GUIDELINES FOR SLEEP STUDIES IN ADULTS

Prepared for the

Australasian Sleep Association

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Ching Li Chai-Coetzer, James Douglas (Chair), David McEvoy, Matthew Naughton, Alister Neill, Peter Rochford, John Wheatley, Christopher Worsnop.

Gaurika Bhalla (ASA secretariat)

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EXECUTIVE SUMMARY

This a consensus statement by a committee of experienced sleep practitioners on the indications and performance of sleep studies in adults. The report draws significantly from several reviews of this type, which are referenced throughout the document (3-8, 27, 37, 56) and randomised controlled trials. This guideline is designed to offer practical suggestions rather than act as an absolute standard. The guideline will require further modification as knowledge and technology continue to evolve. The committee was empanelled by the Australasian Sleep Association. Individual conflicts of interest were declared before the review began and are outlined in the Appendix. Individual conflict of interest statements were vetted by the ASA Board and were declared to all other committee members.

The report highlights the expanding and evolving nature of sleep investigations. It stresses the central role of the expert clinician in establishing the indications for sleep investigations and in the interpretation of sleep study results. A major concern regarding the performance of sleep studies is the lack of uniformity of definitions (e.g. definition of abnormal breathing events) between sleep-centres. This document seeks to improve standards within Australian and New Zealand by encouraging an evidenced-based approach to the performance of sleep testing, by promoting an internationally accepted and uniform set of definitions of sleep disordered breathing and by encouraging a high standard of laboratory quality control. This guideline provides indications for sleep studies and the methods for performing and reporting studies. The statement substantially revises and extends the 1994 and 2005 TSANZ/ ASA (1, 2) guideline on Sleep Studies.

The key changes are:

1. An extensively revised section on home-based and limited channel sleep studies. A clinical investigation flow chart is provided to inform readers of the options for diagnostic pathways for respiratory sleep disorders. The circumstances where the use of type 2, 3 & 4 sleep studies is not recommended has been incorporated into the document.

The committee notes:

a) for all types of sleep studies, the investigation is only one component of the diagnosis. Clinical history and examination are as important and are complementary to the sleep study.
b) that type 2 studies have good diagnostic accuracy (to both “rule-in” and “rule-out” OSA) in selected patients and are an alternative to a type 1 study.
c) increasing evidence supporting the use of some home-based type 3 and 4 type sleep studies to “rule-in” (but not “rule-out”) moderate to severe obstructive sleep apnoea. Such devices may therefore prove useful in populations where there is high prevalence obstructive sleep apnoea or when combined with validated sleep questionnaire(s) that enhance the pre-test probability of moderate to severe obstructive sleep apnoea. Additionally, research where type 3 & 4 studies have been used to rule in OSA have often been in carefully selected patient populations with minimal cardiorespiratory co-morbidities. The committee currently recommends that type 3 and 4 studies are used under the supervision of an accredited sleep physician who has a sound knowledge of the technical diagnostic capabilities and limitations of these devices plus access to type 1 and/ or 2 studies.
d) that type 1 studies remain an important option in the diagnostic armamentarium for sleep disorders ,

e) the use of a clinical tools appropriate for the patient population may help divide patients into high and low pre-test probability for moderate to severe OSA.
f) autotitrating positive airway pressure devices (APAP) in carefully selected populations are as effective as attended manual titration CPAP studies in determining optimal CPAP pressure.
g) there is no evidence to support “routine” in lab CPAP re-titration studies when the clinical response to CPAP treatment remains satisfactory.

2. Guidelines on the indications and performance of sleep studies in non-respiratory sleep disorders are included in the document. Specifically, the committee recommends that:
    a. sleep studies are not required for the routine assessment of isolated insomnia, restless legs syndrome or uncomplicated parasomnias if one of these conditions are considered the likely primary abnormality. Such conditions are usually diagnosed with confidence following careful history and examination.
    b. polysomnography be considered if there is a suspicion of overlapping disorders (e.g. co-existing sleep disordered breathing) or if, following careful clinical assessment, there is doubt about the diagnosis. It is recognised however that insomnia and OSA may co-exist in up to 30% of sleep clinic populations. (109)
    c. an expanded EEG and EMG montage plus continuous synchronised video recording is employed in cases of sleep movement or behaviour disorders that are violent or potentially dangerous, or where there is diagnostic uncertainty. These additional measurements can be helpful in distinguishing between a sleep related seizure disorder, REM behaviour disorder and NREM parasomnias.
    d. in lab polysomnography be performed in all cases of suspected primary hypersomnia or narcolepsy to rule out co-existing disorders such as OSA that can contribute to daytime sleepiness.
    e. the multiple sleep latency test (MSLT) is used as an aid in the diagnosis of patients suspected of narcolepsy or idiopathic hypersomnia.
    f. daytime tests which assess the ability to resist sleep such as the maintenance of wakefulness test (MWT) may be helpful in the management of sleepy patients, particularly for medicolegal and occupational driving purposes, or where there is a discrepancy between PSG findings and symptoms.

INTRODUCTION

The document examines the indications and standards for sleep studies under the following headings:

- Respiratory Sleep Disorders
- Movement and Behavioural Sleep Disorders
- Non-respiratory Disorders of Excessive Daytime Sleepiness
- Insomnia and Other Disorders Characterised by Insufficient Sleep

1. RESPIRATORY SLEEP DISORDERS

The need for common definitions and diagnostic methodologies has become evident, for both clinical and research purposes, particularly in the measurement of respiratory sleep disorders.

Historically, an important problem with respiratory sleep studies has been the lack of agreement on recording methods and on definitions of abnormal respiratory events. In 1999, an evidenced-based guideline on the measurement and scoring of respiratory events was published by the AASM (16) and commonly known as the "Chicago" recommendations. In 2007, scoring rules were subject to a major revision by the AASM (17) and constituted a major advance but contained important omissions and ambiguities, noted by the ASTA/ASA commentary 2010 (18). Many of these issues were clarified and addressed in the 2012 AASM update (119). It should be noted that these various rule sets for respiratory events have a significant impact on the measured AHI, which should be considered when using AHI cut-offs to define disease and disease severity. There are at least three definitions of hypopnoea, all of which may have a significant impact on the AHI obtained. Laboratories should routinely indicate which definitions they are employing for scoring of respiratory events.

It is evident that the burden of disease associated with sleep disorders is great, given their high prevalence and significant associated morbidities. There is pressure on specialized facilities throughout Australia and New Zealand to meet growing demands for diagnosis and treatment. As a result of the obesity epidemic (12, 13) and aging population, rates of OSA have increased. In 1993, the prevalence of moderate to severe OSA (AHI ≥ 15 events/hour) in the Wisconsin cohort was 9% for males and 4% for females. (11) The same group of researchers estimated the prevalence of OSA in the United States between the 2007-2010. (120) During this later period, among adults 30–70 years of age, approximately 13% of men and 6% of women have moderate to severe OSA using the same definitions for apnoea and hypopnoea. This increase in prevalence mandates the need to identify methods to reduce the cost and increase the availability of investigations for OSA. (9, 10).

Additionally, alternate models of care supported by high quality evidence have emerged in the Australian setting. These studies indicate that motivated and well trained health practitioners (sleep nurses (14) and general practitioners (15)) with appropriate sleep physician back-up and utilising type 4 sleep studies and APAP devices can deliver comparable care to traditional models (involving sleep physicians utilising type 1 studies) in *carefully* selected groups of patients with moderate to severe OSA.

1.1 Types of respiratory diagnostic sleep studies. (5)

Respiratory sleep studies may be divided into two broad *categories*:

• Polysomnography (type 1 & 2)
• Limited channel sleep studies (type 3 & 4)

In turn these studies may be *supervised* as follows:
• Attended
• Unattended

Their *duration* may be:
• Full night
• Split-night
• Restricted duration

Type 1
Polysomnography study (PSG) requires the continuous recording of multiple physiological variables to measure sleep architecture and cardio-respiratory function during sleep. This type of study is the reference standard against which other respiratory monitors are evaluated. There is a large body of evidence supporting type 1 sleep studies reliability and accuracy. There is some debate regarding whether type 1 sleep study represents the "gold standard" against which the other types of studies should be compared.

The signals routinely recorded include: two electroencephalogram (EEG) signals, bilateral electro-oculograms (EOGs), submental electromyography (EMG), electrocardiography (ECG), bilateral anterior tibial muscle activity, arterial O_2 saturation, sound, respiratory thoraco-abdominal movements, airflow (nasal pressure and oronasal thermocouples) and body position. Other variables may be additionally recorded such as digital video, transcutaneous CO_2, and oesophageal pressure (to assess respiratory effort). A Type 1 study refers to a laboratory based PSG.

PSG allows measurement of sleep stage and accurate quantification of respiratory events (against time spent asleep). REM sleep is frequently associated with exacerbation of the sleep related breathing abnormality and, in some cases sleep disordered breathing may be confined entirely to REM sleep. It distinguishes obstructive from central events, determines the effects of body position on sleep disordered breathing, allows the recognition of some alternative diagnoses (e.g. periodic limb movement disorder, parasomnias) and may suggest other sleep disorders (e.g. narcolepsy, chronic sleep restriction due to circadian rhythm disturbance). It provides information on sleep fragmentation and arousals which are likely important in the genesis of daytime symptoms arising from abnormal sleep-related respiratory events. Body and head position assessment can be clarified with synchronised video monitoring.

Type 2
A Type 2 study refers to a portable PSG device that is unattended by trained sleep laboratory staff. It records a minimum of seven channels including EEG, EOG, chin EMG, ECG or heart rate, airflow, respiratory effort and oxygen saturation. A higher success rate is generally obtained when type 2 studies are set up by experienced personnel in the home environment. 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.

The available literature indicates that type 2 studies can be used as part of a diagnostic pathway to rule in and rule out suspected sleep apnoea (Figure 1). Type 2 studies set up in the home have been thoroughly evaluated by the Sleep Heart

Health Research (SHHS) Group who performed over 7000 studies to a high technical standard (70) with reasonable agreement with repeated studies at home (71) and in the laboratory (72). Its application in a general clinical sleep apnoea population has been confirmed (73). A New Zealand group (73) reported a failure rate of 6.6%, which was similar to SHHS (70) and an earlier clinical study (74). It is important to distinguish the method by which type 2 studies are implemented. There are three standard methods: 1. the patient comes to the laboratory and is "wired up and sent home; 2. a technician comes to the patient's house and "wires the patient up'; and 3. the patient is provided with instructions and undertakes the "wire up" at home unsupervised. The failure rates of patients wired up in the lab and sent home is higher than home set up with supervision. Nevertheless, this fact needs to be weighed against the practicalities of having staff available to safely go to patient's homes. Campbell (73) found that signal loss is higher and there is a small under-estimate of AHI (approximately 10%) due to greater loss of respiratory effort signals in the home compared to laboratory environment. These differences did not alter treatment advice. A meta-analysis of laboratory versus portable sleep studies (78) concluded that they both provide similar diagnostic information, but type 2 studies may underestimate severity of AHI by around 10%. A screening process of the referral needs to be undertaken by the clinician approving the study to ensure the safety of staff visiting the patient's home is adequate.

