ONTARIO HEALTH TECHNOLOGY ASSESSMENT SERIES

Level 2 Polysomnography for the Diagnosis of Sleep Disorders

A Health Technology Assessment

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Ontario Health

Key Messages

What Is This Health Technology Assessment About?

Sleep is vital to a person's health, and because sleep is important in maintaining many of the body's other vital functions, problems related to sleep have a large impact. Sleep disorders include difficulty falling asleep, staying asleep, or waking up; breathing disruptions during sleep; abnormal movements or behaviours while sleeping; and difficulty regulating sleep or wakefulness.

Sleep disorders are diagnosed by monitoring a person's breathing, heart rate, brain activity, eye movements, body position, and body movements during sleep – this type of test is called polysomnography or a sleep study.

This health technology assessment looked at how effective and cost-effective level 2 polysomnography (unattended, at-home sleep studies) is for diagnosing sleep disorders among adults and children with suspected sleep disorders in comparison with the current practice – level 1 polysomnography – which is performed in clinic. It also looked at the budget impact of publicly funding level 2 polysomnography for at-home sleep studies and at the experiences, preferences, and values of people with sleep disorders.

What Did This Health Technology Assessment Find?

Level 2 polysomnography (unattended, at-home sleep studies) may have good test performance for adults and children, with adequate accuracy, compared with level 1 polysomnography (in-clinic, fully attended).

The economic analysis showed that level 2 polysomnography for adults with suspected sleep disorders could be potentially cost saving but there is high uncertainty in the cost-effectiveness results. Given very limited information, the cost-effectiveness of this technology is also highly uncertain for children and young adults with suspected sleep disorders. The budget impact of publicly funding level 2 polysomnography for adults could range from savings of $22 million to additional costs of $43 million. Publicly funding level 2 polysomnography in children would require additional costs of about $0.005 million over the next 5 years. A clearer understanding of uptake of the technology, test costs, and the implementation pathway for adopting the technology is needed to improve the certainty of the cost-effectiveness and budget impact estimates.

For many people with suspected sleep disorders, undergoing a sleep study at home would be a more comfortable and convenient option than undergoing a sleep study in clinic.

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Abstract

Background

It is estimated that half of Canadians have insufficient sleep, which over time is associated with poor physical and mental health. Currently, the only publicly funded option for the diagnosis of sleep disorders in Ontario is an in-person overnight sleep study, performed in a hospital or independent health facility (known as a level 1 polysomnography). Level 2 polysomnography has been proposed as an alternative that can be conducted at home for the diagnosis of suspected sleep disorders, if considered to have sufficient diagnostic accuracy. We conducted a health technology assessment of level 2 polysomnography for the diagnosis of suspected sleep disorders in adults and children, which included an evaluation of the test performance, cost-effectiveness, and budget impact of publicly funding level 2 polysomnography, and the experiences, preferences, and values of people with suspected sleep disorders.

Methods

We performed a systematic literature search of the clinical evidence to identify diagnostic accuracy, test failures and subjective measures of patient preferences. We assessed the risk of bias of each included study (using the Quality Assessment of Diagnostic Accuracy Studies [QUADAS-2] tool) and the quality of the body of evidence (according to Grading of Recommendations Assessment, Development, and Evaluation [GRADE] Working Group criteria). We performed a systematic literature search of economic evidence and conducted a primary economic evaluation and budget impact analysis to determine the cost-effectiveness and additional costs of publicly funding level 2 polysomnography for adults and children with suspected sleep disorders in Ontario. To contextualize the potential value of using level 2 polysomnography, we spoke with people with sleep disorders.

Results

We included 10 studies that reported on diagnostic accuracy and found level 2 polysomnography had sensitivity ranging between 0.76–1.0 and specificity ranging between 0.40–1.0 (GRADE: Moderate to Very low) when compared with level 1 polysomnography. Studies reported test failure rates from 0% to 20%, with errors present in both level 1 and level 2 tests conducted (GRADE: Very low). As well, some of these studies reported patients were found to have mixed opinions about their experiences, with more people preferring their experience with level 2 testing at home and having better quality of sleep compared with when they underwent level 1 testing (GRADE not conducted).

