studies meeting the selection criteria reported on the effectiveness of unattended sleep studies in a paediatric setting, this case report was included in order to provide some effectiveness information. Nevertheless, the serious limitations with the data from this case report in terms of applicability to the target population should be stressed.

Patel et al (2007) investigated a Level 3 device, Embletta PDS, in an 8-year-old boy with a complaint of habitual snoring. Physical examination revealed enlarged tonsils (tonsil grade 3+). Neuropsychologic abnormality was indicated with the aid of a neuropsychologic evaluation. The Embletta PDS study was carried out in a home setting. Due to the abnormal result in the unattended sleep study (RDI=4.2), the boy underwent tonsillectomy to treat the OSA. Three months after the surgery, the boy had significantly fewer apnoea–hypopnoea events, as revealed by home-based Embletta PDS study (RDI=0.8). A post-treatment neuropsychologic battery test demonstrated an improvement in behavioural and cognitive functioning, with increasing total raw scores on the attention/executive domain and the sensorimotor function domain (Table 23).

Table 23 Neuropsychologic results (n=1) before and after diagnosis of OSA using an unattended sleep study and subsequent treatment in a paediatric setting

Domain	Test	Raw scores		
		Baseline	Post-treatment (3 months)	Difference
Attention/executive function	Total	91	92	+1
	Statue	29	27	–2
	Visual attention	34	37	+3
	Knock-tap	28	28	0
Sensorimotor function	Total	67	75	+8
	Finger tapping (preferred hand)	6	9	+3
	Finger tapping (non-preferred hand)	9	11	+2
	Sequential tapping (preferred hand)	20	19	–1
	Sequential tapping (non-preferred hand)	32	36	+4

Source: Patel & Davidson (2007)

Linked evidence

Due to the very limited available direct evidence, a linked evidence approach was attempted, where evidence of diagnostic accuracy and impact on patient management were linked to provide an indication of the effectiveness of using unattended sleep studies in a paediatric setting. The selection criteria for such an assessment are outlined in Box 12 and Box 13.

Box 12 Criteria for selecting studies to assess the diagnostic accuracy of unattended sleep studies in a paediatric setting

Selection criteria	Inclusion criteria
Population	Children with suspected[a] or previously diagnosed OSA – Subgroups: age range, BMI range, comorbid conditions (eg Downs syndrome, cleft palate, developmental delay)
Index test / intervention	*Level 2* unattended sleep study / polysomnography that includes assessments of: sleep staging (EEG), detection of airflow, respiratory movement, arterial oxygen saturation, electrocardiogram (ECG), and subsequent data analysis and interpretation by an appropriately trained and credentialed medical practitioner OR *Level 3* unattended sleep study involving the assessment of two or more cardiopulmonary parameters (eg detection of airflow, respiratory movement, arterial oxygen saturation, ECG), and subsequent data analysis and interpretation by an appropriately trained and credentialed medical practitioner OR *Level 4* unattended sleep study involving the assessment of one cardiopulmonary parameter (usually oximetry), and subsequent data analysis and interpretation by an appropriately trained and credentialed medical practitioner
Comparator(s)	*Level 1* laboratory-based, overnight, attended (by sleep technician) sleep study / polysomnography that includes assessments of: sleep staging (EEG, EOG, EMG), detection of airflow (quantitative or semi-quantitative nasal transducers), respiratory movement (via transducers on chest or abdominal walls, or via RIP), arterial oxygen saturation (via a pulse oximeter), ECG, leg movement, snoring, body positioning, and subsequent data analysis and interpretation
Outcomes	Sensitivity, specificity, accuracy, negative predictive value, positive predictive value, area under the curve, positive likelihood ratio, negative likelihood ratio, level of agreement Summary measures: diagnostic odds ratio, summary receiver operator characteristic curve
Publication type	Cross-sectional studies where patients were cross-classified on the index test and comparator and/or reference standard. Case-control diagnostic studies were acceptable only if cross-sectional studies were not available. Systematic reviews of cross-sectional studies. Non-systematic reviews, non-research letters, editorials; and animal, in-vitro and laboratory studies, were excluded.
Search period	1980 – April 2009
Language	Non-English language articles were excluded unless they provided a higher level of evidence than the English language articles identified

[a] Suspected on the basis of snoring, behavioural change, learning difficulties, secondary enuresis

BMI = body mass index; ECG = electrocardiogram; EEG = electroencephalogram; EMG = electromyogram; EOG = electrooculogram; OSA = obstructive sleep apnoea; RIP = respiratory inductive plethysmography

Box 13 Criteria for selecting studies to assess the change in management following the use of unattended sleep studies in a paediatric setting

Selection criteria	Inclusion criteria
Population	Children with suspected[a] or previously diagnosed OSA – Subgroups: age range, BMI range, comorbid conditions (eg Downs syndrome, cleft palate, developmental delay)
Index test / Intervention	*Level 2* unattended sleep study / polysomnography that includes assessments of: sleep staging (EEG), detection of airflow, respiratory movement, arterial oxygen saturation, electrocardiogram (ECG), and subsequent data analysis and interpretation by an appropriately trained and credentialed medical practitioner OR *Level 3* unattended sleep study involving the assessment of two or more cardiopulmonary parameters (eg detection of airflow, respiratory movement, arterial oxygen saturation, ECG), and subsequent data analysis and interpretation by an appropriately trained and credentialed medical practitioner

	OR *Level 4* unattended sleep study involving the assessment of one cardiopulmonary parameter (usually oximetry), and subsequent data analysis and interpretation by an appropriately trained and credentialed medical practitioner *± Level 1 study*
Comparator(s)	*Level 1* laboratory-based, overnight, attended (by sleep technician) sleep study / polysomnography that includes assessments of: sleep staging (EEG, EOG, EMG), detection of airflow (quantitative or semi-quantitative nasal transducers), respiratory movement (via transducers on chest or abdominal walls, or via RIP), arterial oxygen saturation (via a pulse oximeter), ECG, leg movement, snoring, body positioning, and subsequent data analysis and interpretation OR *Surgery without use of a prior sleep study*[b]
Outcomes	Additional sleep studies (by type), referral to sleep medicine physician / credentialed medical practitioner, time to diagnosis, time to commencement of treatment, alteration in treatment, treatment type
Publication type	Randomised or non-randomised controlled trials (including before-and-after studies) or cohort studies or uncontrolled pre-test/post-test case series or systematic reviews of these study designs. Non-systematic reviews, non-research letters, editorials; and animal, in-vitro and laboratory studies, were excluded.
Search period	1980 – April 2009
Language	Non-English language articles were excluded unless they provided a higher level of evidence than the English language articles identified

[a] Suspected on the basis of snoring, behavioural change, learning difficulties, secondary enuresis; [b] There is no guarantee that those patients that would currently proceed to surgical treatment without a (Level 1) sleep study—perhaps because of access issues—would not have an unattended sleep study prior to surgical treatment should these unattended sleep studies be publicly funded.

BMI = body mass index; ECG = electrocardiogram; EEG = electroencephalogram; EMG = electromyogram; EOG = electrooculogram; OSA = obstructive sleep apnoea; RIP = respiratory inductive plethysmography

Is it accurate?

Data on the test characteristics of unattended sleep studies in the diagnosis of paediatric OSA, using laboratory-based PSG as the reference standard, were provided by four studies (level III-1 and III-2 diagnostic evidence) (Brunetti et al 2001; Jacob et al 1995; Kirk et al 2003; Zucconi et al 2003) (Table 24).

Zucconi et al (2003), in a moderate-quality study, evaluated the performance of a Level 3 portable cardiorespiratory monitor, POLY-MESAM (MAP, Germany), for diagnosing OSA in 12 children aged between 3 and 6 years. All children received the Level 3 sleep study in a hospital without a sleep technician in attendance. The number of episodes of reduction in airflow of >50%, accompanied by oxygen desaturation >4%, was calculated automatically by computer software either with or without a sleep technician's correction. As all recruited children had RDI/AHI >1 from sleep studies, the sensitivity and PPV were both 100% at this cut-off point. Higher RDI (automatically scored) thresholds resulted in lower sensitivity (90.0% at RDI >3, 78.8% at RDI >5, 80.0% at RDI >10). The null specificity at RDI 3 and 5 was either attributable to the relatively small sample size (n=12) of this study or due to the high index of suspicion in patient selection or loose thresholds. Hand revision of the automatically scored data improved the sensitivity of the POLY-MESAM at RDI/AHI >5 (88.9%) and RDI/AHI >10 (100%), while the sensitivity at RDI/AHI >3 remained unchanged. However, the use of manual revision of the study data appeared to worsen specificity (57.1%) at a RDI/AHI cut-off >10. Lower RDI (automatically scored ± manually revised) or AHI cut-off points when using unattended POLY-MESAM for the diagnosis of paediatric OSA resulted in a higher PPV (81.8%, 70.0–72.7% and 62.5–66.7% at RDI/AHI >3, >5 and >10, respectively) but lower NPV (0%, 0% and 83.3–100%, respectively) at the same thresholds.

The other Level 3 study involved 21 children, aged 2–12 years, with suspected OSA due to adenotonsillar hypertrophy (Jacob et al 1995). All children underwent a home-based Level 3 study on a portable cardiorespiratory recorder. Using AHI >1 as indicative of OSA, the sensitivity and specificity were 100% and 62.5%, respectively; and both accuracy measures reached 100% at RDI/AHI >10. Relatively lower sensitivity (87.5%) and median specificity (76.9%) were attained for detection at AHI >5. The PPV and NPV of the home-based cardiorespiratory recorder study were ≥ 70% and > 90%, respectively, in children with suspected OSA (Jacob et al 1995).

Level 4 sleep studies were investigated by Kirk et al (2003) and Brunetti et al (2001). In the first study, of good quality, a total of 58 children with suspected OSA and aged 4–8 years were recruited. A Level 4 portable monitor, SnoreSat, was used in the diagnosis of OSA. The sensitivity, specificity, PPV, NPV, LR+ and LR– of this Level 4 sleep study were moderately accurate when ODI/AHI ≥5 was used as the threshold for a positive result on the home-based SnoreSat or laboratory-based PSG. The diagnostic performance of another Level 4 device, Vitalog HMS5000, was evaluated in a poor-quality study, which involved 12 children aged 3–10 years with suspected OSA. It was reported that this home-based device attained perfect test sensitivity when OSA was diagnosed with ODI/AHI >1 or >5. The lower ODI/AHI cut-off point (>1) resulted in a significantly improved PPV (100% vs 57.1%). NPV was 100% when ODI >3 or >5 was used as indicative of paediatric OSA. In addition, slightly better specificity (66.7% vs 62.5%) and a higher LR+ (3.0 vs 2.7) was observed at ODI >3 compared with an ODI cut-off of 5 (Brunetti et al 2001).

Table 24 Test characteristics of unattended sleep studies in a paediatric setting

Study	Evidence level and quality	Population	Respiratory event definition	*Index test* Cut-off point	*Reference standard* Cut-off point	Sensitivity % [95% CI]	Specificity % [95% CI]	PPV % [95% CI]	NPV % [95% CI]	LR+ [95% CI]	LR- [95% CI]
Level 3 sleep study											
(Zucconi et al 2003)	Cross-classification study Level III-1 diagnostic evidence CX, P1 Q2 [QUADAS: 11/14	12 children with suspected OSA, aged 3–6 years	Unattended sleep study: apnoea: no airflow, accompanied by oxygen desaturation >4%; hypopnoea: ↓ airflow >50%, accompanied by oxygen desaturation >4% Laboratory-based PSG: apnoea: no airflow, ≥10 s; hypopnoea: ↓ airflow or thoraco-abdominal movement ≥50%, ≥10 s	*Hospital-based POLY-MESAM (auto-scoring)*	*Laboratory-based PSG*						
				RDI >1	AHI >1	100.0 [69.9, 100.0]	—	100.0 [69.9, 100.0]	—	—	—
				RDI >3	AHI >3	90.0 [54.1, 99.5]	0.0 [0.0, 80.2]	81.8 [47.8, 96.8]	0.0 [0.0, 94.5]	0.9 [0.7, 1.1]	∞
				RDI >5	AHI >5	78.8 [40.2, 96.1]	0.0 [0.0, 69.0]	70.0 [35.4, 91.9]	0.0 [0.0, 80.2]	0.8 [0.5, 1.1]	∞
				RDI >10	AHI >10	80.0 [29.9, 98.9]	71.4 [30.3, 94.9]	66.7 [24.1, 94.0]	83.3 [36.5, 99.1]	2.8 [0.8, 9.8]	0.3 [0.0, 1.8]
			Unattended sleep study: apnoea: no airflow, accompanied by oxygen desaturation >4%; hypopnoea: ↓ airflow >50%, accompanied by oxygen desaturation >4% Laboratory-based PSG: apnoea: no airflow, ≥10 s; hypopnoea: ↓ airflow or thoraco-abdominal movement ≥50%, ≥10 s (auto + manual scoring)	*Hospital-based POLY-MESAM (auto + manual scoring)*	*Laboratory-based PSG*						
				RDI >1	AHI >1	100.0 [69.9, 100.0]	—	100.0 [69.9, 100.0]	—	—	—
				RDI >3	AHI >3	90.0 [54.1, 99.5]	0.0 [0.0, 80.2]	81.8 [47.8, 96.8]	0.0 [0.0, 94.5]	0.9 [0.7, 1.1]	∞
				RDI > 5	AHI >5	88.9 [50.7, 99.4]	0.0 [0.0, 69.0]	72.7 [39.3, 92.7]	0.0 [0.0, 94.5]	0.9 [0.7, 1.1]	∞
				RDI >10	AHI >10	100.0 [46.3, 100.0]	57.1 [20.2, 88.2]	62.5 [25.9, 89.8]	100.0 [39.6, 100.0]	2.3 [1.0, 5.5]	0.0
(Jacob et al 1995)	Cross-classification study Level III-2 diagnostic evidence	21 children with suspected OSA, aged 2–12 years	Unattended sleep study: apnoea: ↓ thoraco-abdominal movement ≥80%, ≥3 s or accompanied by oxygen desaturation ≥4%; hypopnoea: ↓ thoraco-abdominal movement 50–80%, accompanied by oxygen desaturation ≥4%	*Home-based portable cardiorespiratory recorder*	*Laboratory-based PSG*						
				RDI >1	AHI >1	100.0 [71.7, 100.0]	62.5 [25.9, 89.8]	81.3 [53.7, 95.0]	100.0 [46.3, 100.0]	2.7 [1.1, 6.5]	0.0

Study	Evidence level and quality	Population	Respiratory event definition	*Index test*	*Reference standard*	Sensitivity % [95% CI]	Specificity % [95% CI]	PPV % [95% CI]	NPV % [95% CI]	LR+ [95% CI]	LR- [95% CI]
				Cut-off point	Cut-off point						
	CX, P1 Q2 [QUADAS: 11.5/14]		Laboratory-based sleep study: apnoea: no airflow; hypopnoea: ↓ thoraco-abdominal movement ≥50%, accompanied by oxygen desaturation ≥4%	RDI >3	AHI >3	87.5 [46.7, 99.3]	76.9 [46.0, 93.8]	70.0 [35.4, 91.9]	90.9 [57.1, 99.5]	3.8 [1.4, 10.6]	0.2 [0.0, 1.1]
				RDI >5	AHI >5	100.0 [56.1, 100.0]	100.0 [73.2, 100.0]	100.0 [56.1,100.0]	100.0 [73.2, 100.0]	∞	0.0
Level 4 sleep study											
(Kirk et al 2003)	Cross-classification study Level III-1 diagnostic evidence CX, P1 Q1 [QUADAS: 12.5/14]	57/58 children with suspected OSA, aged 4–18 years	Unattended sleep study: oxygen desaturation >3%, followed by an increase in oxygen saturation Laboratory-based PSG: apnoea: ↓ airflow >80%; hypopnoea: ↓ airflow 50–80%, associated with oxygen desaturation ≥4% or an arousal	*Home-based SnoreSat*	*Laboratory-based PSG*						
				ODI >5	AHI ≥5	66.7 [46.0, 82.8]	60.0 [40.8, 76.8]	60.0 [40.8, 76.8]	66.7 [46.0, 82.8]	1.7 [1.0, 2.8]	0.6 [0.3, 1.0]
(Brunetti et al 2001)	Cross-classification study Level III-2 diagnostic evidence CX, P1 Q3 [QUADAS: 9.5/14	12 children with suspected OSA and ODI >2, aged 3–10 years	Unattended sleep study: oxygen desaturation >4% Laboratory-based PSG: apnoea: no airflow, accompanied by oxygen desaturation ≥4%; hypopnoea: ↓ airflow ≥50%, accompanied by oxygen desaturation ≥4%	*Home-based Vitalog HMS5000*	*Laboratory-based PSG*						
				ODI >1	AHI >1	100.0 [69.9, 100.0]	—	100.0 [69.9, 100.0]	—	—	—
				ODI >3	AHI >3	100.0 [62.9, 100.0]	66.7 [12.5, 98.2]	90.0 [54.1, 99.5]	100.0 [19.8, 100.0]	3.0 [0.6, 14.9]	0.0
				ODI >5	AHI >5	100.0 [39.6, 100.0]	62.5 [25.9, 89.8]	57.1 [20.2, 88.2]	100.0 [46.3, 100.0]	2.7 [1.1, 6.5]	0.0

AHI = apnoea–hypopnoea index; CI = confidence interval; LR = likelihood ratio; NPV = negative predictive value; ODI = oxygen desaturation index; OSA = obstructive sleep apnoea; PPV = positive predictive value; PSG = polysomnography; RDI = respiratory disturbance index; s = seconds

Two studies were identified that assessed the agreement between unattended sleep studies and laboratory-based PSG in measuring OSA (Table 25). In Zucconi et al's (2003) moderate-quality study, a hospital-based unattended sleep study, using the POLY-MESAM device, and laboratory-based attended PSG were carried out in 12 children with suspected OSA. The data were logarithmically (log) transformed and a mean difference of 0.86 was reported between log PSG AHI and log RDI (auto-scored; log AHI – log RDI). The 95% CI indicated a good agreement between RDI and AHI. When data from POLY-MESAM were manually revised by a sleep technician, better agreement between RDI and PSG AHI was observed, with a tighter 95% CI of the difference between log RDI and log AHI, ranging from 0.3 to 0.9. Jacob et al's (1995) study investigated a portable cardiorespiratory recorder in 21 children with suspected OSA due to adenotonsillar hypertrophy. A fair–good diagnostic agreement was suggested between a Level 3 portable cardiorespiratory recorder study and laboratory based PSG, with a Kappa coefficient of 0.69. The RDI values were also linearly correlated with PSG AHI values ($r=0.80$, $p<0.05$).

Table 25 Other agreement measures of unattended sleep studies in a paediatric setting

Study	Evidence level and quality	Population	Respiratory event definition	*Index test*	*Reference standard*	Agreement measure
				Cut-off point	Cut-off point	
Level 3 sleep study						
(Zucconi et al 2003)	Cross-classification study Level III-1 diagnostic evidence CX, P1 Q2 [QUADAS: 11/14]	12 children with suspected OSA, aged 3–6 years	Unattended sleep study: apnoea: no airflow, accompanied by oxygen desaturation >4%; hypopnoea: ↓ airflow >50%, accompanied by oxygen desaturation >4% Laboratory-based PSG: apnoea: no airflow, ≥10 s; hypopnoea: ↓ airflow or thoraco-abdominal movement ≥50%, ≥10 s	*Hospital-based POLY-MESAM* n/a	*Laboratory-based PSG* n/a	POLY-MESAM (auto scoring): Mean difference (AHI–RDI)[a]: 0.86 Limits of agreement[a]: [0.5, 1.5] (Bland and Altman plot analysis) POLY-MESAM (auto + manual scoring): Mean difference (AHI–RDI)[a]: 0.55 Limits of agreement[a]: [0.3, 0.9] (Bland and Altman plot analysis) r=0.57 (p=0.05) (Pearson χ^2 test)
(Jacob et al 1995)	Cross-classification study Level III-2 diagnostic evidence CX, P1 Q2 [QUADAS: 11.5/14]	21 children with suspected OSA, aged 2–12 years	Unattended sleep study: apnoea: ↓ thoraco-abdominal movement ≥80%, ≥3 s or accompanied by oxygen desaturation ≥4%; hypopnoea: ↓ thoraco-abdominal movement 50–80%, accompanied by oxygen desaturation ≥4% Laboratory-based sleep study: apnoea: no airflow; hypopnoea: ↓ thoraco-abdominal movement ≥50%, accompanied by oxygen desaturation ≥4%	*Home-based portable cardiorespiratory recorder* RDI >1 RDI >3 RDI >5	*Laboratory-based PSG* AHI >1 AHI >3 AHI >5	k= 0.69 (Inter-rater agreement) r=0.80 (p<0.05) (Pearson χ^2 test)

[a] Bland and Altman plot analysis was performed after the raw data from the unattended sleep study and laboratory-based PSG were logarithmically transformed

AHI = apnoea–hypopnoea index; CI = confidence interval; n/a = not applicable; OSA = obstructive sleep apnoea; PSG = polysomnography; RDI = respiratory disturbance index; s = seconds

The results of two case series (level IV diagnostic evidence) that only reported diagnostic yield of unattended sleep studies in a paediatric setting have been presented in Appendix E (Castronovo et al 2003; Poels et al 2003).

Do unattended sleep studies change patient management?

No studies were identified that reported a change in patient management subsequent to using unattended sleep studies in a paediatric setting.

Direct evidence

Summary — Are Level 2, 3 or 4 unattended sleep studies (± Level 1 studies) as, or more, effective than Level 1 laboratory-based (attended) sleep studies alone, or surgery without use of a prior sleep study, for children with suspected or previously diagnosed OSA referred to a specialist paediatric multidisciplinary team?

Minimal evidence was identified that reported a change in the health outcomes of children with OSA, as a consequence of diagnosis with unattended sleep studies. One 8-year-old boy in Patel et al's (2007) case series had improved neuropsychologic functioning after he was identified by a home-based Embletta PDS study as having OSA, and subsequently undergoing tonsillectomy surgery. The number of respiratory events per hour decreased by 81%, from a baseline of 4.2 to 0.8 at 3 months after the surgery (case report). No data were available comparing unattended sleep studies with an attended Level 1 sleep study or surgery without use of a prior sleep study in a paediatric setting.

Linked evidence

Summary — In children with suspected or previously diagnosed OSA, are Level 2 or 3 or 4 unattended sleep studies as accurate as Level 1 laboratory-based (attended) sleep studies at diagnosing or reassessing OSA?

Six studies were identified that provided evidence on the accuracy of unattended sleep studies in diagnosing paediatric OSA, including four cross-classification studies (level III-1 or III-2 diagnostic evidence) and two case series that reported diagnostic yield from unattended sleep studies (level IV diagnostic evidence).

The performance of a Level 3 portable monitor, POLY-MESAM, in diagnosing paediatric OSA was investigated in a hospital setting without a sleep technician in attendance (Zucconi et al 2003). The data from this device were automatically scored with or without manual revision by a sleep technician. At a threshold where discrimination between positive and negative OSA was possible (RDI/AHI >1), the Level 3 sleep study (whether RDIs were automatically or manually scored) had excellent sensitivity (100%) and PPV (100%), although the study was too small to assess this with any certainty. Since none of the involved children had RDI/AHI lower than 1, the specificity and NPV were not calculable at this cut-off point. A Bland and Altman plot analysis demonstrated good agreement between automatically scored RDI and PSG AHI, which was further improved following manual revision of the sleep study data.

In Jacob et al's (1995) study, another Level 3 sleep study was carried out in a home setting. Similar to the unattended POLY-MESAM study, this device showed high sensitivity (87.5–

100%) and NPV (90.9–100%) at different RDI/AHI thresholds, although it performed at lower thresholds than the POLY-MESAM, at >1 and >3. The sensitivity, specificity, PPV and NPV all reached 100%, using RDI/AHI >5 as indicative of paediatric OSA. A moderate to good diagnostic agreement was also demonstrated between the home-based cardiorespiratory recorder study and laboratory-based PSG.

Kirk et al (2003) examined the use of a home-based SnoreSat (Level 4) device in a relatively large population sample (n=58) in children, and found it had modest sensitivity (66.7%), specificity (60.0%), PPV (60.0%) and NPV (66.7%) for diagnosing paediatric OSA at an ODI/AHI threshold of 5. Using the same cut-off point, another Level 4 device, Vitalog HMS5000, demonstrated higher sensitivity (100%), specificity (62.5%) and NPV (100%) (Brunetti et al 2001). However, the PPV was slightly lower (57.1%) than that of the home-based SnoreSat study. Since all recruited children had ODI/AHI >1, home-based Vitalog HMS5000 attained perfect (100%) sensitivity and PPV at this cut-off point.

Summary — Does the use of Level 2, 3 or 4 unattended sleep studies (± Level 1 study), in the diagnosis or reassessment of paediatric OSA, impact on patient management differently compared with the use of Level 1 laboratory-based (attended) sleep studies alone or surgical treatment without use of a prior sleep study?

No studies were identified that assessed a change in patient management in children suspected of, or with previous diagnosis of, OSA as a consequence of using unattended sleep studies in a paediatric setting.

Reassessment of treatment efficacy

There were no studies identified in the searches—potentially relevant to an assessment of the use of unattended sleep studies to reassess treatment efficacy for OSA—that met the selection criteria outlined in Box 14.

Box 14 Criteria for selecting studies to assess the use of unattended sleep studies for reassessing treatment efficacy

Selection criteria	Inclusion criteria
Population	1) Adults with confirmed OSA receiving treatment who have an alteration in their OSA symptoms or their symptoms are unresolved 2) Adults with confirmed OSA receiving treatment who have had an alteration in OSA symptoms (or their symptoms are unresolved) and are a complex case[a] – Baseline disease (OSA) severity subgroups: mild, moderate, severe – Baseline treatment subgroups: CPAP; lifestyle change (including weight management, behavioural change); surgery (including nasal, tonsil or adenoid surgery, corrective surgery for mandible or palate, tracheostomy, UPPP); mandibular advancement splints; sleep positioning devices
Index test / Intervention	1) *Level 3* unattended sleep study involving the assessment of two or more cardiopulmonary parameters (eg detection of airflow, respiratory movement, arterial oxygen saturation, ECG), and subsequent data analysis and interpretation by an appropriately trained and credentialed medical practitioner OR *Level 4* unattended sleep study involving the assessment of one cardiopulmonary parameter (usually oximetry), and subsequent data analysis and interpretation by an appropriately trained and credentialled medical practitioner ± *Level 1 study* 2) *Referral to appropriately trained and credentialed medical practitioner* + *Level 2* unattended sleep study / polysomnography that includes assessments of: sleep staging (EEG), detection of airflow, respiratory movement, arterial oxygen saturation, electrocardiogram (ECG), and subsequent data analysis and interpretation by an appropriately trained and credentialed medical practitioner OR + *Level 3* unattended sleep study involving the assessment of two or more cardiopulmonary parameters (eg detection of airflow, respiratory movement, arterial oxygen saturation, ECG), and subsequent data analysis and interpretation by an appropriately trained and credentialed medical practitioner OR + *Level 4* unattended sleep study involving the assessment of one cardiopulmonary parameter (usually oximetry), and subsequent data analysis and interpretation by an appropriately trained and credentialed medical practitioner ± *Level 1 study*
Comparator(s)	*Referral to sleep physician* + *Level 1* laboratory-based, overnight, attended (by sleep technician) sleep study / polysomnography that includes assessments of: sleep staging (EEG, EOG, EMG), detection of airflow (quantitative or semi-quantitative nasal transducers), respiratory movement (via transducers on chest or abdominal walls, or via RIP), arterial oxygen saturation (via a pulse oximeter), ECG, leg movement, snoring, body positioning, and subsequent data analysis and interpretation
Outcomes	*Safety* Physical harms from testing, eg allergy to electrode adhesive *Effectiveness* Primary: a) patient-relevant: survival/mortality rate, resolution/reduction of symptoms (eg snoring, excessive daytime sleepiness, witnessed apnoea episodes), disease-specific quality of life; b) respiratory events / number of apnoeas or hypopnoeas (eg AHI, RDI), oxygen saturation (eg

	ODI), sleep time and efficiency (eg sleep stage duration/quality, ArI) control of comorbidities (eg hypertension, HbA_{1C} control, heart failure outcomes)
	Secondary: additional sleep studies (by type), referral to sleep physician / credentialed medical practitioner, time to change in treatment, duration of treatment
	Cost-effectiveness
	Cost/health outcome (eg LYG, QALY)
Publication type	*Safety*
	Randomised or non-randomised controlled trials, cohort studies, registers, case series, case reports or systematic reviews of these study designs. Non-systematic reviews, non-research letters, editorials; and animal, in-vitro and laboratory studies, were excluded.
	Effectiveness
	Randomised or non-randomised controlled trials or cohort studies or systematic reviews of these study designs. Non-systematic reviews, letters, editorials; and animal, in-vitro and laboratory studies, were excluded.
	Cost-effectiveness
	Economic studies, modelling, economic analyses
Search period	1980 – April 2009
Language	Non-English language articles were excluded unless they provided a higher level of evidence than the English language articles identified.

[a] Subtle and/or difficult cases (eg complex sleep apnoea, sleep hypoventilation) or patient factors require a supervised study (age, frailty, anxiety, intellectual impairment)

AHI = apnoea–hypopnoea index; ArI = arousal index; CPAP = continuous positive airway pressure; ECG = electrocardiogram; EEG = electroencephalogram; EMG = electromyogram; EOG = electrooculogram; HbA1C = glycosylated haemoglobin; LYG = life-years gained; ODI = oxygen desaturation index; OSA = obstructive sleep apnoea; QALY = quality-adjusted life year; RDI = respiratory disturbance index; RIP = respiratory inductive plethysmography; UPPP = uvulopalatopharyngoplasty

Economic considerations

Background

In its assessment of a new service, the MSAC is required to consider not only the comparative effectiveness and safety of the service but also the comparative cost and cost-effectiveness of the service. Thus, an economic evaluation based on the clinical evidence of adding/substituting the service under MSAC consideration to/for the main comparator(s) in the population and in the setting for which subsidy is required is presented. In addition, an analysis that examines the financial impact to the Australian healthcare system of subsidising the proposed new service is presented.

The purpose of an economic evaluation is to inform the MSAC as to the additional costs and additional gains (health or other socially relevant outcomes) of the proposed service over the comparator when used in the Australian healthcare system. This is to ensure that society's ultimately scarce resources are allocated to those activities from which it will get the most value. That is, it seeks to enhance economic efficiency.

The costing exercise conducted is not intended for fee scheduling purposes, and is not necessarily a recommendation for funding the service at these levels.

Existing literature

The inclusion criteria determined a priori for assessing economic analyses of unattended sleep studies in the diagnosis of OSA are outlined in Box 15, Box 16 and Box 17.

Box 15 Criteria for selecting studies to assess the cost-effectiveness of unattended sleep studies in a non-specialised unit setting

Selection criteria	Inclusion criteria
Population	Adults with suspected OSA[a] – Subgroups: age range, BMI range, comorbid conditions (eg COPD, depressive symptoms, diabetes, CVD, GERD), occupation
Index test / Intervention	*Level 3* unattended sleep study involving the assessment of two or more cardiopulmonary parameters (eg detection of airflow, respiratory movement, arterial oxygen saturation, ECG), and subsequent data analysis and interpretation by an appropriately trained and credentialed medical practitioner OR *Level 4* unattended sleep study involving the assessment of one cardiopulmonary parameter (usually oximetry), and subsequent data analysis and interpretation by an appropriately trained and credentialed medical practitioner ± *Referral to an appropriately trained and credentialed medical practitioner* ± *Level 1 study*
Comparator(s)	*Referral to sleep physician* OR *Level 1* laboratory-based, overnight, attended (by sleep technician) sleep study / polysomnography that includes assessments of: sleep staging (EEG, EOG, EMG), detection of airflow (quantitative or semi-quantitative nasal transducers), respiratory movement (via transducers on chest or abdominal walls, or via RIP), arterial oxygen saturation (via a pulse oximeter), ECG, leg movement, snoring, body positioning, and subsequent data analysis and

	interpretation
Outcomes	Cost per relevant health outcome (eg LYG, QALY, DALY)
Publication type	Economic studies, modelling, economic analyses
Search period	1980 – April 2009
Language	Non-English language articles were excluded unless they provided a higher level of evidence than the English language articles identified.

[a] Suspected on the basis of snoring/gasping/choking while asleep, excessive daytime sleepiness, witnessed apnoea, nocturia

BMI = body mass index; COPD = chronic obstructive pulmonary disease; CVD = cardiovascular disease such as hypertension, coronary artery disease, ischaemic heart disease; DALY = disability-adjusted life year; ECG = electrocardiogram; EEG = electroencephalogram; EMG = electromyogram; EOG = electrooculogram; GERD = gastro-oesophageal reflux disease; LYG = life-years gained; OSA = obstructive sleep apnoea; QALY = quality-adjusted life year; RIP = respiratory inductive plethysmography

Box 16 Criteria for selecting studies to assess the cost-effectiveness of unattended sleep studies in a referral setting

Selection criteria	Inclusion criteria
Population	Adults with suspected OSA[a] and referred to a specialist – Subgroups: age range, BMI range, comorbid conditions (eg COPD, depressive symptoms, diabetes, CVD, GERD), occupation
Index test / Intervention	*Level 2* unattended sleep study / polysomnography that includes assessments of: sleep staging (EEG), detection of airflow, respiratory movement, arterial oxygen saturation, electrocardiogram (ECG), and subsequent data analysis and interpretation by an appropriately trained and credentialed medical practitioner OR *Level 3* unattended sleep study involving the assessment of two or more cardiopulmonary parameters (eg detection of airflow, respiratory movement, arterial oxygen saturation, ECG), and subsequent data analysis and interpretation by an appropriately trained and credentialed medical practitioner *OR* *Level 4* unattended sleep study involving the assessment of one cardiopulmonary parameter (usually oximetry), and subsequent data analysis and interpretation by an appropriately trained and credentialed medical practitioner *± Level 1 study*
Comparator(s)	*Level 1* laboratory-based, overnight, attended (by sleep technician) sleep study / polysomnography that includes assessments of: sleep staging (EEG, EOG, EMG), detection of airflow (quantitative or semi-quantitative nasal transducers), respiratory movement (via transducers on chest or abdominal walls, or via RIP), arterial oxygen saturation (via a pulse oximeter), ECG, leg movement, snoring, body positioning, and subsequent data analysis and interpretation
Outcomes	Cost per relevant health outcome (eg LYG, QALY, DALY)
Publication type	Economic studies, modelling, economic analyses
Search period	1980 – April 2009
Language	Non-English language articles were excluded unless they provided a higher level of evidence than the English language articles identified

[a] Suspected on the basis of snoring/gasping/choking while asleep, excessive daytime sleepiness, witnessed apnoea, nocturia

BMI = body mass index; COPD = chronic obstructive pulmonary disease; CVD = cardiovascular disease such as hypertension, coronary artery disease, ischaemic heart disease; DALY = disability-adjusted life year; ECG = electrocardiogram; EEG = electroencephalogram; EMG = electromyogram; EOG = electrooculogram; GERD = gastro-oesophageal reflux disease; LYG = life-years gained; OSA = obstructive sleep apnoea; QALY = quality-adjusted life year; RIP = respiratory inductive plethysmography

Box 17 Criteria for selecting studies to assess the cost-effectiveness of unattended sleep studies in a paediatric setting

Selection criteria	Inclusion criteria
Population	Children with suspected[a] or previously diagnosed OSA – Subgroups: age range, BMI range, comorbid conditions (eg Downs syndrome, cleft palate, developmental delay)
Index test / Intervention	*Level 2* unattended sleep study / polysomnography that includes assessments of: sleep staging (EEG), detection of airflow, respiratory movement, arterial oxygen saturation, electrocardiogram (ECG), and subsequent data analysis and interpretation by an appropriately trained and credentialed medical practitioner OR *Level 3* unattended sleep study involving the assessment of two or more cardiopulmonary parameters (eg detection of airflow, respiratory movement, arterial oxygen saturation, ECG), and subsequent data analysis and interpretation by an appropriately trained and credentialed medical practitioner *OR* *Level 4* unattended sleep study involving the assessment of one cardiopulmonary parameter (usually oximetry), and subsequent data analysis and interpretation by an appropriately trained and credentialed medical practitioner ± *Level 1 study*
Comparator(s)	*Level 1* laboratory-based, overnight, attended (by sleep technician) sleep study / polysomnography that includes assessments of: sleep staging (EEG, EOG, EMG), detection of airflow (quantitative or semi-quantitative nasal transducers), respiratory movement (via transducers on chest or abdominal walls, or via RIP), arterial oxygen saturation (via a pulse oximeter), ECG, leg movement, snoring, body positioning, and subsequent data analysis and interpretation OR *Surgery without use of a prior sleep study*[b]
Outcomes	Cost per relevant health outcome (eg LYG, QALY, DALY)
Publication type	Economic studies, modelling, economic analyses
Search period	1980 – April 2009
Language	Non-English language articles were excluded unless they provided a higher level of evidence than the English language articles identified

[a] Suspected on the basis of snoring, behavioural change, learning difficulties, secondary enuresis; [b] There is no guarantee that those patients that would currently proceed to surgical treatment without a (Level 1) sleep study—perhaps because of access issues—would not have an unattended sleep study prior to surgical treatment should these unattended sleep studies be publicly funded.

BMI = body mass index; DALY = disability-adjusted life year; ECG = electrocardiogram; EEG = electroencephalogram; EMG = electromyogram; EOG = electrooculogram; LYG = life-years gained; OSA = obstructive sleep apnoea; QALY = quality-adjusted life year; RIP = respiratory inductive plethysmography

One economic analysis from Israel was identified (Reuveni et al 2001). Three diagnostic methods, including a laboratory-based sleep study, an attended limited channel sleep study and a home-based limited channel sleep study, were compared in a hypothetical group of patients with suspected OSA to determine the optimal diagnostic strategy in terms of cost-effectiveness. A two-level decision tree that reflected all possible steps in the diagnosis and treatment of OSA was used for evaluating the cost-effectiveness of the different diagnostic models. Given the uncertainty of the parameters in the decision tree, a sensitivity analysis was warranted. It was assumed that approximately 30% (range 0–50%) of the home-based sleep study arm required a repeated study to attain the same diagnostic equivalent as the laboratory-based PSG. The rates of technical failure for attended PSG, unattended limited channel sleep study and attended limited channel sleep study were 0.5%, 5% and 3%, respectively. A single home-based limited channel sleep study was around 30% less expensive than a laboratory-based PSG (US$175 vs US$250). However, due to the necessity of repeated sleep studies caused by data loss and the poor diagnostic agreement with laboratory-based PSG, the unattended sleep study was not a

cost-saving investigation relative to the laboratory-based PSG in terms of the overall process costs depicted in the decision tree. In this analysis the data loss associated with a home-based study and the diagnostic agreement between an unattended limited channel sleep study and an attended PSG appear to be reasonable estimates. However, the applicability of the conclusion from this economic analysis is limited owing to the cost differences of the home-based sleep studies and the laboratory-based PSG between the Israeli and Australian healthcare settings (see Australian unit costs in Table 27 to Table 31).

