

Independent Health Facilities

Clinical Practice Parameters and Facility Standards

Sleep Medicine, 4th Edition, October 2016



**THE COLLEGE OF
PHYSICIANS &
SURGEONS
OF ONTARIO**

The College of Physicians and Surgeons of Ontario

Vision Statement

Quality Professionals, Healthy System, Public Trust

Our Mandate

Build and maintain an effective system of self-governance.

The profession, through and with the College, has a duty to serve and protect the public interest by regulating the practice of the profession and governing in accordance with the Regulated Health Professions Act.

Our Vision Defined

Quality Professionals, Healthy System, Public Trust.

Our new vision is the framework by which we organize ourselves.

It guides our thinking and actions into the future. It defines not only who we are, but what we stand for, the role we see for ourselves, our critical relationships, in what system we work, and the outcomes we seek.

Each component of our vision is defined below:

Quality Professionals – as a profession and as professionals, we recognize and acknowledge our role and responsibility in attaining at a personal, professional, and at a system-level, the best possible patient outcomes.

We are committed to developing and maintaining professional competencies, taking a leadership position on critical issues that impact the performance of the system, and actively partner to provide tools, resources, measurement, to ensure the optimal performance at all levels of the system.

Healthy System – the trust and confidence of the public and our effectiveness as professionals is influenced by the system within which we operate. Therefore, we, as caring professionals, are actively involved in the design and function of an effective system including:

- accessibility
- the interdependence of all involved
- measurements and outcomes
- continued sustainability

Public Trust – as individual doctors garner the trust of their patients, as a profession we must aim to have the trust of the public by:

- building positive relationships with individuals
- acting in the interests of patients and communities
- advocating for our patients and a quality system

Our Guiding Principles

Integrity, accountability, leadership and cooperation.

The public, through legislation, has empowered the profession to regulate itself through the College.

Central to the practice of medicine is the physician-patient relationship and the support of healthy communities. As the physician has responsibility to the patient, the profession has the responsibility to serve the public through the health-care system.

To fulfill our vision of quality professionals, healthy system, public trust we will work to enhance the health of the public guided by professional competence and the following principles:

Integrity – in what we do and how we go about fulfilling our core mandate:

- Coherent alignment of goals, behaviours and outcomes;
- Steadfast adherence to a high ethical standard.

Accountability to the public and profession – we will achieve this through:

- An attitude of service;
- Accepting responsibility;
- Transparency of process;
- Dedicated to improvement.

Leadership – leading by proactively regulating our profession, managing risk and serving the public.

Cooperation – seeking out and working with our partners – other health-care institutions, associations and medical schools, etc. – to ensure collaborative commitment, focus and shared resources for the common good of the profession and public.

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Preface

The Independent Health Facilities Act (IHFA), proclaimed in April 1990, and amended in 1996 and 1998, gives the College of Physicians and Surgeons of Ontario the primary responsibility for carrying out quality assessments in Independent Health Facilities. These facilities may provide some of the following insured services:

- in diagnostic facilities: radiology, ultrasound, magnetic resonance imaging, computed tomography, nuclear medicine, pulmonary function, and sleep medicine

Note: Sleep medicine encompasses investigative, clinical diagnostic and treatment components. All IHF sleep disorder facilities must provide these three components at the referring physician's request.

- in treatment or surgical facilities: one or more of a variety of procedures in peripheral vascular disease, plastic surgery, obstetrics and gynaecology, dermatology, nephrology, ophthalmology, and their related anaesthetic services and perhaps other specialties.

The College of Physicians and Surgeons of Ontario has a legislative mandate under the Act to perform quality assessment and inspection functions. This responsibility, and others set out by agreement with the Ministry of Health and Long-Term Care, contribute to the College achieving its goals as stated in the College's Mission Statement. An important goal of the College is to promote activities which will improve the level of quality of care by the majority of physicians. The Independent Health Facilities program helps reach this goal by developing and implementing explicit clinical practice parameters and facility standards for the delivery of medical services in Ontario, assessing the quality of care provided to patients, and as a result, promotes continuous quality improvement.

Purpose of Clinical Practice Parameters

The Independent Health Facilities clinical practice parameters and facility standards are designed to assist physicians in their clinical decision-making by providing a framework for assessing and treating clinical conditions commonly cared for by a variety of specialties. The primary purpose of this document is to assist physicians in developing their own quality management program and act as a guide for assessing the quality of patient care provided in the facilities.

Note: The parameters and standards are not intended to either replace a physician's clinical judgment or to establish a protocol for all patients with a particular condition. It is understood that some patients will not fit the clinical conditions contemplated by certain parameters and that a particular parameter will rarely be the only appropriate approach to a patient's condition.

In developing these clinical practice parameters, the objective is to create a range of appropriate options for given clinical situations, based on the available research data and the best professional consensus. The product, therefore, should not be thought of as being “cast in stone”, but rather subject to individual, clinically significant patient differences.

Where appropriate and for clarification, Standards and Guidelines have been identified throughout the clinical practice parameters. A Standard is a generally accepted patient care strategy that reflects a high degree of clinical certainty. A Guideline is a generally accepted patient care strategy that reflects a moderate degree of clinical certainty. Guidelines may be adopted, modified, or rejected according to clinical needs, individual patient considerations, local resources, and physician discretion. Guidelines do not establish inflexible protocols for patient care nor are they meant to replace the professional judgment of physicians.

Role of the College of Physicians and Surgeons

The College adopted the role of a facilitator for the development of clinical practice parameters and facility standards. Representatives of national specialty societies and sections of the Ontario Medical Association, and individuals with acknowledged skill, experience and expertise formed specialty-specific Task Forces.

All Clinical Practice Parameters and Facility Standards undergo an external review process. External reviewers include: Registrars of other regulatory colleges, department heads at relevant academic institutions, relevant national and provincial organizations, independent health facilities, IHF assessors and other stakeholder as determined by the relevant Task Force.

Task Force members ensure that:

- clinical practice parameters must be based on the appropriate mix of current, scientifically-reliable information from research literature, clinical experience and professional consensus.
- any parameter-setting exercise must be done exclusively from the quality perspective. That may well mean that some of the conclusions reached could add to medical care costs.
- parameters have to be flexible enough to allow for a range of appropriate options and need to take into account the variations in practice realities from urban to rural areas.
- parameters need to be developed by consensus and consultation with the profession at large.
- parameters should provide support and assistance to physicians without boxing them in with “cookbook formulas.”
- parameters will need to be regularly updated based on appropriate research studies.
- parameters should reduce uncertainty for physicians and improve their clinical decision-making.
- information on practice parameters must be widely distributed to ensure that all physicians benefit from this knowledge.

Responsibilities of the College

Responsibilities of the College include:

- assessing the quality of care when requested by the Ministry. The College will maintain a roster of physicians, nurses, technologists and others to serve as inspectors and assessors as required.
- inspecting the illegal charging of facility fees by unlicensed facilities when requested by the Ministry.
- monitoring service results in facilities. The College's information system will monitor individual and facility outcome performance. This is a unique feature of the legislation, which for the first time in North America, requires facility operators to establish and maintain a system to ensure the monitoring of the results of the service or services provided in a facility.
- providing education and assisting facilities so that they may continually improve the services they provide to patients. The College will work with and assist physicians in these facilities so that they can develop their own quality management programs based on the parameters and standards, monitor facility performance by conducting quality assessments, work with facilities to continually improve patient services, assist in resolving issues and conducting reassessments as necessary.

Updating this Document

These parameters and standards are subject to periodic review, and amendments in the form of replacement pages may be issued from time to time. Such pages will be mailed automatically to all relevant independent health facilities. It is planned to issue new editions of the parameters and standards at intervals not greater than five years. The external review process will be repeated to validate the new parameters as they are developed.

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Chapter 1 Services Provided in a Sleep Disorder Facility

1.1 Overview of Diagnostic and Treatment Services

Patients are referred to sleep facilities for evaluation of a variety of symptoms, clinical complaints, and presumed diagnoses. Occasionally a physician may request a diagnostic polysomnogram without a consultation, but appropriate evaluation of a suspected sleep medicine diagnosis usually requires a consultation with a sleep medicine specialist. Appropriate evaluation of a suspected sleep medicine diagnosis often requires overnight polysomnography in a sleep disorder facility.

➤ Standards

S1.1.1	All Independent Health Facility Sleep Disorder facilities shall provide consultation with a sleep medicine physician in all major areas of sleep medicine with the exception of Pediatric Sleep Medicine (see the Pediatric section of this document for requirements to provide this service).
S1.1.2	All Independent Health Facility Sleep Disorder facilities shall provide Investigative services for facility assessment of sleep, sleep pathology, drowsiness and alertness, including, but not limited to: <ul style="list-style-type: none">• Polysomnography• Multiple Sleep Latency Tests (MSLT),• Maintenance of Wakefulness Tests (MWT) as outlined in this document.
S1.1.3	Consultation and follow-up visits with sleep medicine specialists shall conform to the standards detailed by the Ontario Ministry of Health and Long Term Care. All visits shall be documented with notes that include clearly stated opinions and recommendations, clear follow up plans, and clear, reasonable designation of who is responsible for ongoing care.
S1.1.4	Investigating and treating children less than 13 years old requires special training, staffing, and lab setups. Any lab doing pediatric assessment must comply with the standards and guidelines detailed in the Pediatric section of this manual.
S1.1.5	When polysomnography is indicated, an <i>overnight</i> study shall be done except as provided below.
S1.1.6	A polysomnogram shall be done over an interval corresponding to the patient's normal sleep interval. When the patient's normal sleep schedule does not correspond to a normal day/ night schedule, for example <ul style="list-style-type: none">• someone who works steady nights and maintains the same schedule when off work, or• someone who has very severely delayed sleep timing, then any polysomnogram conducted shall be timed to correspond to the patient's schedule as closely as practical, with a brief explanation in the requisition and study report. <p>If for any reason a study is done at significant variance to someone's habitual sleep schedule this variance must be clearly justified in the clinical record and noted in the polysomnogram report.</p>

➤ **Guidelines**

G1.1.1	Patients should be seen in consultation by a sleep physician prior to any polysomnogram. This is to ensure a polysomnogram is required; to ensure that an appropriate study montage is selected; and to ensure optimal patient preparation.
G1.1.2	If there is sufficient information available when a referral is triaged, it may be appropriate to arrange a polysomnogram prior to a sleep medicine consultation, but the facility must ensure that a study is indicated; that an appropriate montage is ordered; and that appropriate pre-polysomnogram education is provided to the patient.

1.2 Indications and Contraindications for Polysomnography

In lab overnight polysomnography remains the “gold standard” sleep test when evaluating most patients with a sleep disorder.

➤ **Standards**

S1.2.1	<p>An initial in-lab Level 1 diagnostic polysomnogram is indicated to evaluate:</p> <ul style="list-style-type: none"> • suspected sleep related breathing disorders • someone diagnosed with a sleep disorder via another testing method (e.g. unattended home screening) who has not responded appropriately to therapy for that sleep disorder • suspected narcolepsy, idiopathic hypersomnia or secondary hypersomnia, when the polysomnogram is combined with a multiple sleep latency test • suspected parasomnia disorders • patients with neuromuscular disorders and sleep related symptoms • paroxysmal arousals or other sleep disturbance thought to be seizure related • suspected periodic limb movement disorder
S1.2.2	<p>In a patient with a previous in-lab Level 1 diagnostic polysomnogram, a repeat diagnostic polysomnogram is indicated to evaluate any of the conditions listed above IF a sleep medicine consultant has clearly documented that:</p> <ul style="list-style-type: none"> • there have been significant changes in the clinical history or findings of a person with an established diagnosis which requires assessment by a new polysomnogram <p>OR</p> <ul style="list-style-type: none"> • important diagnostic information required for current management that cannot be obtained from any prior polysomnograms.
S1.2.3	<p>Indications for a Level 1 in-lab therapeutic polysomnogram include:</p> <ol style="list-style-type: none"> 1. Establishing therapy for sleep related breathing disorders (CPAP, BiPAP, ASV etc.) 2. Adjusting incompletely titrated PAP therapy in a patient who had a split night polysomnogram (see below) during which a clear PAP titration could not be attained. 3. Re-evaluating / adjusting of positive airway pressure therapy because of clearly documented:

	<ul style="list-style-type: none"> • Significant changes in body weight or body structure. • Snoring or gasping in sleep on the current PAP therapy prescription despite reasonable adherence to prescribed treatment, and reasonable empiric adjustments to that therapy. • Persistent or new daytime sleepiness or other significant symptoms in a patient diagnosed with a sleep disorder and prescribed treatment, despite reasonable adherence to that treatment and lack of response to reasonable adjustments to that treatment. • Significant persistent events or major pressure leaks on PAP therapy, detected by home/outpatient monitoring, and that have not responded to reasonable therapy adjustments. <ol style="list-style-type: none"> 4. Significant changes in, or development of, a condition likely to affect control of breathing or effectiveness of current therapy. 5. Significant changes in medication therapy likely to affect control of breathing or effectiveness of current therapy. 6. Re-evaluation of obstructive sleep apnea therapy following a surgical procedure of the upper airways. 7. Adjustment of and determining the efficacy of an oral appliance therapy for obstructive sleep apnea. 8. Initiation and adjustment of Bi-Level Positive Airway Pressure therapy (BiPAP) or Adaptive Servoventilation (ASV), or another form ventilatory support that is performed by the facility, in patients where conventional PAP therapy is not indicated or has failed. 9. Titration of ventilator settings with disease and symptom progression in patients with respiratory control disorders in facilities with consulting and technical staff with expertise in this field (as defined elsewhere in this document).
S1.2.4	<p><i>A Split Night Polysomnogram</i> refers to a Level 1, in-lab polysomnogram where the first part of the study is used to establish a clear diagnosis and the second part of the study is used to initiate/ adjust therapy. A split night polysomnogram may be done if all the following conditions are met:</p> <ol style="list-style-type: none"> 1. The split night Polysomnogram must follow a clear and comprehensive procedure for such studies detailed in the sleep facility’s manual. The policy must include explicit criteria to request or order a split night Polysomnogram. For example the facility policy might specify that a technologist could request the on-call physician to approve changing a diagnostic study to a split night study if data gathered adequately confirms a patient has an estimated AHI over 30 events per hour, or is having clear obstructive events causing O₂ desaturations below 75%. 2. There is clear evidence of sleep disordered breathing during diagnostic evaluation with explicit criteria in the policy. 3. A minimum of 2 hours baseline and 3 hours therapy is recommended. However with very severe apnea and verified desaturations below 75% the study may be split earlier. An estimated AHI over 30 events per hour or obstructive events causing O₂ desaturations below 75% are the recommended

	<p>thresholds.</p> <p>4. The split night protocol is ordered BEFORE the study by a sleep medicine physician based on their pre study assessment,</p> <p style="text-align: center;">OR</p> <p>The physician on call has approved a change to a split night protocol based on information provided during the study.</p> <p>5. The patient must give consent to starting therapy, prior to starting any therapy.</p> <p>6. The rationale for initiating PAP prior to the patient discussing the diagnostic results with the physician must be fully discussed with the patient at the earliest opportunity, and must be fully documented in the polysomnogram report.</p> <p>7. A follow-up appointment with sleep medicine is arranged for the patient at an early date.</p>
S1.2.5	<p>A polysomnogram shall NOT be done to:</p> <ol style="list-style-type: none"> 1. Evaluate insomnia in the absence of other symptoms suggesting another primary sleep disorder or lack of response to standard therapy (refractory insomnia), establish a diagnosis of major depression or other mental health disorder. 2. Diagnose chronic lung disease. 3. Exclude a “first night effect” on results from a prior polysomnogram. 4. Re-titrate PAP therapy when there has not been a clearly documented change in the patient’s clinical condition as noted in the standards above.
S1.2.6	<p>A polysomnogram shall NOT be done unless a physician is immediately available to make decisions and provide advice to facility staff re problems or issues with any aspect of the study.</p>

1.3 Positive Airway Pressure (PAP) Therapy Titration and Prescription

The goal of PAP therapy is to relieve obstructive events during sleep, and to improve sleep architecture and arterial oxygen saturation.

➤ **Standards**

S1.3.1	<p>Any physician prescribing therapy for a sleep disorder must ensure the patient or their authorized designate (e.g. Parent; guardian; power of attorney for personal care; etc.) has a reasonable understanding of the diagnosis and options for therapy prior to being given a prescription.</p>
S1.3.2	<p>Clinical assessment of a patient shall be done prior to:</p> <ol style="list-style-type: none"> 1. Any sleep study to titrate or adjust therapy 2. Being issued any prescription for therapy for a sleep disorder, except as provided in the following standard.

S1.3.3	In unusual situations the therapeutic study or portion of a study, and the initial PAP prescription can precede the patient's assessment by sleep medicine physician, provided all of the following conditions are met: 1. There are no contraindications to the therapy prescribed 2. A sleep medicine physician has reviewed the diagnostic findings prior to the therapy prescription - OR - in the case of severe OSA or hypoventilation during a diagnostic sleep study, the case was discussed with the sleep medicine physician on call for the sleep lab prior to therapy being introduced, and the therapy follows the facility's policy and procedure for split night studies. 3. There is clear documentation in the patient's file of the reasons clinical assessment of the patient was not done prior to therapy being initiated 4. This is not the routine protocol for patients attending the facility
S1.3.4	PAP therapy can be adequately titrated in a single study in the majority of patients. There is no indication for several nights of PAP titration.
S1.3.5	Sleep physicians who prescribe therapy for sleep disordered breathing must meet the qualifications outlined in Chapter 2 of this document.
S.1.3.6	Any sleep physician requisitioning PAP therapy initiation/ titration or prescribing PAP therapy must ensure that there are no contra-indications to PAP therapy.

➤ **Guidelines**

G1.3.1	Any physician may prescribe PAP therapy but the Assistive Devices Program (ADP) will only support payments to Ontario residents for PAP prescriptions authorized by ADP approved sleep physicians. Sleep physicians must apply to the MOHLTC ADP program to become approved ADP PAP therapy prescribers
G1.3.2	Selected patients may be prescribed a trial PAP set up prior to a therapeutic polysomnogram to allow acclimatization prior to the in facility titration.

1.4 Multiple Sleep Latency Testing (MSLT)

The MSLT measures the ability to fall asleep in a quiet dark setting, and assesses initial sleep structure if the person falls asleep.

Standards and guidelines listed below apply to the practice of adult sleep medicine (reference: Practice parameters for clinical use of the multiple sleep latency test and the maintenance of wakefulness test. Sleep 20015; 28(1): 113-121). Although the MSLT is being used in evaluation of children, the paucity of evidence regarding pediatric usage and the special issues regarding performance, interpretation, and operating characteristics of these tests in children require separate and specific guidelines and standards. See the Pediatric section of this manual for pediatric standards and guidelines.

➤ **Standards**

S1.4.1	An MSLT is indicated as part of the evaluation of patients suspected of having narcolepsy, idiopathic hypersomnia, or with significant secondary hypersomnia that hasn't responded to therapy of a diagnosed sleep disorder (for example persistent
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	drowsiness in someone with adequately treated sleep apnea).
S1.4.2	Repeat MSLT testing is indicated if a sleep medicine physician has assessed the patient and clearly documented that there is a reasonable probability of narcolepsy, idiopathic hypersomnia, or significant secondary hypersomnia that hasn't responded to therapy, and <ul style="list-style-type: none"> • prior MSLT(s) did not provide objective confirmation, or were unable to be interpreted or • the patient's clinical status has changed significantly since prior MSLT(s)
S1.4.3	MSLT is NOT indicated for: <ul style="list-style-type: none"> • Routine initial evaluation of someone suspected of having obstructive sleep apnea syndrome prior to therapy of any sleep apnea present. • Routine assessment of changes in drowsiness following PAP therapy of sleep disordered breathing. MSLT may be indicated in someone with significant drowsiness that hasn't responded to therapy despite evidence of consistent use of therapy that adequately controls the sleep disordered breathing. • The routine evaluation of sleepiness in medical and neurological disorders other than suspected narcolepsy, idiopathic hypersomnolence, and undiagnosed drowsiness. For example MSLT is not indicated in the routine evaluation of insomnia or circadian rhythm disorders.
S1.4.4	The MSLT consists of a minimum of four 20 minute opportunities to fall asleep during the day, beginning 1.5-3 hours after awakening and recurring every two hours
S1.4.5	An additional fifth nap is to be done if REM intrusion has occurred only once during the first four sleep opportunities.
S1.4.6	The MSLT protocol includes all of the following elements: <ol style="list-style-type: none"> 1. Patients should discontinue sleep influencing medications for 2 weeks before the study. Exceptions are to be discussed in the report. 2. Patients are to record their sleep before the study with a sleep diary covering optimally 14, but at least 7 consecutive nights. 3. Smoking should be stopped 30 minutes before each nap. 4. Vigorous physical activity and bright light are to be avoided during the test. 5. The polysomnogram prior to the MSLT should demonstrate at least 6 hours of sleep. 6. The first sleep opportunity of the MLST is to start between 1.5 - 3 hours after the final awakening 7. Between tested sleep opportunities patients are to remain awake in a supervised setting. 8. The recording montage is to include frontal, central and occipital EEG, bilateral EOG's, and chin EMG. 9. Each test interval is to end after 20 minutes if no sleep of any stage has occurred or 15 minutes after any 30 second epoch of any stage sleep is seen. 10. Bio-calibrations are to be performed before each nap study.

S1.4.7	Scoring the MSLT follows standard AASM sleep stage rules with the exception that any interval of clear REM physiology (low voltage, mixed frequency EEG; absent or very low EMG tone; rapid eye movement) is to be scored as a REM intrusion, even if it doesn't meet criteria to score the entire epoch stage R.
S1.4.8	All violations of the protocol or variations from the protocol that is in use by the facility are to be fully justified and documented in the report.
S1.4.9	Reports are to include, but are not limited to: <ol style="list-style-type: none"> 1. analysis of the presence/ absence of sleep in each test interval 2. the presence of and latency to REM sleep in each test interval 3. the latency to sleep in each test interval and overall mean sleep latency (using 20 minutes for a test interval if no sleep is seen) 4. comments about the preceding sleep and other data as appropriate 5. discussion of any protocol violations, including possible impact on results, and justification of a violation where relevant 6. a clear diagnosis if this is supported by the findings and clinical history 7. recommendations for therapy or follow-up to discuss therapy

➤ **Guidelines**

G1.4.1	MSLTs should be performed following an all-night polysomnogram unless a sleep medicine physician clearly documents reasons to deviate from the standard protocol.
G1.4.2	An additional fifth nap should be considered if abnormal sleep onset is detected in at least one of the first four sleep opportunities, and the decision is documented in the MSLT report.
G1.4.3	Additional frontal leads (FP1-M2, FP2- M1) are recommended to increase detection of eye movement.
G1.4.4	Patients should have urine screening for stimulants and other medications when clinically indicated.
G1.4.5	Considering the known high frequency of short sleep latency and Sleep Onset REM periods (SOREMPs) in unselected normal populations interpreting physicians should be cautious about reaching conclusions based solely on the MSLT results

1.5 Maintenance of Wakefulness Testing (MWT)

The MWT measures the ability of a person to remain awake in a quiet dark setting.

Standards and guidelines listed below apply to the practice of adult sleep medicine (reference: Practice parameters for clinical use of the multiple sleep latency test and the maintenance of wakefulness test. Sleep 2005;28(1) :113-121.) See the pediatrics section of this document for pediatric standards and guidelines.

➤ **Standards**

S1.5.1	An MWT is indicated in assessment of individuals in whom inability to remain awake constitutes a safety issue
S1.5.2	An MWT is indicated in assessment of selected patients with narcolepsy, idiopathic hypersomnia, or secondary hypersomnia where objective evidence of therapy response is required for clinical management. Justification must be documented in the clinical file.
S1.5.3	The 40 minute MWT is recommended. It consists of four 40 minute test intervals beginning 1.5-3 hours after the usual wake-up time and recurring every two hours.
S1.5.4	<p>The MWT protocol includes all of the following elements:</p> <ol style="list-style-type: none"> 1. Patients may be asked based on clinical circumstances to record their sleep for 7 to 14 days with a sleep diary. 2. The use of tobacco, caffeine and other medications by the patient before or during the MWT should be addressed and decided upon by the sleep clinician before the MWT. Urinary drug screening , usually performed on the morning of the test, may be indicated to ensure that other substances are not modifying sleepiness/wakefulness. 3. A PSG need not be performed in laboratory on the night before the test. The perceived sleep data on the night before should be recorded. 4. The room should be maximally insulated from external light. A light source (0.1 to 0.13 lux) should be positioned slightly behind the patient’s head such that it just out of their field of vision. Room temperature should be set at the patient’s comfort level. The patient should be seated with the back and head supported. 5. The conventional montage recorded includes frontal, central and occipital EEG derivations, left and right eye electro-oculograms, mental/submental electromyograms, and electrocardiograms. Biocalibrations are performed prior to each test. 6. Instructions to the patient consist of the following: “ Please sit still and remain awake for as long as possible. Look directly ahead of you , and do not look directly at the light.” Patients are not allowed to use extraordinary measures to stay awake such as slapping the face or singing. 7. Trials are ended after 40 minutes if no sleep occurs, or after unequivocal sleep defined as three consecutive epochs of stage 1 sleep, or one epoch of any other stage sleep. Scoring the MWT follows standard AASM sleep stage rules. 8. Sleep onset is defined as the first epoch with greater than 15 seconds of cumulative sleep in a 30 second epoch. 9. The following data should be recorded: Start and stop times for each trial, sleep latency, total sleep time, stages of sleep achieved for each trial and the arithmetic mean sleep latency of the four trials.

S1.5.5	Scoring the MSW follows standard AASM sleep stage rules
S1.5.6	All deviations of this protocol or additions are to be documented in the report with justifications.
S1.5.7	The normal value for the MWT average (+/- 2 SD) sleep latency to the first epoch of sleep is 30.4 +/- 11.2 minutes.

➤ **Guidelines**

G5.1.1	An MWT may be indicated in assessment of selected patients with narcolepsy, idiopathic hypersomnia, or secondary hypersomnia, who have not clearly responded to therapy, where results would affect clinical management. Justification must be documented in the clinical file.
G5.1.2	Patients should have urine screening for stimulants and other medications .

Chapter 2 Staffing a Facility

2.1 Overview

All of the information in this Chapter is to be regarded as a Standard.

When staffing a sleep disorder facility, the medical, technical and other health care staff involved with patients must meet the qualifications outlined in this chapter.

Documentation for all staff positions is maintained.

2.2 Medical Staff

Each sleep disorder facility has one or more physicians who have expertise in evaluating patients with sleep disorders, assessing, diagnosing and developing and implementing a management plan for patients diagnosed with sleep disorders. These physicians are responsible for:

- interpreting polysomnograms
- and
- providing comprehensive clinical diagnosis and recommendation for management when requested by the referring physician
- and
- triage of all referrals.
- and
- The physician meets the criteria established for physicians practising sleep medicine:
 - on or before October 1, 1996 or
 - after October 1, 1996 or
 - after September 1, 2008

2.3 Physicians Practising Sleep Medicine on or before October 1, 1996

The physician is a member licensed to practice in Ontario by the College of Physicians and Surgeons of Ontario **and**

- entered the practice of sleep medicine on or before October 1, 1996
- and
- has experience from the assessment, diagnosis and treatment of patients with a broad range of primary and secondary sleep disorders. These physicians must provide evidence of interpreting polysomnography for the previous 12 months.

2.4 Physicians who Started the Practice of Sleep Medicine after October 1, 1996, but before September 1, 2008

The physician is a member licensed to practice in Ontario by the College of Physicians and Surgeons of Ontario **and has obtained:**

- A minimum of 12 months full-time or equivalent clinical training in the assessment, diagnosis and treatment and polysomnographic evaluation of patients with a broad range of primary and secondary sleep disorders in a recognized post-graduate training facility providing evidence of when it occurred and verification by a clinical sleep-trained supervisor/program director.
- or**
- Successful completion of the certification examination of the American Board of Internal Medicine in Sleep Medicine or, previously, the American Board of Sleep Medicine.
- or**
- Experience from the assessment, diagnosis and treatment of patients with a broad range of primary and secondary sleep disorders and the interpretation of polysomnograms under the supervision of a physician previously qualified in Sleep Medicine in Ontario. A minimum of 2,000 hours experience and training must be obtained and can occur in a time frame of between 12 and 36 months.

2.5 Physicians who Started, or are Starting the Practice of Sleep Medicine after September 1, 2008

The physician is a member licensed to practice in Ontario by the College of Physicians and Surgeons of Ontario, **and has demonstrated:**

- Appropriate training AND experience in sleep medicine to provide sleep medicine services within an IHF. Documentation must be available to demonstrate that the individual has successfully completed one of the minimum training requirement pathways in the CPSO Change in Scope of Practice for Sleep Medicine document and is in full compliance with any terms, conditions or limitations on their certificate of registration with the College, including any supervision requirement or scope of practice definition (see Appendix II).

Physicians will report to and work with the College to ensure appropriate training and assessment is successfully completed prior to the provision of services within their proposed change in scope of practice. Criteria and processes for appropriate training and practice assessments will be in place through the College's Change in Scope policy.

2.6 Pediatrics

Physicians who wish to practice in the area of pediatric sleep medicine must meet the qualifications as identified above including meeting the requirement of Change of Scope of Practice.

Additional information regarding Pediatric Sleep Medicine is outlined in Chapter 7 and Appendices V and VI of this document.

2.7 Physician Additional Training for Mechanical Ventilation

Prescribing and administering CPAP, spontaneous bi-level positive pressure and/or supplemental oxygen during sleep is routine practice for qualified sleep physicians. However, the use of mechanical ventilation during sleep and/or wakefulness for patients with respiratory failure requires additional training in mechanical ventilation such as respirology. Physician training requirements must be consistent with the ATS/ASDA accreditation document.

2.8 Quality Advisor

The role of the Quality Advisor is an important one. Quality Advisors play a vital role in the overall operation of the Independent Health Facility to ensure that the services provided to patients are being conducted appropriately and safely.

Each IHF licensee is responsible for operating the facility and providing services in accordance with the requirements of the IHFA. Pursuant to O. Reg. 57/92 under the *Independent Health Facilities Act*, every licensee is required to appoint a Quality Advisor to advise the licensee with respect to the quality and standards of services provided in the independent health facility. The Quality Advisor must be a health professional who ordinarily provides insured services in or in connection with the facility and whose training enables him or her to advise the licensee with respect to the quality and standards of services provided in the facility.

2.8.1 Quality Advisor Responsibilities

The Quality Advisor is responsible for advising the licensee with respect to the quality and standards of services provided. In order to fulfill this duty:

- The Quality Advisor shall personally attend the facility at least twice each year, and may attend more frequently, where in the opinion of the Quality Advisor it is necessary based on the volume and types of services provided in the facility. The visits may be coordinated as part of the Quality Advisory Committee (QA Committee) meetings.
- The Quality Advisor shall document all visits to the facility made in connection with the Quality Advisor's role.

- The Quality Advisor shall ensure that a qualified physician be available for consultation during the facility's hours of operation.
- The Quality Advisor shall seek advice from other health professionals where in the opinion of the Quality Advisor it is necessary to ensure that all aspects of the services provided in the facility are provided in accordance with generally accepted professional standards and provide such advice to the licensee.
- The Quality Advisor shall chair the QA Committee. The QA Committee shall meet at least twice a year if the facility employs more than six full-time staff equivalents including the Quality Advisor; otherwise the QA Committee shall meet at least once a year. Regular agenda items should include: review of cases; policies and procedures; quality control matters on equipment; incidents, medical and technical staffing issues.
- All QA Committee meetings shall be documented.
- The Quality Advisor shall obtain copies of assessment reports from the licensee/owner/operator. If deficiencies were identified in the assessment, the Quality Advisor shall review same with the QA Committee and document such review. The Quality Advisor's signature is required on any written plan submitted by the licensee to the College.

The Quality Advisor shall advise the licensee on the implementation of an ongoing quality management (QM) program, which should include, but not be limited to, the following:

- Ensuring ongoing and preventive equipment maintenance
- Follow-up of interesting cases
- Follow-up of patient and/or medical and technical staff incidents
- Continuing education for medical and technical staff
- Ensuring certificates of registration, BCLS etc. are current
- Regular medical and technical staff performance appraisals
- Patient and referring physician satisfaction surveys

The Quality Advisor will advise the licensee, and document the provision of such advice, in connection with the following:

- **Health professional staff hiring decisions**, in order to ensure that potential candidates have the appropriate knowledge, skills and competency required to provide the types of services provided in the facility.
- **Continuing education** for all health professional staff members employed in the facility, as may be required by their respective regulatory Colleges or associations.
- **Appropriate certification** for all health professional staff members employed in the facility with the respective regulatory Colleges or associations.
- **Leadership**, as may be required to address and resolve any care-related disputes that may arise between patients and health professional staff.
- **Appropriate resources** for health professional staff members employed in the facility.
- **Formal performance appraisals** for all health professional staff.
- **Technology** used in the facility, in order to ensure it meets the current standard(s) and is maintained through a service program to deliver optimal performance.

- **Establishment and/or updating of medical policies and procedures** for the facility, e.g. consultation requests, performance protocols, infection control, and standardized reports, and other issues as may be appropriate.
- **Equipment and other purchases** as may be related to patient care.
- **Issues or concerns** identified by any staff member, if related to conditions within the facility that may affect the quality of any aspect of patient care.
- **Establishing and/or updating system(s)** for monitoring the results of the service(s) provided in the facility.

2.8.2 Quality Advisor Duty to Report to Director IHF

If the Quality Advisor has reasonable grounds to believe the licensee is not complying with the licensee's obligation to ensure that services are being provided in accordance with the generally accepted standards and to ensure that the persons who provide services in the facility are qualified to provide those services, the Quality Advisor must inform the Director of Independent Health Facilities forthwith in accordance with the provisions and Regulations under the *Independent Health Facilities Act*.

The Quality Advisor should acknowledge, in writing, his/her role in connection with Quality Assurance.

2.9 Medical Director

Each sleep disorder facility shall appoint a Medical Director.

The Medical Director:

- Is a member licensed to practice in Ontario by the College of Physicians and Surgeons of Ontario
- and
- Has met the training requirements as outlined in the Medical Staff section of this Chapter
- and
- Is responsible for the day-to-day operation and supervision of the sleep disorder facility, which includes regular physical attendance in the lab.

2.10 Continuing Professional Development (CPD) for all Physicians Providing Sleep Medicine Services

The Medical Director/Quality Advisor ensures all physicians in a Sleep Disorders Facility attend continuing education programs directly relevant to the practice of sleep medicine, which comply with their respective College. These activities must be documented at a minimum of 25 hours per year. These activities may include but are not limited to: attendance at case

presentations, quality assurance work, journal reading, on-line education as well as attendance at local, national and international meetings.

2.11 Other Health Care Staff

2.11.1 *Sleep Medicine Associates*

Other physicians may work in the facility as long as such associates work within their scope of practice and prior qualifications.

A sleep medicine associate is defined as a physician evaluating patients (providing consultation and follow-up visits) within their medical specialty and scope of practice for patients diagnosed with sleep disorders. For example, this might be an ENT surgeon or Respirologist who evaluates snoring or sleep-disordered breathing in their usual practice of Otolaryngology or Respirology but does not evaluate the entire range of sleep disorders.

2.11.2 *Technologists*

Each licensed sleep disorder facility has a minimum of one dedicated Registered Polysomnographic Technologist (RPSGT/RST).

All staff providing direct patient care must have current certification in cardiopulmonary resuscitation (BCLS/CPR).

The ratio of technical staff to patients for full, attended monitoring is such that staff is able to conduct proper quality sleep studies and provide necessary attention to patients in a safe and timely fashion. While a number of 1:3 is appropriate in many situations, the number must take into account the medical condition of the patients, whether CPAP is being titrated, etc. Changing technology may also influence the staff to patient ratio. At this time, the number of patients per technologist should not exceed three, for full Level I studies.

In recognition of the increasing interest and activities involving unattended sleep studies and home sleep apnea testing (HSAT), all such evaluations are carried out only by or under the supervision of sleep disorder facilities meeting the standards outlined in this document.

2.11.2.1 Technical Director

Every licensee shall appoint a Technical Director who is a member of the Quality Advisory Committee. The Technical Director is assigned specific duties, by the Quality Advisor, and is responsible for ensuring the Quality Assurance Program is carried out. The Technical Director ensures proper technical equipment and technical staff are in place for the facility's size and services provided. A Technical Director must be Registered (RPSGT) by the Board of Registered Polysomnographic Technologists (BRPT) or Registered Sleep Technologist (RST) and holds

current certification in BCLS.

2.11.2.2 Technical Director Responsibilities

Technical Directors are current with the changing technical trends in the sleep medicine technology field by attending conferences, meetings or other forms of continuing education, reading current relevant literature, and ensuring appropriate dissemination of the materials to technologists employed at the facility.

