

Diagnostic Sleep Medicine Review

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Table of Contents

- Executive Summary 3
- Introduction..... 4
- Diagnostic Sleep Testing in BC – Background..... 5
 - Obstructive Sleep Apnea 5
 - Diagnostic Sleep Studies..... 6
 - HSAT Facilities..... 7
- Key Review Findings 8
 - Jurisdictional Surveys/Scans..... 8
 - Literature and Scientific Review 9
 - Stakeholder Engagement 10
 - Sleep Medicine Advisory Committee 10
 - Sleep Experts (Physicians) 11
 - Referring Physicians 11
 - Home Sleep Apnea Testing Industry 12
 - Patient Voices Network..... 13
 - Wait Time Reporting 14
- Summary..... 15
- Improving Sleep Medicine in BC..... 16
 - Clinical Standards for Level III HSAT Facilities 16
 - Education for Referring Physicians..... 17
 - Wait times for Level I Facilities/Testing 18
- Next Steps..... 20
- References..... 20

Executive Summary

Since late February 2019, the Ministry of Health's Diagnostic Services business unit, on behalf of the Advisory Committee on Diagnostic Facilities (ACDF) and the Medical Services Commission (the Commission), has been engaged in a detailed review of the service delivery environment for provision of diagnostic sleep studies in British Columbia (BC).

This review has included an in-depth jurisdictional scan of diagnostic sleep testing policy and practices both in Canada and internationally, a literature and scientific review, formation of an expert Sleep Medicine Advisory Committee and broad stakeholder engagement.

While there are many different types of sleep disorders, the most common is Obstructive Sleep Apnea, which has been the primary focus of the review. In BC there are seven health authority/hospital-based polysomnography labs and 12 privately-owned polysomnography facilities approved to bill the Medical Services Plan for diagnostics sleep studies. While current ACDF policy does not allow for stand alone home sleep apnea testing facilities to bill the public plan for services, there are roughly 250 of these unaccredited, unregulated facilities providing home sleep apnea testing in BC.

Recognizing the significant scope and importance of this work, the Commission imposed a temporary moratorium on applications for outpatient polysomnography facilities. Originally scheduled to be lifted March 31, 2020, the moratorium was extended to September 30, 2020 to allow the Ministry additional time to complete work to gather and analyse wait time data to be provided through a new facility wait time reporting system, an outcome of the review.

Through the review and stakeholder engagement, three areas of primary need emerged. To improve how diagnostic sleep testing is delivered in BC, it is recommended efforts focus on:

- **Development of clinical standards for home sleep apnea testing facilities:** Formal regulation and accreditation standards will facilitate a consistent quality of practice and improve patient care.
- **Education for referring physicians:** There is a general need to improve practitioner knowledge and consistency in referring practices to reduce inappropriate testing and accompanying system costs, while improving patient care.
- **Improving wait time reporting from approved polysomnography facilities:** Implementing expanded, consistent wait time reporting will furnish the ACDF with more accurate data through which to assess future polysomnography facility applications, while providing evidence-based, geographically-focused insight into the cause of patient wait times for testing.

The practice of diagnostic sleep testing is evolving and expanding as medical practitioners and the general public become more aware of the impacts of sleep disorders.

This review explores the evolution of sleep diagnostics, identifies specific challenges, profiles key stakeholder perspectives and advice and outlines a clear path forward for provision of diagnostic sleep testing in BC.

Introduction

The practice of diagnostic sleep medicine is often referenced as polysomnography, which is one type of diagnostic sleep test – an overnight, monitored study conducted in a sleep lab and considered the ‘gold standard’ of diagnostic sleep medicine studies.

Since February 2019, the Ministry of Health (the Ministry) on behalf of the Advisory Committee on Diagnostic Facilities (ACDF) and the Medical Services Commission (the Commission), has been conducting a review of the service delivery environment for diagnostic sleep studies in British Columbia (BC).

This work was initiated in response to a number of areas of concern the Ministry and ACDF were becoming increasingly aware of, including:

- significant clinical concern regarding the prevalence of unaccredited, unregulated home sleep apnea testing facilities and the overall percentage of testing capacity they currently represent;
- technological advances in home testing and the potential impact if free-standing, home testing facilities were to be approved to bill the Medical Services Plan;
- application of wait time benchmarks approved by the Commission and used by the ACDF when assessing applications for new polysomnography facilities;
- long wait times for assessment by a sleep specialist at ACDF approved facilities; and
- the apparent under-utilization of at least some ACDF approved facilities and related practitioner-referral concerns.

To support the Ministry to conduct this work, the Commission imposed a temporary moratorium on applications to the ACDF for outpatient polysomnography facilities. In February 2020, the Commission extended the temporary moratorium from March 30, 2020 to September 30, 2020, to allow the Ministry additional time to complete work to gather and analyse wait time data from polysomnography facilities in the province.