Patients who may be <u>unsuitable</u> for Type 2 Diagnostic studies:

A. Patient related factors

1. Neuropsychological
   - Severe intellectual disability (this may also be an issue for type 1 studies)
   - Neuromuscular disease
   - Major communication difficulties

2. Severe physical disability with inadequate carer attendance

3. Home environment unsuitable – a number of factors need to be considered including noise level, partner/ family interactions, distance from sleep lab and the safety of any attending staff

4. Discretionary
   - symptoms or results of former testing do not equate with clinical impression
   - patients seeking a second opinion where the original diagnosis is uncertain.
   - where "serious" medico legal consequences may be relevant

B. Sleep disorder related factors

- Parasomnia/ seizure detection requiring infrared camera or extended EEG montage
- Transcutaneous CO_2 monitoring required
- Where video confirmation regarding body positional/ rotational aspects of sleep disordered breathing is essential

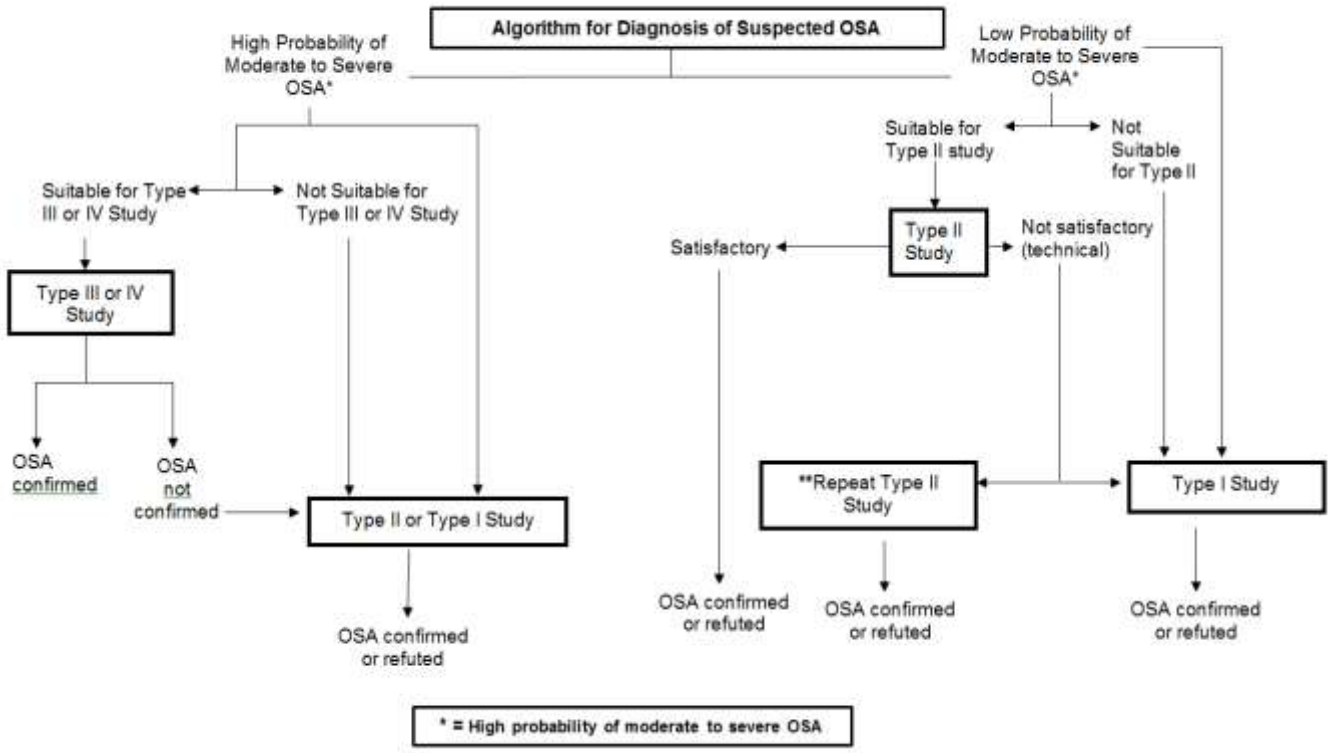

Figure 1. Algorithm for diagnosing suspected OSA.

*. There is variability in the definition of moderate to severe OSA. Readers should note in some articles it is listed as an AHI ≥ 15 (67) and in others an AHI ≥ 30 (76) based on the AASM Chicago criteria of 1999 (16). A variety of clinical tools can ne used to divide patients into high and low probability for moderate to severe OSA.
** NB A repeat Type 2 study is unable to be billed via Medicare within 12 months of the original test.

Type 3

Limited channel sleep studies (type 3 and 4) have a more restricted number of parameters measured, usually a combination of respiratory variables including arterial O_2 saturation, respiratory effort and airflow. In general, sleep staging is omitted from limited sleep studies.

Type 3 studies have at least 4 variables monitored: oximetry plus respiratory effort (chest, abdominal, or both), airflow (nasal or oral by pressure or thermistor), head or body position, jaw movement, ECG, tonometry (a marker of autonomic control), actigraphy and sound (vibration detection or true sound recording). Thus, there is a variety of monitors that can be utilised to achieve a type 3 study. In order to review these more thoroughly, the SCOPER categorization system has been established which includes monitoring **S**leep, **C**ardiovascular, **O**ximetry, **P**osition, **E**ffort and **R**espiratory parameters (85). It is recommended that at a minimum, respiratory effort, airflow and oximetry are recorded (85). Automation of some or all of the data analysis is generally feasible.

Tonometry is also available (marker of autonomic control and thereby sleep) as an adjunct to oximetry. Expensive disposable equipment is required (e.g. Watchpat). It

may add a small amount to diagnostic accuracy of AHI, by reducing the denominator ("total recoding time" to "total sleep time").

At least 15 studies have compared type 3 studies with polysomnography in adults, either simultaneously or on consecutive nights. Most have low AHI thresholds (AHI>5) with correlation coefficients of 0.58 - 0.95, sensitivities of 84 to100% and specificities 59 to 100%. Such studies report failure of data collection between 8-12%. In addition, automatic analysis thresholds are arbitrarily set by manufacturers and may vary between manufacturers. The most predictive variable is the ODI, which is based upon oximetry.

Type 4

A Type 4 study is one that incorporates only one or two measured parameters – for example oxygen saturation, heart rate or airflow. Oximetry is the cornerstone signal of sleep apnoea monitoring. In comparison with all other signals it is the most accurate, quantifiable, reliable and informative signal. The development of the multiwave length oximetry and reduction in size has made oximetry a ubiquitous and accurate marker of hypoxemia. The accuracy of oximetry is estimated to be ± 2% between the arterial oxyhaemoglobin saturation range of 70 – 100% and can accurately track change. Technical factors such as adequate signal acquisition, averaging time and storage sampling frequency are crucial to the reliability of oximetry. Failure rates as low as 3% of patients studied have been reported (76).

Oximetry with heart rate can be used to derive an oxygen desaturation index (ODI) which can be further delineated based upon a ≥3% or ≥4% desaturation (ODI3 or ODI4, respectively). Oximetry can diagnose moderate to severe OSA in populations where there is high pre-test probability of OSA when combined with questionnaires (Berlin (65), OSA50 (76), StopBang (66)) or combined with thorough history and examination. In these settings, oximetry with heart rate correlates with AHI (75) and has high sensitivity (>85%), low specificity (~40-70%) and high ROC AUC (~ 0.90).

A large retrospective study has examined the interaction between obesity, AHI and various ODI levels (2% ODI, 3% ODI & 4 % ODI). (110). 3% ODI performed best across all levels of BMI > 25 kg/m^2 in detecting moderate OSA (AHI ≥ 15 events/hour) and severe OSA (AHI ≥ 30 events/hour) based on Chicago scoring system.

Limitations of oximetry with heart rate are seen in cardiac, pulmonary and neurological patients where differentiation between obstructive and central sleep apnoea is especially important. Low baseline awake oxygen saturation will reduce specificity further. Supplemental oxygen therapy may negate the utility of signal interpretation. The reliance on only one or two signals means that redundancy of information during signal drop out may be very limited. Other limitations include lack of positional data and use of time in bed rather than actual sleep time in calculating the level of respiratory disturbance.

Questionnaires completed by the patient and bed partner regarding estimates of sleep time, body position, presence of snoring etc. may help compliment data recorded from type 4 studies.

It is essential that if type 3 and 4 studies are being used to rule in OSA, there are clearly defined pathways for: a) assessing the pre-test probability of a patient having moderate to severe OSA; b) patients with co-morbidities that could confound the results are excluded; c) inconclusive tests or results at

odds with the clinical suspicion are referred for type 1 or 2 sleep studies and d) in an appropriately resourced clinical environment, where the patients unsuitable for type 3 and 4 studies have been excluded, a positive type 3 or 4 study for moderate to severe OSA in the setting of a high pre-test probability of OSA should result in the cessation of further investigation for sleep disordered breathing.

Oximetry's variable specificity (41% to 100%) and sensitivity (31% to 98%) across a range of studies is due to differences in:

a. study populations (history, examination, questionnaires)
b. comparison groups: usually type 1 attended polysomnography. These studies have limitations
    1. threshold (AHI) for sleep apnoea (86)
    2. denominator for AHI (Total sleep time vs Total recording time),
    3. same vs consecutive night
c. device settings
    signal acquisition averaging time (e.g. 2 vs 20 seconds)
    storage sampling frequency (e.g. 1.0 to 0.1 Hertz)
d. artefact detection
e. medical conditions e.g. Raynaud's phenomenon & haemoglobinopathies

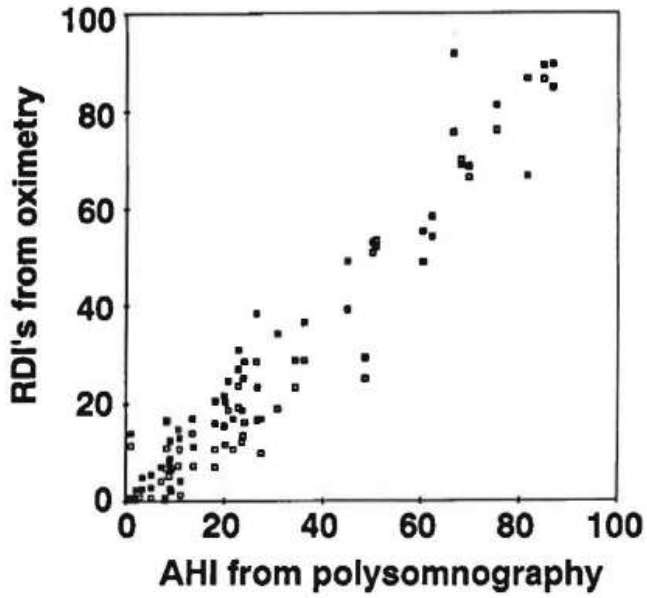

Figure 2: This figure illustrates from an early in-lab study of patients with high probability of OSA indicating a significant correlation of simultaneous ODI with AHI (where desaturation ≥ 3% was part of the definition of hypopnoea) from Rauscher (87)

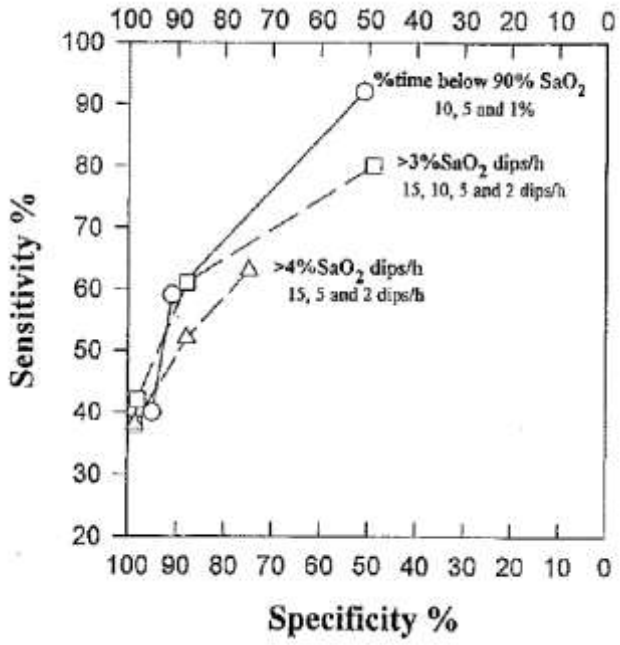

Figure 3: Example of various oximeter derivatives at different thresholds from Gyulay et al.(88), This study compared home oximetry compared to in laboratory PSG.