Technical Director is responsible for the day-to-day operation of the facility and must be physically present in the lab at a minimum on a weekly basis. These duties include but are not limited to:

- Ensuring appropriate patient appointments and staff work schedules for a safe patient:technologist ratio each night.
- Distributing to the referring physicians and agencies the test requisitions and the completed test reports.
- Maintaining proper policies and procedures.
- Maintaining records of equipment calibration, maintenance, and repair procedures.
- Maintaining copies of test observations and reports.
- Maintaining administrative records.
- Ensuring that safety policies and the equipment and facilities necessary for their implementation are in place and in working order.
- Ensuring the safe and reliable performance of tests.
- Observing infection control measures.
- Maintaining all necessary facility supplies.

2.11.2.3 Technical Staff

- a) Technical staff must meet the following criteria:
A. Evidence of post-secondary school education:

Have expertise in a relevant discipline (e.g. BSc in Sciences, BSc or BA in Psychology, Registered Respiratory Therapist, Registered Nurse, Registered Practical Nurse, College Degree in Health Care, College Degree in Medical Technology, Registered EEG Technologist, Registered Pulmonary Function Technologist, Medical Degree).

AND

Demonstrate relevant training of at least six weeks (240 hours) under the supervision of a registered or registry eligible polysomnographic technologist. Appropriate documentation of training is required.

OR

- B. Are registered as a polysomnographic technologist (RPSGT) by the Board of Registered Polysomnographic Technologists or Registered Sleep Technologist (RST)
- b) Non-registered technologists are encouraged to obtain RPSGT credential within three years (6,000 hours) of employment or must demonstrate knowledge, skills and judgment of someone who is exam ready.

Non-registered technologists undergoing training must not be expected to regularly complete a full complement of patients until there is documented evidence of the technologist demonstrating knowledge, skills and judgment of someone who is exam ready.

2.11.2.4 Duties of Polysomnographic Technologists

A polysomnographic technologist works under the general supervision of the Medical Director/ Quality Advisor and/or Technical Director to provide comprehensive evaluation and treatment of sleep disorders.

The duties include but are not limited to the following:

- Gather and Analyze Patient Information:
 - Collect, analyze and integrate patient information in order to identify and meet the patient specific needs (Physical/mental limitations, current emotional/physiological status regarding the testing procedure, pertinent medical/social history), and to determine final testing parameters/ procedures in conjunction with the ordering physician or clinical director and facility protocols.
 - Complete and verify documentation.
 - Explain pre-testing, testing, and post-testing procedures to the patient.
- Testing Preparation Procedures:
 - Prepare and calibrate equipment required for testing to determine proper functioning and make adjustments if necessary.
 - Apply electrodes and sensors according to accepted published standards.
 - Perform appropriate physiologic calibrations to ensure proper signals and make adjustments if necessary.
 - Perform positive airway pressure (PAP) titrations.
- Polysomnographic Procedures:
 - Be aware of all of the facility's Policies and Procedures as set out in the P&P Manual, and where to find all policies to implement if needed.
 - Follow procedural protocols (such as Multiple Sleep Latency Test, Maintenance of Wakefulness Test, parasomnia studies, PAP, oxygen titration etc.) to ensure collection of appropriate data. Follow "lights out" procedures to establish and document baseline values (such as body position, oxyhaemoglobin saturation, respiratory and heart rates, etc.).
 - Perform Polysomnographic data acquisition while monitoring study tracing quality to ensure signals are artifact-free and make adjustments, if necessary.

- Document routine observations together with associated sleep stages and clinical events, changes in procedure, snoring and significant events in order to facilitate scoring and interpretation of polysomnographic results. Make use of notes in data collection to report on the study and observations.
 - Create a summary of the night's observations to include all physiological and polysomnographic events.
 - Implement appropriate interventions (including actions necessary for patient safety and therapeutic intervention such as continuous and bi-level positive airway pressure, oxygen administration, etc.) as indicated by the physician or facility specific policies and procedures.
 - Follow "lights on" procedures to verify integrity of collected data and complete the data collection process (repeats the physiological and instrument calibrations and instructs the patient on completing questionnaires, etc.).
 - Document and report any adverse events.
- Polysomnographic Record Scoring:
 - Demonstrate knowledge and skills necessary to recognize and provide age specific care in the treatment, assessment, and education of neonatal, pediatric, adolescent, adult and geriatric patients, appropriate to their patient population.
 - Score sleep/wake stages by applying professionally accepted guidelines.
 - Score clinical events (such as respiratory events, cardiac events, limb movements, arousals etc.) according to facility specific protocols.
 - the scoring technologist must provide a documented summary of their findings for the interpreting physician.

Note: Simultaneous monitoring and scoring is not acceptable.

- Generate accurate reports by tabulating sleep/wake disorder and clinical event data.
- Comply with applicable laws, regulations, guidelines and standards regarding safety and infection control issues.
- Perform routine and complex equipment care and maintenance.
- Evaluate sleep study related equipment and inventory.
- Maintain current CPR or BCLS certification.
- Demonstrate effective written and spoken communication skills.
- Demonstrate appropriate social skills.
- Respond to study participant's procedural-related inquiries by providing appropriate information.
- Demonstrate the ability to analyze complex situations and apply policy.
- Comply with the Board of Registered Polysomnographic Technologist (BRPT) Standards of Conduct.

2.11.3 *Continuing Medical Education Activities (CME)*

Both full and part-time technical staff in a sleep disorder facility must undertake continuing education activities directly relevant to the practice of sleep medicine. These accredited or non-accredited activities must be documented a minimum of 25 hours per year. These activities can include but are not limited to case presentations, Inter-scorer assessment time, on-line education, reading of journal articles and sleep guidelines, and attendance at in-laboratory , local , national and international meetings.

Chapter 3 Policies and Procedures

3.1 Overview

All of the information in this Chapter is to be regarded as a Standard.

To ensure safe and reliable sleep studies and testing procedures among facilities, written policies and procedures are essential for a uniform response to emergencies, standardization of testing, and quality assurance.

The most current CPSO Practice Parameters should be used as the standard for test protocols.

The facility policies and procedures manual must be reviewed annually and indicate the date of last renewal or revision. In addition, individual policies and procedures must be revised as necessary, and be circulated to all staff at the time of revision. All staff must review and sign-off on the annual review/revision of the policies and procedures manual.

3.2 Policies and Procedures

Written policies and procedures are available for, but not limited to, the following:

3.2.1 Facility

- Overview of the lab
- Scope and limitation of services
- Map location of the lab
- Floor plan and emergency evacuation routes
- Organizational structure
- General office policies and procedures
- Patient Booking System and clinic patient flow
- New patient process including accepted referral sources; procedure to triage/ process referrals and book appointments; standard procedure for consultations, office visits, diagnostic and treatment services; management of patient declining assessment or therapy (see Appendix III).
- Policies and standard procedures for follow-up of established patients
- Management and mandatory reporting of patients to the Ministry of Transportation (see Chapter 13)

3.2.2 Facility Staff

- Appointment and role of the quality advisor
- Job descriptions of clinical and technical staff including BCLS & CME activities
- Delegated acts
- Training of new staff hires

3.2.3 Facility Contacts

- Staff
- Technical support
- Building hydro and security
- Emergencies – Fire, Police, Hospitals
- Vendors

3.2.4 Records and Communication/ Reporting & Privacy Principles

- Policies and procedure for record structure
- Policies for maintenance, storage & destruction as per the *Independent Health Facilities Act - Ontario Regulation 57/92 - Amended to O. Reg. 14/95* (for full regulation, see Appendix I) -

11 (1) Every licensee shall retain a patient's health record or a copy of it for at least six years following:

(a) the patient's last visit; or

(b) if the patient was less than eighteen years old when he or she last visited the facility, the day the patient became or would have become eighteen years old.

(2) Despite subsection (1), a licensee is not required to retain imaging media from any examination other than a mammography for more than three years following:

(a) the patient's last visit; or

(b) if the patient was less than eighteen years old when he or she last visited the facility, the day the patient became or would have become eighteen years old.

(3) Every licensee shall retain the film from a mammography for at least ten years following the patient's last visit. O. Reg. 57/92, s.11.

(4) On the transfer of a licence under section 11 of the Act, the transferor of the licence shall transfer to the transferee of the licence, in a manner that will protect the privacy of the records, the records maintained under section 10 of this Regulation, and the transferee of the licence shall retain those records in accordance with this section.

- Policies for Protection of Personal Health Information and Privacy of Information
- Patient Consent and Procedures

Note: PHIPA - The independent health facility is expected to implement the various privacy procedures and policies to maintain patient information confidentiality within the organization. The organization must respect all laws that apply to it, including laws relating to privacy, confidentiality, and security of records and access to records, including the Personal Health Information Protection Act, 2004.

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- Reporting Policies and Procedures of consultations and tests
- Standard forms including (but not limited to):
 - requisitions
 - flow sheets
 - handouts and prescriptions
 - logs
 - incident/ accident/ complaint forms

3.2.5 Diagnostic and Therapeutic Services (Adult)

- Scope and limitation of services
- Patient preparation
- Methods of performing each test
- International 10-20 system
- Equipment and physiological calibration
- Methods of performing each test including, but not limited to: CPAP, Bilevel PAP, ASV, ETCO₂/TCO₂, Split, supplemental O₂, MSLT, MWT
- Artifact recognition and remedies
- Data analysis and interpretation including AASM and lab specific scoring rules
- Normal values for tests in the lab including but not limited to Sleep Architecture, Respiratory events, Periodic leg movements, arousals, MWT and MSLT (see Chapter 10)
- Scoring manual (see Chapter 9)

3.2.6 Quality Management (see Chapter 6)

3.2.7 Equipment Maintenance (Adult)

- Equipment list
- Routine maintenance, validation and calibration of equipment (logs to be maintained separately for these procedures)

3.2.8 Infection Control and Procedures

- Basic supplies for infection prevention and control, are on site and used appropriately as per current provincial guidelines/policies. Resources are available through the **Provincial Infectious Diseases Advisory Committee** of Public Health Ontario at <http://www.publichealthontario.ca/en/BrowseByTopic/InfectiousDiseases/PIDAC/Pages/Infection-Prevention-and-Control-for-Clinical-Office-Practice.aspx>
- Equipment cleaning and disinfection procedures
- Universal precautions and waste disposal procedures
- Policies for containing highly contagious infections e.g. SARS, Ebola, influenza etc.

3.2.9 Emergency Procedures and Safety Policies

The following list includes the required policies and procedures:

- Fire safety and evacuation plan
- General safety and prevention of adverse effects of testing procedures
- Policy for Oxygen administration and storage
- Specific first aid measures and emergency procedures for:
 - Syncope
 - cardiac arrest/ respiratory arrest
 - chest pain
 - shortness of breath
 - Automated External Defibrillator
 - suspected seizures
 - suspected Stroke or TIA
 - Suspected Hyper or hypoglycemia
 - other medical or psychiatric emergencies
 - how to arrange for transfer of patient to a hospital
- Safety equipment list and medication storage and control
- Policies for staff and patient security
 - general security policies and procedures
 - inappropriate patient behaviour
 - sexual harassment or abuse of patients or staff
 - workplace violence and harassment
- Current Workplace Hazardous Materials Information System (WHMIS) and Material Safety Data Sheets (MSDS) – may be kept in a separate manual/ file
- Current BCLS/CPR certification (according to current Canadian Heart & Stroke Association Guidelines)
- Annual Fire Drill for staff

3.2.10 Incident / Complaint Procedures

- General policies on dealing with and documenting incidents and complaints in the facility including follow up.

Chapter 4 Facilities, Equipment, Test Components & Supplies Standards

4.1 Overview

All of the information in this Chapter is to be regarded as a Standard – except where a provision is specifically stated as a Guideline.

This chapter reviews the minimum requirements for the physical layout, equipment, test components and supplies for the performance of sleep studies.

Sleep studies shall be conducted in accordance with accepted standards and in such a manner as to facilitate obtaining reliable and complete data for diagnostic and therapeutic purposes and must include:

- Overnight Sleep Studies (Polysomnograms or PSGs)
- Studies assessing drowsiness, and sleep structure during naps (Multiple Sleep Latency Test (MSLT))
- Studies assessing ability to stay awake/ alert during the normal awake interval (Maintenance of Wakefulness Test (MWT))

Sleep disorder facilities can be hospital-based or freestanding. Medically unstable patients who require advanced medical treatment during their overnight sleep study should only be studied in hospital facilities.

Note: These building standards were adapted from: Criteria for Assistive Devices Program Approval of Sleep Laboratories that Assess Patients for Sleep-Disordered Breathing and Prescribe CPAP or Bi-level

4.2 Building, Facility and Equipment Standards

S4.2.2	Building Codes	All sleep disorder facilities must conform to the appropriate municipal and provincial regulations governing fire safety standards, accessibility standards, building standards, and medical gas systems.
S4.2.3	Electrical	All medical equipment must be properly grounded. Except for recording wires that are applied directly to the patient, medical equipment should be physically away from the patient. All electro-medical equipment must adhere to the Canadian Electric Codes for Electromechanical Equipment or its equivalent according to the appropriate Risk Class.

S4.2.4	Access	The Accessibility for Ontarians with Disabilities Act, 2005 (AODA) became law on June 13, 2005. Under this landmark legislation, the government of Ontario has developed mandatory accessibility standards that identifies, removes, and prevents barriers for people with disabilities. The AODA applies to all levels of government, nonprofits, and private sector businesses across Ontario who has one or more staff. Please see www.accessontario.com/aoda for further details.
S4.2.5	Layout	<ol style="list-style-type: none"> 1. Each patient must have his/her own bedroom. Each room should be quiet. Ambient temperature should be controlled on site. The washrooms should be easily accessible to patients. Washroom doors should be wheelchair accessible. 2. The facility's equipment must permit the technical staff to monitor each patient unobtrusively and allow the patient to communicate with the technical staff in the event that he/she requires assistance. 3. The facility has the capability to administer supplemental oxygen to patients while following the facility's protocol to administer supplemental oxygen. 4. The facility should be equipped with a recliner/adjustable bed/wedge pillow for patients who require sleeping in an upright position (Guideline).
S4.2.6	Fire Safety	<p>It is each staff person's responsibility to be aware of the facility's policies and procedures with respect to fire safety and fire prevention. Floor plan and evacuation routes diagrams must be posted in each room for easy orientation and evacuation.</p> <p>Emergency exits are not blocked and fire barrier doors are not propped open.</p> <p>A fire safety manual is available and reviewed annually? It includes:</p> <ul style="list-style-type: none"> • Responsibilities for fire prevention. • Classes of fires and extinguishers. • Steps for safe storage of oxygen cylinders. • Steps to be taken upon discovery of a fire. • Plans for reporting a fire. • Emergency evacuation. • Plans and maps. <p>A facility-specific evacuation plan and Fire Drill is prepared and practiced annually. These activities are documented.</p> <p>The building and facility is in compliance with the applicable building code and equipped with safety equipment such as:</p> <ul style="list-style-type: none"> • fire alarms • smoke detectors • carbon monoxide detectors • fire extinguishers and/or sprinklers.

		<p>The location and functioning of the fire extinguisher, smoke detector and carbon monoxide detectors at the facility must be checked regularly and logged by a fire safety company.</p> <p>For specific fire and safety prevention and evacuation procedures, contact your local fire department.</p> <p>Emergency phone numbers are posted near all phones.</p> <p>Upon discovery of a fire, the following response is expected:</p> <ul style="list-style-type: none"> • Activate the alarm. • Remove patients from immediate danger. • Enclose the area, closing doors and windows. • Lights should be on. • Call the fire department, giving location, name and type of fire. • Attempt to extinguish the fire, if it is feasible. • Inform facility manager, medical director, and building maintenance personnel • Do NOT re-enter building until its declared safe by the fire department
<p>S4.2.7</p>	<p>Emergency Equipment/ Measures</p>	<p>The facility must have adequate equipment and training to deal with potential medical emergencies such as basic cardiac life support. The facility has a written protocol for dealing with such emergencies.</p> <p>The following is a list of mandatory emergency equipment required in each facility:</p> <ul style="list-style-type: none"> • Ambubag with mask interface • Resuscitation (CPR) Board • Airway <ul style="list-style-type: none"> - Adult and Paediatric (if conducting paediatric studies) • First Aid Kit • Oxygen concentrator/cylinders with nasal cannula or a T-connector for patients undergoing CPAP titration (See Chapter 11 for O₂ administration Standards) • Automated External Defibrillator • Wheelchair (Guideline)

4.3 Test Components & Supplies

4.3.1 Overnight Sleep Studies (Polysomnograms or PSGs)

Overnight sleep studies should ideally be conducted during the time the patient usually sleeps and, for night shift workers, may be conducted in the daytime in a facility with suitable control of light, noise and climate. During overnight sleep studies, the most useful information is obtained when patients sleep in the supine and lateral positions and all stages of sleep should be observed in each position where possible. The Technical Specifications and equipment required are based on the AASM Manual for the Scoring of Sleep and Associated Events Version 2.3 (Updated April 1, 2016).

Overnight sleep studies may be of two types:

- The first, currently designated Level 1
- The second, currently designated Level 2

Level 1 Sleep Study Required Equipment and Test Components

Impedances need to be less than 10,000 ohms but less than 5,000 ohms is preferred.

Electroencephalogram (EEG)	<p>The recommended derivations are:</p> <p style="text-align: center;">F₄ – M₁</p> <p style="text-align: center;">C₄ – M₁</p> <p style="text-align: center;">O₂ – M₁</p> <p>The backup derivations (Guideline) are:</p> <p style="text-align: center;">F₃ – M₂</p> <p style="text-align: center;">C₃ – M₂</p> <p style="text-align: center;">O₁ – M₂</p>
Electrooculogram (EOG)	<p>E1 – M2 (E1 is placed 1 cm below the left outer canthus)</p> <p>E2 – M2 (E2 is placed 1 cm above the right outer canthus)</p>
Electromyogram (EMG)	<p>1. Two or three electrodes are placed to record EMG:</p> <p style="padding-left: 20px;">i. One midline 1 cm above the inferior edge of the mandible.</p> <p style="text-align: center;">and</p> <p style="padding-left: 20px;">ii. One 2 cm below the inferior edge of the mandible and 2 cm to the right of the midline and/or 2 cm below the center of the inferior edge of the mandible and 2 cm to the left of the midline.</p>

	<p>2. The standard chin EMG derivation consists of either of the electrodes below the mandible referred to the electrode above the mandible. The other inferior electrode is a backup electrode to allow for continued display of EMG activity if one of the primary electrodes malfunctions.</p> <p>3. For detecting bruxism, in addition to the recommended placement of chin EMG electrodes, additional masseter electrodes may be placed if clinically indicated. If using two masseter electrodes, place 2-3 cm apart. If using a single masseter electrode, it can be referenced to chin EMG electrode (Guideline).</p> <p>4. For detecting transient muscle activity in REM sleep, the following applications may be used (Guideline):</p> <ol style="list-style-type: none"> a) Flexor digitorum superficialis b) Extensor digitorum communis <p>5. For diagnosis of REM Behaviour Disorder (RBD), along with Chin EMG electrodes, time-synchronized, audio equipped video PSG is essential to document complex motor behaviours and vocalizations during REM sleep. A diagnosis of RBD is based on such episodes or a characteristic clinical history of dream enactment in addition to PSG evidence of a lack of chin EMG atonia in REM sleep.</p> <p>6. For monitoring rhythmic movement disorder (RMD), bipolar surface EMG electrodes should be placed on the neck paraspinal muscles to record electrical activity in the specified muscles. (Guideline)</p> <hr/> <p>Note: For accurate electrode placement, the patient should be asked to activate the specified muscles so the muscle can be more readily felt. The following are:</p> <ul style="list-style-type: none"> • Anterior tibialis: Patient should raise their foot or tap their foot up and down • Flexor digitorum superficialis: Patient should bend from the base of the fingers and avoid bending at the joints (Guideline) • Extensor digitorum communis: Patient should extend their fingers back without moving wrist (Guideline) • Masseter: Patient should bite down or grind teeth (Guideline) <hr/>
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Limb Movement EMG	<ol style="list-style-type: none"> 1. For monitoring leg movements (LM), surface electrodes are placed longitudinally and symmetrically in the middle of the anterior tibialis muscle so that they are 2 to 3 cm apart or 1/3 of the length of the anterior tibialis muscle, whichever is shorter. 2. Both legs are monitored for the presence of the leg movements. Separate channels for each leg are strongly preferred. Combining electrodes from the 2 legs to give 1 recorded channel may suffice for some clinical settings, but this strategy may reduce the number of LM's detected. 3. Sensitivity limits of -100 and 100 μV(upper/lower) are preferred. 4. Use of 60 Hz (notch) filters should be avoided. Impedances need to be less than 10,000 Ohms. Less than 5,000 Ohms is preferred but may be difficult to obtain. 5. Movements of the upper limbs may be sampled using a similar method as for legs if clinically indicated, or necessary
Respiratory Diagnostic	<ol style="list-style-type: none"> 1. The sensor for detection of blood oxygen is pulse oximetry with a maximum acceptable signal averaging time of 3 seconds. 2. The sensor to detect absence of airflow for identification of apneas is an oronasal thermal sensor. 3. The sensor for detection of airflow for identification of a hypopnea is a nasal air pressure transducer, with or without square root transformation of the signal. 4. The sensor for detection of respiratory effort is either Piezoelectric belts, esophageal manometry, or calibrated or uncalibrated inductance plethysmography.
Respiratory Therapeutic	<ol style="list-style-type: none"> 1. The sensor for detection of blood oxygen is pulse oximetry with a maximum acceptable signal averaging time of 3 seconds. 2. To detect airflow include the digital flow signal integrated from the PAP unit. 3. Include the digital mask leak reading (with or without intentional leak accounted for) from the PAP unit. 4. For BiPAP studies in particular, include the digital pressure reading and the tidal volume where available. 5. The sensor for detection of respiratory effort is either Piezoelectric belts, esophageal manometry, or calibrated or uncalibrated inductance plethysmography. <p style="text-align: center;"><i>Note: Alternative sensors or signals must be used when the signal from the recommended sensor is not reliable.</i></p>

	<p>Alternative signals or sensors include:</p> <ol style="list-style-type: none"> 1. Nasal pressure transducer-to detect absence of airflow for identification of an apnea when the oronasal thermal sensor signal is unreliable. 2. Uncalibrated or calibrated inductance plethysmography or an oronasal thermal sensor -to score hypopneas when the nasal pressure device is not functioning,
Electrocardiogram (ECG)	<ol style="list-style-type: none"> 1. A single modified electrocardiograph Lead II using torso electrode placement. <p>Note: Additional leads may be placed if clinically indicated by physician.</p>
Ancillary Equipment	<ol style="list-style-type: none"> 1. Arterial oxygen saturation <ol style="list-style-type: none"> i. Oximeter ii. External oximeter for validation 2. Body position sensor 3. Infrared / low light audio/visual capability with ability to record. <p>Note: Each bed must have an audio visual system of sufficient quality to identify and assess snoring while continuously monitoring patients.</p>
Optional Equipment (Guideline)	<ol style="list-style-type: none"> 1. Transcutaneous or end tidal carbon dioxide 2. Body position sensors 3. Snoring sensors/microphones (independent of the room microphone for patient communication)

Level 2 Sleep Study Required Equipment and Test Components

Cardiopulmonary assessment as for Level 1 sleep study but without EEG, EOG, and submental EMG for sleep staging and without measurement of limb movements.

4.4 Studies Assessing Drowsiness, Sleep Structure During Naps, and Ability to Stay Awake/Alert (MSLT/MWT)

These studies are normally conducted in accordance with AASM standards.

MSLT/MWT Required Equipment and Test Components

The required nap test components for all types of sleep studies include:

<p>Electroencephalogram (EEG)</p>	<p>The recommended derivations are:</p> <p style="padding-left: 40px;">$F_4 - M_1$</p> <p style="padding-left: 40px;">$C_4 - M_1$</p> <p style="padding-left: 40px;">$O_2 - M_1$</p> <p>The backup derivations (Guideline) are:</p> <p style="padding-left: 40px;">$F_3 - M_2$</p> <p style="padding-left: 40px;">$C_3 - M_2$</p> <p style="padding-left: 40px;">$O_1 - M_2$</p>
<p>Electrooculogram (EOG)</p>	<ol style="list-style-type: none"> 1. $E1 - M2$ ($E1$ is placed 1 cm below the left outer canthus) 2. $E2 - M2$ ($E2$ is placed 1 cm above the right outer canthus) <p>Additional EOG leads (Guideline) are:</p> <p style="padding-left: 40px;">$FP1 - M2$</p> <p style="padding-left: 40px;">$FP2 - M1$</p>
<p>Electromyogram (EMG)</p>	<p>Two or three electrodes are placed to record EMG:</p> <p>One midline 1 cm above the inferior edge of the mandible and</p> <p>One 2 cm below the center of the inferior edge of the mandible and 2 cm to the right of the midline, and/or 2 cm below the center of the inferior edge of the mandible and 2 cm to the left of the midline.</p> <p>The standard chin EMG derivation consists of either of the electrodes below the mandible referred to the electrode above the mandible. The other inferior electrode is a backup electrode to allow for continued display of EMG activity if 1 of the primary electrodes malfunctions.</p>

Electrocardiogram (ECG)	<p>A single modified electrocardiograph Lead II using torso electrode placement.</p> <hr/> <p>Note: Additional leads may be placed if clinically indicated by physician.</p> <hr/>
Audio Visual	<ol style="list-style-type: none"> 1. Monitoring of all patients for recording events of interest or special studies (ancillary equipment). 2. Each bed must have an audio visual system of sufficient quality to identify and assess snoring while continuously monitoring patients.

4.5 Other Procedures

Depending on the clinical situation, additional procedures may be utilized, reported and interpreted in patients with:

4.5.1 Esophageal Pressure monitoring (Guideline)

Respiratory effort may be monitored with an esophageal pressure monitor.

4.5.2 Split Night Study

Treatment may be instituted with positive airway pressure on the same night as the diagnostic study. This may not eliminate the need for a second facility night for CPAP/Bi-level positive pressure titration.

4.5.3 Ventilation monitoring (Guideline)

A reliable measure of ventilation should be used when treatment is undertaken with positive pressure mechanical ventilation. The use of mechanical ventilation during sleep and/or wakefulness requires additional training in mechanical ventilation (i.e., in respirology).

The respiratory effort by intercostal EMG recordings may be assessed.

4.5.4 Esophageal pH (Guideline)

Esophageal pH or impedance may be monitored with an esophageal pH electrode.

4.5.5 NPT (Guideline)

Nocturnal penile tumescence may be monitored through the night.

4.5.6 Seizure montage

A larger number of bilateral EEG leads is required (seizure montage) including bipolar derivations assuring coverage of frontal and temporal regions:

Fp1-F7-T3-T5-O1

Fp1-F3-C3-P3-O1

Fp1-Fz-Cz-Pz-O2

Fp2-F4-C4-P4-O2

Fp2-F8-T4-T6-O2

Note: The current AASM Manual for the Scoring of Sleep and Associated Events - Rules, Terminology and Technical Specifications is the standard for sleep disorder facilities. Scoring must be performed by well-trained technologists (preferably RPSGT).

Chapter 5 Requesting and Reporting Mechanisms

5.1 Overview

All of the information in this Chapter is to be regarded as a Standard.

Individuals are referred to sleep disorder facilities by a variety of different routes. Documenting the referral method and rationale for referral should be maintained as a primary component of each patient's record.

Copies of all reports and records are retained with the requisition for the period of time as specified by Ontario law (see Appendix I, section 11(1) & (2)).

5.2 Referrals

All referrals received by a centre must be triaged:

- to confirm it is appropriate for the centre to provide the assessment requested
- to determine if more information is required before further action;
- to determine if there is information that would improve the assessment;
- to assign appropriate priority for assessment;
- to assign the initial components of assessment and the sequence of those components. In particular triage must reliably identify patients who require, and patients whose care would be optimized, by clinical assessment preceding any sleep lab testing.

Triage should be done by a sleep physician but may be done by an appropriately trained designate with a knowledge of sleep medicine. Any delegation of triage must follow a comprehensive written protocol detailed in the facility's policy and procedure manual, which is designed to reach the requirements listed above. Final approval of the triage for each case must be made by a sleep medicine physician.

There must be mechanisms in place to

- identify patients who should be seen urgently, and tracked so they are seen in a timely manner;
- discuss cases where appropriate triage is unclear, with a designated sleep medicine physician if a non-physician is doing triage, or with the medical director if triage is being done by a sleep medicine physician;
- check that triage targets are being adequately met.

The effectiveness of any such triage process is the responsibility of the Quality Advisor, and is to be evaluated as part of their quality management program.

All referrals must have:

- Signature of the physician, surgeon or nurse practitioner
- Demographic data including any medical conditions and medications.
- Clinical information relevant to the referral.
- Options for “Study Only”, ‘Consultation” or ‘Both’.
- Each diagnostic or therapeutic study, or split night study, or Home Sleep Apnea Test (HSAT) requires a separate specific requisition

Based on the available information, the patient may or may not be seen prior to sleep testing. (see Chapter 8 for Necessary Elements of a Sleep Facility Requisition.)

5.2.1 Patient Self-referral to a Sleep Disorder Facility

Patient self-referral is not acceptable.

5.2.2 Sleep Physician Self-Referral

Because of the close relationship between the sleep physician and the sleep disorder facility there is a potential conflict of interest. Consequently, in most situations, the referral for evaluation should be initiated by the patient’s family/specialist physician.

When the patient is assessed initially and a sleep study is recommended, the sleep physician may refer the patient to their sleep disorder facility for diagnostic and/or treatment evaluation. This is to avoid unnecessary expense and time delay for re-referral for the sleep study from the referring physician. The sleep physician adheres to the following:

- The College of Physicians and Surgeons of Ontario conflict of interest guidelines. (visit www.cpso.on.ca)
- Documentation of the patient’s history and clinical examination, a provisional diagnosis that indicates the benefit for such a study for establishing a proper diagnosis and effective management of the problem.
- Information is communicated to the patient’s primary physician / surgeon/ nurse practitioner.

5.3 Facility Records

5.3.1 Electronic Records

The following is extracted from Components of Medical Records Required by Law. Ontario Regulation 114/94, Section 20 made under the Medicine Act, 1991:

Records required by regulation may be made and maintained in an electronic computer system only if it has the following characteristics:

- The system provides a visual display of the recorded information.
- The system provides a means of access to the record of each patient by the patient's name and, if the patient has an Ontario health number, by the health number.
- The system is capable of printing the recorded information promptly.
- The system is capable of visually displaying and printing the recorded information for each patient in chronological order.
- The system maintains an audit trail that:
 - records the date and time of each entry of information for each patient,
 - indicates any changes in the recorded information,
 - preserves the original content of the recorded information when changed or updated, and
 - is capable of being printed separately from the recorded information for each patient.
- The system includes a password or otherwise provides reasonable protection against unauthorized access.
- The system automatically backs up files and allows the recovery of backed-up files or otherwise provides reasonable protection against loss of, damage to, and inaccessibility of, information.

5.3.2 Log Books

Each sleep disorder facility maintains a variety of log books including, but not limited to:

- **Patient Log:** patient's name, dates of referral, referring physician, date of study, recording technologist, scoring technologist, and reporting date.
- **Incident Log:** all adverse health effects occurring during testing, action taken and outcome.
- **Maintenance Log:** all maintenance, repair, and calibration procedures performed, results obtained and where appropriate, corrective action taken.

5.4 Patient Records

5.4.1 Measurement Techniques

The recording of data is the crucial final common denominator of the polysomnographic process. The recording must be adequate to the goals of the test and must conform to customary practices. Some minor variations in length are permitted, but the polysomnogram must be obtained beginning at the patient's usual time in bed and for the length of their usual sleep requirement. If a change is needed for a specific purpose, the reason must be documented. Every record should be well calibrated, adequately labeled, and reasonably artifact-free so that the accuracy of the test is not compromised.

5.4.2 Scoring and Interpreting Data

Visual scoring of the polygraph-generated record based on the materials presented in *The AASM Manual for the Scoring of Sleep and Associated Events - Rules, Terminology and Technical Specifications* is the standard for sleep disorder facilities. Scoring must be performed by well-trained technologists (preferably RPSGT).

Currently, even with existing or previously accredited equipment facilities must:

- be compliant with the new AASM rules for EEG, EOG, EMG and respiratory signals, including using both thermal and nasal pressure sensors to record respiratory events (see pages 45 and 48 of the AASM manual).
- have modified the reporting software to reflect the parameters to be reported (pages 17-18) and the new sleep stage terminology (see page 24 of the AASM manual).
- comply with scoring stages and events according to the new rules (see Chapter 9).

Sleep scoring must be performed epoch by epoch. Validation of scoring accuracy must be performed as per Chapter 6 of this manual (Quality Management).

Quantitative data derived from polysomnographic studies is incorporated into a report that includes information regarding:

- sleep stages measures, sleep maintenance measures and sleep stage distribution, including measures of sleep fragmentation such as indices of arousals and awakenings.
- types of respiratory patterns and their relationship to sleep stage and sleeping posture.
- arterial oxygen saturation, cardiac rate and rhythm, interpreting the findings.
- movement variables.
- summary of the findings, and interpretation of the findings in the context of the patient's presenting problems and symptoms, with a diagnosis where that is permitted by the available data.
- Follow up.

Note: Reporting physicians must review scored raw data.

5.4.3 Automated Scoring

Systems for automated scoring of sleep study data (sleep structure, respiratory events, limb movements and ECG) have improved, however, the IHF Sleep Medicine Task Force of the College of Physicians and Surgeons of Ontario, the committee responsible for revising the facility standards agrees that none of the currently available systems have sufficient peer-reviewed published assessment to allow adoption by Sleep facilities.

5.4.4 Patient Record Requirements

The record varies as to the type of sleep study performed.

All records must document the following in the detailed technical report of the study (some of which may be retained with the data if in electronic format):

- patient name and birthdate.
- attending and referring physician.
- date of study.
- type of study (e.g. Level 1, 2, diagnostic, CPAP titration, post-op, etc.).
- identification of attending technologist.
- notation of any significant physical or intellectual challenges of the patient.
- patient questionnaires and screening assessments.
- details of any medications or the use of supplemental oxygen, if any during the course of the study.
- times the recording began and ended.
- montage used and any significant deviation from lab's standard montage.
- significant events (e.g. patient distress, disturbance in sleep facility).
- significant staff interventions (e.g. initiation of CPAP or oxygen therapy during the study, CPAP setting changes, details of attendance upon unwell patients).
- document if the head of bed was elevated, or patient slept in a reclining chair.
- Body position, sleep time spent supine, lateral and prone.
- other observations, where appropriate, including a summary.

Following data analysis diagnostic studies must include notations of:

- Identification of scoring technologist
- General
 - time in bed (total study time) and /or "lights off", "lights on"
 - total sleep time
 - sleep efficiency
- Maintenance Measures
 - number of awakenings
 - wake after sleep onset
 - transient EEG arousals
- Sleep Stage Distribution
 - duration and percentage of total sleep time for each sleep stage
 - time to the onset of Non-REM and REM sleep
- Other EEG seen
 - sharp and/or epileptiform activity
 - alpha / beta frequency intrusion in sleep Cardio-Respiratory Variables, as appropriate
- Apnea, hypopnea, and RERA indices (see Chapter 9)
 - type and duration of events
 - relation of events to body position and sleep stage (especially REM sleep)
 - cardiac rate and rhythm, relationship to stage and/or events
 - arterial oxygen saturation
 - results of other parameters measured, such as CO₂

- Movement Variables
 - Limb movements during wake
 - periodic and leg movements and other unusual movements
- Other significant events
 - bruxism
 - sleep talking
 - rhythmic body movements
 - other significant events

Following data analysis, PAP therapy studies must include notations of:

- the same parameters noted above under diagnostic study
- PAP therapy parameters:
 - masks fitted, masks used, problems with masks, optimal mask
 - mouth leaks, and how they were resolved if significant
 - modality(ies) used: CPAP; BiPAP, APAP (auto adjusting PAP), ASV, pressure relief modalities (e.g. C-Flex and EPR) - including when any modality was started, adjusted or stopped
- Pressures used, and response of respiratory events, snoring, and arousals to different pressures, including minimum pressure at which apneas, hypopneas, flow limitation and snoring were eliminated, time on each pressure and final pressure.

5.5 The Polysomnogram Report

An Ontario qualified sleep physician reviews the data, interprets the polysomnogram and issues the final report within four weeks of the study date.

A sample of the relevant raw data reviewed should demonstrate illustrative segments of raw data (e.g. showing periods of repeated, significant apneas with desaturation). This is documented in the patient's file. The sample segments of raw data are required for subsequent testing and to enable third party interpretation.