Our primary economic evaluation showed that for adults with suspected sleep disorders, the new diagnostic pathway with level 2 polysomnography was equally effective (outcome: confirmed diagnosis at the end of the pathway) as the current practice diagnostic pathway with level 1 polysomnography. With the assumption of a lower technical fee for level 2 polysomnography, the new diagnostic pathway with level 2 polysomnography was less costly than the current practice diagnostic pathway (a saving of $27 per person with a wide 95% credible interval [95% CrI, −$137 to $121]), indicating that the results are highly uncertain. For children, a new diagnostic pathway with level 2 polysomnography was associated with additional costs (mean, $9.70; 95% CrI, −$125 to $190), and similarly, this estimate was highly uncertain.

We estimated that the budget impact of publicly funding level 2 polysomnography for adults is uncertain and could range from savings of $22 million to additional costs of $43 million. Publicly funding a diagnostic pathway with level 2 polysomnography for children could result in additional costs of about $0.005 million over the next 5 years.

People with whom we spoke reported that their sleep disorder negatively impacted their day-to-day lives, mental health, social and family relationships, and work. Participants who had experience with in-clinic (level 1) polysomnography described negative experiences they had at the clinic. Most people said they would prefer at-home (level 2) polysomnography over in-clinic (level 1) polysomnography, citing comfort and convenience as the main reasons; however, some people who have physical limitations preferred level 1 (in-clinic) polysomnography because they needed assistance to set up the equipment.

Conclusions

Level 2 polysomnography may have good test performance for adults and children, with adequate diagnostic accuracy, compared with level 1 polysomnography. The economic analyses showed that level 2 polysomnography for adults with suspected sleep disorders could be potentially cost saving but there is high uncertainty in the cost-effectiveness results. Given very limited information, the cost-effectiveness of this technology is also highly uncertain for children and young adults with suspected sleep disorders. The budget impact of publicly funding level 2 polysomnography for adults could range from savings of $22 million to additional costs of $43 million. Publicly funding level 2 polysomnography in children would require additional costs of about $0.005 million over the next 5 years. A clearer understanding of uptake of the technology, test costs, and the implementation pathway for adopting the technology is needed to improve the certainty of the cost-effectiveness and budget impact estimates. People with sleep disorders highlighted how important getting a diagnosis had been in order to be able to seek proper treatment for their sleep disorder and improve their lives. For many people with suspected sleep disorders, undergoing a sleep study at home would be a more comfortable and convenient option than undergoing a sleep study in clinic.

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Objective

This health technology assessment evaluates the test performance and cost-effectiveness of level 2 polysomnography (unattended, at-home sleep studies), compared with that of level 1 polysomnography (attended, in clinic sleep studies; current practice), for diagnosing adults and children with suspected sleep disorders. It also evaluates the budget impact of publicly funding level 2 polysomnography and the experiences, preferences, and values of people with suspected sleep disorders.

Background

Health Condition

Sleep and Fatigue

Sleep is vital for cognitive, physical, and emotional health. It is recommended that adults aged 18 to 64 years get 7 to 9 hours and older adults get 7 to 8 hours of sleep per night.[1,2] However, Canadian adults get an average of 7.12 hours of sleep per night, and only 65% of adults aged 18 to 64 years and 54% of older adults get the recommended number of hours.[1] Moreover, half of the population report concerns about their quality of sleep, frequently having difficulties falling asleep or staying asleep.[1]

Insufficient sleep, both in quality and quantity, has been associated with poor physical and mental health outcomes.[1,3,4] There is a 13% higher rate of chronic stress and there are twice as many Canadian adults with poor mental health among people who report insufficient sleep compared with those who report adequate sleep.[5-8] Insufficient sleep has been linked to anxiety, depression, and obsessive compulsive disorders.[9-11] Furthermore, it is well documented to have detrimental effects on other disorders and may reduce the effectiveness of medications intended to treat high blood pressure, mood disorders, and epilepsy.[12] Insufficient sleep also increases the risk of developing chronic kidney disease, and cardiometabolic risk, which affects insulin sensitivity and increases the risk for developing diabetes.[13-15] Insufficient sleep can also lead to cognitive impairment, which can be a danger in certain circumstances, such as when driving.[16] The Canadian Safety Council published in 2009 that 21% of car accidents were related to fatigue.[17]