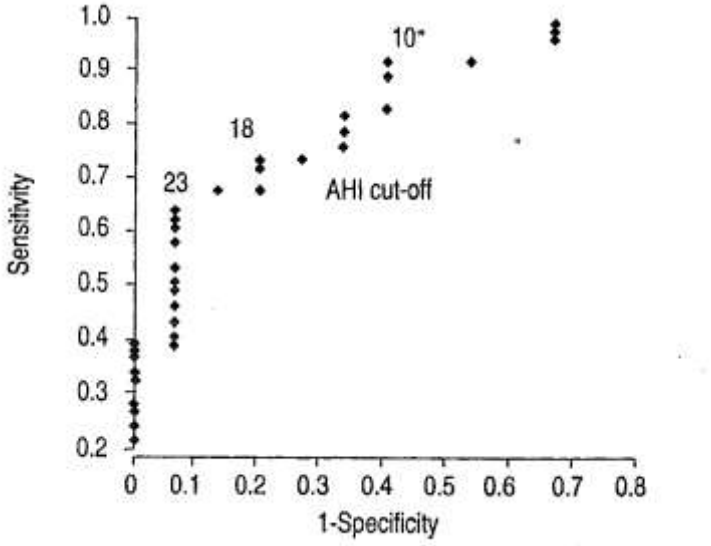

Figure 4: Example of various ROC for AHI measurements using home based oximetry compared with laboratory PSG (AHI>10) (86).

Patients who may be <u>unsuitable</u> for Type 3 and 4 Diagnostic studies include:

1. Populations with a low-pre-test probability of moderate to severe OSA

2. Patients reporting symptoms suggestive of a condition other than sleep disordered breathing which will require more extensive monitoring, e.g. parasomnia, narcolepsy, periodic limb movement disorder, nocturnal epilepsy etc.

3. Patients with any of the following (where nocturnal hypoventilation or central sleep apnoea is likely):
    a. Neuromuscular disease
    b. Severe COPD or restrictive lung disease
    c. Hypoxia and/or hypercapnia at rest, or requiring supplemental oxygen therapy
    d. Morbid obesity and/or suspected obesity hypoventilation syndrome
    e. Significant cardiovascular disease, i.e. recent hospitalisation for acute MI, unstable angina, decompensated heart failure
    f. Chronic narcotic use

4. Inability to perform overnight oximetry in a non-monitored environment. e.g. active significant psychiatric disease

1.2 Choosing the Type of diagnostic respiratory sleep study

In choosing which test or tests are to be used, physicians should have a clear understanding of: (a) the indications for testing; (b) the sensitivity and specificity of the test(s) to diagnose sleep disordered breathing; (c) the overall utility of the test taking into consideration the prevalence of sleep apnoea in their population; (d) the cost /benefit balance of the test in their particular clinical setting; (e) the technical limitations of the monitoring signals utilised in each particular study type; and (f) comorbidities which need to be considered in choosing the type of sleep study.

1.2.1 Screening tools to divide patients into high and low probability for moderate to severe OSA

A key recommendation of this guideline is figure 1 on page 8. Suitable patients with a high pre-test probability of moderate to severe OSA and no significant cardiorespiratory co-morbidities could be initially investigated with a Type 3 or 4 study. This approach would be particularly useful in high prevalence populations or where access to Type 1 or 2 studies is limited. This approach may also be helpful in triaging patients in services that predominantly perform Type 1 or 2 studies. Moderate to severe OSA was chosen because it is estimated that 83% or men and 92% of women with this severity of OSA have not been diagnosed (63). Additionally, patients with moderate to severe OSA have the highest morbidity and also adhere and respond to treatment better than those with mild disease (64). The definition of moderate to severe OSA is variable. Sometimes it is defined as an AHI ≥ 30 events /hour based on the 1999 AASM “Chicago” criteria (16), and on other occasions ≥ 15 events/ hour on the same criteria. Screening tools can assist in determining which patients have a high pre-test probability of moderate to severe OSA. Screening tools that have high sensitivity and negative predictive value properties, maximise the utility of Type 3 and 4 sleep studies.

An ideal screening questionnaire should have three important characteristics (66):
1) Feasibility: Patients and healthcare providers should find the questionnaire user friendly;
2) Accuracy: There should be a clear validation process that leads to high accuracy parameters;
3) Generalizability: Valid results should be realized when the questionnaire is used on different target populations, i.e., the questionnaire has been validated in different study populations.

There are at least four potential settings where use of a screening questionnaire could be beneficial:

- general practice
- sleep clinic
- pre-operative clinic
- occupational setting

There has been a recent review of sleep screening questionnaires (79). Three questionnaires demonstrate good to reasonable psychometric properties to support their validity. These are the Berlin Questionnaire (65), STOPBANG (67, 68,69) and OSA50 (76).

Berlin Questionnaire
The Berlin questionnaire is an OSA questionnaire developed for and validated in primary care and categorises patients as either high or low risk for OSA based on self-reports of snoring, daytime sleepiness, hypertension and obesity (65). The 11 questions were chosen by a panel of sleep physicians without prior evaluation as to their respective discriminatory values. Although published a decade ago, the Berlin questionnaire is not widely used, possibly because of the time required for completion and scoring (76)**.** The predictive parameters of the Berlin questionnaire vary depending on to which patient population they are applied. The sensitivity was 86% in primary care patients (65), and 57–68% in sleep laboratory patients (107). There are some important methodological limitations of the Berlin questionnaire. Patients were pre-screened prior to utilising the questionnaire and analysis of the PSG was not blinded to the result of the Berlin questionnaire.

STOP- Bang Clinical Tool (66,67,68,69)
This was developed and validated initially in pre-operative clinics in patients without previously diagnosed OSA. The design of this questionnaire was robust with factor analysis, reliability check and a pilot study used to determine the screening tool. The tool initially comprised of four yes /no questions covering the domains of **S**noring, **T**iredness, **O**bserved apnoeas and blood **P**ressure (STOP). It was initially designed to detect any severity of obstructive sleep apnoea in a pre-operative cohort of patients. Following design of the questionnaire, it was then administered to 1875 patients all of whom were invited to undertake an overnight polysomnographic study. 177 patients of the validation cohort underwent an overnight polysomnographic study. The sensitivities of the STOP score with the AHI based on AASM Chicago criteria (16) were analysed. The positive predictive values of STOP questionnaire for AHI ≥ 5 events/ hour was further enhanced by the addition of the parameters of **B**MI greater than 35 kg/m^2 , **a**ge >50, **n**eck circumference > 40 cm and male **g**ender.

The STOP-Bang questionnaire (table 1) is quick to administer and can divide patients into low and high risk for OSA. The predictive parameters are good for moderate to severe OSA (table 2) i.e. AHI ≥ 30 events/hour on Chicago criteria (16).

1. *S*noring
   Do you *s*nore loudly (louder than talking or loud enough to be heard through closed doors)?
   Yes No
2. *T*ired
   Do you often feel *t*ired, fatigued, or sleepy during daytime?
   Yes No
3. *O*bserved
   Has anyone *o*bserved you stop breathing during your sleep?
   Yes No
4. Blood *p*ressure
   Do you have or are you being treated for high blood *p*ressure?
   Yes No
5. *B*MI
   *B*MI more than 35 kg/m^2?
   Yes No
6. *A*ge
   *A*ge over 50 yr old?
   Yes No
7. *N*eck circumference
   *N*eck circumference greater than 40 cm?
   Yes No
8. *G*ender
   *G*ender male?
   Yes No

High risk of OSA: answering yes to three or more items
Low risk of OSA: answering yes to less than three items

Table 1 STOP-Bang Scoring Model

AHI >30	
Sensitivity, %	100 (91.0–100.0)
Specificity, %	37.0 (28.9–45.6)
PPV, %	31.0 (23.0–39.8)
NPV, %	100 (93.0–100.0)
Likelihood ratio	1.586 (1.426–1.838)
Odds ratio	>999.999
Area under ROC curve	0.822

Data are presented as average (95% confidence interval).
AHI = apnea–hypopnea index; NPV = negative predictive value; PPV = positive predictive value; ROC = receiver operating characteristic.

Table 2. Predictive parameters for the STOP-Bang questionnaire in detecting severe OSA (n=177). A score ≥ 3 on the STOP-Bang questionnaire is regarded as positive for OSA. (66).

There has been a further study (67) which has refined the utility of the STOP-Bang screening tool for surgical patients. Scores of < 3 make it unlikely patients will have an AHI > 15 events/hour (Chicago criteria, reference 16). A score of 5 to 8 greatly increases the probability of an AHI >15 events/hour.

The STOP-Bang score has been assessed in sleep clinic populations (68, 69). The first study (68) looked at a variety of ways in which information from the STOP-Bang score could be used more discriminately to predict AHI in sleep clinic populations. This study examined 1426 patients in whom the STOP-Bang score was derived and all patients underwent a Type 1 sleep study. Rather than using a binary result (low and high risk for OSA) for the STOP-Bang score, the study examined the benefit of a

cumulative score (0-8) for predicting severity of OSA. For ease of use, a linear model was recommended and the results are displayed in figure 5.

The second study (69), looked at the Sleep Heart Health Study cohort and identified the patients as having a high risk for moderate to severe OSA (RDI ≥ 15 events/hour [RDI defined in reference 70]) based on a STOP-Bang score of ≥ 3.The sensitivity utilising this test was 87%.

A published four- variable screening tool (reference 71) was also applied to this population and it demonstrated good specificity (92.3%) in ruling out moderate to severe OSA. The four variable screening tool divides weight, and blood pressure into a number of categories and also accounts for gender and snoring.

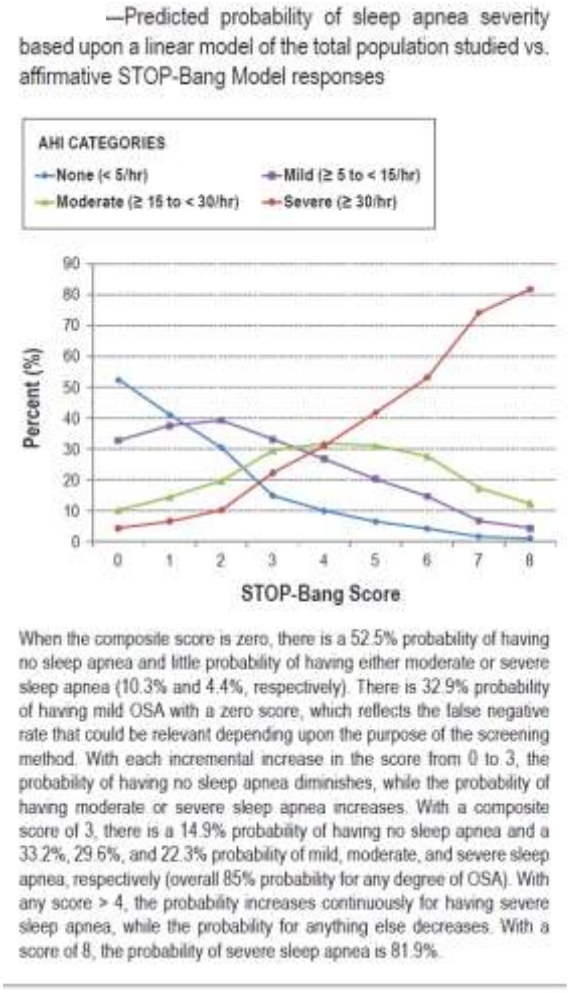

Figure 5. Percent of patients with OSA defined by AHI categories based on cumulative STOP-Bang score. (From reference 68)

OSA50

The OSA50 (76) has recently been developed in an Australian general practice health care setting. The aim of this study was to develop and validate a simplified two-stage method for identifying moderate to severe OSA (AHI > 30 events/ hour of sleep based on Chicago criteria (16)) in primary care consisting of an easy-to-administer screening questionnaire followed by a type 4 sleep study. The type 4 sleep study utilised was the ApneaLink.