Diagnostic Sleep Testing in BC – Background

Obstructive Sleep Apnea

There are many different types of sleep disorders including Insomnia, Restless Legs Syndrome, Narcolepsy and Central Sleep Apnea, with Obstructive Sleep Apnea (OSA) being the most common.

In BC, population-based studies estimate 24.5 percent of adults between the ages 30 to 69 suffer from some level of OSA (629,865 persons in a population of 2,570,880), and the prevalence of moderate to severe OSA in the same population is estimated at 4.8 percent (123,402 persons)ⁱ. This contrasts with the three percent of Canadian adults who report being diagnosed with OSAⁱⁱ. Taken together, these data illustrate that OSA is highly prevalent and significantly under-diagnosed.

OSA sufferers are often unaware of their condition. Nocturnal respiratory pauses associated with OSA cause a person to wake and fall asleep again repeatedly throughout the night, often without their knowledge. Severe OSA is defined when respiratory pauses number greater than 30 per hour, however, patients with more than 70 pauses in breathing per hour have been notedⁱⁱⁱ. This sleep disruption leads to chronic sleep deprivation, periods of reduced blood oxygen level^{iv}, and excessive daytime sleepiness – a major symptom of OSA. Numerous clinical studies show that OSA impacts cardiovascular health. This includes an increased incidence of cardiovascular disease^{v,vi,vii}, fatal and nonfatal cardiovascular events^{viii}, and mortality^{ix}.

Chronic sleep deprivation is associated with difficulty concentrating, memory lapses, low energy, fatigue, lethargy and emotional instability.

Daytime sleepiness occurring at times when a person is expected to be awake and alert can also lead to negative consequences, including drowsy driving and workplace accidents. Drivers with untreated OSA have a seven-fold increased risk of injury when compared to healthy drivers^x and, independent of alcohol effects, almost 20 percent of all serious car crash injuries in the general population are associated with driver sleepiness^{xi}. In BC, Motor Vehicle Branch rules prohibit patients diagnosed with severe OSA from driving unless they are receiving effective treatment as verified by a Registered Respiratory Therapist^{xii}.

See Appendix A - Untreated Obstructive Sleep Apnea: Patient Risks/Economic Impact for further detail.

The most successful method for treating patients with moderate-to-severe OSA is Positive Airway Pressure (PAP). PAP is highly effective at improving sleep quality and quality of life for both patient and bed-partner, and patient risks may be largely mitigated through early OSA diagnosis and PAP treatment.

Diagnostic Sleep Studies

The main types of sleep studies conducted in BC are Level I sleep studies, also known as overnight polysomnography, and Level III sleep studies, also known as portable home monitoring, four-channel and, primarily, home sleep apnea testing (HSAT). Both diagnostic tests are recognised as benefits under the Medical Services Plan (MSP) and have specific Fee Codes and payments assigned to them.¹

Facilities offering outpatient diagnostic services in BC require accreditation from the College of Physicians and Surgeons of BC's (the College's) Diagnostic Accreditation Program (DAP) in order to operate.

In order to bill MSP for diagnostic testing, facilities require formal approval through the ACDF or Commission. Approval is subject to assessment criteria detailed in the Medical and Health Care Services Regulation.

In BC, there are 7 health authority/hospital-based polysomnography labs and 12 privately-owned polysomnography clinics/labs, approved to bill MSP for provision of Level I sleep studies.

Health authority polysomnography facilities, with the exception of UBC Hospital, function solely as sleep labs where overnight testing is conducted. Health authority facilities operate with studies booked by community-based sleep specialists. UBC Hospital has an integrated clinic for patient consulting/triaging.

In contrast, all privately-owned Level I facilities in the province incorporate an integrated clinic and patient consults occur with a sleep expert within the facility. This model appears to provide for quicker access to diagnostic testing as it removes one patient appointment and associated wait time. Many Level I polysomnography facilities (primarily the privately-owned clinics/labs) also provide Level III studies, as and when appropriate.

There are no stand-alone Level III testing facilities in BC approved to bill the MSP as ACDF polysomnography facility approval policy requires that in order for an application for provision of Level III testing to be considered, the facility must provide for a minimum capacity of three beds appropriate for the purpose of Level I overnight polysomnography sleep studies.

Facility applications are assessed against the regulatory requirement to establish "sufficient medical need" and "reasonable utilization of existing facilities" within the geographic catchment area the facility is seeking to be located. For polysomnography, catchment areas are defined as provincial Health Service Delivery Areas (HSDA). Each health authority is divided into three or more HSDAs.

¹ **Level I:** Overnight polysomnography occurs in a monitored setting with the technologist supervising the patient during the night. A complete set of biological signals is acquired including EEG recordings, EOG, EMG, oxygen saturation, thoracic effort, abdominal effort, body position and leg twitches. Assessment of sleep itself is derived from examining the brainwaves.