Sleep Disorders

There are more than 80 recognized sleep disorders.[18] Sleep disorders can be categorized into the following groups: problems falling and staying asleep (e.g., insomnia), sleep-related breathing disorders, central disorders of hypersomnolence, sleep-related movement disorders, circadian rhythm–related problems, and parasomnias (e.g., sleep walking or talking).[12] Furthermore, disturbances in sleep can provide insights into medical conditions such as seizure disorders, Parkinson disease, and dementia (email communication: Murray Moffat; Dec 5, 2022).

Insomnia is a dissatisfaction with sleep quality or duration when having difficulty falling asleep or staying asleep for more than 3 nights a week over a prolonged period (i.e., more than 3 months).[19] It is considered to be the most prevalent sleep disorder in Canada, resulting in large amounts of absenteeism and reduced productivity.[6] Insomnia can be considered a clinical diagnosis, and a sleep study may be

needed to rule out other potential confounding sleep disorders, such as sleep apnea[20] (also email communication: Clodagh Ryan, Dec 5, 2022; Murray Moffat, Mar 27, 2023). It is also recommended that patients struggling with insomnia be assessed for underlying conditions such as psychiatric disorders.[21,22] Treatment recommendations include addressing any underlying conditions such as apnea, or psychiatric disorders, and if necessary cognitive behavioural therapy alone or in combination with medication, as may be appropriate for individual patient needs.[21-26]

Obstructive sleep apnea is another of the most common sleep disorders among Canadians. *Sleep-disordered breathing* is a general term that includes the commonly known and diagnosed obstructive sleep apnea, which is characterized by repetitive episodes during which there is complete or partial upper obstruction of airflow in the airway during sleep, despite ongoing respiratory efforts, and lasts a minimum of 10 seconds.[27] These events often cause blood oxygen saturation levels to fall and are usually terminated by brief arousals from sleep. Periodic pauses in breathing cause stress on the cardiovascular system (as a result of the body experiencing low oxygen and elevated carbon dioxide levels).[28] People with sleep-disordered breathing have reported lower quality of life and cognitive function.[29]

Other forms of apnea are less common: Central sleep apnea occurs when breathing stops because the parts of the brain that coordinate and control breathing-related activity do not function properly; these areas are also associated with neurological disorders and other conditions (such as heart failure).[27] Mixed sleep apnea comprises both obstructive and central sleep apnea.[27]

Apnea is often diagnosed and assessed by calculating the apnea hypopnea index (AHI) – the total number of episodes of apnea and hypopnea divided by the total sleep time. The severity of obstructive sleep apnea is categorized using AHI value; While there are no standard definitions, generally accepted thresholds are AHI *greater than 5* for mild obstructive sleep apnea and *greater than 15* for moderate-to-severe obstructive sleep apnea, with some higher thresholds such as greater than 20, or 25 being considered very severe obstructive sleep apnea.[30] A similar metric is the respiratory disturbance index – the total number of episodes includes episodes in which the person awakens from greater respiratory effort in addition to those from apnea and hypopnea and is also divided by the total sleep time.

Potential Benefits of Treating Sleep Disorders

Treating sleep apnea improves sleep quality, reduces risk for comorbidities, improves patient outcomes and quality of life, and reduces health care utilization.[31] Health care costs and utilization among people with untreated sleep disorders, especially obstructive sleep apnea, are high, and early detection and treatment (e.g., using positive airway pressure devices when sleeping) could lead to cost-savings for a health system.[32-34] One Canadian study estimated that the total economic costs of insufficient sleep are approximately $485 million.[35] Similar findings of economic burden are also seen in the pediatric population; children with obstructive sleep apnea have more hospital visits, especially from their first year to just prior to diagnosis, and estimates suggest that health care services are used more than twice as much by children with obstructive sleep apnea (largely because of respiratory morbidities) than by children without obstructive sleep apnea.[31]