5.5.1 Minimal Standards for a Sleep Study Report

1. **Type of Study:** Baseline /Split / Portable/ Therapeutic (which therapies)/MSLT/MWT
2. **Demographics:**
 1. Patient name
 2. Patient date of birth (age)
 3. Patient gender
 4. Referring physician(s)
 5. Background Medical Data
 - a. Measured height, weight, collar size; calculated BMI
 - b. Current medications

*asterisk sleep medications taken on the night/day of testing

6. Reason for referral and indications for study, including appropriate assessment of pre-treatment drowsiness

3. Sleep Architecture Data

- a. Timing:
 - Lights out/lights ON
 - Total recording Time
 - Total Sleep time
 - Sleep latency
 - REM latency
 - Sleep efficiency
- b. Sleep staging:
 - Total time in each of 4 stages and wake (WASO)
 - Percent of total sleep time spent in each of 4 stages
- c. Sleep Continuity:
 - # of sleep stage shifts
 - # total number and number of types of arousals (SDB, PLMA, spontaneous)
 - Alpha intrusion (none, mild, moderate, severe)
- d. Normal Ranges
 - A table of, or a reference to, normal ranges must be supplied with each sleep study

4. Sleep-disordered breathing:

- Number and Index of Apneas (central, mixed, obstructive) by REM/non-REM and body position
- Number of hypopneas by REM/NREM and body position
 - Number and Index of Respiratory Effort Related Arousals (RERA's) by REM/Non-REM and body position
- Apnea/Hypopnea Index BY REM/non-REM and body position
- Respiratory Arousal Disturbance Index
 - Maximum and mean apnea duration
 - Comment on loudness of snoring
 - Comment on REM-associated hypoventilation or CSR if present

5. Oxygen saturation

- awake saturation
- average saturation in REM/NonREM sleep
- minimum or nadir saturation
- % of night spent \leq 88% saturation

6. Movements and Behaviours

- description of presence of RLS during wake
- PLM index and PLMA index
- Observations of other unusual/ abnormal movements or behaviours

7. Cardiac Findings:

- rate (min, max, average HR)
- Rhythms(s) and extrasystoles

8. Hypnogram:

- All night hypnogram demonstrating sleep states
- Distribution and type of abnormal respiratory events
- Frequency of arousals (respiratory, limb movement-related and spontaneous)
- Oximetry
- Body position.

For therapeutic studies: application of which therapy and PAP pressure settings.

9. Summary /Diagnoses:

The report shall include all of the following:

1. Summary statement regarding quality and continuity of sleep architecture.
2. Diagnoses which can be made (or suggested) by the findings, appropriately qualified by study limitations.
3. Comments that address the reason for referral, and the patient's complaints relative to the study findings.

10. Recommendations:

1. In the event that the patient has not had a sleep medicine consultation with appropriate recommendations, or the patient will not be seen in a timely manner for clinical evaluation appropriate to the sleep study findings, then recommendations justified by the sleep study findings, and the clinical data that is available, are required.
2. Recommendations for and urgency of follow-up /sleep consultation/study. (in accordance with the referral requests).

11. Technical Issues/ standards:

1. List of parameters measured and technology used
2. Normative value table(s)
3. Technical problems during the study and how they may have affected study

12. Therapeutic studies

1. Modalities used (+/- supplemental oxygen)
2. Interfaces used with final suggested mask or mask leak.
3. Final suggested therapy if judged successful
4. Documentation if prescription given to the patient post study
5. Follow-up plans

13. Daytime Sleepiness Tests

1. Documentation of measured or reported sleep on the preceding night.
2. Documentation of stimulant medications taken on the day
3. Report of between nap sleep/activities
4. Individual and average sleep onset during naps. Report of sleep onset REM at any time
5. Interpretation and relationship to normative values (ranges)
6. Recommendations for follow-up/ further study.

5.6 CPAP or Other Positive Pressure Therapy – Vendor Information

For patients who have been tested and CPAP or other positive pressure therapy is being supplied on a trial or final basis, the sleep facility must make the patient aware of the ADP program and request them to sign a document demonstrating their awareness that they can go to a vendor of their choice. (Appendix IV)

Chapter 6 Quality Management

6.1 Overview

The Quality Management Program is intended to monitor the work of the clinic to continuously improve all aspects of the services provided.

➤ **Standards**

S6.1.1	Each facility must have a Quality Management Program supervised by a Quality Advisory Committee (QAC) as set out in the IHFA Regulations (see Appendix I)
S6.1.2	The requirements for, and responsibilities of, the Quality Advisor (QA) are as detailed in Chapter 2 – Staffing a Facility.
S6.1.3	The Quality Advisory Committee (QAC) must consist of The Quality Advisor and the Technical Director; and at least one other health care professional who provides health services in, or in connection with, the IHF; including at least one technologist who conducts overnight polysomnography at the IHF, who may be the Technical Director.
S6.1.4	The QAC is to supervise creation and maintenance of a quality management program adequate to reach specific goals detailed in the facility's Policy and Procedure Manual (see the standard for goals below).
S6.1.5	The QAC must meet at least twice a year with proceedings documented in official minutes maintained by the QA or their designate. Minutes must include all recommendations or conclusions reached by the QAC. Quorum for meetings must be 2, or 50% of the committee, whichever is greater and must include the QA. Members who cannot attend must review the minutes of that meeting, and sign that they concur on each decision, or comment in detail. All such comments are to be reviewed by the QA and action documented or another meeting organized, as appropriate.
S6.1.6	The agenda proposed for a QAC meeting is to be circulated prior to the meeting to all staff providing health services in or in connection with the IHF. The agenda and all staff reading the agenda must protect the privacy of any patient or complainant whose case, issue or complaint will be discussed at the meeting. Issues may be added to the agenda by any staff member if they are submitted to the QA in writing prior to the meeting.
S6.1.7	A QAC member can add an item to the agenda for a QA meeting at any time including during a meeting.
S6.1.8	If all items on the agenda are not discussed at a QAC meeting, the QA is required to ensure the minutes include a brief statement about the item(s) and when they will be discussed.
S6.1.9	Regular QAC agenda items must include: <ul style="list-style-type: none">• all issues raised by any accreditation visit. Such issues are to remain on the agenda until they are clearly finalized.

	<ul style="list-style-type: none"> • any incidents or complaints recorded or received since the last meeting; • any staff or staffing issues submitted to the QAC; • review of current statistics on the time between referral and subsequent events; • review of recent difficult or inconclusive cases; • all equipment or lab configuration issues new or unresolved since the last meeting that have quality assurance implications; • review of referrer and client satisfaction surveys; • status of the systematic review of the facility's policies and procedures. • Any items from previous agendas that have not been finalized.
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6.2 Quality Management Program Goals

➤ Standards

S6.2.1	<p>The program goals shall be detailed in the facility's manual and shall include, but are not limited to, the following:</p> <ul style="list-style-type: none"> • Services provided in the facility are to be safe. • Services provided are to be appropriate to the problem(s) being investigated. • Services provided are to be done in accordance with recommendations and standards available at the facility and published by <ol style="list-style-type: none"> 1. the College of Physicians and Surgeons of Ontario; or 2. the Canadian Sleep Society; or 3. the Ontario Medical Association; or 4. the Canadian Medical Association. • If no applicable recommendation or standard has been published by any of the organizations noted above, then the service is to be provided in accordance with recommendations and standards available at the facility published by: <ol style="list-style-type: none"> 1. the American Academy of Sleep Medicine or 2. the European Sleep Society or 3. a peer reviewed journal in the field • Indications for each sleep study are to be adequately documented. • The facility is to have a system to deal with incomplete or inappropriate requests for services, such as a request for a sleep study without consultation on a patient with insomnia, or a request for assessment of a pediatric patient in a facility that is not staffed or equipped for such work. • Studies conducted in the facility are to be conducted so that results are accurate, with minimal artifact, and minimal variation or error in procedure. • Testing is to be scored accurately and consistently, and in accordance with currently published standards and methods as noted above. • Studies are to be interpreted correctly and as completely as possible from the data, with interpretation that addresses the clinical issues and questions raised and that is <i>not limited</i> to assessment of sleep disordered breathing when there are other significant issues or findings. • Study reports are to contain clear plans for management including reference to the problems or questions raised by the patient, the referring physician, and the
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	<p>physician requisitioning the study.</p> <ul style="list-style-type: none"> • Study reports are to detail clear plans for follow-up with clear assignment of responsibility for follow-up. • Reports are to be completed and transmitted to the referring and other relevant health care providers promptly. • All staff at the facility are to maintain up to date knowledge of sleep medicine appropriate to their role at the facility, in accordance with current guidelines for continuing education from the relevant professional societies, colleges, academies and/or associations.
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6.3 Components of a Quality Management Program

➤ Standards

S6.3.1	The QA is responsible ensure all the following standards are completed and appropriately documented by the QA, the QAC, or an appropriate designate.
S6.3.2	A review of quality management goals and objectives is to be done annually.
S6.3.3	The facility policy and procedures manual is to be reviewed and revised systematically such that the entire manual is reviewed and revised within a 5 year cycle.
S6.3.4	Workplace Hazardous Materials Information System (WHMIS) data and/or Material Safety Data Sheets (MSDS) are to be maintained in the facility and any new WHMIS/MSDS data are to be reviewed at the next QAC meeting, with any appropriate policies and procedures added to the facility manual.
S6.3.5	The safety data on any equipment new to the facility since the last meeting is to be reviewed to ensure that all equipment in the facility meets safety standards.
S6.3.6	All staff or patient complaints, and all incident or any accident reports since the last meeting are to be discussed at the next QAC meeting, with documentation of any actions taken to prevent similar issues.
S6.3.7	The facility is to have a program to periodically calibrate and validate facility equipment. Results, any corrective actions required, and the outcome of those actions, are to be reviewed and documented by the QAC.
S6.3.8	The QAC is to review the tests and procedures conducted at the facility each year for anomalous or unusual patterns, particularly if any such patterns were noted in a facility inspection.
S6.3.9	<p>The QAC is to supervise and document a review, at least annually, of a random selection of at least 10 polysomnogram records, including a selection of diagnostic and therapy/split studies to ensure that:</p> <p>Any tests conducted were appropriate to the problems presented by the patient, and to any issues or clinical questions raised by referring/ ordering health care provider.</p> <p>Technical problems or issues encountered during the study were clearly documented and appropriately addressed during the study.</p>

	Any treatment introduction/ titration conducted was clearly indicated; appropriate to the problems presented by the patient; properly conducted.
S6.3.10	The QAC is to supervise and document a review, at least annually, of a random selection of at least 1% of records, or 10 records, whichever is greater, to ensure that HSAT was utilized appropriately (see HSAT Chapter for the indications and contraindications for the use of HSAT studies)
S6.3.11	<p><i>Technologist scoring:</i></p> <p>The QAC is to supervise and document programs checking inter-scorer reliability of all scoring technicians/technologists. This must consist of an internal and external program. Please refer to the Sleep Medicine “Reference Tools for Facilities” on the CPSO website for an assessment tool to assist with inter-scorer reliability.</p> <p><u>Internal Facility Program:</u> A sample of at least 2 hours of scoring for all parameters from a minimum of 10 PSG records (and an additional 10 HSAT records if applicable) is to be checked by another board registered technologist at least annually. The committee is to document action taken and results achieved to correct any significant anomaly in scoring patterns that are identified, with a further review of any technician/ technologist with significant scoring anomalies to take place within 3 months.</p> <p><u>External Program:</u> All scoring technologists are to participate in a regular external assessment/ review, such as the American Academy of Sleep Medicine inter-Scorer Reliability Program, or similar – using that program’s standards. The committee is to document action taken and results achieved to correct any significant anomalies identified, with a further review is to take place within 3 months. If significant scoring anomalies by any technician/ technologist persist at the 2nd review in either of the programs listed above, then all records from that scorer are to be reviewed in detail, corrected, and countersigned by the facility’s Technical Director until the QA committee demonstrates and documents that the anomalous pattern has been resolved.</p> <p><i>Sleep medicine physician record review and reporting:</i></p> <p>The QAC is to supervise and document programs checking the interpretation of polysomnograms at the facility.</p> <p><u>Internal program:</u> A sample of at least 5 randomly selected diagnostic polysomnograms and at least 5 randomly selected therapy or split night polysomnograms is to be reviewed at least annually by a sleep medicine physician who meets the qualifications outlined in this manual, and who did not interpret the study. At least one study must be included from each physician interpreting studies at the facility. If there is only one physician interpreting studies at a facility then an internal program is not required.</p> <p><u>External program:</u> Every facility must have a minimum of 10 randomly selected representative records (and an additional 10 HSAT records if applicable) reviewed annually by a sleep medicine physician from another facility, who meets the qualifications outlined in this manual.</p> <p>Both review processes are to assess whether or not:</p> <ol style="list-style-type: none"> 1. the studies done were appropriate to the problems presented;

	<ol style="list-style-type: none"> 2. the studies were done following appropriate protocols; 3. the results were reported and interpreted correctly; 4. clear and appropriate recommendations and suggestions were made to the referring physician. <p>The quality advisor shall document that they have</p> <ol style="list-style-type: none"> 1. reviewed both the internal and external review reports at least annually; 2. discussed all comments and recommendations with the relevant physician(s) and/or technologist(s); and 3. undertaken any appropriate action and follow-up
S6.3.12	<p>The QAC shall supervise and document a program of annual performance reviews for all staff who have patient contact, including documentation of action taken to correct any significant deficiencies in performance.</p> <p>All registration certificates, BCLS certificates, etc. must be valid and current for all staff.</p> <p>The QAC shall review the CME activities of the technical and medical staff meet the relevant College or Society requirements, for example that all specialist physicians have fulfilled their annual RCPSC MOCOMP requirements.</p>
S6.3.13	<p>The QAC shall arrange regular discussion of interesting/ challenging cases seen at the facility at least annually, and ensure any teaching points are disseminated to the staff.</p>
S6.3.14	<p>The QAC shall review any training or education program at the facility, for example a program to train technologists to score polysomnograms, and prepare a brief report on the program at least annually for discussion at a QAC meeting.</p>
S6.3.15	<p>The QAC shall document corrective action for anomalies identified in any of the reliability checks detailed above, and document further checks that show effectiveness of the corrective action.</p>
S6.3.16	<p>The QAC shall review results from regular surveys of patient, physician and staff satisfaction, conducted at least annually, and shall document actions to address any suggestions, problems or issues raised (see Appendix IX).</p>

6.4 Monitoring the Program

➤ Standards

S6.4.1	<p>The QA is responsible for all aspects of the program including any aspect delegated to any other staff member.</p>
S6.4.2	<p>Minutes of each QAC meeting shall be circulated to all members of the QAC for comment and revision, and once finalized by the QA they shall be circulated to all staff. Recommendations from the QAC shall be reviewed at a General Staff meeting, held at least annually, including all staff who provide health services in or in connection with the FACILITY (including, but not limited to, sleep technologists, nurses, nurse practitioners, psychologists, and physicians).</p> <p>Quorum for such meetings shall be 50% of the staff, or 2, whichever is greater.</p>

	Staff may attend by telemedicine, or by secure conference call. Staff members who cannot attend are to review the meeting minutes, and sign that they concur, or comment. All comments submitted are to be reviewed by the QA and action documented or another meeting organized, as appropriate.
S6.4.3	Records are to be maintained at the FACILITY in a form that is clear and easily accessible to a reviewer, and shall include: <ol style="list-style-type: none"> 1. Minutes of the Quality Advisory Committee. 2. Minutes of General Staff Meetings. 3. All the reviews and surveys noted above, and any subsequent commentary/ suggestions/ recommendations/ follow-up

6.5 Quality Management of Outsourced Study Scoring

➤ **Standards**

S6.5.1	A facility that utilizes an external service for scoring polysomnograms must follow all of the components of a Quality Management Program detailed above.
S6.4.2	A facility that utilizes any form of external scoring of sleep studies must ensure that every scoring technologist has timely and complete access to all technical notes taken during the study, and to all other appropriate data collected pre and post study, including the requisition and all questionnaires.
S6.4.3	A facility that utilizes an external service for polysomnograms must have at least one staff member who attends the facility who is trained and experienced in scoring polysomnograms and who participates in an external assessment/ review program as detailed above, with acceptable results that are documented in the facility.
S6.4.4	A facility that utilizes an external service for scoring of polysomnograms must maintain regularly updated documentation that any service utilized completes their own internal and external facility programs as detailed above. If the facility utilizes a service that cannot provide regularly updated evidence of such programs, the facility must annually review the entire study scoring for at least 1% of all studies, or 10 studies, whichever is greater, for all studies scored externally.
S6.4.5	A facility that utilizes any form of external scoring of sleep studies owns the records and is responsible to maintain and store the record in accordance with applicable laws. The facility must be able to access the raw data, and must be able to be able to generate reports and snapshots from the record without unreasonable delay.

Chapter 7 Performance, Diagnosis and Management of Pediatric Sleep Related Disorders

7.1 Overview

All of the information in this Chapter is to be regarded as a Standard.

Children are physiologically distinct from adults: normal behaviour, physiology and the pattern of disease, as well as its presentation and management, changing markedly across age ranges. Furthermore many specific disease entities are unique to childhood. There is therefore significant risk for both misdiagnosis and mismanagement unless the personnel staffing sleep facilities and sleep clinics caring for children with suspected sleep related disorders are knowledgeable of these differences. As a consequence if children are to be evaluated, not only the sleep physicians but also the technical personnel need to have the appropriate level of knowledge and background training. The facility also needs to have both the appropriate equipment and the necessary physical layout in order to perform pediatric sleep studies.

7.2 Definitions

Patients aged 13 to 18 years of age. Both normal physiology and the spectrum of disease in post-pubertal children do not differ markedly from young adults. Sleep studies in children 13 and over can be scored using adult criteria (AASM Manual for the Scoring of Sleep and Associated Events). So long as they are aware of the circadian and developmental issues associated with adolescence, sleep technologists and physicians should not require any additional training to appropriately score, evaluate, and manage these patients.

Patients aged 4 to 12 years of age. In younger children both physiology and disease spectrum may vary markedly from adults. Even for disorders with similar pathophysiology (i.e. obstructive sleep apnea), the presentation, sequelae, and management varies significantly from adults with the same disorder. Therefore personnel involved in the care of these children need to have sufficient knowledge and training required to provide optimum care for these children, including the use of age-appropriate criteria (AASM Manual for the Scoring of Sleep and Associated Events) for scoring the sleep study. Consequently for children in this age group to be safely studied in a sleep facility the sleep physician must have the necessary specialized training (see Appendix V), and the facility must have the required specialized age appropriate equipment.

Patients aged 3 years of age and under. These children are a unique population in terms of physiology, disease spectrum, risks, and management. Notwithstanding the limited numbers of pediatric laboratories in Ontario, these patients must be referred to a pediatric sleep center that has both the resources and expertise required for the diagnosis and management of these

children. Ideally this would be based in an institution with all of the appropriate resources necessary for this population. Given the specificity of both equipment and caregiver knowledge required to perform an adequate and safe workup of these young children, this will ideally (based on current resources) be in a Specialized Pediatric Center (definition below). Given the paucity of these centers, sleep studies may be performed in a Pediatric Sleep Facility (definition below), as long as they are able to provide an equivalent level of care. This means that not only that the facility is required to have the necessary age appropriate equipment, but also the personnel (sleep technologists as well as physicians) must have the necessary knowledge and expertise to perform and interpret the studies.

Consequently, there needs to be a designated physician who has, in effect, an equivalent level of training, knowledge and expertise as the physicians staffing the sleep programs at the Specialized Pediatric Centers. This physician will not only interpret the study, but also assume responsibility for the care of these patients during the night of study acquisition. This includes availability of the responsible physician with pediatric training to be physically present during the study if the need arises.

Note: These guidelines are primarily directed towards otherwise healthy children. In children over aged 3 the presence of other complicating co-morbidities, such as trisomy 21, congenital heart defects, neuromuscular disease, craniofacial anomalies or sickle cell anemia should also be factored in when considering referral to a specialized pediatric center.

Note: Children aged 3 and under have a very specific set of problems, and therefore should be studied in a specialized pediatric center, or a pediatric sleep facility that is specifically equipped (not only equipment but also personnel both sleep technologists as well as physicians) to do so (above). For children aged 4 to 12 to be studied safely outside of a specialized pediatric center requires either the personnel have the documented required level of training, including relevant continuing relevant medical education, or the establishment of a defined two-way link between the community facility and a specialized pediatric center, willing to act as a resource for the community facility, as well as providing quality assurance.

Specialized pediatric center: a tertiary center, usually affiliated with a University, that is capable of providing care for children of all ages, down to neonates, and with personnel with the necessary knowledge and expertise to deal with the full spectrum of disorders these children are subject to, examples being the Hospital for Sick Children, Children’s Hospital of Eastern Ontario, London Health Sciences Center, and McMaster University Medical Center.

Pediatric sleep facility: a facility that has -

- i. Personnel with the necessary knowledge regarding pediatric sleep disorders, sleep disordered breathing, as well as normal childhood development and diseases. They are also knowledgeable of and use the appropriate scoring criteria for each age range
- ii. Appropriate equipment for the ages studied (appropriate sized cribs, facilities for the parent to sleep, for breast feeding, etc.)

7.3 Staffing

There is a shortage in Canada of physicians who have training in pediatric sleep medicine; the few there are being primarily located in pediatric academic health centers. Outside of these centers most laboratories are staffed by sleep physicians most of whom have had little or no formal pediatric training. This is compounded by the fact that initial referral and subsequent treatment may be orchestrated by family practitioners or pediatricians with little or no sleep training. Acknowledging the limited numbers of sleep physicians with formal pediatric training, if pediatric sleep studies are to be performed certain minimum standards need to be met to ensure an appropriate level of knowledge and care.

Physician

Physician

Please refer to Chapter 2 for basic physician qualifications in Pediatrics.

Facility Physician. The sleep facility physician must be aware of the age-appropriate rules for scoring sleep studies, to ensure quality assurance while overseeing the sleep technologist. The sleep facility physician must be aware of the physiologic changes occurring during normal childhood, as well as the presentation and pattern of sleep associated disorders occurring at different ages, in order to accurately interpret the study. This is especially so if the referring community physician has no detailed knowledge of these disorders, and hence needs guidance in using the sleep study results to come to a diagnosis and formulate a treatment plan.

Sleep Technologist -

Set Up - The technologist must be aware of the appropriate sensors to be used in children, as well as the age-appropriate techniques required for setting up a sleep study in uncooperative subjects.

Sleep studies scoring - The technologist must know the age-appropriate criteria/rules for scoring pathologic events, as well as the normal values (AASM Manual for the Scoring of Sleep and Associated Events).

The setup and scoring of a pediatric sleep study can be learned by reading the appropriate texts and manuals, supplemented by clinical experience. Ideally the technologist will have received sufficient "on-the-job" training (minimum of 3 months, with primary responsibility for the setting up and scoring of at least 20 pediatric sleep studies) from an experienced technologist (mentor) to provide them with sufficient knowledge and technical expertise.

7.4 Sleep Disorder Facility

The facility is set up specifically for the age range of the children to be studied. This means not only the appropriate equipment but also the necessary physical layout (privacy, appropriate toilet facilities, sleeping arrangements for parents in the same room) in order to perform pediatric sleep studies.

Triage

There needs to be a clear system of triage for all referrals made to the facility, with a physician designated to specifically triage pediatric referrals. This individual needs to fulfill the physician criteria for pediatric facility sleep physician (above), thereby acting as the resource physician for the facility (available on call when pediatric sleep studies are performed). The purpose of triage is both to determine which patients are appropriate for study (and which require referral to a more appropriate site), as well as the appropriate montage and technologist instructions.

Split Night Studies

A single overnight polysomnographic study is sufficient to exclude clinically important sleep apnea, providing both REM sleep and sleep in the supine position are observed.

In patients with severe and unambiguous OSAS, the initiation of treatment with CPAP may be incorporated into the diagnostic study night. A list of protocols for the use of split night studies must be available.

Note: As with adults, although there is evidence of difference in sleep quality between the first night and subsequent nights in the sleep facility ("first night effect"), this difference is rarely of clinical significance. Routine booking of two consecutive night studies is therefore not clinically warranted. In this case the first night study should be reviewed, and the rationale for the necessity of a second study documented prior to initiation of the second night, in order for it to be justified.

7.5 Equipment Specifications

Pediatric studies necessitate a few additions and some specific training as children present some unique challenges for an overnight sleep study. The following equipment is necessary in sleep studies in infants or young children.

- **CO₂ MONITOR:** The most common breathing disorder during sleep in children is obstructive hypopnea or hypoventilation occurring in the absence of arousals and frequently with elevation of end-tidal CO₂ (in the presence of only mild degrees of desaturation). For this reason it is desirable to monitor CO₂ in children, either by end-tidal CO₂ or transcutaneous monitors (both have their advantages and disadvantages, ideally both would therefore be available for use in the appropriate situation).

- **OXYHAEMOGLOBIN SATURATION:** Due to both frequent movement and reduced patient cooperation it is frequently difficult to maintain accurate saturation readings in young children. Consequently single use stick on sensors are preferable to reusable clamp-on style probes, which are more likely to be dislodged, attempts at reattachment usually resulting in arousals and disturbed sleep.
- **CHEST AND ABDOMINAL RESPIRATORY BANDS:** In children over the age of 6 months, the presence or absence of Paradoxical Inward Rib Cage Motion is a valuable tool (PIRCM), and the strain gauges should be of the appropriate sizes.
- **BEDDING AND ACCOMMODATION:** It is customary during pediatric studies to have one parent present. A sleeper chair or other accommodation should be available. It is acceptable for the parent to sleep in the bedroom with the child or infant during the study. The study bed must have adequate side rails and end guards placed for safety.
- Many patients referred for pediatric sleep testing may also suffer from development disorders or serious neurologic, pulmonary, or cardiac diseases. The facility must be prepared carefully even before the testing night to ensure patient's safety and the technologist should have training and experience with children, as well as sufficient knowledge to recognize signs of illness / distress in children. Resuscitation equipment (such as Ambubag) must be of an appropriate size for the age ranges studied.

Interpretation of pediatric sleep studies to accurately diagnose pathology requires that both the technologist scoring, and the physician interpreting the study are aware of normative values for the age range being studied and the significance of recorded physiological variables in order to be able to both report, and interpret the sleep study appropriately. As noted this therefore requires additional training for both the technologists and the reviewing physician commensurate with the patient population being studied.

7.6 Limb Actigraphy

Miniaturized units are available for children and have the advantage of being able to be used on an ongoing basis at home, without the cost and effects on sleep patterns associated with facility polysomnography. The procedure is reasonably valid for children over the age of 9 months, but the assessment requires an accurate log of sleep wake behavior, and does not provide data on the respiratory status.

Actigraphy is not, however, the best method if interest is in the precise timing of sleep and wake epochs or precise timing of sleep onsets. The largest discrepancies between actigraphy and PSG measures are typically around sleep-wake and wake-sleep transitions.

Actigraph measures are unlikely to provide sufficiently accurate information to assign diagnoses of sleep disorders, but may have utility for screening and assessment of treatment.

Note: Overnight polysomnography in an attended sleep facility remains the standard for the diagnoses and evaluation of Obstructive Sleep Apnea and other sleep disorders.

Limb actigraphy has been used and validated in many research studies as a method of measuring sleep patterns and sleep fragmentation in children. Its use in clinical situations to diagnose disease in individual patients has, however, yet to be determined.

Actigraphy's primary clinical use is in providing either objective confirmation or refuting sleep history / diaries in patients complaining of sleep disturbance, such as insomnia, sleep schedule disorders (poor sleep hygiene, advanced or delayed sleep phase, irregular sleep schedules) sleep walking, or sleep state misperception.

7.7 Indications for Polysomnography in Children

7.7.1 Insomnia

Insomnia is a common parental complaint. In the vast majority of cases the cause is behavioral or developmental. As in adults, diagnosis and management is therefore primarily based on a detailed history and rigorous examination to rule out organic causes. In rare cases polysomnography may be warranted to rule out an organic disease (Appendix VI), but should only occur after a detailed history and physical examination, and the indication should be clearly documented.

7.7.2 Restless Legs Syndrome and Periodic Limb Movement Disorder

Restless legs syndrome (RLS) may present in late childhood and adolescence. The prevalence of RLS in children is reported to be around 2%, 40% of adults with RLS dating the onset of symptoms prior to their 20th birthday, with a high incidence of familial history. Delayed diagnosis is a common report in this population. Most cases of RLS in children are idiopathic, though associations with iron deficiency and uraemia have been reported. Diagnosis is primarily clinical, based on established criteria for children 12 years old or younger, adult criteria being applied to those over aged 12 years. PSG is not required to make the diagnosis, but may be required to rule out other causes of hypersomnolence, and to document the frequency of periodic leg movements. Periodic Leg Movement Disorder (PLMD) is a linked but separate disorder. Although there are established criteria for diagnosing PLMD in children the precise significance of PLMD, and its treatment, remains a matter of debate. PSG data is not required to make the diagnosis, but is indicated to document the frequency of PLMS, and to rule out other organic causes of sleepiness, such as OSAS and narcolepsy.

Note: Since the significance of RLS and PLMD in childhood remains debatable, with no clearly established treatment protocols, children should be referred to experienced centers for treatment and follow-up.

7.8 Suspected Sleep Disordered Breathing

7.8.1 Snoring

The primary concern in a snoring child is whether this signifies the presence of Obstructive Sleep Apnea Syndrome (OSAS). It is estimated that around 7% to 10% of children snore, of whom between 20 to 30% have significant OSAS. Snoring / OSAS represent a spectrum of disorder, ranging from partial, intermittent obstruction resulting in sleep fragmentation and its consequences through to "full-blown" OSAS with repeated episodes of desaturation and even obstructive hypoventilation (Appendix VI).

Note: Although the American Academy of Pediatrics recommends a formal PSG for every child in whom OSAS is suspected, particularly if considering adenotonsillectomy, this is not practical given the current number of available pediatric capable sleep facilities.

7.8.2 Obstructive Sleep Apnea Syndrome (OSAS)

As noted, there are no clinical criteria that allow for reliable differentiation of patients with uncomplicated snoring from those with true OSAS, nor which patients with "primary snoring" actually require therapeutic intervention. Currently, polysomnography is the most objective test available for assessing the severity of OSAS in a child. It is indicated for any child in whom OSAS is clinically suspected, particularly if either CPAP or surgery is being considered (though recorded overnight oximetry can be used as an alternative). There are normative values for polysomnography in children (Uliel S et al Chest 2004;125:872-878), an obstructive apnea/hypopnea index of greater than 1 per hour being abnormal. Although there may be significant night to night variability in the number of apnoeic events, there is no evidence that repeated sleep studies improve the diagnostic accuracy. Assessment of the presence and severity of OSAS is provided by the sum of history, physical examination, and facility evaluation, the decision for therapeutic intervention, as well as actual therapy, being based, in the absence of definitive studies, on clinical experience and reason.

In conclusion full overnight sleep study is the current standard for those individuals in whom OSAS is suspected, particularly if CPAP or surgical therapy is considered. Multiple night studies are not generally indicated for diagnosis. Subsequent sleep studies are predicated upon the patient's diagnosis and changing status.

Note: Iatrogenic intervention may have been a precipitating factor in the death of several children with OSAS. Sedatives and muscle relaxants should therefore be avoided, or at least used under medical supervision, in any child with suspected or proven OSAS. Close post-operative monitoring is therefore also required in any child with significant OSAS until proven safe for discharge.

7.9 Respiratory Control Disorders

Sleep is associated with changes in both neurologic control of respiration and respiratory mechanics. In individuals with disorders affecting either the medulla or brainstem, diseases affecting neuromotor function of the respiratory muscles, advanced lung diseases, and morbid obesity sleep may further diminish the individual's ability to maintain adequate gas exchange. Sleep related hypoventilation may be remarkably asymptomatic unless specifically sought. There therefore needs to be a high index of suspicion in these patients. In the presence of unexplained sleep related hypoxemia or hypercapnea formal PSG is required to evaluate the patient's respiratory status during sleep and, if appropriate, initiate treatment to optimize gas exchange.

Note: Hypoventilation may be missed if carbon dioxide levels are not routinely monitored. Technologists staffing the sleep facility need to be aware of the central hypoventilation syndromes, so that blood gas measurements can be initiated in any child with unexplained hypoxemia

7.9.1 Observed Central Apnea

Central sleep apnea (CSA) is characterised by absence or decrease of flow with absence or decrease of respiratory effort. In the vast majority of cases where parents observe a brief pause in respiration in an otherwise physically and developmentally normal child, the cause is actually a normal physiologic apnea. Work up is therefore to exclude other, more sinister causes of central apnea (Appendix VI), usually by a detailed history and physical examination, supported by appropriate facility investigations. Formal PSG is rarely required in the absence any other findings, rarely providing any additional useful information.

7.9.2 Primary Respiratory Failure

Patients with severe obstructive or restrictive lung disease, as well as those with neuromuscular disease or thoracic cage deformities which impair respiratory function may require formal PSG in order to document and manage hypoxemia and/or hypercapnia during sleep.

Symptoms and signs warranting further investigation may include cor pulmonale, polycythemia, chronic hypoventilation, disturbed sleep, morning headaches, or daytime hypersomnolence. Similarly, patients with known respiratory disease, but unexpected severity of sequelae (e.g. cor pulmonale/polycythemia) may require sleep evaluation to rule out sleep associated hypoventilation.

Management may include supplemental oxygen therapy, positive pressure ventilation, either invasive or noninvasive, or phrenic nerve pacing, depending upon each individual's

circumstances (Appendix VI), and therefore needs to be guided by a physician with the appropriate level of knowledge and training in Respiratory Medicine.

If these patients are to be studied, appropriate policies and protocols should be developed. Formal detailed protocols for the therapeutic delegated acts should be in place to guard against, for example, exacerbation of hypercapnic respiratory failure due to high flow oxygen therapy.

7.9.3 Apparent Life Threatening Event (ALTE)

An apparent life threatening event (ALTE) is defined as “an episode that is frightening to the observer, and that is characterized by some combination of apnea, color change, marked change in muscle tone, choking and gagging. In some cases the observer fears that the child has died”. The concern of parents and clinicians caring for infants under 1 year is the specific risk of any one child subsequently succumbing to sudden infant death syndrome (SIDS).

Although there are multiple differing causes for both ALTE and SIDS, in a significant number of these children there is an underlying maturational disorder in cardio respiratory control, and the child is therefore at increased risk of succumbing to SIDS (Appendix VI).

Children are commonly referred to sleep facilities for evaluation with the expectation that studying these children provides additional data on either the cause of the event or the risk of SIDS in the individual child, to aid in their management. There is no test or parameter currently available with sufficient sensitivity or specificity to make a formal sleep study of any additional clinical use in children in whom rigorous evaluation has failed to reveal an underlying abnormality. Therefore, as with central sleep apnea, in the absence of any other feature or finding, PSG rarely provides any useful additional information, or helps to predict the risk of subsequent SIDS. Separating a true event from observer misperception of a physiological apnea, and evaluating the etiology of a true ALTE is achieved by detailed history, clinical evaluation, and facility exclusion of known causes of apnea in children.

If history or observation by a trained individual suggests this to have been a true event, the investigative approach is to first exclude known causes of sudden cardio respiratory events. PSG may be warranted in children where defined abnormalities such as persisting hypercapnia, apnea over one year of age, or unexplained nocturnal hypoxemia indicate an underlying disorder that can best be delineated by formal polysomnography. A PSG is therefore not part of the routine work-up of suspected or “near miss” SIDS.

7.10 Indications for a Follow-up Polysomnography Study

Indications for a follow-up polysomnography study include:

- monitoring of continuous positive airway pressure (CPAP) therapy due to changes in the following:
 - significant change in body weight or body structure due to growth
 - reoccurrence of snoring or gasping in sleep on CPAP
 - development of daytime sleepiness
 - failure of response to prescribed treatment or a change in symptoms.
 - change in compliance
- initiation of Bi-Level Positive Airway Pressure therapy (BiPaP/ CPAP)
- titration of ventilator settings (invasive and noninvasive) with disease and symptom progression in patients with respiratory control disorders
- following a surgical procedure of the upper airways (adenotonsillectomy) if there is reason to doubt less than complete success (persisting snoring)
- adjustment of and determining the efficacy of oral appliance therapy for obstructive sleep apnea
- a significant change or development of a medical condition including cardio-respiratory, neuro-psychiatric and/or sleep disorder.

7.11 Parasomnias and Other Sleep Disorders

Parasomnias are clinical disorders that consist of undesirable physical or experiential phenomena occurring during sleep. They are disorders of arousal, partial arousal, or sleep transition and may be associated with REM or NREM sleep. They are subdivided into arousal disorders, sleep/ wake transition disorders, parasomnias usually associated with REM sleep, or other parasomnias.

7.11.1 *Sleep Walking and Sleep Terrors*

Sleep walking and sleep terrors are more common in children than adults, but may carry over into adulthood. There is commonly a family history, which suggests a genetic component. They commonly occur as a confusional event due to partial arousal out of slow wave sleep.

Diagnosis is usually made by history, particularly if present since childhood. However, in the presence of late onset, or atypical features that are suggestive of nocturnal epileptiform activity, formal polysomnography may be required to make the diagnosis. Even in the presence of a classical history, a detailed search for specific psychopathological triggers is required.