In the development data set, four items were significantly predictive of moderate to severe OSA. See table 3.

	If yes, SCORE
Obesity: Waist circumference* - Males >102cm or Females >88cm	3
Snoring: Has your snoring ever bothered other people?	3
Apneas: Has anyone noticed that you stop breathing during your sleep?	2
50: Are you aged 50 years or over?	2
TOTAL SCORE:	..... / 10 points

* Waist circumference to be measured at the level of the umbilicus.

Table 3 – OSA50 elements. Score ranges from 0 to 10.

The area under the curve to detect moderate to severe OSA (AHI ≥30) using the OSA-50 questionnaire was 0.84 (95% CI 0.75 to 0.94, p<0.001) for the developmental data set. Using a cut off score of ≥ 5 out of 10, this questionnaire had a sensitivity of 100% (95% CI 86% to 100%), NPV of 100% (95% CI 73% to 100%), specificity of 29% (95% CI 17% to 44%) and PPV of 48% (95% CI 35% to 63%).

Results from the ApneaLink were analysed against AHI derived from a simultaneous Type 2 sleep study with scoring of respiratory events based on the AASM Chicago criteria (16). ROC curves for the ApneaLink 3% ODI and AHI20-50 (based on nasal flow) against PSG in the development group were highly predictive of moderate to severe OSA with ROC AUC values of 0.96 (95% CI 0.91 to 1.00, p<0.001) and 0.95 (95% CI 0.89 to 1.0, <0.001), respectively. The 3%ODI was selected for use in the two-stage model because oximetry was technically more reliable than nasal airflow measurements with fewer failures (only 3% patients with failed oximetry).

The diagnostic characteristics of the two-stage model using a cut-off values of ≥ 5/10 for the OSA50 questionnaire and ≥ 16/h for the 3%ODI, revealed the model was capable of identifying moderate to severe OSA with a high sensitivity and specificity and had an overall diagnostic accuracy (sum of the true positive and true negative rate) of 91% in the development set.

The two step model was then assessed on a validation group of 78 participants. Using cut offs of OSA50 score ≥ 5/10 and a 3%ODI ≥ 16/hour on an ApneaLink, the sensitivity and specificity were both > 80%, the negative predictive value was 96% and the overall diagnostic accuracy (sum of true positive and true negative rate) was 83%. Although the positive predictive value was lower that anticipated in the validation group at 56%, review of the “false positives” indicated that the minimum PSG AHI was 18.9 events/hour and half the group reported excessive daytime

sleepiness with Epworth Sleepiness Scale scores ≥ 12, suggesting that these patients would likely gain benefit from therapy taking into account their symptoms.

There were minimal exclusion criteria used in this study. Only pregnant women, patients with significant cognitive impairment, a poorly controlled psychiatric disorder or patients who had previously received treatment for OSA were excluded.

Summary of OSA Clinical Tools

There are an increasing number of well validated questionnaires for OSA that have been utilised in general practice populations, peri-operative and sleep clinic settings. These may assist clinicians in determining who is likely to have moderate to severe OSA and who may be suitable to proceed directly to Type 3 or 4 sleep studies. Additionally, these tools may be helpful in determining the urgency to proceed to a Type 1 or 2 study where type 3 or 4 sleep studies are not readily available.

1.3 Indications for sleep studies for sleep disordered breathing

There are three broad indications in relation to sleep related breathing disorders:
1.3.1 Diagnostic studies: to aid making a diagnosis and to classify severity of sleep disordered breathing (SDB)
1.3.2 Intervention studies: to implement and titrate, or confirm effectiveness of a new treatment
1.3.3 Follow-up studies: to follow the progress of a patient

1.3.1 Diagnostic Studies

Diagnostic studies are performed to identify and quantify severity of SDB:
1.3.1.1 suspected obstructive sleep apnoea (OSA) syndromes
1.3.1.2 suspected central sleep apnoea (CSA) syndromes
1.3.1.3 suspected sleep hypoventilation syndromes (sleep-disordered breathing associated with disorders of respiratory muscles, chest wall or lung e.g. muscular dystrophy, kyphoscoliosis, chronic obstructive pulmonary disease, and SDB associated with neurologic disorders)
1.3.1.4 suspected SDB in association with recognized predisposing non-respiratory disorders (e.g. congestive heart failure, significant tachyarrhythmias, neurological disease, morbid obesity, acromegaly, hypothyroidism)
1.3.1.5 suspected SDB when upper airway surgery or bariatric surgery is being contemplated to treat snoring or SDB.

1.3.1.1 Suspected Obstructive Sleep Apnoea Syndromes
High-risk patients in whom the question of OSA arises tend to fall into one of groups:
a) Patients with a history of habitual loud snoring and marked daytime sleepiness and in whom apnoeas have also been witnessed. There is a high probability these patients have OSA and a sleep study is recommended. Higher risk patients include those who are obese (BMI > 35 kg/m^2), increased neck circumference (> 43 cm in men, > 40 cm in women), those with tonsillar hypertrophy and/or retrognathia. Patients with co-morbidities of congestive heart failure, atrial fibrillation, treatment refractory hypertension, type 2 diabetes, stroke, nocturnal dysrhythmias, pulmonary hypertension, high-risk driving populations (such as commercial truck drivers), and those being evaluated for bariatric surgery also represent high risk. The OSA50 or STOP-Bang questionnaire may help identify patients at risk for moderate to severe OSA. A sleep study is generally recommended in higher risk patients with symptoms of SDB.

b) Patients in whom the history is less clear-cut. For example, snoring may be reported as positional and have developed in association with weight gain and the patient may complain of mild daytime sleepiness. Other features that may suggest the presence of OSA include body mass index (BMI) > 30 kg/m^2. In the absence of the above features or high risk co-morbidities (see [a] above) it is reasonable to defer a sleep study in these patients pending response to measures to relieve nasal obstruction, reduce weight, or reduce alcohol consumption where these are thought to contribute. Exceptions, where sleep study should proceed, would include patients with a history of an accident or "near miss" at work or when driving that could be related to sleepiness. Also, a sleep study should proceed if specific intervention for snoring (e.g. surgery, mandibular advancement splint) is being planned (see section 1.3.1.5 below). Where a sleep study has been deferred, formal follow-up is necessary with a plan to proceed with the study where symptomatic response to simple measures has been inadequate. Such patients should be advised of the importance of recognizing and reporting the occurrence of symptoms of sleep disruption, suggesting sleep apnoea may have supervened.

1.3.1.2 Suspected Central Sleep Apnoea Syndrome

Patients in whom the question of central sleep apnoea arises tend to fall into one of three groups:

a) Idiopathic Central Sleep Apnoea is an uncommon cause of SDB. In patients with a history of recurrent witnessed apnoeic events associated with sleep fragmentation, excessive daytime sleepiness, and/or insomnia, should proceed to a laboratory-based sleep study.

b) Cheyne-Stokes Breathing Syndrome is characterised by a cyclical fluctuation in breathing with periods of central apnoea alternating with periods of hyperpnoea in a gradual waxing and waning fashion. Cheyne-Stokes breathing is often observed in association with congestive heart failure (in 30-50% of patients with an ejection fraction of <40%) or neurological disease (usually cerebrovascular) (20, 21). Hypersomnolence can occur as a result of arousals seen during the hyperpnoeic phase of the breathing cycle. Significant hypoxemia may occur during the hypopnoeic phase. OSA is also common in patients with severe congestive heart failure (20, 22) and may predispose to a decline in left ventricular function and quality of life (23). Suspected cases should proceed to a laboratory-based sleep study.

c) High Altitude Sleep Apnoea (not relevant in Australia or New Zealand).

1.3.1.3.Suspected Sleep Hypoventilation Syndromes

Sleep-disordered breathing in association with disorders of respiratory muscles, chest wall or lung (e.g. muscular dystrophy, kyphoscoliosis, obesity hypoventilation syndrome, chronic obstructive pulmonary disease (COPD))

In patients with respiratory disorders in whom complications such as right heart failure, polycythaemia and hypercapnic respiratory failure appear disproportionately severe relative to the impairment of daytime respiratory function, the possibility of OSA or sleep hypoventilation should be considered, particularly if obese and/or known to snore habitually. A laboratory-based sleep study should be considered in the investigation of such patients.

Patients with respiratory and/or upper airway muscle weakness or chest wall deformity may develop sleep hypoventilation in advance of daytime respiratory or right heart failure (24, 25). Hence, laboratory-based sleep studies should be considered in this group if symptoms of disturbed sleep, nocturnal dyspnoea, snoring, morning headache, daytime sleepiness, orthopnoea or progressive weakness are present (24). Studies should also be considered if signs of pulmonary hypertension or other cardiorespiratory dysfunction occur. Elevation of awake $PaCO_2$

and base excess in such patients may also indicate a sleep-related respiratory disturbance.
Sleep disordered breathing may also occur in association with some neurological disorders such as Congenital Central Hypoventilation Syndrome, brainstem or high spinal cord lesions.

1.3.1.4 Sleep-disordered breathing in association with recognized predisposing non-respiratory disorders.
A sleep study should be considered in patients with these disorders particularly if there is a history of excessive daytime sleepiness or deteriorating cardiorespiratory function not explicable on other grounds. In conditions where the prevalence of OSA is high, such as acromegaly (prevalence of more than 50% in unselected patients (26)), a sleep study should be a routine investigation.

1.3.1.5 Suspected sleep apnoea where upper airway surgery or bariatric surgery is being considered to treat snoring or SDB
A sleep study should be undertaken whenever upper airway surgery or bariatric surgery is being contemplated to treat snoring. The reasons for this are:

a. the results may alert the surgeon and anaesthetist to the presence of clinically unsuspected sleep apnoea. This might indicate the need for alternative or additional treatments, or for particular vigilance in the early post-operative period because of increased potential for upper airway obstruction and/or impaired ability to arouse due to residual anaesthetic and/or analgesic effects.
b. the cause of excessive sleepiness is investigated in patients in whom excessive daytime sleepiness is part of the rationale for surgery.

1.3.2. INTERVENTION STUDIES
Intervention studies are performed to implement and titrate, or confirm the effectiveness of a treatment. Such therapies include pharmaceutical agents, oxygen administration, oral appliances, nasal expiratory airway pressure devices, continuous positive airway pressure (CPAP), upper airway surgery, sleep posture modification devices and non-invasive ventilation (NIV). The effectiveness or otherwise of these treatments to reverse or alleviate sleep disordered breathing should be confirmed in patients with OSA.

The majority of treatment studies undertaken are for OSAHS. Additionally most treatment studies involve application of CPAP. This document will confine itself to the description of types of studies, goals of treatment. The CPAP titration study is only one component of the treatment of sleep disordered breathing. Education of the patient and long term evaluation of the patients' symptoms, quality of life, adherence and side effects of the treatment being equally important. Patient education and motivation to use CPAP accounts for a greater variance in CPAP adherence than standard biometric or anthropometric markers of OSA severity.