Level III: 3 to 14 multichannel home sleep testing. Measures respiratory airflow through the nose and mouth while patients are sleep. Also measures oxygen saturation and respiratory effort.

Best practices for determining appropriate polysomnography capacity for a given population have not been established. In BC Level I polysomnography capacity varies significantly depending on where a person lives – from a high of 4.39 beds per 100,000 population in the Okanagan HSDA to zero in Fraser North and North Shore/Garibaldi HSDA. On a provincial basis, the BC average is 1.64 beds per 100,000 population. As a comparator, Ontario averages 4.78 beds per 100,000 population, while Alberta and Saskatchewan average 0.69 and 0.86 beds per 100,000 population.

See Appendix B - polysomnography beds per 100,000 population.

HSAT Facilities

Although B.C. has significantly increased the number and location of Level I polysomnography beds over the past five to eight years (almost completely through privately-owned facilities approved to bill MSP), the province has also seen huge growth in privately-owned, unregulated/unaccredited, stand-alone HSAT facilities.

HSAT facilities provide only Level III testing. These facilities are not approved to bill MSP, nor do they have patients pay directly for the diagnostic test; rather they rely on the sale and ongoing maintenance of therapy equipment, primarily Continuous Pulmonary Airway Pressure (CPAP) machines, to generate revenue.

HSAT facilities began to appear 10 to 15 years ago to fill a diagnostic testing vacuum, largely attributed to a lack of Level I facilities and associated long wait lists, real and perceived. As HSAT technology has advanced and public awareness of the impacts of sleep issues (particularly OSA) has increased, the industry has burgeoned to the point that, as of March 1, 2020, there are roughly 250 unaccredited, unregulated, stand-alone facilities providing Level III diagnostic sleep testing in BC. A similar proliferation of HSAT facilities has occurred in many Canadian jurisdictions.

Provision of Level III testing by HSAT facilities is acknowledged to be an appropriate, medically necessary service in many jurisdictions. Several countries including the United States, have adopted HSAT as an alternative to polysomnography when used to diagnose uncomplicated patients^{xiii}.

However, lack of HSAT clinical standards and unknown variation in clinical and business ethics have raised several concerns ranging from practitioner referral practices to potential conflict of interests as they relate to an unregulated facility providing both diagnosis and the sale of treatment devices.

In January 2019, multiple concerns were brought forward to the College. Examples cited indicated that some HSAT facilities were claiming to provide information that Level III testing is not designed to produce, adjusting reports to meet requirements for extended health care funding of therapy devices and to meet Motor Vehicles Branch requirements for treatment.

The HSAT industry, having recently experienced accreditation requirements in Alberta and seeing BC begin a process that could result in facility regulation, began to organize itself.

Today, the vast majority of the 250 HSAT facilities in BC belong to the British Columbia Respiratory and Sleep Providers Association (BCRSPA). The BCRSPA has hired Alberta Counsel, an Edmonton-based lobby group, to represent the Association, particularly with its relationship with government.

In November 2019, the BCRSPA sent to the Ministry an unsolicited Data Collection Project report. The report summarized data from 18 BCRSPA member companies and stated that, in 2018, BCRSPA member companies undertook 61,095 Level III sleep tests and employed 520 individuals at 160 facilities in BC.

Based on feedback from HSAT firms participating in the Ministry engagement sessions detailed in this report, and the overall findings of the Ministry's review, the College's DAP formally added home sleep apnea testing to the list of diagnostic services that are accredited by the DAP program.

In March 2020, HSAT facilities were notified of the upcoming accreditation requirement and active work towards developing the accreditation standards continues.

Recently, the BCRSPA has worked with the Ministry of Health to verify a current list of member facilities operating in BC and the BCRSPA coordinated facility responses and assisted Ministry staff to quickly compile a provincial inventory of available Bi-Pap and Oxygen Concentrators, as part of COVID-19 response planning.

Key Review Findings

A detailed and extensive review of the current environment of sleep medicine was conducted by the Ministry's Diagnostic Services unit. This review included jurisdictional scans, literature reviews, and consultations ranging from experts to associations and patients. The review's findings and areas of needs are detailed below.

Jurisdictional Surveys/Scans

The Ministry worked with a consultant to undertake a survey of Canadian jurisdictions and review of public facing documentation from select international jurisdictions (Australia, the United Kingdom and Medicaid in the United States).

In addition, key Canadian jurisdictions (Alberta, Saskatchewan, Manitoba, Ontario, Quebec and Nova Scotia) were approached with a request to identify one or more subject matter experts to complete a questionnaire on sleep studies developed by the Ministry. Officials from Alberta, Saskatchewan, Manitoba and Ontario completed the survey. Details for Nova Scotia and Quebec were gleaned from public facing documents.

Following the survey, calls were set with each of the responsive subject matter experts and the specific policies and practices in their jurisdictions were reviewed in detail.