A moderate-quality, more complex decision analytic model was developed by Deutsch et al (2006), in which three types of sleep study diagnostic approach were compared—unattended home-based sleep studies, attended split-night PSG and attended full-night PSG. The model structure was a three-arm decision-analytic model. In each arm the patient receives one of the three diagnostic modalities, followed by either additional sleep studies and/or, if positive for OSA, CPAP titration. This is followed by a Markov cycle over a 5-year period in which patients either die or remain in one of four health states—OSA treated, no OSA treated [false positives], OSA untreated [false negatives] and no OSA. All treatment was assumed to be CPAP, and it was assumed that patients identified without clinically significant OSA (RDI/AHI ≥10) will not develop it over a 5-year time horizon. The patient population was a hypothetical cohort of persons aged 30–64 years, of whom 85% were men. All were at moderate to high risk of OSA on the basis of excessive daytime sleepiness, persistent snoring and witnessed sleep apnoeas. An OSA pre-test probability (or diagnostic yield) of 82% was selected for this modelled cohort. Cost-effectiveness was assessed from a third-party payer perspective and only direct healthcare costs were considered. Health outcomes were expressed in terms of quality-adjusted life years (QALYs). A Monte Carlo simulation (10 000 iterations) was performed, with simultaneous sampling from all base-case parameter probability distributions, in order to determine the incremental cost-effectiveness ratios, which were then plotted on the cost-effectiveness plane. This model predicted that none of the diagnostic strategies are dominated by another, and that acceptance of a diagnostic strategy will depend on the willingness to pay of the payer. Both costs and QALYs were lowest for the home sleep studies pathway (cost-effectiveness ratio (CER) = US$1838/QALY), as both patient drop-outs and lower rates of CPAP acceptance in this pathway led to a greater number of patients with untreated OSA and thus poorer QoL compared with patients receiving either the split-night PSG (CER = US$1979/QALY) or full-night PSG (CER = US$2092/QALY). Costs were lower, primarily because fewer patients received long-term CPAP treatment rather than because the technology itself is cheaper.

Although the structure of this economic evaluation and the selection of utilities was credible, the validity of certain inputs in terms of their applicability to the current Australian situation is uncertain. The inputs were chosen on the basis of selected literature rather than a systematic review of all literature. Thus, the estimates of central tendency, around which probability distributions were constructed, for the inputs on the accuracy of home-based sleep studies; the proportion of technical failures / unsuccessful studies; the pre-test probability of OSA; and the effectiveness of auto-CPAP titration may not necessarily be representative. The unit costs are, however, similar to the Australian unit costs. The model was found to be robust to univariate sensitivity analysis, but it is unclear as to what range of estimates were assessed in these one-way analyses. Probabilistic sensitivity analysis was conducted, and the use of a full-night PSG was found to be both more costly and more effective than home-based sleep studies as a

diagnostic strategy (99% in the north-eastern quadrant of the cost-effectiveness plane, incremental cost-effectiveness ratio (ICER) = US$11 586/QALY gained).

A third study, by Chervin et al (1999), compared the cost-utility of three OSA diagnostic modalities—laboratory-based PSG, home-based sleep study and no testing—using a decision tree model. The patients hypothesised in modelling analysis were adults with suspected OSA, aged 60–69 years, predominantly male and with many having cardiovascular disease. Patients with positive results from PSG or an unattended sleep study underwent CPAP (laboratory-based titration). In the no-testing arm, all patients suspected of having OSA based on clinical assessment received empirical therapy (CPAP). The health outcome, QALYs, was measured in a time horizon of 5 years after the initial diagnostic evaluation. The authors discovered that attended PSG provided improved QALYs over both a home-based sleep study and no testing at an acceptable cost. The ICERs for PSG over home testing and empirical therapy were US$13 431/QALY gained and US$9165/QALY gained, respectively. Univariate sensitivity analysis indicated that the results of the cost-utility comparison were robust for the model of varying plausible utilities, pre-test probabilities of OSA, test characteristics, costs and survival rates, except for the utilities of CPAP treatment in those patients without OSA. A Monte Carlo simulation (1000 iterations for PSG vs unattended sleep study, and 1000 iterations for PSG vs no testing) demonstrated that none of the diagnostic modalities dominated the others. The probabilities of an ICER <US$40 000 for PSG over unattended sleep study and no testing were 0.88 and 0.58, respectively.

However, the applicability of Chervin et al's results to the Australian healthcare setting is in question owing to the dubious structure of the decision tree as well as the plausible ranges of input variables: 1) additional costs for further (PSG) testing due to technical failure and uncertain results from a home-based sleep study were not considered; 2) patients with positive results from an unattended sleep study received laboratory-based titration CPAP, which is different from the clinical practice in Australia, where most patients would receive APAP treatment after a home-based sleep study; 3) in the home-based sleep study arm and in the no testing arm, patients with false positive results underwent ongoing CPAP treatment for 5 years whereas, in reality, this group of patients would be reassessed and discontinued from treatment in the first 1 or 2 months; 4) false negatives from unattended sleep studies or from clinical assessment would be detected during follow-up with the aid of a sleep study, and receive delayed treatment rather than being left untreated for 5 years, as assumed in Chervin et al's (1999) study; 5) the home-based sleep study in this cost-utility analysis performed much better than average (sensitivity 95% (80–95%); specificity 96% (70–96%); PPV 99%; NPV 77%); and 6) the costs for laboratory-based PSG (US$1190) and home-based sleep study (US$440) were more expensive than those in Australia.

Economic analysis

Evidence about effectiveness of the intervention from this review

When undertaking economic analysis, initially a systematic review (and/or meta-analysis) is produced to determine whether there is evidence that the intervention is comparatively effective (see 'Effectiveness' sections of this report, page 45, 63 and 104). The decision as to whether to perform an economic evaluation is based on evidence of relative safety and

effectiveness compared with the comparator. If the evidence indicates that the intervention is likely to be no worse in terms of safety and effectiveness outcomes, an economic evaluation should be considered. The type of economic evaluation is determined by the net benefits and harms associated with the intervention relative to the comparator (Table 26).

Table 26 Type of economic evaluation that should be presented for various classifications of a service under MSAC consideration

Classification	Type of economic evaluation
The service is more effective than the appropriate comparator and is associated with improved safety.	Cost-consequences, cost-effectiveness, cost-utility, cost–benefit
The service is more effective than the appropriate comparator and is no worse than the comparator in terms of safety.	Cost-consequences, cost-effectiveness, cost-utility, cost–benefit
The service is more effective than the appropriate comparator but is associated with reduced safety.	
(i) Overall, there are net benefits to patients as the benefits from improved effectiveness outweigh the harms from reduced safety and/or changed risk profile.	Cost-consequences, cost-effectiveness, cost-utility, cost–benefit
(ii) Overall, the service is no worse than the comparator because the benefits from improved effectiveness at least offset the harms from reduced safety and/or changed risk profile.	Cost-consequences, cost-effectiveness. This may be reducible to cost-minimisation (ie presentation of an incremental cost-effectiveness for the base case may be inappropriate if net clinical benefits are assumed to be zero)
(iii) Overall, there are net harms to patients as the harms from reduced safety and/or changed risk profile outweigh the benefits from improved effectiveness.	No economic evaluation needs to be presented; the MSAC is unlikely to recommend government subsidy of this service.
The service is no worse than the comparator in terms of effectiveness but is associated with improved safety.	Cost-consequences, cost-effectiveness, cost-utility, cost–benefit
The service is indisputably demonstrated to be no worse than the comparator in terms of both effectiveness and safety.	Cost-minimisation. In the case where there is any uncertainty around the conclusion that the service is no worse than the comparator in terms of effectiveness and safety, cost-consequences, cost-effectiveness, and/or cost-utility analyses should be provided.
The service is no worse than the comparator in terms of effectiveness but is associated with reduced safety.	No economic evaluation needs to be presented; the MSAC is unlikely to recommend government subsidy of this service.
The service is less effective than the comparator but is associated with improved safety.	
(i) Overall, there are net benefits to patients as the benefits from improved safety and/or changed risk profile outweigh the harms from reduced effectiveness.	Cost-consequences, cost-effectiveness, cost-utility, cost–benefit
(ii) Overall, the proposed service is no worse than the comparator because the benefits from improved safety at least offset the harms from reduced effectiveness and/or changed risk profile.	Cost-consequences, cost-effectiveness (which may be reducible to cost-minimisation, ie presentation of an incremental cost-effectiveness for the base case may be inappropriate if net clinical benefits are assumed to be zero)
(iii) Overall, there are net harms to patients as the harms from reduced effectiveness outweigh the benefits from improved safety and/or changed risk profile.	No economic evaluation needs to be presented; the MSAC is unlikely to recommend government subsidy of this service.
The proposed service is less effective than the comparator and is no worse than the comparator in terms of safety.	No economic evaluation needs to be presented; the MSAC is unlikely to recommend government subsidy of this service.
The proposed service is both less effective than the comparator and is associated with reduced safety compared with the comparator.	No economic evaluation needs to be presented; the MSAC is unlikely to recommend government subsidy of this service.

Diagnosis in a non-specialised unit setting

In a non-specialised unit setting no studies provided data on patient survival following the use of unattended sleep studies. Other patient health outcomes, such as QoL, change in symptoms, number of respiratory events, and control of comorbidities after home-based sleep studies, were reported by two case series. No comparative evidence was identified that indicated a change in patient health outcomes after the use of Level 3 or Level 4 sleep studies relative to referral to a sleep physician (± Level 1 sleep study) in a non-specialised unit setting. However, the limited evidence from the literature and the expert opinion from the Advisory Panel suggest that patients with serious clinical symptoms and either abnormal or normal unattended sleep study results would still be referred to a specialist. The limited comparative evidence regarding the use of unattended sleep studies in a referral setting indicates neither a statistically nor a clinically significant difference in patient health outcomes between unattended sleep studies and its comparator, a Level 1 sleep study. Furthermore, the Advisory Panel suggested that OSA treatments in patients with OSA diagnosed with the aid of unattended sleep studies would be the same as those with OSA confirmed by a Level 1 sleep study. Therefore, it would be not unreasonable to expect, in a non-specialised unit setting, no significant difference in terms of diagnostic effectiveness between Level 3 or Level 4 sleep studies and referral to a sleep physician (± Level 1 sleep study).

No comparative evidence in terms of the safety of unattended sleep studies relative to referral to a sleep physician (± Level 1 sleep study) was identified. Both unattended and attended sleep studies are non-invasive and would be unlikely to cause significant physical or psychological harms, although minor adverse events from sleep studies, such as itching and redness from sensor placement, might occur. Expert opinion suggests that the same range of treatment options would be available for the proposed and current diagnostic strategies. The first-line treatment for adult OSA, continuous positive airway pressure (CPAP), is deemed a relatively safe treatment modality. Therefore, it is expected that use of unattended sleep studies would be as safe as referral to a sleep physician (± Level 1 sleep study).

As Level 1 sleep studies have been regarded as the reference standard in the diagnosis of OSA, Level 3 or Level 4 sleep studies have, understandably, worse diagnostic accuracy than a Level 1 sleep study.

Diagnosis in a referral setting

Survival was not reported after the use of unattended sleep studies in adults with suspected OSA in a referral setting. No statistically or clinically significant difference was observed in other patient-relevant health outcomes between the comparator (Level 1 sleep study) and Level 2 sleep studies (effectiveness outcomes: number of respiratory events, sleep time and time to commencement of treatment) or Level 4 sleep studies (effectiveness outcomes: QoL and number of respiratory events). Although a resolution of symptoms and a reduction in the number of apnoea/hypopnoea episodes were reported after the diagnosis of OSA with the aid of Level 3 sleep studies, these outcomes were not compared with a Level 1 sleep study. However, since there is evidence that Level 3 sleep studies, by measuring a higher number of cardiorespiratory parameters, have better diagnostic performance than Level 4 sleep studies, and the treatments after Level 3 and Level 4 sleep studies are no different, it would be not unexpected that Level 3 sleep studies would also be no worse than the comparator (Level 1 sleep study) in terms of diagnostic effectiveness.

As mentioned in the above section, unattended sleep studies would be as safe as Level 1 sleep studies and would have lower test accuracy in the diagnosis of OSA.

Diagnosis in a paediatric setting

Minimal evidence of improved patient health outcomes after the use of unattended sleep studies in a paediatric setting was provided by one case report. The comparative effectiveness of unattended sleep studies relative to a Level 1 sleep study or surgery without the use of a prior sleep study was not identified.

The proportion of children who would undergo surgery (eg adenotonsillectomy) without having pre-procedural diagnostic testing would be similar in the proposed clinical pathway (with the use of unattended sleep studies) to that in the current clinical pathway (with the use of an attended sleep study). Although children with an uncertain result following the use of unattended sleep studies would receive an additional Level 1 sleep study, it is still possible that a small proportion of children would receive unnecessary treatment (surgery) due to false positive test results from unattended sleep studies. Unattended sleep studies may therefore not be as safe as a Level 1 sleep study (because of this false positive risk) but are safer than surgery without use of a prior sleep study.

Unattended sleep studies are not as accurate as Level 1 sleep studies in the diagnosis of paediatric OSA.

Reassessment of treatment efficacy

No evidence was identified that could inform an assessment of the use of unattended sleep studies to reassess treatment efficacy for OSA.

Methods of economic evaluation

Type of economic evaluation

Diagnosis in a non-specialised unit setting

Due to the different diagnostic accuracy of unattended and attended sleep studies, the time to correct diagnosis (and treatment) and the costs associated with correct diagnosis would differ. Therefore, the cost difference per correct diagnosis between unattended (Level 3 or 4) sleep studies and referral (± Level 1 sleep study) was calculated.

Both false negative and false positive test results from unattended studies may have an impact on patient health outcomes. Delayed diagnosis due to a false negative test might have an impact on patients' and their partners' QoL. However, no evidence was identified to indicate such a possibility. According to the Advisory Panel, delayed diagnosis due to false negative test results is unlikely to be associated with negative health outcomes. Time to correct diagnosis is not clinically important because, as is currently the case (and the change in management evidence suggests), patients would be triaged for referral and additional sleep studies on the basis of their clinical symptoms rather than the test result alone. This is supported by the results in the referral setting, which indicate no difference in health outcomes between the two diagnostic strategies. Therefore, the impact of delayed diagnosis on health outcomes is not considered in the analysis, and a cost-effectiveness analysis in terms of health outcomes is not warranted.

False positives from an unattended study may result in unnecessary treatment of OSA with CPAP. Given that CPAP is a relatively safe treatment, no considerable negative outcomes other than cost are likely to be associated with this unnecessary treatment. The decision tree structure for unattended sleep studies compared with referral (± Level 1 sleep study) in the diagnosis of OSA in a non-specialised unit setting is presented in Figure 11.

Diagnosis in a referral setting

Unattended sleep studies in a referral setting were not found to lead to differential health outcomes compared with the use of an attended Level 1 sleep study. Therefore, the cost difference per correct diagnosis between unattended (Level 2, 3 or 4) and attended (Level 1) sleep studies is the only outcome presented in the economic analysis. Figure 12 is the decision tree structure for unattended sleep studies compared with a Level 1 sleep study in the diagnosis of OSA in a referral setting.

Diagnosis in a paediatric setting

There was no comparative evidence regarding change in management or health outcomes in a paediatric setting. It may be possible to extrapolate from the referral setting, given that the paediatric setting is a referral setting and the diagnostic accuracy data are similar. However, treatment of positive paediatric cases involves surgery (eg adenotonsillectomy), which may be associated with physical and/or psychological harms. Therefore, unnecessary treatment due to false positive test results may be associated with adverse effects. The overall adverse impact of surgery on patients' health depends on the magnitude of the surgical complications and the proportion of patients who would receive surgery due to false positive results. There have been opinions from the Advisory Panel that significant short-term and long-term adverse consequences, such as significant bleeding, need of blood transfusion, speech problems and bulbar paralysis, are rare. In addition, only a small proportion of children would receive sleep studies prior to receiving surgery and, of these, a low proportion would proceed to surgery from a false positive test result (Table 30). Therefore, it was considered that adverse events from unnecessary adenotonsillectomy would be trivial and would not be considered in the economic analysis. The decision tree structure for sleep studies in the diagnosis of OSA in a paediatric setting is presented in Figure 13.

In summary, the current available clinical evidence suggests that there is no clinically important difference in patient health outcomes following the use of unattended or attended sleep studies as an approach to OSA diagnosis in the settings under examination. Therefore, a cost comparison per correct diagnosis between unattended and attended sleep studies was warranted.

Reassessment of treatment efficacy

There is a complete absence of evidence and plausible modelling inputs regarding the use of unattended sleep studies for reassessing the efficacy of OSA treatment. Therefore, it is not warranted to perform an economic evaluation for this indication.

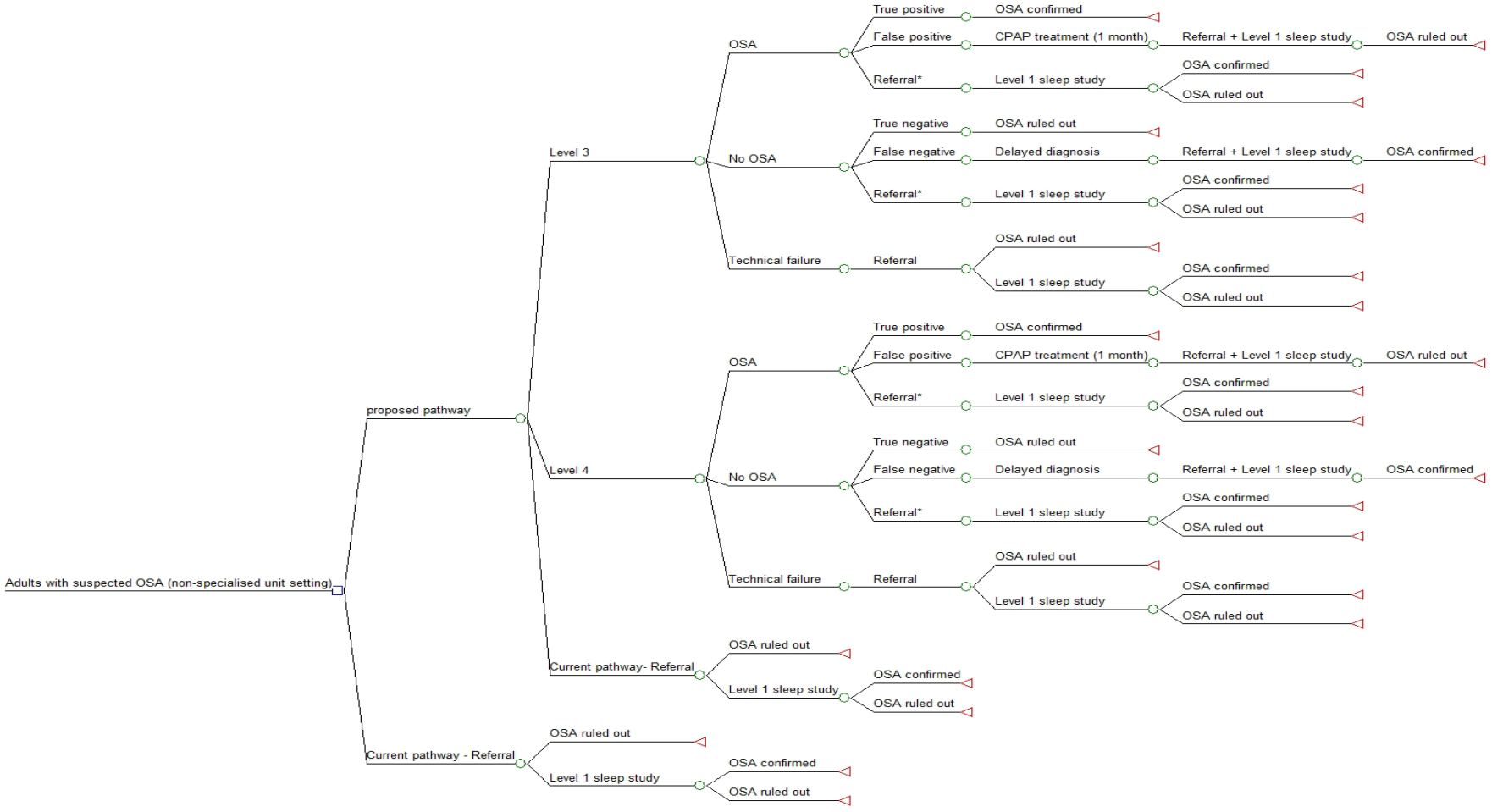
Approach to the economic evaluation

Costs were estimated from the perspective of the Australian society. Therefore, all non-trivial costs, regardless of who bears them, were included. Patients' travel cost, time away from work, and lost or reduced productivity associated with OSA and its diagnosis were not considered. The time horizon of the analysis commenced from the patient's initial

medical consultation for suspected sleep apnoea until a correct diagnosis was established, which was assumed to be within 1 month. Therefore, discounting was not applicable. The decision trees for economic evaluation in terms of incremental cost per correct diagnosis in a non-specialised unit setting, a referral setting and a paediatric setting are presented in Figure 11, Figure 12 and Figure 13, respectively.

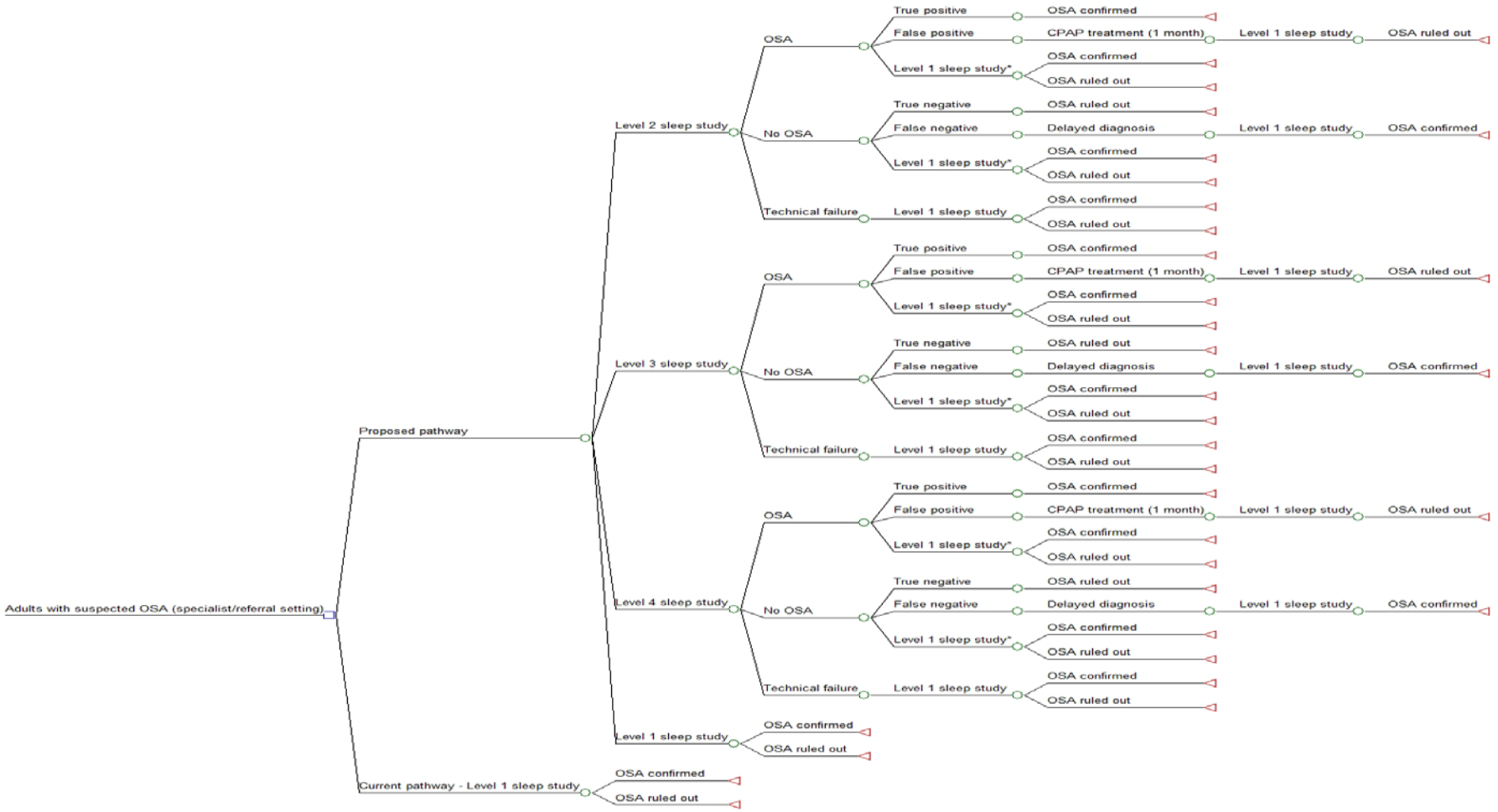
In the calculation of the cost difference between the proposed diagnostic pathway involving unattended sleep studies and the current clinical pathway, additional costs for further sleep studies and follow-up visits were taken into account. These included costs for patients receiving unattended sleep studies that were affected by technical failure, or false negative or uncertain test results, and costs for unnecessary treatment due to false positive test results.

Figure 11 Decision tree for unattended sleep studies in the diagnosis of OSA in a non-specialised unit setting



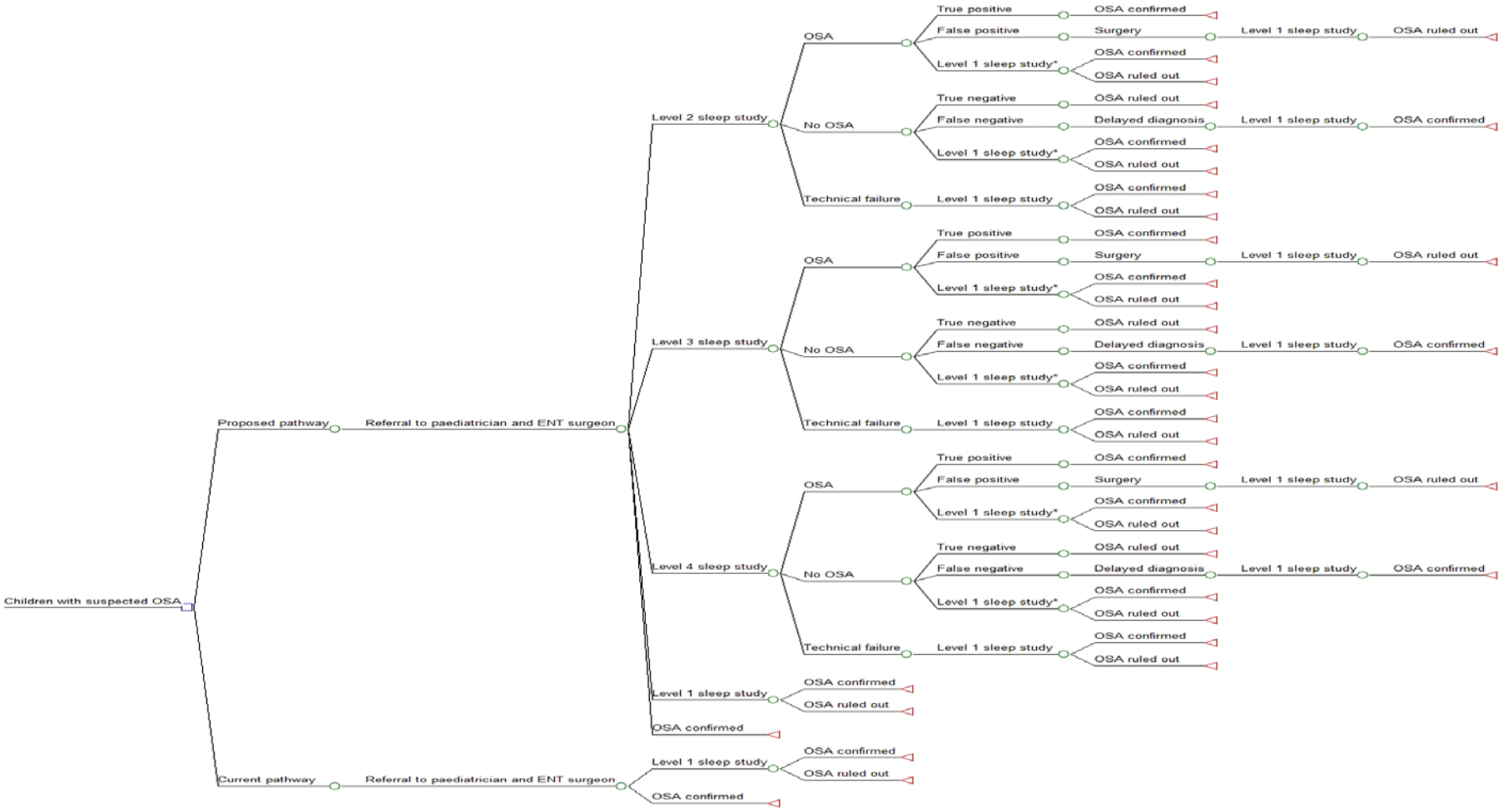
* Patients with uncertain results from unattended sleep studies would be referred for a Level 1 sleep study.

Figure 12 Decision tree for unattended sleep studies in the diagnosis of OSA in a referral setting



* Patients with uncertain results from unattended sleep studies would receive an additional Level 1 sleep study.

Figure 13 Decision tree structure for unattended sleep studies in the diagnosis of OSA in a paediatric setting



* Patients with uncertain results from unattended sleep studies would receive an additional Level 1 sleep study.

Inputs to the economic evaluation

Assumptions used in the economic evaluation

A number of assumptions were made to confine the economic evaluation to the most likely scenarios:

- The prevalence of OSA in the target population for unattended sleep studies in Australia is the same as the study population from which diagnostic yield data were retrieved.
- The technical failure rate from a laboratory-based PSG is trivial and thus assumed to be zero.
- Patients would receive a Level 1 sleep study after experiencing technical failure or after getting uncertain/false negative results from any level of an unattended sleep study.
- AHI/RDI/ODI thresholds of ≥15 in adults and ≥5 in children are used to detect moderate to severe OSA that is clinically relevant.
- Patients would be treated by APAP following an unattended sleep study.

Variables used in the economic evaluation

The input variables used in the economic evaluation of unattended sleep studies in the diagnosis of OSA in a non-specialised unit setting, referral setting and paediatric setting are summarised in Table 27, Table 29 and Table 30, respectively. Due to an absence of data from the literature, some input variables in the paediatric setting were borrowed from the corresponding data in the referral setting, given that the paediatric setting is a particular type of referral setting (based on expert opinion from the Advisory Panel).

Table 27 Input variables for economic analysis of unattended sleep study in the diagnosis of OSA in a non-specialised unit setting

Variable	Value (range)	Source of estimate
Transition probabilities		
Proposed clinical pathway		
The probability of patients with suspected OSA who would be referred without having a Level 3 or Level 4 sleep study	35% (30–40%)	The Advisory Panel
The probability of patients with suspected OSA who would receive a Level 3 sleep study	33% (31–36%)	The Advisory Panel
Technical failure rate of a Level 3 sleep study	5% (0–33%)	Included papers[a] The Advisory Panel
The probability of getting a positive test result from a Level 3 sleep study	85% (2 –93%)	Bridevaux et al (2007); Davidson et al (1999); Liam (1996); Stepnowsky et al (2004); Tiihonen et al (2009)
The probability of getting an uncertain positive result from a Level 3 sleep study	20% (15–30%)	The Advisory Panel
Positive predictive value of a Level 3 sleep study	88% (7 –100%)	Carter et al (2004); Yin et al (2006)
The probability of getting an uncertain negative result from a Level 3 sleep study	50% (25–75%)	The Advisory Panel
Negative predictive value of a Level 3 sleep study	68% (60–75%)	Carter et al (2004); Yin et al (2006)

The probability of patients with suspected OSA who would receive a Level 4 sleep study	32% (29–34%)	The Advisory Panel
Technical failure rate of a Level 4 sleep study	1% (0–5%)	The Advisory Panel
The probability of getting a positive test result from a Level 4 sleep study	71% (64–83%)	Bar et al (2003); Saeki et al (1999)
The probability of getting an uncertain positive result from a Level 4 sleep study	25% (0–40%)	The Advisory Panel
Positive predictive value of a Level 4 sleep study	85% (75–95%)	The Advisory Panel
The probability of getting an uncertain negative result from a Level 4 sleep study	60% (30–90%)	The Advisory Panel
Negative predictive value of a Level 4 sleep study	54% (5–54%)	Gergely et al (2009)
In technical failure cases, the probability of OSA being ruled out by a specialist without having a Level 1 sleep study	0%	The Advisory Panel
Current clinical pathway		
The probability of patients whose OSA being ruled out without having a Level 1 sleep study	0%	The Advisory Panel
Unit costs		
Initial consult—general practitioner attendance (level 'C')	$65	MBS item 36[b]
Follow-up consult—general practitioner attendance (level 'B')	$34	MBS item 23[b]
Consultant physician attendance, referral	$143	MBS item 110[b]
Consultant physician attendance, follow-up	$71	MBS item 116[b]
Level 1 sleep study	$556	MBS item 12203[b]
Level 3 sleep study	$162 ($146–$178)[c]	See Table 28
Level 4 sleep study	$137 ($123–$151)[c]	See Table 28
Cost of APAP treatment (1 month)	$350	The Advisory Panel

[a] Sources: Ancoli-Israel et al (1981); Calleja et al (2002); Dingli et al (2003); Faber et al (2002); García-Díaz et al (2007); Lloberes et al (2001); Quintana-Gallego et al (2004); Redline et al (1991); Reichert et al (2003); Ruiz-López et al (2009); Smith et al (2007); Tiihonen et al (2009; Tonelli de Oliveira et al (2009); Whittle et al (1997); Yin et al (2005), (2006); [b] Source: Medicare Australia (2010); [c] The lower and upper limits of the range are equal to 90% and 110%, respectively, of the base case.

APAP = auto-adjusting positive airway pressure; OSA = obstructive sleep apnoea

Table 28 Unit costs of items associated with Level 3 and Level 4 sleep studies

Item	Cost	
	Level 3 sleep study	Level 4 sleep study
Lab system:		
Capital	$20	$10
Maintenance/insurance	$4	$2
Office	$5	$5
Disposable items	$10	$10
Staff salary:		
Secretarial (booking, typing, phone, reception)	$20	$20
Technological—set up, retrieval	$43	$30
Technological—overnight	$0	$0
Technological—analysis	$22	$22

Medical—reporting	$38	$38
Total	$162	$137

Source: Australasian Sleep Association / Thoracic Society of Australia and New Zealand

Table 29 Input variables for economic analysis of unattended sleep study in the diagnosis of OSA in a referral setting

Variable	Value (range)	Source of estimate
Transition probabilities		
Proposed clinical pathway		
The probability of patients with suspected OSA who would receive a Level 1 sleep study	60% (55–65%)	ASA /TSANZ
The probability of patients with suspected OSA who would receive a Level 2 sleep study	20% (18–22%)	ASA /TSANZ
Technical failure rate of a Level 2 sleep study	10% (5–20%)	Abdenbi et al (2002); Ancoli-Israel et al (1997); Escourrou et al (2000); Fry et al (1998); Gagnadoux et al (2002); Mykytyn et al (1999); Portier et al (2000) The Advisory Panel
The probability of getting a positive test result from a Level 2 sleep study	68% (48–83%)[a]	Abdenbi et al (2002)
The probability of getting an uncertain positive result from a Level 2 sleep study	8% (5–10%)	The Advisory Panel
Positive predictive value of a Level 2 sleep study	97% (82–100%)[a]	Portier et al (2000)
The probability of getting an uncertain negative result from a Level 2 sleep study	75% (70–80%)	The Advisory Panel
Negative predictive value of a Level 2 sleep study	85% (71–93%)[a]	Portier et al (2000)
The probability of patients with suspected OSA who would receive a Level 3 sleep study	9% (8–10%)	ASA /TSANZ The Advisory Panel
Technical failure rate of a Level 3 sleep study	5% (0–33%)	Included papers[b] The Advisory Panel
The probability of getting a positive test result from a Level 3 sleep study	85% (25–93%)	Bridevaux et al (2007); Davidson et al (1999); Liam (1996); Stepnowsky et al (2004); Tiihonen et al (2009)
The probability of getting an uncertain positive result from a Level 3 sleep study	8% (5–10%)	The Advisory Panel
Positive predictive value of a Level 3 sleep study	83% (69–88%)	Reichert et al (2003); Tonelli de Oliveira et al (2009); Whittle et al (1997)
The probability of getting an uncertain negative result from a Level 3 sleep study	85% (80–90%)	The Advisory Panel
Negative predictive value of a Level 3 sleep study	73% (65–91%)	Reichert et al (2003); Tonelli de Oliveira et al (2009); Whittle et al (1997)
The probability of patients with suspected OSA who would receive a Level 4 sleep study	11% (9–13%)	ASA /TSANZ The Advisory Panel
Technical failure rate of a Level 4 sleep study	1% (0–5%)	The Advisory Panel
The probability of getting a positive test result from a Level 4 sleep study	71% (64–83%)	Bar et al (2003); Saeki et al (1999)
The probability of getting an uncertain positive result from a Level 4 sleep study	25% (0–40%)	The Advisory Panel

Positive predictive value of a Level 4 sleep study	87% (43–100%)	Fietze et al (2004); Pang et al (2006); Pittman et al (2004); Ryan et al (1995); Schafer et al (1997); Takeda et al (2006); Wiltshire et al (2001)
The probability of getting an uncertain negative result from a Level 4 sleep study	95% (90–100%)	The Advisory Panel
Negative predictive value of a Level 4 sleep study	70% (41–100%)	Fietze et al (2004); Pang et al (2006); Pittman et al (2004); Ryan et al (1995); Schafer et al (1997); Takeda et al (2006); Wiltshire et al (2001)
Current clinical pathway		
The probability of patients whose OSA being ruled out without having a Level 1 sleep study	0%	The Advisory Panel
Unit costs		
Consultant physician attendance, referral	$143	MBS item 110 [c]
Consultant physician attendance, follow-up	$71	MBS item 116 [c]
Level 1 sleep study	$556	MBS item 12203 [c]
Level 2 sleep study	$317	MBS item 12250 [c]
Level 3 sleep study	$162 ($146–$178)[d]	See Table 28
Level 4 sleep study	$137 ($123–$151)[d]	See Table 28
Cost of APAP treatment (1 month)	$350	The Advisory Panel

[a] The range is the 95% confidence interval of the base case; [b] Sources: Ancoli-Israel et al (1981); Calleja et al (2002); Dingli et al (2003); Faber et al (2002); García-Díaz et al (2007); Lloberes et al (2001); Quintana-Gallego et al (2004); Redline et al (1991); Reichert et al (2003); Ruiz-López et al (2009); Smith et al (2007); Tiihonen et al (2009); Tonelli de Oliveira et al (2009); Whittle et al (1997); Yin et al (2005), (2006); [c] Source: Medicare Australia (2010); [d] The lower and upper limits of the range equal to the 90% and 110%, respectively, of the base case.