1.3.2.1 Intervention studies of CPAP therapy for OSAHS.

Options of CPAP titration for patients with OSA:

1. Manual pressure adjustment by a sleep technologist during attended laboratory polysomnography (PSG) (This is regarded as the standard of care (27))
2. Split night studies
3. Autotitrating device titrations (see APAP section)
4. Diurnal sleep studies
5. Empiric pressure trials (outside the scope of this document)

6. Pressure determined by a priori equations (outside the scope of this document)

Standard components of a titration study:

1. All patients undertaking a titration study for sleep disordered breathing must have a diagnosis established by an acceptable method (see diagnostic sleep study section above) prior to a treatment study.

2. There should be a written protocol for each sleep service based on evidence and the local experience and judgement of sleep technologists and clinicians to attain the best possible titration in any given patient (27).

3. All Potential PAP titration patients (including those patients prior to a diagnostic study where the clinical suspicion of OSA is high and a Split-Night Study is a possibility) should receive adequate PAP education, hands-on demonstration, careful mask fitting, and acclimatization prior to titration (27, 28).

   Two randomised controlled trials (29, 30) have demonstrated the benefits of adopting psychological interventions prior to the CPAP titration study to enhance rate of CPAP uptake, time to CPAP uptake and adherence**.**

1.3.2.1.1 Manual pressure adjustment by a sleep technologist during attended laboratory polysomnography (PSG)

Aims of titration for patients with OSA:

A successful titration is one in which there is an trade-off between increasing CPAP pressure to eliminate respiratory events and decreasing CPAP pressure to minimize emergence of CPAP pressure-related side effects (31).

A Consensus recommendation from the AASM (27) asserted that the optimum pressure determined on a titration study should reflect control of the patient's obstructive respiration by a low RDI (preferably <5 events per hour) at the selected pressure, a minimum sea level SpO2 above 90% at the pressure, and with a leak within acceptable parameters at the pressure.

This guideline (27) went on to define a grading system for optimal, good, adequate and unacceptable titration based on consensus agreement of the PAP Titration Task Force and a system proposed by Hirshkowitz and Sharafkhaneh (32).

The grading system for manually titrated attended full or split sleep studies proposed the following:

An optimal titration reduces the RDI<5 to per hour for at least a 15-min duration and should include supine REM sleep at the selected pressure that is not continually interrupted by spontaneous arousals or awakenings. It should be noted that it may not be possible to achieve supine REM on the final treatment pressure for many patients.

A good titration reduces the overnight RDI to ≤10 per hour or by 50% if the baseline RDI is <15 per hour, and should include supine REM sleep that is not continually interrupted by spontaneous arousals or awakenings at the selected pressure.

An adequate titration is one that does not reduce the overnight RDI ≤10 per hour but does reduce the RDI by 75% from baseline (especially in severe OSA patients), or one in which the titration grading criteria for optimal or good are met with the exception that supine REM sleep did not occur at the selected pressure.

An unacceptable titration is one that does not meet any one of the above grades.

It is recommended that CPAP implementation in complex cases (e.g. patients with overlapping cardiorespiratory dysfunction or central sleep apnoea) be achieved by attended polysomnography.

1.3.2.1.2 Split night sleep studies:

The AASM practice parameters for PSG (8) indicate split night sleep studies are reasonable when the following conditions are met:

a) an AHI of at least 40 events/hour is documented during a minimum of 2 hours of diagnostic PSG OR
   an AHI of 20 to 40 events/hour associated with pronounced obstructive features (e.g., if there are also repetitive long obstructions and major de-saturations). However, at AHI values below 40 events/hour, determination of CPAP pressure requirements, based on split-night studies, may be less accurate than in full-night calibrations.
b) CPAP titration is carried out for more than 3 hours (because respiratory events can worsen as the night progresses).
c) PSG documents that CPAP eliminates or nearly eliminates the respiratory events during REM and NREM sleep, including REM sleep with the patient in the supine position.

It assumed the patient will have had the same preparatory education and acclimatisation as for a full night titration study (see standard components of a titration study above).

Studies that have compared adequacy of prescribed pressure, CPAP adherence, and patient acceptance have found no significant differences for adult patients undergoing full-night vs. split-night CPAP titration studies with the possible exception that pressures determined from split-night studies may be lower for patients with mild-to-moderate OSA who may not manifest the maximal severity of their condition during the limited titration portion of the night (27).

A repeat Positive Airways Pressure titration study should be considered if the initial titration does not achieve the (b) or (c) criteria above. Alternatively, a trial of an autotitrating positive airways pressure device may be considered in selected patients.

1.3.2.1.3 Autotitrating Positive Airway Pressure (APAP) Sleep studies

The following section covers the many factors the clinician needs to consider about autotitrating CPAP. In each section, the evidence is summarised and recommendations are made. For many patients with uncomplicated OSA, APAP titration represents an acceptable way of determining an optimal long-term CPAP pressure.

It is difficult to make definitive statements about the use of autotitrating CPAP at home to determine the ideal pressure for the treatment of OSA or how it compares with titrating CPAP during a sleep study in a sleep laboratory as clinical studies would need to be performed with each model of autotitrating CPAP that become available. The ideal study would be a randomized controlled trial comparing manual titration in a sleep laboratory with the specific model of autotitrating CPAP assessing clinically relevant outcomes such as sleepiness, quality of life, cardiovascular disease, car crashes and mortality over a period of time.

In addition, is not clear how to best determine the ideal CPAP level during polysomnography and in particular which parameters should be assessed when making decisions about altering pressure levels. It would be expected that the level of CPAP chosen should eliminate obstructive apnoeas, hypopnoeas and snoring, but it is not clear how much emphasis should be placed on eliminating flattening of the inspiratory loops of pressure and flow signals, eliminating arousals related to respiratory events, eliminating central apnoeas and hypopnoeas and what is the optimal oxygen saturation to achieve. There is a proposed system for adequate titration stated above (32) for in lab titration studies.

It has been shown in bench studies and patients that flattening of the flow contour from a CPAP system is associated with raised upper airway resistance and flow limitation. (33). It has also been shown in patients that the rounding of the CPAP inspiratory flow contour correlates better with low oesophageal pressures compared with elimination of apnoeas, hypopnoeas and arousals (34). It is not clear though, whether eliminating flattening of the inspiratory loops either with manual titration or autotitrating CPAP produces greater beneficial clinical outcomes than only eliminating snoring, hypopnoeas and apnoeas. It is possible that raising the pressure too high may induce central apnoeas and hypopnoeas and that it may worsen clinical outcomes by reducing patient adherence to treatment and/or disturbing sleep itself.

The AASM has guidelines for manual titration of CPAP and recommends the elimination of apnoeas, hypopnoeas, snoring and respiratory effort related arousals (RERAs), although this is based on consensus rather than evidence (8, 27).

Thus, it is not clear if manual titration of CPAP is the best method against which to compare home titration. Some advantages of manual titration during a laboratory sleep study are the ability to immediately deal with mask problems, recognize central or complex sleep apnoea and sleep related hypoventilation, to ensure that the patient has some sleep when supine, and to know if REM sleep occurred (35, 36, 37).

Home titration may have the advantage that the patient is sleeping in his/her more natural environment and so sleep during titration may better reflect his/her sleep when on long term treatment with CPAP. It is easier to have the titration over multiple nights so that other factors such as the use of alcohol and body position can also be included (38).

Even though there are not studies comparing both methods with long term clinical outcomes, there are studies in which the CPAP levels obtained with the two methods are compared. The published evidence is limited by the comparison of a specific device with a specific algorithm to manual titration. Due to proprietary commercial information, the details of the algorithms that are used in these machines to alter the level of CPAP and to identify hypopnoeas and apnoeas and produce an AHI are not generally available to clinicians. Also, manufacturers are often updating their devices and releasing new models so even when there are published evaluations of pumps

these evaluations do not necessarily apply to pumps being used currently (39). Thus, choosing devices relies on clinical studies directly assessing autotitrating CPAP with standard CPAP, and assessing patients' clinical responses to treatment with autotitrating CPAP. The latter approach can be difficult in individual patients in routine clinical care because of the placebo effect (39).

Suitable patients for autotitrating CPAP

If home autotitration is to be used to determine a suitable level of CPAP, care needs to be given in identifying patients who may or may not be suitable for this approach. Most studies using home autotitration have performed it in patients with moderate to severe OSA, with wide ranges of age, AHI and symptoms with a few key exclusions.

Patients tend to be excluded if there is concern about the possibility of: having significant hypoxaemia during sleep unrelated to OSA, having central sleep apnoea, having other significant sleep disorders or having other medical disorders that make home titration difficult. One of the largest and more recent studies, the HomePAP study (40), had the following exclusion criteria for home autotitration:

- COPD (with FEV1/ FVC < 70% & FEV1 < 50% predicted)
- Regular use of supplemental oxygen
- Waking oxygen level less than 92%
- Awake hypercapnia or hypoventilation syndrome
- Heart failure
- Chronic narcotic use
- Neuromuscular / chest wall disease
- Alcohol abuse
- Significant other sleep disorders
- Uncontrolled psychological or psychiatric disorder

<u>Recommendation</u>:

- Home autotitration of CPAP is suitable for a wide range of patients.
- Common sense is required to make sure that the patient is able to use the pump and mask at home.
- Home CPAP autotitration is not suitable for those who may have central sleep apnoea, in those who may have significant hypoxaemia during sleep due to conditions other than OSA, significant other sleep disorders or other medical conditions that limit the patient's ability to use the therapy at home during the titration phase.

Pressure level

Different autotitrating CPAP pumps have been designed to detect and respond to different parameters. Some devices simply adjust for apnoeas and hypopnoeas, others use these plus snoring and/or evidence of airflow limitation such as flattening of the inspiratory flow curve. Some have used detection of vibrations or the forced oscillation technique (FOT) (41, 42).

Bench studies using a breath waveform stimulator to detect flattened inspiratory flow, and a patient simulator model to replicate snoring, obstructive apnoeas and central

apnoeas, flow limitation and mouth leaks have shown that different autotitrating CPAP pumps vary widely in their ability to detect and respond to respiratory events, snoring and flattened inspiratory flow (42, 43).

The recommended effective level of pressure from autotitration can been determined in different ways. It may be the maximum pressure that was achieved during the duration of the recording, or more commonly, it is the 95^{th} or 90^{th} percentile pressure. For example, the 95^{th} percentile pressure is the pressure below which the pump delivers for 95 % of the recorded time. In other words, the pressure only went above this level for 5 % of the time. Llobres (44) directly compared the 90^{th} and 95^{th} percentiles and found the mean pressures to be similar, 10.7 ± 2.7 cm H_20 and 11.5 ± 2.9 cm H_20, respectively. What is relevant for clinicians is the comparison between an effective, clinically relevant pressure determined by manual titration and one derived from autotitrating CPAP (44, 45).

Rapid increases or significant fluctuations in CPAP without significant mask leak may indicate an inappropriate response of the CPAP pump to sleep –wake transitions. In these cases, titrating the CPAP level manually during polysomnography in a sleep laboratory may be necessary (46).

In summary, the effective pressure derived from autotitrating CPAP is similar to that obtained from manual titration of CPAP in a sleep laboratory. However, it should be recognized that this can vary from person to person and is dependent on the characteristics of the particular model of autotitrating CPAP and on the criteria that are used to adjust CPAP levels during manual titration and the skill and experience of the person applying them.

Recommendations:

- The effective pressure derived from autotitrating CPAP should be that which is recommended by the manufacturers. This is usually the 95^{th} or 90^{th} percentile pressure.
- It cannot be assumed that data from one model of autotitrating CPAP can be applied to another model.
- Rapid increases or significant fluctuations in CPAP without significant mask leak may indicate an inappropriate response of the CPAP pump to sleep-wake transitions. In these cases titrating the CPAP level manually during polysomnography in a sleep laboratory may be necessary.

The number of nights needed to determine an effective pressure

Recommendation:

- For many patients one night of autotitrating CPAP is enough to determine the effective pressure, but not in all patients. Some will need several nights, so a minimum of three nights is recommended (46, 47).