Key Findings – How does sleep medicine in BC compare to other jurisdictions?

- All Canadian jurisdictions examined, except Ontario, publicly cover both Level I and Level III sleep testing. Ontario publicly covers only Level I testing.
- Although Ontario does not cover Level III testing, they have roughly 690 overnight Level I Polysomnography beds. BC has the second highest number of Polysomnography beds with 71, with a population roughly one-third of Ontario's.
- Saskatchewan, Manitoba and Ontario fund, at differing levels, patient cost of prescribed Continuous Positive Airway Pressure (CPAP) machines. Ontario requires purchasing from a preferred vendor to receive funding and does not allow diagnostic providers on the preferred vendor list; this is to eliminate, to the degree possible, the potential conflict of interest inherent when the same facility both diagnoses the sleep issue and then sells the treatment device(s). It is not known how successful this strategy is in eliminating potential conflict of interest situations.
- All Canadian jurisdictions surveyed have a burgeoning home sleep apnea testing facility industry.
- No HSAT facilities are approved to bill the public plan in any Canadian jurisdiction.
- At the time of this scan, only Alberta had moved to require accreditation of HSAT facilities.
- In the United States, Medicare will cover a 3-month trial of CPAP therapy if the beneficiary has been diagnosed with OSA. If it is determined the CPAP machine is necessary beyond the 3-month trial, the beneficiary will pay 20 percent of the Medicare-approved machine rental amount. After the beneficiary has rented the machine for 13 months, they own it.
- In Australia, a general practitioner may directly refer a patient for either a Level I or Level III study without a personal assessment by a sleep or respiratory specialist, provided that screening questionnaires suggest a high pre-test probability for a diagnosis of symptomatic, moderate-to-severe OSA.
- NHS England is the only international jurisdiction examined that has established guaranteed maximum wait times (6 weeks) for diagnostic sleep tests.
- NHS England has set the same compensation rate for Level III sleep studies as for Level I polysomnography. This appears to be a deliberate policy to encourage practitioners to order an unattended home test as the default diagnostic, except for complex cases.

See Appendix C - Polysomnography and Sleep Medicine: A Jurisdictional Review.

Literature and Scientific Review

Ministry staff conducted a comprehensive search of primary scientific literature, focussing on systematic reviews, clinical guidelines, and position statements from regulating bodies on sleep medicine.

The intent of this work was to identify best practices in sleep medicine diagnostic techniques and equipment used to diagnose sleep disorders, with a focus on Level I and Level III testing, the two types of diagnostic sleep testing most commonly performed in BC.

Key Findings – A summary of best practices

- OSA is the only sleep disorder that can be diagnosed using a Level III (HSAT) sleep study.
- Level III/HSAT studies have excellent sensitivity for identifying true positives, however they lack the ability to rule out OSA through a negative test.
- Use of HSAT may particularly benefit patients with a high pretest probability of moderate-to-severe OSA, particularly where patient access to Level I studies is known to be an issue.
- The need for, and appropriateness of, an HSAT must be based on the patient’s medical history and a face-to-face examination by a medical provider, either in person or via telemedicine.
- An HSAT should not be used for general screening of asymptomatic clinical populations.
- Level I attended overnight studies are the only recommended method for diagnosing sleep disorders in children, elderly, those with special needs and patients with significant comorbid disorders.
- The Canadian Thoracic Society supports the use of HSAT to diagnose uncomplicated patients, however raising awareness of patient conditions that impact the accuracy and appropriateness of HSAT is critical.
- The ability to interpret HSAT studies should not be limited by physician specialty, provided appropriate training and experience has been obtained and the physician is associated with an accredited sleep facility.
- Guidelines from Canadian and American Sleep Medicine experts agree that accreditation by a governing body, and oversight by an expert in sleep medicine are both essential elements to an effective HSAT program.

See Appendix D - draft copy, Polysomnography Literature and Scientific Review

Note: Following acceptance by the Commission, it is intended to circulate a draft copy of the Polysomnography Literature and Scientific Review to sleep experts for their input and comment.

Stakeholder Engagement

Sleep Medicine Advisory Committee

Acting as an expert advisory group, with a mandate to provide clinical knowledge and expertise to inform and support this review, the Ministry’s Sleep Medicine Advisory Committee is comprised of two senior sleep expert physicians working in the health authority system and two long-time sleep expert physicians from privately-owned facilities that are approved to bill MSP for polysomnography services.

Since April 2019, the Committee has been meeting monthly; members’ experience and expertise have been instrumental in identifying issues within the current environment for sleep medicine in BC, creating materials for stakeholder engagement and consultation and aiding in the development of several key documents.

Key Findings – Committee informed outputs

- Current patient pathway for diagnostic sleep medicine in BC, highlighting obstacles and issues.
- A proposed future patient pathway, identifying system revisions that address the issues and reflect learnings from the review.
- Draft/recommended competency table for diagnostic sleep medicine, covering recommended clinical and technical competencies for providing and interpreting both Level I and Level III sleep studies.