7.11.2 *Sleep Enuresis*

Sleep enuresis in childhood is a common problem, with the diagnosis usually evident on clinical inquiry. A PSG rarely provides any useful additional information, unless there is specific reason to suspect an associated sleep disorder (such as OSAS)

7.11.3 *Diagnosis of Non-REM Parasomnias*

In the majority of cases of parasomnia, the diagnosis can be reliably made by a detailed history alone. However, in complicated or atypical situations, for example when sleep-related seizures are suspected, detailed overnight polysomnography, including selected EEG montage and continuous video monitoring, may be required.

Suggested indications for full polysomnography are:

- to rule out sleep-related seizures, if the episodes are atypical because of the nature of the event or because stereotypic features are suggestive of frontal lobe seizures, timing of the events, age of onset, frequency, and presence of daytime seizures
- potentially violent or injurious behavior
- excessive daytime sleepiness
- a history which suggests sleep apnea
- features suggestive of Munchausen's by proxy, where hidden camera video monitoring may be required.

In order to assess nocturnal seizures a full EEG is performed in conjunction with polysomnography. The resources for this may not, however, be available in many laboratories, and a modified montage, concentrating on the areas of interest (frontal, temporal, vertex, occipital) may need to be used.

7.11.4 *Parasomnias*

Disorders of arousal, such as sleepwalking, confusional arousals and sleep terrors are common in childhood, with an estimated incidence as high as 40%. Sleep walking occurs primarily in middle childhood. Confusional arousals occur primarily in toddlers. Sleep terrors occur primarily in children aged 4-12 years old, resolving in adolescence. All three are related to partial or incomplete arousal from slow wave sleep and occur predominantly during the first third of the night.

Diagnosis

There is frequently a family history of parasomnia. Usually the diagnosis can be reliably made on history alone although overnight polysomnography may be required if atypical features are present.

Parasomnias include REM sleep behavior disorder (rare in children), hypnagogic hallucinations/sleep paralysis in the absence of narcolepsy, bruxism, rhythmic movement disorder, periodic limb movement disorder, and sleep talking. Although the precise incidence of these abnormalities is unknown, both rhythmic movement disorder (including head banging, head rolling and body rocking), and sleep talking appear quite common, whereas the others appear relatively rare during childhood. The diagnosis is again usually readily apparent on history alone, with overnight polysomnography indicated only if atypical features are present (Appendix VI).

Chapter 8 Sleep Facility Requisitions: Necessary Elements

Each sleep disorder facility maintains their own requisitions and a separate requisition for each type of study (Overnight Sleep Studies (Polysomnograms or PSGs), Studies assessing drowsiness, and sleep structure during naps (Multiple Sleep Latency Test (MSLT), and Studies assessing ability to stay awake/ alert during the normal awake interval (Maintenance of Wakefulness Test (MWT)). The elements of a sleep requisition include, but are not limited to the following:

1. Letterhead identifying the name, address, phone numbers and fax of the facility.
2. Referred patient's demographics. Include date of referral, date of birth, gender, health card and means of contacting (phone at home, work or cell and optionally email).
3. Referring physicians' demographics including address, billing number and signature. An option to send a copy to another physician caring for the patient.
4. Purpose of referral including options of sleep study only, consult only or combination of sleep study and consultation. A checkbox to allow the referring physician to indicated whether the referral is routine or urgent.
5. Medical indications for referral and reasons for degree of urgency. This could be an open-ended paragraph or tick box or both.
6. A list of medications and an indication if the referring physician wants any medication held for the sleep study.
7. A box or stamp to allow and demonstrate triage (with initials and date) of the referral by the IHF physician including urgency and any special consideration such as additional testing (MSLT/MWT the next day), additional equipment to be used (CO₂ monitoring), pediatric study, re-titration study starting pressures etc.
8. Request for information regarding special needs for language, ambulation, and care assistance, caregiver or parental accompaniment.
9. Inquiry as to whether previous sleep studies have been done as well as date and location. (The purpose here is to obtain previous results for comparison before consultation/testing as well as ensure that two studies have not been performed in the previous year in Ontario.
10. A specific requisition is required for portable sleep studies (see Appendix VIII).

Chapter 9 Scoring Specifications

Adapted from the American Academy of Sleep Medicine Manual of the Scoring of Sleep and Associated Events version 2.3 (April 2016). Copyright.

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TERMINOLOGY OF SLEEP STAGES:

- a. Stage W (Wakefulness)
- b. Stage N1 (NREM 1)
- c. Stage N2 (NREM 2)
- d. Stage N3 (NREM 3)
- e. Stage R (REM)

Score epochs using the following parameters:

- a) Score sleep stages in 30-second, sequential epochs commencing at the start of the study
- b) Assign a stage to each epoch after lights out
- c) If two or more stages coexist during a single epoch, assign the stage comprising the greatest portion of the epoch
- d) When three or more segments of the epoch meet the criteria for N1, N2, N3, or REM:
 - i) Score the epoch as sleep if the majority of the epoch meets criteria for N1, N2, N3 or REM
 - ii) Assign the sleep stage that occurs for the majority of sleep within the epoch

Note: Stage N3 represents slow wave sleep (frequency of 0.5-2.0 Hz and minimum amplitude of 75 μ V peak to peak in frontal derivations) and replaces the R & K nomenclature of stages 3 and 4 sleep.

Note: These are adult standards. For pediatrics use appropriate specifications

9.1 APNEAS

An apnea is scored when all of the following criteria are met:

- a) There is a drop in the peak signal excursion by $\geq 90\%$ of the pre-event baseline using an oronasal thermal sensor (diagnostic study), PAP device flow (titration study).
- b) The duration of the $\geq 90\%$ drop in sensor signal is ≥ 10 seconds

Classify an apnea in an adult based upon inspiratory effort:

- a) Score a respiratory event as an OBSTRUCTIVE APNEA if it meets the apnea criteria and is associated with continued or increased inspiratory effort throughout the entire period of absent airflow.
- b) Score a respiratory event as a CENTRAL APNEA if it meets the apnea criteria and is associated with absent inspiratory effort throughout the entire period of absent airflow.
- c) Score a respiratory event as a MIXED APNEA if it meets the apnea criteria and is associated with absent inspiratory effort in the initial portion of the event, followed by resumption of inspiratory effort in the second portion of the event.

9.2 HYPOPNEAS

Note: The adoption of the revised AASM criteria (Oct 2012) to be implemented in October 2013 for definition of hypopnea may increase the AHI by as much as two-fold. Physicians comparing results of studies before and after the adoption of this new definition should interpret studies in the light of the possibility of any change being due to definition change as well as a clinical change in the status of the patient's sleep-disordered breathing.

(New revised scoring rules as per the 2015 AASM Manual for the Scoring of Sleep and Associated Events Version 2.3)

(The facility must choose which criteria will be used and state this in their Policy and Procedure Manual. The facility cannot use both scoring criteria)

A. Score a hypopnea if all of the following criteria are met:

- a) The peak signal excursions drop by $\geq 30\%$ of pre-event baseline using nasal pressure (diagnostic study), PAP device flow (titration study), or an *alternative* hypopnea sensor (diagnostic study)
- b) The duration of the peak signal excursions drop by $\geq 30\%$ is ≥ 10 seconds.
- c) There is a $>3\%$ (RECOMMENDED) oximeter desaturation from the pre-event baseline or the event is associated with an arousal.

OR

B. Score a hypopnea if all of the following criteria are met:

- a) The peak signal excursions drop by $\geq 30\%$ of pre-event baseline using nasal pressure (diagnostic study), PAP device flow (titration study), or an *alternative* hypopnea sensor (diagnostic study)
- b) The duration of the peak signal excursions drop by $\geq 30\%$ is ≥ 10 seconds.
- c) There is a $>4\%$ (ACCEPTABLE) oximeter desaturation from the pre-event baseline or the event is associated with an arousal.

RERAs:(Optional) as outlined in the facility policy and procedure manual

Score a RERA if all of the following criteria are met:

- a) There is a sequence of breaths lasting ≥ 10 seconds characterized by increased respiratory effort, or flattening of the inspiratory portion of the nasal pressure (diagnostic study), or PAP device flow (titration study) waveform leading to an arousal from sleep when sequence of breaths do not meet criteria for an apnea or hypopnea.
- b) A respiratory event is seen which does not meet the amplitude and/or desaturation criteria for hypopnea as outlines above but which does cause arousal.

Note: RERAs would be the definition of the above and if there is a sequence of breaths lasting ≥ 10 seconds characterized by increased effort or flattening of the nasal pressure waveform leading to an arousal from sleep when the sequence of breaths does not meet criteria for an apnea/hypopnea.

9.3 SLEEP RELATED HYPOVENTILATION SYNDROME

(Canadian Thoracic Society guidelines: Diagnosis and treatment of sleep disordered breathing in adults. Can Respir J Vol 13. no 7 pg 387-392, 2006.)

Diagnostic criteria:

The individual must fulfill criteria A and B (level of evidence D).

- a) One or more of the following:
 - Right heart failure;
 - Pulmonary hypertension;
 - Excessive daytime sleepiness that is not explained by other factors;
 - Erythrocytosis; and
 - Hypercapnia during wakefulness (PaCO_2 greater than 45 mmHg).
- b) Sleep monitoring demonstrates one or both of the following:
 - An increase in PaCO_2 during sleep greater than 10 mmHg from awake supine values;
 - Sustained hypoxemia (arterial oxygen saturation [SaO_2] less than 90%) during sleep not related to apnea or hypopnea.

Severity criteria:

SHVS is described as severe if at least one of criteria A, B or C are fulfilled (level of evidence D).

- a) Awake hypoxemia (partial pressure of oxygen [PaO_2] less than 60 mmHg or SaO_2 less than 90%).
- b) SaO_2 less than 85% for more than 50% of the sleep time.
- c) Right heart failure, biventricular failure or pulmonary hypertension secondary to SHVS.

9.4 CHEYNE-STOKES BREATHING RULE

Score Cheyne-Stokes Breathing if there are at least 3 consecutive cycles of cyclical crescendo and decrescendo change in breathing amplitude and at least 1 of the following:

- a) Five or more central apneas or hypopneas per hour of sleep
- b) The cyclical crescendo and decrescendo change in breathing amplitude has a duration of at least 10 consecutive minutes

Chapter 10 Normative Data for Sleep in Adults and Pediatric Patients

10.1 Overview

Sleep is highly variable and the concept of normative data may not exactly match the clinical importance of various findings. The mean and 2 SD (or median and range) of the sleep stage variables are more of a general guideline as prior sleep history, the first night facility effect and between patient variability can be more important. Nevertheless, the interpreted sleep study should have reference to the normal range for the benefit of the referring physician.

There are generally accepted norms for the two major sleep latencies:

1. The sleep latency should be greater than 5 minutes and less than 30 minutes.
2. The REM latency should be greater than 70 minutes.

The sleep stages have been reported in several data sets and vary mainly by age.

Two sources for adults are described below. There are no large Canadian data sets. Whatever source is used, it should be referenced in the patient report.

1. The normal data listed below come from a data set collected at the University of Florida, published in **Electroencephalography of human sleep : Clinical applications. John Wiley and Sons New York, Ny 1974. Pgs 26-68.** Each gender and age sample had at least ten subjects and values represent the average of night two and three from three consecutive nights' polysomnograms.

Note: The software programs currently in use in most labs refer to sleep stage as per cent of total sleep time (Time from sleep onset to morning awakening after time awake in the night is subtracted). These data are actually reported as % of SPT (sleep period time:time from sleep onset to morning awakening) which is by definition the same or longer.

10.2 Adult Normal Values

Normal sleep stages

Age group 20 to 29

%SPT	Men (mean)	2 SD	Women (mean)	2 SD
Stage N1	4.44	3.24	4.18	4.78
Stage N2	45.54	10.3	52.37	11.78
Stage N3	20.76	9.56	17.69	13.46
Stage REM	28.00	11.32	25.23	7.26
Sleep Efficiency (%)	96%	8%	96%	4%

Normal sleep stages

Age group 30 to 39

%SPT	Men (mean)	2 SD	Women (mean)	2 SD
Stage N1	5.71	6.86	4.17	3.30
Stage N2	56.89	14.72	53.77	15.46
Stage N3	12.46	11.16	14	14.52
Stage REM	23.47	4.72	26.22	10.54
Sleep Efficiency (%)	97%	4%	96%	12%

Normal sleep stages

Age group 40 to 49

%SPT	Men (mean)	2 SD	Women (mean)	SD
Stage N1	7.56	6.06	5.64	4.00
Stage N2	54.75	22.28	54.01	17.50
Stage N3	8.54	13.68	12.05	16.62
Stage REM	22.85	8.00	26.67	8.20
Sleep Efficiency (%)	91%	12%	96%	4%

Normal sleep stages

Age group 50 to 59

%SPT	Men (mean)	2 SD	Women (mean)	2 SD
Stage N1	7.56	7.9	4.85	4.4
Stage N2	61.71	20.6	57.80	13.0
Stage N3	4.92	15.4	10.63	12.14
Stage REM	21.48	8.02	21.77	6.54
Sleep Efficiency (%)	92%	8%	93%	14%

Normal sleep stages

Age group 60 to 69

%SPT	Men (mean)	2 SD	Women (mean)	2 SD
Stage N1	9.73	7.94	7.69	8.24
Stage N2	56.79	17.52	54.78	17.98
Stage N3	2.66	10.10	7.17	13.62
Stage REM	23.09	7.18	21.43	8.08
Sleep Efficiency (%)	90%	14%	87%	18%

Normal sleep stages

Age group 70 to 79

%SPT	Men (mean)	2 SD	Women (mean)	2 SD
Stage N1	9.47	6.92	6.59	4.56
Stage N2	55.49	33.34	52.22	16.68
Stage N3	1.36	4.68	10.03	16.78
Stage REM	17.68	13.26	19.46	8.46
Sleep Efficiency (%)	77%	40	82%	18%

2. A more recent data set from Austria used 2012 AASM criteria for scoring sleep. The population was 100 healthy sleepers (60 women, 40 men) age 19 to 77 years using one night polysomnogram.

Mitterling Thomas, Hogl Brigit, Schonwald SV, Hackner H, Gabelia D, Biermayr M, Frauscher B. Sleep and respiration in 100 healthy Caucasian sleepers- A polysomnographic study according to AASM standards. Sleep 2015 Vol 38 (6) ;867-875.

Data are given as median and 10% to 90% range.

Normal sleep stages

Men and women together by age group

Values are median and 10% to 90% range

%SPT	Age<30 years	31-40 years	41-50 years	51-60 years	>60 years
Stage N1	8.7 (3.4 -16.5)	10.2(3.7-26)	9.2(3.9-20.4)	9.3(3.4-35)	10.3(4.0-20.5)
Stage N2	45(29-55)	45(18-59)	46(27-58)	46(20-57)	44(22-55)
Stage N3	21(15-38)	19(10-31)	14(6-30)	16(0-21)	15(2-36)
Stage REM	16(8-24)	14(7-21)	15(1-26)	12(1-19)	10(2-22)
Sleep Efficiency (%)	87(72-94)	87(57-95)	84(61-93)	83(34-92)	80(45-91)
Arousal index	12(6-33)	13(4-41)	12(3-29)	17(8-40)	13(7-28)

edition.Elsevier Inc 2004.

10.3 Pediatric normal values

For pediatric data: Sleep is highly variable and the concept of normative data may not exactly match the clinical important of various findings. The mean and 2 SD of the sleep stage variables are more of a general guideline as prior sleep history, the first night facility effect and between patient variability can be more important. The normal data listed below come from a data set collected at the University of Florida , published in : Electroencephalography of human sleep : Clinical applications. John Wiley and Sons New York, Ny 1974. Pges 26-68. Each gender and age sample had at least ten subjects and values represent the average of night two and three from three consecutive nights' polysomnograms.

The normal Sleep latency is generally considered to be between 5 and 30 minutes.

Normal sleep stages

Age group 13 to 15

%TST	Boys (mean)	2 SD	Girls (mean)	2 SD
Stage N1	4.25	4.04	3.01	2.56
Stage N2	44.00	11.98	48.66	12.50
Stage N3	23.96	12.94	21.69	6.70
Stage REM	26.7	6.24	25.63	7.6
Sleep Efficiency (%)	96%	4%	96%	2%

Normal sleep stages

Age group 16 to 19

%TST	Men (mean)	2 SD	Women (mean)	2 SD
Stage N1	4.02	2.70	3.75	3.18
Stage N2	49.05	14.96	49.43	9.02
Stage N3	23.0	6.48	23.43	3.92
Stage REM	22.02	3.26	22.12	3.55
Sleep efficiency	94%	3%	95%	2%

For younger children, a variety of references (below) can be summarized as follows

Normal sleep stages

Age group 3 – 12¹⁻⁵

Ref 4	Boys + Girls (mean)	2 SD
Total Sleep Time (3 – 5)	475 mins	42 mins
Total Sleep Time (6 – 12)	472 mins	44 mins
% TST (3 to 5) – (6 – 12)		
Stage N1	5%	2 - 3%
Stage N2	36 - 42%	7 - 8%
Stage N3	23 -26%	7 – 8%
Stage REM	20 -21%	4 -5%
Sleep Latency(min)	28 min	30 min
Sleep Efficiency (%)	89 – 90%	7%

References.

- 1) Montgomery-Downs HE, O'Brien LM, Giulliver TE, Gozal D. Polysomnographic characteristics in normal preschool and early school-aged children. *Pediatrics*.2006;117:741.
- 2) Coble PA, Kupfer DJ, Taska LS, Kane J. EEG sleep of normal healthy children. Part 1; Findings using standard measurement methods. *Sleep*. 1984;7:289.
- 3) Marcus CL, Omlin KJ, Basinsiki DJ et al. Normal polysomnographic values in children and adolescents. *ARRD* 1992;156:1235.
- 4) Uliel S, Tauman R, Greenfield M, Sivan Y. Normal polysomnographic respiratory values in children and adolescents. *Chest* 2004;125;872.
- 5) Wong TK, Galster P, Lau TS, Lutz JM, Marcus CM. Reliability of scoring arousal in normal children and children with obstructive sleep apnea syndrome. *Sleep*.2004;27:1139.
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Chapter 11 **Basic Guidelines for the Facility Titration of Positive Airway Pressure in Adults with Obstructive Sleep Apnea Syndrome**

References:

1. Clinical Guidelines for the manual Titration of Positive Airways pressure in Adult patients (age >11 years) with Obstructive Sleep Apnea
2. Journal of Clinical Sleep Medicine Vol 4 #2, 2008.
3. Hirshkowitz M, Sharafkhan A. positive airway pressure therapy of OSA. Semin Respir Crit Care med 2005;26: 68-79.
4. Kushida CA, Littner M, Morgenthaler T et al. Practice parameters for the indications for polysomnography and related procedures: an update for 2005. Sleep 2005; 28:499-521.
5. New England Journal of Medicine publication: Adaptive Servo-Ventilation for Central Sleep Apnea in Systolic Heart Failure (SERVE-HF)". Martin R. Cowie, M.D., Imperial College London -- London, UK. <http://www.nejm.org/doi/full/10.1056/NEJMoa1506459>

All of the information in this Chapter is to be regarded as a Guideline.

The referenced guidelines are only minimally adapted here. It is intended that these recommendations be incorporated into the policies and procedure manuals and followed in a standard fashion.

Recommendations for CPAP titration in adults are:

1. CPAP candidates should receive education, hands –on demonstration and careful mask fitting as well as acclimatization prior to titration. A period of home acclimatization may be optionally considered.
2. CPAP should be increased until the following obstructive respiratory events are eliminated (no specific order): Apneas, hypopneas, RERA's and snoring or until a maximum pressure of 20 cm H₂O is reached. The airflow signal used should be either that generated by the CPAP device or by using a pressure transducer to measure the difference between the mask and the outlet of the machine.
3. In CPAP naïve patients, the recommended minimum starting pressure is 4 cm H₂O
4. Pressure changes are made by 1 cm H₂O increments after at least 5 minute intervals to eliminate these events:
 - Two or more obstructive apneas
 - If the titration is started too low, pressure can be increased more quickly if severe desaturation (SaO₂<75%) occur.
 - Three or more hypopneas
 - Five or more RERA's
 - Or greater than three minutes of unambiguous snoring.

5. Split night titrations follow the same rules with the titration portion of the night being greater than three hours.
6. The goal of the final pressure is to keep the AHI to less than 5 /hour, SaO₂ greater than 90% and mask leak at an acceptable level for the given manufacturer's guidelines. Supine sleep should be requested as time permits at the highest pressure reached, ideally in REM sleep.
7. Monitor leak rates. Intentional mask leak rates vary depending on the type of mask used. Leak should be monitored to intervene and correct the leak rather than over-titrating the pressure in the presence of a high leak.
8. When pressure relief is used, include the setting (e.g. C-Flex or EPR)

Recommendations:

Laboratories may differ in the application of these more controversial elements but the facilities written policy on each of these elements should be clear:

1. A higher starting pressure may be used for patients with an elevated BMI, patients intolerant of lower starting pressures and for re-titration studies.
2. "Exploration" of higher CPAP to attain better sleep quality or see if limb movements resolve should not exceed 5 cm H₂O. Notation for this exploration and its effects should be clear.
3. If the patient awakens and reports the pressure is too high, the pressure should be lowered and the titration re-started when sleep is resumed.
4. After 30 minutes of stability, down titrations by 1 cm H₂O may be considered to determine the point at which flow limitation reappears or to see if reactive central apneas resolve.
5. Oxygen desaturation events not related to obstructive events should not trigger pressure changes.
6. A grading system may be used in defining the adequacy of the CPAP titration as long as the definitions of the grade level are given in the report. Alternatively the actual findings of the titration may be given with interpretation of whether it met the titration goals or not.

Examples of Grading:

- a) Optimal titration: Reduces AHI < 5 events/hr for at least 15 minutes including supine REM sleep that is not continuously interrupted by spontaneous arousals or awakenings.
- b) Good titration: Reduces the AHI < or equal to 10 events/hr or by 50% if the baseline AHI < 15 events/hr and includes REM sleep supine that is not continuously interrupted by spontaneous arousals or awakenings at the selected pressure.
- c) Adequate titration: Does not reduce the AHI < or equal to 10 events/hr but does reduce the AHI by 75% from baseline, or the criteria for good or optimal titration are met but supine REM sleep did not occur at the selected pressure.
- d) Inadequate titration: does not meet the previous grades.

1. A repeat CPAP titration should be considered if an optimal or good titration is not achieved.

2. CPAP mask fit/mask change or readjustment should be performed whenever significant unintentional leak occurs.
3. If supine sleep has not been achieved at the final pressure the patient may be awakened and asked to turn supine.

Recommendations for Bi- level titrations in adult with OSA (without associated respiratory failure secondary to COPD, other chronic respiratory conditions or to neuromuscular disorders):

1. Bi-level therapy should be considered when high CPAP pressures are not tolerated, or if there are continued obstructive respiratory events over 15 cm H₂O CPAP.
2. The recommended minimum starting pressure is 8 cm H₂O (IPAP) and 4 cm H₂O (EPAP). The recommended minimum differential pressure (IPAP-EPAP) is 4 cm and the recommended maximum differential pressure is 10 cm H₂O.
3. The IPAP and EPAP pressure is raised in 1 cm H₂O increments to alleviate obstructive apneas (2 or more apneas in a 5 minutes period). The IPAP pressure is raised in 1 cm H₂O increments for hypopneas (3 or more hypopneas in 5 minutes) or RERA's (5 or greater RERA's in 5 minutes) or at least 3 minutes of unambiguous snoring.
4. Caution: When Cheyne Stokes Breathing (CSB) or Central Sleep Apnea (CSA) is present, consider whether the IPAP may be too high, and take a longer time to raise the pressure.
5. For Bi-level in the Spontaneous/Timed (S/T) mode, include the back-up rate (BUR) in breaths per minute, and where applicable for the titration device, include the Trigger and Cycle setting, or Timed Inspiration.

Specific recommendations for titration during Split Night studies:

1. Laboratories may or may not choose to use split night studies with appropriate protocols.
2. A minimum of 2 hours baseline and 3 hours therapy is recommended. Ideally a minimum of 2 hours baseline data collection is recommended for assessment of a split study. However with very severe apnea and verified desaturations persistently below 75%, the study may be split earlier if the apnea is unequivocal and saturations are validated.
3. A recommended estimated AHI of 30 events/hr is recommended for a split night study.
4. Upward increments of 2 to 2.5 cm H₂O pressures may be used in a split night to save time.
5. Nevertheless, a repeat titration may be needed if the split titration does not generate an optimal or good grade result.

Specific Recommendations for Supplemental Oxygen

This refers only to patients who do not have COPD or neuromuscular disorders, or known hypercapnea.

1. Supplemental O₂ should be considered when the awake supine saturation is less than 80% for 2 consolidated minutes over a 5 minute period. (see Home Oxygen Program (HOP) application form)

2. Supplemental O₂ should be added in 1 liter per minute (L/min) increments to achieve saturations of greater than 88%.
3. Supplemental O₂ should be connected to the CPAP device outlet using a T-connector.

Adaptive Servoventilation (ASV)

Note: At the time of writing this standard, the indications and safety of Adaptive Servoventilation remain undetermined, particularly for congestive heart failure.

Adaptive Servo-Ventilation (ASV) targeted to normalize the apnea-hypopnea index

(AHI) is indicated for the treatment of CSAS related to CHF.

In response to a Field Safety Notice issued by ResMed in May 2015, the AASM advised physicians to stop prescribing ASV to treat central sleep apnea in patients with symptomatic heart failure and left ventricular ejection fraction (LVEF) <45%.

Physicians are encouraged to read the full statements from the AASM and ResMed for important patient care recommendations, including ResMed's clarification that ASV therapy is contraindicated for patients with symptomatic, chronic heart failure with reduced LVEF and moderate to severe predominant central sleep apnea. Additional notifications will be posted as necessary. Healthcare providers and patients who have questions or would like more information are encouraged to call 1-800-478-9010 and visit www.SERVE-HFFAQs.com.

This therapy may be chosen for Cheyne-Stokes Breathing or a patient with combined obstructive and central apneas (Complex Sleep Apnea). In Ontario, a trial of Adaptive Servoventilation may be an option, particularly if CPAP, or Bi-level therapy with a backup rate are unsuccessful.

Cheyne-Stokes breathing is diagnosed when there are 3 or more consecutive apneas and/or central hypopneas separated by a cyclic crescendo decrescendo change in breathing amplitude with a cycle length of 40 seconds or more AND there are 5 or more respiratory events per hour of sleep associated with the crescendo decrescendo breathing pattern recorded over 2 or more hours of monitoring. It is usually seen in congestive heart failure, following a stroke or rarely in an idiopathic form. Positive pressure therapy should only be undertaken if CHF has been optimally medically managed and the patient is euvolemic.

1. EPAP is first titrated to control obstructive events as with CPAP titrations and beginning with 4 cm H₂O of pressure.
2. Inspiratory pressure support is then (auto-titrated) above the EPAP to dampen the swings of the cyclic peak flows.

For patients with hypercapnic respiratory failure, no general algorithm is recommended but in laboratories where this is treated under the supervision of appropriately trained physician, empiric algorithms should be part of the policy and procedures.

Guidelines for Supplemental Oxygen administration

The purpose of low-flow supplemental oxygen is to raise the blood oxygen levels without risking untoward rises in CO₂ which are unpredictable and often not quickly reversible.

In general, each referral known to be on oxygen must be more carefully scrutinized at the point of physician triage. If the facility has only one Oxygen concentrator (hence only one O₂ dependent booking per night), this can only be guaranteed to go about 5 liters/minute (L/min).

FOR BASELINE STUDIES:

A) For patients **known to be on oxygen**:

If the prescribed domiciliary oxygen is between one and two L/min, the referring physician will be asked if the study is requested on or off oxygen with the understanding that sleep-disordered breathing will be underestimated on oxygen therapy as desaturation is part of the hypopnea definition.

If the prescribed domiciliary oxygen is above 2 L/min and below 5 L/min, the patient can be studied on their usual oxygen therapy.

If the prescribed oxygen is above 4 L/min, the patient will be referred to a hospital-based facility.

B) For patients who arrive hypoxic and are **not known to be on domiciliary oxygen**:

The first step is to confirm the accuracy of the saturation monitor on the technologist's finger.

If the saturation is above 88% supine and awake, the study will be done in the usual fashion. If the saturation is below 88%, the physician on call will be called and asked whether supplemental oxygen should be given from the outset or whether, if very low and symptomatic for example, the patient should be transferred to an emergency room

C) For patients whose **initial saturation is normal** and who demonstrate significant **hypoxemia during the night unrelated to apneas or hypopneas**:

In general, the sleep study will be no worse than what is happening to the patient at home, but if saturations are falling in a sustained fashion and the saturation monitor is checked to be reliable to below 85%, once again the physician on call should be called to decide whether supplemental oxygen should be commenced.

Usually this will be no greater than 2 L/min as the hypercapneic status of the patient is often unknown at the time. If the patient is known to be eucapneic, higher flow rates can be administered up to 5 L/min.

FOR POSITIVE PRESSURE THERAPY STUDIES:

Usually the hypoxic status of the patient will have been known from the baseline study. An arterial blood gas result may be available and the triage physician should outline how oxygenation is to be handled.

- D) For patients **who develop hypoxemia during the night** in a sustained fashion and is apparently **related to an increase in CPAP pressure**. This may occur in a congestive heart failure patient. It is presumably due to decreased venous return caused by the positive pressure therapy. The CPAP pressure should be lowered until the oxygenation improves.
- E) For patients who **develop sustained desaturation (85-90 %) which does not respond to CPAP** pressure alone during the course of a CPAP titration, Bilevel therapy may be tried (+/- Back Up Rate). If there is no improvement in the oxygen saturation, then supplemental O₂ may be added at 1 or 2 liters per minute. Higher flows cannot be used unless the patient is known to be normocapneic on a recent arterial blood gas. If the technologist is in doubt about the addition of oxygen, the physician on call should be consulted.

Chapter 12 Recommended Variables Required in a Sleep Consultation Report

All of the information in this Chapter is to be regarded as a Guideline.

Recognizing the multi-disciplinary nature of sleep medicine, there will be a different emphasis in consultation arising from the varying disciplines; however, these are the suggested core elements of consultation dependent on the clinical presentation:

1. Reason for referral
2. Patient identification: age, gender, occupation.
3. Sleep history
 - 24 hour weekday/weekend sleep/wake habits including bedtime, prebed habits, perceived sleep latency, awakenings during the night, morning awakening and feelings of refreshment, patterns of shift work or international travel.
 - previous sleep issues, from childhood onward
 - confirmation or history by sleep partner if possible and issues arising from the sleep environment
 - pertinent negatives (excluding other sleep disorders, i.e. RLS parasomnias, features of narcolepsy)
 - family history of sleep disorders
 - for Insomnia patients: family history of mood (unipolar and bipolar) and anxiety disorders, alcohol and substance abuse, suicide
4. Assessment of daytime sleepiness and driving risk
 - examples of situations/times when patient reports fatigue, falling asleep in the waking hours
 - assess driving “ exposure” (occupation, commuting hours), use of heavy machinery
 - document history of near- miss and MVA related to sleep
 - Epworth sleepiness scale, or other validated scale of drowsiness
5. Past history
 - medical (including all current medications); report of nasal congestion and causes, bruxism or TMJ problems
 - surgical (particularly of the upper airways if OSA is under consideration)
 - psychiatric history (has patient ever seen a psychiatrist or had a psychiatric admission) and whether any episodes (diagnosed or otherwise) of mood disorder, mania, anxiety disorder, alcohol abuse/dependence substance abuse/dependence, prescription medication misuse

6. Lifestyle issues:
 - exercise habit and timing
 - caffeine intake
 - tobacco use
 - Alcohol habit and timing
 - recreational drug use

7. All sleep medicine physicians should be able to:
 - a. Collect vital signs
 - b. Adequate head and neck evaluation/airways
 - c. Screen for mood/anxiety disorders
 - d. Do basic neurological exam (as indicated)

8. Incorporation of sleep study(ies) and Facility findings

9. Diagnoses and Therapeutic Recommendations, including:
 - documentation of informing patients regarding treatment side effects and cautions
 - potential notification of Ministry of Transportation
 - further investigations and possible consultations

10. Follow-up plans:
 - a clear plan must be stated for follow-up, with clear designation of responsibility for each component

Chapter 13 Sleepiness and Driving: Patient assessment, Patient Education and Obligations to Report

The medico-legal basis of the reporting of patients as unfit to drive by physicians rests in the Ontario Traffic Act.

13.1 The Current Law - R.S.O. 1990, c. H.8, s. 203

Report of medical practitioner

203. (1) Every legally qualified medical practitioner shall report to the Registrar the name, address and clinical condition of every person sixteen years of age or over attending upon the medical practitioner for medical services who, in the opinion of the medical practitioner, is suffering from a condition that may make it dangerous for the person to operate a motor vehicle. R.S.O. 1990, c. H.8, s. 203 (1).

No action for complying with subs. (1)

(2) No action shall be brought against a qualified medical practitioner for complying with this section. R.S.O. 1990, c. H.8, s. 203 (2).

Reports privileged

(3) The report referred to in subsection (1) is privileged for the information of the Registrar only and shall not be open for public inspection, and the report is inadmissible in evidence for any purpose in any trial except to prove compliance with subsection (1). R.S.O. 1990, c. H.8, s. 203 (3).

13.2 The Proposed Law

There is a bill **not** yet passed whose aim (in its postscript) is to alleviate the obligation to report from physicians and optometrists and put this obligation on prescribed persons (yet to be defined): On a day to be named by proclamation of the Lieutenant Governor, section 203 is repealed and the following substituted: (See: 2015, c. 14, s. 55)

Medical reports

Mandatory reports

203. (1) Every prescribed person shall report to the Registrar every person who is at least 16 years old who, in the opinion of the prescribed person, has or appears to have a medical condition, functional impairment or visual impairment that is identified as a medical condition, functional impairment or visual impairment that must be reported to the Registrar under this section in a prescribed code, standard or other publication, or a part thereof, that was prepared by the Canadian Council of Motor Transport

Administrators or by the governing college of a health profession referred to in Schedule 1 to the *Regulated Health Professions Act, 1991*.

Discretionary reports

(2) A prescribed person may report to the Registrar a person who is at least 16 years old who, in the opinion of the prescribed person, has or appears to have a medical condition, functional impairment or visual impairment that may make it dangerous for the person to operate a motor vehicle.

Authority to make discretionary report prevails over duty of confidentiality

(3) The authority to make a report under subsection (2) prevails over any duty of confidentiality imposed on the prescribed person by or under any other Act or by a standard of practice or rule of professional conduct that would otherwise preclude him or her from providing the information described in that subsection to the Registrar.

Required to meet the person

(4) Subsections (1) and (2) only apply if the prescribed person actually met the reported person for an examination or for the provision of medical or other services, or in the circumstances prescribed by regulation.

Authority to make discretionary report is not a duty

(5) Subsections (2) and (3) do not impose a duty on a prescribed person to report to the Registrar.

Note: Until and unless that bill is passed and the prescribed persons are defined, we are left with the previous statute (R.S.O. 1990, c. H.8, s. 203).

13.3 Task Force's Views

This Section outlines the task force's views of what the sleep clinician's role is in developing **their medical opinion** and in educating the sleep patient.

In addition to the regular sleep history the patient should be assessed for driving history and for impairment related to driving:

The driving and sleep history must include the question of whether the patient drives or drives for a living, the length and time of day of work commutes, any history of sleepiness while driving, falling asleep or near misses while driving, frequency of drowsiness while driving and, finally, accidents due to falling asleep while driving. This history may need to be obtained from partners and family members as well whenever possible.

A tool available for assessment of drowsiness is the Epworth sleepiness score. Other validated scales of sleepiness may be used if supported by peer reviewed literature (see Appendix VII).

The overnight polysomnogram can assess the degree of sleep fragmentation and whether there is a sleep disorder that may contribute to daytime sleepiness such as OSA. The MSLT can assess the degree of daytime sleepiness and help support a diagnosis of narcolepsy; the MWT is an objective measure of the ability to overdrive any daytime sleepiness. Fortunately, these tests are available in Ontario sleep facilities and can be repeated on therapy for subsequent comparisons. The highest standard of technical attention should be placed on these studies because so much is resting on their results and the interpreting physician must be aware of test limitations.

The physician treating sleep disorders faces a large potential array of conditions that may impair driving. Some of these are not medical conditions but life and work issues which may confound the assessment of attributable sleepiness. Sleep restriction, shift work and parenting of newborns are more prevalent than obstructive apnea and narcolepsy. For example, after a 12 hour night shift, the person driving home in the morning will be sleepy. The longer the commute, the greater the probability of an unwanted sleep intrusion. These patients do not have a medical condition but may not be safe to drive.

The sleep consultation will also have documented other co-existing medical conditions and the use of any stimulant or sedating medications which may add or subtract from the fitness to drive equation.

The sleep physician is therefore uniquely positioned to develop a medical opinion regarding fitness to drive from a sleepiness/sleep disorder perspective, based on available history and objective testing. The gathering of such information and the judgment made should be documented in each patient.