OSA = obstructive sleep apnoea; APAP: auto-adjusting positive airway pressure; ASA: Australasian Sleep Association; MBS: Medicare Benefits Schedule; TSANZ: Thoracic Society of Australia and New Zealand

Table 30 Input variables for economic analysis of unattended sleep study in the diagnosis of OSA in a paediatric setting

Variable	Value (range)	Source of estimate
Transition probabilities		
Proposed clinical pathway		
The probability of children with suspected OSA who would undergo surgery without having a sleep study	75% (70–80%)	The Advisory Panel
The patient breakdown among Level 1, Level 2, Level 3 and Level 4 sleep studies in those who need a sleep study	80:0:10:10	The Advisory Panel
Technical failure rate of a Level 2 sleep study	10% (5–20%)	Adapted from the referral setting
The probability of getting a positive test result from a Level 2 sleep study	68% (48–83%)	Adapted from the referral setting
The probability of getting an uncertain positive result from a Level 2 sleep study	8% (5–10%)	Adapted from the referral setting
Positive predictive value of a Level 2 sleep study	97% (86–100%)	Adapted from the referral setting
The probability of getting an uncertain negative result from a Level 2 sleep study	75% (70–80%)	Adapted from the referral setting
Negative predictive value of a Level 2 sleep study	85% (71–93%)	Adapted from the referral setting
Technical failure rate of a Level 3 sleep study	5% (0–33%)	Adapted from the referral setting

The probability of getting a positive test result from a Level 3 sleep study	33% (29–83%)	Jacob et al (1995); Poels et al (2003); Zucconi et al (2003)
The probability of getting an uncertain positive result from a Level 3 sleep study	8% (5–10%)	Adapted from the referral setting
Positive predictive value of a Level 3 sleep study	85% (70–100%)	Jacob et al (1995); Zucconi et al (2003)
The probability of getting an uncertain negative result from a Level 3 sleep study	85% (80–90%)	Adapted from the referral setting
Negative predictive value of a Level 3 sleep study	73% (65–91%)	Adapted from the referral setting
Technical failure rate of a Level 4 sleep study	1% (0 –5%)	Adapted from the referral setting
The probability of getting a positive test result from a Level 4 sleep study	50% (21–53%)	Brunetti et al (2001); Castronovo et al (2003); Kirk et al (2003)
The probability of getting an uncertain positive result from a Level 4 sleep study	25% (0–40%)	Adapted from the referral setting
Positive predictive value of a Level 4 sleep study	59% (57–60%)	Brunetti et al (2001); Kirk et al (2003)
The probability of getting an uncertain negative result from a Level 4 sleep study	95% (90–100%)	Adapted from the referral setting
Negative predictive value of a Level 4 sleep study	70% (41–100%)	Adapted from the referral setting
Current clinical pathway		
The probability of children who undergo surgery without having a sleep study	80% (75–85%)	The Advisory Panel
Unit costs		
Initial consult—general practitioner attendance (level 'C')	$65	MBS item 36 [a]
Consultant physician attendance, surgery or hospital	$249	MBS item 132 [a]
Consultant physician attendance, follow-up	$125	MBS item 133 [a]
Level 1 sleep study	$663	MBS item 12210 [a]
Level 2 sleep study	$317	MBS item 12250 [a]
Level 3 sleep study	$162 ($146–$178)[b]	See Table 28
Level 4 sleep study	$137 ($123–$151)[b]	See Table 28
Cost of APAP treatment (1 month)	$350	The Advisory Panel

[a] Source: Medicare Australia (2010); [b] The lower and upper limits of the range are equal to 90% and 110%, respectively, of the base case.

Table 31 Procedural cost of adenotonsillectomy

Item	Cost	Source of estimate
Professional fee—surgeon	$275	MBS item 41789
Anaesthesia initiation	$112	MBS item 20320
Anaesthesia time units	$37	MBS item 23023
Hospital facility services	$1 652	Total average charge per AR-DRG V5.1 Private Hospital Data Bureau; D11Z – Tonsillectomy and/or Adenoidectomy[a]
Total	$2 076	

Sources: AIHW (2009); Medicare Australia (2010)

[a] Average length of hospital stay: 1.1 days

Sensitivity analysis of the economic evaluation

Sensitivity analysis of all key variables was conducted to examine the robustness of the cost comparison between use of unattended sleep studies and Level 1 sleep studies in the diagnosis of OSA.

Given that the unit cost of a Level 3 or Level 4 sleep study was provided by the Applicant, and that the Medicare schedule fee, should it be listed on the MBS, may be different from that estimate, a 10% variation of the base-case cost was examined in one-way sensitivity analysis to explore the impact of this variation on the cost comparison results (Table 27, Table 29 and Table 30). In addition, threshold analyses were conducted to identify the price of a Level 3 or Level 4 study at which the use of unattended sleep studies in the diagnosis of OSA would be no longer cost saving.

Results of the economic evaluation

The results of the cost comparison between the proposed diagnostic pathway (using unattended sleep studies) and the current clinical pathway (using Level 1 sleep studies) are summarised in Table 32.

Table 32 Summary of cost comparison results in various settings per correct diagnosis per capita[a]

Setting	Proposed clinical pathway	Current clinical pathway	Incremental cost[b]
Non-specialised unit setting	$691	$835	–$144
Referral setting	$754	$770	–$16
Paediatric setting	$525[c]	$472[c]	$53

[a] The economic analysis was carried out in a scenario where AHI thresholds of ≥15 in adults and ≥5 in children are used as indicative of OSA that is clinically relevant. The results of the economic evaluation are the most conservative estimates of incremental costs; [b] A negative incremental cost represents a cost saving resulting from the use of unattended sleep study in the diagnosis of OSA; a positive incremental cost represents a net additional cost resulting from the use of unattended sleep study in the diagnosis of OSA; [c] The relatively lower cost of a correct diagnosis for each child with suspected OSA is attributable to the unique situation in paediatric clinical practice where the vast majority (75% in proposed clinical pathway and 80% in current clinical pathway) of children who are referred for suspicion of OSA would undergo surgery without having a sleep study. However, the cost savings from the lower uptake of sleep studies is somewhat counterbalanced by the relatively higher consultant physician fees for both the initial visit and the follow-up visits in the paediatric setting.

The above table indicates that the cost per correct diagnosis of OSA using unattended sleep studies is *lower* than that using a laboratory-based PSG both in a non-specialised unit setting and in a referral setting. However, the use of unattended sleep studies for the diagnosis of paediatric OSA is more *expensive* than the current diagnostic pathway.

Sensitivity analysis

All variables in Table 27, Table 29 and Table 30 were examined by one-way sensitivity analysis. The results of these sensitivity analyses are summarised in Table 33, Table 34 and Table 35.

Table 33 Results of one-way sensitivity analyses for the cost comparison in a non-specialised unit setting

Variable	Incremental cost[a]		
	Lower limit[b]	Base case[b]	Upper limit[b]
Referral without having a Level 3 or Level 4 sleep study	–$182[c]	–$144	–$105[d]
Technical failure from a Level 3 sleep study	–$151	–$144	–$104
Positive result from a Level 3 sleep study	–$97	–$144	–$150

Uncertain positive result from a Level 3 sleep study	–$152	–$144	–$127
True positive from a Level 3 sleep study	–$117	–$144	–$173
Uncertain negative result from a Level 3 sleep study	–$150	–$144	–$138
True negative from a Level 3 sleep study	–$142	–$144	–$145
Technical failure from a Level 4 sleep study	–$145	–$144	–$140
Positive result from a Level 4 sleep study	–$138	–$144	–$155
Uncertain positive result from a Level 4 sleep study	–$177	–$144	–$124
True positive from a Level 4 sleep study	–$124	–$144	–$163
Uncertain negative result from a Level 4 sleep study	–$155	–$144	–$132
True negative from a Level 4 sleep study	–$144	–$144	–$144
Unit cost of a Level 3 sleep study	–$149	–$144	–$139
Unit cost of a Level 4 sleep study	–$148	–$144	–$140

[a] A negative incremental cost represents a cost saving resulting from the use of unattended sleep study in the diagnosis of OSA; [b] Based on the lower estimate, base case and upper estimate in the plausible range for variables presented in Table 27; [c] Lower limit in the sensitivity analysis is based on the assumption that 30% of the patients with suspected OSA would be referred without having a Level 3 or Level 4 sleep study, and the proportions of patients who would receive Level 3 and Level 4 sleep studies are 36% and 34%, respectively; [d] Upper limit in the sensitivity analysis is based on the assumption that 40% of the patients with suspected OSA would be referred without having a Level 3 or Level 4 sleep study, and the proportions of patients who would receive Level 3 and Level 4 sleep studies are 31% and 29%, respectively.

The above sensitivity analyses in a non-specialised unit setting indicate that the results of cost comparison between the proposed and current diagnostic pathways are robust (Table 33). The use of unattended sleep studies in the diagnosis of OSA would incur *savings* within the plausible ranges of variables as provided in Table 27.

Table 34 Results of one-way sensitivity analyses for the cost comparison in a referral setting

Variable	Incremental cost[a]		
	Lower limit[b]	Base case[b]	Upper limit[b]
Uptake of a Level 1 sleep study	–$47[c]	–$16	$15[d]
Technical failure from a Level 2 sleep study	–$20	–$16	–$9
Positive result from a Level 2 sleep study	–$1	–$16	–$27
Uncertain positive result from a Level 2 sleep study	–$18	–$16	–$15
True positive from a Level 2 sleep study	$2	–$16	–$20
Uncertain negative result from a Level 2 sleep study	–$18	–$16	–$15
True negative from a Level 2 sleep study	–$15	–$16	–$17
Technical failure from a Level 3 sleep study	–$17	–$16	–$8
Positive result from a Level 3 sleep study	–$4	–$16	–$19
Uncertain positive result from a Level 3 sleep study	–$17	–$16	–$15
True positive from a Level 3 sleep study	–$6	–$16	–$20
Uncertain negative result from a Level 3 sleep study	–$16	–$16	–$16
True negative from a Level 3 sleep study	–$16	–$16	–$16
Technical failure from a Level 4 sleep study	–$16	–$16	–$15
Positive result from a Level 4 sleep study	–$13	–$16	–$21
Uncertain positive result from a Level 4 sleep study	–$26	–$16	–$10
True positive from a Level 4 sleep study	$11	–$16	–$24
Uncertain negative result from a Level 4 sleep study	–$17	–$16	–$16
True negative from a Level 4 sleep study	–$16	–$16	–$16

Unit cost of a Level 3 sleep study	–$18	–$16	–$15
Unit cost of a Level 4 sleep study	–$18	–$16	–$15

[a] A negative incremental cost represents a cost saving resulting from the use of unattended sleep study in the diagnosis of OSA; [b] Based on the lower estimate, base case and upper estimate in the plausible range for variables presented in Table 29; [c] Lower limit in the sensitivity analysis is based on the assumption that 55% of the patients with suspected OSA would receive a Level 1 sleep study, and the proportions of patients who would undergo Level 2, Level 3 and Level 4 sleep studies are 22%, 10% and 13%, respectively; [d] Upper limit in the sensitivity analysis is based on the assumption that 65% of the patients with suspected OSA would receive a Level 1 sleep study, and the proportions of patients who would undergo Level 2, Level 3 and Level 4 sleep studies are 18%, 8% and 9%, respectively.

Table 34 presents the results of the one-way sensitivity analyses for the referral setting. In a referral setting the decision tree model (Figure 12) is sensitive to the uptake of Level 1 sleep studies once unattended sleep studies are introduced. The use of unattended sleep studies would incur *additional* costs when a higher than anticipated proportion of patients with suspected OSA receive a Level 1 sleep study in the proposed clinical pathway (Table 34). However, given that the number of Level 1 studies appears to have decreased since Level 2 studies received interim funding on the MBS (Figure 4, page 13), it appears unlikely that this potential increase in uptake will be realised. The true positive rates from Level 2 and Level 4 sleep studies were also found to affect the base-case model when varied according to the lower limit of the plausible range, ie if Level 2 or Level 4 sleep studies demonstrate higher false positive rates in the diagnosis of OSA than suggested in the base case (Table 34). The potential increase in costs from the use of unattended sleep studies with a higher false positive rate than suggested in the base case was higher for Level 4 studies than Level 2 studies when compared with current practice. All other scenarios as described in Table 29 found that the proposed diagnostic process involving unattended sleep studies is *cost saving* relative to current pathway.

Table 35 Results of one-way sensitivity analyses for the cost comparison in a paediatric setting

Variable	Incremental cost[a]		
	Lower limit[b]	Base case[b]	Upper limit[b]
Surgery without having a sleep study in the proposed pathway	$95[c]	$53	$11[d]
Technical failure from a Level 2 sleep study	$53	$53	$53
Positive result from a Level 2 sleep study	$53	$53	$53
Uncertain positive result from a Level 2 sleep study	$53	$53	$53
True positive from a Level 2 sleep study	$53	$53	$53
Uncertain negative result from a Level 2 sleep study	$53	$53	$53
True negative from a Level 2 sleep study	$53	$53	$53
Technical failure from a Level 3 sleep study	$53	$53	$53
Positive result from a Level 3 sleep study	$53	$53	$50
Uncertain positive result from a Level 3 sleep study	$53	$53	$53
True positive from a Level 3 sleep study	$56	$53	$50
Uncertain negative result from a Level 3 sleep study	$53	$53	$53
True negative from a Level 3 sleep study	$53	$53	$53
Technical failure from a Level 4 sleep study	$53	$53	$53
Positive result from a Level 4 sleep study	$50	$53	$53
Uncertain positive result from a Level 4 sleep study	$54	$53	$52
True positive from a Level 4 sleep study	$53	$53	$53
Uncertain negative result from a Level 4 sleep study	$53	$53	$53
True negative from a Level 4 sleep study	$53	$53	$53

Unit cost of a Level 3 sleep study	$53	$53	$53
Unit cost of a Level 4 sleep study	$53	$53	$53
Surgery without having a sleep study in the current pathway	$14[e]	$53	$92[f]

[a] A positive incremental cost represents a net additional cost resulting from the use of unattended sleep study in the diagnosis of OSA; [b] Based on the lower estimate, base case and upper estimate in the plausible range for variables presented in Table 30; [c] Lower limit in the sensitivity analysis is based on the assumption that 70% of the children with suspected OSA would undergo adenotonsillectomy without having a sleep study, and the remaining children would receive a Level 1, Level 2, Level 3 or Level 4 sleep study in the ratio 80:0:10:10; [d] Upper limit in the sensitivity analysis is based on the assumption that 80% of the children with suspected OSA would undergo adenotonsillectomy without having a sleep study, and the remaining children would receive a Level 1, Level 2, Level 3 or Level 4 sleep study in the ratio 80:0:10:10; [e] Lower limit in the sensitivity analysis is based on the assumption that 75% of the children with suspected OSA would undergo adenotonsillectomy without having a sleep study, and the remaining children would receive a Level 1, Level 2, Level 3 or Level 4 sleep study in the ratio 80:0:10:10; [f] Upper limit in the sensitivity analysis is based on the assumption that 85% of the children with suspected OSA would undergo adenotonsillectomy without having a sleep study, and the remaining children would receive a Level 1, Level 2, Level 3 or Level 4 sleep study in the ratio 80:0:10:10.

Sensitivity analyses indicate that the cost comparison in the paediatric setting is also robust. The use of unattended sleep studies for the diagnosis of OSA would incur *additional* costs in a paediatric setting. The probability of children undergoing surgery without having a sleep study is the variable that appears to have the most impact on the net cost between the use of unattended and attended sleep studies in the diagnosis of OSA. A lower proportion of children proceeding directly to surgery will increase the net cost to $95 per child in the proposed clinical pathway.

As noted earlier, given that the estimates of the unit costs for Level 3 and Level 4 unattended sleep studies were taken from the Applicant, threshold analyses were undertaken to determine the price of a Level 3 or Level 4 sleep study at which the use of unattended sleep studies would be more expensive to society than the use of laboratory-based PSG. The results of threshold analyses in a non-specialised unit setting and a referral setting are presented in Figure 14 and Figure 15, respectively.

Figure 14 Results of threshold analyses for the unit costs of Level 3 and Level 4 sleep studies in a non-specialised unit setting

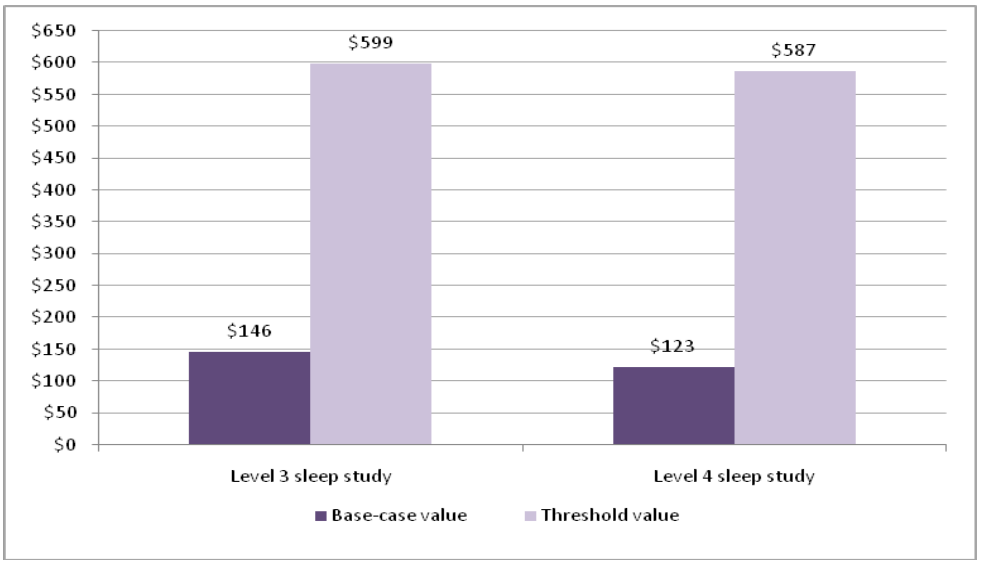


Figure 15 Results of threshold analyses for the unit costs of Level 3 and Level 4 sleep studies in a referral setting

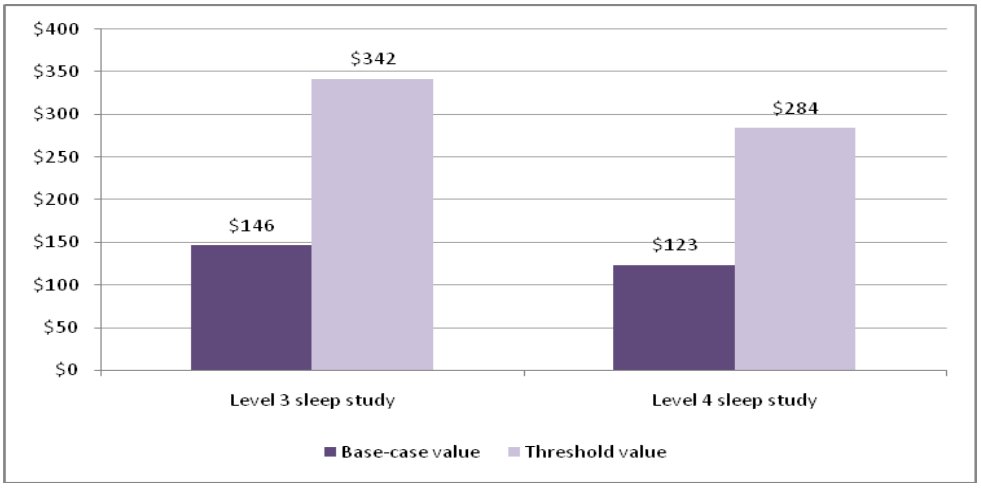


Figure 15 indicates that, in a referral setting, when the unit cost of a Level 3 sleep study reaches $342, or that of a Level 4 sleep study reaches $284, the proposed diagnostic pathway involving unattended sleep studies will no longer be cost saving relative to the current pathway using an attended Level 1 sleep study. The threshold analyses in a non-specialised unit setting suggest even higher cost values for Level 3 and Level 4 sleep studies at which the use of unattended sleep studies would incur additional cost during the diagnostic process (Figure 14). As the MBS fees for Level 1 and Level 2 sleep studies are $543 and $310, respectively, it is unlikely that the price of a Level 3 or Level 4 sleep study would reach the threshold values as presented in Figure 14 and Figure 15. Therefore, the diagnosis of OSA with the aid of unattended sleep studies is expected to be *cost saving* both in a non-specialised unit setting and a referral setting, despite the uncertain unit cost of a Level 3 or Level 4 sleep study.

The threshold analyses in a paediatric setting suggest that, even if the cost of a Level 3 or Level 4 sleep study drops to $0, the use of unattended sleep studies in the diagnosis of paediatric OSA would not be cost saving because of the additional costs associated with unnecessary adenotonsillectomy in children with false positive results from unattended sleep studies.

Financial incidence analysis

Likely number of investigations per year

As previously described in the section addressing clinical need / burden (see page 10), 35 896 patients had a principal diagnosis of OSA in Australia in 2006–07, using ICD-10-AM coding. Of these, 30 329 (84.5%) patients were 14 years of age or older, and the remaining 5567 were assumed to be treated in a paediatric setting. Calculations of the number of patients with suspected OSA in a non-specialised unit setting, a referral setting and a paediatric setting are given in Table 36. The flowcharts and input variables of the OSA diagnostic processes in various healthcare settings are outlined in the 'Economic analysis' section (Figure 11, Figure 12, Figure 13, Table 27, Table 29 and Table 30).

Table 36 Clinical need for unattended sleep studies in the diagnosis of OSA in various settings

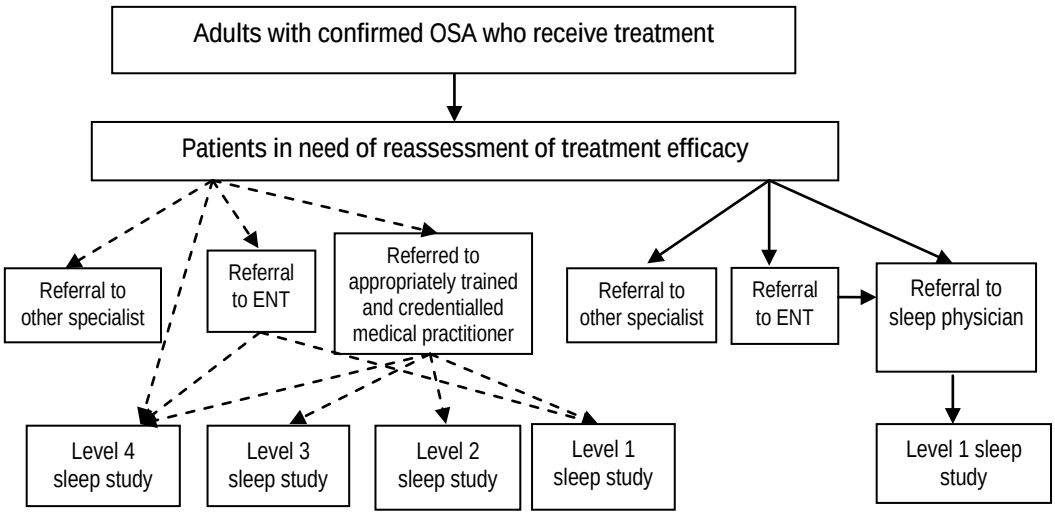
Item	Cut-off point	Base case (range)	Source of estimate
Non-specialised unit setting			
Number of patients with confirmed OSA		30 329	See page 10
Possibility of getting a positive result from a PSG	AHI ≥5	80% (53–100%)	Abraham et al (2006); Carter et al (2004); Eskafi et al (2006); Fietze et al (2004); García-Díaz et al (2007); Pittman et al (2004; Quintana-Gallego et al (2004); Tonelli de Oliveira et al (2009)
	AHI ≥15	53% (25–82%)	Included papers[a]
Number of patients with suspected OSA in a non-specialised unit setting[b]	AHI ≥5	37 911	
	AHI ≥15	57 225	
Referral setting			
Number of patients with suspected OSA in a non-specialised unit setting	AHI ≥5	37 911	
	AHI ≥15	57 225	
Possibility of patients who would be referred without having a Level 3 or Level 4 sleep study		35% (30–40%)	See Table 27
Number of patients with suspected OSA in a referral setting[c]	AHI ≥5	13 269	
	AHI ≥15	20 029	
Paediatric setting			
Number of patients with confirmed OSA		5 567	See page 10
Possibility of getting a positive result from a PSG	AHI ≥1	100% (62–100%)	Brunetti et al (2001); Jacob et al (1995); Kirk et al (2003); Poels et al (2003); Zucconi et al (2003)
	AHI ≥5	42% (29–75%)	Brunetti et al (2001); Jacob et al (1995); Kirk et al (2003); Poels et al (2003); Zucconi et al (2003)
Number of patients with suspected OSA in a paediatric setting[b]	AHI ≥1	5 567	
	AHI ≥5	13 255	

[a] Sources: Abraham et al (2006); Baltzan et al (2000); Carter et al (2004); Dingli et al (2003); Eskafi et al (2006); Fietze et al (200); García-Díaz et al (2007); Gergely et al (2009); Gyulay et al (1993); Pang et al (2006); Pittman et al (2004); Portier et al (2000) Quintana-Gallego et al (2004); Reichert et al (2003); Ryan et al (1995); Sériès et al (2005); Smith et al (2007); Whittle et al (1997); Wiltshire et al (2001); [b] The number of patients with suspected OSA = the number of patients with confirmed OSA ÷ the possibility of getting a positive result from a PSG; [c] The number of patients with suspected OSA in a referral setting = the number of patients with suspected OSA in a non-specialised unit setting x the possibility of patients who would be referred after having a Level 3 or Level 4 sleep study.

AHI = apnoea–hypopnoea index; PSG = polysomnography; OSA = obstructive sleep apnoea

The flowcharts estimating the clinical need for unattended sleep studies in reassessing treatment efficacy are outlined in Figure 16 and Figure 17. It should be noted that these reassessment pathways are *not* complete, as further Level 1 sleep studies (in patients with a study affected by technical failure and those with uncertain/false negative results from unattended sleep studies) and unnecessary treatment (in patients with false positive test results) were not included due to lack of data and plausible clinical estimates. The inputs into these flowcharts are listed in the tables below each pathway (Table 37 and Table 38).

Figure 16 Flowchart to estimate the clinical need for unattended sleep studies when reassessing treatment efficacy in adults



Note 1: Dashed line: proposed clinical pathway; solid line: current clinical pathway

Note 2: The % unaccounted for at each distribution point in the above pathway do not require further testing or referral

ENT = ear, nose and throat

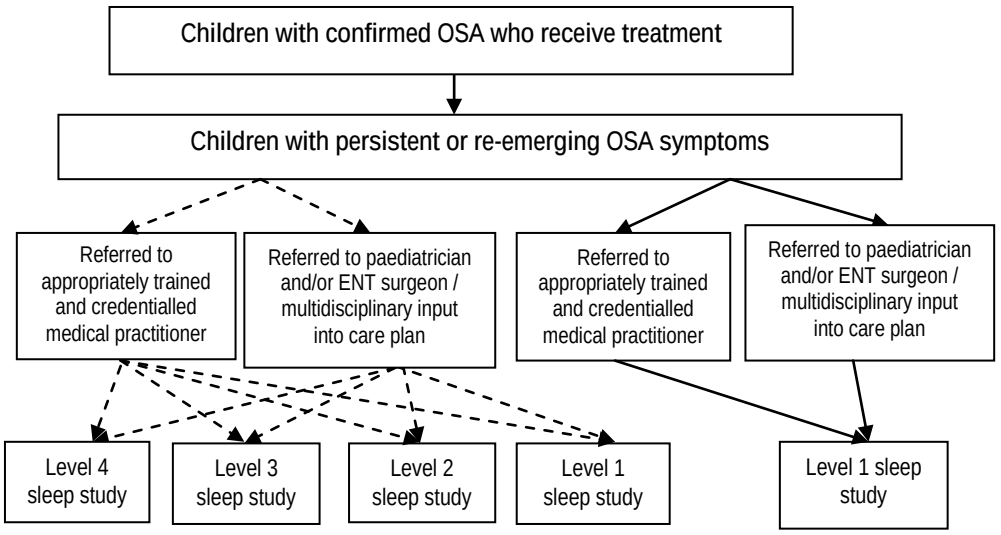
Table 37 Input variables for financial analysis of unattended sleep study in the reassessment of treatment efficacy in adults

Patient breakdown		
	Proportion[a]	Number of patients
Proposed clinical pathway		
Adults with confirmed OSA who receive treatment		30 329
Patients receiving treatment who would need reassessment	25%	7 582
Patients in need of reassessment who would be referred to an appropriately trained and credentialed medical practitioner	60%	4 549
Patients in need of reassessment who would be referred to an ENT surgeon	20%	1 516
Patients in need of reassessment who would be referred to other specialists	15%	1 137
Patients in need of reassessment who would receive a Level 4 sleep study without being referred	5%	379
Patients referred to an appropriately trained and credentialed medical practitioner who would receive a Level 1 sleep study	80%	3 639
Patients referred to an appropriately trained and credentialed medical practitioner who would receive a Level 2 sleep study	0%	0
Patients referred to an appropriately trained and credentialed medical practitioner who would receive a Level 3 sleep study	10%	455
Patients referred to an appropriately trained and credentialed medical practitioner who would receive a Level 4 sleep study	10%	455
Patients referred to an ENT surgeon who would receive a Level 1 sleep study	25%	379
Patients referred to an ENT surgeon who would receive a Level 4 sleep study	25%	379
Current clinical pathway		
Adults with confirmed OSA who receive treatment		30 329

Patients receiving treatment who would need reassessment	25%	7 582
Patients in need of reassessment who would be referred to a sleep physician	65%	4 928
Patients in need of reassessment who would be referred to an ENT surgeon	20%	1 516
Patients in need of reassessment who would be referred to other specialists	15%	1 137
Patients referred to an ENT surgeon who would need further referral to a sleep physician	50%	758
Patients referred to a sleep physician who would receive a Level 1 sleep study	100%	5 687
Unit costs		
Item	Cost	Source of estimate
Initial consult—general practitioner attendance (level 'C')	$65	MBS item 36
Follow-up consult—general practitioner attendance (level 'B')	$34	MBS item 23
Consultant physician attendance, referral	$143	MBS item 110
Consultant physician attendance, follow-up	$71	MBS item 116
Specialist attendance, surgery or hospital	$81	MBS item 104
Specialist attendance, surgery or hospital, follow-up	$41	MBS item 105
Cost of a Level 1 sleep study	$556	MBS item 12203[b]
Cost of a Level 2 sleep study	$317	MBS item 12250[b]
Cost of a Level 3 sleep study	$162	See Table 28
Cost of a Level 4 sleep study	$137	See Table 28

[a] Source: the Advisory Panel; [b] Source: Medicare Australia (2010)

Figure 17 Flowchart to estimate the clinical need for unattended sleep studies when reassessing treatment efficacy in children



Note 1: Dashed line: proposed clinical pathway; solid line: current clinical pathway

Note 2: The % unaccounted for at each distribution point in the above pathway do not require further testing or referral

ENT = ear, nose and throat

Table 38 Input variables for financial analysis of unattended sleep study in the reassessment of treatment efficacy in children

Patient breakdown		
	Proportion[a]	Number of patients
Proposed clinical pathway		
Children with confirmed OSA who receive treatment		5 567
Children receiving treatment who would need reassessment	25%	1 392
Children in need of reassessment who would be referred to an appropriately trained and credentialed medical practitioner	50%	696
Children in need of reassessment who would be referred to a paediatrician and/or ENT surgeon	50%	696
Children referred to an appropriately trained and credentialed medical practitioner who would receive a Level 1 sleep study	80%	557
Children referred to an appropriately trained and credentialed medical practitioner who would receive a Level 2 sleep study	0%	0
Children referred to an appropriately trained and credentialed medical practitioner who would receive a Level 3 sleep study	10%	70
Children referred to an appropriately trained and credentialed medical practitioner who would receive a Level 4 sleep study	10%	70
Children referred to a paediatrician and/or ENT surgeon who would receive a Level 1 sleep study	80%	557
Children referred to a paediatrician and/or ENT surgeon who would receive a Level 2 sleep study	0%	0
Children referred to a paediatrician and/or ENT surgeon who would receive a Level 3 sleep study	10%	70
Children referred to a paediatrician and/or ENT surgeon who would receive a Level 4 sleep study	10%	70
Current clinical pathway		
Children with confirmed OSA who receive treatment		5 567
Children receiving treatment who would need reassessment	25%	1 392
Children in need of reassessment who would be referred to an appropriately trained and credentialed medical practitioner	50%	696
Children in need of reassessment who would be referred to a paediatrician and/or ENT surgeon	50%	696
Children referred to an appropriately trained and credentialed medical practitioner who would receive a Level 1 sleep study	100%	696
Children referred to a paediatrician and/or ENT surgeon who could receive a Level 1 sleep study	100%	696
Unit costs		
Item	Cost	Source of estimate
Initial consult—general practitioner attendance (level 'C')	$65	MBS item 36
Consultant physician attendance, referral	$143	MBS item 110
Consultant physician attendance, follow-up	$71	MBS item 116
Consultant physician attendance, surgery or hospital	$249	MBS item 132
Consultant physician attendance, surgery or hospital, follow-up	$125	MBS item 133
Cost of a Level 1 sleep study	$556	MBS item 12203[b]
Cost of a Level 2 sleep study	$317	MBS item 12250[b]
Cost of a Level 3 sleep study	$162	See Table 28
Cost of a Level 4 sleep study	$137	See Table 28

[a] Source: the Advisory Panel; [b] Source: Medicare Australia (2010)

Costs to the Australian healthcare system overall

The total costs of unattended sleep studies to the Australian healthcare system include co-payments; and costs of disposables, hospital services, capital equipment and medical services, regardless of the person or agency who incurs them. The base-case cost implications of using unattended sleep studies for the diagnosis of OSA are shown in Table 39. In the event that there is leakage of the technology for use for other patient indications, such as somnambulism, night terrors, hypersomnia, shiftwork sleep disorders and so on, the financial impacts could be considerable. The financial implications of unattended sleep studies in scenarios other than the base case (ie minimum and maximum estimates) are provided in Appendix F.

When the numbers of patients with suspected OSA in a non-specialised unit setting, a referral setting and a paediatric setting are 37 911, 13 269 and 5567 (see page 10), respectively, the total cost of the diagnostic process would be $39 124 128 if unattended sleep studies are used in all healthcare settings. The use of unattended sleep studies in the diagnosis of OSA would result in cost *savings* of $5 459 220 and $212 303 relative to current diagnostic pathways in a non-specialised unit setting and a referral setting, respectively. However, an *additional* cost of $295 051 relative to the current clinical pathway for unattended sleep studies in the diagnosis of paediatric OSA would be borne by the healthcare system. When the target population for unattended sleep studies is estimated based on higher AHI cut-off points, namely AHI ≥15 for adult OSA and AHI ≥5 for paediatric OSA, there would be 57 225, 20 029 and 13 255 patients having suspicion of OSA in a non-specialised unit setting, a referral setting and a paediatric setting, respectively. Under this scenario the cost implications of unattended sleep studies would be a *saving* of $8 240 332, a *saving* of $320 457 and an *additional* $702 502 in a non-specialised unit setting, a referral setting and a paediatric setting, respectively.

Table 39 Total costs to the Australian healthcare system overall (diagnosis, base case)

Setting	Proposed clinical pathway			Current clinical pathway			Incremental cost[b]
	Number of patients	Unit cost[a]	Total cost	Number of patients	Unit cost[a]	Total cost	
AHI cut-off ≥5 in adults, ≥1 in children							
Non-specialised unit setting	37 911	$691	$26 196 674	37 911	$835	$31 655 894	–$5 459 220
Referral setting	13 269	$754	$10 004 779	13 269	$770	$10 217 082	–$212 303
Paediatric setting	5 567	$525[c]	$2 922 675	5 567	$472	$2 627 624	$295 051
Total			*$39 124 128*			*$44 500 600*	*–$5 376 472*
AHI cut-off ≥15 in adults, ≥5 in children							
Non-specialised unit setting	57 225	$691	$39 542 149	57 225	$835	$47 782 481	–$8 240 332
Referral setting	20 029	$754	$15 101 553	20 029	$770	$15 422 010	–$320 457
Paediatric setting	13 255	$525[c]	$6 958 750	13 255	$472	$6 256 248	$702 502
Total			*$61 602 452*			*$69 460 739*	*–$7 858 287*

[a] See Table 32; [b] A negative incremental cost represents a cost saving resulting from the use of unattended sleep study in the diagnosis of OSA; a positive incremental cost represents a net additional cost resulting from the use of unattended sleep study in the diagnosis of OSA; [c] The relatively lower cost of a correct diagnosis for each child with suspected OSA is attributable to the unique situation in paediatric clinical practice where the vast majority (75% in proposed clinical pathway and 80% in current clinical pathway) of children who are referred for suspicion of OSA would undergo surgery without having a sleep study. However, the cost savings from the lower uptake of sleep studies is somewhat counterbalanced by the relatively higher consultant physician fees for both the initial visit and the follow-up visits in the paediatric setting.

The costs for the reassessment process, from the point of medical consultation for altered or unresolved OSA symptoms until the first diagnostic sleep study, would be

$4 270 096 for adult patients and $1 279 436 for children, should unattended sleep studies for the reassessment of treatment efficacy be listed on the MBS (Table 40). In total the use of unattended sleep studies would *save* Australian society $1 029 905, based on the incomplete reassessment pathways as presented in Figure 16 and Figure 17.

Table 40 Total costs to the Australian healthcare system overall (reassessment)

	Proposed clinical pathway	Current clinical pathway	Incremental cost[a]
In adults	$4 270 096	$5 157 067	–$886 972
In children	$1 279 436	$1 422 369	–$142 933
Total	*$5 549 532*	*$6 579 436*	*–$1 029 905*

[a] A negative incremental cost represents a cost saving resulting from the use of unattended sleep study in the diagnosis of OSA.

Costs to the Australian Government

The Australian Government is responsible for payment of the rebate on items from the MBS. As patients will be investigated for OSA as out-patients, the rebate for a private patient on items in the MBS would be 85% of the schedule fee, except for the general practitioner attendance fees, for which Medicare will reimburse 100% of the MBS fees. Some items associated with OSA diagnostic process, such as a hospital facility services fee for an unnecessary adenotonsillectomy procedure or APAP machine leasing fees, would not be covered by Medicare.

The AR-DRG version 5.1 indicates that the public to private patient split for sleep apnoea is approximately 17% and 83%, respectively (AIHW 2009). It is, therefore, possible to assume that 83% of unattended sleep studies would be eligible for MBS reimbursement, with the remaining 17% coming under the Australian Health Care Agreements between the states/territories and the Commonwealth.

Should unattended sleep studies be publicly funded for use in clinical practice, the total cost of the OSA diagnosis pathway to the Australian Government is estimated at between $27 478 883 and $43 284 633, using the different PSG AHI cut-off points in the calculation of the number of potential candidates for home-based sleep studies. The use of unattended sleep studies in the diagnosis of OSA would *save* the Australian Government from $4 217 181 to $6 365 556 in a non-specialised unit setting, and from $225 595 to $340 521 in a referral setting. However, the cost impact of unattended sleep studies in a paediatric setting would be an *additional cost* of between $176 209 and $419 545 relative to the current diagnostic pathway (Table 41).

Table 41 Total costs to the Australian Government (diagnosis, base case)

Setting	Proposed clinical pathway			Current clinical pathway			Incremental cost[a]
	Number of patients	Unit cost	Total cost	Number of patients	Unit cost	Total cost	
AHI cut-off ≥5 in adults, ≥1 in children							
Non-specialised unit setting	31 466	$585	$18 422 849	31 466	$720	$22 640 030	–$4 217 181
Referral setting	11 013	$634	$6 982 556	11 013	$655	$7 208 151	–$225 595
Paediatric setting	4 621	$449[b]	$2 073 478	4 621	$411	$1 897 269	$176 209
Total			*$27 478 883*			*$31 745 450*	*–$4 266 567*
AHI cut-off **≥15 in adults,** ≥5 in children							
Non-specialised unit setting	47 496	$585	$27 808 074	47 496	$720	$34 173 630	–$6 365 556
Referral setting	16 624	$634	$10 539 707	16 624	$655	$10 880 228	–$340 521
Paediatric setting	11 001	$449[b]	$4 936 851	11 001	$411	$4 517 306	$419 545
Total			$43 284 633			$49 571 165	–$6 286 532

[a] A negative incremental cost represents a cost saving resulting from the use of unattended sleep study in the diagnosis of OSA; a positive incremental cost represents a net additional cost resulting from the use of unattended sleep study in the diagnosis of OSA; [b] The relatively lower cost of a correct diagnosis for each child with suspected OSA is attributable to the unique situation in paediatric clinical practice where the vast majority (75% in proposed clinical pathway and 80% in current clinical pathway) of children who are referred for suspicion of OSA would undergo surgery without having a sleep study. However, the cost savings from the lower uptake of sleep studies is somewhat counterbalanced by the relatively higher consultant physician fees for both the initial visit and the follow-up visits in the paediatric setting.