See Appendices E and F - Patient Pathway and Technician and Draft Medical Practitioner Competency Tables.

Sleep Experts (Physicians)

Multiple consultations were held with sleep experts across the province. Participating physicians included those working solely in privately-owned facilities (approved to bill MSP) as well as those working in health authorities.

Key Findings - Concerns from sleep medicine physicians in BC

- There is no standardized approach in terms of referral practices into health authority polysomnography facilities.
- General agreement that referring physicians require guidelines to assist them in making consistent, appropriate referrals for sleep disorder testing.
- Agreement that, in conjunction with guidelines, referring physicians would benefit from a broader education program to assist with making consistent, appropriate referrals.
- Difficulty for out-of-country physicians to have credentials recognized as sleep physicians in BC (one senior sleep expert indicated that the current rules are overly strict and that “the College is a bottleneck in credentialing”).
- Without a professional regulatory environment for Respiratory Therapists, there is a lack of training standards/consistent skills development and no recognized technical qualification or standards for instructing and scoring of portable monitoring (HSAT) testing.
- Concern over the College’s lack of enforcement of the restriction of registrants from working for, or contracting with, unaccredited facilities.

Referring Physicians

Based on sleep expert comments about the need for referring practitioner education, a voluntary, anonymous Referring Practitioners’ Survey was developed and run twice in both the Doctors of BC and the Divisions of Family Practice electronic newsletters.

A total of 83 individuals completed the survey (a 38 percent response rate).

Key Findings – Concerns from referring physicians

- 52 percent of responding practitioners do not change (sleep diagnostic) referral practices based on patient symptoms. Referral rationale is based on facility access, location, and practitioner familiarity rather than patient symptoms, severity index or complexity of patient.
- 36 percent of practitioners are not comfortable advising treatments other than CPAP for OSA.
- 56 percent of practitioners were not aware of Motor Vehicle Branch guidelines concerning when patients diagnosed with OSA may continue driving.
- 23 percent of physicians do not consider themselves as being responsible for ongoing care of patient following referral for sleep disorder testing.
- In qualitative responses practitioners expressed a need for:
 - physician education on sleep disorders.
 - guidelines on referral and appropriate testing for different types of sleep studies.
 - centralized referrals and a standard requisition form.

See Appendix G - Referring Practitioners' Survey Summary

Home Sleep Apnea Testing Industry

HSAT facilities provide only Level III diagnostic sleep testing. Patients are instructed in the use of the equipment at the HSAT facility and then take the portable monitoring equipment and self-administer the test overnight in their home.

In the past decade, BC has seen huge growth in HSAT facilities spurred by technology advances and greater awareness of the impacts of sleep issues, particularly OSA. As of March 1, 2020, there are roughly 250 stand-alone HSAT facilities providing Level III diagnostic sleep testing in BC.

These facilities:

- are not approved to bill MSP nor accredited by the College's DAP;
- provide sleep testing free of charge to patients, earning revenue by selling, to some proportion of patients, a CPAP machine or other therapeutic device. Depending on the model, CPAP machines can be more than \$2,000); and
- usually contract specialists to interpret their tests with no oversight regarding the qualifications of the specialists to interpret sleep studies.

In July 2019 the Ministry held two separate half-day in-person engagement sessions with owners and operators of HSAT facilities in the province. Notice was sent to every HSAT facility known at the time. Those firms that replied with the required information, including the number of facilities operated, locations and capacity, received an invitation to the in-person consultation. A total of 30 individuals representing 17 HSAT firms of the 22 known to operate in BC at the time attended the July sessions.

Key Findings - perspective and concerns of the HSAT industry

HSAT operator participants:

- emphasized their industry emerged from a lack of capacity in the public system. They also stated there are no excessive wait times for testing in their sector;
- positioned Level III testing as an additional means to triage patients for potential Level I testing and emphasized their role in physician support and education;
- identified challenges associated with not accepting physician-referred patients for whom HSAT is not medically appropriate. As HSAT facility operators cannot refer a patient directly for Level I testing, the patient would have to go back to the original practitioner for another referral. Concerns were expressed that patients may not accept the additional time required, and that if they do send the patient back with a recommendation for a specialist consult or Level I test, they may not get future referrals from that practitioner;
- emphasized the continuum of care they provide, with many facilities following and monitoring patients once treated with CPAP therapy. These follow-up services are not billed to MSP. They also spoke to requests received from health authorities to provide care (CPAP therapy instruction, follow up), both in the hospital and with discharge planning;
- indicated that increased legitimacy of HSAT facilities (through some level of accreditation) would be beneficial and help position HSAT as 'respectable' within the healthcare system;
- identified the need for a defined linkage/relationship between HSAT facilities, sleep specialist physicians and Level I labs, so that patients not appropriate for Level III testing can be referred for Level I testing in a more efficient manner – and that a standardized requisition form would be a component of such a linkage; and
- expressed concern that the Ministry and CPSBC may set accreditation standards without meaningful input from the HSAT industry, and if those standards are too onerous or financially difficult to achieve, facilities may go out of business and reduce the Level III testing capacity HSAT facilities represent.