Note: To make an assessment, the physician must have actually seen and examined the patient. There is no single test or test result alone, (including the AHI) which should solely determine fitness to drive.

Patient (and public) education is also an important function of the sleep physician and sleep clinic. Whether reported or not, each patient should be advised of the effect of their particular sleep disorder on alertness and warned of the additive effect of sleep-deprivation, alcohol and sedating medications on their ability to drive or operate heavy machinery. The advice should be documented.

13.4 Reporting Guidelines Recommended by this Task Force

To make an assessment, the physician must have actually seen and examined the patient. There is no single test or test result alone, including the AHI, which should solely determine fitness to drive.

The current [MTO reporting forms](#) allow the reporting physician to provide commentary as to whether the patient is unsafe to drive.

13.4.1 For non-commercial drivers:

a. Uncontrolled Narcolepsy with or without Cataplexy:

1. Diagnosis of uncontrolled narcolepsy must be reported.
2. Diagnosis of uncontrolled cataplexy must be reported.

b. Uncontrolled Hypersomnia:

Uncontrolled hypersomnia/sleepiness must be reported.

c. Uncontrolled Sleep Apnea:

1. If a patient declines assessment after referral, the sleep medicine physician should have a policy in place to notify the referring physician of the refusal and to suggest the referring physician consider the patient's fitness to drive.
2. A patient with diagnosed sleep apnea and a history of falling asleep while driving (FAWD), must be reported if refusing treatment (Mandatory Reporting).
3. A patient with severe sleep apnea who does not have any available history of significant drowsiness requires further assessment. It is strongly recommended that they have an MWT and thorough clinical assessment that is well documented to assist the physician in deciding whether or not they must be reported to the MTO.

13.4.2 For Commercial Drivers

We recommend the Canadian Thoracic Society guidelines be followed.

13.4.3 For Specific Occupations, e.g. Railway Conductors

We recommend following the industry standards if developed.

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Chapter 14 Home Sleep Apnea Testing (HSAT)

14.1 Overview

There is a considerable body of literature confirming the utility of unattended home sleep apnea testing as a diagnostic option for suspected OSAS in patients without other sleep or medical co-morbidity. Practice standards are required for the application of this evolving technology, to ensure appropriate usage and quality assurance in Ontario.

In 2010, the Canadian Sleep Society and Canadian Thoracic Society published a position paper on the usage of home sleep apnea testing for the diagnosis of OSAS in adults (A Blackman et al., *Can Respir J* 2010;17(5):229-232). This was based on consensus and expert opinion regarding best practice standards from stakeholders across Canada. The Sleep Medicine Taskforce has adapted the position paper, with some modifications to reflect the Ontario Health care system.

This chapter does not address use of HSAT devices *for triage*. Portable devices being used *for triage*, as opposed to *diagnosis*, may be useful in select settings where there are issues with resources or access.

14.2 Conflict of Interest

1. No aspect of a HSAT sleep test, including but not limited to delivery and/or pickup of the device, may be performed by a home care company and/or PAP therapy provider.
2. The CPSO's Conflict of Interest Policy should be reviewed by going to www.cpso.on.ca.

14.3 Indications and Pre-Test Requirements

Conditions where home sleep apnea testing is appropriate:

- HSAT can be used, as an alternative to polysomnography (PSG), to confirm the diagnosis of OSA in patients with a moderate to high pre-test probability of OSAS.
- HSAT can be used to evaluate suspected sleep disordered breathing in patients for whom in-facility PSG is not possible by virtue of immobility, safety, or critical illness.

Conditions where home sleep apnea testing is not appropriate:

- HSAT is not appropriate for general screening of asymptomatic populations.
- HSAT is not appropriate for the diagnosis of OSA in patients with significant comorbid medical conditions such as pulmonary disease, neuromuscular disease, or congestive heart failure that may degrade the accuracy of HSAT.

- HSAT is not appropriate for the diagnostic evaluation of patients suspected of having other sleep disorders such as insomnia, periodic limb movement disorder, or central sleep apnea.
- HSAT has not been validated in children and is not appropriate for use in patients under the age of 12.

HSAT testing should be performed only by physician, nurse practitioner, or dentist order. The ordering practitioner need not necessarily be a sleep specialist, but should have performed a history and examination sufficient to determine the following:

- a) A best estimate of the probability of OSA;
- b) The presence of any significant cardiopulmonary or neurological comorbidities;
- c) The presence of any significant comorbid sleep disorders such as insomnia, periodic limb movement disorder, or central sleep apnea;
- d) Triage information including identification of patients working in safety-critical occupations.

Appropriate documentation that the above requirements have been met needs to be maintained by the facility performing the testing (see Appendix VIII for a Sample Portable Sleep Apnea Test Requisition).

14.4 Setting, Staffing and Supervision

HSAT testing must be performed under the auspices of a sleep facility or hospital accredited sleep clinic with written policies and procedures. The testing and analysis should be performed under the supervision of a sleep medicine physician who is responsible for quality assurance and interpretation of the study results. An experienced sleep technologist/technician must educate patients in sensor application and score the study.

A CPSO qualified sleep physician must oversee the procedures surrounding ordering and conduct of tests, and must report the study results after reviewing the raw scored data from the HSAT using scoring criteria consistent with current published AASM standards.

14.5 Equipment Requirements

HSAT used for diagnosis of obstructive sleep apnea must record airflow, respiratory effort, heart rate and blood oxygenation, ideally using the same sensor systems and parameters used for in-facility sleep study. Additional data channels/modalities can be used.

The HSAT device must allow for display of raw data with the capability of manual scoring or editing of automated scoring by a qualified sleep technologist/technician with the RPSGT or RST credential, or sleep physician.

The use of all devices must follow comprehensive written policies which include appropriate infection control, privacy, and safety guidelines. All devices must have regular maintenance and

calibration which is appropriately documented. The handling of all reports must follow established patient privacy and confidentiality guidelines.

Other HSAT technologies

At this time technologies that assess parameters other than those listed above are NOT recommended by the committee for the portable diagnosis of sleep apnea. This will evolve as evidence for accurate diagnosis using other methods accumulates.

14.6 Scoring and Interpretation

Qualifications and Training of Sleep Technologists for HSAT

- Technical personnel must be trained by a registered sleep technologist with the RPSGT or RST credential, and training should be signed off by the Medical Director of the sleep center, a sleep specialist.
- Scoring must be in accordance with current the AASM guidelines.
- Maintain CPD as required

The interpretation report for a home sleep apnea testing study conducted to diagnose sleep apnea should comment upon and/or confirm:

- i. Pre and Post-test sleep questionnaires and their impact on the test validity.
- ii. Pre-test probability estimate of OSAS.
- iii. Potential confounding effect of medical co-morbidities and medications.
- iv. Technical quality of study.
- v. Presence of snoring (if available on recording).
- vi. Heart rate abnormalities.
- vii. Severity of the obstructive sleep apnea/hypopnea if present.
- viii. The severity of desaturations, and validity of these parameters if they are in question.
- ix. Presence and potential significance, or lack thereof, of central and mixed respiratory events.
- x. Respiratory patterns that may be artifactual, or suggest complicated sleep apnea syndrome and/or hypoventilation.
- xi. Possible differential diagnosis for non-specific oximetry patterns.
- xii. Suggestions for further investigations and management.
- xiii. Highlight critically abnormal test results or results which may need further diagnostic clarification.

14.7 Follow-up

The ordering health care provider is responsible for acting on the HSAT test results. Post-test follow-up must include a review of test results and referral and treatment options where appropriate.

Referral to a sleep medicine specialist should occur in the following circumstances:

- a) The HSAT findings suggest a diagnosis of OSAS;
- b) The HSAT test is negative or technically inadequate in a patient with a high pre-test probability of OSAS, in which case an in-facility PSG should be considered;
- c) The patient requires therapy for their sleep disorder.

14.8 Quality Assurance

Please refer to Chapter 6 (Quality Management).

Chapter 15 Telemedicine

15.1 Overview

Telemedicine is a form of medical practice where a health care provider sees a patient who is physically at a different site, via a secure audiovisual link.

Telemedicine allows patients to be seen closer to their homes and expands the number of health care providers able to service a given population. Other relevant policies All telemedicine appointments must conform to the current CPSO policies regarding telemedicine (<http://www.cpso.on.ca/policies-publications/policy/telemedicine>).

➤ **Standards**

S15.1.1	Every physician seeing a sleep medicine patient via telemedicine (henceforth “the provider”) shall hold the qualifications and meet the requirements specified elsewhere in this manual;
S15.1.2	The provider shall conduct any interview via the Ontario Telemedicine Network (OTN) following OTN rules and procedures, and following all relevant OTN and CPSO policies;
S15.1.3	The Provider shall NOT use any modality to conduct an interview except a modality provided/ sanctioned by OTN (i.e. Skype, Google chat, etc. are NOT TO BE USED)
S15.1.4	The centre hosting a patient being seen via telemedicine (henceforth “the host centre”) shall ensure that the patient understands that telemedicine is the proposed assessment modality, preferably well before the appointment;
S15.1.5	The host centre shall provide the patient the option to decline this form of assessment;
S15.1.6	The host centre shall have a comfortable, private, secure area where the patient is to be seen that conforms to relevant privacy regulations;
S15.1.7	The host centre shall have an attendant that can be called into the room at any point during an interview;
S15.1.8	The host centre shall have suitable equipment so that the patient can clearly and reliably see and hear the physician, and vice versa;
S15.1.9	The host centre shall have the equipment and trained staff who can: i. measure height, weight, neck circumference, blood pressure, oxygen saturation; ii. allow visualization, and preferably documentation, of relevant body parts during assessment, such as oral and nasal anatomy; whenever this would be relevant, such as with an initial consultation.
S15.1.10	All physicians shall use their professional judgment to determine whether telemedicine is appropriate in a particular circumstance each and every time its use is contemplated. In doing so, physicians shall consider whether practising telemedicine will enable them to satisfy all relevant and applicable legal and professional obligations, and to meet the standard of care.

S15.1.11	If a patient declines assessment via the host centre, and the physician who was to see the patient shall assist the patient making other arrangements, for example by making a referral to a centre where the patient can be seen by a physician in person.
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➤ **Guidelines**

G15.1.1	Telemedicine assessment should not be used for the assessment of people suspected of conditions that require physical assessment that cannot be accommodated by the technology available at both the centre hosting the patient and the centre where the physician is located. An example is assessment of a patient with suspected central apnea from heart failure if the assessing physician doesn't have access to a remote stethoscope to listen to the lung fields and heart sounds.
G15.1.2	Telemedicine assessment is a recommended method to follow people who live remotely from the centre where the physician would see them, for example to follow response to therapy, except when the physician's professional judgement is that telemedicine is not appropriate.

Please refer to the [CPSO Policy on Telemedicine](#) which sets out the CPSO's expectations of physicians who practise telemedicine.

APPENDICES

Appendix I **Independent Health Facilities Act - Ontario Regulation 57/92 - Amended to O. Reg. 14/95**

Note: Ontario Regulation 57/92 has previously been amended. Those amendments are listed in the Table of Regulations - Legislative History Overview which can be found at www.e-laws.gov.on.ca. Facilities are encouraged to check the Government Website for updates.

Quality Advisor and Advisory Committee

1(1) Every licensee shall appoint a Quality Advisor to advise the licensee with respect to the quality and standards of services provided in the independent health facility.

(2) If the Quality Advisor dies or ceases to be the quality advisor, the licensee shall appoint a new Quality Advisor forthwith.

(3) The Quality Advisor must be a health professional who ordinarily provides insured services in or in connection with the independent health facility and whose training enables him or her to advise the licensee with respect to the quality and standards of services provided in the facility.

(4) It is a condition of a licence that the Quality Advisor be a physician if all the insured services provided in the independent health facility that support the facility fees that the licensee may charge are provided by physicians.

(5) In subsection (4), an insured service supports a facility fee if the facility fee is for or in respect of a service or operating cost that supports, assists or is a necessary adjunct to the insured service.

(6) A licensee who is qualified under subsection (3) may appoint himself or herself as the quality advisor only if there is no other health professional who is qualified to be the quality advisor who will consent to be the Quality Advisor. O Reg 57/92, s.1.

2(1) Every licensee shall appoint an advisory committee to advise the quality advisor.

(2) The advisory committee shall consist of health professionals who provide health services in or in connection with the independent health facility.

(3) The Quality Advisor shall be the chair of the advisory committee.

(4) Every licensee shall use his or her best efforts to ensure that there is a representative on the advisory committee from the health profession and each specialty and sub-specialty of medicine, practitioners of which provide health services in or in connection with the independent health facility. O Reg. 57/92, s.2.

3(1) Every licensee shall give the Director the name of the Quality Advisor in writing forthwith after the quality advisor is appointed.

(2) If the quality advisor dies or ceases to be the Quality Advisor, the licensee shall inform the Director in writing forthwith.

(3) Every licensee shall give the Director, on request, the names of the members of the advisory committee in writing. O. Reg. 57/92, s.3.

Standards

- 4** (1) Every licensee shall ensure that all aspects of the services provided in the independent health facility are provided in accordance with generally accepted professional standards.
- (2) Every licensee shall ensure that the persons who provide services in the independent health facility are qualified, according to generally accepted professional standards, to provide those services.
- (3) If the Quality Advisor has reasonable grounds to believe that this section is not being complied with, he or she shall inform the Director forthwith. O. Reg. 57/92, s.4.
- 5** Every licensee shall keep a system to monitor the results of the services provided in the independent health facility. O. Reg. 57/92, s.5.
- 6** (1) Every licensee shall ensure that all tissues removed from a patient during an operation or curettage performed in an independent health facility are sent to a facility for examination and report unless the physician performing the operation or curettage is of the opinion that it is not necessary according to generally accepted medical standards.
- (2) The licensee shall ensure that a short history of the case and a statement of the findings of the operation or curettage are sent with the tissues. O. Reg. 57/92, s.6.

Records of Employees

- 7** (1) Every licensee of an independent health facility shall maintain, for each employee of the facility who is not a physician, an employment record setting out the employee's qualifications and employment history including a record of any registration with or licensing by the governing body of a health profession.
- (2) Every licensee shall retain an employee's employment record for at least two years after the employee ceases to be an employee. O. Reg. 57/92, s.7.
- 8** (1) Every licensee of an independent health facility shall maintain a record of qualifications and work history for:
- (A) each person the licensee contracts with to manage the facility; and
 - (B) each person who is not a physician who the licensee contracts with to provide patient-related services in the facility.
- (2) The record shall include a record of any registration with or licensing by the governing body of a health profession.
- (3) Every licensee shall retain the record for a person the licensee contracts with for at least two years after the licensee ceases to contract with the person. O. Reg. 57/92, s.8.
- 9** (1) Every licensee shall maintain a declaration of professional standing for each physician who provides professional services in the independent health facility.
- (2) A declaration of professional standing must include the following information:
- 1. The physician's name
 - 2. The physician's registration number with the College of Physicians and Surgeons of Ontario

3. The physician's number registered with the Health Insurance Division of the Ministry of Health.
 4. The class of the physician's licence issued under Part III of the Health Disciplines Act and any terms and conditions attached to it.
 5. The physician's specialty.
- (3) Every licensee shall give the Director a copy of each declaration of professional standing, forthwith after the obligation to maintain it begins under subsection (1).
- (4) Every licensee shall give the Director a written statement of any change in a declaration of professional standing forthwith after the change.
- (5) Subsections (3) and (4) do not apply with respect to physicians providing services on a temporary basis for less than twelve weeks. O. Reg. 57/92, s.9.

Patient Records

- 10** (1) Every licensee of an independent health facility shall keep, for each person who is or was a patient, a health record relating to the health services provided in the facility.
- (2) A patient's health record must include:
- (a) the patient's name and home address
 - (b) the patient's date of birth
 - (c) the patient's health number
 - (d) the name of any attending physician or practitioner and his or her number as registered with the Health Insurance Division of the Ministry of Health
 - (e) the name of any referring physician or practitioner and his or her number as registered with the Health Insurance Division of the Ministry of Health
 - (f) a history of the patient
 - (g) a written record of any orders for examinations, tests, consultations or treatments
 - (h) particulars of any examination of the patient
 - (i) any reports of examinations, tests or consultations including any imaging media from examinations and any physicians' interpretive or operative reports
 - (j) any reports of treatment including any physicians' operative reports
 - (k) any orders for and reports of any discharge of the patient from supervised care
 - (l) any consents; and
 - (m) any diagnoses of the patient.
- (3) A patient's health record need not contain a history of the patient if the patient came to the independent health facility for diagnostic services only and received on such service.
- (4) Every licensee shall ensure that every part of a patient's record has a reference on it identifying the patient or the record.
- (5) If information in a patient's record is kept in the form of a chart, each entry in the chart must be dated and it must be initialled by the person authorizing the entry. O. Reg. 57/92, s.10.

11 (1) Every licensee shall retain a patient's health record or a copy of it for at least six years following:

(a) the patient's last visit; or

(b) if the patient was less than eighteen years old when he or she last visited the facility, the day the patient became or would have become eighteen years old.

(2) Despite subsection (1), a licensee is not required to retain imaging media from any examination other than a mammography for more than three years following:

(a) the patient's last visit; or

(b) if the patient was less than eighteen years old when he or she last visited the facility, the day the patient became or would have become eighteen years old.

(3) Every licensee shall retain the film from a mammography for at least ten years following the patient's last visit. O. Reg. 57/92, s.11.

(4) On the transfer of a licence under section 11 of the Act, the transferor of the licence shall transfer to the transferee of the licence, in a manner that will protect the privacy of the records, the records maintained under section 10 of this Regulation, and the transferee of the licence shall retain those records in accordance with this section.

Section 12 of the Regulation is revoked and the following substituted:

12 (1) No licensee shall allow any person to have access to any information concerning a patient that is not subject to the Personal Health Information Protection Act, 2004 except in accordance with subsection (3).

(2) The reference to "information concerning a patient" in subsection (1) includes information or copies from a health record, even if anything that could identify the patient is removed.

(3) A licensee may provide information described in subsection (1) to the following persons if anything that could identify the patient is removed from the information:

1. Any person, if the information is to be used for health administration or planning or health research or epidemiological studies and the use is in the public interest as determined by the Minister.

2. Cancer Care Ontario. O Reg. 346/04, s.2.

Books and Accounts

12.1(1) This section applies to licensees of independent health facilities that are funded under section 24 of the Act, other than independent health facilities whose funding is based solely on the Ministry of Health publication titled "Schedule of Facility Fees".

(2) Every licensee shall keep the following records in relation to the independent health facility:

1. Current financial records showing:

(i) the amounts paid by the Minister to the licensee under section 24 of the Act.

(ii) the revenue earned by the licensee from facility fees charged by the licensee for or in respect of services or operating costs that support, assist or are a necessary adjunct to the primary insured services set out in the licensee's licence, and

(iii) the expenditures, assets and liabilities of the facility that relate to the costs paid by the Minister under section 24 of the Act.

2. A reporting record listing each service provided in the facility that is a primary insured service set out in the licensee's licence and each service provided in the facility that is a funded service under section 24 of the Act and showing how many of each of such services are provided.

3. An annual income and expense statement showing the income received and the expenses incurred by the licensee in connection with the services mentioned in paragraph 2.

4. An annual inventory of the assets of the facility that have an acquisition cost exceeding \$3,500 and that relate to the costs paid by the Minister under section 24 of the Act.

(3) Every licensee shall ensure that the records required under section (2):

(a) are kept in the independent health facility; and

(b) are kept in a bound or loose-leaf book or are recorded by a system of mechanical or electronic data processing or any other information storage device.

(4) Every licensee shall ensure that any part of a record required under subsection (2) that relates to a period of time is retained for at least six years following the end of the period.

(5) Every licensee shall ensure that the accounts of the independent health facility are audited by a person licensed under the *Public Accountancy Act*. O. Reg. 283/94, s.1, *part*.

12.2 Every licensee of an independent health facility shall furnish such information and accounts as the Director may require. O. Reg. 283/ 94, s.1, *part*.

Notices

13 Every licensee of an independent health facility,

(a) who decides to cease operating the facility at a future date shall give the Director, as soon as possible, written notice of the date; and

(b) who ceases operate the facility shall give the Director, within seven days after the date the licensee ceases to operate the facility, written notice of the date. O. Reg. 57/92, s.13.

14 Every licensee of an independent health facility shall give the Director:

(a) if the licensee is a corporation, written notice of any change in the location of the licensee's head office within ten days after the change; and

(b) written notice of any change in the name under which the licensee carries on business within ten days after the change. O. Reg. 57/ 92, s.14.

Miscellaneous

15 It is a condition of a licence that the licensee post the first page of the licence in a conspicuous place in the independent health facility. O. Reg. 57/92, s.15.

16 (1) The fee for a licence is \$100.

(2) The fee for the transfer of a licence is \$100.

(3) The fee for the renewal of a licence is \$100. O. Reg. 57/92, s.16.

17 The administrative charge for the purposes of section 36 of the Act is \$50. O. Reg. 57/92, s.17.

Appendix II Change in Scope of Practice Requirements and Forms

The College of Physicians and Surgeons of Ontario – Expectations for Physicians Planning to Change their Scope of Practice to include *Sleep Medicine*

Recommendations of the CPSO Sleep Medicine Working Group

Working Group Objective: To develop a decision-making framework to assist the College in responding to requests from physicians who wish to practice adult and adolescent (age 13 and older) Sleep Medicine.

CPSO’s Changing Scope of Practice Policy: The CPSO has gradually moved towards a system of performance measurement, i.e. focusing on a physician’s competence in a field of practice rather than simply relying on paper credentials (e.g. specialty certification). The CPSO “Changing Scope of Practice” Policy is based on these principles. It states that “a physician’s ability to perform competently in his or her scope of practice is determined by the physician’s knowledge, skills and judgment, which are developed through training and experience in that scope of practice”. To learn more about the Scope policy, follow the link: [Changing Scope of Practice | Policy | Policies & Publications | College of Physicians and Surgeons of Ontario](#)

The Policy also indicates a physician’s scope of practice is determined by the:

- patients the physician cares for,
- procedures performed,
- treatments provided, and
- practice environment.

Background:

The CPSO created a Working Group composed of various experts in Sleep Medicine from a variety of backgrounds to develop a decision-making framework, within the context of the Scope policy, in order to assist the CPSO in evaluating requests from physicians intending to practice Sleep Medicine, both in a hospital and a facility setting.

The Change of Scope of practice policy came into effect in November of 2002. Physicians who were practicing Sleep Medicine prior to this are not required to report a change of scope of practice. All other physicians, who have changed their scope of practice to include Sleep Medicine since 2003 should have already reported this change to the CPSO. All physicians who wish to change their scope of practice in the future to include Sleep Medicine must also report to the CPSO their intention to do so.

The Sleep Medicine Working Group's main task is to develop minimum training standards for physicians wishing to practice Sleep Medicine in the Province of Ontario. The need for this arises out of the lack of national standards for Sleep Medicine training, as well as the lack of a Canadian certification process in Sleep Medicine. Physicians practicing Sleep Medicine do so from a variety of backgrounds, but the majority come from the areas of respirology, psychiatry, neurology, internal medicine, otolaryngology and family practice. The intent of the working group is to develop minimum standards that both physicians and the College can utilize in guiding training in Sleep Medicine. These standards were developed in 20xx and revised in 2015. If in the future a national certification process in Sleep Medicine is developed then these standards will need to be revisited.

The Independent Health Facilities (IHF) recommendations on training required for Sleep Medicine for physicians who began practice in this area after 1996 include:

- a minimum of 12 months full-time or equivalent clinical training in the assessment, diagnosis and treatment and polysomnographic evaluation of patients with a broad range of primary and secondary sleep disorders in a recognized post-graduate training centre, providing evidence of when it occurred and verification by the supervising physician.

Or

- successful completion of the certification examination of the American Board of Sleep Medicine or equivalent.

Or

- experience obtained from the assessment, diagnosis and treatment of patients with a broad range of primary and secondary sleep disorders and the interpretation of polysomnograms under the supervision of a physician in a sleep disorder facility who meets the criteria in this document. A minimum of 2,000 hours experience and training must be obtained and can occur in a time frame of between 12 and 36 months. Physicians must provide documented evidence of this training.

The minimum number of hours of experience required is based upon the amount of time that a trainee would spend in a fellowship of one year's duration.

In the United States since 2006, certification in Sleep Medicine takes place through several member boards of the American Board of Medical Specialties (ABMS). Prior to 2006, physicians could seek specialist certification through the American Board of Sleep Medicine, however this organization no longer provides exams in Sleep Medicine. The current ABMS boards that offer certification in Sleep Medicine are the following:

American Board of Family Medicine
American Board of Internal Medicine
American Board of Pediatrics
American Board of Psychiatry and Neurology
American Board of Otolaryngology

The working group has relied heavily on the Accreditation Council on Graduate Medical Education (ACGME) Program Requirements for Graduate Medical Education in Sleep Medicine document dated 2004. The Working Group drew elements from this document to determine the minimum content of a training program in Sleep Medicine. This content is described below.

Implementation Date: The CPSO Changing Scope of Practice policy applies retroactively to all physicians (hospital and IHF-based) who began practising sleep medicine after September 1, 2008.

Since the Changing Scope of Practice policy came into effect on June 1, 2003, physicians who have been practising sleep medicine – in any setting – between June 1, 2003 and September 1, 2008 have a duty to self-report this information to the CPSO if they have not already done so.

While the ‘change in scope of practice’ process generally involves training, supervision and assessment, not all components may apply in every case. As with all Change in Scope of Practice issues, in arriving at a decision, the CPSO would review each physician’s individual circumstances.

Minimum Training Requirements for Sleep Medicine

Preamble

The following pathways for training are meant to be used for physicians wishing to enter the field of clinical Sleep Medicine in the Province of Ontario. Physicians who were practicing Sleep Medicine prior to the publication of the College’s Policy on Change of Scope of Practice in 2003 need not inform the College of their practice. All physicians who are engaged in the practice of Sleep Medicine are subject to the normal regulatory processes of the College.

This document sets out the CPSO’s expectations with regard to physicians who wish to practice adult and adolescent (age 13 and older) sleep medicine in a patient population. Note that additional training (beyond what is outlined in this document) is required for physicians who wish to practice sleep medicine in relation to: 1) neonatal and pediatric patients, and 2) patients with complex health issues, e.g. patients with Down Syndrome, developmentally delayed adolescents, complicated respiratory failure patients who require mechanical ventilation, etc.

In order for a physician to become eligible to practice Sleep Medicine in Ontario, they must have adequate training and experience. As there is currently no formal, accredited fellowship process in Sleep Medicine in Canada, one of the following pathways may be taken in order to demonstrate to the College that the physician has appropriate and adequate training and experience in Sleep Medicine. Note that with the exception of Pathway 1, all pathways will require a degree of supervision and then the option for a College-directed assessment at some point following the completion of the Pathway.

PATHWAY 1 – Accredited Fellowship Pathway

The physician has:

- a. Completed an ACGME-accredited training program in Sleep Medicine in the United States AND
- b. Successfully completed the sponsoring specialty's certification examination in Sleep Medicine.

PATHWAY 2 – Academic NON-Accredited Fellowship Pathway

The physician has:

- a. Completed a training program sponsored by an accredited Canadian Medical School Department or Division with a duration equivalent to 12 months of full time clinical training. The Program must be structured such that it has:
 - i. A designated program director
 - ii. Standard, written training objectives.
 - iii. A formal, regular evaluation process
 - iv. A mechanism to report the Program's assessment of the individual's competence at the end of the program.
 - v. All components contained within the attached document entitled "Mandatory Components of Sleep Medicine Training Programs in Ontario"
 - vi. A mechanism to document all training experiences including the number and types of all sleep studies interpreted equivalent to that which is contained in the CPSO IHF Sleep Medicine Checklist.
 - vii. Completed the program in less than 36 months.
- b. Met the training criteria for the European Sleep Research Society (ESRS) Examination in Sleep Medicine AND successfully completed the ESRS Examination.

PATHWAY 3 – NON-Academic, NON-Accredited Fellowship Pathway

The physician has:

- a. Completed a personalized training program in Sleep Medicine with a duration equivalent to 12 months of full time training. The Program must be approved by the CPSO prior to the start of training, and must be structured such that it has:
 - i. A minimum of two supervisors, acceptable to the CPSO, who agree to report on the content of the training no less than quarterly. The supervisors agree to be the Most Responsible Physician (MRP) for all patient assessments for the duration of the training program.
 - ii. Written objectives of training
 - iii. A formal, regular evaluation process

- iv. A mechanism to report the supervisors' assessment of the individual's competence at the end of the program.
 - v. All components contained within the attached document entitled "Mandatory Components of Sleep Medicine Training Programs in Ontario".
 - vi. A mechanism to document all training experiences including the number and types of all sleep studies interpreted equivalent to that which is contained in the CPSO IHF Sleep Medicine Checklist.
- b. Completed the program in less than 36 months.

PATHWAY 4 – Significant Practice Experience in Sleep Medicine¹

The physician has:

- a. Clinical practice experience in Sleep Medicine for the immediate past 5 years, in which at least 50% of their clinical time has been spent assessing patients, interpreting sleep studies and managing patients with sleep disorders.
- b. Provided testimonials of practice experience in Sleep Medicine through the provision of a letter of support from the director of every sleep facility in which the physician has worked, during that five year period. The letters of support should attest to the proportion of the physician's clinical time spent in the practice of sleep medicine, and the physician's competency in the components contained within the attached document entitled "Mandatory Components of Sleep Medicine Training Programs in Ontario". The CPSO would need to evaluate the testimonials for acceptability.

¹ This category is meant to apply to physicians with significant experience from other jurisdictions and to physicians who have some training in Sleep Medicine, but not enough to satisfy the other pathways.

Supervision and Assessment Requirements Following the Completion of Training

Once training in any of the above pathways is complete, there may be a requirement for supervised practice, followed by a College-directed assessment prior to being granted a change in scope of practice to an individual. These requirements are outlined in the table below.

PATHWAY	IS SUPERVISION REQUIRED AFTER TRAINING IS COMPLETED? (training outlined in the pathways)	LEVEL OF SUPERVISION	DURATION OF SUPERVISION	ASSESSMENT REQUIRED?
Pathway 1: Accredited Fellowship Pathway	NO ²	N/A	N/A	NO
Pathway 2: NON-Accredited Academic Pathway	YES ³	LOW	6 MONTHS	DISCRETIONARY
Pathway 3: NON-Academic, NON-Accredited Pathway	YES	MODERATE then DISCRETIONARY (after assessment)	3 MONTHS DISCRETIONARY	YES – The CPSO-directed assessment to take place after three months of moderate supervision; re-assessment could be directed if there is a period of additional supervision.
Pathway 4: Physicians with significant practice experience	YES	MODERATE then DISCRETIONARY (after assessment)	3 MONTHS DISCRETIONARY	YES – The CPSO-directed assessment to take place after three months of moderate supervision; re-assessment could be directed if there is a period of additional supervision.

² Physicians who have completed a US fellowship program in Sleep Medicine are expected to have successfully completed the sponsoring specialty's certification exam in Sleep Medicine; otherwise, they too may be subject to a period of supervised practice similar to those physicians identified in Pathway 2.

³ Physicians who have completed a Canadian fellowship program are required to undergo a six-month period of supervision; this six-month period of low-level supervision serves as a proxy for the examination.

**COMPONENTS OF SLEEP MEDICINE TRAINING
PROGRAMS IN ONTARIO**
(Based on ACGME Program Requirements for Graduate Medical Education in
Sleep Medicine)

A. Mandatory Components of Training Programs

The following components must be included in all training programs in Sleep Medicine.

1. Technical and Diagnostic Skills

Trainees must have formal instruction, clinical experience, and demonstrated competence at the completion of training in the following:

- A) The indications for and potential pitfalls and limitations of diagnostic tests and the interpretation of the results in the context of the clinical situation. These diagnostic tests must include the following:
 - a. diagnostic polysomnograms (scoring, recognition of artifact, and interpretation)
 - b. therapeutic polysomnograms (positive airway pressure therapy including CPAP/BPAP/ASV, oral appliances)
 - c.. multiple sleep latency testing
 - d. maintenance of wakefulness testing
 - e. compliance reports for use of positive airway pressure therapy or other devices

- B) Skills necessary to perform polysomnograms from preparation and hookup of the patient to the completion of the study, including multiple sleep latency and maintenance of wakefulness tests

2. Foundational Knowledge of Sleep

Trainees must have formal instruction in, and demonstrate comprehensive knowledge of:

- A) Fundamental mechanisms of sleep and major theories in sleep medicine, including:
 - a. Basic neurological sleep mechanisms
 - b. Chronobiological mechanisms
 - c. Respiratory physiology and pathophysiology during sleep
 - d. Cardiovascular physiology and pathophysiology during sleep
 - e. Sleep across the life span
- B) Airway anatomy
- C) Nosology for sleep disorders: The International Classification of Sleep Disorders
- D) Etiopathogenic characterization of sleep disorders

- E) Sleep pharmacology (i.e. medication effects on sleep)

3. Clinical Assessment Skills

Trainees must have sufficient clinical experience as outlined in the Checklist of Clinical Sleep Training Experience that is attached (Appendix 1). Trainees must have formal instruction in, and demonstrate comprehensive knowledge of the clinical manifestations, diagnostic strategies, and treatment of the following sleep disorders:

- A) Sleep disordered breathing including obstructive sleep apnea, central sleep apnea, and sleep hypoventilation syndromes
- B) Insomnia
- C) Primary CNS disorders of sleepiness including narcolepsy and idiopathic hypersomnolence
- D) Parasomnias
- E) Circadian rhythm disorders
- F) Sleep-related movement disorders including restless legs syndrome

Trainees must also demonstrate knowledge of:

- A) Medical and psychiatric disorders displaying symptoms likely to be related to sleep disorders (e.g., the relationship between hypertension and sleep apnea)
- B) The impact of treatment for sleep disorders on other medical and psychiatric conditions.

4. Other Aspects of Sleep Medicine

Trainees must have instruction in, and demonstrate skills in the following other aspects of sleep medicine:

- A) Communication of the clinical impression to the patient and family in a clear and compassionate way that takes into account the patient's cultural values and education
- B) Documentation of the relevant history and physical examination and communication of a succinct clinical impression and plan in a consultation letter
- C) Effective participation in an interprofessional healthcare team and collaboration with community agencies in the care of patients with sleep disorders
- D) Managerial aspects of a sleep facility, including staffing, equipment, and appropriate triage of referrals
- E) Patient advocacy in the form of promotion of healthy sleep habits, knowledge of funding programs for positive airway pressure therapy, and motor vehicle safety in patients with sleep disorders

- F) Critical appraisal of the scientific literature, and the application of evidence-based medicine to patient care.
- G) Ethical and legal aspects of sleep medicine

B. Components of Programs that are Desirable but not Mandatory

The following components of training programs in sleep medicine are desirable but not mandatory for consideration of the training program. These components are important aspects of Sleep Medicine, but are areas in which the absence of formal training will not affect the trainee's ability to practice in a safe manner. Many of these components of practice will be learned as the trainee transitions to independent practice.

1. Technical and Other Skills

Trainees may have formal instruction, clinical experience, and demonstrated competence at the completion of training in the following:

- A) Cardiopulmonary resuscitation
- B) Actigraphy;
- C) Imaging studies, including magnetic resonance imaging
- D) scoring and interpretation of full EEG montages with additional leads for seizure detection
- E) Administration and interpretation of psychological tests
- F) Ambulatory monitoring technology

2. Foundational Knowledge of Sleep

Trainees may have formal instruction in, and demonstrate knowledge of:

- A) Endocrine physiology and pathophysiology during sleep
- B) Gastrointestinal physiology and pathophysiology during sleep

3. Clinical Assessment Skills

Trainees may have formal instruction, and demonstrate knowledge and skills, in pediatric and neonatal sleep medicine.

ACGME Approved: June 2004 Effective: June 2004 Editorial Revisions: April 2005
Editorial Revisions: June 2005 ACGME-Approved Minor Revision: February 12, 2008
Effective: April 12, 2008

Revisions: CPSO Sleep Medicine Working Group on Change in Scope of Practice:
October 14, 2010

Checklist for Completion of Training Requirements in Sleep Medicine – Pathway 1

This checklist follows the mandatory components of training in sleep medicine for physicians who have followed Pathway 1. Please complete all components of the following checklist for consideration of acceptance of your training in sleep medicine.

Name of Physician Changing Scope of Practice: _____

CPSO Number: _____

- a. I have completed a training program in Sleep Medicine accredited by the American College of Graduate Medical Education (ACGME).

Please attach proof of completion of ACGME-accredited training program in Sleep Medicine

- b. I have successfully completed the sponsoring specialty's certification examination in Sleep Medicine.

Please attach copy of certification

Attestation

I hereby declare that I have received the training and have the experience required to practice in the field of Sleep Medicine and that all information provided above is correct.