The use of unattended sleep studies to reassess treatment efficacy could cost the government up to $3 989 422 on the basis of the incomplete clinical pathway that could be costed. When compared with the costs of the current reassessment pathway, the cost implications of unattended sleep studies would result in a cost *saving* to the Australian Government of $724 993 (Table 42).

Table 42 Total costs of to the Australian Government (reassessment)

	Proposed clinical pathway	Current clinical pathway	Incremental cost[a]
In adults	$3 075 517	$3 699 670	–$624 154
In children	$913 905	$1 014 744	–$100 839
Total	*$3 989 422*	*$4 714 414*	*–$724 993*

[a] A negative incremental cost represents a cost saving resulting from the use of unattended sleep study in the diagnosis of OSA.

Other relevant considerations

Accreditation of laboratories and medical professionals

The high prevalence of OSA has meant high public demand for attending sleep centres where sleep studies are performed and the diagnosis of OSA is either established or ruled out. However, with this proliferation of sleep centres worldwide, there have been concerns regarding the non-standardised training of technical personnel and the study procedures in some sleep centres, which has, to some extent, resulted in variation in the quality of sleep studies across sleep centres (Surani et al 2009).

There is an academic training program in sleep disorder evaluation in Australia. The Royal Australasian College of Physicians (RACP) guidelines require a minimum of 12 months' core training for a medical professional who will be partly involved in the clinical practice of sleep medicine. A sleep medicine specialist, however, requires training for 3 years before he/she is qualified (Thoracic Society of Australia and New Zealand & Australasian Sleep Association 2006). The accreditation process for sleep disorder services has been developed by the ASA and the Thoracic Society of Australia and New Zealand (2006). Although accreditation is currently voluntary, the ASA guidelines—as with clinical guidelines in other countries, eg the American Academy of Sleep Medicine (AASM) guidelines and European guidelines—stress the importance of satisfactorily trained and credentialed medical professionals to diagnose OSA. These guidelines suggest that the calibration of portable cardiorespiratory monitors, the performance of unattended sleep studies, and the scoring (including automatic scoring by computer software) and interpretation of the recording data should occur under the supervision of accredited sleep technicians or a physician in order to assure the quality of sleep study results (Collop et al 2007; Hensley et al 2005; Pevernagie et al 2009).

In 1998–09 a compulsory physician accreditation process was instituted co-jointly by the RACP and the Australian Department of Health. Sleep studies were only subsequently reimbursed by Medicare for accredited sleep medicine practitioners from any physician specialty. This relates to the majority of sleep studies in Australia, given that most of this activity is performed in a private health (Medicare-funded) setting (Marshall et al 2007).

Apart from the importance of having trained and accredited health professionals diagnosing OSA, there are advantages in terms of the clinical management of OSA patients as well. Parthasarathy et al reported that the absence of accreditation or certification of medical professionals providing sleep studies was associated with a high rate of patient discontinuation of CPAP treatment, with an odds ratio of 1.9 ($p=0.03$). The use of certified physicians and accredited sleep centres leads to improved patient education and treatment of nasal obstruction, which subsequently increases patient compliance and satisfaction during OSA treatment (Parthasarathy et al 2006). It has been suggested that, with regard to unattended sleep studies, patient compliance with the instructions given by sleep professionals is, sometimes, more critical than the diagnostic accuracy of the sleep devices themselves (Collop et al 2007). Therefore, it is not unexpected that, with the use of trained and credentialed personnel in sleep centres, the effectiveness of unattended sleep studies in improving patient health outcomes might be improved by enhancing patient compliance during the investigation.

Reliability of test interpretation

There was a lack of consensus in the included literature on both the definition of apnoea/hypopnoea events and the cut-off point for AHI/RDI/ODI as indicative of OSA. This meant the synthesis of study results was difficult and their applicability to Australian clinical practice uncertain. The ASA guidelines suggested a standard definition and cut-off point of respiratory events according to the AASM-Chicago criteria, as described in the 'Background' section of this report (see page 5) (Hensley et al 2005).

Recorded data from home-based sleep studies can be scored either automatically by computer software or manually by an accredited sleep technician. The automatic scoring has advantages in that it is labour saving and, more importantly, it avoids inter- or intra-reader variability. However, manual scoring might outperform automatic scoring for many reasons: 1) evidence has demonstrated that manual scoring results in better diagnostic agreement between unattended sleep studies and laboratory-based PSG; 2) automatic scoring fails to assess the overall quality of the recording data; and 3) automatic scoring has difficulty in distinguishing between the sleep stage and wakefulness (Calleja et al 2002; Dingli et al 2003; Esnaola et al 1996; Flemons et al 2003; Golpe et al 2002; Hensley et al 2005; Overland et al 2005). Therefore, a fully automatic scoring of data from sleep studies is not recommended by the ASA guidelines; instead, computer scoring should be manually checked against the raw data in credentialed laboratories and be reported by credentialed medical practitioners (Hensley et al 2005).

Inter- and intra-reader variability is a concern when data are manually scored. Bridevaux et al (2007) reported limited inter-observer agreement among eight physicians scoring the results from a Level 3 Embletta® study. The intra-class correlation coefficient (ICC) of agreement was 0.73 for RDI, 0.67 for apnoea index and 0.71 for hypopnoea index. Poel et al (2003), however, observed good inter-reader agreement on thoracic movement signal (k=0.91), airflow signal (k=0.83) and oxygen saturation signal (k=0.90). The heterogeneous results of inter-observer agreement in different studies are attributable to, although not necessarily limited to, readers with different levels of experience at scoring data from sleep studies (Bridevaux et al 2007). The ASA suggest that inter-/intra-reader reliability when scoring cardiorespiratory parameters, such as apnoea/hypopnoea events, oxygen saturation and sleep stages, in individual sleep laboratories should conform to international benchmarks. On the majority of sleep variables, 80% agreement is required, except for arousal (55% agreement), according to ASA guidelines (Hensley et al 2005). Quality assurance programs designed for improving inter-/intra-reader agreement are recommended by both the ASA and AASM to guarantee the scoring accuracy and reliability of various levels of sleep studies (Collop et al 2007; Hensley et al 2005).

Technological considerations

Potential data loss is the main objection to unattended sleep studies, as sensors may be detached or batteries discharged unnoticeably, requiring repeat sleep studies. Lloberes et al (2001) compared the use of unattended sleep studies in the home and the laboratory and found similar rates of signal failure. However, *attended* laboratory-based PSG generally has less data loss than unattended sleep studies for two reasons: first, the recording from attended sleep studies is monitored by a sleep technician, who can detect the abnormal data and rectify technical problems at anytime during the investigation; and second, attended PSG usually involves recording of redundant signals from different channels. For example, both nasal pressure transduction and oronasal thermocouples

measure the change in airflow; therefore, the data loss from the dislodgement of one sensor might be backed up by other working sensors. With very few exceptions (Fry et al 1998), data loss was observed in the majority of studies that investigated the performance of unattended sleep studies (especially Level 2 studies), with the highest rate of 33% reported by Golpe et al (2002). The incidence of data loss may have varied across the studies as a consequence of, for example, the complexity of the equipment used, the patient's compliance and the experience of the medical professional involved. In general, lower level (Level 3 and Level 4) sleep studies could be expected to have less data loss due to their less complicated nature and fewer signals to be recorded during testing (expert opinion from the Advisory Panel). A higher level of patient compliance with instructions would, understandably, result in a lower technical failure rate.

The sensors of portable sleep monitors can be applied either by a sleep technician at the patient's home or in a sleep centre (and then the patient returns home with the device) or by the patient himself/herself at home. The former method is preferred if conditions permit, as the technician can check if all components of the device are firmly attached, properly hooked up and working well. Golpe et al observed that home-based sleep studies with the devices set up by a technician reduced the occurrence of uninterpretable data by more than three-quarters (from 33% to 7%) when compared with those studies where the sensors were applied by the patient independently (Golpe et al 2002). However, there are potential personal safety concerns for sleep technicians setting up equipment for an unattended sleep study during a home visit (expert opinion from the Advisory Panel).

Sticky tape is essential for EOGs and EMGs which record signals in mobile settings; solid sensor to skin attachment is critical for reducing data loss and better recording quality (Broughton et al 1996). Batteries should also be checked before the sleep study starts to ensure there is enough power to provide an adequate recording for a prolonged period.

Other technical limitations of unattended sleep studies are movement artefacts occurring during wakefulness. Home-based sleep studies are carried out in an unattended setting where unpredictable situations, such as midnight telephone calls or pets jumping on the beds, cannot be controlled (Broughton et al 1988). As the patient's sleep condition is not monitored by a sleep technician, responsive behaviours to these occurrences are recorded (artefacts) along with normal sleep, and the difference in the patient's status is not flagged. Videotape of unattended sleep studies or a sleep diary to report unexpected conditions is highly recommended to address these recording artefacts (Broughton et al 1996).

Sensor inadequacy is the other shortcoming of unattended sleep studies. There is some evidence that the oronasal thermocouple or thermistor is not as accurate as nasal pressure transduction in estimating the actual respiratory amplitude. Therefore, unattended sleep monitors that only use thermocouple or thermistor techniques to detect airflow changes are not as efficient as complete PSG systems in revealing hypopnoea events, as both oronasal temperature and pressure are recorded by laboratory-based PSG (Berg et al 1997; Douglas 2003; Hensley et al 2005; McNicholas 2008). Another example is the measurement of respiratory effort. Inductance plethysmography, although not perfect, has been found to be a superior method to impedance movement sensors in recording chest and abdominal movements. Laboratory-based PSG, which uses both channels, is usually more accurate in detecting changes in the volume of the chest and abdomen than unattended sleep studies, which only record impedance signals (American

Academy of Sleep Medicine Task Force 1999; Douglas 2003; McNicholas 2008). This higher level of performance is expected for the gold standard procedure.

Indications for unattended sleep studies

There is consensus that unattended sleep studies are indicated for populations with a relatively high (40–60%) pre-test probability of OSA in patients without significant comorbidities, eg cardiac or respiratory diseases (Collop et al 2007; Douglas 2003; Hensley et al 2005). The conditions that are indispensable for carrying out an unattended sleep study include a preliminary comprehensive patient clinical evaluation by a medical practitioner, raw recording data available for review and accessibility to laboratory-based PSG when required (Hensley et al 2005). Given the limitations of unattended sleep studies, including the restriction in recorded signals and poorer diagnostic accuracy relative to laboratory-based PSG, unattended sleep studies are deemed not appropriate for patients with suspected OSA under the following three conditions: 1) subjects having difficulties in understanding or complying with the instructions of medical professionals, eg patients with some psychiatric disorder; 2) patients with more than one type of sleep disorder; and 3) sleep studies undertaken for medico-legal purposes, eg people who operate heavy machinery or transport (Douglas 2003; Hensley et al 2005).

Potential leakage of unattended sleep studies

Although, in some cases (as presented above), unattended sleep studies are not a suitable diagnostic option, there are cases where home-based sleep studies can provide unique advantages over attended sleep studies—although not necessarily for the diagnosis of OSA. Using mobile devices, unattended sleep studies are capable of recording patients' sleep under unusual conditions considered attributable to certain sleep problems, eg shiftwork sleep disorders (Akerstedt & Kecklund 1991; Torsvall & Akerstedt 1987). In addition, carrying out sleep studies in a home setting facilitates the diagnosis of parasomnias, such as somnambulism and night terrors, which have been proved to occur at reduced frequency in a laboratory setting (Guilleminault et al 1995). Because of their prolonged monitoring and ease of repetition, unattended sleep studies may be superior to laboratory-based PSG for arriving at a diagnosis of disorders in which the patient's sleep/wake cycle is redistributed around the clock (eg hypersomnia and Kleine-Levin syndrome) or very infrequent events (eg sleep-related epileptic seizure) (Broughton et al 1996). In addition, home-based sleep studies can be used as oxygen titration studies, as a supplement to oxygen studies, and for patients with Cheyne-Stokes respiration, heart failure, cerebral palsy and other disorders that cause altered respiratory motor drive or gas exchange abnormalities (expert opinion from the Advisory Panel).

Access and equity

In determining the recommendation for a health technology to receive public funding, the MSAC also considers access and equity issues related to the intervention.

Unattended sleep studies have been recognised as a useful alternative to laboratory-based PSG, given that the latter usually has long waiting lists and is not accessible to a proportion of patients with sleep disorders. In Escorrou et al's (2003) investigation across Europe, 95% of the sleep medicine providers expressed a clear need for

unattended sleep studies in their clinical practice, mainly to increase their capacity to perform sleep studies (88%). Other reasons for having unattended sleep studies included reducing study costs, increasing patient acceptance and facilitating better sleep quality.

Access to laboratory-based PSG can be limited in regions of Australia, particularly those areas outside metropolitan centres (expert opinion from the Advisory Panel). If unattended sleep studies are available in clinical practice, fewer patients would need to attend sleep laboratories to undergo attended PSG. Unattended sleep studies potentially improve equity, since they allow greater access for patients in rural and regional areas. Expert opinion (the Advisory Panel) suggests that unattended Level 2 studies may eventually replace laboratory-based PSG in rural and remote locations due to access considerations. The ASA guideline recommends that clinicians who use unattended sleep studies for diagnosing sleep disorders in remote and rural areas should work under supervision of, or with input from, qualified medical professionals and facilities (Hensley et al 2005). Furthermore, as patients are, at present, triaged for sleep tests according to the clinical severity of their presenting symptoms, unattended sleep studies would promote equity in healthcare by allowing earlier diagnosis of OSA using portable cardiorespiratory monitors in patients with minor OSA symptoms, who are currently at the bottom of waiting lists for laboratory-based PSG.

The efficacy and accessibility of split-night studies and home-based (automatic) CPAP titration are determinants in choosing the type of diagnostic sleep study. Split-night sleep studies have been demonstrated to be adequate for CPAP titration and improving patients' long-term health outcomes (Douglas 2003; McArdle et al 2000; Patel et al 2007; Strollo et al 1996). There is also reasonable evidence showing the effectiveness of home-based CPAP titration (Coppola & Lawee 1993; Fletcher et al 2000; White & Gibb 1998). Obviously, an unattended sleep study is not a sensible choice if home-based CPAP titration is not accessible to the subjects, since performing a home-based sleep study and subsequent laboratory-based CPAP titration would have no advantages (eg reducing sleep centre accommodation) over split-night sleep studies.

Patient perspective

As an independent and modifiable risk factor for the development of cardiovascular diseases and psychological disorders and a known cause of automobile accidents, OSA has been widely recognised as a public health concern (Adams et al 2007; Harris et al 2009; Marin et al 2005; Newman et al 2001; Parra et al 2000; Shahar et al 2001; Teran-Santos et al 1999). Evidence has shown that OSA has a substantial adverse impact on patients' quality of life (Parish & Lyng 2003; Siccoli et al 2008). In addition, OSA affects the life of OSA patients' bed partners, whose sleep can be greatly disturbed by snoring, apnoea episodes and restless sleep (Doherty et al 2003; McArdle et al 2001). Bed partners of OSA patients have poorer self-reported health status when compared with the general population (McArdle et al 2001). OSA patients might be requested by their partners to sleep alone, which could exert additional pressure on patients' psychological health. Diagnosis of OSA using various levels of sleep studies and subsequent treatment has been proved to control patients' symptoms and improve the QoL of both the OSA patients and their bed partners (Doherty et al 2003; Parish & Lyng 2003; Siccoli et al 2008).

Both laboratory-based and home-based sleep studies have advantages and disadvantages. Therefore, a shared decision-making process between patients and clinicians, based on

patients' full access to relevant evidence and information, is critical. Laboratory-based PSG is recognised as the gold standard for diagnosing OSA. Due to the long waiting lists for a laboratory-based sleep study, patients with severe symptoms should have higher priority. While patients wait for an attended PSG, unattended sleep studies are a possible alternative. Expert opinion from the Advisory Panel indicated that the shorter waiting time for home-based sleep studies relative to laboratory-based PSG, although not clinically important, might be significant from a patient's perspective, particularly if they have suspected mild OSA and are always at the bottom of the triaging queue. In other words, home testing (mainly Level 3 and Level 4 sleep studies) can assist in the prioritisation of patients for urgent OSA treatment.

There is conflicting evidence on patient preferences for laboratory-based PSG and home-based sleep studies. In some studies patients favoured a home-based sleep study, as it took place in a familiar and comfortable setting, where subjects could control their sleep timing and reduce the first night effect to a minimum extent (Abraham et al 2006; Broughton et al 1996; Douglas 2003). Lloberes et al (2001) studied patients in Barcelona receiving two unattended studies, one in the laboratory and one in the home. The studies were done on consecutive nights with the order randomised. Patients reported similar subjective rates of sleep quality and sleep duration whether having the study in the home or the laboratory. Despite this, the majority of patients still had a preference for a home study (53%) compared with a laboratory study (28%), with 19% indicating no preference. However, in other studies, patients preferred an attended PSG over a home-based study for the following reasons: fewer wires, no headgear, or less glue and tape in a laboratory-based PSG; a technician supervising the investigation without the worry about detachment of the sensors during the investigation; and, contrary to popular belief, better quality of sleep in a laboratory (Fry et al 1998; Portier et al 2000).

The descriptions of the sleep studies currently listed on the MBS (MBS items 12210, 12202, 12250 etc) stress that these studies are 'overnight investigations'. However, it is suggested by the Advisory Panel that sleep studies (both attended and unattended) are not necessarily always undertaken in the evening; they may be carried out during the daytime, especially for infants, who have normal sleeping periods during the day, and shiftworkers.

Discussion

Is it safe?

Minimal evidence was identified to assess the safety of unattended sleep studies in diagnosing OSA. A small proportion of adult patients (2%) complained of significant skin redness from a Level 4 device, ClearPath System Nx-301. Mild to moderate redness and itching occurred in about one-third (36%) and one-fifth (18%), respectively, of adult patients who underwent these studies. Although none of the included studies reported adverse consequences from unattended sleep studies in a paediatric setting, potential skin allergy to electrode adhesives (eg latex adhesives) is not unexpected. For safety reasons, nasal masks, instead of full masks, are suggested by the Advisory Panel during unattended sleep studies of children. In addition, supervision is recommended during the performance of sleep studies (no matter what level of sleep study) in very young children or patients with dementia or cognitive impairment in order to prevent untoward accidents (American Thoracic Society 1996)

Other potential harms of using unattended sleep studies, which were not reported by the included studies, possibly due to their rarity, include electrical risks from portable devices that use batteries instead of AC power, burns from faulty probes and accidents owing to patients being distracted by applied monitors during driving (Collop et al 2007). Furthermore, owing to the lack of supervision by a medical professional, unattended sleep studies should be carried out with caution in adult patients with heart failure, spinal injury and chronic obstructive pulmonary disease; and in children with Down's syndrome, achondroplasia and other neurocognitive disorders (expert opinion from the Advisory Panel).

None of the included studies compared the safety of unattended sleep studies with that of laboratory-based PSG. However, as PSG has been recognised as the reference standard in diagnosing OSA, there is a possibility that unattended sleep studies are not as safe as the attended PSG in that false positives from unattended studies could result in inappropriate treatment, which might lead to adverse events in patients. In addition, psychological harms, eg anxiety, can be associated with the 'establishment' of an OSA diagnosis by false positive results.

Expert opinion from the Advisory Panel suggests that the time gained in diagnosis and management of OSA with unattended sleep studies is unlikely to be clinically important, as patients are currently triaged for PSG on the basis of symptom severity. Therefore, an earlier correct diagnosis of OSA using unattended sleep studies or a delayed diagnosis of OSA due to a false negative from an unattended sleep study is unlikely to impact on patient safety. Referral for PSG on the basis of symptom severity is still likely to occur, even when an unattended sleep study has produced an OSA negative result from a highly symptomatic patient.

Is it effective?

No studies were identified that reported on the effectiveness of unattended sleep studies for reassessing treatment efficacy in terms of patient health outcomes. In terms of using

unattended sleep studies to diagnose OSA in various healthcare settings, the direct evidence available was limited and not of high quality. This justified the use of a supportive linked evidence approach, ie assessing the diagnostic accuracy of unattended sleep studies and their impact on patient management. Minimal evidence was identified regarding the linkage between test results and treatment decisions. Conversely, the majority of studies included in this assessment provided data on the diagnostic accuracy of unattended sleep studies relative to the reference standard, laboratory-based PSG, in diagnosing adult or paediatric OSA.

Several approaches were used for evaluating the diagnostic accuracy of unattended sleep studies. The Pearson χ^2 test was commonly used when comparing the AHI/RDI/ODI from an unattended sleep study with the PSG AHI. This method is not recommended as it measures the degree of association between tests to determine if they are measuring the same underlying parameter but, does not provide information on the level of agreement between the tests concerning that parameter (Bland & Altman 1987; Flemons et al 2003; Li & Flemons 2003). The Cohen's Kappa coefficient assesses the diagnostic agreement between two tests, but is less commonly used and is unfamiliar to most clinicians (Streiner & Norman 1995). The Bland and Altman plot analysis calculates the actual difference between the AHI/RDI/ODI values from an unattended sleep study and the corresponding PSG AHI values. The mean difference and limits of agreement from the Bland and Altman approach therefore provide better measures of agreement between tests than the Pearson correlation coefficient. However, the Bland and Altman analysis limits of agreement can be strongly affected by data from populations with a high AHI. The limits of agreement perform better in the lower AHI range, usually where the diagnostic threshold lies (Flemons et al 2003; Li & Flemons 2003). Test characteristics such as sensitivity, specificity, PPV, NPV, LR+ and LR– are the most widely used variables to determine how well an unattended sleep study correctly classifies patients as having or not having OSA at an arbitrary cut-off point. However, simply dichotomising study results into positive and negative can cause a loss of information.

A diagnostic test is an *ideal* one if its sensitivity, specificity, NPV and PPV all reach 100%. In practice, however, diagnostic tests vary in this regard. An alteration of the threshold for a positive/negative diagnostic result would change the characteristics of the index test. For a specific unattended sleep study the sensitivity and NPV will increase, while the specificity and PPV decrease, when OSA is diagnosed at a lower threshold. Decisions on determining the most favourable balance of sensitivity and specificity require compromise based on the purpose of using unattended sleep studies. Given that these studies are used as a triage test in the clinical pathway for diagnosing OSA, sensitivity (or true-positive rate) and NPV are of more importance relative to specificity and PPV in assessing the value of unattended sleep studies, particularly in a non-specialised unit setting. With fair specificity and PPV, an unattended sleep study should have maximal sensitivity and NPV in order to reduce the number of patients with false negative results.

The heterogeneity in patients' health outcomes, as well as in the diagnostic accuracy of unattended sleep studies, is noteworthy across the studies included in this report. The differences might be attributable, to some extent, to the following: different patient inclusion/exclusion criteria; a variety of portable devices used or types of signals measured; lack of consensus on the definition of respiratory events; variation in AHI/RDI/ODI cut-off points; sleep technicians with different levels of experience at data scoring or various computer software employed to detect respiratory events; and a lack of concordance on data interpretation. The above factors make comparison of

effectiveness evidence from distinct studies difficult. The analysis of results, especially outliers, should take into account the precision of the estimates (eg standard deviation and 95% CI), which are a direct reflection of the sample size and the study design. Data from studies with small patient numbers (eg n<50) from lower levels of evidence (level IV diagnostic or interventional evidence) or from studies of poor quality should be interpreted with caution.

Diagnosis in a non-specialised unit setting

Direct evidence of the effectiveness of unattended sleep studies in a non-specialised unit setting was limited to two case series of poor quality (level IV interventional evidence). Both studies demonstrated a significant benefit of Level 3 sleep studies on health outcomes for patients with suspected heart failure or stable heart failure. OSA-related symptoms, comorbid hypertension and sleep quality were improved after the diagnosis of OSA using unattended sleep studies and subsequent treatment such as CPAP, MAD and palatal implant. Furthermore, patients had less respiratory events after the treatment. However, the diagnosis and treatment of OSA did not appear to ameliorate patients' health-related QoL. Whether or not these Level 3 studies would have a similar effect on patient health outcomes as Level 1 sleep studies cannot be determined, given that the studies were uncontrolled.

With regards to linked evidence, seven moderate- to good-quality cross-classification studies provided data on the accuracy of unattended sleep studies in a non-specialised unit setting, using attended PSG as the reference standard (level III-1 or III-2 diagnostic evidence). Various AHI/RDI/ODI cut-off points were used in one study and across studies. Quintana-Gallego et al (2004) reported high accuracy of a home-based Apnoescreen II study in diagnosing OSA, with AUCs above 0.85 at AHI ≥5, ≥10 and ≥15. The test characteristics of four Level 3 devices, Apnoescreen II, Stardust II, Embletta and LifeShirt system, were evaluated in cohorts of patients with suspected OSA or heart failure. It was discovered that a threshold of RDI ≥5 was superior to RDI ≥15 in triaging patients and ruling out false negatives, with sensitivity ranging from 82.5% to 100% and NPV of 100% at RDI/AHI ≥5, compared with sensitivity between 68.4% and 93.8% and NPV of no more than 75.0% at a higher cut-off point (≥15).

In terms of Level 4 sleep studies, none of the identified cross-classification studies reported diagnostic accuracy at ODI/AHI ≥5. Moderate sensitivity (63.2–77%) and NPV (53.3–54.3%) were obtained for Level 4 devices at an AHI threshold of 15.

Using other statistical approaches than test accuracy characteristics, the extent of diagnostic agreement differed between specific unattended sleep studies and the laboratory-based PSG. The home-based Stardust II, Stardust® Sleep Recorder and Embletta studies demonstrated poor agreement with the reference standard, while moderate to good agreement was reported between the unattended studies—LifeShirt system, SleepStrip or Pulsox-M24—and laboratory-based PSG.

It would appear that patient selection in a non-specialised unit setting is critical, as unattended sleep studies had better diagnostic accuracy when patients were selected on the basis of suspected OSA. Equally important is the selection of the sleep device and the OSA threshold to be used for that unattended sleep study. Level 3 studies appeared to perform better than Level 4 studies in this setting. An OSA threshold of RDI/AHI ≥5 resulted in better diagnostic performance for Level 3 studies and a concomitant

ODI/AHI ≥15 or 25 threshold for Level 4 studies. Level 2 studies were not considered for this setting, in accordance with the clinical pathway depicted in Figure 5.

Evidence of a change in patient management after the diagnosis of OSA with the aid of unattended sleep studies was provided by two case series (level IV interventional evidence). In 81 patients who received unattended oximetry, about 60% (49/81) of patients with ODI >20 were referred to a respiratory physician, and another 7% (6/81) to an ENT specialist. The waiting time was double for an ENT referral compared with that for respiratory physician referral (60 days vs 125 days). Martinez et al determined that not all patients with abnormal results were referred, while nearly one-quarter of patients with normal results were still referred. In addition, the authors observed that there was half the rate of additional PSG testing in those with a normal (14%), as opposed to abnormal (28%), result from a Level 4 sleep study (Martinez et al 2005). Thus, referrals and additional sleep studies will usually be reduced in patients who have had an unattended sleep study, although clinical judgment regarding the need for further assessment appears to ultimately prevail in situations where a patient is symptomatic but the initial sleep study's results are negative (potential false negatives).

The body of evidence included in this assessment report was appraised according to NHMRC methodological guidelines (NHMRC 2008b). This appraisal considered the evidence-base, in particular the number of studies and their methodological quality; homogeneity of the studies' results; clinical relevance of the safety and effectiveness data; generalisability of the evidence to the population with suspected OSA; and applicability of the evidence to the Australian healthcare system. Table 43 presents the results of appraisal of the evidence arising from a non-specialised unit setting and considered in this assessment.

Table 43 Assessment of body of evidence for effectiveness of unattended sleep studies in a non-specialised unit setting—linked evidence approach (diagnostic accuracy)

Component	A	B	C	D
	Excellent	Good	Satisfactory	Poor
Evidence-base			Level III studies with low risk of bias, or level I or II studies with moderate risk of bias	
Consistency		Most studies consistent and inconsistency may be explained		
Clinical impact				Slight or restricted (or unknown)
Generalisability		Population(s) studied in the body of evidence are similar to the target population		
Applicability		Applicable to Australian healthcare context with few caveats		

Note: For an explanation of this table see 'Body of evidence matrix' on page 42

Diagnosis in a referral setting

Evidence of a change in the symptoms, QoL and number of respiratory events in adult patients with OSA diagnosed using unattended sleep studies in a referral setting was

reported by eight studies. The evidence was largely of poor quality despite the availability of comparative studies (including level II interventional evidence).

The two highest level studies (albeit of poor quality) provided direct evidence of the clinical effectiveness of Level 4 sleep studies. In Whitelaw et al's (2005) RCT excessive daytime sleepiness was improved after the diagnosis of OSA by the home-based SnoreSat study and following 4-week APAP treatment, with scores on the ESS reducing by an average of 3.4 points (from 11.6 to 8.2). This figure was identical to the mean ESS decrease of 3.4 in the group of patients who had their diagnosis of OSA confirmed by laboratory-based PSG and who likewise underwent APAP treatment for 4 weeks ($p=0.27$). Similar results were reported in the cohort study by Berry et al (2008). These studies suggest that OSA patients' symptoms were controlled regardless of whether they had been diagnosed by Level 4 unattended sleep studies or through laboratory-based PSG. A flow-on effect on patient QoL was apparent in these two studies, with better QoL reported after the unattended sleep study diagnosis and subsequent treatment, which is consistent with the results observed after laboratory-based PSG diagnosis and subsequent treatment. The two types of test appeared to be equally effective in terms of reducing clinical symptoms for those patients referred to a specialist with suspicion of symptomatic or clinically important OSA. However, the poor quality of these studies suggests that caution should be applied when interpreting these results.

The case series by Antic et al (2009) was the only study carried out in an Australian setting that assessed the effectiveness of a Level 4 home-based sleep study[20]. All subjects receiving this test either underwent 3 months of APAP (home-based titration) treatment (nurse-led care) or received additional laboratory-based PSG and 3 months of CPAP (laboratory-based titration) treatment (physician-directed care). A comparison of the ESS and MWT results between the two models of care suggested that the use of laboratory-based PSG as a supplementary test in the diagnosis of OSA did not influence the impact of unattended sleep studies on patients' symptom control. In this study the impact of symptom control on patients' QoL was not apparent.

Direct evidence of the effect of unattended sleep studies on the secondary outcomes of respiratory events and commencement of treatment were supportive of the results on the impact on patient clinical symptoms (primary outcome). The results suggested that there was a linear relationship in the mean reduction of respiratory events according to the risk status of the population studied. A moderate-quality cohort study by White and Gibb (1998) reported a mean AHI reduction of approximately 60 in patients with severe OSA receiving either a Level 2 unattended sleep study or a Level 1 study. They also indicated that there was no significant difference in the time to commencement of treatment between the home-based NightWatch System™ group and the laboratory-based PSG group, although a trend for less waiting time for APAP (home-based titration) treatment was observed in the unattended sleep study group (34.3 days vs 47.9 days, $p=0.59$).

With respect to Level 4 unattended sleep studies, Berry et al's (2008) cohort study found that the mean changes in AHI/PAT index, although slightly higher with laboratory-based PSG, were not significantly different between the two groups. However, in Whitelaw et

[20] The study is actually a randomised controlled trial comparing nurse-led versus physician-directed care. However, as *all* patients received a Level 4 study, for the purposes of this assessment this study is a case series.

al's (2005) RCT, the AHI decrease of 20.3 in the PSG group was significantly greater than the ODI reduction of 12.4 in the home-based SnoreSat group, which is attributable to baseline AHI differences between the groups. However, the post-treatment AHI/ODI did not differ between the two groups (5.7 vs 4.2, p=0.06).

Thus, the direct evidence suggests that clinical outcomes (primary or secondary) are similar regardless of whether the sleep study used is an unattended Level 2 or 4 study or an attended Level 1 study. The evidence on Level 3 studies was non-comparative, and so comparative effectiveness cannot be directly assessed.

Linked evidence in the report found that selected Level 2 and 3 unattended studies have moderate to high test performance, on a range of diagnostic accuracy measures, relative to laboratory-based PSG. Sensitivity was generally high, although specificity was variable. NPVs were also high, although the likelihood of incorrect negative results (false negatives) was in the range 15–20% for the highest quality Level 2 studies and l9–35% across Level 3 studies that varied in quality.

Four studies of moderate quality reported on the agreement between Level 2 and Level 1 studies and the results were heterogeneous. Moderate levels of agreement between a home-based Compumedics PS-2 system and laboratory-based PSG were observed by Iber et al (2004), while the Minisomno® Level 2 system performed poorly against the same reference standard in two studies (limits of agreement allowed clinically important differences between the two tests) (Gagnadoux et al 2002; Portier et al 2000). Three studies of very high quality (Dingli et al 2003; García-Díaz et al 2007; Parra et al 1997) showed good agreement between Level 1 studies and the Level 3 Embletta, Apneoscreen II and Edentrace II devices. Lower quality studies showed that the agreement between the Level 3 devices and laboratory-based PSG was often clinically unacceptable. Whether this is a fault of the conduct and design of the study or a reflection on the performance of the device itself is unclear.

A general trend in the evidence-base was that manually scored unattended sleep studies had better congruence with laboratory-based PSG than automatic scoring techniques.

The test accuracy of Level 4 studies was lower than that observed for Level 3 studies, which is not surprising given the reduced number of physiological parameters measured. The highest level of evidence available (good-quality level III-1 diagnostic evidence) in the correct population (suspected OSA) reported moderate to good diagnostic accuracy overall, with AUCs in the range 0.71–0.89 (Baltzan et al 2000; Golpe et al 2002). The highest quality level II and III-1 diagnostic evidence found that test sensitivity ranged more widely for the Level 4 studies across various diagnostic thresholds (55–92%), with specificity somewhat less variable (75–98%). NPVs were moderate to high (75–95%) across thresholds. In terms of agreement in OSA diagnoses between Level 4 and Level 1 studies, the level and quality of evidence was poorer than that of Level 3 studies and the results were heterogeneous. Only two studies showed reasonable levels of agreement between Level 4 studies and laboratory-based PSG using a portable Sleep Data Recorder or Compumedics P2 System, or a finger oximeter AVL-Minolta Pulsox 7 device (Ayappa et al 2004; Golpe et al 1999).

Thus, the accuracy of unattended sleep studies tends to diminish as fewer physiological parameters are measured. Level 2 and 3 studies generally perform acceptably, although selection of the device and detection threshold is important. Level 4 studies can perform acceptably but the evidence-base indicates that performance can vary widely depending

on the thresholds and devices selected. It is difficult to draw any conclusions about their general utility, given the poor quality and heterogeneity of the evidence-base.

Whittle et al observed that the median time to diagnosis with a Level 3 sleep study was 18 days, compared with 47 days with laboratory-based PSG—the difference was statistically significant (Whittle et al 1997). Expert opinion suggests, however, that, given that patients are currently triaged for additional testing on the basis of clinical symptoms, a difference in waiting time is unlikely to result in adverse health outcomes. This is supported by both the linked evidence, showing that treatment choices did not differ whether patients received an unattended or attended sleep study, and the direct evidence mentioned earlier, where there was no apparent difference in the health outcomes of patients receiving the two types (unattended and attended) of tests. A similar conclusion was presented in a narrative expert review, stating that:

> 'The patient's symptoms are the more important part of this equation and there is good evidence that sleepiness and its resolution determines the success of CPAP more than the sleep study.....there really is no evidence that greater precision in sleep studies leads to a greater precision in disease definition and management. Sleep specialists should not be embarrassed to function in this very clinical way.' (Stradling & Davies 2004, p.75).

Table 44 provides an overall assessment of the body of evidence underpinning this evaluation of the effectiveness of Level 2 and 3 unattended studies in a referral setting. A similar summation of the evidence for Level 4 unattended studies is given in Table 45.

Table 44 Assessment of body of evidence for effectiveness of unattended sleep studies in a referral setting—Level 2 and Level 3 unattended studies (direct and linked evidence)

Component	A	B	C	D
	Excellent	Good	Satisfactory	Poor
Evidence-base			Level III studies with low risk of bias, or level I or II studies with moderate risk of bias	
Consistency		Most studies consistent and inconsistency may be explained		
Clinical impact			Moderate	
Generalisability		Population(s) studied in the body of evidence are similar to the target population		
Applicability		Applicable to Australian healthcare context with few caveats		

Note: For an explanation of this table see 'Body of evidence matrix' on page 42

Table 45 Assessment of body of evidence for effectiveness of unattended sleep studies in a referral setting—Level 4 unattended studies (direct and linked evidence)

Component	A	B	C	D
	Excellent	Good	Satisfactory	Poor
Evidence-base				Level IV studies, or level I to III studies with high risk of bias
Consistency			Some inconsistency reflecting genuine uncertainty around clinical question	
Clinical impact			Moderate	
Generalisability		Population(s) studied in the body of evidence are similar to the target population		
Applicability		Applicable to Australian healthcare context with few caveats		

Note: For an explanation of this table see 'Body of evidence matrix' on page 42

Diagnosis in a paediatric setting

Minimal direct evidence was available to inform of the impact of unattended sleep studies on patients' health outcomes in children with suspected OSA. In the case report of a boy aged 8 years the patient's neuropsychologic functioning was improved and the RDI value returned to normal (RDI=0.8) after the diagnosis of OSA using home-based Embletta PDS and subsequent tonsillectomy. No studies provided a higher level of evidence, comparative or non-comparative, on whether unattended sleep studies would result in a change in the health outcomes of children.

Four studies (level III-1 or III-2 diagnostic evidence) were identified that reported the diagnostic accuracy of Level 3 and Level 4 unattended sleep studies. In general, moderate to good diagnostic agreement was demonstrated between unattended sleep studies and the reference standard, laboratory-based PSG. The diagnosis of OSA was established at a lower RDI/ODI threshold (>1, >3 or >5) in paediatric patients than in adults. Level 3 and Level 4 sleep studies showed perfect sensitivity of 100% at RDI/ODI >1. When RDI/ODI >5 was defined as a positive result, the unattended sleep studies were able to detect two-thirds or more of the paediatric OSA. Extreme results of test characteristics were observed in one study (Zucconi et al 3003). In this moderate-quality cohort of 12 children, an unattended POLY-MESAM study yielded null NPV and specificity at a RDI threshold of both 1 and 5. Given the moderate to good NPV (66.7–100%) and specificity (60.0–100%) from other studies at the same diagnostic thresholds, the extraordinary results in Zocconi et al's study were more likely attributable to the small sample size or the different population (patients with higher risk of OSA were involved) in this study. Not enough evidence was available to determine whether RDI/ODI >1 or RDI/ODI >5 is the optimal cut-off point in diagnosing paediatric OSA.

No studies that met the selection criteria reported a change in management following the diagnosis of OSA with the aid of unattended sleep studies.

An assessment of the body of evidence relating to the use of unattended sleep studies in a paediatric setting is provided in Table 46.

Table 46 Assessment of body of evidence for effectiveness of unattended sleep studies in a paediatric setting—linked evidence approach (diagnostic accuracy)

Component	A	B	C	D
	Excellent	Good	Satisfactory	Poor
Evidence-base			Level III studies with low risk of bias, or level I or II studies with moderate risk of bias	
Consistency		Most studies consistent and inconsistency may be explained		
Clinical impact				Slight or restricted (or unknown)
Generalisability		Population(s) studied in the body of evidence are similar to the target population		
Applicability		Applicable to Australian healthcare context with few caveats		

Note: For an explanation of this table see 'Body of evidence matrix' on page 42

What are the economic considerations?