Prior to this review, government had never directly engaged with the industry, and the number of facilities and Level III tests conducted, and the proportion of Level III tests conducted in HSAT facilities vs those billed to MSP, were unknown.

Patient Voices Network

The Ministry engaged with the Patient Voices Network, a programming extension of Patients as Partners, to seek feedback from patient volunteers who had undergone sleep testing in BC.

In September 2019, 22 participants were sent a secure/anonymous link to a Ministry survey concerning sleep diagnostics in BC. Of the 22 participants, 18 viewed the survey, 14 completed the survey and 4 submitted partial feedback.

Most significantly, survey findings corroborated trends that emerged from previous research, including the Referring Practitioners' Survey, as well as from discussions with key stakeholders such as the Ministry's Sleep Medicine Advisory Committee and the HSAT companies.

Items corroborated included:

- there is a lack of patient follow-up from the patient's primary care provider following their sleep test/receiving a therapeutic device; and
- an absence of a clear/singular patient pathway can make it difficult and confusing for patients to get the care they need.

Another notable finding was that, of those who were recommended and attained a therapeutic device, all received at least partial reimbursement from a third-party insurer or other funding organization such as BC's Provincial Respiratory Outreach Program.

The significant proportion of therapeutic device (CPAP machine) funding coming from insurance and funding agencies may assist in potential future regulation regarding what these funding sources approve payment for (i.e. payment only for prescribed devices where the diagnostic testing was done by an accredited facility).

Wait Time Reporting

Through stakeholder consultation, the Ministry became aware that the practice of referring patients to HSAT facilities is influenced by the perception of excessive wait times at accredited Level I sleep labs. This is particularly so for those health authority sleep labs that do not operate internal clinics and rely on community sleep specialists for patient consulting/triaging and study bookings.

Based in part on this perception, and to meet the demand for sleep testing, many physicians refer patients to unaccredited HSAT facilities.

Total patient wait time incorporates the wait time from referring practitioner to specialist (Wait 1) and the wait between the specialist consult and the diagnostic test (Wait 2).

Through its consultations the Ministry became aware that the reported long wait time for polysomnography may be largely driven by Wait 1 – the time taken to see a specialist.

If this is the case, approving additional Level I polysomnography facilities or bed capacity would not alleviate long patient wait times. As such it was identified that any new process for facility wait time reporting must identify Wait 1 separately from Wait 2 wherever possible.

This knowledge, coupled with a lack of confidence in the Ministry's previous ad-hoc/on-demand method of gathering polysomnography facility wait times in order to assess polysomnography applications to the ACDF, led Ministry staff to determine that a new system of monthly wait time reporting for all polysomnography facilities approved to bill MSP is required.

Summary

Through the work undertaken, several issues emerged and three areas of primary need were identified: education for referring practitioners, clinical standards for Level III HSAT facilities and wait times for testing at Level I facilities.

Clinical standards for Level III HSAT facilities

- HSAT facilities provide important capacity for diagnostic sleep testing. While many operators have expressed that their facilities operate with the highest of clinical standards, there is currently no process to confirm what those standards are, or how consistently they are applied across the industry. Formal regulation would provide a standardized framework for all facilities and ensure patients receive diagnostic studies in accordance with best practices.

Education for referring practitioners

- Groups the Ministry consulted with – sleep specialist physicians, HSAT operators and referring practitioners themselves – stressed the need to improve knowledge and consistency in referring practices. Greater education for referring practitioners will increase patient safety by reducing inappropriate testing, accompanying system costs and patient frustration from repeat testing.

Wait times for testing at Level I facilities

- The ACDF has assessed an increasing number of polysomnography facility applications over the past five or more years. Accessing existing-facility wait time data that may be used with confidence when assessing facility applications has been increasingly difficult, with reported wait times rarely aligning with peer-reviewed published data that estimates three percent of the population of North America have undiagnosed sleep disorders², or anecdotal information concerning long wait times. Through the review it became clearer that much of the patient wait time issues may be the time to see community-based sleep specialists for consultation/triaging, rather than time to test once a booking has been made. A consistent and ongoing approach to wait time reporting is needed, both to assess facility applications and to have a better idea of overall diagnostic sleep testing capacity needs.

² *Canadian Respiratory Journal* 2014 Jan-Feb; 21(1): e4-10. *Sleep laboratory test referrals in Canada: Sleep Apnea Rapid Response Survey* <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3938242/>

Improving Sleep Medicine in BC

Having identified three key areas of improvement for diagnostic sleep testing in BC, the Ministry's Diagnostic Services unit has initiated the following work to improve the service delivery environment for provision of sleep medicine in the province.