Outcomes:

Patient outcomes are more important than precise pressure level when comparing with different modes of CPAP initiation, such as manual laboratory titration versus home autotitrating CPAP.

Polysomnographic outcomes
Overall, studies have shown that autotitrating CPAP at home is at least as effective as CPAP with manual titration in reducing the AHI and improving sleep architecture (48, 49, 50).

Patient outcomes

West (52) compared six months of Autoset (Resmed™) with six months of fixed CPAP after one week of Autoset (to determine the 95th percentile pressure) and six months of fixed CPAP with the level determined by a formula. There was no difference over the six months between the three groups in sleepiness (ESS and MWT), quality of life and blood pressure.

McArdle (51) found no difference in sleepiness, quality of life or blood pressure over four weeks when CPAP was implemented with manual laboratory titration aiming to eliminate apnoeas, hypopnoeas, snoring and flow limitation and reduce arousals, with one night of the ResMed Autoset at home to determine the 95th percentile pressure and one night of Autoset in the sleep laboratory.

Recommendations:

- Using fixed pressure CPAP when the effective pressure has been determined by autotitrating CPAP at home is at least as effective as CPAP which has been set with manual titration, in improving sleepiness and quality of life.
- There is no consistent patient preference for autotitrating CPAP or fixed CPAP.

Factors that may affect CPAP adherence

Recommendation:
- Using fixed pressure CPAP, when the effective pressure has been determined by autotitrating CPAP at home, is associated with similar adherence with CPAP as occurs when CPAP has been set with manual titration (51, 52).

Conclusion

Using autotitrating CPAP at home for at least three nights is an option for determining the effective level of CPAP for patients planning to use fixed level CPAP in the long term. It is not possible to recommend either home titration of CPAP with an autotitrating pump or laboratory polysomnography to titrate CPAP over the other.

Home CPAP autotitration is not suitable for those who may have any of the following:
- central sleep apnoea,
- significant hypoxaemia during sleep (due to conditions other than OSA),
- significant accompanying sleep disorders in addition to OSA or
- co-morbidities that limit home titration.

The recommended fixed pressure for long term use is the 95th or 90th percentile pressure achieved by the autotitrating pump as per the manufacturers' instructions. It should be recognized that even after several nights or weeks of autotitration there can still be some doubt about the amount and type of sleep that the patient had during this period and how valid the recommended pressure might be. Thus, the patient should be reviewed soon after using CPAP with a fixed pressure level based

on the level obtained from the autotitrating device. The clinical response should be assessed especially if there is persisting sleepiness or snoring. If there are any concerns about the clinical response the patient may need to have a sleep study using CPAP in a sleep laboratory.

In addition, the clinician should discuss the available options with each patient and take into consideration each patient's preferences.

Manufacturers are often updating their devices and releasing new models, so even when there are published evaluations of pumps these evaluations do not necessarily apply to pumps being currently marketed.

1.3.2.1.4 Diurnal sleep studies

Diurnal and nocturnal titration result in comparable therapeutic pressures, equivalent resolution of sleep disordered breathing and improvement in subjective sleepiness after 1-12 weeks of treatment, particularly for patients with severe OSA (27).

1.3.2.2 Sleep studies to assess efficacy of oral appliance therapy for OSA

Follow-up sleep testing is not indicated for patients with primary snoring (54).

Current guidelines (54) suggest all patients with OSA should undergo a follow up type 1 or type 3 sleep study. This is because the rate of treatment success is not predictable with oral appliances. Additionally, some patients experience an increase in AHI with oral appliance treatment.

This strategy may be questioned with a recent publication demonstrating in the subgroup of patients with mild and moderate OSA, a mean residual AHI less than 10 events / hour was achieved. (117) In this study, only one type of specific oral appliance was utilised and results may not be applicable to the range of oral appliances available. The accompanying editorial (118) suggests for patients with mild to moderate OSA where symptoms are controlled no further testing is probably required.

Follow up however is especially important in patients with an elevated ODI 4%, severe OSA or patients with excessive daytime sleepiness.

1.3.2.3 Intervention studies for nasal expiratory airway pressure devices for OSA

Given that this technology has only recently been introduced into clinical practice, it is recommended that all patients treated with this device for OSA undergo sleep studies to assess its efficacy. An exception to this may be simple snoring where there has been reported good symptomatic benefit.

1.3.2.4 Sleep studies to assess the efficacy of behavioural strategies

The major behavioural treatment options include weight loss and positional therapy.

After substantial weight loss (i.e. 10% or more of body weight), a sleep study is routinely indicated to ascertain whether PAP therapy is still needed or whether adjustments in PAP level are necessary (8). Autotitrating CPAP study may be another suitable way to reassess the effect of weight changes on pressure levels.

Because not all patients normalize AHI when non-supine, correction of OSA by position should be documented with PSG before initiating this form of treatment as a primary therapy (56).

1.3.2.5 Sleep studies to assess efficacy following upper airway surgery for OSA patients

Given the heterogeneity of response to this type of therapy (57), it is recommended that polysomnography be performed to assess outcome.

1.3.2.6 Intervention studies of oxygen therapy

A sleep study is not necessary solely for the purposes of establishing a patient with COPD on home O_2 treatment.(2) This decision is usually made on the basis of wakeful PaO_2 (58). There is no evidence that isolated nocturnal desaturation causes progressive pulmonary hypertension (59) and one study has shown no significant treatment effect on survival or pulmonary haemodynamics from nocturnal oxygen therapy in such patients (60).

With respect to OSA, oxygen supplementation is not recommended as a primary treatment (61). If supplemental oxygen is used as an adjunct to other primary therapies to treat hypoxemia, follow-up must include documentation of resolution of the hypoxemia (54).

1.3.2.7 Intervention studies of NIV therapy for sleep disordered breathing

1.3.2.7.1 Chronic Alveolar Hypoventilation (CAH) Syndromes:

The Noninvasive Positive Pressure Ventilation (NPPV) Titration Task Force of the American Academy of Sleep Medicine recommends the following (62):

“NPPV titration with polysomnography (PSG) is the recommended method to determine an effective level of nocturnal ventilatory support in patients with CAH. In circumstances in which NPPV treatment is initiated and adjusted empirically in the outpatient setting based on clinical judgment, a PSG should be utilised if possible to confirm that the final NPPV settings are effective or to make adjustments as necessary.”

1.3.2.7.2 Disorders requiring servo-adaptive ventilators:

Given the relative inexperience with this form of therapy, limited long term outcome data and the fact that adjustments in end expiratory pressure settings to stabilise the upper airway may be required, the committee recommends that a Type 1 study is indicated in the titration and assessment of sleep indices with this form of therapy. More studies are required to judge whether simpler forms of monitoring are sufficient to predict long term success with this therapy.

1.3.3 FOLLOW-UP STUDIES

Where treatment for a sleep-related breathing disorder has been successfully instituted, it is important to ensure its long-term efficacy. Objective assessments of long term treatment adherence and breathing stability (e.g. microprocessor-based CPAP compliance, AHI and leak meters) and validated measures of effectiveness

(e.g. Epworth Sleepiness Scale score, general or disease-specific quality of life measurements) are highly desirable.

Routine follow-up sleep studies are not necessary in patients who have experienced a reversal of symptoms and are stable.

However, weight change (greater than 10 % in either direction) or the recurrence of snoring or daytime sleepiness on CPAP or oral appliances may indicate the need for repeat diagnostic and/or therapeutic studies.

Persistence of daytime sleepiness despite optimal use of CPAP is common (111). In the quoted study, 32% of patients with an initially elevated Epworth Sleepiness Scale score had a persistently elevated score three months later despite objective CPAP adherence of > 5 hours/night. Additional causes of sleepiness such as depression, diabetes mellitus, obesity per se, medications and sleep restriction need to be considered.

2. MOVEMENT AND BEHAVIOURAL DISORDERS OF SLEEP

2.1 Parasomnias

These conditions are undesirable physical events or experiences that occur during entry into sleep, within sleep or during arousals from sleep. Such conditions include: disorders of arousal from NREM sleep (confusional arousals, sleepwalking and sleep terrors, sleep-talking), REM Sleep Behaviour Disorder, nightmares and bruxism.

A clinical evaluation of the parasomnia with emphasis on age of onset, time of event relative to sleep onset, frequency, regularity and duration of event is often sufficient to diagnose common, uncomplicated, noninjurious parasomnias without the need for polysomnography (8).

2.2 Seizure Disorders

Epilepsy is a chronic condition characterised by the occurrence of paroxysmal electrical discharges in the brain and manifested by changes in consciousness, motor control or sensory function. The term ‘sleep related seizure disorder’ encompasses conditions with recurrent seizures during sleep.

Indications for in lab polysomnography with parasomnias and sleep related seizure disorders: (8)

Polysomnography with an extended bilateral montage and video monitoring is recommended to assist with the diagnosis of paroxysmal arousal or other sleep disorders that are thought to be seizure-related when the initial clinical evaluation and results of standard EEG are inconclusive.

Polysomnography, with additional EEG derivations and video recording, is indicated in evaluating sleep related behaviours that are violent or otherwise potentially injurious to the patient or others.

Polysomnography is indicated when evaluating patients with sleep behaviours suggestive of parasomnias that are unusual or atypical because of the patient’s age at onset; the time, duration, or frequency of occurrence of the behaviour; or the specifics of the particular motor patterns in question (e.g., stereotypical, repetitive,

or focal).

Polysomnography may be indicated when the presumed parasomnia or sleep related seizure disorder does not respond to conventional therapy.

Technical Factors related to sleep studies (8)

In digital EEG recordings, the sampling rate must be adequate to identify brief paroxysmal discharges.

The minimum channels required for the diagnosis of parasomnia or sleep-related seizure disorder include sleep-scoring channels (EEG, EOG, chin EMG); EEG using an expanded bilateral montage; and EMG for body movements (anterior tibialis or extensor digitorum). Synchronised audiovisual recording and documented technologist observations during the period of study are also essential.

Interpretation of polysomnography with video and extended EEG montage requires skills in both sleep medicine and seizure recognition. It is essential that a polysomnographer, sleep physician or neurologist experienced in seizure recognition be assigned to these studies. Where none is available, appropriate consultation is sought or the patient referred to a centre with the appropriate expertise.

2.3. Restless Legs Syndrome and Periodic Limb Movements

Restless legs syndrome (RLS) is a sensorimotor disorder characterised by a complaint of irresistible urge to move the legs. Periodic Limb Movement Disorder (PLMD) is characterised by periodic episodes of repetitive, highly stereotyped periodic leg movements and accompanied by clinical sleep disturbance that cannot be accounted for by another primary sleep disturbance. Periodic limb movements during sleep often accompany RLS. Although PLMD can exist independent of RLS, it is estimated that 80.2% of individuals with RLS have evidence of PLMS on PSG (138).

Polysomnography is not routinely indicated to diagnose or treat restless legs syndrome, except where uncertainty exists in the diagnosis.

The evaluation should include a clinical history and physical examination. Special emphasis on complaints of leg discomfort, the occurrence of leg or body jerks, restless sleep, and reports of insomnia or excessive daytime sleepiness should be sought. The clinical history should include bed partner observation, if possible. Physical examination should focus on excluding a peripheral neuropathy that can mimic RLS. Serum ferritin, complete blood count, urinalysis, and biochemistry testing should be undertaken to look for secondary causes of RLS (e.g., iron deficiency anaemia, uraemia).

The validated NIH criteria can be used to establish the diagnosis of RLS (96, 97). The validated RLS rating scale (98) can be used to establish severity of patients' symptoms; this scale may be useful in directing treatment as well.