Since there was no evidence that unattended sleep studies for the diagnosis of OSA changed patients' health outcomes in a clinically important way relative to current diagnostic and clinical practice in various healthcare settings, no economic evaluation in terms of final health outcomes is warranted. Instead, a comparison between the cost for the proposed diagnostic pathway (with the use of unattended sleep studies) and that for the current pathway (with the use of an attended Level 1 sleep study) was performed to examine whether unattended sleep studies are cost saving in the diagnosis of OSA in a non-specialised unit setting, a referral setting and a paediatric setting. Due to a complete absence of evidence, no economic evaluation for the use of unattended sleep studies for reassessing treatment efficacy was undertaken. Financial incidence analysis was carried out to estimate the cost implications of unattended sleep studies for the diagnosis of OSA and for treatment reassessment.

The cost comparison analysis and the financial analysis have taken account of the whole diagnostic process, from a patient's first presentation at the doctor's office until a correct diagnosis of OSA is reached. The decision tree structures were developed in line with clinical practice in Australia. Although the unit cost of an unattended sleep study is much cheaper than that of laboratory-based PSG, the cost of further confirmatory tests associated with the reduced diagnostic accuracy and technical failure rate of unattended sleep studies, along with the cost of unnecessary treatment for patients with false positive test results, can offset the lower unit cost of the unattended sleep study. The cost comparison analysis and the financial analysis indicated that, in both a non-specialised unit setting and a referral setting, the proposed diagnostic pathway with the use of unattended sleep studies is cost saving relative to the current clinical pathway, where

OSA is confirmed with attended PSG. Extensive sensitivity analyses suggest that the results are robust for most of the examined variables, with the exception of the uptake of Level 1 sleep studies once unattended sleep studies are available and the true positive rates from Level 2 and Level 4 sleep studies in a referral setting. Furthermore, threshold analyses confirmed that unattended sleep studies are cost saving, as the unit cost of a Level 3 or a Level 4 sleep study is unlikely to exceed the threshold identified. In the paediatric setting, however, the proposed diagnostic pathway involving unattended sleep study is more expensive than the current clinical pathway, although not to a great extent. This result reflects that, during the process of diagnosing paediatric OSA, the costs for further Level 1 sleep studies and unnecessary treatment (adenotonsillectomy) would exceed the savings from using the lower-cost unattended sleep studies.

Unlike the diagnostic pathways, the reassessment pathways in the financial analysis were incomplete because of the absolute lack of evidence from the literature and poor confidence in generating plausible estimates on the basis of expert opinion. The cost implications of unattended sleep studies for reassessing treatment efficacy were estimated from the point of a doctor visit for altered or unresolved OSA symptoms until the uptake of the first sleep study (attended or unattended). The costs of additional laboratory-based PSG in patients with technical failure, false negatives or uncertain results from an unattended study, as well as the costs of treatment on the basis of false positive test results, were not included. It should be highlighted that, although the use of unattended sleep studies for reassessing treatment efficacy seems to incur less cost to the government and to Australian society than the current reassessment process, it would actually either result in an additional cost or be less cost saving than what has been estimated in this assessment report, due to the uncalculated downstream costs.

There are several issues that should be taken into account when interpreting the results from the cost comparison analysis and financial incidence analysis in this assessment report. First, a Level 1 sleep study is assumed to be the only available diagnostic test and comparator for the proposed diagnostic pathway involving unattended sleep studies. In Australia, however, the use of unattended sleep studies has been gaining momentum, and so it is likely that the cost implications determined by these economic and financial analyses may not be accurately estimated because the technology is *already* replacing attended sleep studies in a limited fashion. For example, the Australian Government has subsidised Level 2 unattended sleep studies since 1 October 2008 on an interim funding basis.

Second, it should be borne in mind that the results of the cost comparison analysis and financial analysis were conditional on the assumptions and inputs of the evaluation. The purpose of the evaluation is to synthesise evidence and assumptions so as to allow decision-makers to gain insight into the relations between assumptions and outcomes. Should a better estimate be available for any of the variables, the evaluation would need to be updated.

Third, travel costs (from patients' homes to sleep laboratories) for patients living in remote areas were not considered. Since those patients receiving an unattended sleep study usually go to the hospital and pick up the device before the testing and return the equipment on the following day, it is reasonable to assume that the travel cost for an unattended sleep study (two trips) would exceed that for a laboratory-based PSG (one trip) (expert opinion from the Advisory Panel). Therefore, the exclusion of travel costs could result in an underestimate of the costs associated with unattended sleep studies relative to a Level 1 sleep study. However, as the vast majority of patients in Australia

live near cities or regional centres where sleep laboratories are located, the omission of patients' travel costs is unlikely to have a substantial impact on the estimate of the overall cost implications of unattended sleep studies.

Fourth, although the costs of treatment due to false positive test results from an unattended sleep study in the diagnosis of OSA have been included in the analysis, adverse events from unnecessary treatment (in both the diagnostic and reassessment processes) were not included. In the cost comparison analysis and financial analysis it was assumed that all adult patients with false positives would be treated by APAP. Given that this treatment is a relatively safe procedure, the adverse consequences would be trivial. However, in children with suspected OSA an unnecessary adenotonsillectomy might cause short- and long-term harms to the patient, which could require further treatment and attendant costs. The costs of OSA diagnosis with the aid of unattended sleep studies in the paediatric setting may therefore have been potentially underestimated, and the proposed diagnostic pathway involving unattended sleep studies might result in worse health outcomes than the current diagnostic pathway.

In order to simplify the cost comparison analysis and financial analysis, the downstream costs for the treatment of complications from adenotonsillectomy were not considered, as the adverse consequences from this procedure were deemed to be insignificant. However, there is still a proportion, although very small, of patients who would receive unnecessary adenotonsillectomy; and post-procedural adverse events do occur, although rare. Therefore, the cost implications of unattended sleep studies for the diagnosis and reassessment of OSA in a paediatric setting were somewhat underestimated by this assessment report.

Finally, potential leakage of unattended sleep studies, such as for the diagnosis of shiftwork-related sleep disorders, parasomnias, hypersomnia and Kleine-Levin syndrome, was identified. It is expected that the cost implications of unattended sleep studies would exceed the estimates in this assessment report, should these studies be used for a wider range of indications than the diagnosis and reassessment of OSA.

Other relevant considerations

The main considerations not captured by the evidence-base that could impact on decision-making regarding the public funding of unattended sleep studies primarily relate to:

- the technological failure rate associated with these studies (and thus the need for such studies to be repeated);
- the frequent patient preference to have the studies performed in the home—for convenience, given that sleep quality and duration are often the same between unattended and attended studies;
- the potential leakage of unattended sleep studies to patient indications other than suspected OSA;
- the importance of access to OSA diagnostic testing, particularly for rural and remote communities where patients might otherwise forgo or delay proper assessment due to lack of availability of Level 1 PSG;

- the need to reduce waiting times for Level 1 sleep studies; while waiting times may not necessarily result in poor health outcomes for patients, they could affect QoL and relationships with bed partners. The increasing rate of obesity in Australia is also likely to impact on the availability of Level 1 sleep studies in the future; and

- the need to ensure that there is adequate education of health professionals ordering unattended sleep studies as well as appropriate credentialling and training of professionals in reading and interpreting these tests.

Conclusions

Safety

The likelihood of adverse events from unattended sleep studies is low. Minor complications, as reported by one study, include skin redness and itching from placement of the sensors. Overall, unattended sleep studies are safe diagnostic investigations. However, in order to prevent the occurrence of untoward accidents, caution should be used when considering unattended sleep studies for very young children or patients with neurocognitive disorders.

No comparative data were identified that could inform an assessment of the safety of unattended sleep studies relative to laboratory-based PSG. Physical and psychological harms are theoretically possible as a consequence of false positive results from an unattended sleep study and subsequent unnecessary treatment. An earlier (less waiting time) or delayed (false negative results) diagnosis of OSA using unattended sleep studies is not expected to impact on the relative safety of these tests (ie compared with a Level 1 sleep study). Patients are currently triaged for Level 1 sleep studies on the basis of symptom severity, and this is still likely to occur even when an unattended sleep study has produced an OSA-negative result for a highly symptomatic patient.

Effectiveness

The effectiveness of unattended sleep studies for diagnosing OSA is summarised according to their use in specific healthcare settings.

Diagnosis in a non-specialised unit setting

Only weak, sparse evidence (level IV interventional evidence) was available to determine the impact of unattended sleep studies on patients' health outcomes in a non-specialised unit setting. The identified evidence suggested that the diagnosis of OSA using unattended sleep studies and subsequent treatment with CPAP, MAD or palatal implant would provide a benefit in terms of improving patient symptoms, reducing the occurrence of apnoea/hypopnoea events, and perhaps reducing comorbid hypertension. There was no concomitant impact on health-related QoL. The significance of these apparent health benefits in comparison with those purchased with the use of Level 1 sleep studies could not be ascertained.

Linked evidence of the diagnostic accuracy of unattended sleep studies in a non-specialised unit setting, using laboratory-based PSG as the reference standard, was provided by seven cross-classification studies (level III-1 or III-2 diagnostic evidence). Level 3 sleep studies provided good diagnostic accuracy at a RDI/AHI threshold of 5, with AUC of 89.6%, and sensitivity, specificity, NPV and PPV of > 82%. Using a higher RDI cut-off would result in better diagnostic specificity at the cost of lower sensitivity and NPV. This would not be appropriate in this setting as the aim is to reduce the number of false negative diagnoses. Level 4 sleep studies, in which few cardiopulmonary parameters are recorded and evaluated for diagnosing OSA, were, understandably, not as accurate as Level 3 sleep studies. Selected Level 4 sleep devices demonstrated good

specificity and PPV but moderate sensitivity and NPV. Given the generally poor NPV, it is suggested that caution should be applied when using Level 4 studies in this setting, in conjunction with judicious patient and device selection.

Two case series reported outcomes of a change in patient management as a result of the diagnosis of OSA using a Level 4 sleep study in a non-specialised unit setting (level IV interventional evidence). A positive OSA result using this unattended study led to a majority (60.5%) of patients being referred to a respiratory physician, a small proportion (7.4%) referred to an ENT specialist, and the remaining patients treated and followed up in the primary healthcare setting. This suggests that, in an Australian primary care setting, approximately 30% of patients diagnosed with OSA according to an unattended sleep study would not be referred. The evidence also indicated that sleep testing or referrals are still undertaken even in patients with a 'normal' unattended sleep study result. This suggests that clinical judgment regarding the need for further assessment will be the final arbiter in determining what is best for the patient.

Overall, the limited nature of the direct evidence and the lack of comparative data make it difficult to conclude that unattended sleep studies would be as, or more, effective than referral to a sleep physician or use of a Level 1 sleep study at improving the health outcomes of patients, based on direct evidence alone. Using linked evidence, at a RDI cut-off of ≥5 Level 3 sleep studies demonstrated reasonable accuracy for the diagnosis of adult OSA in a non-specialised unit setting. Therefore, in this setting Level 3 studies may be a reasonable alternative to Level 1 studies if patient selection, device and OSA threshold selection are optimised, particularly since limited low-level evidence suggests that the use of an unattended sleep study can affect patient management. Level 4 sleep studies, however, are not as accurate as Level 3 sleep studies in ruling out false negatives at the higher RDI/ODI threshold of ≥15. Level 4 studies would need to be used cautiously and interpreted in the context of patient symptom severity, as the poor NPV of the test will mean that approximately half of the negative test results reported by these studies for patients suspected of OSA are actually incorrect.

Expert opinion suggests that the spectrum of disease identified will not change as a consequence of the use of unattended sleep studies, and that treatment options will not differ. Thus, if the unattended devices are of similar accuracy to Level 1 studies and they lead to a change in patient management, the health outcomes for patients are likely to be similar to those purchased by Level 1 studies. This assumption is lent weight by the direct evidence available in the referral setting, which showed no difference in the health outcomes of patients receiving the two types of sleep study.

Diagnosis in a referral setting

Limited direct evidence of varying quality suggests that patient health outcomes (clinical symptoms and respiratory events) are similar regardless of whether a diagnosis is made with the use of an unattended Level 2 or 4 study or an attended Level 1 study. The evidence on Level 3 studies was non-comparative, and so comparative effectiveness could not be directly assessed.

Selected Level 2 and 3 unattended studies were found to have moderate to high test performance on a range of diagnostic accuracy measures relative to laboratory-based PSG. The test accuracy of Level 4 studies was lower than that observed for Level 3 studies, which is not unexpected given the reduced number of physiological parameters being measured.

The accuracy of unattended studies tended to diminish as fewer physiological parameters were measured. The likelihood of a false negative result increased in conjunction with a reduction in the number of physiological parameters measured. Level 2 and 3 studies generally perform acceptably, although selection of the device and detection threshold is important. Level 4 studies can perform acceptably but the evidence-base indicates that performance can vary widely depending on the thresholds and devices selected. It is difficult to draw any conclusions about their general utility, given the poor quality and heterogeneity of the evidence-base.

The evidence-base indicates that use of unattended sleep studies will result in a change in patient management. In the situation where all patients would normally receive a Level 1 sleep study, approximately 60% would not receive further testing after an unattended sleep study. The use of unattended sleep studies would therefore result in an earlier diagnosis of OSA; this time difference, although not clinically relevant, might be significant from the patient's point of view.

Diagnosis in a paediatric setting

The direct evidence regarding the impact of unattended sleep studies on children's health outcomes was insufficient to determine its benefit relative to attended PSG, although the authors of a case report observed a reduction in apnoea/hypopnoea events and improvement in neuropsychologic functioning after a home-based Embletta PDS study and subsequent tonsillectomy surgery for a child.

Data on the diagnostic accuracy of Level 3 or Level 4 sleep studies, using laboratory-based PSG as the reference standard, were provided by four relatively small cross-classification studies (n=12–58) (level III-1 or III-2 diagnostic evidence). With the exception of extreme NPV results in one study, the sensitivity and NPV were moderate to good (both 66.7–100%) when using a threshold of RDI/ODI >1 and >5 as indicative of OSA. Good agreement between RDIs/ODIs from unattended sleep studies and PSG AHIs were proved by Bland and Altman plot analysis and an intra-class correlation test.

No studies that met the selection criteria reported a change in management following the diagnosis of OSA in children with the aid of unattended sleep studies.

Based on the limited evidence available, unattended sleep studies showed moderate to good accuracy in diagnosing paediatric OSA when positive results were defined as RDI/ODI >1 or >5. The benefit of these studies on the health outcomes of children with suspected OSA remains uncertain. It is also unclear whether the use of these studies would change management in this population (eg the need for additional sleep studies / PSG). Due to the lack of comparative evidence and sparse linked evidence, the effectiveness of unattended sleep studies for this patient population, relative to Level 1 sleep studies, is currently undetermined.

Reassessment of treatment efficacy

No evidence was available with which to assess the effectiveness of unattended sleep studies for reassessing treatment efficacy.

Economic considerations

For a complete estimate of the costs associated with the OSA diagnostic process, the cost comparison and financial incidence analyses that were undertaken included further confirmatory Level 1 sleep study testing due to false negative or uncertain results from an unattended study, or as a consequence of technical failure of an unattended study; as well as costs associated with unnecessary treatment for false positive unattended sleep study results. It should be stressed that the actual cost implications of unattended sleep studies could be overestimated by this assessment as Level 2 studies already receive interim funding in Australia. In order to reduce overall uncertainty, the economic and financial analyses of this report were developed using a scenario whereby Level 1 sleep studies are the only available option in clinical practice.

The cost comparison analysis suggested that the costs for the proposed OSA diagnostic pathway involving unattended sleep studies would be $691, $754 and $525 per capita in a non-specialised unit setting, a referral setting and a paediatric setting, respectively. The use of unattended sleep studies would *save* $144 per capita in a non-specialised unit setting and $16 in a referral setting relative to clinical practice where laboratory-based PSG is the only diagnostic test available. However, the proposed diagnostic pathway involving unattended sleep studies would incur an *additional cost* of $53 per capita in a paediatric setting, which is largely owing to the additional costs associated with unnecessary adenotonsillectomy. The results of the cost comparison analysis are robust when the values of the input variables are varied within a plausible range in a non-specialised unit setting and a paediatric setting. However, in a referral setting the use of unattended sleep studies in the diagnosis of OSA would no longer be cost saving in potential scenarios where a higher proportion of patients receive a Level 1 sleep study once unattended sleep studies are available, or if higher false positive rates than expected are observed from Level 2 or Level 4 sleep studies.

The numbers of patients with suspected OSA in a non-specialised unit setting, a referral setting and a paediatric setting are estimated to be in the ranges 37 911–57 225, 13 269–20 029 and from 5567–13 225, respectively, according to different AHI thresholds (AHI ≥5/≥1 and AHI ≥15/≥5). Should unattended sleep studies be used in clinical practice, the whole diagnostic process would cost the Australian society overall between $39 124 128 and $61 602 452. The cost *savings* to Australian society incurred by unattended sleep studies is estimated to be $5 459 220 to $8 240 332 in a non-specialised unit setting and $212 303 to $320 457 in a referral setting, relative to the current diagnostic pathway. However, the use of unattended sleep studies would cost an *additional* $295 051 to $702 502 in a paediatric setting relative to the current diagnostic pathway. When unattended sleep studies are used in all healthcare settings, the cost to the Australian Government would range between $27 478 883 and $43 284 633, which is $4 266 567 to $6 286 532 *less* than the cost for the current diagnostic process involving laboratory-based PSG as the only available sleep study.

Unlike the diagnostic pathway, the use of unattended sleep studies for reassessing treatment efficacy was not completely costed in the financial analysis. Due to the absence of valid or plausible estimates, the costs for further Level 1 sleep studies following technical failure, false negatives and uncertain test results from unattended studies, and the costs of unnecessary treatment in patients with false positive results, were not considered. Based on the incomplete reassessment pathway, the use of unattended sleep studies would cost the Australian healthcare system overall $5 549 532, which is

$1 029 905 *less* than the current reassessment pathway. The cost implications of unattended sleep studies to the Australian Government would be a cost *saving* of $724 993. It should be emphasised that the actual costs borne by the whole healthcare system and the government would be higher than estimated in this evaluation for reassessment because of the exclusion of downstream costs.

Appendix A Advisory Panel and evaluators

Advisory Panel – Application 1130 – Home-based (unattended) sleep studies

Member	Expertise
Prof Ken Thomson (Chair)	Radiology
Dr Kwun Fong (Deputy Chair)	Thoracic Medicine
Prof Justin Beilby	MSAC Economics Sub-Committee
Prof Donald Campbell	General Medicine, Epidemiology
Mr Gary Carr	Consumer Health
A/Prof Dominic Fitzgerald	Paediatrics
Dr Walid Jammal	General Practice
Dr John Malouf	Ear, Nose and Throat Surgery
Prof Matthew Naughton	General Respiratory and Sleep Medicine

Evaluators

Name	Organisation
Ms Tracy Merlin	Lead Researcher/Manager, Adelaide Health Technology Assessment
Ms Zhaohui Liufu	Research Officer, Adelaide Health Technology Assessment
Dr Shuhong Wang	Health Economist and Research Fellow, Adelaide Health Technology Assessment

Appendix B Search strategies

Table 47 contains the search terms for this review, which were developed on a PubMed platform and modified slightly depending on the database being searched. The search was broad to cover both initial diagnosis and treatment reassessment, and to cover literature on safety, effectiveness and cost-effectiveness, as well as diagnostic accuracy and change in management studies used in the linked evidence approach.

Electronic bibliographic databases were searched to find relevant studies (those meeting the inclusion criteria) addressing each of the research questions developed for this assessment of unattended sleep studies. These databases are described in Table 48. Unattended sleep studies only appear in the literature since 1980, so the search period was restricted from 1980 (or, if inception of the database was later, from that date) until April 2009.

Table 47 Search terms used

Element of clinical question	Search terms
Population	Human [MeSH] AND Sleep apnea syndromes [MeSH]; Airway resistance [MeSH]; Snoring [MeSH]; "sleep apnea"; "sleep apnoea"; OSA; snor*; "sleep disordered breathing"; (daytime OR daily OR day) AND (tired* OR fatigue OR sleep*); SAS; hypopnea; hypopnoea
Intervention/test	Polysomnography [MeSH]; Monitoring, Physiologic [MeSH]; polysomnogr*; "sleep study"; "sleep studies"; PSG; Electrocardiography [MeSH]; Electroencephalography [MeSH]; electromyography [MeSH]; Electrooculography [MeSH]; Electrophysiologic techniques, cardiac [MeSH]; Respiratory function tests [MeSH]; electrocard*; electroencephal*; electromyo*; electrooculogr*; EEG; ECG; EOG; EMG AND "level 2"; "level 3"; "level 4"; unattended; home; portable; ward; Oximetry [MeSH]; oximetr*
Comparator (if applicable)	n/a
Outcomes (if applicable)	n/a
Limits	1980 – April 2009

MeSH = Medical subject heading, based on a Medline/PubMed platform

n/a = not applicable

Table 48 Bibliographic databases

Electronic database	Time period
Cochrane Library – including, Cochrane Database of Systematic Reviews, Database of Abstracts of Reviews of Effects, the Cochrane Central Register of Controlled Trials (CENTRAL), the Health Technology Assessment Database, the NHS Economic Evaluation Database	1980 – 04/2009
Current Contents	1993 – 04/2009
Embase.com (including Embase and Medline)	1980 – 04/2009
Pre-Medline	1980 – 04/2009
ProceedingsFirst	1993 – 04/2009
Web of Science – Science Citation Index Expanded	1995 – 04/2009
EconLit	1980 – 04/2009

Additional sources of literature—peer-reviewed or grey literature—were sought from the sources outlined in Table 49, and from the health technology assessment agency websites provided in Table 50. Websites of specialty organisations were also searched for any potentially relevant information (Table 51).

Table 49 Additional sources of evidence (1980 – 04/2009)

Source	Location
Internet	
Australian Clinical Trials Registry	http://www.actr.org.au
NHMRC: National Health and Medical Research Council (Australia)	http://www.health.gov.au/nhmrc/
US Department of Health and Human Services (reports and publications)	http://www.os.dhhs.gov/
New York Academy of Medicine Grey Literature Report	http://www.nyam.org/library/greylit/index.shtml
Trip database	http://www.tripdatabase.com
Current Controlled Trials metaRegister	http://controlled-trials.com/
National Library of Medicine Health Services/Technology Assessment Text	http://text.nlm.nih.gov/
U.K. National Research Register	https://portal.nihr.ac.uk/Pages/NRRArchive.aspx
Google Scholar	http://scholar.google.com/
Websites of health technology assessment agencies	See Table 50
Websites of Specialty Organisations	See Table 51
Hand searching (journals from 2008–09)	
Sleep medicine	Library or electronic access
Sleep	Library or electronic access
Thorax	Library or electronic access
European Respiratory Journal	Library or electronic access
Chest	Library or electronic access
Respiration	Library or electronic access
Physiological Measurement	Library or electronic access
Sleep Medicine Reviews	Library or electronic access
Journal of Sleep Research	Library or electronic access
Sleep and Behavioural Rhythms	Library or electronic access
Journal of Clinical Sleep Medicine	Library or electronic access
American Journal of Respiratory and Critical Care Medicine	Library or electronic access
Expert Clinicians	Library or electronic access
Expert clinicians	
Studies other than those found in regular searches	The MSAC Advisory Panel
Pearling	
All included articles had their reference lists searched for additional relevant source material	

Table 50 Websites of health technology assessment agencies

Health Technology Assessment Agency	Website
AUSTRALIA	
Australian Safety and Efficacy Register of New Interventional Procedures – Surgical (ASERNIP-S)	http://www.surgeons.org/Content/NavigationMenu/Research/ASERNIPS/default.htm
Centre for Clinical Effectiveness, Monash University	http://www.med.monash.edu.au/healthservices/cce/evidence/
Centre for Health Economics, Monash University	http://chpe.buseco.monash.edu.au
AUSTRIA	
Institute of Technology Assessment / HTA unit	http://www.oeaw.ac.at/english/home.html
CANADA	
Agence d'Evaluation des Technologies et des Modes d'Intervention en Santé (AETMIS)	http://www.aetmis.gouv.qc.ca/site/home.phtml
Alberta Heritage Foundation for Medical Research (AHFMR)	http://www.ahfmr.ab.ca/publications/
The Canadian Agency for Drugs And Technologies in Health (CADTH)	http://www.cadth.ca/index.php/en/
Canadian Association for Health Services and Policy Research (CAHSPR)	http://www.cahspr.ca/
Centre for Health Economics and Policy Analysis (CHEPA), McMaster University	http://www.chepa.org
Centre for Health Services and Policy Research (CHSPR), University of British Columbia	http://www.chspr.ubc.ca
Health Utilities Index (HUI)	http://www.fhs.mcmaster.ca/hug/index.htm
Institute for Clinical and Evaluative Studies (ICES)	http://www.ices.on.ca
Saskatchewan Health Quality Council (Canada)	http://www.hqc.sk.ca
DENMARK	
Danish Centre for Evaluation and Health Technology Assessment (DACEHTA)	www.sst.dk/Planlaegning_og_behandling/Medicinsk_teknologivurdering.aspx?lang=en
Danish Institute for Health Services Research (DSI)	http://www.dsi.dk/engelsk.html
FINLAND	
Finnish Office for Health Technology Assessment (FINOHTA)	http://finohta.stakes.fi/EN/index.htm
FRANCE	
L'Agence Nationale d'Accréditation et d'Evaluation en Santé (ANAES)	http://www.anaes.fr/
GERMANY	
German Institute for Medical Documentation and Information (DIMDI) / HTA	http://www.dimdi.de/static/en
THE NETHERLANDS	
Health Council of the Netherlands Gezondheidsraad	http://www.gr.nl/index.php
Institute for Medical Technology Assessment (Netherlands)	http://www.imta.nl/
NEW ZEALAND	
New Zealand Health Technology Assessment (NZHTA)	http://nzhta.chmeds.ac.nz/
NORWAY	
Norwegian Centre for Health Technology Assessment (SMM)	http://www.kunnskapssenteret.no/
SPAIN	
Agencia de Evaluación de Tecnologias Sanitarias, Instituto de Salud "Carlos III"I/Health Technology Assessment Agency (AETS)	http://www.isciii.es/htdocs/en/investigacion/Agencia_quees.jsp
Andalusian Agency for Health Technology Assessment (Spain)	http://www.juntadeandalucia.es/salud/orgdep/AETSA/default.asp?V=EN
Catalan Agency for Health Technology Assessment (CAHTA)	http://www.aatm.es/cgi-bin/frame.pl/ang/pu.html

SWEDEN	
Center for Medical Health Technology Assessment	http://www.cmt.liu.se/english?l=en
Swedish Council on Technology Assessment in Health Care (SBU)	http://www.sbu.se/en
SWITZERLAND	
Swiss Network on Health Technology Assessment (SNHTA)	http://www.snhta.ch/
UNITED KINGDOM	
Health Technology Board for Scotland	http://www.htbs.org.uk/
NHS Quality Improvement Scotland	http://www.nhshealthquality.org/
National Institute for Clinical Excellence (NICE)	http://www.nice.org.uk/
The European Information Network on New and Changing Health Technologies	http://www.euroscan.bham.ac.uk/
University of York NHS Centre for Reviews and Dissemination (NHS CRD)	http://www.york.ac.uk/inst/crd/
UNITED STATES	
Agency for Healthcare Research and Quality (AHRQ)	http://www.ahrq.gov/clinic/techix.htm
Harvard School of Public Health – Cost-Utility Analysis Registry	https://research.tufts-nemc.org/cear/default.aspx
Institute for Clinical Systems Improvement (ICSI)	http://www.icsi.org
Minnesota Department of Health (US)	http://www.health.state.mn.us/htac/index.htm
National Information Centre of Health Services Research and Health Care Technology (US)	http://www.nlm.nih.gov/hsrph.html
Oregon Health Resources Commission (US)	http://egov.oregon.gov/DAS/OHPPR/HRC/about_us.shtml
Office of Health Technology Assessment Archive (US)	http://fas.org/ota/
U.S. Blue Cross/ Blue Shield Association Technology Evaluation Center (Tec)	http://www.bcbs.com/consumertec/index.html
Veteran's Affairs Research and Development Technology Assessment Program (US)	http://www.research.va.gov/default.cfm

Table 51 Specialty websites

American Academy of Sleep Medicine	http://www.sleepeducation.com/index.aspx
American Sleep Apnea Association	http://www.sleepapnea.org/
American Thoracic Society	http://www.thoracic.org/
Australasian Sleep Technologists Association	http://www.sleeptechnologists.org/
Board of Registered Polysomnographic Sleep Technologists	http://www.brpt.org/
British Sleep Society	http://www.sleeping.org.uk/
British Thoracic Society	http://www.brit-thoracic.org.uk/
Canadian Thoracic Society	http://www.lung.ca/cts-sct/home-accueil_e.php
Home Sleep Studies Australia	http://www.homesleep.com.au/
Narcolepsy and Overwhelming Daytime Sleep Society of Australia	http://www.nodss.org.au/sleep_apnoeas.html
National Center on Sleep Disorders Research	http://www.nhlbi.nih.gov/about/ncsdr/
Sleep Disorders Australia	http://www.sleepoz.org.au/
Royal Australian College of General Practitioners	http://www.racgp.org.au/
Royal Australasian College of Surgeons	http://www.surgeons.org/
Sleep Studies Australia	http://www.sleepstudies.com.au/

The Australian Lung Foundation	http://www.lungnet.com.au/
The Thoracic Society of Australia and New Zealand	http://www.thoracic.org.au/
World Association of Sleep Medicine	http://www.wasmonline.org/
World Federation of Sleep Research and Sleep Medicine Societies, including: • American Academy of Sleep Medicine (AASM) • Asian Sleep Research Society (ASRS) • Australasian Sleep Association (ASA) • Canadian Sleep Society (CSS) • European Sleep Research Society (ESRS) • Federation of Latin American Sleep Societies (FLASS) • Sleep Research Society (United States) (SRS)	http://www.wfsrsms.org/
Woolcock Institute of Medical Research	http://www.woolcock.org.au/

Appendix C Studies included in the review

Non-specialised unit setting

Study Location Study period	Study design and appraisal[a]	Inclusion/exclusion criteria	Study population	Reference standard and/or comparator	Index test	Respiratory event definition	Outcomes
Non-specialised unit setting, Level 3 sleep study							
(Carter et al 2004) Sleep Disorders Center, Dallas Veterans Affairs Medical Center, the United States Feb 2002 – March 2002	Cross-classification study Level III-2 diagnostic evidence CX P1 Q2 [QUADAS: 10/14]	*Inclusion* Patients with clinically suspected OSA, scheduled to undergo routine PSG in a sleep disorders centre *Exclusion* NR	N=10 Gender: M/F 8/2 Age: 48.8±14.2 years BMI: 32.4±5.6 kg/m^2 ESS score: 13.4±4.5 OSA symptom: Loud snoring: 9 (90%) Witnessed apnoeas: 9 (90%) Excessive daytime sleep: 8 (80%) Non-refreshed sleep: 9 (90%) Night time arousals: 3 (30%) Morning headaches: 8 (80%) Nasal obstruction: NR	*Ref standard* Laboratory-based PSG (manual scoring)	Home-based LifeShirt system (Vivometrics, Inc., USA) Respiratory inductance plethysmographs (two channels, thoracic and abdominal)+ ECG + pulse oximeter Auto scoring, a registered sleep technologist and a certified physician reviewed the data	Apnoea: ↓ airflow or tidal volume amplitude >75%, ≥10 s; or a less significant ↓ airflow or tidal volume amplitude with the presence of oxygen desaturation ≥3% Hypopnoea: ↓ airflow or tidal volume amplitude >25%	*Effectiveness* *Linked evidence:* Sensitivity Specificity PPV NPV LR+ LR– Spearman correlation coefficient Pearson correlation coefficient
(Eskafi et al 2006) Malmö University Hospital, Sweden	Prospective case series Level IV interventional evidence CX (no	*Inclusion* Patients previously hospitalised at the Department of Cardiology, with diagnosis of stable, mild to moderate CHF, New York Heart Association functional	N=17/58 Gender: M/F 17/0 Age: 68.4±5.7 years BMI: 25.3±3.5 Case of CHF: Ischaemic heart disease: 13	Nil	Hospital-based or home-based EdenTrace II Plus Multirecording System (EdenTech Corp., USA) Airflow (oronasal) + respiratory effort (thoracic) + oxygen saturation + body position + snoring	↓ airflow ≥50%, ≥10 s, associated with oxygen desaturation ≥4%	*Effectiveness* *Direct evidence:* Change in symptoms Change in QoL Change in ODI Treatment type

Study Location Study period	Study design and appraisal[a]	Inclusion/exclusion criteria	Study population	Reference standard and/or comparator	Index test	Respiratory event definition	Outcomes
NR	comparison) P1 Q3 [NHS CRD: 3.5/6]	classes II-III, and left ventricular systolic dysfunction[b] *Exclusion* Patients previously treated for SA, with dental problems preventing the use of a MAD, with tempero-mandibular joint problems, likely to undergo cardiac surgery within 1 year, suffered from any other severe disease likely to interfere with QoL within the following year, with any serious mental condition, or with alcohol or drug abuse	(76%) Dilated cardiomyopathy: 2 (12%) Hypertension: 1 (6%) Valvular disease: 1 (6%) Nasal obstruction: NR		Scoring: unknown Mandibular advancement device (6 months)		
(Patel & Davidson 2007) University of California, the United States April 1998	Prospective case series Level IV interventional evidence CX P1 Q3 [NHS CRD: 2/6]	*Inclusion* Patients with suspected OSA based on symptoms, eg snoring *Exclusion* NR	A 47-year-old male, with a long history of primary complaint of snoring, with a weight gain in the past 10 years, with witnessed sleep apnoea and daytime sleepiness, and having obesity and hypertension	Nil	Home-based Embletta PDS (Embla, USA) EEG + airflow (nasal pressure + oral thermistor) + respiratory effort (thoracic movements) + heart rate + oxygen saturation Auto scoring	NR	*Effectiveness* *Direct evidence:* Change in symptoms Control of comorbidities Treatment type
			A 43-year-old male, with a long history of primary complaint of snoring, with a weight gain in the past several years, with witnessed sleep apnoea and daytime sleepiness, and having obesity and hypertension	Nil	As above APAP		

Study Location Study period	Study design and appraisal[a]	Inclusion/exclusion criteria	Study population	Reference standard and/or comparator	Index test	Respiratory event definition	Outcomes
			A 29-year-old male, with complaint of snoring, with a BMI of 28 kg/m^2		As above Palatal implants		
(Quintana-Gallego et al 2004) Virgen del Rocio Hospital, Spain NR	Cross-classification study Level III-2 diagnostic evidence CX P1 Q2 [QUADAS: 10.5/14]	***Inclusion*** Patients with stable heart failure due to systolic dysfunction ***Exclusion*** Patients with unstable heart failure during the study, with acute myocardial infarction in the past 3 months, or having unstable angina, congenital heart disease, or arterial oxygen tension <60 mmHg	N=75 Gender: M/F 65/10 Age: 56.1±11.7 years BMI: 28.6±4.4 kg/m^2 Causes of heart failure: Ischaemic: 32 (42%) Idiopathic: 30 (39%) Nasal obstruction: NR	***Ref standard*** Laboratory-based PSG	Home-based Apnoescreen II (Erich Jaeger Gmbh & CoKg, Germany) Airflow (oronasal thermistor) + respiratory effort (thoracic and abdominal) + oxygen saturation + body position + wristband actigraphy A technician hooked up the device in patients' home Scoring: unknown	Apnoea: no airflow, ≥10 s Hypopnoea: ↓ airflow ≥50%, ≥10 s, accompanied by oxygen desaturation ≥4%	***Effectiveness*** *Linked evidence:* AUC Sensitivity Specificity
(Smith et al 2007) [c] General cardiology out-patient clinics, the United Kingdom NR	Cross-classification study Level III-2 diagnostic evidence CX P1 Q2 [QUADAS: 10/14]	***Inclusion*** Patients with diagnosis of symptomatic but stable CHF for ≥1 month on optimal medical therapy, and with objective evidence of left ventricular systolic dysfunction (echocardiographic LVEF <45%)[d] ***Exclusion*** Patients with acute coronary syndrome within the past 3 months, primary valvular heart disease, or stroke with	N=20 Gender: M/F: 14/6 Age: 61±10 years BMI: 29±6 kg/m^2 LVEF: 33%±12% Aetiology of CHF: Ischaemic heart disease: 13 (65%) Dilated cardiomyopathy: 7 (35%) Atrial fibrillation: 3 (15%) Nasal obstruction: NR	***Ref standard*** Laboratory-based PSG (manual scoring)	Home-based Embletta (Flaga, Iceland) Air flow (nasal) + respiratory effort (2 channels: thoracic and abdominal) + finger pulse oximeter + body position Manual scoring	Apnoea: no airflow, ≥10 s Hypopnoea: ↓ airflow or respiratory movement ≥50%, ≥10 s	***Effectiveness*** *Linked evidence:* Sensitivity Specificity PPV NPV LR+ LR– Kappa coefficient

Study Location Study period	Study design and appraisal[a]	Inclusion/exclusion criteria	Study population	Reference standard and/or comparator	Index test	Respiratory event definition	Outcomes
		residual neurological deficit					
(Yin et al 2005) Japan April 2003 – Sep 2003	Prospective case series Level IV diagnostic evidence CX P1 Q3 [QUADAS: 5/14]	***Inclusion*** Patients complaining of snoring ***Exclusion*** NR	N=62 Gender: M/F 45/17 Age: 45.6±18.2 years BMI: 26.1±6.4 kg/m^2 Nasal obstruction: NR	Nil	Home-based Stardust II (Respironics Inc, USA) Airflow (nasal pressure) + respiratory effort (thoracic and abdominal movement) + snoring signal + oxygen saturation + pulse rate + body position Auto scoring and manual scoring	Apnoea: ↓ airflow >80%, ≥10 s Hypopnoea: ↓ airflow >50%, accompanied by oxygen desaturation ≥3%, ≥10 s	***Effectiveness*** *Linked evidence:* Diagnostic yield
(Yin et al 2006) Japan NR	Cross-classification study Level III-2 diagnostic evidence CX P1 Q2 [QUADAS: 10.5/14]	***Inclusion*** Patients with suspected OSA ***Exclusion*** NR	N=44 Gender: M/F 40/4 Age: 52.3±13.5 years BMI: 26.7±5.3 kg/m^2 Nasal obstruction: NR	***Ref standard*** Laboratory based PSG	Home-based Stardust II (Respironics Inc, USA) Airflow (nasal pressure) + respiratory effort (thoracic and abdominal movement) + snoring signal + oxygen saturation + pulse rate + body position Auto scoring	↓ airflow >50%, accompanied by oxygen desaturation ≥3%, ≥10 s	***Effectiveness*** *Linked evidence:* Sensitivity Specificity PPV NPV LR+ LR– Mean difference / limits of agreement Pearson correlation coefficient
Non-specialised unit setting, Level 4 sleep study							
(Abraham et al 2006) Three clinics in the United States and one	Cross-classification study Level III-2 diagnostic evidence	***Inclusion*** Patients with stable NYHA class III systolic HF (left ventricular ejection fraction ≤35%)[e]	N=50 Subgroup: patients with stable HF Gender: M/F: 34/16 Age: 55.5±12.8 years	***Ref standard*** Laboratory-based PSG (manual scoring)	Home-based ClearPath System (CPS) Nx-301 (Nexan Inc., Alpharetta, USA) 2-lead ECG + pulse oximetry + respiratory effort	Oxygen desaturation ≥3%	***Safety*** Physical harms ***Effectiveness*** *Linked evidence*:

Study Location Study period	Study design and appraisal[a]	Inclusion/exclusion criteria	Study population	Reference standard and/or comparator	Index test	Respiratory event definition	Outcomes
clinic in the United Kingdom NR	CX P1 Q2 [QUADAS: 10/14]	***Exclusion*** Patients with cerebrovascular, neuromuscular, terminal disease, or severe chronic obstructive pulmonary disease; patients with a known dermatologic condition or allergy which might interfere with the application of the sensors or medical adhesives; or patients with documented myocardial infarction within 6 weeks	Race: White: 44 (88%) African American: 5 (10%) Native American: 1 (2%) Aetiology of heart failure: Ischaemic: 23 (46%) Dilated: 21 (42%) Hypertrophic: 2 (4%) Viral: 1 (2%) Symptoms of HF: Shortness of breath: 37 (74%) Paroxysmal nocturnal dyspnoea: 17 (34%) Dyspnoea on exertion: 21 (42%) Angina: 9 (18%) Orthopnoea: 2 (4%) Dizziness: 1 (2%) Lower extremity oedema: 2 (4%) LVEF: 26.4±13.5% BMI: 32.6±6.5 kg/m^2 SBP: 120±17.9 mmHg DBP: 73.9±8.7 mmHg Pulse: 61.7±21.6 bpm MLWHF QoL score: 61.7±21.6 ESS score: 10.6±4.4	***Comparator*** Laboratory-based CPS	Nurses wired up the CPS in clinics Manual scoring		Sensitivity

Study Location Study period	Study design and appraisal[a]	Inclusion/exclusion criteria	Study population	Reference standard and/or comparator	Index test	Respiratory event definition	Outcomes
			Nasal obstruction: NR				
(Fietze et al 2000) Department of Cardiology, Humboldt University, Germany NR	Prospective case series Level IV diagnostic evidence CX (no comparison) P1 Q3 [QUADAS: 4.5/14]	***Inclusion*** Patients with cardiac pacemaker[f] ***Exclusion*** NR	N=192 Gender: M/F 100/92 Age: 62.2±12.2 years BMI: 25.7±3.5 kg/m^2 Reasons for pacemaker: Sick sinus syndrome: 100 (52%) AV block: 58 (30.2%) Atrial fibrillation with bradycardia: 19 (9.9%) A combination of sick sinus syndrome and AV block: 11 (5.7%) Comorbidities: Coronary heart disease: 111 (58%) Arterial hypertension: 59 (31%) Left heart failure: 37 (19%) Diabetes: 26 (14%) Rheumatoid arthritis: 25 (13%) Obstructive lung disease: 16 (8%) Renal disease: 9 (5%) Hyperlipidemia: 38 (20%) Hyperuricemia: 25 (13%) Nasal obstruction: NR	Nil	Home-based MESAM IV device (MAP, Germany) Oxygen saturation + heart rate + snoring + body position Manual scoring	Oxygen desaturation ≥4%	***Effectiveness*** *Linked evidence*: Diagnostic yield

Study Location Study period	Study design and appraisal[a]	Inclusion/exclusion criteria	Study population	Reference standard and/or comparator	Index test	Respiratory event definition	Outcomes
(Gergely et al 2009) Shiga University of Medical Science Hospital, Japan Aug 2006 – Aug 2007	Cross-classification study Level III-1 diagnostic evidence CX P1 Q1 [QUADAS: 12/14]	***Inclusion*** Patients with symptoms of SA ***Exclusion*** Patients with errors in SleepStrip recording, without SleepStrip study, without PSG study; having PSG earlier than SleepStrip study, or quitting the study	N=83 Gender: M/F: 68/15 Age: 50.3±1.4 years BMI: 25.8±0.5 kg/m^2 Nasal obstruction: NR	***Ref standard*** Laboratory-based PSG (manual scoring)	Home-based SleepStrip (S.L.P. Ltd, Tel Aviv, Israel) Nasal flow Auto scoring Home-based Portable Pulsox-M24 (Konica-Minolta, Japan)	Apnoea: ↓ airflow ≥88%, last >10 s Hypopnoea: ↓ airflow ≥50%, >10 s Oxygen desaturation ≥3%	***Effectiveness*** *Linked evidence:* Sensitivity Specificity PPV NPV LR+ LR– Kappa coefficient
(Martinez et al 2005) Division of General Internal Medicine, Mayo Clinic College of Medicine, Rochester, Minnesota, USA Sep 2001 – May 2002	Retrospective case series Level IV diagnostic and interventional evidence CX (no comparison) P1 Q2 [NHS CRD: 4/6] Q3 [QUADAS: 8/14]	***Inclusion*** Random sample of medical records of patients with suspected obstructive sleep apnoea syndrome who were referred to general internists ***Exclusion*** No previous diagnosis of obstructive sleep apnoea syndrome *[artefactual data excluded]*	N=100/375 Gender: M/F 49/51 Age: 57.0±15.0 years BMI: 30.0±8.0 kg/m^2 (54% obese, BMI ⩾30) Symptoms: Habitual snoring: 66 (66%) Witnessed apnoea: 33 (33%) Excessive daytime sleepiness: 42 (42%) Insomnia: 14 (14%) Hypertension: 60 (60%) Nasal obstruction: NR	Nil	Home-based Pulse oximeter - 2500 PalmSAT (Nonin Medical Inc, Plymouth, Minnesota) Oxygen saturation Manual scoring	1) Oxygen desaturation events >4% 2) Oxygen saturation <90% (cumulative time with oxygen saturations <90%) (CT_{90}) ODI: total number of desaturation events per hour of recording time	***Effectiveness*** *Linked evidence* Diagnostic yield Additional sleep studies Patient referral Time to diagnosis Treatment type
(Saeki et al 1999) Department of Neurological	Prospective case series Level IV diagnostic evidence	***Inclusion*** Patients with acromegaly who were scheduled for transphenoidal adenomectomy, with	N=6 Gender: M/F 6/0 Age: 49.3±8.3 years BMI: 24.8±2.1 kg/m^2	Nil	Hospital-based Pulse oximeter, Pulsox-5 (Minolta, Japan) Oxygen saturation + pulse rate Auto scoring	Oxygen saturation <90% and/or oxygen desaturation ≥4%	***Effectiveness*** *Linked evidence*: Diagnostic yield

Study Location Study period	Study design and appraisal[a]	Inclusion/exclusion criteria	Study population	Reference standard and/or comparator	Index test	Respiratory event definition	Outcomes
Surgery, Chiba University, Japan NR	CX (no comparison) P1 Q3 [QUADAS: 4.5/14]	habitual snoring and nocturnal hypopnoea or witness apnoea episode ***Exclusion*** NR	Nasal obstruction: NR				
(Sériès et al 2005) Montreal, Halifax and Quebec City, Canada NR	Cross-classification study Level III-2 diagnostic evidence CX P1 Q1 [QUADAS: 12.5/14]	***Inclusion*** Patients with at least one clinical episode of CHF, with left ventricular systolic dysfunction (LVEF <40%), with New York Heart Association functional class 2–4, and with stable condition and stable optimal cardiac medications in the past 4 weeks[g] ***Exclusion*** Patients with history of unstable angina, cardiac surgery, and/or documented myocardial infarction in the past 3 months	N=50 Gender: M/F 41/9 Age: 63±10 years BMI: 29.5±5.2 kg/m^2 Nasal obstruction: NR	***Ref standard*** Laboratory-based PSG (manual scoring)	Home-based Stardust® Sleep Recorder (Respironics, Inc., USA) Oxygen saturation + pulse rate + body position Manual scoring	Oxygen desaturation ≥2% followed by a rise in oxygen saturation	***Effectiveness*** *Linked evidence:* Sensitivity Specificity PPV NPV LR+ LR– Mean difference / limits of agreement
(West et al 2001) University of Hospital Nottingham, the United Kingdom NR	Prospective case series Level IV interventional evidence CX (no comparison)	***Inclusion*** Patients who would be referred either to ENT or respiratory medicine by general practitioners ***Exclusion*** NR	N=100 Nasal obstruction: NR	Nil	Home-based Oximetry Oxygen saturation + heart rate OR Video oximetry, Visilab Oxygen saturation + sleep status + heart rate +	Oxygen desaturation ≥4%	***Effectiveness*** *Linked evidence:* Patients referral

Study Location Study period	Study design and appraisal[a]	Inclusion/exclusion criteria	Study population	Reference standard and/or comparator	Index test	Respiratory event definition	Outcomes
	P1 Q3 [NHS CRD: 3.5/6]				respiratory sound + movement Scoring (unknown)		

[a] Methods of quality assessment and explanations for terminology, eg CX, P1, Q3, are given in Table 7; [b] Patients were recruited on the assumption that SA is a common comorbidity condition in patients with CHF; and untreated SA is believed to be associated with an increased risk of death in patients with coronary artery disease (Eskafi et al 2006); [c] One of the authors, Neil Douglas, was in the Medical Advisory Board of ResMed until May 2006 and is a stockholder of ResMed; [d] Patients were recruited on the assumption that symptoms of CHF and SDB overlap, and few patients actually complain of daytime sleepiness, although CHF patients with SDB have measured daytime sleepiness (Smith et al 2007); [e] Patients were recruited based on the evidence that sleep-disordered breathing is associated with the development of cardiovascular disease, such as heart failure and hypertension, and that sleep disordered breathing is common in patients with heart failure (Abraham et al 2006); [f] Patients were recruited on the assumption that bradycardic rhythm disorders commonly occur in patients who suffer from sleep-disordered breathing (Fietze et al 2000); [g] Patients were recruited based on the assumption that sleep-related breathing disorders are involved in the pathophysiology and progression of CHF (Sériès et al 2005).

AUC = area under the curve; AV = atrioventricular; BMI = body mass index; CHF = congestive heart failure; CPAP = continuous positive airway pressure; DBP = diastolic blood pressure; ECG = electrocardiography; EEG = electroencephalography; ENT = ear, nose and throat; ESS = Epworth Sleepiness Scale; HF = heart failure; LR+ = positive likelihood ratio; LR- = negative likelihood ratio; LVEF = left ventricular ejection fraction; MAD = mandibular advancement device; MLWHF = Minnesota Living With Heart Failure; NYHA = New York Heart Association; NPV = negative predictive value; NR = not reported; ODI = oxygen desaturation index; OSA = obstructive sleep apnoea; PPV = positive predictive value; PSG = polysomnography; QoL = quality of life; RDI = respiratory disturbance index; SA = sleep apnoea; SBP = systolic blood pressure

Referral setting

Study Location Study period	Study design and appraisal[a]	Inclusion/exclusion criteria	Study population	Reference standard and/or comparator	Index test	Respiratory event definition	Outcomes
Referral setting, Level 2 studies							
(Abdenbi et al 2002) Hôpital Antoint-Béclère, France NR	Prospective case series Level IV diagnostic evidence CX (no comparison) P1 Q3 [QUADAS: 5.5/14]	***Inclusion*** Patients with suspected SA, with daytime sleepiness and habitual loud snoring ***Exclusion*** NR	N=25 Age: mean 52 years (range 45–72 years) BMI: mean 28 kg/m^2 (range 26–35 kg/m^2) Nasal obstruction: NR	Nil	Home-based CID 108 and CID 102 (CIDELEC, Sainte-Gemmes-sur-Loire, France) CID 108: EEG (2 channels) + EOG (2 channels) + EMG (2 channels) CID 102: airflow (nasal) + respiratory effort + tracheal sounds + oxygen saturation + heart rate + body position 10 out of 25 patients were hooked up in the hospital Auto + manual editing	Apnoea: ↓ airflow ≥90% Hypopnoea: ↓ airflow 30–90% + oxygen desaturation ≥3%	***Effectiveness*** *Linked evidence*: Diagnostic yield
(Ancoli-Israel et al 1997) University of California, the United States NR	Cross-classification study Level III-2 diagnostic evidence CX P1 Q2 [QUADAS: 11/14]	***Inclusion*** Patients with suspected sleep apnoea and normals (ie no suspicion of sleep apnoea) ***Exclusion*** NR	N=36 Gender: M/F 34/2 Age: 48.5±7.4 years Nasal obstruction: NR	***Ref standard*** Laboratory-based PSG (manual scoring)	Home-based NightWatch System™ (Healthdyne Technologies, USA) Eye movement+ airflow (nasal) + respiratory effort (thoracic and abdominal movement) + oximetry + heart rate + body position + leg movement Device hooked up in the sleep laboratory Auto + manual editing	Apnoea: no airflow, ≥10 s Hypopnoea: ↓ airflow ≥50%	***Effectiveness*** *Linked evidence*: Sensitivity Specificity PPV PNV LR+ LR– Spearman correlation coefficient
(Escourrou et al 2000)	Prospective case series	***Inclusion*** Patients with snoring and various degrees of	N=14 Gender: M/F 13/1	Nil	Home-based Ambulatory PSG	NR	***Effectiveness*** *Linked evidence*:

Study Location Study period	Study design and appraisal[a]	Inclusion/exclusion criteria	Study population	Reference standard and/or comparator	Index test	Respiratory event definition	Outcomes
Hôpital Béclère, France NR	Level IV diagnostic evidence CX P1 Q3 [QUADAS: 4/14]	daytime somnolence ***Exclusion*** NR	Age: range 36–60 years BMI: mean = 31.9 kg/m^2 Nasal obstruction: NR		EEG (2 channels) + EMG (2 channels) + EOG + airflow (oronasal thermistor) + respiratory effort (thoracic) + oximetry Technician set up the devices at home Auto scoring		Diagnostic yield
(Fry et al 1998) MCP Hahnemann School of Medicine, Allegheny University of the Health Sciences, the United States NR	Prospective case series Level IV diagnostic evidence CX P1 Q3 [QUADAS: 5/14]	***Inclusion*** Patients referred to a sleep disorders centre for evaluation of sleep-related complaints, aged 18–80 years ***Exclusion*** NR	N=77 Gender: M/F 49/28 Age: mean = 49.3 years (range 20–75 years) Nasal obstruction: NR	Nil	Home-based (n=77) Laboratory-based (unattended) (n=16/77) DigiTrace Home Sleep System EEG (4 channels) + EOG + EMG + airflow (naso-oral thermocouple) + respiratory effort (thoracic and abdominal movements) + ECG + oxygen saturation leg movement + body position + snoring sound Patients were hooked up by a technician in the sleep laboratory Auto scoring	Apnoea: no airflow, ≥10 s Hypopnoea: noticeable ↓ airflow, ≥10 s, associated with oxygen desaturation >2% or EEG arousal	***Effectiveness*** *Linked evidence*: Diagnostic yield
(Gagnadoux et al 2002) Hôpital Saint Antoine sleep laboratory, Hôpital Tenon, and Hôpital A. Mignot,	Cross-classification study Level III-2 diagnostic evidence CX P1 Q1 [QUADAS:	***Inclusion*** Patients with clinical suspicion of SA, based on symptoms of snoring + excessive daytime sleepiness + witnessed apnoea, and with physical capacity to comply with the diagnostic tests	N=99 Gender: M/F 82/17 Age: mean = 52 years BMI: mean = 27.5 kg/m^2 Nasal obstruction: NR	***Comparator*** Hospital-based Tele-monitored Minisomno® (Sefam-Nellcor-Puritan-Benett, France) Patients tele-monitored by the	Home-based Minisomno® (Malline-Krodt; Les Ulis Courtabouef, France) EEG (2 channels) + EOG + EMG + airflow (oronasal thermistors) + respiratory effort (thoracic and abdominal) + oxygen	Apnoea: no airflow, ≥10 s Hypopnoea: ↓ respiratory movement ≥50%, ≥10 s	***Effectiveness*** *Linked evidence*: Mean difference / limits of agreement

Study Location Study period	Study design and appraisal[a]	Inclusion/exclusion criteria	Study population	Reference standard and/or comparator	Index test	Respiratory event definition	Outcomes
Versailles, France May 1997 – April 1998	13.5/14]	 ***Exclusion*** Patients with decompensated concomitant disease, with mental retardation, or failing (or unable) to give their consent		sleep laboratory technician. The technician checked the quality of recordings every 30 minutes for 5 minutes. He/she instructed the nurse to resite electrodes giving faulty signals	saturation + ECG The experienced sleep technician applied the electrodes in sleep laboratory Manual scoring		
(Iber et al 2004)[b] The United States NR	Cross-classification study Level III-1 diagnostic evidence CX P1 Q2 [QUADAS: 11.5/14]	***Inclusion*** Non-Sleep Heart Health Study (SHHS) patients recruited from seven SHHS field sites, screened by a verbally administered Sleep Habits Questionnaire, with a minimum of 4 hours of scorable data contiguously collected on at least 1 respiratory channel, and 1 EEG channel ***Exclusion*** NR	N=64 Gender: M/F 34/30 Age: median = 57 years (range 40–76 years) BMI: 31.3±10.5 kg/m^2 ESS score: 7.5±4.8 Nasal obstruction: NR	***Ref standard*** Laboratory-based PSG (manual scoring)	Home-based Compumedics PS-2 system (Compumedics, Australia) EEG + EOG + EMG + airflow (nasal-oral thermocouple) + respiratory effort (thoracic and abdominal movement) + pulse oximetry Devices hooked up by a certified technician Manual scoring	Apnoea: no or almost no airflow, ≥10 s Hypopnoea: ↓ airflow or respiratory movement ≥30%, ≥10 s accompanied by oxygen desaturation ≥3% (4%)	***Effectiveness*** *Linked evidence*: Sensitivity Specificity PPN PNV Weighted Kappa coefficient
(Mykytyn et al 1999) Sleep Disorders Unit, Repatriation / General Hospital,	Prospective case series Level IV diagnostic evidence CX	***Inclusion*** Patients with symptoms of loud snoring and daytime sleepiness, referral to the sleep laboratory for diagnosis of OSA	N=10 Age: 54.4±2.7 years BMI: 29.6±1.7 kg/m^2 Nasal obstruction: NR	Nil	Laboratory-based (unattended) Compumedics PS1-Series Portable Sleep System (Compumedics Ltd, AU) EEG + EOG (2 channels) + EMG + air flow (oronasal	Obstructive apnoea: no airflow, ≥10 s, with continued thoraco-abdominal wall movement Hypopnoea: ↓ airflow ≥50% or thoraco-abdominal movement,	***Effectiveness*** *Linked evidence*: Diagnostic yield

Study Location Study period	Study design and appraisal[a]	Inclusion/exclusion criteria	Study population	Reference standard and/or comparator	Index test	Respiratory event definition	Outcomes
Australia NR	P1 Q3 [QUADAS: 5/14]	***Exclusion*** NR			thermistor) + respiratory efforts (thoracic and abdominal) + ECG + pulse oximetry + body position + leg movement (2 channels) After initial optimisation, no technical intervention during recording period Manual scoring	≥10 s	
(Portier et al 2000) Centre Hospitalo-Universitaire de Rouen, France NR	Cross-classification study Level III-2 diagnostic evidence CX P1 Q1 [QUADAS: 12/14]	***Inclusion*** Patients referred to a sleep laboratory for suspected SA ***Exclusion*** Patients with disability that prevented their cooperation for the PSG at home or living too far away from the sleep laboratory	N=103 Gender: M/F 84/19 Age: 52±10 years BMI: 31±6.3 kg/m^2 Comorbidities: Chronic bronchitis: 16 (16%) Systemic hypertension: 46 (45%) Coronary insufficiency: 9 (9%) Diabetes: 9 (9%)	***Ref standard*** Laboratory-based PSG (Respisomnograph e by Mallinkrodt) (auto+ manual scoring)	Home-based Minisomno (Mallinkrodt, France) EEG (2 channels) + EMG + EOG (2 channels) + airflow (mouth and nose thermistors) + respiratory effort (thoracic and abdominal) + oximetry Technicians set up the devices in the sleep laboratory Auto + manual scoring	Apnoea: ↓ airflow ≥75%, ≥10 s Hypopnoea: ↓ airflow ≥25%, ≥10 s	***Effectiveness*** *Linked evidence*: Sensitivity Specificity PPV NPV LR+ LR– Mean difference / limits of agreement
(White & Gibb 1998) National Jewish / University of Colorado Sleep Center, the United States NR	Prospective cohort study Level III-2 interventional evidence C1 P1 Q2 [NHMRC: 4/6]	***Inclusion*** Patients with AHI >30 in laboratory-based PSG or home-based sleep studies, aged over 21 years and referred to a sleep disorders centre ***Exclusion*** Patients with severe cardiopulmonary, renal	N=60 Home-based group: n=30 Gender: M/F 27/3 Age: mean±SEM = 50.5±1.8 years BMI: Male: mean±SEM = 33.8±1.5 kg/m^2 Female: mean±SEM	***Comparator*** Laboratory-based PSG (manual scoring) + laboratory-based CPAP titration (MRP CPAP unit (Healthdyne, USA)) + CPAP treatment for 6–8 weeks	Home-based NightWatch System™ (Healthdyne Technologies, USA) Eye movement + airflow (nasal) + respiratory effort (thoracic and abdominal movement) + oximetry + heart rate + body position + leg movement Devices hooked up by a respiratory therapist at home	Apnoea: no airflow, ≥10 s Hypopnoea: ↓ airflow >50%, associated with oxygen desaturation >4% or arousal	***Effectiveness*** *Direct evidence:* Change in AHI Sleep quality after treatment Time to commencement of treatment

Study Location Study period	Study design and appraisal[a]	Inclusion/exclusion criteria	Study population	Reference standard and/or comparator	Index test	Respiratory event definition	Outcomes
		disease, or with important arrhythmia, requiring oxygen therapy or need nocturnal ventilation	= 37.2±3.3 kg/m^2 Neck size: Male: mean±SEM = 44.2±0.6 cm Female: mean±SEM = 40.0±3.5 cm In-lab group: n=30 Gender: M/F 25/3 Age: mean± SEM = 48.2±2.5 years BMI: Male: mean±SEM = 33.0±1.6 kg/m^2 Female: mean±SEM = 47.6±2.6 kg/m^2 Neck size: Male: mean±SEM = 45.0±0.7 cm Female: mean±SEM = 45.6±2.7 cm (p>0.05 in all patient characteristic except BMI in females) Follow-up: 6–8 weeks after CPAP treatment Nasal obstruction: NR		Manual scoring Home-based CPAP titration (MRP CPAP unit (Healthdyne, USA)) + CPAP treatment for 6–8 weeks		
Referral setting, Level 3 sleep study							
(Ancoli-Israel et al 1981)	Cross-classification study	*Inclusion* Patients with sleep	N=36 Gender: M/F: 23/13	*Ref standard* Laboratory-based	Home-based and laboratory-based	Apnoea: no airflow ≥10 s Hypopnoea: ↓ airflow	*Effectiveness* *Linked evidence*

Study Location Study period	Study design and appraisal[a]	Inclusion/exclusion criteria	Study population	Reference standard and/or comparator	Index test	Respiratory event definition	Outcomes
Sleep Disorders Clinic, San Diego Veterans Administration Medical Center, the United States NR	Level III-1 diagnostic evidence CX P1 Q3 [QUADAS: 9.5/14]	complaints suggestive of SA or nocturnal myoclonus, referred to a sleep disorders clinic ***Exclusion*** NR	Age: mean = 64.0 years (range 31–79 years) BMI (in 17 'overweight' patients): mean = male: 26.2 kg/m^2 female: 22.2 kg/m^2 Nasal obstruction: NR	PSG (manual scoring)	Medilog portable analogue recorder Respiratory effort (2 channels: thoracic and abdominal) + EMG + wrist activity Manual scoring	≥50%, ≥10 s	Sensitivity
(Bridevaux et al 2007) Division of Pulmonary Medicine, University Hospital of Lausanne, Switzerland NR	Prospective case series Level IV diagnostic evidence CX (no comparison) P1 Q3 [QUADAS: 3.5/14]	***Inclusion*** Patients with suspected OSA, referred to a sleep disorders centre ***Exclusion*** NR	N=11 Gender: M/F 11/0 Age: 54±14 years BMI: 27±4 kg/m^2 ESS: 10±7 Neck circumference: 43±2 cm Nasal obstruction: NR	Nil	Home-based Embletta PDS® (ResMed Corporation, Iceland) Air flow (nasal) + respiratory effort (thoracic and abdominal movement) + oxygen saturation + pulse rate + body position Manual scoring	Apnoea: no airflow, ≥10 s Hypopnoea: ↓ thoraco-abdominal movement ≥50%, ≥10 s	***Effectiveness*** *Linked evidence* Diagnostic yield
(Calleja et al 2002) Hospital Txagorritxu, Vitoria-Gasteiz, Spain July 1997 – March 1998	Cross-classification study Level III-2 diagnostic evidence CX P1 Q2 [QUADAS: 10/14]	***Inclusion*** Patients with clinically suspected sleep apnoea/hypopnoea syndrome at a sleep outpatient clinic referred to a sleep laboratory Clinical suspicion of sleep apnoea determined using standardised questionnaire at clinical	N=79/86 Gender: M/F: 89%/11% Age: 52±11.1 years BMI: 30.1±4.4 kg/m^2 Invalid studies: 7(8%) Nasal obstruction: NR	***Ref standard*** Laboratory-based full channel PSG (manual scoring) *Unclear if attended*	Unattended laboratory-based Cardiorespiratory polygraphy system—MERLIN (Healthdyne Technologies, Marietta, GA, USA) Air flow (oronasal) + respiratory effort (2 channels: thoracic and abdominal) + tracheal sounds + cardiac frequency + oxygen saturation + body position + CPAP level	Apnoea: no airflow (thermistor signal) ≥10 s Hypopnoea: ↓ airflow ≥50% (thermistor signal) ≥10 s + ≥3% in oxygen desaturation and/or EEG arousal	***Effectiveness*** *Linked evidence* AUC Sensitivity Specificity PPV NPV

Study Location Study period	Study design and appraisal[a]	Inclusion/exclusion criteria	Study population	Reference standard and/or comparator	Index test	Respiratory event definition	Outcomes
		interview; presence of snoring, breathing pauses, excessive daytime sleepiness etc. ***Exclusion*** NR			Manual scoring + automatic scoring *Index test and reference standard performed simultaneously*		
(Coppola & Lawee 1993) Mercy Hospital, the United States NR	Retrospective case series Level IV interventional evidence CX (no comparison) P1 Q2 [NHS CRD: 4/6]	***Inclusion*** Patients with moderate to severe OSA (RDI ≥20), diagnosed by home-based sleep study and treated by CPAP (home-based titration) ***Exclusion*** Patients with serious comorbidities	N=11 Gender: M/F 9/2 Age: 49±13 years BMI: 49.5±1.9 kg/m^2 Nasal obstruction: NR	Nil	Home-based Edentrace Recording System (Eden Prairie, USA) Airflow + respiratory effort (thoracic) + oxygen saturation + heart rate Manual scoring APAP (home-based titration)	NR	***Effectiveness*** *Direct evidence* Change in symptoms Change in RDI
(Davidson et al 1999) Department of Otolaryngology – Head and Neck Surgery, University of California, San Diego School of Medicine, San Diego, California NR	Prospective case series Level IV diagnostic evidence CX (no comparison) P1 Q3 [QUADAS: 7/14]	***Inclusion*** Consecutive adult patients suspected of sleep apnoea syndrome who were referred to ENT clinic ***Exclusion*** NR	N=100 Gender: M/F 83/17 Age: 52.0±13.0 years BMI: 32.0±8.0 kg/m^2 Neck circumference: 43±5.0 cm Systolic blood pressure: 129±19.0 mmHg Diastolic blood pressure: 81±12.0 mmHg Symptoms (0–4, with 4 = severe): Snoring: 2.5±0.9	Nil	Home-based AutoSet Recorder (ResMed Corp, San Diego) Airflow (nasal) + pulse oximetry (oxygen saturation + pulse) *[presumably respiratory effort too, according to device specifications, but no mention in the paper]* Manual scoring	Apnoea: no nasal airflow, ≥10 s Hypopnoea: ↓ nasal airflow ≥50% OSA: AHI ≥15/hour OSA or upper airway resistance syndrome: AHI <15/hour + strong clinical suspicion	***Effectiveness*** *Linked evidence* Diagnostic yield

Study Location Study period	Study design and appraisal[a]	Inclusion/exclusion criteria	Study population	Reference standard and/or comparator	Index test	Respiratory event definition	Outcomes
			Witnessed apnoea: 2.3±1.6 Daytime hypersomnolence: 3.0±1.3 Morning headache: 1.2±1.4 Arm/leg movements: 2.0±1.6 ESS: 12.0±6.0 Nasal obstruction: assessed but NR				
(Davidson et al 2003) Department of Otolaryngology – Head and Neck Surgery, University of California, San Diego School of Medicine, San Diego, California 1999	Prospective case series Level IV diagnostic evidence CX (no comparison) P2 Q3 [QUADAS: 5/14]	***Inclusion*** Adult patients with sleep-disordered breathing (primarily snoring) referred for sleep testing ***Exclusion*** Minors, pregnant women, patients with dementia	N=44/59 Gender: M/F NR Age: 48.0±12.4 years BMI: 30.1±8.5 kg/m^2 Neck circumference: 40.8±4.7 cm Nasal obstruction: NR	Nil	Home-based AutoSet Portable II Plus (distributed as Embletta, ResMed, Poway, Calif) Measurement parameters not reported Automatic scoring	Apnoea: ↓ nasal airflow ≥75%, ≥10 s Hypopnoea: ↓ nasal airflow 50–75%, ≥8 s	***Effectiveness*** *Linked evidence* Diagnostic yield
(Dingli et al 2003) Sleep Centre, Royal Infirmary NHS Trust,	Cross-classification study Level II diagnostic evidence	***Inclusion*** Consecutive patients referred to the sleep centre with possible obstructive sleep	N=61 Gender: M/F: 47/14 Age: 50±11 years BMI: 31±6 kg/m^2	***Ref standard*** Laboratory-based full channel PSG (manual scoring)	Unattended home-based Embletta device Air flow (nasal) + respiratory effort (2 channels: thoracic and abdominal) + pulse	Apnoea: no airflow ≥10 s Hypopnoea: ↓ thoraco-abdominal movement ≥50% ≥10 s	***Effectiveness*** *Linked evidence* Agreement (Kappa)

Study Location Study period	Study design and appraisal[a]	Inclusion/exclusion criteria	Study population	Reference standard and/or comparator	Index test	Respiratory event definition	Outcomes
Edinburgh, Scotland, UK NR	CX P1 Q1 [QUADAS: 14/14]	apnoea/hypopnoea syndrome and self-reported daytime sleepiness (ESS >10) or two other major symptoms of OSAHS ***Exclusion*** Living >50 miles from the sleep centre and immobility	Technical failure in home studies of 11 patients (18%); 50 completed Nasal obstruction: NR		oximetry (oxygen saturation + pulse rate) + body position Manual scoring + automatic scoring *Index test applied and set up by patient*		
(Faber et al 2002) Department of Otorhinolaryngology, Aarhus University Hospital, Denmark NR	Prospective case series Level IV diagnostic evidence CX P1 Q3 [QUADAS: 5/14]	***Inclusion*** Patients with suspected OSA and/or snoring, referred to Otorhinolarygology of a hospital ***Exclusion*** NR	N=54 Gender: M/F 48/6 Age: 47.4±12.0 years BMI: 28.1±4.1 kg/m^2 Neck circumference: 42.8±3.5 cm ESS score: 11.2±5.0 Nasal obstruction: NR	Nil	Home-based AutoSet (ResMed Ltd., Australia) Airflow (nasal pressure) + respiratory effort (thoracic and abdominal movement) + pulse oximetry Auto scoring Hospital-based AutoSet (ResMed Ltd., Australia) + acoustic reflectometry system, SRE2100 (RhinoMetrics, Denmark) Airflow (nasal pressure) + respiratory effort (thoracic and abdominal movement) + pulse oximetry + acoustic signal Auto scoring	Apnoea: no airflow (nasal pressure), ≥10 s Hypopnoea: ↓ airflow >30%, ≥10 s	***Effectiveness*** *Linked evidence* Diagnostic yield
(García-Díaz et al 2007)	Cross-classification study	***Inclusion***	N=62/65	***Ref standard***	Home-based	Apnoea: no oronasal airflow, ≥10 s	***Effectiveness***

Study Location Study period	Study design and appraisal[a]	Inclusion/exclusion criteria	Study population	Reference standard and/or comparator	Index test	Respiratory event definition	Outcomes
Hospitales Universitarios Virgen del Rocio, Sevilla, Spain; and Hospital San Juan de Dios, Sevilla, Spain NR	Level II diagnostic evidence CX P1 Q1 [QUADAS: 13/14]	Consecutive patients with suspected sleep apnoea/hypopnoea syndrome referred to sleep laboratory ***Exclusion*** Physical or mental impairment that ruled out use of equipment	Gender: M/F 54/11 Age: 54.0±10.4 years BMI: 30.1±3.9 kg/m^2 Systolic blood pressure: 139±8.3 mmHg Diastolic blood pressure: 86.6±18.4 mmHg Symptoms: Snoring: 54 (87%) Witnessed apnoea: 41 (66%) Hypertension: 27 (44%) Cardiovascular comorbidity: 9 (15%) ESS: 12.0±3.7 Nasal obstruction: NR	Laboratory-based PSG (manual scoring)	Apnoescreen II (Erich Jaeger GMBH & CoKg, Wuerzburg, Germany) Airflow (oronasal thermistor) + respiratory effort (bands) + oxygen saturation (pulse oximetry) + snoring + ECG + body position + wrist actigraphy Manual scoring Technician set up in patient's home	Hypopnoea: ↓ airflow ≥50% associated with either an oxygen desaturation ≥4% (and/or EEG arousal in PSG study), ≥10 s	*Linked evidence* AUC Sensitivity Specificity LR+ LR – Mean difference / limits of agreement
(Liam 1996) University Hospital, Kuala Lumpur, Malaysia April–July 1995	Prospective case series Level IV evidence CX (no comparison) P2 Q3 [QUADAS: 5/14]	***Inclusion*** Patients referred to a chest clinic and admitted to a hospital, with a history of excessive fatigue and excessive daytime sleepiness associated with chronic nocturnal heavy snoring with or without witnessed apnoea and nocturnal choking ***Exclusion***	N=15 Gender: M/F 15/0 Age: 43.0±12.9 years BMI: 33.4±9.1 kg/m^2 Comorbidities: Hypertension: 7 (47%) Rhinitis: 6 (40%) Diabetes: 1 (7%) Ischemic heart disease: 1 (7%) End-stage renal failure: 1 (7%)	Nil	Hospital-based The Edentrace II system (EdenTec Corporation, USA) Airflow (oronasal thermistor) + respiratory effort (thoracic) + finger oximeter + heart rate + body position + snoring sound Auto scoring	Apnoea: no airflow, ≥10 s (obstructive: with continuing respiratory efforts; central: with an absence of repertory efforts; mixed: combination of an initial central component followed by an obstructive component) Hypopnoea: ↓ airflow or respiratory movement ≥50%,≥10 s, associated with oxygen desaturation ≥4%	***Effectiveness*** *Linked evidence* Diagnostic yield

Study Location Study period	Study design and appraisal[a]	Inclusion/exclusion criteria	Study population	Reference standard and/or comparator	Index test	Respiratory event definition	Outcomes
		Patients with anatomical defect of the upper airway which might predispose the patient to develop OSA, excluded by ENT surgeon	Respiratory obstruction syndrome: Oedematous uvular: 1 (7%) Relatively large tongues: 4 (27%)				
(Lloberes et al 2001) Servei de Pneumologia, Hospital General Vall d'Hebron, Barcelona, Spain NR	Prospective case series Level IV evidence CX (no comparison) P1 Q3 [QUADAS: 7/14]	***Inclusion*** Consecutive patients referred to outpatient sleep clinic for clinically suspected sleep apnoea/hypopnoea syndrome ***Exclusion*** Residence outside Barcelona metropolitan area, shiftwork, lack of transportation facilities, symptoms suggesting narcolepsy or periodic leg movement disorder, psychophysical handicap hindering performance of a home study	N=32/35 Gender: NR Age: 55.5±11.7 years BMI: 29.1±3.1 kg/m^2 Nasal obstruction: NR	Nil	Home-based or laboratory-based (patients received both studies; order was randomised; both were unattended) Sibel-Home 300 (Sibel SA, Barcelona, Spain) Air flow (nasal thermistor) + respiratory effort (thoracic and abdominal movement) + snoring (microphone) + oxygen saturation + pulse rate (finger pulse-oximetry) + body position Manual scoring	Apnoea: no oronasal airflow, ≥10 s Hypopnoea: discernible ↓ in airflow ≥10 s, followed by ≥3% ↓ SaO_2	***Effectiveness*** *Linked evidence* Diagnostic yield
(Miyata et al 2007) Nagoya University School of Health Sciences, Japan NR	Cross-classification study Level III-2 diagnostic evidence CX P1	***Inclusion*** Patients with OSA diagnosed by PSG ***Exclusion*** NR	N=18 Gender: M/F 18/0 Age: 51.0±10.8 years BMI: 25.1±3.7 kg/m^2 Nasal obstruction: NR	***Ref standard*** Laboratory-based PSG (manual scoring)	Home-based LT-200 (Fukudadenshi, Japan) Airflow (oronasal thermistor) + respiratory effort (thoracic and abdominal movements) + oxygen saturation (pulse oximetry) + snoring + body position	Apnoea: no airflow (through the mouth and nose), ≥10 s Hypopnoea: ↓ airflow associated with either an oxygen desaturation >3% or arousal, ≥10 s	***Effectiveness*** *Linked evidence* Mean difference / limits of agreement Pearson correlation coefficient

Study Location Study period	Study design and appraisal[a]	Inclusion/exclusion criteria	Study population	Reference standard and/or comparator	Index test	Respiratory event definition	Outcomes
	Q3 [QUADAS: 8/14]				Manual scoring		
(Parra et al 1997) Servei de Pneumologia, Hospitals de Barcelona, Spain NR	Cross-classification study Level II diagnostic and Level III-2 interventional evidence CX P1 Q1 [QUADAS: 12/14]	***Inclusion*** Patients referred to a hospital for evaluation of suspected SA ***Exclusion*** NR	N=89 Gender: M/F 73/16 Age: 54±12 years BMI: 29±4 kg/m^2 Nasal obstruction: NR	***Ref standard*** Laboratory-based PSG (manual scoring)	Home-based Edentrace II, Model 3711 (Edentec Corporation, USA) Airflow (nasal/oral thermistor) + respiratory effort (thoracic) + oxygen saturation + heart rate + body position Technician hooked up the devices (n=50) Manual scoring	Apnoea: no airflow, ≥10 s Hypopnoea or thoracic movement, ≥10 s, associated with oxygen desaturation ≥2%	***Effectiveness*** *Linked evidence* Sensitivity Specificity Mean difference /limits of agreement Change in management
(Redline et al 1991) Roger Williams General Hospital, Rhode Island Hospital, Brigham and Women's Hospital, and Veterans Administration Hospital, the United States NR	Prospective case series Level IV diagnostic evidence CX P1 Q3 [QUADAS: 4.5/14] Q2 [NHMRC: 4/6]	***Inclusion*** Patients referred to a sleep laboratory for suspected sleep disturbance (n=24); or patients with obstructive or restrictive pulmonary diseases (n=7); or relatives of patients with OSA (n=16); or normal volunteers (n=4) ***Exclusion*** NR	N=51 Gender: M/F 37/14 Age: mean = 47.0 years BMI: mean = 29.6 kg/m^2 Nasal obstruction: NR	***Ref standard*** Laboratory-based PSG (manual scoring)	Home-based Edentec Monitoring System, model 4700 Scanner (Eden-Prairie, USA) Airflow (nasal/oral thermistry) + respiratory effort (thoracic) + oxygen saturation + heart rate + movement Manual scoring	Apnoea: no airflow, ≥10 s Hypopnoea: discernible airflow, ≥10 s, associated with oxygen desaturation ≥4%	***Effectiveness*** *Linked evidence* Diagnostic yield
(Reichert et al 2003) Sequoia Hospital, Sleep Disorders Center, the United States	Cross-classification study Level III-1 diagnostic evidence CX	***Inclusion*** Patients referred to a sleep laboratory by community physicians because of suspicious OSA, based on symptoms (including	N=51 Gender: M/F 38/13 Age: mean = 52 years (standard error: 2.1 years) BMI: mean = 30 kg/m^2 (standard error: 1.0 kg/m^2)	***Ref standard*** Laboratory-based PSG (manual scoring) ***Comparator***	Home-based NovaSom QSG™ (Sleep Solutions Inc., USA) Airflow (nasal and oral sound) + respiratory effort (thoracic) + oxygen saturation + heart rate +	Apnoea: no airflow, ≥10 s Hypopnoea: ↓ airflow ≥50%, ≥10 s, accompanied by oxygen desaturation ≥2%	***Effectiveness*** *Linked evidence* Sensitivity Specificity PPV