Clinical Standards for Level III HSAT Facilities

College of Physicians and Surgeons of BC's Diagnostic Accreditation Program

The College, through its Diagnostic Accreditation Program (DAP), has the responsibility and authority to accredit all public and private diagnostic facilities in BC, irrespective of their funding source.

Optimal patient outcomes for any diagnostic service depend on the development, implementation and ongoing improvement of standardized patient care frameworks. The development of accreditation standards has achieved these goals for other diagnostic studies.

Currently, HSAT facilities in BC that provide Level III sleep testing are not accredited and operate without recognized clinical standards or other consistent frameworks or other standards of practice. The development of such standards for Level III sleep testing have been identified as a key requirement emerging from the Ministry's review and to ensure the best, most consistent patient experience with diagnostic sleep studies.

In November 2019, the DAP formally agreed to undertake the work to develop Level III sleep testing standards and to require facilities to be accredited to these standards in order to provide such a diagnostic service.

In February 2020, the Ministry hosted a teleconference with the College and executive members of the BCRSPA (HSAT association); during this discussion the BCRSPA was informed of the upcoming accreditation requirements. On March 18, 2020, formal notice of this requirement was directed to all known HSAT facilities.

The DAP continues to work on the draft accreditation standard, outlining the minimum criteria for the program, and plans to have draft standards reviewed by an expert panel in May 2020. Following that, the standards will be widely disseminated to all diagnostic sleep medicine stakeholders, including all polysomnography and HSAT facilities, for a 90-day period during which all parties can submit feedback concerning the draft standards.

The DAP has stated their intention to accompany the accreditation standard with a standardized provincial requisition form for Level III testing and Ministry staff have agreed to facilitate the development of this standardized form in conjunction with the Guidelines and Protocols Advisory Committee.

Education for Referring Physicians

Guidelines and Protocols Advisory Committee

Referring practitioner lack of sleep medicine education/understanding has been identified by numerous sources as a current shortcoming in establishing effective delivery of sleep medicine services to patients in BC. As the practitioner making the original referral, some level of sleep medicine knowledge, including where to most appropriately direct patients, is key to optimum clinical outcomes.

The proliferation of unaccredited HSAT facilities has contributed to a situation where:

- a significant percentage³ of all sleep testing in the province is done by unaccredited, unregulated HSAT facilities, outside of the MSP system;
- a large proportion of referring practitioners are unaware that stand-alone HSAT facilities are not government-regulated or accredited by the College's DAP; and
- respirologists and sleep experts have expressed concern that patients with medical conditions not appropriate for Level III testing are still being referred to HSAT facilities, when they should be referred to an approved polysomnography facility, or specialist consultation, and possible Level I sleep testing.

In conjunction with the development of accreditation standards, guidelines for referring practitioners are essential for improving the delivery of diagnostic sleep studies in accordance with accepted best practices.

Following a referral from the Commission Chair, Ministry staff worked with the Guidelines and Protocols Advisory Committee (GPAC) to establish sleep medicine as a priority topic for guideline development.

In conjunction with the Sleep Medicine Advisory Committee, Ministry staff proposed a scope for the development of two sleep medicine guidelines (Obstructive Sleep Apnea; Sleep Disorders in Adults: Recognition and Referral) and a standardized, provincial requisition form for Level III sleep studies to be created as part of the GPAC guidelines.

In November 2019, the GPAC Executive approved the proposed scope and Ministry staff worked closely with the GPAC secretariat to assemble a Sleep Medicine Guideline Working Group, with a mandate to produce both guidelines and the standardized requisition form.

On March 6, 2020, the Sleep Medicine Guideline Working Group held its first meeting. Development of the standardized Level III testing requisition form was prioritized as it had been identified by the DAP as a necessary element of facility accreditation, and significant progress was made in establishing the content of the form.

On March 25, 2020, all GPAC work was postponed due to the ongoing COVID-19 pandemic. Completion of the two guidelines and standard requisition form will resume as soon as possible.

³ Estimated by at least one senior practicing sleep expert to be 85 – 90 percent of all testing in B.C.

Wait times for Level I Facilities/Testing

Polysomnography Facility Monthly Wait Time Reporting

To improve the system of wait time data collection and ensure that a consistent approach to wait time reporting is being taken, throughout the latter quarter of 2019 and beginning of 2020, the Ministry consulted with clinical and operational leaders of every approved polysomnography facility in the province to develop a comprehensive monthly facility wait time reporting program to anonymously identify, for each patient tested: Wait 1 and Wait 2; the health region of origin, the patient's sleep issue; and, priority level.

One of the key purposes of requiring facility wait time reporting is its use in assessing applications to the ACDF for new, expansion or relocation to polysomnography facilities in BC. An application may not be approved unless the key regulatory requirements of "sufficient medical need" and "reasonable utilization of existing facilities" have been met.