Signature of Applicant: _____

Date: _____

Checklist for Completion of Training Requirements in Sleep Medicine – Pathway 2

This checklist follows the mandatory components of training in sleep medicine for physicians who have followed Pathway 2. Please complete all components of the following checklist for consideration of acceptance of your training in sleep medicine.

Name of Physician Changing Scope of Practice: _____

CPSO Number: _____

- a. Completed a training program sponsored by an accredited Canadian Medical School Department or Division with a duration equivalent to 12 months of full time clinical training.

Please document dates and duration of training in the table below. Use additional pages as necessary:

	Location	Start Date	Stop Date	Total Days	Supervisor's Initial
Document Location and dates of training with supervisor's initials					

i. Designated Program Director

Name of Program Director: _____

Contact Address: _____

Phone number _____

Email Address _____

Please have the Program Director initial each mandatory component of training below to attest to completion of training.

ii. Standard, written training objectives

Please attach training objectives of program

iii. Formal, regular evaluation process

Please attach completed in training evaluation reports utilized in the training program.

iv. Contains all components contained within the attached document entitled “Mandatory Components of Sleep Medicine Training Programs in Ontario”.

Please have supervisors initial each mandatory component of training below to attest to completion of training.

1. Technical and Other Skills

Trainees must have formal instruction, clinical experience, and demonstrated competence at the completion of education in the following:

- A) The indications for and potential pitfalls and limitations of diagnostic tests and the interpretation of the results in the context of the clinical situation. These diagnostic tests must include the following:
 - a. polysomnography, scoring and interpretation of polysomnograms and recognition of artifacts, including:
 - i) performance and interpretation of CPAP titrations,
 - (ii) performance and interpretation of bilevel titrations,
 - (iii) performance and interpretation of adaptive servoventilation studies.
 - b. multiple sleep latency testing;

- c. maintenance of wakefulness testing;
 - d. evaluation of polysomnograms that involve treatment, including dental devices, positive airway pressure therapy, etc.
 - e. compliance reports for use of positive airway pressure therapy or other devices
- B) Skills necessary to perform polysomnographies from preparation and hookup of the patient to the completion of the study, including multiple sleep latency and maintenance of wakefulness tests;
- C) Scoring and interpretation of polysomnograms and recognition of artifacts;-
- D) Consultative skills in sleep medicine in a variety of medical, surgical, and psychiatric settings;

I certify that each of the above components of training have been completed satisfactorily:

Initials of Program Director

Date:

2. Foundational Knowledge of Sleep

Trainees must have formal instruction in, and demonstrate comprehensive knowledge of:

- A) fundamental mechanisms of sleep, major theories in sleep medicine, and the generally-accepted facts of basic sleep mechanisms:
- a. Basic neurological sleep mechanisms;
 - b. Chronobiological mechanisms;
 - c. Respiratory physiology during sleep and pathophysiology;
 - d. Cardiovascular physiology during sleep and pathophysiology;
 - e. Sleep across the life span.
- B) airway anatomy
- C) nosology for sleep disorders: The International Classification of Sleep Disorders
- D) etiopathogenic characterization of sleep disorders
- E) pharmacology of sleep (i.e. medication effects on sleep)

I certify that each of the above components of training have been completed satisfactorily:

Initials of Program Director:

Date:

3. Clinical Assessment Skills

Trainees must have sufficient clinical experience as outlined in the Checklist of Clinical Sleep Training Experience that is attached (Appendix 1). Trainees must have formal instruction in, and demonstrate comprehensive knowledge of clinical manifestations of the following aspects of sleep disorders. :

- A) evaluation of patients presenting with excessive sleepiness;
- B) evaluation of patients presenting with difficulty initiating or maintaining sleep;
- C) evaluation of patients presenting with parasomnias;
- D) biological rhythm disorders;
- E) medical, neurologic, and psychiatric disorders displaying symptoms likely to be related to sleep disorders (e.g., the relationship between hypertension and snoring);
- F) Biological, psychological, social, economic, ethnic, and familial factors which significantly influence the evaluation and treatment of sleep disorders; and
- G) The nature of the interactions between treatment for sleep disorders and other medical, neurologic, and psychiatric treatment.

I certify that each of the above components of training have been completed satisfactorily:

Initials of Program Director

Date:

4. Diagnostic Skills

Trainees must have formal instruction in, and demonstrate comprehensive knowledge of diagnostic strategies in sleep disorders.

- A) etiologies, prevalence, diagnosis, and treatment of all of the sleep disorders in the current nosology of sleep medicine;
- B) the use, reliability, and validity of the generally-accepted techniques for diagnostic assessment

I certify that each of the above components of training have been completed satisfactorily:

Initials of Program Director:

Date:

5. Treatment of Sleep Disorders

Trainees must have formal instruction in, and demonstrate comprehensive knowledge in the treatment of sleep disorders

- A) treatment approaches for obstructive sleep apnea, to include nasal CPAP, bilevel PAP, upper airway surgery, oral appliances, and position education;
- B) treatment of Central Sleep Apnea
- C) treatment approaches for insomnia, to include cognitive-behavioral therapies and pharmacological therapy;
- D) treatment approaches for narcolepsy and idiopathic CNS hypersomnolence;
- E) treatment approaches for parasomnias;
- F) treatment of circadian rhythm disorders.
- G) treatment of obesity hypoventilation syndrome.

I certify that each of the above components of training have been completed satisfactorily:

Initials of Program Director:

Date:

6. Other Aspects of Sleep Medicine

Trainees must have formal instruction in, and demonstrate comprehensive knowledge in the following other aspects of Sleep medicine

- A) legal aspects of sleep medicine;
- B) critically appraising the professional and scientific literature, and applying new contributions to management and care of patients.

I certify that each of the above components of training have been completed satisfactorily:

Initials of Program Director

Date:

v. Supervisors' assessment of the individual's competence at the end of the program.

Please attach a final assessment of the physician's competence from each supervisor at the end of the training program.

vi. Documentation of all training experiences including the number and types of all sleep studies interpreted equivalent to that which is contained in the CPSO IHF Sleep Medicine Checklist.

Please complete this checklist and have it initialed by your supervisor(s)

	Trainee	Supervisor
I have received an equivalent of at least 12 months full-time hours experience and training in sleep medicine		
My Supervisor is a qualified Sleep Specialist		
I have personally set-up at least 5 patients for overnight studies		
I have personally scored at least 25 sleep studies (should be a sufficient broad spectrum of studies to ensure proper training, e.g. sleep apnea, insomnia, etc.)		
I have reviewed and interpreted the raw data of at least 200 polysomnograms		
I have personally interpreted 50 CPAP titration studies		
I have personally supervised and interpreted at least 5 BiPAP titration studies		
I have personally interpreted at least 20 MSLTs		
I have personally interpreted at least 10 MWTs		
I have evaluated at least 25 insomnia patients		
I have evaluated at least 10 patients with RLS/PLMS		
I have evaluated at least 50 obstructive apnea patients		
I have evaluated at least 10 central apnea patients		
I have evaluated and managed at least 10 narcolepsy/idiopathic hypersomnolence patients		
I have evaluated and managed at least 10 patients with circadian rhythm sleep disorders		
I have evaluated and managed at least 10 parasomnia patients		
I have triaged at least 200 patients		
I have been trained to report to the Ministry of Transportation regarding driver's license revocations		

vii. The program must be completed in less than 36 months

Please enter start and finish dates of program below:

Start Date: _____ Finish Date: _____

Attestation

I hereby declare that I have received the training and have the experience required to practice in the field of Sleep Medicine and that all information provided above is correct.

Signature of Applicant: _____

Date: _____

Checklist for Completion of Training Requirements in Sleep Medicine – Pathway 3

This checklist follows the mandatory components of training in sleep medicine for physicians who have followed Pathway 3. Please complete all components of the following checklist for consideration of acceptance of your training in sleep medicine.

Name of Physician Changing Scope of Practice: _____

CPSO Number: _____

- a. Completed a personalized training program in Sleep Medicine with a duration equivalent to 12 months of full time training. The Program must be structured such that it:

- Please document dates and duration of training in the table below. Use additional pages as necessary:

	Location	Start Date	Stop Date	Total Days	Supervisor's Initial
Document Location and dates of training with supervisor's initials					

- b. Contains all components contained within the attached document entitled “Mandatory Components of Sleep Medicine Training Programs in Ontario”.

Please have supervisors initial each mandatory component of training below to attest to completion of training.

1. Technical and Other Skills

Trainees must have formal instruction, clinical experience, and demonstrated competence at the completion of education in the following:

A) The indications for and potential pitfalls and limitations of diagnostic tests and the interpretation of the results in the context of the clinical situation. These diagnostic tests must include the following:

a. polysomnography, scoring and interpretation of polysomnograms and recognition of artifacts, including:

- i) performance and interpretation of CPAP titrations,
- (ii) performance and interpretation of bilevel titrations,
- (iii) performance and interpretation of adaptive servoventilation studies.

b. multiple sleep latency testing;

c. maintenance of wakefulness testing;

b. evaluation of polysomnograms that involve treatment, including dental devices, positive airway pressure therapy, etc.

c. compliance reports for use of positive airway pressure therapy or other devices

B) Skills necessary to perform polysomnographies from preparation and hookup of the patient to the completion of the study, including multiple sleep latency and maintenance of wakefulness tests;

C) Scoring and interpretation of polysomnograms and recognition of artifacts;

D) Consultative skills in sleep medicine in a variety of medical, surgical, and psychiatric settings;

I certify that each of the above components of training have been completed satisfactorily:

Name of Supervisor: _____

Date: _____

Initials of Supervisor: _____

2. Foundational Knowledge of Sleep

Trainees must have formal instruction in, and demonstrate comprehensive knowledge of:

- A) fundamental mechanisms of sleep, major theories in sleep medicine, and the generally-accepted facts of basic sleep mechanisms:
 - a. Basic neurological sleep mechanisms;
 - b. Chronobiological mechanisms;
 - c. Respiratory physiology during sleep and pathophysiology;
 - d. Cardiovascular physiology during sleep and pathophysiology;
 - e. Sleep across the life span.
- B) airway anatomy
- C) nosology for sleep disorders: The International Classification of Sleep Disorders
- D) etiopathogenic characterization of sleep disorders
- E) pharmacology of sleep (i.e. medication effects on sleep)

I certify that each of the above components of training have been completed satisfactorily:

Name of Supervisor: _____ Date: _____

Initials of Supervisor: _____

3. Clinical Assessment Skills

Trainees must have sufficient clinical experience as outlined in the Checklist of Clinical Sleep Training Experience that is attached (Appendix 1). Trainees must have formal instruction in, and demonstrate comprehensive knowledge of clinical manifestations of the following aspects of sleep disorders. :

- A) evaluation of patients presenting with excessive sleepiness;
- B) evaluation of patients presenting with difficulty initiating or maintaining sleep;
- C) evaluation of patients presenting with parasomnias;
- D) biological rhythm disorders;

- E) medical, neurologic, and psychiatric disorders displaying symptoms likely to be related to sleep disorders (e.g., the relationship between hypertension and snoring);
- F) Biological, psychological, social, economic, ethnic, and familial factors which significantly influence the evaluation and treatment of sleep disorders; and
- G) The nature of the interactions between treatment for sleep disorders and other medical, neurologic, and psychiatric treatment.

I certify that each of the above components of training have been completed satisfactorily:

Name of Supervisor: _____ Date: _____

Initials of Supervisor: _____

4. Diagnostic Skills

Trainees must have formal instruction in, and demonstrate comprehensive knowledge of diagnostic strategies in sleep disorders.

- A) etiologies, prevalence, diagnosis, and treatment of all of the sleep disorders in the current nosology of sleep medicine;
- B) the use, reliability, and validity of the generally-accepted techniques for diagnostic assessment

I certify that each of the above components of training have been completed satisfactorily:

Name of Supervisor: _____ Date: _____

Initials of Supervisor: _____

5. Treatment of Sleep Disorders

Trainees must have formal instruction in, and demonstrate comprehensive knowledge in the treatment of sleep disorders

- A) treatment approaches for obstructive sleep apnea, to include nasal CPAP, bilevel PAP, upper airway surgery, oral appliances, and position education;
- B) treatment of Central Sleep Apnea

- C) treatment approaches for insomnia, to include cognitive-behavioral therapies and pharmacological therapy;
- D) treatment approaches for narcolepsy and idiopathic CNS hypersomnolence;
- E) treatment approaches for parasomnias;
- F) treatment of circadian rhythm disorders.
- G) treatment of obesity hypoventilation syndrome.

I certify that each of the above components of training have been completed satisfactorily:

Name of Supervisor: _____ Date: _____

Initials of Supervisor: _____

6. Other Aspects of Sleep Medicine

Trainees must have formal instruction in, and demonstrate comprehensive knowledge in the following other aspects of Sleep medicine

- A) legal aspects of sleep medicine;
- B) critically appraising the professional and scientific literature, and applying new contributions to management and care of patients.

I certify that each of the above components of training have been completed satisfactorily:

Name of Supervisor: _____ Date: _____

Initials of Supervisor: _____

i. Has a minimum of two supervisors, acceptable to the CPSO, who agree to report on the content of the training no less than quarterly. The supervisors agree to be the Most Responsible Physician (MRP) for all patient assessments for the duration of the training program.

- Attestation of Supervisors (use additional pages as necessary if more than one supervisor)

viii. A formal, regular evaluation process

- Please detail the evaluation process utilized in the training program in the space below.

ix. Written objectives of training

- Please attach written objectives of training.

x. A mechanism to report the supervisors' assessment of the individual's competence at the end of the program.

- Please attach a final assessment of the physician's competence from each supervisor at the end of the training program.

xi. A mechanism to document all training experiences including the number and types of all sleep studies interpreted equivalent to that which is contained in the CPSO IHF Sleep Medicine Checklist.

- Please complete this checklist and have it initialed by your supervisor(s)

	Trainee	Supervisor
I have received an equivalent of at least 12 months full-time hours experience and training in sleep medicine		
My Supervisor is a qualified Sleep Specialist		
I have personally set-up at least 5 patients for overnight studies		
I have personally scored at least 25 sleep studies (should be a sufficient broad spectrum of studies to ensure proper training, e.g. sleep apnea, insomnia, etc.)		
I have reviewed and interpreted the raw data of at least 200 polysomnograms		
I have personally interpreted 50 CPAP titration studies		

I have personally supervised and interpreted 5 BiPAP titration studies		
I have personally interpreted at least 20 MSLTs		
I have personally interpreted at least 10 MWTs		
I have evaluated at least 25 insomnia patients		
I have evaluated at least 10 patients with RLS/PLMS		
I have evaluated at least 50 obstructive apnea patients		
I have evaluated at least 10 central apnea patients		
I have evaluated and managed at least 10 narcolepsy/idiopathic hypersomnolence patients		
I have evaluated and managed at least 10 patients with circadian rhythm sleep disorders		
I have evaluated and managed at least 10 parasomnia patients		
I have triaged at least 200 patients		
I have been trained to report to the Ministry of Transportation regarding driver's license revocations		

xii. The program must be completed in less than 36 months

Please enter start and finish dates of program below:

Start Date:

Finish Date:

xiii. The proposed program, including supervisors, must be evaluated by the CPSO to ensure that they are acceptable before the physician embarks on the training.

CPSO Staff to confirm acceptance of program prior to starting program

Attestation

I hereby declare that I have received the training and have the experience required to practice in the field of Sleep Medicine and that all information provided above is correct.

Signature of Applicant: _____

Date: _____

Checklist for Completion of Training Requirements in Sleep Medicine – Pathway 4

This checklist follows the mandatory components of training in sleep medicine for physicians who have followed Pathway 4. Please complete all components of the following checklist for consideration of acceptance of your training in sleep medicine.

Name of Physician Changing Scope of Practice: _____

CPSO Number: _____

- a. The physician must have clinical practice experience in a jurisdiction in North America in Sleep Medicine for the immediate past 5 years, in which at least 50% of their clinical time has been spent assessing patients, interpreting sleep studies and managing patients with sleep disorders.

Please document dates and duration of practice in the table below. Use additional pages as necessary:

Name of Sleep Clinic	Address	Medical Director of Clinic	Start work date	Stop Work Date

b. The physician must provide evidence of the amount and quality of their Sleep Medicine practice through the provision of a letter of support from the director of every sleep lab in which they worked during that five year period. The letters of support should attest to the physician’s competence in the components contained within the attached document entitled “Mandatory Components of Sleep Medicine Training Programs in Ontario”.

Please attach a letter from the director of each sleep lab in which you have worked in the last five years. Please note that the letters must refer to the document entitled “Mandatory Components of Sleep Medicine Training Programs in Ontario”.

c. Note that the CPSO will evaluate the evidence for the acceptability of practice experience.

Attestation

I hereby declare that I have received the training and have the experience required to practice in the field of Sleep Medicine and that all information provided above is correct.

Signature of Applicant: _____

Date: _____

Appendix III Referral Update Form

FOR YOUR ACTION

Date

Address
Address
Address

Dear Dr.

Re:

DOB:

This notice is to inform you that we were unable to see your patient for a sleep assessment as requested by you for the following reason(s):

- We have been unable to reach the patient after several attempts
- Your patient cancelled their scheduled appointment and did not reschedule another appointment
- Your patient declined a sleep study and/or consultation
- Your patient did not show for sleep study test
- Your patient did not complete the sleep study test and departed prematurely
- Your patient wishes to contact us at a later date to set up for a sleep assessment or study
- Your patient did not show for the consultation OR follow up assessment despite a reminder
- Our records indicate your patient did not pursue therapy as recommended.
- Other:

If your patient has an increased level of sleepiness which may result in inattentiveness, reduced reaction times and increased risk of motor vehicle and work related accidents, please advise the patient not to drive or operate machinery when tired or sleepy, and use precautionary countermeasures. **Consider reporting the patient to the Ministry of Transportation, pursuant to the current legislation.**

We recommend that you discuss this issue with your patient soon, and consider re-referral to a sleep facility.

Sincerely,

Dr.
Sleep Lab clinic name

Appendix IV Information on CPAP/Bilevel Access for patients

You have been prescribed a mask and positive pressure machine for your sleep apnea.

This therapy is partly funded in Ontario under the Assistive Devices Program. Your sleep facility and physician will provide you with a prescription. You may obtain the machine, mask, and other supplies from ANY of a number of home care companies who are ADP approved. Most ADP-approved vendors can supply any of the equipment you have been prescribed.

All sleep clinics must provide you with a list of suppliers in your area. You may choose from any of these suppliers to work with to obtain the mask and machine. You may change suppliers at any time.

I have read and understand this information,

Patient signature

Appendix V Pediatric Training Experience

In addition to the training expected for a sleep physician, to be responsible for the performance and interpretation of pediatric sleep studies the sleep facility physician therefore needs to have the appropriate level of training. This should include a minimum of three months training in a recognized pediatric sleep centre with exposure to at least 90 pediatric polysomnograms covering the entire range of pediatric sleep disorders, and documented interpretation of 45 PSGs. In addition, to demonstrate ongoing maintenance and upgrading of knowledge, at least 25 hours of documented CPD hours should be directly related to pediatric sleep medicine.

Disorders to be covered during this training should include at least

- At least 30 children, across all ages, with obstructive sleep apnea.
- Exposure to and management of children with behavioural insomnia, including sleep association disorder and limit setting disorder
- Exposure to and management of children with circadian sleep disorders: sleep phase delay (adolescents)
- Exposure to and management (invasive and non-invasive ventilation) of at least 10 children with central hypoventilation syndrome (congenital or acquired)
- Exposure to children and management of at least 10 children with hypoventilation secondary to primary neuromotor disease.
- At least 5 children with narcolepsy.
- At least 5 children with RLS /PLMS.

Theoretical and Background Clinical Training

It is impossible to learn the entire field of pediatric sleep medicine in a three months period. The purpose of this training is therefore to ensure that the physician has a minimum knowledge required to diagnose and treat the common disorders. This requires not only a knowledge of the scope of disorders covered under pediatric sleep medicine, but also an appreciation of the changes in physiology and disease spectrum with age, and familiarity with the diagnosis and treatment of these disorders. The knowledge gained will not be sufficient to make the physician an expert in this field, but should allow them to proficiently diagnose and treat the common disorders, while be able to recognize the more rare and complex disorders, sufficient to refer to the appropriate specialized pediatric center. The purpose of this training is therefore to “fill in” specific areas relevant to the practice of pediatric sleep medicine that would not have been covered already in the physician’s prior training. This is obviously contingent on their prior area of expertise and training:

1. Pediatric respirologist: will have background knowledge of normal pediatric development, as well as respiratory physiology and developmental changes relevant to pediatric sleep medicine, but may not have the appropriate knowledge of neurobehavioural disorders, neurologic disorders (e.g. nocturnal seizure recognition) as well as issues regarding circadian rhythm, insomnia, etc.

2. Pediatric neurologist: will have also background knowledge of normal pediatric development, as well as neurologic disorders (nocturnal seizure recognition), but may not have the appropriate knowledge respiratory physiology and developmental changes relevant to pediatric sleep medicine sleep.

In addition both pediatric respirologists and neurologists will have to learn the “technology” of the sleep facility: the essentials of sleep facility recordings, as well as basic electronics (amplifier set up and artefact recognition) and electrical safety.

3. Sleep physicians caring for adults may not have the necessary knowledge and respect to the developmental physiology of children, as well as the changing pattern of disease associated with the various stages of childhood. Similarly, their knowledge of the relevant disorders during adolescence and childhood will be contingent upon their background training: a psychiatrist may have training in neurobehavioural disorders, but will not have training in respiratory disorders, or respiratory physiology, and vice versa for an individual with an adult respiratory background. They will also have to learn the essentials of the patient interview in pediatric sleep medicine, particularly in respect to dealing with family interviews.

Consequently the precise curriculum needs to be tailored for each individual, sufficient to fill in their identified knowledge gaps.

Below is an outline of the relevant areas that should be covered if not already done so in the physician’s prior training.

1. Normal Physiology
 - a. Neurophysiology of sleep, basic brain mechanisms underlying REM and NREM sleep
 - b. Sleep states and sleep stages
 - i. Normal variation with age
 - ii. Physiologic significance: impact on respiration, sleep deprivation
 - c. Circadian rhythmicity (basic mechanisms)
 - i. The characteristics of the circadian clock
 - ii. Neural basis of circadian rhythmicity
 - iii. Interaction between activity, sleep and circadian rhythm.
 - iv. Genetics of sleep states and circadian rhythms
2. Sleep disordered breathing: its presentation, clinical significance, and sequelae
 - a. Obstructive sleep apnea: its spectrum (OSA, obstructive hypopneas, upper airway resistance syndrome, chronic mouth breathing)
 - b. Central sleep apnea: recognition diagnosis of physiologic versus pathologic.
 - c. Central hypoventilation syndromes, both primary / congenital as well as secondary to neurologic and neuromotor disease
 - d. Sleep disordered breathing secondary to chronic medical conditions
3. Sleep disordered breathing: its diagnosis, and therapy

- a. Have an approach to the history and physical examination of a child presenting with sleep disordered breathing.
 - b. Nasal, bilevel and auto continuous positive airway pressure (CPAP, autoCPAP, NIPPV).
 - c. Role of nocturnal oxygen.
 - d. Pharmacological and behavioral approach.
 - e. Surgical approaches.
 - f. Orthodontic approaches: from distraction to appliances.
4. Insomnia: disorders of initiating and maintaining sleep
- a. Behavioral and psychological sleep disorders, including bedtime resistance, sleep onset, maintenance association problems
 - b. Behavior and sleep: impact on learning and memory
 - c. Hygiene and sleep, including circadian rhythm disorders
 - d. Epidemiology of sleep disorders and of sleep habits
 - e. The disorders of sleep/wake schedule
 - f. Understand the pharmacology of hypnotic and wake-promoting medications, and be cognizant of the effects of other medications on sleep.
 - g. Have an approach to the history, physical examination and appropriate investigations of a child presenting with disordered sleep
5. Parasomnias
- a. Narcolepsy and the hypersomnia
 - b. Sleepwalking
 - c. Periodic limb movement disorder and restless leg syndrome
 - d. Confusional arousals and sleep terrors
6. Excessive daytime sleepiness: causes, investigation, and treatment
7. Familiar with the technical aspects of polysomnography, including:
- a. Lead placement and procedures for Level 1 polysomnography.
 - b. Procedures and protocols for performing Level 1 diagnostic polysomnography and positive pressure titration (including CPAP, BiPAP, and adaptive servo-ventilation).
 - c. Scoring of a Level 1 polysomnogram, including sleep staging, respiratory events, EKG interpretation, leg movements, and abnormal movements such as bruxism.
 - d. Identification of sources of artifact and the proper steps towards correction.
 - e. Interpretation of multiple sleep latency testing.

Appendix VI Pediatrics Diagnosis & Management Resource and Reference Tool

Overview

Because children have a specific physiology and disease spectrum, personnel in sleep laboratories and sleep clinics caring for children with suspected sleep related disorders need to be knowledgeable of:

1. normal pattern of development, specifically related to sleep.
2. patterns of disease, with their presentation across the ages, in order to accurately diagnose and treat children with sleep related disorders.
3. current standards of treatment and monitoring of these disorders

Since multiple reviews are already available to reader, in this edition of the standards of practice the clinical description of disorders in adults has been removed. The pediatric section is, however, still included to provide a readily accessed summary of the issues and disorders found in pediatric sleep medicine.

Clinical Disorders

Insomnia

Insomnia is a common parental complaint. In the vast majority of cases the cause is either parental misunderstanding of what is normal, age appropriate behavior or secondary to a primary behavioral and developmental disorder. Consequently, as in adults, diagnosis and management is primarily based on a detailed history and rigorous examination to rule out organic causes.

As noted, in the vast majority of cases, childhood “insomnia” is due to behavioural issues rather than organic disease, examples being:

1. Toddlers; sleep association disorder, where the infant requires parental presence to return to sleep following normal nocturnal arousals
2. Adolescents; poor sleep hygiene / irregular sleep schedules / sleep phase delay, where the child has a shortened / irregular sleep schedule with sleep “catch up” at weekends, anxiety related insomnia.

Consequently explanation and behavioural modification rather than pharmacologic intervention, remains the mainstay of treatment. If insomnia is deemed to be secondary to a

primary psychiatric disorder such as anxiety or depression, treatment should be aimed at the primary psychiatric disorder. Because of the concerns regarding the paucity of good data in the use of hypnotics / sedatives in children, they should only be used in very distinct circumstances, and only by physicians experienced with their use.

Polysomnography may occasionally be warranted to rule out a primary neurologic diagnosis, circadian rhythm sleep disorders, restless legs syndrome, and (rarely, since direct questioning and sleep diary should provide this information) to document sleep pattern and hygiene. However, even more than in adults, the artificiality of the study set-up, technical requirements, and strangeness of the sleep setting may significantly affect the sleep pattern and therefore limit the reliability of the data obtained. Polysomnography therefore should only be performed after a detailed history and physical examination, and the precise indication (e.g. suspected underlying disorder or condition) clearly documented.

Restless Legs Syndrome and Periodic Limb Movement Disorder

Restless Leg Syndrome

RLS is a common, frequently under diagnosed sensorimotor condition, presenting as a **(1)** prominent urge to move the legs, **(2)** associated by uncomfortable or unpleasant sensations, **(3)** exacerbated if unable to move, **(4)** relieved by movement with a circadian profile being worse in the evening. Severity can range from mild to severe, with significant impact on sleep, mood, cognitive function and quality of life. It is usually idiopathic, but may be associated with iron deficiency or uraemia.

Approximately 40 % of affected adults report an onset before the age of 20 years, and delays in diagnosis are common. The estimated prevalence in children is around 2%. Making the diagnosis is dependent upon the presence of 4 essential features, supported by a positive family history and response to treatment. Adult criteria can be used in children 12 years and older, with specific pediatric diagnostic criteria to be used in children under 12 years old.

Periodic Limb Movement

Periodic limb movements (PLMS) are rhythmic movements, classically extension of the big toe, and dorsiflexion of the ankle, though with considerable variability in motor pattern. Periodic Leg Movement Disorder (PLMD) is a linked but separate disorder to RLS, the majority of patients with RLS also having PLMD. PLMS can also occur in narcolepsy, REM sleep behaviour disorder, OSA, and is associated with ADHD, amongst other medical conditions. The presence of PLMS (particularly an index of greater than 5) index is supportive, but not specific for the diagnosis of RLS.

The significance of RLS and PLMD in childhood remains debatable, with no clearly established treatment protocols. First line treatment is usually non-pharmacologic, primarily good sleep hygiene and regular sleep scheduling, as well as restriction of drugs and agents known to aggravate RLS/PLMD. Various pharmacologic treatments have been used, but there is limited data on either their long term effectiveness, or potential side effects. Further research into the

long term consequence and therapy is therefore clearly needed. Until this data is available children with RLS / PLMD should be referred to experienced centers for treatment and follow-up.

Suspected Sleep Disordered Breathing

Snoring

It is estimated that around 7% to 10% of children snore. In contrast to adults, there is no difference in incidence between the genders, while between 20 to 30% of children with a history of snoring have significant OSAS.

Snoring represents a spectrum of disorder, ranging from partial, intermittent obstruction through to "full-blown" Obstructive Sleep Apnea Syndrome (OSAS). In children, as with snoring in adults, the primary problem facing clinicians is separating simple snoring (not associated with any medical disorder, and without any significant pathophysiologic sequelae) from complicated snoring (such as that associated with OSAS). Given the limited availability of pediatric capable sleep facilities in Ontario, it is not practical to perform full PSG on every child with snoring. This is complicated by the fact that there are no good clinical criteria on which to reliably separate children with overt disease from those with simple snoring.

There is, moreover, evidence that even "primary" snoring (no evidence of impairment of respiration on PSG) may actually have a detrimental long term effect upon childhood learning in some children. Consequently there is ongoing debate regarding the precise clinical significance and appropriate evaluation of primary snoring in children. Until this is resolved, the presence of other symptoms or comorbid disorders (sleep fragmentation, poor school performance, chronic mouth breathing and "adenoidal facies") needs to be factored into treatment decisions. This is therefore an additional reason why a child needs to be evaluated by a physician knowledgeable of these issues.

Adenotonsillectomy remains the primary treatment for complicated snoring. Ideally formal PSG would be performed in every child where surgery is contemplated. This would allow documentation of the severity of the obstruction, and hence assessment of need and possible risks of surgery, while providing a baseline to allow for evaluation of success (or lack thereof) post-surgery. There are, however, insufficient pediatric capable sleep facilities for this to be possible. Treatment decisions will therefore have to be based on clinical grounds in significant numbers of children. It should be noted that recorded overnight oximetry can be used to reliably diagnose OSAS in the presence of snoring, as well as predict the risk of significant post-operative complications, making formal polysomnography unnecessary in a significant percentage of these children.

Conclusion

Formal evaluation in a sleep facility is ideally required to evaluate the presence of complicated snoring, or snoring associated with medical and/or psychological symptoms that suggest the following:

- a diagnosis of Obstructive Sleep Apnea Syndrome
- CPAP or surgical treatment and objective corroboration of severity of snoring, or presence of other confounding factors, which are required to assess place and subsequent success of therapy.

Obstructive Sleep Apnea Syndrome (OSAS)

As noted, there are no clinical criteria that allow for separating patients with uncomplicated snoring from those with true OSAS, nor which patients with “primary snoring” actually require therapeutic intervention. Currently, polysomnography is the most objective test available for assessing the severity of OSAS in a child. It is indicated for any child in whom OSAS is clinically suspected, particularly if either CPAP or surgery is being considered (though recorded overnight oximetry can be used as an alternative). There are normative values for polysomnography in children, an obstructive apnea/ hypopnea index of greater than 1 per hour being abnormal. Although there may be significant night to night variability in the number of apnoeic events, there is no evidence that repeated sleep studies improves the diagnostic accuracy. Assessment of the presence and severity of OSAS is provided by the sum of history, physical examination, and facility evaluation, the decision for therapeutic intervention, as well as actual therapy, being based, in the absence of definitive studies, on clinical experience and reason.

Conclusion

Full overnight sleep study is the current standard for those individuals in whom OSAS is suspected, particularly if CPAP or surgical therapy is considered. Multiple night studies are not generally indicated for diagnosis. Treatment decisions should not be made based purely on the sleep study results, but also a detailed history and physical examination. Subsequent sleep studies are predicated upon the patient’s changing status.

Post-sleep Study Interventions

As noted, there remain major gaps in our understanding of the precise significance and clinical spectrum of snoring and OSAS in children, complicated by the absence of any long term therapeutic trials of either surgical or medical therapy for OSAS in children. Consequently treatment decisions are largely dependent upon a combination of clinical experience, supported by objective evidence of sleep disordered breathing (polysomnography) and clinical evidence of overt “disease” such as history of sleep fragmentation, poor school performance, or chronic nasal obstruction.

Compared to adults, the primary therapy therefore for sleep related airway obstruction in children is adenotonsillectomy, with reported therapeutic “cures” in 80-90% of cases. Obesity

previously formed a relatively rare cause of sleep-related upper airway obstruction in children. With the increasing prevalence of obesity in Western societies, children included, this is no longer the case. CPAP has been used in children, though frequently with poor compliance. There have also been reports of facial remodeling due to a pressure effect on growing bones associated with long term use. Long term CPAP therefore needs to be used with caution in young children.

Treatment options

Patient factors include:

Conservative	Avoiding nocturnal sedation (pharmacological and alcohol) Weight loss (where appropriate)
Medical	Treating nasal obstruction (medication) CPAP (concerns re facial remodeling in young children)
Surgical	Adenoidectomy/tonsillectomy Nasal Surgery (where indicated) Craniofacial surgery (with overt abnormalities of facial skeleton)

Indications for Treatment of OSAS in Children

In view of the growing concerns about the potential long term consequences on growth and intellectual function of sleep disordered breathing, it is striking how little we know of the natural history of sleep disordered breathing in children, compounded by the paucity of controlled therapeutic trials. Thus, it is difficult for clinicians to come to any evidence-based risk/benefit evaluation in the management of individual patients. Until this data is available, physicians caring for these patients will have to use clinical acumen and experience in their therapeutic decision making. Treatment options are listed in the preceding table.

In general only the more severely affected children are at risk of significant cardiopulmonary damage. Increasing evidence suggests that many more children with milder OSAS, and its resulting sleep fragmentation, may, however, suffer from resulting long-term impact on neurocognitive function. Exactly what markers should be used to determine this risk, and hence guide therapy, remain to be identified. The treatment of OSAS should therefore be based on the severity of symptoms (detailed history supported by PSG), as well as magnitude of clinical complications and the etiology of upper airway obstruction.

NOTE: Recovery from an episode of obstruction is dependent upon arousal. Suppression of arousal, particularly if coexistent with muscle relaxation has the potential for significantly exacerbating OSAS. Iatrogenic intervention has been implicated as a precipitating factor in the death of several children with pre-existing OSAS. Sedatives and muscle relaxants should therefore be avoided, or at least used under medical supervision, in any child with suspected or proven OSAS. Close post-operative (whether adenotonsillectomy or other surgery) monitoring is therefore mandatory in any child with significant OSAS until proven safe for discharge.

Follow-up

As in adulthood, sleep disordered breathing (SDB) comprises a spectrum of disorders, ranging in severity from patients with only mild, intermittent episodes of obstruction, characterized by snoring, through to patients with severe, life threatening disease resulting in growth failure and cor pulmonale. Although there is general agreement on the management at the extremes of the clinical spectrum, the lack of any controlled trials or long term follow-up studies limits any scientific approach to the management of children with mild to moderate disease. Follow up polysomnograms may be appropriate in cases where it is not clear whether the OSAS is severe enough to warrant surgical intervention.

Routine outpatient clinical follow-up is recommended to determine the response to treatment (surgical intervention) and the level of compliance (CPAP therapy). There remains debate regarding the value of follow-up sleep studies in children treated surgically, since many children may still have some residual degree of obstruction, though usually improved compared to pre-surgical intervention. Follow-up sleep studies are certainly indicated if there is no significant change in their snoring, but are probably not indicated if the snoring is completely abolished. If the child's clinical condition deteriorates, (e.g., increasing daytime sleepiness, secondary enuresis, observed obstructive events, failure to thrive, deteriorating school performance, increasing obesity), then follow-up sleep studies maybe indicated. Regular follow up sleep studies are obviously required in children receiving ongoing medical therapy (e.g. CPAP).

Due to the rapid changes in growth that occur in children, follow up may need to be more frequent in order to assess the impact of these growth changes on therapeutic requirements.

Monitoring

As with adults, one night is usually all that is required to titrate CPAP in the majority of children. There is no data, unfortunately, as to the therapeutic effectiveness of auto-adjusting CPAP devices in children. Due to initial patient anxiety, a second night may be required to achieve optimal pressure titration and familiarization, and a follow-up study within 2-3 months to confirm therapeutic success and ensure ongoing compliance. This, however, needs to be justified in the report. Repeat overnight polysomnography with CPAP is indicated if a child has a change in symptoms, significant weight gain or weight loss, or significant growth.