Study Location Study period	Study design and appraisal[a]	Inclusion/exclusion criteria	Study population	Reference standard and/or comparator	Index test	Respiratory event definition	Outcomes
NR	P1 Q2 [QUADAS: 11.5/14]	snoring, witnessed apnoea and excessive daytime sleepiness), scheduled for overnight in-lab PSG ***Exclusion*** NR	Symptom: Snoring: 30 (59%) Witnessed apnoea: 25 (49%) Daytime sleepiness: 20 (39%) Frequent awakenings: 5 (10%) Night-time gasping: 3 (6%) Unrefreshing sleep: 1 (2%) Nasal obstruction: NR	Laboratory-based NovaSom QSG™	snoring sound Auto scoring		NPV
(Ruiz-López et al 2009) The Pneumology Department, Arrixaca Hospital, Spain In 2006	Prospective case series Level IV diagnostic evidence CX (no comparison) P1 Q3 [QUADAS: 5.5/14]	***Inclusion*** Patients with evident snoring and witness apnoeas or scores of >9 on the ESS, carried out sleep studies at home in a pneumology department ***Exclusion*** Patients with no valid recording or inadequate duration in home-based sleep studies	N=189 Nasal obstruction: NR	Nil	Home-based Ambulatory polygraphy, BeasSC20 (Breas Medical AB, Sweden) Airflow (nasal pressure) + respiratory effort (thoracic and abdominal movements) + oxygen saturation + body position Manual scoring	Two ways: Apnoea: ↓ airflow (nasal pressure) >90%, ≥10 s Hypopnoea: ↓ airflow by nasal pressure or thoracic-abdominal movements >30%, ≥10 s, associated with oxygen desaturation ≥3% (4%) Desaturation: oxygen desaturation ≥3% (4%)	***Effectiveness*** *Linked evidence* Diagnostic yield
(Stepnowsky et al 2004) Health Services Research & Development	Retrospective case series Level IV	***Inclusion*** Adult patients (18+ years) referred for sleep apnoea diagnostic testing and	N=1091/1220 Gender: M/F 947 (87%) / 144 (13.2%) Age: 52.5±12.9 years	Nil	Home-based NovaSom QSG™ (Sleep Solutions Inc, Palo Alto, CA) Airflow (oronasal) +	Apnoea: no airflow, ≥10 s Hypopnoea: ↓ airflow >50%, ≥10 s and ≥4% oxygen desaturation	***Effectiveness*** *Linked evidence* Diagnostic yield

Study Location Study period	Study design and appraisal[a]	Inclusion/exclusion criteria	Study population	Reference standard and/or comparator	Index test	Respiratory event definition	Outcomes
Services, Veteran Affairs San Diego Healthcare System, San Diego, California USA	interventional evidence CX P1 Q3 [QUADAS: 6/14]	monitored for 3 nights for 3+ hours each night ***Exclusion*** NR	(range 18–100) BMI: 33.0±6.8 kg/m^2 (range 17.7–63.6) ESS: 10.7±6.1 (range 0–24) Referral from: Pulmonary medicine: 44% ENT: 20% Sleep medicine: 13% Other: 6% Neurology: 6% General Practice: 6% Internal Medicine: 6% Psychiatry: 0.2% Dental Medicine: 0.1% Nasal obstruction: NR		respiratory effort (thoracic and abdominal movement) + pulse oximetry (oxygen saturation + pulse rate) + snoring Automatic scoring		
(Tiihonen et al 2009) Department of Clinical Neurophysiology, Kuopio University Hospital and University of Kuopio, Kuopio, Finland NR	Prospective case series Level IV diagnostic evidence CX, P1 Q3 [QUADAS: 6/14]	***Inclusion*** Clinical patients with suspected sleep disorders, especially OSA, judged to require a sleep study ***Exclusion*** NR	N=275 Gender: M/F 193/82 Novel device: M/F 77/29 Embletta: M/F 116/53 Age: Novel device: 44.6±13.0 years Embletta: 47.4±11.3 years BMI: Novel device: 27.8±5.9 kg/m^2 Embletta: 29.0±4.7 kg/m^2	***Comparator*** Home-based Level 3 sleep study (Embletta) n=169 *Patient set-up of device* Manual scoring	Novel Level 3 ambulatory device n=106 Airflow (oronasal) + respiratory effort (thoracic and abdominal movement) + pulse oximetry (pulse rate + oxygen saturation + body position + snoring *Patient set-up of device*	Apnoea: airflow <20% of reference amplitude, ≥10 s Hypopnoea: airflow <70% of reference amplitude + oxygen desaturation ≥4% within 20 s	***Effectiveness*** *Linked evidence* Diagnostic yield

Study Location Study period	Study design and appraisal[a]	Inclusion/exclusion criteria	Study population	Reference standard and/or comparator	Index test	Respiratory event definition	Outcomes
			Technical failure in 48 (17.5%) Nasal obstruction: NR		Manual scoring		
(Tomlinson & John Gibson 2006) A regional sleep investigation centre, the United Kingdom NR	Retrospective case series Level IV interventional evidence CX P1 Q2 [NHS CRD: 4/6]	***Inclusion*** Patients having snoring with unrefreshing sleep or excessive daytime somnolence (ESS score >10), with self-reported nocturnal choking or confirmed witnessed apnoeas, with a raised BMI (>30) or collar size >42.5 cm, referred to a regional investigation centre, diagnosed with OSA by a home-based sleep study, and treated by CPAP for longer than 3 months ***Exclusion*** NR	N=118 Gender: M/F 106/12 Age: mean = 43.9 years (range 19–67 years) BMI: mean = 34.8 kg/m^2 (range 21–55 kg/m^2) ESS score: mean = 15.4 (range 6–24) Nasal obstruction: NR	Nil	Home-based AutoSet Portable II Plus (ResMed Ltd, UK) Airflow (nasal pressure) + respiratory effort (thoracic and abdominal movement) + pulse oximetry + body position + snoring Auto scoring CPAP (ODI ≥5)	Apnoea: no airflow, ≥10 s Hypopnoea: ↓ airflow >50%	***Effectiveness*** *Direct evidence* Change in symptoms
(Tonelli de Oliveira et al 2009) Brazil NR	Cross-classification study Level III-1 diagnostic evidence CX P2	***Inclusion*** Patients referred for evaluation of suspected OSA, aged above 18 years old ***Exclusion*** Patients with severe	N=121 Gender: M/F 84/37 Age: 45 ±11 years BMI: 28.7 ±5.4 kg/m^2 ESS score: 11 ±5 Comorbidities: 34/121 (28%)	***Ref standard*** Laboratory-based PSG (manual scoring)	Home-based Somnocheck (Weinmann GmbH, Germany) Airflow (nasal) + respiratory effort (thoraco-abdominal movement) + oximeter + body position Auto scoring	Apnoea: no airflow, ≥10 s Hypopnoea: ↓ airflow ≥50% or any discernable ↓ airflow associated with arousal oxygen desaturation ≥3%	***Effectiveness*** *Linked evidence* AUC Sensitivity Specificity PPV NPV

Study Location Study period	Study design and appraisal[a]	Inclusion/exclusion criteria	Study population	Reference standard and/or comparator	Index test	Respiratory event definition	Outcomes
	Q1 [QUADAS: 13/14]	comorbidities (cancer, heart failure etc), with difficulties that would interfere with the sleep studies, living outside the metropolitan area, or pregnant women	Nasal obstruction: NR				LR+ LR– Mean difference / limits of agreement
(Whittle et al 1997) Sleep Laboratory, Respiratory Medicine Unit, Royal Infirmary of Edinburgh, the United Kingdom Feb 1994 – July 1996	Cross-classification study Level III-2 diagnostic evidence CX P1 Q2 [QUADAS: 10/14]	***Inclusion*** Patients referred to a sleep clinic for investigation of suspected SA ***Exclusion*** Patients physically or mentally incapable of using portable sleep study equipment unsupervised and no family assistance available, or with a clinical suspicion of cataplexy or periodic leg movement disorder	N=23 Gender: M/F 19/4 Age: 59±9 years BMI: 30±4 kg/m^2 Nasal obstruction: NR	***Ref standard*** Laboratory-based PSG (manual scoring)	Home-based Edentrace system, Model 3711 (Edentec Corporation, USA) Airflow (nasal/oral thermistor) + respiratory effort (thoracic) + oxygen saturation + ECG + body position Auto scoring	Apnoea: no airflow, >10 s Hypopnoea: ↓ respiratory movement >50%, >10 s	***Effectiveness*** *Linked evidence* Mean difference / limits of agreement Pearson correlation coefficient
	Cross-classification study Level III-2 diagnostic evidence CX P1 Q2 [QUADAS: 11/14]	***Inclusion*** Patients referred to a sleep clinic for investigation of suspected SA ***Exclusion*** Patients physically or mentally incapable of using portable sleep study equipment	N=150 Gender: M/F 130/20 Age: 48±13 years BMI: 31±5 kg/m^2 Control group (only in the change in management and cost comparison analysis) n=75 Gender: M/F 56/19	***Ref standard*** Laboratory-based PSG (manual scoring)	Home-based Edentrace system, Model 3711 (Edentec Corporation, USA) Airflow (nasal/oral thermistry) + respiratory effort (thoracic) + oxygen saturation + ECG + body position Manual scoring	Apnoea: no airflow, >10 s Hypopnoea: ↓respiratory movement >50%, >10 s	***Effectiveness*** *Linked evidence* Sensitivity Specificity PPV NPV LR+ LR– Pearson correlation

Study Location Study period	Study design and appraisal[a]	Inclusion/exclusion criteria	Study population	Reference standard and/or comparator	Index test	Respiratory event definition	Outcomes
		unsupervised and no family assistance available, or with a clinical suspicion of cataplexy or periodic leg movement disorder	Age: 49±14 years BMI: 33±10 kg/m^2 Nasal obstruction: NR				coefficient Additional studies Referral Time to diagnosis Treatment
Referral setting, Level 4 sleep study							
(Antic et al 2009)[c] Adelaide Institute for Sleep Health, Alfred Hospital and John Hunter Hospital, Australian March 2004 – Sep 2006	Prospective case series Level IV intervention evidence CX (no comparison) P1 Q 2 [NHS CRD: 4.5/6]	***Inclusion*** Patients referred with clinical suspicion of OSA, with ESS score ≥8, with history of snoring 'most nights' or 'every night', aged 18–75 years, willing to trial CPAP, and with ODI >27 ***Exclusion*** Patients with unstable cardiovascular diseases, with neuromuscular disease affecting or potentially affecting respiratory muscles; with moderate to severe respiratory disease or documented hypoxemia or awake SaO_2 <92%, or with psychiatric disease that limited the ability to give informed consent or complete the study	N=195 Group 1 n=100 Gender: M/F 72/28 Age: 49.9±1.2 years BMI: 35.1±0.7 kg/m^2 ESS score: 13.7±0.4 Neck circumference: 44.1±0.4 cm Group 2 n=95 Gender: M/F 72/23 Age: 50.3±1.3 years BMI: 34.0±0.6 kg/m^2 ESS score: 13.4±0.4 Neck circumference: 44.0±0.4 cm p>0.05 in all patient characteristics Nasal obstruction: NR Follow-up: 3 months	Nil	Home-based Masimo Radical Oximeter (Masino, USA) Oxygen saturation Manual scoring Group 1 (supervised by a specialist nurse experienced in sleep disorders and the management of patients receiving CPAP): home auto-titrating CPAP + fixed-pressure CPAP Group 2 (traditional physician-directed care): laboratory-based PSG + laboratory CPAP titration + fixed-pressure CPAP	Oxygen desaturation >2%	***Effectiveness*** *Direct evidence* Change in symptoms Change in disease-specific QoL

Study Location Study period	Study design and appraisal[a]	Inclusion/exclusion criteria	Study population	Reference standard and/or comparator	Index test	Respiratory event definition	Outcomes
(Ayappa et al 2004)[d] New York University July 2002 – June 2003	Cross-classification study Level III-1 diagnostic evidence CX P1 Q1 [QUADAS: 12/14]	***Inclusion*** Patients with a suspected OSA, presenting to a sleep disorder centre and healthy volunteers without any symptoms of sleepiness ***Exclusion*** NR	N=59/66 For the 56 patients with suspected OSA: Gender: M/F 35/21 Age: 24–72 years BMI: 38.2±8.7 kg/m^2 ESS score: 13±6 For the 10 healthy volunteers: Gender: M/F 3/7 Age: 23–36 years BMI: 23±4.0 kg/m^2 Nasal obstruction: NR	***Ref standard*** Laboratory-based PSG (manual scoring)	Hospital-based (n=52)or home-based (n=7) Portable Sleep Data Recorder (Pro-Tech, USA) (n=56) or Compumedics P2 System (Australia) (n=3) Airflow (nasal cannula) + oximetry + body position	Apnoea: ↓ airflow >90% Hypopnoea: ↓ airflow >50%, or ↓ airflow 20–50% followed by sudden resolution of the flow limitation shape and/or followed by oxygen desaturation >4%	***Effectiveness*** *Linked evidence* Sensitivity Specificity PPV NPV LR+ LR– Mean difference / limits of agreement
(Ayappa et al 2008)[e] New York University Sleep Disorders Center, the United States April 2005 – Aug 2006	Cross-classification study Level III-2 diagnostic evidence CX P1 Q2 [QUADAS: 11.5/14]	***Inclusion*** Patients with sleep complaints suggestive of sleep-disordered breathing, presenting to a sleep disorders centre for evaluation ***Exclusion*** Patients unable to read English or unable to wear any device on the forehead	N=77 Gender: M/F 60/17 Age: mean = 46 years (range 26–74 years) BMI: mean = 30 kg/m^2 (range 21–70 kg/m^2) Nasal obstruction: NR	***Ref standard*** Laboratory-based PSG (manual scoring)	Home-based ARES™ Unidorder Airflow (nasal pressure) + snoring sound + oxygen saturation + pulse rate + head movement + head position Auto scoring + manual editing	Apnoea: no airflow, ≥10 s Hypopnoea 4%: ↓ airflow >50%, accompanied by oxygen desaturation ≥3.5% and resaturation Hypopnoea 1%: ↓ airflow >50%, accompanied by oxygen desaturation and resaturation ≥1% and ≥1 surrogate arousal indicator	***Effectiveness*** *Linked evidence* Sensitivity Specificity LR+ LR–
(Baltzan et al 2000) Royal Victoria	Cross-classification study Level III-1 diagnostic	***Inclusion*** Patients with suspicion of OSA, scheduled to receive nocturnal PSG in a sleep laboratory	N=66/97 For the total 97 patients: Gender: M/F 72/25 Age: 51.8±14.6 years	***Ref standard*** Laboratory-based PSG (manual scoring)	Home-based OxiFlow Airflow (oronasal thermistor) + oxygen saturation (finger	Apnoea: no airflow, ≥10 s Hypopnoea: 1) ↓ airflow ≥50% accompanied by oxygen	***Effectiveness*** *Linked evidence* AUC Sensitivity

Study Location Study period	Study design and appraisal[a]	Inclusion/exclusion criteria	Study population	Reference standard and/or comparator	Index test	Respiratory event definition	Outcomes
Sleep Laboratory, Canada Sep 1996 – March 1997	evidence CX P1 Q1 [QUADAS: 12/14]	***Exclusion*** Patients with severe OSA and studied by PSG with split-night protocols or during the daytime	BMI: 28.4±6.2 kg/m^2 ESS score: 9.6±5.1 Symptoms: Habitual snoring: 82 (85%) Witnessed apnoea: 57 (59%) Nasal obstruction: NR		pulse oximeter) Auto scoring	desaturation ≥4%; 2) ↓airflow ≥25% accompanied by oxygen desaturation ≥4%; 3) ↓airflow ≥20% accompanied by oxygen desaturation ≥4%; 4) ↓airflow ≥50% accompanied by oxygen desaturation ≥2%; or 5) ↓airflow ≥25% accompanied by oxygen desaturation ≥2%	Specificity Pearson correlation coefficient
(Bar et al 2003) The clinic sleep laboratory of the Technion Sleep Medicine Centre, Israel NR	Prospective case series Level IV diagnostic evidence CX P1 Q3 [QUADAS: 6/14]	***Inclusion*** Patients with suspected OSA, referred to a sleep laboratory, and healthy adult volunteers, without complaints of snoring or daytime sleepiness ***Exclusion*** Patients with permanent pacemaker, non-sinus cardiac arrhythmias, peripheral vasculopathy or neuropathy, severe lung disease, status postbilateral cervical or thoracic sympathectomy, finger deformity that precludes adequate	N=14/102 In the total 102 patients: Gender: M/F 78/24 Age: 41.4±15.2 years BMI: 26.8±5.5 kg/m^2 ESS score: 8.3±5.8 Nasal obstruction: NR	Nil	Home-based Watch_PAT 100 (Itamar Medical Ltd., Israel) + Nonin OEM 2 8000 J pulse oximetry (Nonin, Sweden) Arterial pulse wave volume, heart rate, oxygen saturation, wrist activity Auto scoring	↓ PAT, associated with ↑ heart rate or wrist activity; ↓ arterial pulse wave volume, associated with oxygen desaturation ≥3%; or oxygen desaturation ≥4%	***Effectiveness*** *Linked evidence* Diagnostic yield

Study Location Study period	Study design and appraisal[a]	Inclusion/exclusion criteria	Study population	Reference standard and/or comparator	Index test	Respiratory event definition	Outcomes
		sensor application, using α-adrenergic receptor blockers, or alcohol or drug abuse during the last 3 years					
(Berry et al 2008) Malcolm Randall VAMC Medical Center, the United States NR	Prospective cohort study Level III-2 interventional evidence C1 P1 Q3 [NHMRC: 3.5/6]	***Inclusion*** Patients referred for a sleep study for suspected OSA, with high risk of moderate to severe OSA (with daytime sleepiness (ESS ≥12) and the presence of ≥2 of the following: loud habitual snoring, witnessed apnoea/gasping or treatment for hypertension) ***Exclusion*** Patients with moderate to severe CHF, moderate to severe chronic obstructive pulmonary disease, awake hypercapnia, neuromuscular disease, or cataplexy, with significant symptoms of restless legs syndrome, using nocturnal oxygen or daily potent narcotics, with uncontrolled psychiatric disorder, having night-shift or	N=79 Watch_PAT100 group: n=40 Gender: M/F 34/6 Age: 50.9±11.4 years BMI: 35.2±5.7 kg/m^2 ESS score: 16.4±4.4 PSG group: n=39 Gender: M/F 35/4 Age: 54.8±11.9 years BMI: 35.5±11.2 kg/m^2 ESS score: 16.6±3.7 Nasal obstruction: NR	***Comparator*** Laboratory-based PSG CPAP (laboratory-based titration)	Home-based Watch_PAT100 (Itamar Medical, Israel) Peripheral arterial tone (PAT) + oxygen saturation + heart rate + actigraphy Auto scoring APAP (home-based titration) (6 weeks)	↓ PAT accompanied by ↑ heart rate and changes in oxygen saturation (using a specific algorithm)	***Effectiveness*** *Linked evidence* Change in symptoms Change in QoL RDI

Study Location Study period	Study design and appraisal[a]	Inclusion/exclusion criteria	Study population	Reference standard and/or comparator	Index test	Respiratory event definition	Outcomes
		rotating shiftwork, or with a history of receiving diagnostic study for a sleep disorder or previous treatment with CPAP or upper airway surgery					
(Fietze et al 2004) Centre of Sleep Medicine, Charité–Universitätsmediz in Berlin, Germany NR	Cross-classification study Level III-1 diagnostic evidence CX P1 Q2 [QUADAS: 10.5/14]	***Inclusion*** Patients referred to a sleep centre with possible OSA, with self-reported daytime sleepiness (ESS score >10) or two other major symptoms of OSA, with an ODI of 5–30 on the initial home recording ***Exclusion*** Patients with daily alcohol consumption >0.5 g alcohol/kg body weight	N=35 Gender: M/F 32/3 Age: 58±11 years BMI: 26±3 kg/m^2 Nasal obstruction: NR	***Ref standard*** Laboratory-based PSG (manual scoring)	Home-based Portable MESAM IV device (MAP) Finger pulse oximetry + heart rate + ECG (single-lead) + respiratory sound + body position Hooked up by trained technicians Manual scoring	Oxygen desaturation ≥3% with absence of moving artefacts and irrespective of co-existing changes in snoring or heart rate	***Effectiveness*** *Linked evidence* Sensitivity Specificity PPV NPV LR+ LR– Spearman correlation coefficient
(Fletcher et al 2000) The sleep disorders clinics, Veterans Affairs Medical Center and University of Louisville, Hospital, the United States	Prospective case series Level IV interventional evidence CX (no comparison) P1 Q2 [NHS CRD: 4/6]	***Inclusion*** Patients with a history of excessive daytime sleepiness, with heavy snoring, with witnessed apnoea if bed partner information was available ***Exclusion*** Patients with complicating medical	N=63 Patients completing diagnostic and APAP titration studies sufficient to establish a diagnosis of OSA and effective treatment pressure (OSA-TIT): n=35 Age: 54.2±1.7 years BMI: 36.4±1.7 kg/m^2 ESS score: 16.6±0.6	Nil	Home-based CPAP nasal mask + finger oximeter + chest belt Airflow (nasal) + oxygen saturation + body position Manual scoring and auto scoring Intervention: APAP	Apnoea: ↓ airflow >85%, ≥10 s Hypopnoea: ↓ airflow >40%	***Effectiveness*** *Direct evidence* Change in symptoms Change in RDI Additional sleep studies

Study Location Study period	Study design and appraisal[a]	Inclusion/exclusion criteria	Study population	Reference standard and/or comparator	Index test	Respiratory event definition	Outcomes
NR		illnesses or acute decompensation requiring hospitalisation, with a previously established diagnosis of OSA, or with suspected complicating sleep disorders, such as narcolepsy or restless legs syndrome	CQ score: 40.3±1.4 Patients with unsatisfactory results in home diagnostic study to establish a diagnosis of OSA (UNSAT-DIAG): n=9 Age: 48.9±0.3 years BMI: 35.5±3.4 kg/m^2 ESS score: 12.0±1.8 CQ score: 38.2±3.3 Patients with sufficient diagnostic study results showing ODI <10 (OSA-NEG): n=9 Age: 45.2±3.2 years BMI: 34.0±2.4 kg/m^2 ESS score: 15.0±1.9 CQ score: 39.6±1.5 Patients with OSA who did not complete sufficient APAP titration studies to establish an effective CPAP treatment pressure (OSA-UNTIT): n=10 Age: 49.3±2.9 years BMI: 35.6±2.4 kg/m^2 ESS score: 16.6±1.6 CQ score: 39.1±2.3				

Study Location Study period	Study design and appraisal[a]	Inclusion/exclusion criteria	Study population	Reference standard and/or comparator	Index test	Respiratory event definition	Outcomes
			No significant difference in the patient parameters among the four groups (p>0.001), except in age between OSA-TIT and UNSA-DIAG groups; and in ESS score between OSA-TIT and OSA-UNTIT				
(Golpe et al 1999) The Sleep Unit and the Respiratory Section, University Hospital Marqués de Valdecilla, Spain July 1993 – Feb 1998	Retrospective cohort study—cross-classified Level III-2 diagnostic evidence CX P1 Q1 [QUADAS: 12/14]	***Inclusion*** Patients with suspected OSA, referred to a sleep unit, undergoing both home oximeter and PSG, with two of the following symptoms: snoring, witnessed apnoeas, and daytime sleepiness ***Exclusion*** Patients with inadequate oximetry data (poor signals, artefacts etc) or losing more than 10% of their body weight and reporting resolution of their symptoms	N=116 Gender: M/F 104/12 Age: 50±13 years BMI: 29.6±6.4 kg/m^2 Mean AHI 23.7±24.7 Comorbidities: COPD (FEV1 <80% of predicted value and FEV1/VC <70%): 18 (16%) Diurnal arterial oxygen tension: 79.3±23.7 mmHg Nasal obstruction: NR	***Ref standard*** PSG (manual scoring)	Home-based Finger oximeter, AVL-Minolta Pulsox 7 Oxygen saturation Patient's own set-up of the equipment Auto scoring	1) Oxygen desaturation ≥4%, ≥10 s (DI4%) 2) Oxygen resaturation ≥3%, ≥10 s (RI3%) 3) Oxygen saturation <90% (cumulative percentage of time at saturations <90%) (CT_{90}%)	***Effectiveness*** *Linked evidence* AUC Sensitivity Specificity PPV NPV Mean difference / limits of agreement
(Golpe et al 2002) The Sleep Disorders Unit, Marqués de Valdecilla University	Cross-classification study Level III-1 diagnostic and Level III-2 interventional evidence	***Inclusion*** Patients with suspected sleep apnoea/hypopnoea syndrome referred to sleep unit, living within 30 km of the unit. All had at least two of the	N=55/59 Gender: M/F 53/2 Age: 52.7±13.3 years BMI: 30.3±4.6 kg/m^2 Nasal obstruction: NR	***Ref standard*** Attended laboratory-based PSG (manual scoring)	Home-based Apnoescreen I (CNS-Jaeger, Hochberg, Germany) Airflow (oronasal thermistor) + body position + wrist actimetry + pulse oximetry (pulse rate and arterial oxygen saturation)	Apnoea: no airflow, ≥10 s Hypopnoea: discernible ↓ airflow ≥10 s accompanied by oxygen desaturation ≥4% and/or arousal AHI: average number of	***Effectiveness*** *Linked evidence* AUC Mean difference / limits of agreement Hypothetical change in management—

Study Location Study period	Study design and appraisal[a]	Inclusion/exclusion criteria	Study population	Reference standard and/or comparator	Index test	Respiratory event definition	Outcomes
Hospital, Spain NR	CX P1 Q1 [QUADAS: 14/14] Q2 [NHMRC: 4/6]	following symptoms: loud snoring, witnessed apnoeas and daytime drowsiness ***Exclusion*** Patients with physical or mental impairment that precluded use of the equipment			Automatic scoring + manual scoring Randomised Group 1 (n=28): Technician set-up of the equipment Randomised Group 2 (n=27): Patient's own set-up of the equipment	episodes of apnoea and hypopnoea per hour of sleep	alteration in treatment
(Gyulay et al 1993) Sleep disorders centre, Royal Newcastle Hospital, Australia NR	Cross-classification study Level III-1 diagnostic evidence CX P1 Q2 [QUADAS: 11/14]	***Inclusion*** Patients with suspected OSA, referred to a sleep disorders centre, with habitual snorers ***Exclusion*** Patients with significant chronic lung disease, living too far from the laboratory for overnight oximetry to be feasible, or having grossly abnormal oximetry	N=98 Gender: M/F 77/21 Age: 50.0±2.5 years BMI: 30.2±1.2 kg/m^2 Comorbidities: Obesity (BMI ≥30 kg/m^2): 47/98 (48%) Hypertension: 44/98 (45%) Nasal obstruction: NR	***Ref standard*** Laboratory-based PSG (manual scoring) ***Comparator*** Clinical assessment	Home-based Pulse oximeters, Model Biox 3700 (Ohmeda, USA) Oxygen saturation + pulse rate Auto scoring	Oxygen desaturation ≥2% (DI2), 3% (DI3), or 4% (DI4), and/or oxygen saturation <90%	***Effectiveness*** *Linked evidence* Sensitivity Specificity
(Jobin et al 2007) Laboratoire du sommeil, CHUM – Hôtel Dieu, Montréal, Québec, Canada March 2003 – May 2004	Cross-classification study Level III-2 diagnostic evidence CX P1 Q1 [QUADAS: 12/14]	***Inclusion*** Patients referred to a sleep clinic ***Exclusion*** Patients with inability to perform ambulatory PSG, history of neuromuscular disease, severe lung	N=94/104 Gender: M/F 62/32 Age: 49.3±1.1 (SEM) years (range 22–76 years) BMI: 30.5±0.8 (SEM) kg/m^2 (range 16.1–55.9 kg/m^2) Neck circumference: 39.9±0.4 (SEM) cm (range 31–53 cm)	***Comparator*** Level 3 home-based sleep study (Suzanne PSG Recording System, Nellcor Puritan Bennett (Melville) Ltd, Ottawa, Ontario, Canada)	Home-based Remmers Sleep Recorder, RSR (SnoreSat, SagaTech Electronics Inc, Calgary, Alberta, Canada) *Applied by patient* Pulse oximetry (oxygen	*Index test:* RDI: number of episodes/hour that arterial oxygen falls ≥4% below baseline *Comparator:* Apnoea: no airflow, ≥10 s Hypopnoea: discernible ↓ airflow >50% or <50% reduction in airflow +	***Effectiveness*** *Linked evidence* Diagnostic yield

Study Location Study period	Study design and appraisal[a]	Inclusion/exclusion criteria	Study population	Reference standard and/or comparator	Index test	Respiratory event definition	Outcomes
		disease, unstable coronary artery disease, referral for parasomnia	ESS: 11.7±0.5 (SEM) (range 0–21) Technical failure: 10 (9.6%) Nasal obstruction: NR	*Applied by patient* Airflow (nasal cannula) + respiratory effort (thoracic + abdominal) + body position + pulse oximetry (pulse rate and arterial oxygen saturation) + snoring Manual scoring	saturation + pulse rate) + snoring + body position Automatic scoring	oxygen desaturation ≥4% RDI: average number of episodes of apnoea and hypopnoea per hour of recording time	
(Nader et al 2006) MetroHealth Medical Center, the United States Jan 1999 – Aug 2004	Retrospective case series Level IV interventional evidence CX (no comparison) P1 Q2 [NHS CRD: 4/6]	***Inclusion*** Patients with suggestive of OSA by clinical history or physical examination, admitted to an academic centre, with overnight ODI ≥10, with no inpatient PSG, and with follow-up PSG as outpatient ***Exclusion*** Patients with failure to follow up for outpatient PSG, with a known diagnosis of OSA, without diagnostic oximetry, or refusing therapy	N=124 Comorbidities: Chest pain: 56 (45%) Cardiac arrhythmias: 3 (2%) CHF: 21 (17%) Shortness of breath: 28 (23%) COPD: 24 (19%) Asthma: 11 (9%) Pneumonia: 6 (5%) Stroke: 24 (19%) Seizure: 4 (3%) MVA: 2 (2%) PVD/cellulitis: 9 (7%) Renal failure: 5 (4%)	Nil	Hospital-based Portable pulse oximeters, Nellcor® NPB-290/NPB-295, (Pleasanton, USA) Oxygen saturation + pulse rate Auto + manual editing Treatment (decided at the discretion of the attending physician on the medical ward, the attendant pulmonary consult physician, or both): Group 1: auto-adjusting CPAP titration at hospital, then fixed CPAP pressure at home Group 2: no auto-adjusting CPAP titration and no CPAP	Oxygen saturation <90% and/or oxygen desaturation ≥3% ≥10 s	***Effectiveness*** *Direct evidence*: Change in ODI Time to diagnosis Time to commencement of treatment

Study Location Study period	Study design and appraisal[a]	Inclusion/exclusion criteria	Study population	Reference standard and/or comparator	Index test	Respiratory event definition	Outcomes
			Miscellaneous: 9 (7%) Nasal obstruction: NR Follow-up: Group 1: 77.2±14.4 days Group 2: 80.9±10.5 days		treatment		
(Noda et al 1998) Nagoya University Hospital, Japan NR	Case series Level IV diagnostic evidence CX (no comparison) P1 Q3 [QUADAS: 3.5/14]	***Inclusion*** Male patients with OSA diagnosed by standard PSG ***Exclusion*** NR	N=18 Gender: M/F 18/0 Age: 51.3±10.9 years BMI: 27.7±10.2 kg/m^2 AHI: 45.1±15.8 Comorbidities: Hypertension: 7 (39%) Left ventricular hypertrophy + hypertension: 4 (22%) Left ventricular hypertrophy + hypertension + old myocardial infarction: 1 (6%) Transient atrial fibrillation: 1 (6%) Nasal obstruction: NR	Nil	Home-based An Apnomonitor device (Chest MI, Co., Japan) Airflow (nasal) + tracheal sound + ECG Auto scoring	NR	***Effectiveness*** *Linked evidence* Diagnostic yield
(Olson et al 1999) University of Newcastle and	Cross-classification study—retrospective Level III-2 diagnostic	***Inclusion*** Patients suspected of OSA receiving home oximetry who also had a PSG	N=793 Gender: M/F NR Age: NR BMI: NR	***Ref standard*** Laboratory-based PSG (scoring NR)	Home-based Pulse oximetry (Biox 4700, Ohmeda Corp, Boulder, Co, USA)	Apnoea and hypopnoea not defined Relationship between (1)	***Effectiveness*** *Linked evidence* Sensitivity Specificity

Study Location Study period	Study design and appraisal[a]	Inclusion/exclusion criteria	Study population	Reference standard and/or comparator	Index test	Respiratory event definition	Outcomes
Sleep Disorders Centre, Royal Newcastle Hospital, Newcastle, NSW, Australia Jan 1994 – July 1997	evidence CX P2 Q3 [QUADAS: 7/14]	***Exclusion*** Not reported	ESS score: NR Nasal obstruction: NR		Oxygen saturation + pulse rate Scoring method NR	arterial oxygen saturation <90% greater than 1% of recording time (CT_{90}) and (2) Δ Index, and AHI investigated	LR+ LR– Spearman correlation coefficient
(Pang et al 2006) Georgia Sleep Center, the United States Oct–Nov 2004	Cross-classification study Level III-2 diagnostic evidence CX P1 Q2 [QUADAS: 11.5/14]	***Inclusion*** Patients referred to a sleep centre for attended overnight PSG ***Exclusion*** Not reported	N=37/39 In the total 39 patients: Gender: M/F 17/22 Age: 52.1±12.2 years BMI: 35.7±5.2 kg/m^2 ESS score: 14.9±3.5 Nasal obstruction: NR	***Ref standard*** Laboratory-based PSG (manual scoring)	Home-based SleepStrip Airflow (2 nasal and 1 oral thermistors) Auto scoring	Apnoea: ↓ airflow >88%, ≥10 s Hypopnoea: ↓ airflow >50%, ≥10 s	***Effectiveness*** *Linked evidence* Sensitivity Specificity Kappa coefficient
(Pittman et al 2004)[f] The clinical sleep laboratory of Brigham and Women's Hospital, the United States June 2002 – Dec 2002	Cross-classification study Level III-2 diagnostic evidence CX P1 Q2 [QUADAS: 11.5/14]	***Inclusion*** Patients with suspected OSA referred to a sleep laboratory ***Exclusion*** Patients with history of peripheral vascular disease, peripheral neuropathy, non-sinus cardiac rhythm, permanent pacemaker, severe lung disease, status-post bilateral cervical or thoracic sympathectomy, finger	N=29 Gender: M/F 21/8 Age: 43.2±10.8 years BMI: 33.9±7.1 kg/m^2 ESS score: 9.2±4.7 Nasal obstruction: NR	***Ref standard*** Laboratory-based PSG (manual scoring)	Home-based Watch_PAT (Itamar Medical Ltd., Israel) + Nonin 8000J pulse oximeter (Nonin Medical, Inc., USA) Arterial pulse wave volume, heart rate, oxygen saturation, wrist activity Auto scoring	↓ arterial pulse wave volume, associated with ↑ heart rate or wrist activity; ↓ arterial pulse wave volume, associated with oxygen desaturation ≥3%; or oxygen desaturation ≥4%	***Effectiveness*** *Linked evidence* AUC Sensitivity Specificity PPV PNV LR+ LR– Mean difference /limits of agreement Kappa coefficient

Study Location Study period	Study design and appraisal[a]	Inclusion/exclusion criteria	Study population	Reference standard and/or comparator	Index test	Respiratory event definition	Outcomes
		deformity that precluded adequate sensor application, or use of α-adrenergic receptor-blocking agents					
(Rollheim et al 1999) Vestfold Central Hospital and Haukeland University Hospital, Norway NR	Prospective case series Level IV diagnostic evidence CX P1 Q3 [QUADAS: 4.5/14]	***Inclusion*** Patients referred for suspected OSA, free from significant upper airway disease during the recordings ***Exclusion*** NR	N=11 Gender: 11/0 Age: mean = 49.7 years (range 30–68 years) BMI: mean = 27.1 kg/m^2 (range 21.5–33.1 kg/m^2) Neck circumference: mean = 41.5 cm (range 38–44 cm) Nasal obstruction: NR	Nil	Home-based: A non-specified device Airflow (upper airway pressure + oronasal thermistor) Scoring: unknown Hospital-based: Device measuring airway pressure and flow (not specified) Airflow (upper airway pressure + oronasal thermistor) Scoring: unknown	Apnoea: no airflow, ≥10 s Hypopnoea: ↓ airflow >50%, ≥10 s	***Effectiveness*** *Linked evidence* Diagnostic yield
(Ryan et al 1995) Birmingham Heartlands hospital, the United Kingdom	Cross-classification study Level III-2 diagnostic evidence CX P1 Q3 [QUADAS: 9.5/14]	***Inclusion*** Patients referred to a sleep clinic with suspected SA ***Exclusion*** Patients under 16 years of age, with an awake baseline oxygen saturation of ≤90%, or having known cardiorespiratory,	N=69 Gender: M/F 57/12 Age: 48±12 years BMI: 29.6±5.2 kg/m^2 Nasal obstruction: NR	***Ref standard*** Laboratory-based PSG (auto +manual scoring)	Home-based Minolta Pulsox-7 Oxygen saturation + pulse rate Manual scoring	Oxygen desaturation ≥4%	***Effectiveness*** *Linked evidence* Sensitivity Specificity PPV PNV LR+ LR–

Study Location Study period	Study design and appraisal[a]	Inclusion/exclusion criteria	Study population	Reference standard and/or comparator	Index test	Respiratory event definition	Outcomes
		neuromuscular, or skeletal disease					
(Schafer et al 1997) Department of Internal Medicine, University of Bonn, Germany NR	Cross-classification study Level III-1 diagnostic evidence CX P1 Q2 [QUADAS: 11/14]	***Inclusion*** Patients with suspected sleep-related breathing disorders, with daytime sleepiness, involuntary falling asleep, or nocturnal snoring, and referred to sleep laboratory by GP, pulmologists, and cardiologists *Exclusion* NR	N=114 Gender: M/F 100/14 Age: 56±11 years BMI: 30.8±6.8 kg/m^2 Lung function: FEV1: 2.9±0.9 L FEV1/FVC: 72.4±16.4% PaO_2: 70±8.7 mmHg Nasal obstruction: NR	***Ref standard*** Laboratory-based PSG (manual scoring)	Home-based MESAM IV device (MAP Medizintechnik, Martinsried) digital recording device Heart rate + oximeter + snoring sounds + body position Manual scoring	Oxygen desaturation ≥4% or 2%, accompanied by a visible change in heart rate	***Effectiveness*** *Linked evidence* Sensitivity Specificity PPV NPV
(Sériès et al 1993) Centre de Pneumologie, Hôspital Laval, Canada NR	Cross-classification study Level II diagnostic evidence CX P1 Q1 [QUADAS: 12/14]	***Inclusion*** Patients referred to a sleep clinic for suspected SA because of loud snoring, nocturnal choking and witnessed apnoea or awakening, bad sleep quality, and daytime sleepiness ***Exclusion*** NR	N=240 Gender: M/F 216/24 Age: 24–68 years BMI: mean = 31.7 kg/m^2 Nasal obstruction: NR	***Ref standard*** Laboratory-based PSG (manual scoring)	Home-based Biox IVA oximeter (Ohmeda, USA) Oxygen saturation + pulse rate Scoring: unknown	Oxygen desaturation followed by a rapid return to the baseline oxygen saturation	***Effectiveness*** *Linked evidence* Sensitivity Specificity PPV NPV LR+ LR–
(Takeda et al 2006) Division of Cardiovascular	Cross-classification study Level III-2 diagnostic evidence	***Inclusion*** Patients suffering from sleep disturbance, consulted the division of repertory medicine in	N=135 Gender: M/F 112/23 Age: 54.0±15.6 years BMI: 25.8±3.9 kg/m^2	***Ref standard*** Laboratory-based PSG (manual scoring)	Home-based Apnomonitor III (CHEST, Japan) Oxygen saturation + pulse rate	Oxygen desaturation ≥3%	***Effectiveness*** *Linked evidence* Sensitivity Specificity