Indications for polysomnography (8):

1. If uncertainty exists about the diagnosis of restless legs syndrome.

2. Polysomnography is indicated when a diagnosis of periodic limb movement disorder is considered, without concomitant RLS.

3. If a concomitant sleep disorder e.g. OSA is suspected.

Technical considerations:

The minimum channels required for the evaluation of periodic limb movements and related arousals include EEG, EOG, chin EMG, and left and right anterior tibialis surface EMG. Respiratory effort, airflow, and oximetry should be used simultaneously if sleep apnoea or upper-airway resistance syndrome is suspected to allow a distinction to be made between inherent periodic limb movements and those limb movements associated with respiratory events.

Intra-individual and a night-to-night variability exists in patients with periodic limb movement disorder, and a single study might not be adequate to establish this diagnosis.

3. NON RESPIRATORY DISORDERS OF EXCESSIVE DAYTIME SLEEPINESS

3.1 DIAGNOSIS OF NARCOLEPSY (5,6)

The diagnosis of narcolepsy may be made confidently by history alone only when daytime hypersomnolence and classical cataplexy symptoms are present. The latter symptom is highly specific for this disease. However, sleep studies (PSG and multiple sleep latency test (MSLT)) are an invaluable adjunct to diagnosis particularly in cases in which a history of cataplexy is absent or equivocal. Additionally because this condition is life long and its diagnosis may have significant implications for driving and vocational choices, and medications to treat this disorder may carry significant risk, objective testing is highly desirable. PSG is used primarily to exclude other causes of excessive daytime sleepiness (eg OSA), and is also traditionally employed as part of the MSLT protocol to confirm that the patient had sufficient sleep the night prior to the MSLT. The MSLT findings of a mean sleep latency of less than 8 minutes and 2 or more sleep onset REM periods, in the absence of a history of chronic sleep restriction or acute sleep deprivation, or absence of another sleep disorder is consistent with a diagnosis of narcolepsy. The combination of a mean sleep latency of less than 5 minutes and 2 or more REM onset sleeps on MSLT is reasonably sensitive and specific for narcolepsy but still cannot be relied on alone for the diagnosis (99). If, following careful history taking and sleep testing (PSG and MSLT) there remains diagnostic uncertainty, CSF hypocretin levels might be considered (100). In atypical cases, brain MRI may be useful to rule out structural lesions mimicking the condition.

3.2 DIAGNOSIS OF PRIMARY HYPERSOMNIA AND OTHER DISORDERS LEADING TO HYPERSOMNOLENCE

The diagnosis of primary hypersomnia is one of exclusion. PSG is therefore required to rule out common sleep disorders such as OSA that can lead to hypersomnolence. An assessment of sleep-wake schedules using a sleep diary with or without actigraphy over a 2-3 week period can also be helpful to exclude chronic sleep restriction. MSLT should be performed to objectively confirm the presence of hypersomnolence. Other rare disorders such as Prader-Willi Syndrome, Myotonic

Dystrophy and Klein Levin Syndrome are associated with pathological sleepiness (and in the instance of the first two disorders, may be associated with sleep onset REMs) and may thus enter the differential diagnosis of idiopathic hypersomnia or narcolepsy. However, these conditions are usually readily identified by careful clinical history and examination, supplemented by genetic testing in some instances.

DEPRESSION

It is also important to recognise that depression is frequently associated with reports of daytime fatigue and sleepiness. Patient reported sleepiness is better predicted by the presence of depression than by AHI in both general and sleep clinic populations (114, 115, 116). Clinical review of the patient before and after OSA diagnosis and treatment should therefore include an assessment for an underlying depressive disorder.

3.3 QUANTIFICATION AND VERIFICATION OF EXCESSIVE DAYTIME SLEEPINESS FOR MANAGEMENT PURPOSES

Objective tests of daytime sleepiness such as MSLT and the maintenance of wakefulness test (MWT) are not recommended routinely for the management of patients with sleep disorders. Response to treatment can usually be judged clinically and with the assistance of validated questionnaires such as the Epworth Sleepiness Scale. However, where there is reason to suspect this type of assessment is unreliable (eg over reporting or under reporting of symptoms by patients), and it is important to have a clear idea of the level of daytime impairment for management, (e.g. driver licensing or medicolegal purposes), tests such as the MSLT and MWT may be useful. The MWT has a stronger a priori rationale as a test of daytime alertness, and may therefore be more relevant than the MSLT to assess occupational and driving safety. There can be considerable discrepancy between MSLT and MWT findings in the same subject (101) suggesting that the two tests provide different information about sleepiness or sleep propensity.

3.3.1 Multiple Sleep Latency Test

The MSLT provides an objective measure of the ability or tendency to fall asleep. Four to five evenly spaced 20-minute daytime nap opportunities with the patient lying in a quiet darkened room are provided and the time to sleep and REM sleep onset (if any) is quantified from EEG/ EOG and EMG recordings. The patient is instructed to attempt to fall asleep and the mean sleep latency result is taken to be indicative of sleep propensity.

The reader is directed to a recent American Academy of Sleep Medicine publication for a detailed description of the performance of the MSLT, reporting of results and test interpretation (7) . Measurement of respiratory parameters is not generally indicated in an MSLT. Sleep diaries or actigraphy prior to MSLT may be helpful in interpretation. The urine drug screen is usually performed in the morning but its timing and circumstances may be altered by the clinician.

Where an MSLT is conducted on a patient known to have a respiratory sleep disorder and using treatment, the test should be conducted with the patient using treatment, for example using CPAP. If this is not done there is a risk of prolonging sleep latency through the occurrence of respiratory events at sleep onset.

3.3.2 Maintenance Of Wakefulness Test

The MWT provides an objective measure of the ability to stay awake for a defined time. This test consists of four evenly spaced 40-minute test periods in the daytime during which the patient is asked to resist sleep while sitting comfortably in an arm chair in a darkened room. Patients are not allowed to use extraordinary measures to stay awake (such as slapping the face or singing) during each 40 minute trial. The patient must not engage in any activities prior to or during these test periods that may increase arousal levels. EEG/EOG and EMG are measured and the latency to sleep onset (if any) is quantified. The test has a stronger a priori rationale as a measure of a patient's daytime vigilance or ability to resist sleep than the MSLT.

The reader is directed to the most recent American Academy of Sleep Medicine publication for a detailed description of the performance of the MWT, reporting of results and test interpretation (7,). Measurement of respiratory parameters is not generally indicated in a MWT. There are generally fewer normative data for the MWT than the MSLT, but some normative data for the Australian population are available (102). Drug screening may be indicated to ensure that sleepiness/wakefulness on the MWT is not influenced by substances other than medically prescribed drugs. The urine drug screen is usually performed in the morning but its timing and circumstances may be altered by the clinician.

3.3.3 Osler Test

The Osler test (103) is essentially the same as the MWT with the exception that sleep onset is determined from psychomotor performance rather than EEG/ EOG and EMG (i.e. absence of button pressing response to a light presented at frequent regular intervals). Mean sleep latency using this test agrees closely with MWT results (104) obtained in the same patients with sleep disorders. There is less experience in Australia and New Zealand with this test than MSLT and MWT, and fewer published reports of normal results. It has the potential advantage that it can be performed in centres that do not have a sleep laboratory. It may allow some cost savings when performed in a sleep laboratory because of reduced requirements for technician EEG real time observation and subsequent scoring.

4. INSOMNIA AND DISORDERS OF INSUFFICIENT SLEEP

4.1 Indications for Sleep Study

This is no evidence to support the routine use of PSG in the assessment of patients with insomnia (105) or circadian sleep disorder (106). However, if there is a history suggestive of sleep disordered breathing, PLMD or complex parasomnias that might be contributing to prolonged sleep latency or disrupted sleep patterns, polysomnography should be considered. However it should be recalled that approximately 30 % of patients have concomitant OSA and insomnia (109).

4.2 Sleep Diary and Actigraphy

Systematic recordings of subjective estimates of sleep and bed times made over days or weeks by patients who present with complaints of insomnia can be

invaluable in assessing the nature of their insomnia (eg distinguishing delayed or advanced phase insomnia from psychophysiological insomnia) and can be useful in following response to treatment interventions. Sleep and bed times assessed objectively with 24-hour actigraphy measurements may be used also in special circumstances to corroborate the subjective sleep reports or point to a possible problem of sleep misperception. Actigraphy usually includes estimates of light and dark exposure across the day night period.

5. MEASUREMENT TECHNIQUES FOR SLEEP STUDIES

5.1 Preparation and instructions to patients prior to study.

The preparation and education of the patient prior to the study enhances the quality of data obtained. Results of studies performed while the patient is acutely unwell, such as early during an inpatient admission may be obscure the true nature of sleep disordered breathing. For example, studies performed while the patient is in respiratory failure may provide information for acute management but should not be used as a basis to establish the patient on long term treatment. Similarly, patients with COPD are likely to demonstrate more sleep hypoxaemia during an acute exacerbation of their disease.

The use of alcohol, sedatives and hypnotics immediately prior to the study may exaggerate an underlying problem with obstructive sleep apnoea, nevertheless patients chronically using such medications may experience rebound insomnia on the night of the sleep study if they are withheld. It is the responsibility of the clinician ordering the test to decide whether it should be performed following the withdrawal of aggravating drugs or after appropriate treatment of underlying disease. The decision is likely to hinge on the particular question to be answered. In some instances, studies under both circumstances may be desirable. At the very least, the physician reporting the test should be fully aware of the condition of the patient at the time of sleep study and interpret the result accordingly.

Patients should be instructed to follow normal activities of daily living prior to presentation for the study. Unless the study is being performed for a special purpose, patients should maintain their regular sleep habits prior to the study.

5.2 Polysomnography

5.2.1 General

Respiratory sleep studies should employ, whenever possible, non-invasive methods for evaluating sleep, respiratory and cardiac function. A complete and permanent record of the study should be made and a written report issued (*see Laboratory Report).*

5.2.2 Signal recording

Detailed guidelines for standardised signal recording methodology can be found in the AASM Manual for the Scoring of Sleep and Associated Events 2012 (119). The ASTA/ASA commentary 2010(18) provides interesting background reading on the earlier version of the AASM manual, but should not be used as the current methodology guideline. The ASA recommends that sleep laboratories adopt the recommended technical specifications (for adults) for signal recording (Visual, Cardiac and Respiratory) as published in the AASM 2012 Manual (119).

5.2.3 Other Measurements

Other measurements may be incorporated into the sleep study to investigate specific disorders, such as oesophageal pH monitoring for gastro –oesophageal reflux. These should be considered as adjuncts to those outlined above.

Other protocols may be required for patients presenting to sleep clinics that use variables referred to in this section. Examples are the Multiple Sleep Latency Test and Maintenance of Wakefulness Test, which are used to objectively assess the degree of daytime sleepiness (*see Section 3*).

5.2.4 Calibration of Measurements

Physical calibration:
Calibration of quantitative instruments against appropriate standard reference values, where the absolute value is important, must occur at regularly scheduled intervals. Calibration of the electrical output signal of a quantitative instrument will also be necessary when, as is usually the case for PSG, the signal is recorded by a digital PSG recording system. For continuous signals (eg SpO_2, $PtcCO_2$, CPAP pressure, sound level, EEG), a minimum of 2 points must be performed that span the expected range of the measurement. In the case of level signals (such as body position and room light) calibration of each level must be performed.

The frequency of calibration depends on the stability of the transducer and the likelihood that an intrinsic or extrinsic factor could cause an error in the value reported. If the signal is critical to the interpretation of the study, for example SpO_2 or CPAP pressure, it should be checked prior to each study.

Accurate determination of sleep stage requires measurement of the amplitude of the EEG signals and hence the gain of EEG amplifiers should also be calibrated. In most systems the gain is stable over a long period of time and monthly calibration of these amplifiers is adequate. The accuracy of high and low pass filter settings of all high-frequency amplifiers should also be checked.