Respiratory Control Disorders

Overview

Sleep is associated with changes in both neurologic control of respiration and respiratory mechanics. As a result, even in normal individuals, sleep is associated with relative hypoventilation. In individuals with disorders affecting either the medulla or brainstem, diseases affecting neuromotor function of the respiratory muscles, or advanced lung diseases, sleep may further diminish these individual's ability to maintain gas exchange and/or a patent airway. Sleep disordered breathing, particularly sleep-related hypoventilation, may be remarkably asymptomatic unless specifically sought. There therefore needs to be a high index

of suspicion in these patients. To obtain an accurate assessment of the overall clinical status of these patients it is necessary to evaluate the patient's respiratory status during sleep and if appropriate devise therapeutic measures during sleep to optimize gas exchange and lessen or fend off for longer the cardio respiratory sequelae of the underlying disorder.

Observed Central Apnea

Central sleep apnea (CSA) is a heterogeneous group of disorders leading to a respiratory pattern during sleep predominantly composed of central apneas and hypopneas (absence or decrease of flow with absence or decrease of respiratory effort).

Central Sleep Apnea - Cheyne-Stokes Respiration (CSA-CSR) is an easily identifiable subgroup of this disorder in which during individual sleep-disordered breathing events there is a characteristic waxing and waning of respiratory effort with arousal at the greatest point of respiratory effort. CSA-CSR is often associated with congestive heart failure or cerebrovascular accident and may exist in the waking state as well.

CSA-non-CSR may exist in a congenital form (CCHS), central form (i.e. syringomyelia) pharmacologically-induced form (narcotic use) and an idiopathic form. Patients may often be non-obese and present with insomnia, but suspected from observation or by association with their other disorders.

Respiratory system mechanics, arterial blood gases and neuroradiologic imaging are often necessary in sorting out the reason for CSA-non-CSR.

The treatment of central sleep apnea is, firstly, the treatment of any underlying cardiac or neurologic disorder and removal of any central depressant medication to the level possible. Positive pressure therapy, Bilevel therapy and the addition of a backup rate may support the respiratory system during sleep but sometimes chronic nocturnal ventilation using a volume or pressure cycled ventilator may be required. Oxygen therapy alone may be helpful in some instances. The use of respiratory stimulants has generally proven unrewarding.

Note: Therapeutic polysomnograms with measured gas exchange responses are required to assist the response to any or several therapies.

Specialist consultation and management are required in these complex cases; as previously outlined a qualified subspecialist (usually Respirology) is indicated if nocturnal ventilation is being used.

Respiratory Motor Failure

This group is comprised of patients with either severe obstructive or restrictive lung disease (including morbid obesity), or a primary neuromotor disease such that the respiratory system is unable to maintain adequate ventilation. In initial stages these individuals may present with sleep associated hypoxemia and/or hypercapnia with or without daytime awake hypoxemia or

hypercapnia. Although respiratory drive is initially normal, consequent to the chronic hypoventilation there may be secondary blunting of respiratory drive, and consequently surprisingly little in the way of overt symptoms related to their hypoventilation. A formal PSG is usually required to both confirm diagnosis and documentation of severity for prognosis or monitoring of therapy.

Symptoms and signs warranting further investigation may include cor pulmonale, polycythemia, chronic hypoventilation, disturbed sleep, morning headaches, or daytime hypersomnolence. Similarly, patients with known respiratory disease, but unexpected severity of sequelae (e.g., cystic fibrosis or bronchopulmonary dysplasia complicated by cor pulmonale/polycythemia, yet with awake PaO₂ >55 mm Hg) require sleep evaluation to rule out compounding sleep associated hypoventilation.

This group also includes patients with neuromuscular disease or thoracic cage deformities which impair respiratory function. In addition to the consequences of worsening alveolar ventilation and ventilation perfusion mismatch during sleep, there is the issue of resulting muscle fatigue, in which case CPAP or BiPAP may also have a possible role in improving respiratory muscle function and alleviating respiratory failure.

There is a wide range of severity within this group, ranging from mild hypoventilation purely during sleep through to marked hypoventilation when awake and asleep.

The prognosis varies depending upon the underlying diagnosis. In addition, there is a subgroup of patients who show profound hypoxemia and hypoventilation specifically during REM sleep, due to the loss of use of accessory muscles of respiration.

Overnight polysomnography is indicated in individuals with unexplained sleep-related hypoxemia and hypercapnia. This is to assess the severity of the sleep associated hypoventilation and to aid in monitoring the effectiveness of the therapy employed. This may include supplemental oxygen therapy, positive pressure ventilation, either invasive or non-invasive, or phrenic nerve pacing, depending upon each individual's circumstances.

Disorders of Respiratory Drive

Damage to or primary dysfunction of the respiratory nuclei of the medulla can result in blunted or absent respiratory drive. In the most severe cases this will result in central hypoventilation even while awake, whereas milder cases may result in apparently normal respiration awake, but significant sleep related hypoventilation. This dysfunction may be either primary (congenital) or secondary (trauma, surgery, infection). Since the primary disorder is blunting of central respiratory drive, these patients may be remarkably asymptomatic even in the presence of fairly significant hypoventilation. The commonest presentation is unexplained sleep related hypoxemia, though a fair number may present with late sequelae, such as cor pulmonale, or may have profound hypercapnea in response to additional stress such as pneumonia or administration of sedating / anesthetic agents. Secondary central hypoventilation is usually suspected based on a prior history of brain stem injury, whereas congenital central

hypoventilation may have little preceding history, while paradoxically presenting at any age. Central hypoventilation therefore needs to be considered in any child with unexplained sleep related desaturation, and confirmed or excluded by measurement of arteriolar CO₂ levels. If central hypoventilation is suspected or diagnosed these children therefore need to be referred to specialized pediatric centers with expertise in these conditions, since ongoing follow up, and some form of long term ventilatory support, is almost always required.

Note: If CO₂ levels are NOT monitored routinely, there needs to be a system in place for the reliable measurement of carbon dioxide levels (blood gas or end tidal CO₂). In addition the technologists attending the sleep facility need to be aware of the central hypoventilation syndromes and their manifestations, so that blood gas measurements can be initiated in any child with unexplained hypoxemia

Conclusion

Nocturnal polysomnography with transcutaneous capnography (preceded by arterial blood gas analysis) may be warranted in patients with the various impairments of respiratory control described above and particularly if they have persistent hypercapnea or, in the case of lung disease, disproportionate hypercapnea or daytime hypoxemia. Ancillary measures of effort such as diaphragmatic or intercostal EMG or esophageal pressures may be indicated in selected individuals with these disorders to sort out the component of central respiratory impairment.

It is particularly important in such studies to see REM sleep because in the absence of drive to intercostal muscles, hypoventilation, gas exchange and potential cardiac arrhythmias may be most severe at this sleep stage.

On the basis of baseline results, therapeutic strategies for nocturnal respiratory support may then be devised for further therapeutic studies. Pediatric appropriate policies and protocols should be developed.

While the baseline studies may occasionally be performed in an independent health facility, arterial blood gases being available or recently obtained elsewhere, it is generally recommended for reasons of safety, that baseline and therapeutic studies be performed in a hospital setting where equipment for orotracheal suction, oxygen therapy, blood gas analysis and the potential for intubation for mechanical ventilation are available. Many such patients have also higher needs for lifts, care of catheters and repositioning at night.

Occasionally such patients are inpatients and unstable from a cardio respiratory point of view and then a portable attended full polysomnography is recommended in their unit of hospital care so that the rest of their safety is protected while sleep-related diagnoses and therapies are instituted.

Formal detailed protocols for the therapeutic delegated acts should be in place to guard against, for example, respiratory failure due to high flow oxygen therapy.

Apparent Life Threatening Event (ALTE)

An apparent life threatening event (ALTE) is defined as *“an episode that is frightening to the observer, and that is characterized by some combination of apnea, color change, marked change in muscle tone, choking and gagging. In some cases the observer fears that the child has died”*¹².

The concern of parents and clinicians caring for infants under 1 year suffering from an ALTE is their specific risk of subsequently succumbing to sudden infant death syndrome (SIDS).

Although there are a host of differing causes for both ALTE and SIDS, there is objective data that in a significant number of these children there is an underlying maturational disorder in cardio respiratory control and that the child is therefore at increased risk of succumbing to SIDS. SIDS is clearly sleep-related.

Populations of children with an increased risk can be identified both clinically and epidemiologically. Objective abnormalities in cardio respiratory control have been identified in some children at apparent increased risk.

Children are commonly referred to sleep facilities for evaluation with the expectation that studying these children provides additional data on the specific risk of SIDS in the individual child, to aid in their management. There is no test or parameter currently available with sufficient sensitivity or specificity to make a formal sleep study of clinical use in children in whom rigorous evaluation has failed to reveal an underlying abnormality.

There is, at this time, ongoing debate as to the actual effectiveness of therapy of those children in whom no underlying abnormality is identified.

Separating a true event from observer mis-appreciation of a physiological apnea, and evaluating the etiology of a true ALTE is by detailed history, clinical evaluation, and facility exclusion of known causes of apnea in children. If history or observation by a trained individual suggests this to have been a true event, the investigative approach is to first exclude known causes of sudden cardio respiratory events. Sleep studies may be warranted in children where defined abnormalities such as persisting hypercapnia, apnea over one year of age, or unexplained nocturnal hypoxemia indicate an underlying disorder that can best be delineated by formal polysomnography.

Conclusion

In the majority of episodes of an apparent observed apnea, a diagnosis can be made by close attention to the history, supported by ancillary tests as indicated. Only if there is supportive evidence (arterial blood gases, abnormal EEG, evidence of neurologic disease) is a sleep study indicated to evaluate a significant sleep-related respiratory disorder. Sleep studies do not provide additional significant information in children with ALTE in whom a rigorous clinical evaluation has failed to reveal an underlying cause or abnormality.

Apparent Life Threatening Event (ALTE)

The treatment of a child following an ALTE event remains controversial, primarily because, as noted, it can occur as a consequence of a variety of disorders, all of which have different prognoses and clinical significance. Formal evaluation in the sleep facility is only rarely of use in the patient's clinical management and only in relation to specific clinical situations. Treatment is therefore primarily aimed at any identified underlying causes.

Apnea Monitors

Apnea monitoring is reserved for infants less than one year of age with a history of a definite and apparent cardio respiratory event and in whom no underlying treatable disorder was identified. However, despite a 30 year history of the use of apnea monitors in apnea of infancy, there remains ongoing debate as to their indications, effectiveness, and psychosocial sequelae. Since evaluation and treatment comprise a whole, including parental education (significance of events, indications and performance of CPR, parental support), managing children with a history of ALTE should be by pediatricians with expertise in this problem, with the sleep facility providing evaluation where clinically indicated.

Primary Respiratory Failure

The management of central hypoventilation syndrome (CHS) in children depends upon the etiology, age of the child, severity, and prognosis. Other than the rare congenital central hypoventilation syndrome (CCHS), in the majority of cases central hypoventilation occurs as a result of a primary neuromotor or respiratory disorder. Furthermore, CHS clearly encompasses a range of severity and prognosis, with some children showing normal awake ventilation and only mild sleep state related hypoventilation through to children with profound hypoventilation throughout the day and night. Managing hypoventilation must be incorporated in the overall management of the child. Therapeutic options include:

- symptomatic
- pharmacological
- assisted ventilation.

Parasomnias and Other Sleep Disorders

Atypical Features

Nocturnal seizures, although infrequent, may present a diagnostic challenge, as they are frequently misdiagnosed as nightmares, night terrors, or hysteria. Nocturnal seizures commonly present as clusters, usually motor in nature, of 30 - 40 seconds in length. They most typically

occur in slow wave sleep (i.e. in the earlier portion of sleep), but can occur in light sleep or naps, and are not necessarily associated with daytime seizures. Movements are frequently unilateral or localizing (at least initially), and stereotypical, compared to more coordinated and purposeful (nightmares /sleep walking) or generalized purposeless (night terrors). The risk of recurrence is high (in the order of 70% within 2 years).

Consequently, children presenting with atypical features, such as repeated stereotypical sleep-related motor episodes, or associated daytime events, should be referred to a pediatric neurologist or sleep specialist for review. An overnight polysomnography in combination with 16 lead EEG recording may be necessary, if clinically indicated.

In summary, the parasomnias constitute a diverse group of disorders. In the more common situation, with typical presentation, and history dating back to childhood, a formal sleep study is not generally required. Occasionally, with atypical presentation, they may be difficult to differentiate from nocturnal epileptiform events, which may occur spontaneously or in association with other medical syndromes or causes of hypersomnolence. In the presence of late onset, atypical features, daytime symptomatology, or apparent associated violent behavior, objective evaluation, with overnight polysomnography as a minimum, is indicated.

Post-sleep Study Interventions

Treating many of the childhood-onset parasomnia disorders such as sleep walking, night terrors, and sleep-related enuresis is usually self-limiting. They may not require any specific remedy other than advice to parents about safety measures for any potential self-harm with nocturnal wandering, and behavioural approaches for sleep enuresis. Treatment of sleep enuresis associated with organic pathology should be directed to the underlying disorder. In some instances where psychological disturbances prevail, psychotherapeutic interventions are required.

Evaluating Sleepiness-Related Daytime Function by Querying Wakefulness Inability and Fatigue: Sleepiness-Wakefulness Inability and Fatigue Test (SWIFT)

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Study Objectives: Routine assessment of daytime function in Sleep Medicine has focused on “tendency to fall asleep” in soporific circumstances, to the exclusion of “wakefulness inability” or inability to maintain wakefulness, and fatigue/tiredness/lack of energy. The objective was to establish reliability and discriminant validity of a test for wakefulness inability and fatigue, and to test its superiority against the criterion standard for evaluation of sleepiness—the Epworth Sleepiness Scale (ESS).

Methods: A 12-item self-administered instrument, the Sleepiness-Wakefulness Inability and Fatigue Test (SWIFT), was developed and administered, with ESS, to 256 adults ≥ 18 years of age (44 retook the tests a month later); consecutive patients with symptoms of sleep disorders including 286 with obstructive sleep apnea ([OSA], apnea-hypopnea index ≥ 5 /h sleep on polysomnography [PSG]), 49 evaluated with PSG and multiple sleep latency test for narcolepsy and 137 OSA patients treated with continuous positive airway pressure (CPAP).

Results: SWIFT had internal consistency 0.87 and retest intraclass coefficient 0.82. Factor analysis revealed 2 factors—general wakefulness inability and fatigue (GWIF) and driving wakefulness inability and fatigue (DWIF). Normal subjects differed from patients in ESS, SWIFT, GWIF, and DWIF. SWIFT and GWIF (but not DWIF) had higher area under ROC curve, Youden’s index, and better positive and negative likelihood ratios than ESS. ESS, SWIFT, GWIF, and DWIF improved with CPAP. Improvements in SWIFT, GWIF, and DWIF (but not ESS) were significantly correlated with CPAP compliance.

Conclusions: SWIFT is reliable and valid. SWIFT and its factor GWIF have a discriminant ability superior to that of the ESS.

Keywords: Sleepiness, wakefulness inability, fatigue, obstructive sleep apnea, Epworth Sleepiness Scale

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Sleepiness is a commonly reported public health problem. In a 2002 National Sleep Foundation (NSF) poll,¹ 7% reported sleepiness almost every day and another 9% a few days a week, for a total of 16%. Seventeen percent reported having dozed off while at the wheel of a vehicle, and 1% reported having an accident because they dozed off or *were too tired* (emphasis added). In other words, accidents were attributed to either dozing off or being tired. According to the National Highway Traffic Safety Administration (NHTSA),² “NHTSA data indicate in recent years there have been about 56,000 crashes annually in which driver drowsiness/fatigue (emphasis added) was cited by police. Annual averages of roughly 40,000 nonfatal injuries and 1,550 fatalities result from these crashes.” Sleep apnea patients report not just daytime sleepiness, but also being tired, fatigued, or having a lack of energy, and these complaints may be more frequent than sleepiness in sleep apnea.³ Sleepiness (and its adverse effect of auto accidents) may be multifactorial, with elements of inability maintaining wakefulness when necessary or desired (wakefulness inability), tendency to doze off in soporific circumstances, and fatigue/tiredness/lack of energy. However, the specialty of Sleep Medicine has tended to focus rather exclusively on routine evaluation of daytime function by measuring sleepiness defined as tendency to fall asleep in soporific circumstances (using the multiple sleep latency test [MSLT])⁴

BRIEF SUMMARY

Current Knowledge/Study Rationale: There is not a questionnaire instrument to measure wakefulness inability or difficulty staying awake in situations where staying awake is desirable, or one that simultaneously addresses symptoms related to pathological sleepiness and to fatigue/tiredness/lack of energy in sleep disorders patients. Conceivably, what could be better than being able to fall asleep when one wants to (low MSLT [Mean Sleep Latency Test] and even high ESS [Epworth Sleepiness Scale]), but be able to stay awake when one wants to and feel refreshed (not tired) during the day?

Study Impact: A reliable and valid self-rating instrument (Sleepiness-Wakefulness Inability and Fatigue Test or SWIFT) was created and shown to be superior to the criterion standard for sleepiness (ESS) with regard to specificity, sensitivity and discriminate ability. It should be added to the ESS in evaluating daytime consequences of sleep disorders.

and the Epworth Sleepiness Scale [ESS]^{5,6}, to the exclusion of wakefulness inability (difficulty maintaining wakefulness) and fatigue, in sleep disordered patients.

The MSLT defines sleepiness as the ability to fall asleep in a dark room when asked to do so. According to a review paper to establish Standards of Practice for the clinical use of the MSLT and MWT (Maintenance of Wakefulness Test), “the wide range in MSL makes it difficult to establish a specific threshold value for excessive sleepiness or to discriminate

patients with sleep disorders from non-patients.⁷⁷ Further, “the MSL change between pre- and post-treatment for an individual is probably meaningful, although comparison of these data with the normative values is not helpful.⁷⁷ This may be related to the use of a behavior (the ability to fall asleep quickly when lying down in a dark room) that may be a desirable and adaptive trait rather than abnormal state. The MWT^{8,9} sought to correct this by asking subjects to try and stay awake in a dimly lit room. However, staying awake sitting in a dimly lit room doing nothing is not particularly advantageous (as opposed to staying awake when sitting in a dimly lit car and driving). The MSLT and MWT measure different abilities,^{10,11} and treatment may improve “wakefulness inability” (the MWT) more than “sleep tendency” (MSLT).¹² Both the MSLT and MWT require a large investment in time and resources.

There are self-rating questionnaire instruments that aim to measure sleepiness, the most commonly used being the ESS. The ESS queries for tendency to fall asleep in a variety of circumstances, often soporific. Sanford et al.¹³ have reported the distribution of the ESS. In their sample of normal subjects, median ESS was 7-8, and 30.7% of normal subjects without insomnia reported an ESS score ≥ 10 , the widely used cutoff for abnormal excessive sleepiness. It has been shown that the ESS does not measure the same ability as the MWT.^{14,15} In patients who are severely sleepy on the MWT, the ESS was insensitive to the level of sleepiness as measured by the MWT. The ESS may¹⁶ or may not¹⁷ be correlated with the MSLT. A sample of 10,000 subjects with 71% response rate showed no correlation between the ESS and the adverse consequence of automobile accidents, although there was a correlation between dozing off while stopped in traffic (item 8 on ESS) and automobile accidents.¹⁸

Sleep disordered patients report fatigue, lack of energy, and tiredness in addition to sleepiness.³ Fatigue, tiredness and lack of energy are largely interchangeable terms, as suggested by Merriam-Webster Dictionary’s¹⁹ definitions of fatigue as “weariness or exhaustion from labor, exertion, or stress”, and tired as “drained of strength and energy: fatigued often to the point of exhaustion.” Although these symptoms may be separable from sleepiness/wakefulness inability (wakeful being defined by Merriam-Webster Dictionary as “not sleeping or able to sleep”), it is not clear that sleep disordered patients, the general public and the NSF,¹ or the police and the NHTSA,² can separate these symptoms clearly.

Conceivably, what could be better than being able to fall asleep when one wants to (low MSLT and even high ESS), but be able to stay awake when one wants to and feel refreshed (not fatigued) during the day? Is the ability to fall asleep easily a pathological problem or an adaptive ability?²⁰ This leads to the question of whether we should be querying instead the ability to stay awake when desired, along with fatigue.

There does not seem to be a questionnaire instrument to measure wakefulness inability or difficulty staying awake in situations where staying awake is desirable. Although fatigue inventories such as the 83-item Multidimensional Fatigue Inventory (MFI)²¹ and its 30-item short form (MFSI-sf)²² exist, there is no single short questionnaire that simultaneously addresses symptoms related to pathological sleepiness and to fatigue/tiredness/lack of energy in sleep disordered patients.

Thus, these other domains of sleep disorder complaints are not routinely queried or measured.

The hypothesis was that a self-rating instrument for assessing wakefulness inability and fatigue can be created that is reliable (with good internal consistency and test-retest reliability in normal subjects) and valid (with good ability to discriminate between normal individuals and sleep disordered patients, and to show improvement with treatment of sleep disorders such as obstructive sleep apnea [OSA]), and that such a test incorporating wakefulness inability and fatigue is superior to the criterion standard for sleepiness (ESS) with regard to specificity, sensitivity, and discriminant ability.

METHODS

A 12-item questionnaire (Sleepiness-Wakefulness Inability and Fatigue Test, or SWIFT) was developed. Subscale A has 6 questions related to difficulty staying awake/wakefulness inability in different situations that might affect performance or cause adverse consequences; subscale B has 6 questions related to fatigue, tiredness or lack of energy in different situations that might affect performance or cause adverse consequences, all answered on a 4-level (scored 0-3) Likert scale. Items were prepared by the author based on apparent face validity, with the inclusion of more than one item related to driving. The SWIFT is shown in **Table 1**.

Normal Subjects

After obtaining approval from the Wayne State University Human Investigations Committee, adult subjects (age ≥ 18 years) were recruited over a period of 10 weeks by means of a group e-mail to medical students at Wayne State University as well as by personal solicitation of subjects in public places such as malls and parks. After reading an informational sheet, they were asked to fill out questionnaires seeking their gender, age, educational level, occupation, race, height, weight, medical/psychiatric problems, medicines taken, sleep habits, and presence or absence of sleep symptoms including snoring, observed or perceived apneic episodes in sleep, insomnia, fatigue, and sleepiness. They were also asked to complete the SWIFT and the ESS. Subjects willing to be contacted again in a month to retake the questionnaire were asked for contact information, and were contacted after a month to again complete the questionnaire.

A total of 403 subjects filled out the questionnaire. Subjects with incomplete questionnaires (49) were excluded. In order to examine the normal range of sleepiness, wakefulness inability, and fatigue, it was decided to exclude subjects with issues known to affect sleepiness, wakefulness inability, and fatigue, such as CNS-active or psychotropic medicines (53), CNS disorders (3), untreated depression (19), and history of observed/perceived apneic episodes in sleep (23). This left 256 normal subjects (87 male, 169 female; age range 18-92 years; 190 White, 26 Black, 5 Hispanic, 11 Asian American, 6 South Asian American, 18 Other; 4 with less than high school education, 23 high school graduates, 52 with some college, 101 with college degrees, and 76 with graduate degrees; National Statistics socioeconomic classification included: 10 higher professional or managerial, 50 lower professional or managerial, 26 intermedi-

Table 1—Sleepiness-Wakefulness Inability and Fatigue Test (SWIFT)

Name: _____

Date: _____

If this is the first time you are filling this out for this study, answer keeping in mind the last one month. Mark symptoms present only if they have been present for at least one month. If you have filled out this questionnaire before for this study, answer based on the period of time since you last filled this out. Be sure to answer every question to the best of your ability. This questionnaire refers to your usual way of life in recent times. Even if you have not done some of these things recently try to work out how they would have affected you. Use the following scale to choose the most appropriate number for each situation:

A How much of a problem is it to stay awake during the day (or your usual wake period if you sleep during the day)?

	Not at all	Just a little	Pretty Much	Very Much
1 Struggling to stay awake during the day	0	1	2	3
2 Difficulty staying awake while driving	0	1	2	3
3 Difficulty staying awake stopped at a traffic signal	0	1	2	3
4 Difficulty staying awake at work or while doing tasks	0	1	2	3
5 Difficulty staying awake while reading or studying	0	1	2	3
6 Difficulty staying awake in social situations	0	1	2	3

B How much of a problem has fatigue, tiredness or lack of energy been for you?

	Not at all	Just a little	Pretty Much	Very Much
1 Feeling tired when at work or while doing tasks	0	1	2	3
2 Lack of energy during social situations	0	1	2	3
3 Struggling with fatigue during the day	0	1	2	3
4 Feeling tired while reading or studying	0	1	2	3
5 No energy to do tasks that do not absolutely have to be done	0	1	2	3
6 Difficulty driving because of fatigue	0	1	2	3

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The total score is the sum of the scores of all 12 items (A1-6, B1-6), with a maximum possible score of 36.

ate occupations, 3 small employers and own account workers, 12 lower supervisory and technical, 4 routine occupations, 36 retired or unemployed, and 115 students. Forty-four of them retook the SWIFT and ESS a month later.

Determining Reliability

To determine internal consistency, Cronbach α was calculated for the SWIFT (and the ESS) using data from the normal subjects. To determine test-retest reliability, intraclass coefficients were calculated using the normal subjects with test and retest data. If these tests showed good reliability (Cronbach α and intraclass coefficient > 0.8), factor analysis with varimax rotation was performed using SWIFT data.

Additional Analyses in Normal Subjects

Correlation between ESS and SWIFT was calculated. Males and females were compared with regard to age, BMI, time in bed, SWIFT and ESS, as were subjects who completed the questionnaire again and those who did not. Correlations were calculated between SWIFT and ESS on the one hand, and age, time in bed and BMI on the other. If there was a significant correlation between SWIFT and age, normal subjects were divided into two age groups to determine if the correlation persisted. If it did not, factor analysis and correlations were performed again by age group.

Correction for Multiple Statistical Analyses

In order to correct for multiple statistical analyses, the false discovery rate method was applied to primary but not to condi-

tional analyses (analyses performed only as a result of another statistically significant analysis).²³ This method rank orders the p-values of the analyses. For k analyses, one p value of 0.05/k was accepted as significant, one p value of 0.05/k-1 was accepted as significant, and so on.

Determining Validity

After establishing good reliability for the SWIFT, validity was determined for SWIFT and its factors using data from normal subjects and sleep disordered patients, and SWIFT and its factors were compared with ESS to establish superiority.

Sleep Disordered Patients

All new patients presenting with sleep disorder symptoms to an AASM accredited Sleep Disorders Center during a 15-month period were administered the SWIFT and ESS at the time of the initial evaluation. If appropriate, they underwent a polysomnography (PSG) to evaluate for OSA using American Academy of Sleep Medicine (AASM) scoring criteria,²⁴ or a PSG with MSLT to evaluate for Narcolepsy. New patients who had previously been evaluated/treated for OSA anywhere were excluded from analysis. All patients with significant OSA (apnea-hypopnea index (AHI) ≥ 15 /h sleep, or ≥ 5 /h sleep with comorbid sleepiness, hypertension, or cardiovascular disease, evaluated as new patients over the 15-month period, were offered standard treatment. Patients opting for continuous positive airway pressure (CPAP) were administered a PSG with CPAP titration, and were prescribed CPAP at the optimum determined pressure. At a follow-up office visit between 1 and 3 months after CPAP

prescription, they were again administered the SWIFT and ESS, and CPAP compliance data were downloaded if available.

Data were available for 286 adult subjects (age ≥ 18 years, 192 males, 94 females) who presented with sleep disorder symptoms and had documented OSA (AHI ≥ 5 /h sleep). After excluding subjects with AHI ≥ 5 /h sleep on the PSG preceding the MSLT (who were counted among the adult OSA subjects), and patients who were administered the MSLT on CPAP, data were available for 49 adult subjects (17 males, 32 females) who were administered PSG with MSLT for suspicion of narcolepsy (because of unexplained sleepiness with no clinical evidence of OSA, off CNS-active medicines, including psychotropic medicines, for five half-lives). These 49 subjects were independent of and not a subset of the 286 OSA patients. Repeat ESS and SWIFT and compliance data from follow-up visits after CPAP initiation were available for 137 adult OSA patients (98 males, 39 females).

Determining Discriminant Validity

To determine discriminant validity, SWIFT (and SWIFT factor) and ESS scores were compared between the normal subjects and the OSA patients, as well as between normal subjects and patients evaluated for suspicion of narcolepsy. To further determine discriminant validity, SWIFT (and SWIFT factor) and ESS scores were compared in OSA patients before and after CPAP treatment, and the number of patients with abnormal SWIFT (and SWIFT factor) and ESS scores before and after CPAP treatment were compared. Correlations were calculated between compliance and improvement in ESS, SWIFT, and SWIFT factors identified by factor analysis.

Statistics of Diagnostic Tests

A diagnostic test identifies 2 groups: those with the disorder and those without the disorder. The sensitivity (also called true-positive rate) of a test is the probability of a positive test in the disordered population, whereas the specificity is the probability of a negative test in a disorder-free population; and the value (1-specificity) is also called the false-positive rate. The positive predictive value is the probability of a subject with a positive test having the disorder. The negative predictive value is the probability that a subject with a negative test does not have the disorder. Sensitivity and specificity are not affected by prevalence of the disorder, whereas positive and negative predictive values are affected. This means sensitivity and specificity can be accurately calculated when using a normal sample and a sample of disordered subjects, but predictive values cannot (they require a population sample for accurate calculations). A test with higher sensitivity and specificity than another is the superior test. However, a test may have higher sensitivity but lower specificity than another, or vice versa. Therefore, comparing 2 tests requires combining specificity and sensitivity. The likelihood ratio of a positive test or positive likelihood ratio (ρ_+) is the ratio of the probability of a positive test in a disordered subject (true-positive rate) to the probability of a positive test in a normal subject (false-positive rate), and is calculated as [sensitivity/(1-specificity)]. The likelihood ratio of a negative test or negative likelihood ratio (ρ_-) is the ratio of the probability of a negative test in a disordered subject to the probability of a negative test in a normal subject, calculated as [(1-sensitivity)/specificity]. Both likelihood ratios may range from 0 to α .

A positive likelihood ratio < 1 indicates a useless test, as does a negative likelihood ratio > 1 . With a diagnostic test based on a continuously measured variable, a decision or cutoff threshold allows sensitivity and specificity to be combined into the Youden's index γ , which is the true positive rate minus the false positive rate, calculated as [sensitivity-(1-specificity)] (also written as [sensitivity + specificity -1]). A perfect test (with sensitivity and specificity of 1) results in a Youden's index of 1, whereas a useless test has a Youden's index of 0. When the cutoff threshold is increased, the proportions of both true positives (sensitivity) and false positives (1-specificity) will increase. The receiver operating characteristic (ROC) is a graph of sensitivity against (1-specificity). A perfect test has an area under the ROC (AUC) of 1, a useless test has an AUC of 0.5. Bewick et al. have written an excellent but concise and simple discussion of these tests.²⁵ Since neither specificity nor sensitivity are affected by prevalence of the disorder, therefore positive and negative likelihood ratios, Youden's index and AUC are also not affected by prevalence when they are applied to population-based samples.

Determining Test Superiority

To determine which test is superior in discriminating normal subjects from sleep disordered patients, the AUC for the 2 tests can be compared. Visually, if the ROC for one test is entirely within the ROC of another test, then the second test seems certainly superior. Confidence intervals can be obtained for the AUC and statistical comparisons performed between the AUC for 2 tests using various nonparametric and binormal methods.^{26,27} A nonparametric distribution and correlated ROCs were assumed for this report. Different methods for calculating confidence intervals of Youden's index and likelihood ratios also exist, and a general method based on constant χ^2 boundaries was used for this analysis.²⁸ However, since the AUC is not dependent on a cutoff threshold, and diagnostic decisions are based on cutoff thresholds, a test may have a smaller AUC yet be more suitable than another, and the AUC is not a suitable measure of diagnostic excellence. Youden's index is a more suitable measure of diagnostic superiority.²⁹ Although Youden's index is a good single summary measure of comparison between two tests, positive and negative likelihood ratios are an even better test of superiority.³⁰ If test A has positive likelihood ratio greater than that for test B, and negative likelihood ratio lesser than that for test B, then test A is superior overall to test B. AUC, Youden's index, and positive and negative likelihood ratios (along with confidence intervals) were calculated for the ESS, SWIFT and its factors, using data from the normal subjects and OSA patients, as well as data from the normal subjects and patients evaluated for suspicion of narcolepsy. The AUC for SWIFT and ESS were compared. If there was a significant difference in favor of SWIFT, then the AUC for its factors were also compared with the AUC for ESS.

To determine which test is superior in showing improvement with treatment, effect sizes may be used. However, it is more important clinically to have a cutoff score (such as mean + 1 SD), above which the test is considered high and below which it is considered normal, and to show superiority in conversion of patients from abnormal scores before treatment to normal scores after treatment, therefore χ^2 analyses were also performed.

Additional Analyses in Sleep Disordered Patients

Correlation coefficients were calculated between ESS and SWIFT and its factors on the one hand, and sleep efficiency, arousal index, periodic limb movement arousal index (PLMAI), and AHI and lowest oxygen saturation (for OSA patients), mean sleep latency (MSL) and sleep onset REM periods [SOREMPS] (for patients evaluated for narcolepsy), with corrections for false discovery rate for multiple tests.

RESULTS

Reliability

Cronbach α using data from the 256 normal subjects was 0.87 for SWIFT and 0.80 for ESS. Upon retest, the intraclass correlation coefficient for SWIFT was 0.82 ($p < 0.001$), and for ESS 0.91 ($p < 0.001$).

Factor Analysis

Factor analysis of SWIFT with varimax rotation revealed 2 factors: Factor 1 (36% of variance) included 9 items (A1, A4, A5, A6, B1, B2, B3, B4, B5), and was called general wakefulness inability and fatigue (GWIF) based on the generality of the items. Factor 2 (20% of variance) included 3 items (A2, A3, B6), and was called driving wakefulness inability and fatigue (DWIF) based on these items being related to driving. **Table 2** gives the factor loadings.

Additional Analysis of Normal Subjects

ESS was correlated with SWIFT ($r = 0.64$, $p < 0.001$). There was no difference between males and females in age, BMI, hours in bed, SWIFT, or ESS. Those who completed the questionnaires again had a lower BMI (24.1 vs. 26.6, equal variances not assumed, $t = 2.9$, $df = 68.6$, $p = 0.005$) than those who did not, but there were no other significant differences. After

the false discovery rate correction, there were significant negative correlations between age and SWIFT ($r = -0.25$, $p < 0.001$) as well as ESS ($r = -0.14$, $p = 0.024$). There were no other significant corrected correlations.

Upon dividing the subject group into young adults (ages 18-45, $n = 188$) and middle-aged to older adults (age > 45 , $n = 68$), ESS and SWIFT were no longer correlated with age in either group. **Table 3** gives the measures of central tendency and dispersion for age, hours in bed, BMI, SWIFT, ESS, and the GWIF and DWIF factors for the 188 young adults and 68 middle-aged to older adults; the 85th percentile generally corresponds very closely to mean + 1 SD, and 95th percentile to mean + 2 SD.

Table 2—Factor analysis matrix of SWIFT

	Factor 1	Factor 2
B4	0.79	0.25
B3	0.77	0.19
B1	0.74	0.02
B2	0.73	0.09
A5	0.73	0.21
B5	0.72	0.04
A1	0.69	0.22
A4	0.56	0.10
A6	0.46	0.32
A2	0.04	0.90
A3	0.15	0.84
B6	0.26	0.80

Rotated component matrix for normal subjects by age group: A1, A4, A5, A6, B1, B2, B3, B4, B5 load on Factor 1 (GWIF: general wakefulness inability and fatigue), with a maximum possible score of 27. A2, A3 and B6 load on Factor 2 (DWIF: driving wakefulness inability and fatigue), with a maximum possible score of 9.

Table 3—Normal subjects: mean, SD, medians and percentiles

	Mean	SD	Median	Mean + 1 SD	85 th percentile	Mean + 2 SD	95 th percentile
Young adults (18-45 y)							
Age	27.4	6.4	26.0	33.8	35.0	40.2	41.6
BMI	25.6	6.0	24.4	31.6	30.9	37.6	37.6
Time in bed (h)	7.7	1.6	7.5	9.3	8.5	10.9	11.0
ESS	6.8	4.1	5.0	10.9	11.0	15.0	15.0
SWIFT	7.1	4.9	6.0	12.0	12.0	16.9	17.6
GWIF	6.6	4.4	6.0	11.0	10.0	15.4	15.6
DWIF	0.6	1.1	0.0	1.7	1.8	2.8	3.0
Middle-aged to older adults (> 45 y)							
Age	63.2	12.8	26.0	76.0	79.3	88.8	87.1
BMI	27.8	5.9	24.4	33.7	33.3	39.6	40.8
Time in bed (h)	7.8	1.4	7.5	9.2	9.0	10.6	10.1
ESS	5.8	4.0	5.0	9.8	10.7	13.8	14.6
SWIFT	4.7	4.3	6.0	9.0	9.0	13.3	13.6
GWIF	4.2	3.9	6.0	8.1	8.0	12.0	13.0
DWIF	0.5	0.9	0.0	1.4	1.7	2.3	3.0

Mean, median, standard deviation, mean + 1 and + 2 standard deviations, and 85th and 95th percentiles are shown by age group for age, BMI, time in bed, the ESS, SWIFT, and the general wakefulness inability and fatigue (GWIF), and driving wakefulness inability and fatigue (DWIF) factors of the SWIFT.