Study Location Study period	Study design and appraisal[a]	Inclusion/exclusion criteria	Study population	Reference standard and/or comparator	Index test	Respiratory event definition	Outcomes
and Respiratory Medicine, Kobe University Hospital, Japan Dec 2000 – Aug 2005	CX P1 Q3 [QUADAS: 8.5/14]	a hospital ***Exclusion*** NR	ESS score: 9.46±4.53 Nasal obstruction: NR		Manual scoring		PPV NPV LR+ LR– Pearson correlation coefficient
(Westbrook et al 2005)[g] Murrieta Sleep Medical Clinic, Pomona Valley Hospital; and Long Beach Veteran's Administration Hospital, the United States NR	Cross-classification study Level III-2 diagnostic evidence CX P1 Q2 [QUADAS: 11/14]	***Inclusion*** Patients referred for PSG by specialist referrals or primary care physicians (n=210); or patients with hypertension, cardiovascular disease or diabetes (n=36); or presumably healthy subjects (n=53) ***Exclusion*** Patients aged <18 years or >70 years, or being pregnant	N=284/299 Gender: M/F 176/108 Age: mean = 4.9 years Nasal obstruction: NR	***Ref standard*** Laboratory-based PSG (manual scoring) ***Comparator*** Laboratory-based (attended) ARES Unicorder (auto scoring)	Home-based ARES Unicorder (advanced Brain Monitoring Inc., USA) Oxygen saturation + pulse rate + snoring + head position Auto scoring	If baseline oxygen saturation ≥95, both oxygen desaturation and resaturation of 2.2%, accompanied by arousal; if baseline oxygen saturation 93–95%, both oxygen desaturation and resaturation of ≥2.5%; if baseline oxygen saturation 91.5–93%, oxygen desaturation and resaturation of ≥3.0% and ≥2.7, respectively; if baseline oxygen saturation 88–91.5, oxygen desaturation and resaturation of ≥3.5% and ≥3.0, respectively; if baseline oxygen saturation 40–88%, oxygen desaturation and resaturation of ≥4.0% and ≥3.2, respectively	***Effectiveness*** *Linked evidence* Sensitivity Specificity PPV NPV Mean difference / limits of agreement Pearson correlation coefficient
(Williams et al 1991) VA Medical	Cross-classification study Level III-2 diagnostic	***Inclusion*** Patients referred to a sleep disorders clinic with suspected sleep	N=36/40 Gender: M/F NR Age: With OSA:	***Ref standard*** Laboratory-based PSG	Home-based Omeda Biox 3700 IV or Nellcor N100	Index test: OSA = oxygen desaturation ≥4%, and saturation to a value of	***Effectiveness*** *Linked evidence* Sensitivity Specificity

Study Location Study period	Study design and appraisal[a]	Inclusion/exclusion criteria	Study population	Reference standard and/or comparator	Index test	Respiratory event definition	Outcomes
Center, West Los Angeles; UCLA Sleep Disorders Center, Los Angeles, California, USA NR	evidence CX P2 Q2 [QUADAS: 10/14]	apnoea ***Exclusion*** NR	55.8±12.9 years Without OSA: 54.4±18.1 years BMI: With OSA: 29.1±8.8 kg/m^2 Without OSA: 21.4±4.5 kg/m^2 Nasal obstruction: NR		Pulse oximetry (oxygen saturation + pulse rate) Scoring method NR	≤90% Reference standard: AI: >10 apnoeas per hour; apnoeas defined as no airflow, ≥10 s	PPV NPV
(Whitelaw et al 2005) Departments of Medicine and Community Health Sciences, University of Calgary, Canada NR	Randomised controlled trial Level II interventional evidence C1 P1 Q3 [NHMRC: 1/3]	***Inclusion*** Patients referred by family doctors to a sleep centre, with a history suggesting OSA in association with somnolence or fatigue ***Exclusion*** Patients referred for non-respiratory sleep disorder as primary reason, without significant daytime symptoms, with serious comorbidity (heart failure, stroke, cor pulmonale, severe COPD, hypoventilation, etc), or with significant physiologic consequences of OSA	N=288 *SnoreSat group* n=156 Age: 46.9±9.7 years BMI: 31.8±5.6 kg/m^2 Neck circumference: 40.9±3.8 cm ESS score: 11.6±4.8 *PSG group* n=132 Age: 46.9±10.2 years BMI: 32.1±6.1 kg/m^2 Neck circumference: 41.0±3.6 cm ESS score: 11.6±4.4 (p>0.05) in all patient parameters Nasal obstruction: NR	***Comparator*** Laboratory-based PSG+ APAP	Home-based SnoreSat (SagaTech, Canada) Oxygen saturation Auto scoring Intervention: APAP	Oxygen desaturation ≥4%, ≥10 s	***Effectiveness*** *Direct evidence* Change in symptoms Change in disease-specific QoL Change in RDI (AHI)
(Wiltshire et al	Cross-classification	***Inclusion***	N=84	***Ref standard***	Home-based	Oxygen desaturation ≥4%	***Effectiveness***

Study Location Study period	Study design and appraisal[a]	Inclusion/exclusion criteria	Study population	Reference standard and/or comparator	Index test	Respiratory event definition	Outcomes
2001) Department of Respiratory Medicine, Bristol Royal Infirmary, the United Kingdom NR	study Level III-2 diagnostic evidence CX P1 Q3 [QUADAS: 9.5/14]	Patients referred from ENT, primary-care physician and other chest physicians for assessment of suspected SA using full polysomnography ***Exclusion*** NR	Nasal obstruction: NR	Laboratory-based PSG	Ohmeda Biox3740 (Ohmeda Co, USA) Oxygen saturation Auto scoring		*Linked evidence* Sensitivity Specificity PPV NPV LR+ LR– Mean difference / limits of agreement Pearson correlation coefficient
(Wong et al 2008) St. Vincent's Hospital, Australia NR	Cross-classification study Level III-1 diagnostic evidence CX P1 Q1 [QUADAS: 12/14]	***Inclusion*** Patients referred to a sleep clinic for suspected sleep-disordered breathing, due to have diagnostic polysomnography, aged 18–55 years ***Exclusion*** None	N=34 Gender: M/F 33/1 Age: 41.9±10.3 years BMI: 30.2±5.4 kg/m^2 ESS score: 11.9±4.7 Nasal obstruction: NR	***Ref standard*** Laboratory-based PSG (manual scoring)	Home-based Flow Wizard (DiagnoseIT, Australia) Airflow (nasal pressure) + snoring Auto scoring	Apnoea: no airflow, ≥10 s Hypopnoea: ↓ airflow ≥50%, ≥10 s	***Effectiveness*** *Linked evidence* AUC Sensitivity Specificity PPV NPV LR+ LR– Mean difference /limits of agreement

[a] Methods of quality assessment and explanations for terminology, eg CX, P1, Q3, are given in Table 7; [b] One of the authors, Mark H. Sanders, is a consultant to Respironics. The other author, Stuart F. Quan, provides intangible support to the SHHS; [c] One of the authors, Nick A. Antic, has received financial support for research in terms of equipment from Respironics and ResMed for a current study and Masimo. Another author, R. Doug McEvoy, received grants from the Respironics Sleep and Respiratory Foundation for an investigator-initiated multicentre trial. Equipment grants are also pending for the Respironics Foundation and ResMed for the same trials; [d] Three of the authors, Norman, Rapoport and Ayappa, receive support from Fisher & Paykel Healthcare, Pro-Tech instruments; [e] The study was supported by grants from Advanced Brain Monitoring and National Institute of Health. One of the authors, Ayappa, has received research support from Fisher & Paykel Healthcare and Korosensor. Another author, Norman, has received research support form Fisher & Paykel Healthcare. Rapoport has received research support form Fisher & Paykel Healthcare, Genzyme, Guidant Korosensor and St. Jude Medical, and has performed speaking engagements for Genzyme, Guidant, Respironics, ResMed and St. Jude Medical, and has consulted for Invacare, Sanofi-Aventis, Boehringer Ingelheim, and Restore Medical. Ayappa, Norman and Rapoport all hold US patents and intellectual property rights covering techniques and analysis algorithms for the diagnosis of OSA and techniques for administering CPAP; [f] Two of the authors, Pittman and White, are consultants for Itamar Medical Ltd., developer of the Watch_PAT device. Itamar Medical provided the funding necessary to perform the study. Subsequent to all data collection and initial data analysis, Pittman became an employee of Respironics Inc. White is also a consultant for Respironics Inc., WideMED Ltd., the Alfred Mann Foundation and Aspire Medical; [g] The authors, Westbrook, Cvetinovic, and Zavora are shareholders in Advanced Brain Monitoring, Inc.

AHI = apnoea–hypopnoea index; AUC = area under the curve; BMI = body mass index; CHF = congestive heart failure; COPD = chronic obstructive pulmonary disease; CPAP = continuous positive airway pressure; CQ = Cleveland Questionnaire; DBP = diastolic blood pressure; EEG = electroencephalography; ENT = ear, nose and throat; EMG = electromyogram; EOG = electrooculogram; ESS = Epworth Sleepiness Scale; FEV1 = forced expiratory volume in 1 second; FVC = forced vital capacity; GP = general practitioner; HF = heart failure; LVEF = left ventricular ejection fraction; LR+ = positive likelihood ratio; LR- = negative likelihood ratio; MLWHF = Minnesota Living With heart Failure; MVA = motor vehicle accident; NR = not reported; ODI = oxygen desaturation index; OSA = obstructive sleep apnoea; PaO_2 = partial pressure of oxygen in arterial blood; PAT = peripheral arterial tone; PSG = polysomnography; PVD = peripheral vascular disease; QoL = quality of life; RDI = respiratory disturbance index; SaO_2 = arterial oxygen saturation; SA = sleep apnoea; SAQLI = Sleep Apnea Quality of Life Index; SBP = systolic blood pressure; SDB = sleep-disordered breathing

Paediatric setting

Study Location Study period	Study design, and appraisal[a]	Inclusion/exclusion criteria	Study population	Reference standard and/or comparator	Index test	Respiratory event definition	Outcomes
Paediatric setting, Level 3 sleep study							
(Jacob et al 1995) Montreal Children's Hospital Aug 1992 – Oct 1994	Cross-classification study Level III-2 diagnostic evidence CX P1 Q2 [QUADAS: 11.5/14]	***Inclusion*** Children aged 2–12 years, with suspected OSA due to adenotonsillar hypertrophy, referred to an otolaryngology clinic or sleep laboratory ***Exclusion*** Children with severe disease requiring urgent treatment or receiving treatment before unattended sleep studies, with neurological abnormality, sharing beds with other siblings, having unsafe neighbourhood, or living far away from the hospital	N=21 Gender: M/F 13/8 Age: median: 7.0 years	***Ref standard*** Laboratory-based PSG	Home-based portable cardiorespiratory recorder Respiratory effort (thoracic and abdominal movement + respiratory inductive plethysmography) + ECG + oxygen saturation + pulse rate + pulse waveform Equipment was set up by a technician Manual scoring	Apnoea: ↓ respiratory movement ≥80%, ≥3 s or accompanied by oxygen desaturation ≥4% Hypopnoea: ↓ respiratory movement 50–80%, accompanied by oxygen desaturation ≥4%	***Effectiveness*** *Linked evidence* Sensitivity Specificity PPV NPV LR+ LR– Kappa coefficient Pearson correlation coefficient
(Patel & Davidson 2007) University of California, the United States April 1998	Prospective case series Level IV interventional evidence CX P1 Q3 [NHS CRD 2/6]	***Inclusion*** Patients with suspected OSA ***Exclusion*** NR	N=1/4 An 8-year-old boy, referred for surgical evaluation for snoring, with normal height, weight and BMI, with tonsil grade of 3+, without allergic rhinitis, breathing through his nose at night	Nil	Home-based Embletta PDS (Embla, USA) EEG + airflow (nasal pressure + oral thermistor) + respiratory effort (thoracic movements) + heart rate + oxygen saturation Auto scoring	NR	***Effectiveness*** *Direct evidence* Change in neuropsychologic results Change in RDI
(Poels et al 2003)	Prospective case series	***Inclusion***	N=24	Nil	Home-based	Apnoea: ↓ airflow ≥90%, ≥10 s	***Effectiveness***

Study Location Study period	Study design, and appraisal[a]	Inclusion/exclusion criteria	Study population	Reference standard and/or comparator	Index test	Respiratory event definition	Outcomes
Two academic clinics and seven general ORL clinics in the Netherlands Jan 2001 – Sep 2001	Level IV diagnostic evidence CX P1 Q3 [QUADAS: 5/14]	Children aged 2–7 years, scheduled for adenotonsillectomy for the treatment of habitual snoring and/or possible OSA, with a Brouillette OSA score of –1 or higher ***Exclusion*** Children with previous tonsil surgery, fever on the day of recording, neurologic or craniofacial abnormalities, or inability of caregivers to understand the Dutch language	Gender: M/F 12/12 Age: 4.2±1.6 years Median Brouillette OSA score: 2.54 Tonsil size: Not visible: 0 (0%) Extending to the pillars: 2 (8%) Enlarged, not meeting uvula: 11 (46%) 'Kissing' at midline: 11 (46%)		The HCRD, Embletta PDS (Flaga hf Medical Devices, Iceland) Airflow (nasal pressure) + respiratory effort (thoracic movements) + heart rate + oxygen saturation + body position Caregivers hooked up devices Manual scoring	Hypopnoea: ↓ airflow ≥50%, ≥10 s Desaturation: oxygen saturation <90% or oxygen desaturation ≥4%, ≥10 s	*Linked evidence* Diagnostic yield
(Zucconi et al 2003) Sleep Disorders Center, San Raffaele Scientific Institute and Hospital, Italy NR	Cross-classification study Level III-1 diagnostic evidence CX P1 Q2 [QUADAS: 11/14]	***Inclusion*** Children with a clinical and sleep history of highly suspected OSA, aged 3–6 years ***Exclusion*** NR	N=12 Gender: M/F 7/5 Age: 4.0±0.8 years BMI: 16.6±3.5 kg/m^2 Symptoms: Snoring onset: 18.7±11.3 months Familiarity for habitual snoring: 10 (83%) Excessive daytime sleepiness: 6 (25%) Failure to thrive: 3 (13%) Daytime irritability: 12 (100%)	***Ref standard*** Laboratory-based PSG (manual scoring)	Hospital-based POLY-MESAM (MAP, Germany) Airflow (oronasal thermistors) + respiratory effort (thoracic and abdominal) + snoring sound + ECG + pulse oximeter + body position Auto scoring and auto + manual editing	Apnoea: no airflow (not related to previous body movements), accompanied by oxygen desaturation >4% Hypopnoea: ↓ airflow >50%, accompanied by oxygen desaturation >4%	***Effectiveness*** *Linked evidence* Sensitivity Specificity PPV NPV Mean difference / limits of agreement Pearson correlation coefficient

Study Location Study period	Study design, and appraisal[a]	Inclusion/exclusion criteria	Study population	Reference standard and/or comparator	Index test	Respiratory event definition	Outcomes
			Recurrent upper airway infection: 12 (100%) Forced daytime oral respiration: 12 (100%)				
Paediatric setting, Level 4 sleep study							
(Brunetti et al 2001) Clinica Pediatric III, Italy NR	Cross-classification study Level III-2 diagnostic evidence CX P1 Q3 [QUADAS: 9.5/14]	***Inclusion*** Children with habitual snoring, with ODI >2 ***Exclusion*** NR	N=12 Gender: M/F 8/6 Age: 7.5±2.4 years (range 3.67 – 10 years) Oral breathing: >9/12	***Ref standard*** Laboratory-based PSG (scoring: unknown)	Home-based Vitalog HMS5000 (Markos srl, Italy) Oxygen saturation + heart rate + snoring + body position Scoring: unknown	Oxygen desaturation >4%	***Effectiveness*** *Linked evidence* Sensitivity Specificity PPV NPV LR+ LR–
(Castronovo et al 2003) I.R.C.C.S. Hospital San Raffaele, Italy NR	Prospective case series Level IV diagnostic evidence CX (no comparison) P1 Q3 [QUADAS: 4.5/14]	***Inclusion*** Children attending kindergartens, with habitual snoring ***Exclusion*** NR	N=154 Gender: M/F 89/65 Age: 3.9±0.9 years Weight: 17.4±3.5 kg Height: 104.3±3.5 cm Medical history: Allergies: 33 (21.4%) Upper airway infections: 93 (60.4%) Ear, nose and throat surgery: 22 (14.3%) Passive smoking: 80 (52.0%)	Nil	Home-based MESAM IV device Oxygen saturation + pulse rate + body position + snoring sound Manual scoring	Oxygen desaturation ≥4%	***Effectiveness*** Diagnostic yield

Study Location Study period	Study design, and appraisal[a]	Inclusion/exclusion criteria	Study population	Reference standard and/or comparator	Index test	Respiratory event definition	Outcomes
			Nocturnal mouth breathing: 130 (84.4%) Diurnal oral breathing: 96 (62.3%)				
(Kirk et al 2003) Alberta Lung Association Sleep Center, Foothills Hospital or Pediatric Sleep Laboratory, Alberta, Children Hospital Oct 2000 – Jan 2002	Cross-classification study Level III-1 diagnostic evidence CX P1 Q1 [QUADAS: 12.5/14]	*Inclusion* Children aged 4–18 years, with suspected OSA, referred to a paediatric sleep clinic by community general practitioners, paediatricians or otolaryngologists *Exclusion* Children with complex medical conditions (Down syndrome, Pierre Robin syndrome, cleft palate, cerebral palsy, craniofacial synostosis syndromes, neuromuscular disease, congenital heart disease, achondroplasia, myelomeningocele	N=58 Gender: M/F 32/26 Age: ≥13 years: 7 (12%) 8–12 years: 26 (45%) 1–7 years: 25 (43%)	*Ref standard* Laboratory-based PSG (manual scoring) *Comparator* Laboratory-based SnoreSat (auto scoring)	Home-based SnoreSat (SagaTech Electronics, Canada) Oxygen saturation Caregiver applied the sensor Auto scoring	Oxygen desaturation >3%, followed by an increase in oxygen saturation	*Effectiveness* *Linked evidence* Sensitivity Specificity PPV NPV LR+ LR–

[a] Methods of quality assessment and explanations for terminology, eg CX, P1, Q3, are given in Table 7.

BMI = body mass index; ECG = electrocardiography; EEG = electroencephalography; LR+ = positive likelihood ratio; LR- = negative likelihood ratio; NPV = negative predictive value; NR = not reported; ODI = oxygen desaturation index; OSA = obstructive sleep apnoea; PPV = positive predictive value; PSG = polysomnography; RDI = respiratory disturbance index.

Cost-effectiveness literature

Study Location Study period	Study design, and appraisal	Study population	Reference standard and/or Comparator	Index test	Respiratory event definition	Outcomes
(Chervin et al 1999) The United States NR	Decision tree analysis and Monte Carlo simulation Time horizon: 5 years	A hypothetical cohort of patients with suspected OSA Gender: M/F >1 Age: 60–69 years Comorbidities: cardiovascular diseases (in many patients)	*Comparators* Laboratory-based full night PSG No testing	Unattended sleep studies	NR	*Cost-effectiveness* Cost-effectiveness ratio (cost/QALY) Incremental cost-effectiveness ratio (cost/QALY)
(Deutsch et al 2006) The United States NR	Decision analytic model, Markov cycle and Monte Carlo simulation Time horizon: 5 years 3rd Party Payer perspective	A hypothetical cohort of patients suspected of having OSA. Gender: M/F: 85/15 Age: 30–64 years	*Comparators* Laboratory-based full night PSG Laboratory-based split night PSG	Unattended home partial sleep monitoring	AHI/RDI ≥10	*Cost-effectiveness* Cost-effectiveness ratio (Cost/QALY) Incremental cost-effectiveness ratio (cost/QALY)
(Reuveni et al 2001) Israel NR	Modelled analysis in Israeli health system	A hypothetical cohort of patients suspected of having OSA	*Comparator* Laboratory-based PSG Attended partial sleep monitoring study	Unattended partial sleep monitoring study	NR	*Cost-effectiveness* Diagnostic decision analysis

AHI = apnoea–hypopnoea index; NR = not reported; OSA = obstructive sleep apnoea; PSG = polysomnography; QALY = quality-adjusted life year; RDI = respiratory disturbance index

Appendix D Excluded studies

Not a study, a systematic review, or a meta-analysis (44)

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Appendix E Additional results of assessment

Table 52 Diagnostic yield of unattended sleep studies in a non-specialised unit setting

Study	Evidence level and quality	Population	Index test	Respiratory event definition	Diagnostic yield
Level 3 sleep study					
(Yin et al 2005)	Prospective case series Level IV diagnostic evidence CX, P1 Q3 [QUADAS: 5/14]	62 patients with suspected OSA	Home-based Stardust II (auto scoring)	Apnoea: ↓ airflow >80%, ≥10 s Hypopnoea: ↓ airflow >50%, accompanied by oxygen desaturation ≥3%, ≥10 s	RDI: mean = 35.5 ± 19.0 AI: mean = 18.2±14.5 HI: mean = 17.3±10.0
			Home-based Stardust II (manual scoring)		RDI: mean = 25.3±21.4 (p<0.001) AI: mean = 19.7±21.4 (p>0.05) HI: mean = 5.6±4.5 (p<0.001)
Level 4 sleep study					
(Martinez et al 2005)	Retrospective case series Level IV diagnostic evidence CX, P1 Q3 [QUADAS: 8/14]	100 patients with suspected OSA randomly selected from 325 medical records	Home-based Pulse oximeter - 2500 PalmSAT	Oxygen desaturation events >4%	ODI >5: 52/100 (52%)
				Oxygen saturation <90% (cumulative time with oxygen saturations <90%) (CT_{90})	CT_{90} >1%: 49/100 (49%)
(Fietze et al 2000)	Prospective case series Level IV diagnostic evidence CX, P1 Q3 [QUADAS: 4.5/14]	192 patients with cardiac pacemaker	Home-based MESAM IV device	Oxygen desaturation >4%	ODI: mean = 9.13±11.9 ODI ≥5: 92/192 (47.9%) ODI ≥10: 63/192 (32.3%)
(Saeki et al 1999)	Prospective case series Level IV diagnostic evidence CX, P1 Q3 [QUADAS: 3.5/14]	6 patients with acromegaly and suspected OSA	Hospital based Pulsox-5	Oxygen saturation <90% and/or oxygen desaturation ≥4%	ODI: mean = 29.1±15.4 (range 7.8–45.5) ODI ≥5: 6/6 (100.0%) ODI ≥15: 5/6 (83.3%)

AI = apnoea index; HI = hypopnoea index; ODI = oxygen desaturation index; OSA = obstructive sleep apnoea; RDI = respiratory disturbance index

Table 53 Diagnostic yield of unattended sleep studies in a referral setting

Study	Evidence level and quality	Population	Index test	Respiratory event definition	Diagnostic yield
Level 2 study					
(Abdenbi et al 2002)	Prospective case series	25 patients with	Home-based CID 108 and	Apnoea: ↓ airflow ≥90%	AHI >15: 17/25 (68.0%)

Study	Evidence level and quality	Population	Index test	Respiratory event definition	Diagnostic yield
	Level IV diagnostic evidence CX, P1 Q3 [QUADAS: 5.5/14]	suspected OSA	CID 102	Hypopnoea: ↓ airflow 30–90%, accompanied by oxygen desaturation ≥3%	
(Fry et al 1998)	Prospective case series Level IV diagnostic evidence CX, P1 Q3 [QUADAS: 5/14]	16/77 patients with suspected sleep disordered breathing	Laboratory-based unattended DigiTrace Home Sleep System	Apnoea: no airflow, ≥10 s Hypopnoea: noticeable ↓ airflow, ≥10 s, associated with oxygen desaturation >2% or EEG arousal	AHI: mean = 29.7
(Mykytyn et al 1999)	Prospective case series Level IV diagnostic evidence CX, P1 Q3 [QUADAS: 5/14]	10 with suspected OSA	Laboratory-based (unattended) Compumedics PS1-Series Portable Sleep System	Apnoea: no airflow, ≥10 s Hypopnoea: ↓ airflow or thoraco-abdominal movement ≥50%, ≥10 s	AHI: mean = 22
(Escourrou et al 2000)	Prospective case series Level IV diagnostic evidence CX, P1 Q3 [QUADAS: 4/14]	14 patients with suspected OSA	Home-based ambulatory PSG	NR	AHI: 1st night: mean = 46±32 2nd night: mean = 38±39 (p>0.05, Paired t-test)
Level 3 sleep study					
(Jobin et al 2007)	Cross-classification study Level III-2 diagnostic evidence CX, P1 Q1 [QUADAS: 12/14]	94 patients referred to a sleep clinic	Home-based sleep study (Suzanne PSG Recording System)	Apnoea: no airflow, ≥10 s Hypopnoea: discernible ↓ airflow >50% or <50% reduction in airflow + oxygen desaturation ≥4%	RDI: mean = 12.9 (range 5.4–28) RDI ≥5: mean = 9.9±1.0 (SEM)
(Davidson et al 1999)	Prospective case series Level IV diagnostic evidence CX, P1 Q3 [QUADAS: 7/14]	100 consecutive adult patients suspected of sleep apnoea syndrome who were referred to ENT clinic	Home-based AutoSet Recorder	Apnoea: no nasal airflow, ≥10 s Hypopnoea: ↓ nasal airflow ≥50%	AHI ≥5: 93% AHI ≥10: 84% AHI ≥15: 71%
(Lloberes et al 2001)	Prospective case series Level IV evidence	32 consecutive patients referred to outpatient	Home-based or laboratory-based Sibel-Home 300	Apnoea: no oronasal airflow, ≥10 s Hypopnoea: discernible ↓ in airflow ≥10 s, followed by	AHI: mean = 29.8±25.0

Study	Evidence level and quality	Population	Index test	Respiratory event definition	Diagnostic yield
	CX, P1 Q3 [QUADAS: 7/14]	sleep clinic for clinically suspected sleep apnoea/hypopnoea syndrome	Laboratory-based (unattended) Sibel-Home 300	≥3% ↓ SaO_2	AHI: mean = 30.0±26.5
(Stepnowsky et al 2004)	Retrospective case series Level IV interventional evidence CX, P1 Q3 [QUADAS: 6/14]	1091 adult patients (18+ years) referred for sleep apnoea diagnostic testing	Home-based NovaSom QSG™	Apnoea: no airflow, ≥10 s Hypopnoea: ↓ airflow >50%, ≥10 s and ≥4% oxygen desaturation	AHI >5: 85.3–87.0%[a] AHI >10: 86.0–86.8%[a] AHI >15: 86.5–87.5%[a]
(Tiihonen et al 2009)	Prospective case series Level IV diagnostic evidence CX, P1 Q3 [QUADAS: 6/14]	275 patients referred to a sleep clinic	Home-based sleep study (Embletta) n=169	Apnoea: airflow <20% of reference amplitude, ≥10 s Hypopnoea: airflow <70% of reference amplitude + oxygen desaturation ≥4% within 20 s	RDI <5: 49.1% RDI 5–15: 26% RDI 16–29: 11.8% RDI ≥30: 13%
			Novel Level 3 ambulatory device n=106		RDI <5: 51.9% RDI 5–15: 25.5% RDI 16–29: 8.5% RDI ≥30: 14.2%
(Ruiz-López et al 2009)	Prospective case series Level IV diagnostic evidence CX, P1 Q3 [QUADAS: 5.5/14]	189 patients with suspected OSA	Home-based BeasSC20 device	Apnoea: ↓ airflow >90%, ≥10 s Hypopnoea: ↓ airflow or thoraco-abdominal movements >30%, ≥10 s, associated with oxygen desaturation ≥3%	RDI: mean = 37.9±26.1 [95% CI: 34.2, 41.7] (range 0.4–105)
				Apnoea: ↓ airflow >90%, ≥10 s Hypopnoea: ↓ airflow or thoracic-abdominal movements >30%, ≥10 s, associated with oxygen desaturation ≥4%	RDI: mean = 30.2±25.7 [95% CI: 6.6, 33.9] (range 0.1–97.8)
				Oxygen desaturation ≥3%	ODI: 35.9±25.6 [95% CI: 32.3, 40.0] (range 0–108.2)
				Oxygen desaturation ≥4%	ODI: 26.1±19.4 [95% CI: 23.2, 28.8] (range 0–97.8)
(Liam 1996)	Prospective case series Level IV evidence CX, P2 Q3 [QUADAS: 5/14]	15 patients with suspected OSA	Hospital-based Edentrace II system	Apnoea: no airflow, ≥10 s Hypopnoea: ↓ airflow or respiratory movement ≥50%, ≥10 s, associated with oxygen desaturation ≥4%	RDI: mean = 60.8±30.9 RDI >5: 15/15 (100%) RDI >10: 15/15 (100%) RDI >15: 14/15 (93.3%) RDI >30: 11/15 (73.3%)

Study	Evidence level and quality	Population	Index test	Respiratory event definition	Diagnostic yield
(Faber et al 2002)	Prospective case series Level IV diagnostic evidence CX, P1 Q3 [QUADAS: 5/14]	54 patients with suspected OSA	Home-based AutoSet device	Apnoea: no airflow, ≥10 s Hypopnoea: ↓ airflow >30%, ≥10 s	RDI: mean = 44.1±21.5
			Hospital-based AutoSet device + acoustic reflectometry system, SRE2100	Apnoea: no airflow, ≥10 s Hypopnoea: ↓ airflow >30%, ≥10 s	RDI: mean = 45.5±22.0 (p=0.52)
(Davidson et al 2003)	Prospective case series Level IV diagnostic evidence CX, P2 Q3 [QUADAS: 5/14]	44 adult patients with sleep disordered breathing (primarily snoring) referred for sleep testing	Home-based AutoSet Portable II Plus (distributed as Embletta)	Apnoea: ↓ nasal airflow ≥75%, ≥10 s Hypopnoea: ↓ nasal airflow 50–75%, ≥8 s	AHI night 1 (n=44): mean = 19.8±15.0 AHI night 2 (n=44): mean = 19.5±15.1 AHI night 3 (n=23): mean = 17.3±13.0
(Redline et al 1991)	Prospective case series Level IV diagnostic evidence CX, P1 Q3 [QUADAS: 4.5/14]	29/51 patients with suspected sleep disturbance, obstructive or restricted pulmonary diseases, relatives of patients with OSA or healthy people	Home-based Edentec 4700 Scanner	Apnoea: no airflow, ≥10 s Hypopnoea: discernible airflow ↓, ≥10 s, associated with oxygen desaturation ≥4%	RDI: 1st night: mean = 18.4 ±27.7 2nd night: mean = 17.4 ±25.7 (p=0.21) (Paired Student's t-test (two-tailed))
(Bridevaux et al 2007)	Prospective case series Level IV diagnostic evidence CX, P1 Q3 [QUADAS: 3.5/14]	11 patients with suspected OSA	Home-based Embletta PDS®	Apnoea: no airflow, ≥10 s Hypopnoea: ↓ thoraco-abdominal movement ≥50%, ≥10 s	RDI: mean = 21.3±11.0 (range 1.9–43.1) RDI >5: 10/11 (90.9%) RDI >10: 10/11 (90.9%) RDI >15: 9/11 (81.8%) RDI >30: 2/11 (18.2%)
Level 4 sleep study					
(Jobin et al 2007)	Cross-classification study Level III-2 diagnostic evidence CX, P1 Q1 [QUADAS: 12/14]	94 patients referred to a sleep clinic	Home-based Remmers Sleep Recorder, RSR (SnoreSat)	Arterial oxygen falls ≥4% below baseline	RDI: mean = 8.8 (range 2.9–18.2) RDI ≥5: mean = 4.4±0.5 (SEM)
(Bar et al 2003)	Prospective case series Level IV diagnostic evidence CX, P1	14 patients with suspected OSA or healthy people	Home-based Watch_PAT 100	↓ arterial pulse wave volume, associated with ↑ heart rate or wrist activity; ↓ arterial pulse wave volume, associated with oxygen desaturation	Day 1: PAT index ≥5: 14/14 (100.0%) PAT index ≥15: 10/14 (71.4%) Day 2:

Study	Evidence level and quality	Population	Index test	Respiratory event definition	Diagnostic yield
	Q3 [QUADAS: 6/14]			≥3%; or oxygen desaturation ≥4%	PAT index ≥5: 12/14 (85.7%) PAT index ≥15: 9/14 (64.3%)
(Rollheim et al 1999)	Prospective case series Level IV diagnostic evidence CX, P1 Q3 [QUADAS: 4.5/14]	11 patients with suspected OSA	Hospital-based, a non-specified device	Apnoea: now airflow, ≥10 s Hypopnoea: ↓ airflow >50%, ≥10 s	RDI: mean = 19.2 RDI >10: 5/11 (45.5%)
			Home-based, a non-specified device		RDI: mean = 7.8 (p=0.03, Paired t-test) RDI >10: 6/11 (54.5%)
(Noda et al 1998)	Case series Level IV diagnostic evidence CX, P1 Q3 [QUADAS: 3.5/14]	18 patients with OSA	Home-based An Apnomonitor	NR	RDI: mean = 45.1±15.8

[a] Stable range across three nights of testing

AHI = apnoea–hypopnoea index; NR = not reported; ODI = oxygen desaturation index; OSA = obstructive sleep apnoea; PAT = peripheral arterial tone; RDI = respiratory disturbance index

Table 54 Diagnostic yield of unattended sleep studies in a paediatric setting

Study	Evidence level and quality	Population	Index test	Respiratory event definition	Diagnostic yield
Level 3 sleep study					
(Poels et al 2003)	Prospective case series Level IV diagnostic evidence CX, P1 Q3 [QUADAS: 5/14]	24 children with suspected OSA	Home-based HCRD, Embletta PDS	Apnoea: ↓ airflow ≥90%, ≥10 s Hypopnoea: ↓ airflow ≥50%, ≥10 s Desaturation: oxygen saturation <90% or oxygen desaturation ≥4%, ≥10 s	RDI >1: 7/7 (100%) RDI >5: 2/7 (28.6%) RDI >25: 1/7 (14.3%)
Level 4 sleep study					
(Castronovo et al 2003)	Prospective case series Level IV diagnostic evidence CX, P1 Q3 [QUADAS: 4.5/14]	122/154 children with suspected OSA	Home-based MESAM IV device	Oxygen desaturation ≥4%	ODI: 4.7±7.6 ODI ≥5: 23/109 (21.1%)

ODI = oxygen desaturation index; OSA = obstructive sleep apnoea; RDI = respiratory disturbance index

Appendix F Further scenarios for financial analysis

The data from the Australian Government indicated that 30 329 adults and 5567 children were diagnosed as OSA in 2006 – 07. The base case that 80% and 53% of adult patients and 100% and 42% of paediatric patients with suspected OSA would have their diagnosis confirmed by PSG at AHI ≥5 and ≥15, respectively, was chosen to simplify the financial analysis.

Further scenarios are costed in this section and outline the minimum and maximum cost implications of unattended sleep studies (Table 55 and Table 56).

Table 55 Total costs to the Australian healthcare system overall (diagnosis, minimum and maximum estimate)

Setting	Cost of proposed clinical pathway		Cost of current clinical pathway		Incremental cost[a]	
	Lower limit[b]	Upper limit[b]	Lower limit[b]	Upper limit[b]	Lower limit[b]	Upper limit[b]
AHI cut-off ≥5 in adults, ≥1 in children						
Non-specialised unit setting	$20 957 339	$39 542 149	$25 324 715	$47 782 481	–$4 367 376	–$8 240 332
Referral setting	$6 860 420	$17 258 918	$7 005 999	$17 625 155	–$145 579	–$366 237
Paediatric setting	$2 922 675	$4 713 992	$2 627 624	$4 238 103	$295 051	$475 889
Total	*$30 740 434*	*$61 515 059*	*$34 958 338*	*$69 645 739*	*–$4 217 904*	*–$8 130 680*
AHI cut-off ≥15 in adults, ≥5 in children						
Non-specialised unit setting	$25 557 730	$83 829 356	$30 883 799	$101 298 860	–$5 326 068	–$17 469 504
Referral setting	$8 366 366	$36 588 906	$8 543 901	$37 365 328	–$177 536	–$776 422
Paediatric setting	$3 896 900	$10 078 190	$3 503 499	$9 060 772	$393 401	$1 017 417
Total	*$37 820 996*	*$130 496 451*	*$42 931 199*	*$147 724 960*	*–$5 110 203*	*–$17 228 509*

[a] Negative incremental cost represents a cost saving resulting from the use of unattended sleep study in the diagnosis of OSA; positive incremental cost represents a net additional cost resulting from the use of unattended sleep study in the diagnosis of OSA; [b] Based on the lower estimate, base case and upper estimate in the plausible range for variables presented in Table 36.

Table 56 Total costs to the Australian Government (diagnosis, minimum and maximum estimate)

Setting	Cost of proposed clinical pathway		Cost of current clinical pathway		Incremental cost[a]	
	Lower limit[b]	Upper limit[b]	Lower limit[b]	Upper limit[b]	Lower limit[b]	Upper limit[b]
AHI cut-off ≥5 in adults, ≥1 in children						
Non-specialised unit setting	$14 738 279	$27 808 074	$18 112 024	$34 173 630	–$3 373 745	–$6 365 556
Referral setting	$4 788 038	$12 045 380	$4 942 732	$12 434 547	–$154 694	–$389 167
Paediatric setting	$2 073 478	$3 344 319	$1 897 269	$3 060 111	$176 209	$284 208
Total	*$21 599 795*	*$43 197 772*	*$24 952 025*	*$49 668 287*	*–$3 352 230*	*–$6 470 515*
AHI cut-off ≥15 in adults, ≥5 in children						
Non-specialised unit setting	$17 973 511	$58 953 117	$22 087 834	$72 448 095	–$4 114 323	–$13 494 978
Referral setting	$5 839 071	$25 536 205	$6 027 722	$26 361 239	–$188 651	–$825 034
Paediatric setting	$2 764 637	$7 149 923	$2 529 692	$6 542 306	$234 945	$607 617
Total	*$26 577 219*	*$91 639 244*	*$30 645 248*	*$105 351 640*	*–$4 068 029*	*–$13 712 396*

[a] Negative incremental cost represents a cost saving resulting from the use of unattended sleep study in the diagnosis of OSA; positive incremental cost represents a net additional cost resulting from the use of unattended sleep study in the diagnosis of OSA; [b] Based on the lower estimate, base case and upper estimate in the plausible range for variables presented in Table 36.

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