With consistent wait time data, the ACDF will no longer have to rely on narrow, 'point of time' information with little or no detail behind the summary provided when considering polysomnography applications.

As data will be received monthly, capacity or other trends may be tracked on a facility or regional basis, as appropriate. Importantly, when comparing wait time data from health authorities vs privately-owned Level I sleep labs the ACDF will know it is comparing consistent data.

With an ability to separate Wait 1 from Wait 2, the Ministry should, over time, be able to identify specific wait time issues and take what actions may be appropriate – including not approving additional facilities where the issue may be lack of consulting specialists, not number of polysomnography beds.

By tracking patient health region of origin (by health authority or optional Health Services Delivery Area), the Ministry and Commission will be better informed concerning patient origin and some patients may potentially be repatriated to facilities closer or with shorter wait times.

In February 2020, the Ministry undertook a 'soft launch' of the new monthly wait time reporting system for all approved Level I polysomnography facilities in the province. Throughout this month, staff worked closely with individual facilities to resolve any issues they experienced with the reporting material. On March 1, the new reporting system formally launched, with 100 percent facility compliance.

By mid-March 2020, facilities began to inform the Ministry that many appointments for Level I testing were being cancelled due to the evolving COVID-19 pandemic situation. On March 19, the Ministry suspended, until further notice, data collection and wait time reporting for all polysomnography facilities to allow health authorities and the Ministry to focus on a coordinated response to the COVID-19 emergency in BC.

Although temporarily in abeyance due to the COVID-19 pandemic, the development – and acceptance by all provincial polysomnography facilities – of standard monthly wait time reporting, is a significant outcome of the Ministry’s review.

This new system should, over time, provide data to help address three of the key items identified as issues leading to the review:

- application of wait time benchmarks approved by the Medical Services Commission and used by the ACDF when assessing applications for new polysomnography facilities;
- long wait times for assessment by a sleep specialist at ACDF approved facilities; and,
- the apparent under-utilization of at least some ACDF approved facilities and related practitioner-referral concerns.

In addition to addressing items leading to the review, by obtaining wait times through fully anonymized individual referral and study date, the Ministry expects to:

- better address the key regulatory requirements that must be considered by the ACDF when assessing polysomnography facility applications (establishing “sufficient medical need” and “reasonable utilization of existing facilities”);
- have a readily-available source of information for referring physicians to potentially help dispel perceptions concerning overly long wait times at polysomnography facilities; and
- over time, build a capacity-based model to determine need for services by using wait time data to help establish the appropriate capacity for overnight polysomnography beds per 100,000 population. If a capacity model was to be established, there would no longer be a need to gather wait times.

Finalization of the wait time reporting system and allowing time to gather enough facility data to assess future polysomnography facility applications was the reason for the current polysomnography moratorium to be extended to September 30, 2020.

It is hoped the reporting can be re-launched, without a need to further extend the moratorium on polysomnography applications, currently scheduled to be lifted September 30, 2020.

Next Steps

The issues concerning diagnostic sleep testing in B.C. are complex and interconnected. By focusing on clinical standards for Level III testing, education for referring practitioners and consistent wait time reporting for Level I facilities, the Ministry is advocating for a multi-pronged approach to address the most pressing current issues.

To support the Province's response to COVID-19, the work identified in this report has been temporarily paused. As the pandemic slows the immediate objective will be to resume the initiatives already underway, including:

- Polysomnography facility monthly wait time reporting.
- Support and assist the College in the development and implementation of HSAT/Level III sleep testing accreditation standards.
- Support and assist GPAC in completing the two sleep medicine guidelines, and standard requisition form for Level III testing.
- Following rollout and dissemination of GPAC guidelines, complete a follow-up referring practitioner' survey to assess effectiveness of the guidelines in educating referring practitioners.

Once these initiatives have resumed an assessment of the potential impacts of approving Level III testing facilities to bill MSP will be conducted. It is estimated this will be needed roughly within 12 months following accreditation roll-out.

When facility accreditation is fully implemented, consideration should be given to approaching funding agencies and third-party insurers, recommending CPAP therapy reimbursement be limited to those patients whose diagnosis testing was completed in a DAP accredited facility.

Submitted by:

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Beneficiary and Diagnostic Services Branch
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Appendix A: Untreated Obstructive Sleep Apnea: Patient Risks/Economic Impact

Appendix B: Polysomnography beds per 100,000 population

Appendix C: Polysomnography and Sleep Medicine: A Jurisdictional Review

Appendix D: draft copy, Polysomnography Literature and Scientific Review

Appendix E: Current Patient Pathway and proposed Future Patient Pathway

Appendix F: draft Technician and Draft Medical Practitioner Competency Tables

Appendix G: Referring Practitioners' Survey Summary

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