Upon performing factor analysis separately for each age group, there were the same 2 factors for young adults, accounting for the same 36% and 20% of variance. For middle-aged to older adults, Factor 2 remained the same (A2, A3, B6) and accounted for 19% of variance. Factor 1 separated into 3 factors. The new Factor 1 (A1, A4, B1, B2, B3, B5) accounted for 27% of variance, while A5 and B4 (17% of variance), and A6 (10% of variance) became new separate factors, suggesting that wakefulness inability/fatigue while reading or studying may separate from general wakefulness inability/fatigue in middle-aged to older adults.

OSA Patients

Of the 286 patients with $AHI \geq 5$, 86 were young adults (ages 18-45 years) and 200 were middle-aged to older adults (age > 45 years). The 188 normal young adults differed significantly from the 86 young adults with $AHI \geq 5$ in age, SWIFT, GWIF, DWIF, and ESS. **Table 4** gives the means and standard deviations. **Table 5** gives the AUC and, using cutoffs at greater than mean + 1 SD (> 10 for ESS, > 12 for SWIFT, > 11 for GWIF, and > 1 for DWIF), the sensitivity, specificity, positive likelihood ratio, negative likelihood ratio, and Youden's index. SWIFT and GWIF but not DWIF had better AUC, positive and negative likelihood ratios and Youden's index than ESS. **Figure 1** shows that the ROC for ESS was entirely within the ROC for SWIFT and GWIF. However, there was no significant difference between AUC for ESS and SWIFT.

The 68 normal middle-aged to older adults differed significantly from the 200 middle-aged to older adults with $AHI \geq 5$ in age, SWIFT, GWIF, DWIF, and ESS. **Table 4** gives the means and standard deviations. **Table 5** gives the AUC and, using cutoffs at greater than mean + 1 SD (> 9 for ESS, > 9 for SWIFT, > 8 for GWIF, and > 1 for DWIF), the sensitivity, specificity, positive likelihood ratio, negative likelihood ratio, and Youden's index. SWIFT, GWIF, and DWIF had better AUC, positive and negative likelihood ratios, and Youden's index than ESS. **Figure 2** shows the ROC for ESS was entirely within the ROC for SWIFT and GWIF. The AUC was significantly higher

Table 4—Normal subjects vs. OSA patients: means and SD

	Young adults (18-45 y)		Middle-aged to older adults (> 45 y)	
	Normal	With OSA (AHI \geq 5)	Normal	With OSA (AHI \geq 5)
Age*	27.4 (6.4)	37.3 (6.2)	63.2 (12.8)	58.5 (8.9)
ESS*	6.8 (4.1)	9.7 (5.5)	5.8 (4.0)	9.2 (5.5)
SWIFT*	7.1 (4.9)	12.9 (7.3)	4.7 (4.3)	12.0 (7.9)
GWIF*	6.6 (4.4)	11.4 (6.2)	4.2 (3.9)	10.4 (6.6)
DWIF*	0.6 (1.1)	1.4 (1.8)	0.5 (0.9)	1.6 (2.0)

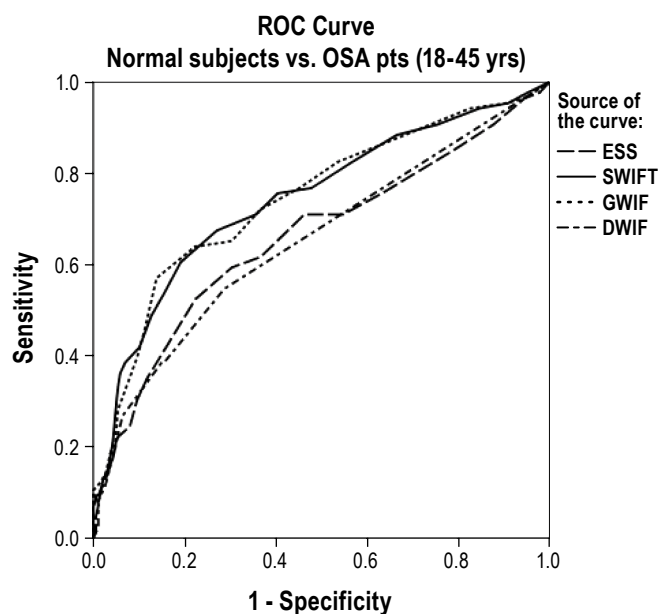
*Normal different from OSA patients at $p < 0.001$ for both age groups. All values mean (SD).

Table 5—Normal subjects vs. OSA patients: indices of test superiority

	Young adults (18-45 y)		Middle-aged to older adults (> 45 y)	
	Value	95% CI	Value	95% CI
AUC for ESS	0.660	0.585-0.734	0.688	0.620-0.757
AUC for SWIFT*	0.743	0.676-0.809	0.793	0.736-0.850
AUC for GWIF*	0.743	0.677-0.810	0.793	0.733-0.851
AUC for DWIF	0.652	0.578-0.725	0.669	0.602-0.737
sensitivity for ESS	0.453	0.368-0.535	0.430	0.395-0.457
sensitivity for SWIFT*	0.488	0.405-0.563	0.565	0.532-0.587
sensitivity for GWIF*	0.453	0.372-0.525	0.540	0.508-0.561
sensitivity for DWIF	0.384	0.302-0.462	0.430	0.397-0.453
specificity for ESS	0.819	0.780-0.857	0.809	0.706-0.887
specificity for SWIFT*	0.872	0.834-0.906	0.868	0.771-0.932
specificity for GWIF*	0.888	0.851-0.921	0.882	0.787-0.943
specificity for DWIF*	0.846	0.808-0.882	0.853	0.755-0.921
ρ_+ for ESS	2.508	1.670-3.731	2.249	1.364-4.093
ρ_+ for SWIFT*	3.826	2.445-6.016	4.269	2.351-8.794
ρ_+ for GWIF*	4.060	2.503-6.654	4.590	2.419-9.967
ρ_+ for DWIF	2.488	1.573-3.910	2.924	1.638-5.848
ρ_- for ESS	0.667	0.543-0.811	0.705	0.613-0.856
ρ_- for SWIFT*	0.587	0.482-0.713	0.501	0.443-0.607
ρ_- for GWIF*	0.615	0.516-0.737	0.525	0.466-0.625
ρ_- for DWIF	0.729	0.610-0.864	0.668	0.593-0.800
γ for ESS	0.273	0.147-0.392	0.239	0.102-0.343
γ for SWIFT*	0.361	0.239-0.469	0.433	0.303-0.519
γ for GWIF*	0.342	0.224-0.446	0.422	0.295-0.503
γ for DWIF	0.229	0.110-0.344	0.283	0.151-0.375

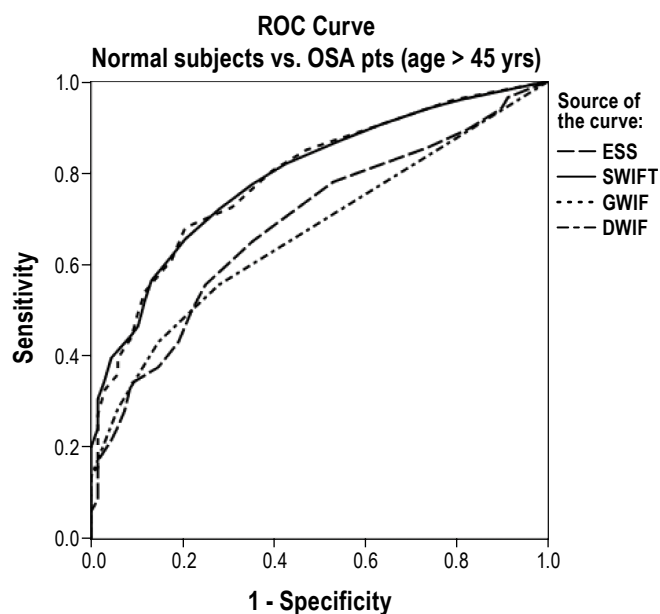
*Value superior to value for ESS in both age groups. [†]AUC significantly higher than that for ESS in middle-aged to older adults. ρ_+ and ρ_- are likelihood ratios for positive and negative test. γ , Youden's index. Mean + 1 SD used as cut-offs for calculation of sensitivity, specificity, ρ_+ , ρ_- and γ . Young adults: ESS > 10, SWIFT > 12, GWIF > 11, DWIF > 1. Middle-aged to older adults: ESS > 9, SWIFT > 9, GWIF > 8, DWIF > 1.

Figure 1—ROC curves for ESS, SWIFT, GWIF, and DWIF for normal subjects vs. OSA patients in age group 18-45 years



ESS, Epworth Sleepiness Scale; SWIFT, Sleepiness-Wakefulness Inability and Fatigue Test; GWIF, general wakefulness inability and fatigue factor; DWIF, driving wakefulness inability and fatigue factor.

Figure 2—ROC curves for ESS, SWIFT, GWIF, and DWIF for normal subjects vs. OSA patients in age group > 45 years



ESS, Epworth Sleepiness Scale; SWIFT, Sleepiness-Wakefulness Inability and Fatigue Test; GWIF, general wakefulness inability and fatigue factor; DWIF, driving wakefulness inability and fatigue factor.

for SWIFT ($z = 2.36$, $p = 0.018$) than for ESS, and the AUC was also significantly higher for GWIF than for ESS ($z = 2.35$, $p = 0.019$), but not for DWIF.

There were no significant correlations found in the OSA patients between ESS, SWIFT, GWIF, or DWIF on the one hand, and sleep efficiency, PLMAI, or lowest oxygen saturation on the other. SWIFT ($r = 0.16$, $p = 0.006$), GWIF ($r = 0.15$, $p = 0.009$) and DWIF ($r = 0.14$, $p = 0.023$), but not ESS, were significantly correlated with arousal index. ESS ($r = 0.14$, $p = 0.018$) and GWIF ($r = 0.14$, $p = 0.022$), but not SWIFT or DWIF, were significantly correlated with AHI.

CPAP Treatment

ESS, SWIFT, GWIF, and DWIF improved significantly in patients on CPAP in both age groups (36 young adults: $t = 7.1$, $df = 35$, $p < 0.001$ for ESS, $t = 7.0$, $df = 35$, $p < 0.001$ for SWIFT, $t = 7.4$, $df = 35$, $p < 0.001$ for GWIF, $t = 3.4$, $df = 35$, $p = 0.002$ for DWIF; 101 middle-aged to older adults: $t = 9.7$, $df = 100$, $p < 0.001$ for ESS, $t = 12.2$, $df = 100$, $p < 0.001$ for SWIFT, $t = 11.5$, $df = 100$, $p < 0.001$ for DWIF, $t = 7.7$, $df = 100$, $p < 0.001$ for DWIF). Effect sizes and 95% confidence intervals for the 137 subjects were as follows: ESS 0.96 (0.07, 1.63), SWIFT 1.07 (-0.20, 1.98), GWIF 1.04 (-0.03, 1.82), DWIF 0.75 (0.43, 0.93). One hundred fourteen of 137 (83.2%) subjects were compliant (use ≥ 4 h/night) for $\geq 70\%$ of nights. Compliance was significantly correlated with improvement in SWIFT ($r = 0.21$, $p = 0.015$), GWIF ($r = 0.18$, $p = 0.034$) and DWIF ($r = 0.18$, $p = 0.032$), but not ESS ($r = 0.11$, $p = 0.216$). Improvement in SWIFT ($r = 0.22$, $p = 0.011$) and GWIF ($r = 0.24$, $p = 0.004$) were also significantly correlated with AHI, but im-

provement in DWIF or ESS were not. **Table 6** gives by age group the pre- and post-treatment data, as well as numbers above and below the cutoffs before and after treatment, effect sizes, and χ^2 statistics. SWIFT, GWIF, DWIF, and ESS were all valuable in demonstrating conversion from abnormal to normal values with CPAP use.

Patients Evaluated for Narcolepsy

Of 49 patients evaluated with PSG and MSLT for evaluation of narcolepsy, 37 were young adults (ages 18-45 years), and 12 were middle-aged to older adults (age > 45 years). Ten of the young adults and none of the middle-aged to older adults met MSLT criteria for diagnosis of narcolepsy—a 20% positive diagnostic rate, which is comparable to the 20% (170 of 832) positive diagnostic rate for the MSLT reported earlier in sleepy patients without OSA.³¹ The young adults with narcolepsy were significantly younger than the young adults without narcolepsy (24.1, SD 5.3 vs. 38.4, SD 13.6), but did not significantly differ from them in ESS, SWIFT, GWIF, or DWIF. The 188 normal young adults differed significantly from the 37 young adults evaluated for suspicion of narcolepsy in SWIFT, GWIF, DWIF, and ESS, but not in age. **Table 7** gives the means and standard deviations. **Table 8** gives the AUC and, using cutoffs at greater than mean + 1 SD (> 10 for ESS, > 12 for SWIFT, > 11 for GWIF, and > 1 for DWIF), the sensitivity, specificity, positive likelihood ratio, negative likelihood ratio, and Youden's index. SWIFT, GWIF, and DWIF had better AUC, positive and negative likelihood ratios, and Youden's index than ESS. **Figure 3** shows the ROC for ESS was entirely within the ROC for SWIFT and GWIF. The AUC was significantly higher for SWIFT ($z = 2.29$, $p = 0.022$) than for

Table 6—Before and on CPAP treatment

	Mean	SD	# with high scores	# with normal scores	Effect size (95% confidence intervals)	χ^2 for high and normal scores	p-value for χ^2
Young adults (age 18-45 y)							
Before CPAP							
Sample size	36						
Age	37.56	6.20					
AHI	28.77	28.78					
ESS	10.33	5.16	18	18			
SWIFT	13.44	7.04	19	17			
GWIF	11.97	6.11	16	20			
DWIF	1.47	1.68	14	22			
On CPAP							
Compliance %	75.2	24.8					
ESS*	4.67	4.15	3	33	1.23 (-0.46,2.58)	13.2	< 0.001
SWIFT*	5.67	6.07	5	31	1.20 (-1.10,3.18)	10.6	0.001
GWIF*	5.28	5.46	5	31	1.17 (-0.83,2.95)	6.7	0.010
DWIF*	0.39	0.90	3	33	0.81 (-0.13,1.01)	7.7	0.006
Middle-aged to older adults (age > 45 y)							
Before CPAP							
Sample size	101						
Age	58.92	8.98					
AHI	47.11	3					
ESS	9.78	5.45	47	54			
SWIFT	12.83	7.74	62	39			
GWIF	11.02	6.49	61	40			
DWIF	1.81	2.00	48	53			
On CPAP							
Compliance %	81.7	22.3					
ESS*	5.64	3.93	19	82	0.88 (-0.19,1.64)	16.4	< 0.001
SWIFT*	6.13	5.22	26	75	1.02 (-0.49,2.04)	24.7	< 0.001
GWIF*	5.52	4.43	25	76	0.99 (-0.27,1.86)	24.8	< 0.001
DWIF*	0.60	1.18	16	85	0.74 (0.35-0.97)	22.0	< 0.001

*Significant improvement, p < 0.01.

Table 7—Normal subjects vs. MSLT patients: means and SD

	Young adults (18-45 y)		Middle-aged to older adults (> 45 y)	
	Normal	Evaluated for narcolepsy	Normal	Evaluated for narcolepsy
Age	27.4 (6.4)	29.2 (8.1)	63.2 (12.8)	55.0 (6.7)
ESS*	6.8 (4.1)	11.7 (5.1)	5.8 (4.0)	11.6 (6.9)
SWIFT*	7.1 (4.9)	19.8 (7.8)	4.7 (4.3)	16.8 (7.0)
GWIF*	6.6 (4.4)	16.8 (6.3)	4.2 (3.9)	14.5 (5.5)
DWIF*	0.6 (1.1)	3.0 (2.2)	0.5 (0.9)	2.3 (2.3)

*Normal different from patients evaluated for narcolepsy, significant at p < 0.05 for both age groups. All values mean (SD).

ESS. The AUC was also significantly higher for GWIF than for ESS (z = 2.07, p = 0.038), but not for DWIF.

The 68 normal middle-aged to older adults differed significantly from the 12 middle-aged to older adults evaluated for suspicion of narcolepsy in age, SWIFT, GWIF, DWIF, and ESS. **Table 7** gives the means and standard deviations. **Table 8** gives the AUC and, using cutoffs at greater than mean

+ 1 SD (> 9 for ESS, > 9 for SWIFT, > 8 for GWIF, and > 1 for DWIF), the sensitivity, specificity, positive likelihood ratio, negative likelihood ratio, and Youden's index. SWIFT, GWIF and DWIF had better AUC, positive and negative likelihood ratios, and Youden's index than ESS. **Figure 4** shows the ROC for ESS was entirely within the ROC for SWIFT and GWIF. However, there was no significant difference between AUC for ESS and SWIFT.

There were no significant correlations found in the patients evaluated for narcolepsy between ESS, SWIFT, GWIF, or DWIF on the one hand and sleep efficiency, AHI, PLMAI, arousal index, or number of SOREMPs on the MSLT, on the other. ESS but not SWIFT, GWIF, or DWIF was significantly negatively correlated with mean sleep latency on the MSLT (r = -0.408, p = 0.004).

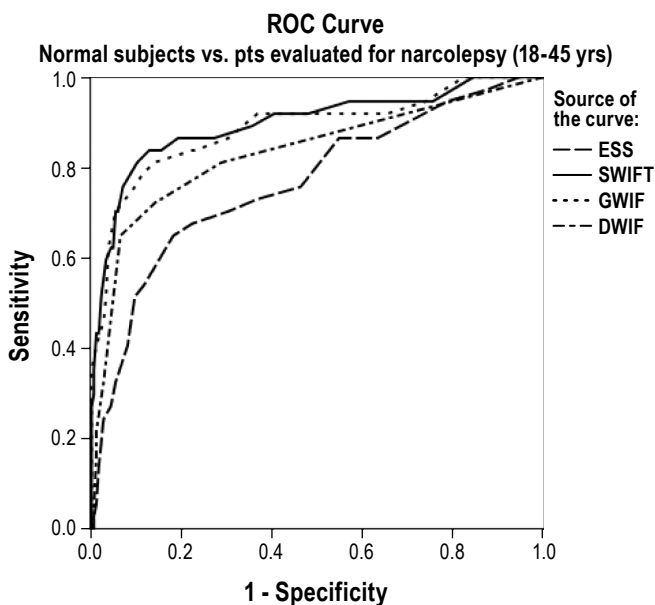
DISCUSSION

The SWIFT has high internal consistency as shown by high Cronbach α , and high test-retest reliability shown by high intra-class coefficient. Thus, the SWIFT is a reliable test.

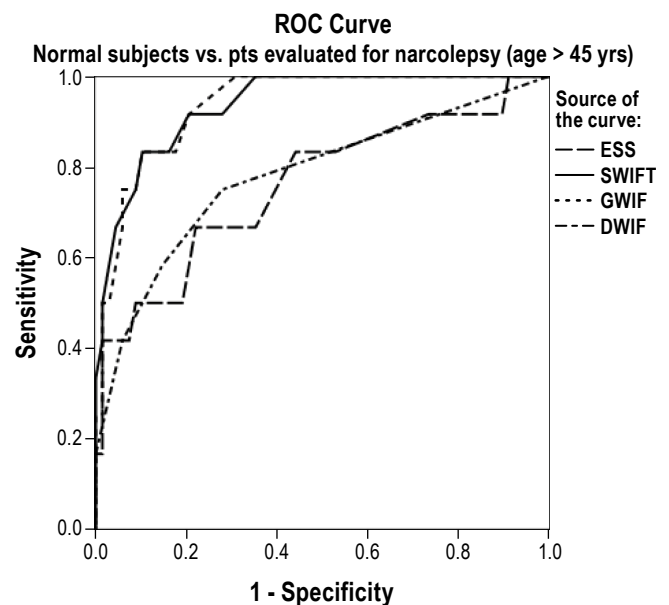
Table 8—Normal subjects vs. MSLT patients: indices of test superiority

	Young adults (18-45 y)		Middle-aged to older adults (> 45 y)	
	Value	95% CI	Value	95% CI
AUC for ESS	0.767	0.676-0.857	0.761	0.595-0.927
AUC for SWIFT [†]	0.898	0.831-0.965	0.938	0.877-0.999
AUC for GWIF [†]	0.888	0.818-0.958	0.939	0.882-0.996
AUC for DWIF [*]	0.833	0.748-0.918	0.780	0.618-0.942
sensitivity for ESS	0.649	0.494-0.781	0.500	0.237-0.758
sensitivity for SWIFT [*]	0.838	0.695-0.929	0.833	0.544-0.970
sensitivity for GWIF [*]	0.784	0.638-0.889	0.833	0.546-0.969
sensitivity for DWIF [*]	0.730	0.578-0.848	0.583	0.307-0.818
specificity for ESS	0.818	0.789-0.845	0.809	0.762-0.854
specificity for SWIFT [*]	0.872	0.844-0.890	0.868	0.817-0.892
specificity for GWIF [*]	0.888	0.860-0.909	0.882	0.832-0.906
specificity for DWIF [*]	0.846	0.816-0.869	0.853	0.804-0.894
ρ_+ for ESS	3.587	2.335-5.045	2.615	0.996-5.200
ρ_+ for SWIFT [*]	6.563	4.463-8.469	6.296	2.964-8.953
ρ_+ for GWIF [*]	7.017	4.549-9.755	7.083	3.241-10.355
ρ_+ for DWIF [*]	4.731	3.136-6.472	3.967	1.569-7.745
ρ_- for ESS	0.468	0.259-0.642	0.618	0.284-1.001
ρ_- for SWIFT [*]	0.186	0.080-0.361	0.192	0.034-0.559
ρ_- for GWIF [*]	0.243	0.123-0.421	0.189	0.034-0.546
ρ_- for DWIF [*]	0.320	0.175-0.518	0.489	0.203-0.862
γ for ESS	0.468	0.282-0.626	0.309	-0.001-0.612
γ for SWIFT [*]	0.710	0.539-0.819	0.701	0.360-0.861
γ for GWIF [*]	0.672	0.498-0.797	0.716	0.377-0.876
γ for DWIF [*]	0.575	0.393-0.717	0.436	0.111-0.712

*Value superior to value for ESS in both age groups. [†]AUC significantly higher than AUC for ESS in young adults. ρ_+ and ρ_- are likelihood ratios for positive and negative test. γ , Youden's index. Mean + 1 SD used as cut-offs for calculation of sensitivity, specificity, ρ_+ , ρ_- and γ . Young adults: ESS > 10, SWIFT > 12, GWIF > 11, DWIF > 1. Middle-aged to older adults: ESS > 9, SWIFT > 9, GWIF > 8, DWIF > 1.

Figure 3—ROC curves for ESS, SWIFT, GWIF, and DWIF for normal subjects vs. patients evaluated for narcolepsy in age group 18-45 years

ESS, Epworth Sleepiness Scale; SWIFT, Sleepiness-Wakefulness Inability and Fatigue Test; GWIF, general wakefulness inability and fatigue factor; DWIF, driving wakefulness inability and fatigue factor.

Figure 4—ROC curves for ESS, SWIFT, GWIF, and DWIF for normal subjects vs. patients evaluated for narcolepsy in age group > 45 years

ESS, Epworth Sleepiness Scale; SWIFT, Sleepiness-Wakefulness Inability and Fatigue Test; GWIF, general wakefulness inability and fatigue factor; DWIF, driving wakefulness inability and fatigue factor.

The twelve test items of the SWIFT load on to two different factors. Factor 1 seems to be a measure of general wakefulness inability and fatigue, while Factor 2 seems to measure driving wakefulness inability and fatigue, indicating that it may be possible to measure separately general and driving related concepts/symptoms.

The ability of SWIFT, GWIF, and DWIF to discriminate between normal subjects and patients with OSA, as well as patients presenting with symptoms suggesting narcolepsy, shows that the SWIFT is a valid test, as does the ability to show significant improvement with CPAP treatment of OSA.

The SWIFT and GWIF are superior to the ESS (the criterion standard) in discriminating between normal subjects and patients with OSA in both age groups, with regard to sensitivity/specificity/discriminant validity, as shown by AUC (statistically significantly so for middle-aged and older adults), Youden's index, as well as the positive and negative likelihood ratios. The SWIFT and GWIF are also superior to the ESS in discriminating between normal subjects and patients evaluated for narcolepsy in both age groups, with regard to sensitivity/specificity/discriminant validity, as shown by AUC (statistically significantly for young adults), Youden's index, and positive and negative likelihood ratios. All the ROCs for ESS (young and middle-aged to older adults, patients with OSA, and patients evaluated with narcolepsy) were entirely within the ROCs for SWIFT and GWIF. Given the rarity of narcolepsy, comparisons were made using patients evaluated for narcolepsy rather than patients diagnosed with narcolepsy. However, patients with OSA were excluded from this group; patients not positive for narcolepsy were as sleepy, fatigued, and unable to maintain wakefulness as the patients with narcolepsy. Thus, SWIFT and GWIF may be more useful than ESS in terms of clinical utility in discriminating between normal and sleep disordered subjects.

Effect sizes were similar for improvement in ESS, SWIFT, and GWIF (but lower for DWIF) with CPAP treatment in young adults. In middle-aged to older adults, effect sizes for SWIFT and GWIF were higher than those for ESS and DWIF. Comparisons of the number of patients with high ESS, SWIFT, GWIF, and DWIF before and after CPAP treatment revealed significant differences in both age groups. Improvement in SWIFT, GWIF, and DWIF, but not ESS, was significantly correlated with compliance. This compliance-response relationship lends more confidence in the use of the SWIFT or GWIF rather than the ESS is assessing treatment response with CPAP despite similar effect sizes for SWIFT, GWIF, and ESS. The finding that only ESS, but not SWIFT, GWIF, or DWIF, is correlated with MSLT suggests that subjects were able to separate the concept of tendency to fall asleep (as measured by the MSLT and the ESS) from wakefulness inability and fatigue. The finding that SWIFT, GWIF, and DWIF, but not ESS are correlated with arousal index suggests that they are a better measure of lack of sleep quality than the ESS. The finding that wakefulness inability and fatigue did not load on to separate factors on factor analysis suggests that subjects may have a hard time separating these two concepts.

The separation of data into two groups by age necessitated by a correlation between age and SWIFT as well as ESS in the combined group, provides a built-in replication, and similar findings in the two independent age groups (though more robust

in the middle-aged to older adults in the case of OSA and in young adults in the case of patients evaluated for narcolepsy) lend increased confidence to the results.

Mills et al. have reported that predictors of fatigue in OSA include BMI, depression scores, and soluble tumor necrosis factor receptor I (sTNF-RI), but not the severity of OSA as measured by AHI or mean oxygen saturation.³² Tumor necrosis factor- α (TNF- α) and interleukin-6 (IL-6) are increased in OSA and narcolepsy.³³ Adding measures of fatigue to the measurement scale for daytime functioning, and changing the measurement scale to measure wakefulness inability rather than tendency to fall asleep may improve the measurement of the daytime consequences of sleep disorders.

Masa et al.³⁴ reported habitual sleepiness affecting 3.6% of drivers, with an odds ratio of 13.7 for highway automobile accidents, and with considerable ESS overlap between these subjects and controls. 50% of habitually sleepy drivers had ESS < 9. This suggests that propensity to fall asleep in other circumstances (as measured by ESS) is neither necessary nor sufficient to cause increased risk for auto accidents. Although a sample of 10,000 subjects with 71% response rate showed no correlation between the ESS and the adverse consequence of automobile accidents, there was a correlation with dozing off while stopped in traffic.¹⁸ Increased risk for auto accidents may be the result of a complex mix of wakefulness inability, fatigue, and inattention/cognitive impairment, all of which may occur in sleep disordered or sleep deprived subjects. Measurement of increased risk for auto accidents may require questions directly related to wakefulness inability and fatigue while driving, as in the DWIF factor of the SWIFT. The question whether DWIF might be predictive of risk for auto accidents needs to be elucidated in further research.

This study was designed to determine if the SWIFT is a reliable and valid instrument, and if it is superior to the criterion standard, ESS in terms of specificity/sensitivity/discriminant ability, and therefore, possibly, clinical utility. We have shown that the SWIFT is reliable and has discriminant validity, that it has two factors (GWIF and DWIF), and that the SWIFT and its GWIF factor are superior to the ESS in discriminating between normal subjects and sleep disordered patients. These tests measure sleepiness/wake inability and assist in screening/diagnosis. However, they are not meant to discriminate between different causes of difficulties with wakefulness inability or sleepiness. SWIFT should be added to ESS in evaluating daytime consequences of sleep disorders. The two tests together comprise 20 questions and can form a quick questionnaire for use in the office to screen for sleepiness, wakefulness inability, and fatigue, with cutoffs of > 10 for ESS, > 12 for SWIFT, > 11 for GWIF, > 1 for DWIF in young adults (ages 18-45 years), and with cutoffs of > 9 for ESS, > 9 for SWIFT, > 8 for GWIF, > 1 for DWIF in middle-aged to older adults (age > 45 years).

A limitation of this study is that item selection was based on face validity rather than qualitative evaluation using patient focus groups. Another limitation is that the control group was recruited by means of a group e-mail to medical students and by personal solicitation in public places, and it is not clear whether this cohort of normal subjects generalizes to the population and whether it is comparable to the patient groups presented. Further, although the SWIFT and its factors are a better mea-

sure for differentiating between normal subjects and sleep disordered patients than the ESS, the areas under the curve still leave a lot to be desired. However, though there may eventually be a simple blood test to measure sleepiness, wakefulness inability, and fatigue, for now we are left with questionnaires as possibly the best proxies, though objective measures such as the psychomotor vigilance test or the divided attention driving test are other candidates.³⁵ This study was a clinical rather than an experimental study. Since the MWT is not routinely performed clinically, this study did not compare the SWIFT with the MWT. Future directions might include a study of the SWIFT using the MWT.

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Appendix VIII Sample Portable Sleep Apnea Test Requisition

Patient: DOB: Referring MD: CC:		OHIP: Phone:	
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Exclusion Requirements Confirmation:

All 3 of the following are required to proceed with a home sleep study test:

- The patient is over 13 years of age
- The patient does not have any significant cardiac, pulmonary, or neuromuscular disease
- The patient does not have any other sleep disorder (insomnia, suspected narcolepsy/idiopathic hypersomnia, periodic limb movement disorder, central sleep apnea)

Indications: (check all that apply)

- | | | |
|--------------------------------------|---|---|
| <input type="checkbox"/> snoring | <input type="checkbox"/> witnessed apnea | <input type="checkbox"/> non-restorative sleep |
| <input type="checkbox"/> drowsiness | <input type="checkbox"/> fatigue related accident | <input type="checkbox"/> poorly controlled hypertension |
| <input type="checkbox"/> obesity | <input type="checkbox"/> abnormal airway | <input type="checkbox"/> follow-up post OSA treatment (post weight loss or surgery) |
| <input type="checkbox"/> other _____ | | |

Height : cm **Weight:** kg **Neck circumference:** cm

Screening Criteria:

Adjusted Neck Circumference

OSA risk by ANC score <43 43-48 >48
 low mid high

neck circumference in cm: _____

- history of hypertension +4
- habitual snoring +3
- choking/ gasping most nights +3

Adjusted Neck Circumference =

- or -

STOP-BANG

OSA risk by SB score ≤ 2 3-4 ≥5
 low mid high

1 pt each for Snoring Tired Observed Apnea Pressure (HT or HT tx)

STOP score = _____ / 4

1 pt each for BMI > 35 Age > 50 Neck > 40 cm Gender-male

BANG score = _____ / 4

STOP- BANG score = / 8

- or -

Other recognized OSA screening test

Other Instructions for the test:

- _____

Physician Signature

Print Name

Date

Appendix IX Surveys

a) SAMPLE Patient Satisfaction Survey

The following example identifies the three goals of a survey of a sleep clinic/facility and leaves the patient an opportunity for additional comments not identified on the survey questions.

In a continuing effort to ensure quality of patient care, kindly answer the following questions.

(circle the applicable response)

Did you have any difficulty with our location or parking? Yes No

When you had your consultation with the physician, did they adequately address your concerns? Yes No

Were you given enough information to prepare for the sleep test? Yes No

Were all your questions answered by the technologist? Yes No

Was your waiting time for the appointment reasonable? Yes No

Please rate us from a scale of 1 (POOR) to 5 (EXCELLENT) for the following:

Cleanliness of the clinic	1	2	3	4	5
Noise level in the bedroom	1	2	3	4	5
Room temperature	1	2	3	4	5
Professionalism of our staff	1	2	3	4	5
Staff's willingness and promptness to assist you	1	2	3	4	5
Overall, how satisfied you are with the care at our facility	1	2	3	4	5

Any additional comments:

Patient Satisfaction Survey Facts

Survey questionnaires should cover 3 areas:

- 1) Quality issues (satisfaction with medical care)
- 2) Access issues (ease of referral or appointment) and
- 3) Interpersonal issues (are the physicians and staff caring and compassionate)

A five point scale utilized by the National Committee of Quality Assurance (NCQA) may be used and ranges from “Poor” to ‘Excellent’

Question should include an open ended question. An option for anonymity would reveal honest results. The frequency of surveying is variable and for example, may include every patient or every fourth patient.

b) SAMPLE Referring Physician Survey

Name of facility _____

Please answer the following questions regarding your experience with the above facility by filling in the blank or circling the number that best describes your answer.

1. How long have you referred patients to this facility? _____ years or _____ months

2. How satisfied are you with how long it generally takes: (Please rate each item by circling the number that best describes your opinion)

Not Applicable	Very Dissatisfied	Dissatisfied	Neutral	Satisfied	Very Satisfied
to get an appointment for a patient at this facility?	1	2	3	4	5
to obtain written results (a written consultation) from this facility, once your patient is seen?	1	2	3	4	5
to get an oral report from this facility when it is required because of an urgent or emergency situation, once your patient is seen?	1	2	3	4	5

3. How often do you speak to a physician at the IHF regarding the patient's clinical condition before your patient receives a diagnostic work-up?

Never	Rarely	Occasionally	Sometimes	Often	Almost all the time
1	2	3	4	5	6

4. Approximately how many patients have you referred to this facility in the past 6 months? _____ (number of patients referred)

5. Do you refer your patients to more than one facility of this type?

1 No (if you circled No, please **skip to Question number 7**)

2 Yes

6. What are the reasons you refer patients to this particular facility?

(Please circle all that apply.)

1 Nearer Patient's home

2 Has specialized equipment needed for test requested

3 Turnaround time to receive the results is shortest

4 Has staff that speak other languages, and thus can better understand my patients

5 Is able to quickly see patients when feedback is urgently required

- 6 Has convenient hours of operation
- 7 Quality of the services provided
- 8 Other, please describe _____

Please skip to Question number 8.

7. What are the reasons you refer patients only to this facility? (Please circle all that apply.)

- a Only facility of its type in this community
- b Our group has a service contract with this facility
- c Facility is located near this practice and is thus convenient for patients
- d Has staff that speak other languages and thus can better understand my patients
- e Has specialized equipment needed for tests requested
- f Turn-around time to receive results is short
- g Nearest patients' homes
- h Is able to quickly see patients when feedback is urgently required
- i Quality of the services provided
- j Has convenient hours of operation
- k Other, please describe _____

8. Please rate each item by circling the number that best describes your experience with the IHF based on your contacts in the last 6 months.

	Never	Seldom	Sometimes	Frequently	Usually
The waiting period for a test to be done is long.	1	2	3	4	5
Requests for consultation are handled promptly.	1	2	3	4	5
The facility accommodates patients when the test is urgently required.	1	2	3	4	5
The interpreting physician is available to you for consultation.	1	2	3	4	5
This facility meets the needs of my patients whose first language is other than English or French.	1	2	3	4	5
The recommendations received are useful in patient management.	1	2	3	4	5
The recommendations are clearly stated.	1	2	3	4	5
The reports received are too wordy.	1	2	3	4	5

Reports of results are sent out in a timely fashion. 1 2 3 4 5

The consulting physician orders tests in addition to those you requested. 1 2 3 4 5

When tests are added the resulting recommendations add information important to patient care. 1 2 3 4 5

The interpreting physician's findings are generally consistent with your clinical findings. 1 2 3 4 5

9. Have you been dissatisfied with a consult you received from this facility in the past six months? 1 No 2 Yes
If 2 (Yes), please explain:

10. Overall, how satisfied are you with the contacts you have had with this facility in the past six months?

Very	Dissatisfied	Neutral	Satisfied	Very Satisfied
1	2	3	4	5

Thank you for participating in this survey. Please return the survey in the envelope provided.

Our address is:

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Chapter 7 and Appendix X

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