Technical and digital specifications for PSG recording are stated in the AASM scoring manual (119). The ASA recommends adoption of the technical and digital specifications for routine PSG recordings (including impedances, digital resolution, sampling rates and filter settings) as published in the AASM 2012 Manual (119).

Biological checks:

Biological checks are an important adjunct to physical calibration methods and apply to signals and phenomena for which there is no primary reference. Such checks include –

Eyes closed/eyes open EEG
Eye movements (vertical, horizontal, blinks)
Submental muscle activation
Respiration (nasal/oral flow, abdominal/thoracic movement)
Limb movements

Biological checks must be performed at the beginning of each PSG.

Physical calibration checks and all biological checks should be appropriately labelled and permanently recorded along with the PSG to provide confirmation of signal accuracy and integrity.

5.2.5 Quality Control

Information regarding quality management systems is contained within the current ASA/NATA document (108).

5.2.6 Data storage
The PSG record should be complete (allowing full disclosure of the raw data) and a copy retained. An appropriate data backup and recovery regime should be in place to guard against data loss.

5.3 Scoring and Reporting

Detailed guidelines for standardised event definitions and scoring methodology can be found in companion documents AASM 2007 (17), ASTA/ASA commentary 2010 (18). Further guidelines have been published by the AASM in 2012 (113, 119).
The ASA recommends adoption of the adult scoring rules for sleep stage, arousals, cardiac events, PLMS and respiratory events as published in the AASM 2012 Manual (119). Definitions of Respiratory Events including apnoeas, hypopnoeas, respiratory effort-related arousals (RERA), hypoventilation and Cheyne-Stokes breathing must be adopted without modification (119). Hypopnoeas must be scored using the AASM recommended definition. Scoring of hypopnoeas as obstructive or central is optional (119).

General guidance regarding the parameters to be reported for Polysomnography has been published in the AASM 2012 Manual (119).

5.3.1 Severity Criteria For OSA (13, 54)

5.3.1.1 The apnoea – hypopnoea index (AHI)

The AHI has been used in clinical trials and epidemiological studies to classify delineate patients as having OSA and to classify the severity of OSA.

The Chicago criteria (16) recommend the following classification of OSA severity:

Normal:	AHI <5 events per hour of sleep
Mild OSA:	AHI 5 ≤ 15 events per hour of sleep
Moderate OSA:	AHI 15 ≤ 30 events per hour of sleep
Severe OSA:	AHI > 30 events per hour of sleep

The use of an event frequency of 5 per hour as a minimum value to diagnose OSA was based on epidemiological data that suggest it may be associated with measurable health effects such as sleepiness, motor vehicle accidents and hypertension (89,90). The latter risk appears substantial at 30 events per sleep hour. In addition, intervention studies suggest treatment of subjects with between 5 and 15 events per hour of sleep relieves sleepiness and may improve neurocognitive function (91-93).

This AHI grading needs to be used with caution in describing severity of sleep disordered breathing in present day laboratories. The research studies underpinning the Chicago recommendations on OSA severity used oronasal thermistors and

respiratory inductance plethysmography to score respiratory events and in general, most definitions of hypopnoea incorporated a 4% arterial oxygen desaturation but not an arousal. However, most clinical laboratories now use nasal pressure, a more sensitive index of airflow, to detect sleep disordered breathing events. Many laboratories have adopted the definition of hypopnoea which includes arousals and does not mandate a 4% fall in arterial oxygen saturation but accepts a 3% fall in arterial oxygen saturation Thus, studies will now generally be scored with higher AHI values than would have been scored in the original studies defining syndrome severity, but lower than those scored using Chicago criteria. Clinicians using the above criteria should adjust the AHI cut-offs based on the best available evidence (preferably data obtained from their own laboratory comparing previous and present day recording and scoring methods). (112)

The Respiratory Disturbance Index (RDI) is defined as the AHI plus the RERA Index, and is optional for inclusion in reports of sleep studies (119). There are no data which have validated the use of the RDI in describing the severity of sleep disordered breathing, and this Index should be used with caution as described in the preceding paragraph.

5.3.1.2 Daytime Sleepiness

An assessment of sleepiness severity should be undertaken in all patients using the Epworth Sleepiness Scale (ESS) (94), or another validated questionnaire to assess excessive daytime sleepiness, while recognising that the ESS is neither sensitive nor specific in the diagnosis of OSA. A score of 0-10 is within the normal range, 11-15 indicates mild-moderate daytime sleepiness, and a score of 16-24 indicates moderate to severe excessive daytime sleepiness and may be associated with an increased risk of motor vehicle crashes.

The Chicago consensus standards (16) also provide guidance in the assessment of severity of daytime hypersomnolence.

5.3.1.3 Sleep Hypoxemia

Severe oxygen desaturation has been classified as an oxygen saturation <85% for more than 2% of the total PSG sleep time, while minimal or no desaturation has been classified as no PSG sleep saturation less than 90% Severe Desaturation as defined by total sleep time with oxygen saturation < 85% is weakly associated with a reduction in some neurocognitive performance measures. (95).

An oxygen saturation of <85% for more than 50% of sleep time (breathing air) has been suggested (16) as another threshold value defining severe sleep-related hypoventilation.

The nadir oxygen saturation during sleep has not been demonstrated to be an independent predictor of any short or long term cardiovascular or neurocognitive outcome, and is not considered to be a useful severity index.

5.3.1.4 Further considerations

The above are useful guidelines for grading the severity of sleep disordered breathing and its cardinal manifestation, daytime sleepiness. However, the clinician, in assessing the likely importance of disease and potential benefits of treatment in an individual patient, must be alert to specific aspects of the patient's sleep study and other pertinent clinical findings. An assessment of the severity of sleep disordered breathing in clinical practice should include:

i) *Careful evaluation of the PSG pattern of sleep disordered breathing.* In general the higher the AHI the more severe the sleep apnoea, but important sleep-disordered breathing may be present with low AHI values. For example, RERAs are not included in the AHI, yet may be contributing to adverse clinical outcomes. Sleep disordered breathing events may be confined to the supine position and/or REM sleep. If supine sleep and/ or REM sleep are under represented on the study night the computed AHI will underestimate the severity of the underlying OSA. The reader should note that supine sleep can potentially be over-represented on the PSG night. If obstructive events are unusually long, desaturation may be severe but AHI low. The level of oxygen desaturation is worthy of independent consideration particularly in the context of co-existing respiratory or cardiovascular disease and obesity. Thus, the reporting physician should carefully review sleep study findings including raw data, and a qualitative interpretation should be provided along with AHI and other data.

ii) *The patient's clinical circumstances.* Marked daytime sleepiness with a low AHI may indicate that the severity of sleep disordered breathing has been underestimated by the sleep study, but equally, alternate or additional causes for the sleepiness may be present, such as poor sleep hygiene, chronic sleep restriction, sedating drugs, depression or periodic limb movements of sleep. The impact of the sleepiness should also be considered. For example, sleepiness in a long distance bus or truck driver will be of particular importance. There is emerging literature that suggests that moderate-severe OSA with elevated 4% Oxygen Desaturation Index is an independent risk factor for cardiovascular disease. Thus, the presence of co-existing cardiovascular risk factors or disease in a patient may influence the clinician to advise treatment at a lower AHI severity cut off than might normally be the case (54).

5.3.2 The laboratory report for Type 1 and 2 sleep studies

A written report should be issued at the completion of all sleep studies detailing:

a) the variables measured.
b) sleep staging, including total sleep time, sleep efficiency, wake after sleep onset, sleep latency, stage R sleep latency, percentage of time in the various sleep stages, and frequency of arousals.
c) frequency and type of abnormal respiratory events (e.g. central or obstructive).
d) relationships of disordered breathing to posture sleep stage or treatment intervention when relevant.
e) oxygen saturation, described in quantitative terms using either a continuous saturation versus time plot or by using discrete intervals (e.g. sleep time spent within various ranges of saturation). The lowest saturation recorded during abnormal respiratory events should be noted.
f) transcutaneous PCO_2 ($PtcCO_2$) trends, where measured.
g) any disturbance of cardiac rate or rhythm, and its relationship to abnormal respiratory events, if measured. Include mean heart rate asleep.

h) the frequency of periodic limb movements and any associated sleep fragmentation.
i) medications (including sedatives) and alcohol that may have influenced the results.
j) technical comments
k) scoring definitions used, and supporting references
l) the physician's interpretation/conclusions should provide a summary of the relevant normal and abnormal findings from a review of the raw study data together with the above summary data, including comments on sleep staging, respiratory scoring, cardiac abnormalities, any abnormal behaviours or movements, and effectiveness of any applied therapy. The conclusion should provide a clear diagnosis and severity rating for diagnostic studies, and only make relevant recommendations regarding therapy from intervention studies.

The committee recommends a minimum of 12 minutes per study is required for the sleep physician to assimilate the clinical data, review the raw sleep study data, take into consideration technicians' comments and observations and prepare a report. For many studies a longer length of time will be required.

5.3.3 The Laboratory Report for Type 3 and 4 sleep studies

Type 3 & 4 study reports should include the following:

1. Type of device used
2. Technical adequacy of test
3. Date of testing
4. Duration of test recording
5. Respiratory Event Index (REI) and total number of respiratory events. The criteria used for apnoeas & hypopnoeas should be defined.

The respiratory event index (REI) is defined in the context of OOC testing devices as:

$$\text{REI} = \frac{[\text{apneas} + \text{hypopneas}]}{\text{Total sleep or recording time (h)}}$$

Reference (85).

6. A summary of oxygen desaturations during recording period
    - which may be ODI
    - % of time below certain thresholds
    - Mean O_2 saturation
    - minimum and/or maximum O_2 saturations
7. Heart rate during the recording period
8. Interpretation (based upon test results and clinical information), including at a minimum whether the test results support a diagnosis of obstructive sleep apneoa or not
9. Signature of interpreting sleep physician

The reader is directed to recent systematic reviews (83, 85) for guidance on those specific devices that have been demonstrated to have diagnostic utility and those that have not. These reviews and the source references provide information on the respiratory parameters measured in each device. A companion paper provides

guidance on how to assess the quality of studies on limited channel devices. In principle, statements concerning transducers and instrumentation made relevant to type 1 and 2 studies also apply to type 3 and 4 studies.

6. SLEEP LABORATORY FACILITIES AND PERSONNEL REQUIREMENTS

Appropriate standards for sleep laboratory facilities and personnel are detailed elsewhere, in the “Accreditation of Sleep Disorders Services” document published jointly by the ASA and NATA (108). These standards address requirements regarding: organization and administration; staffing and direction; policies and procedures; staff development, teaching and research; facilities; provision for emergencies; quality assurance; meetings; and the policies and procedures manual.

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8. APPENDIX

The following conflicts or potential conflicts of interest were declared by members of the committee

1. Current or recent (last 3 years) involvement with company or companies with a financial interest in devices or methods for performing sleep studies
    a. Direct financial interest (Nil for JD,AN, JW, DM,CW,PR,CC-C, MN)
    b. Employee, or engaged in a consulting capacity (including medical advisory boards, expert testimony) (Nil for JD,AN, JW,DM,CW,PR, C-C, MN)
    c. Substantial research support (Nil for JD,AN, JW,DM,CW, PR, CC-C,MN)
    d. Sponsored attendance at national or international meetings (Nil for JD,AN,JW,DM,CW,PR, CC-C,MN)

2. Direct or indirect financial benefit has been received from performing or reporting type I & II sleep studies. (Yes -JD,AN,JW,DM,CW, C C-C,MN, PR)

Individual COI statements are available from the secretariat of the Australasian Sleep Association.