The least invasive treatments for obstructive sleep apnea are the use of positional devices that alter sleeping position (such as pillows), oral appliances (such as a mandibular advancement device), and medications (such as steroids administered through the nose) to keep the upper airway open during sleep.[36,37] Additionally, because obstructive sleep apnea is highly correlated with obesity,

treatments for weight loss including lifestyle changes and bariatric surgery may reduce the severity of apnea episodes.[2,38,39]

If more intensive treatments are needed, there are positive airway pressure devices, which force a gentle stream of compressed room air through a mask into a person's upper airway to help the airway remain open.[40] Continuous positive airway pressure (CPAP) devices[2,38,39] are the most commonly used treatment for moderate-to-severe obstructive sleep apnea[39,41] Other types of devices are autotitrating positive airway pressure (APAP) and bilevel positive airway pressure (BPAP) devices.[2,38,39] A 2022 systematic review and meta-analysis found that the use of positive airway pressure devices improved patient symptoms – demonstrated by reduced Epworth Sleepiness Scale scores.[42] However, another review[43] found that there were too few well-conducted comparative studies to be able to determine the impact of CPAP on long-term patient outcomes based on disease severity, patient characteristics, or type of CPAP used.

Patients may require surgery to improve airflow through their airway when positive airway pressure devices are not well tolerated or effective.[32-34] For children, American Academy of Pediatrics guidelines recommend adenotonsillectomy as a primary treatment; this treatment was found to improve obstructive sleep apnea symptoms.[44] The use of CPAP was also found to be effective in children; however, due to issues with adherence in this population, CPAP was not recommended as a first-line treatment.[44]

Clinical Need and Population of Interest

In Canada, insufficient sleep is widespread, with one-half of adults reporting having trouble either falling asleep or staying asleep and one-third of adults reporting having difficulty staying awake.[6] Approximately 6% to 10% of adults in Canada have severe insomnia.[45] In 2016 and 2017, 6.4% of adults in Canada had sleep apnea diagnoses – an increase from 2009 when only 3% of adults had sleep apnea diagnoses.[46] Older age is a risk factor for disordered sleep, with diagnoses of apnea[46] and incidence of fatigue-related fatal vehicle accidents[16] increasing with age.[47] Sleep disorder breathing, such as obstructive sleep apnea, is estimated to occur in between 1 to 5% of children.[44,48]

Globally, approximately 936 million people have obstructive sleep apnea, but prevalence varies greatly by country.[49,50] In New Zealand, rates are around 12.5% for men and 3.4% for women, while in the United States, 33.9% of men and 17.4% of women have obstructive sleep apnea. Switzerland has the highest rates; 83.8% of men and 60.8% of women having sleep apnea.[47] In Japan, a study with healthy adults without obesity found that one-quarter of individuals had airflow limitations during sleep and were thus at risk for obstructive sleep apnea.[51] Global prevalence of obstructive sleep apnea in children has been estimated between 0.1 (in Singapore) to as high as 13% (in Italy).[49]

Ontario may be providing insufficient access to testing to people with suspected sleep disorders. In 2011, the Canadian Thoracic Society recommended that all patients with suspected sleep disorders be seen by a sleep specialist within 6 months of referral. However, this is not the case in Ontario, with average wait times being close to 1 year for both adults and children[52-54] (also, email communications: Murray Moffat; Dec 5, 2022; Reshma Amin; Apr 12, 2023) A 2020 study in Alberta found that shorter wait times for diagnosis were associated with better patient outcomes and better adherence to treatments.[51]

Current Diagnostic Pathway

In Ontario, the current pathway (Figure 1) for diagnosing suspected sleep disorders that are covered by the Ontario Health Insurance Plan (OHIP) begins when a patient visits their primary care provider with concerns about their sleep, either because they are experiencing sleep problems (such as insufficient sleep) or because another person (usually, a partner, parent, or guardian) has noticed signs of concern such as snoring or episodes of apnea.

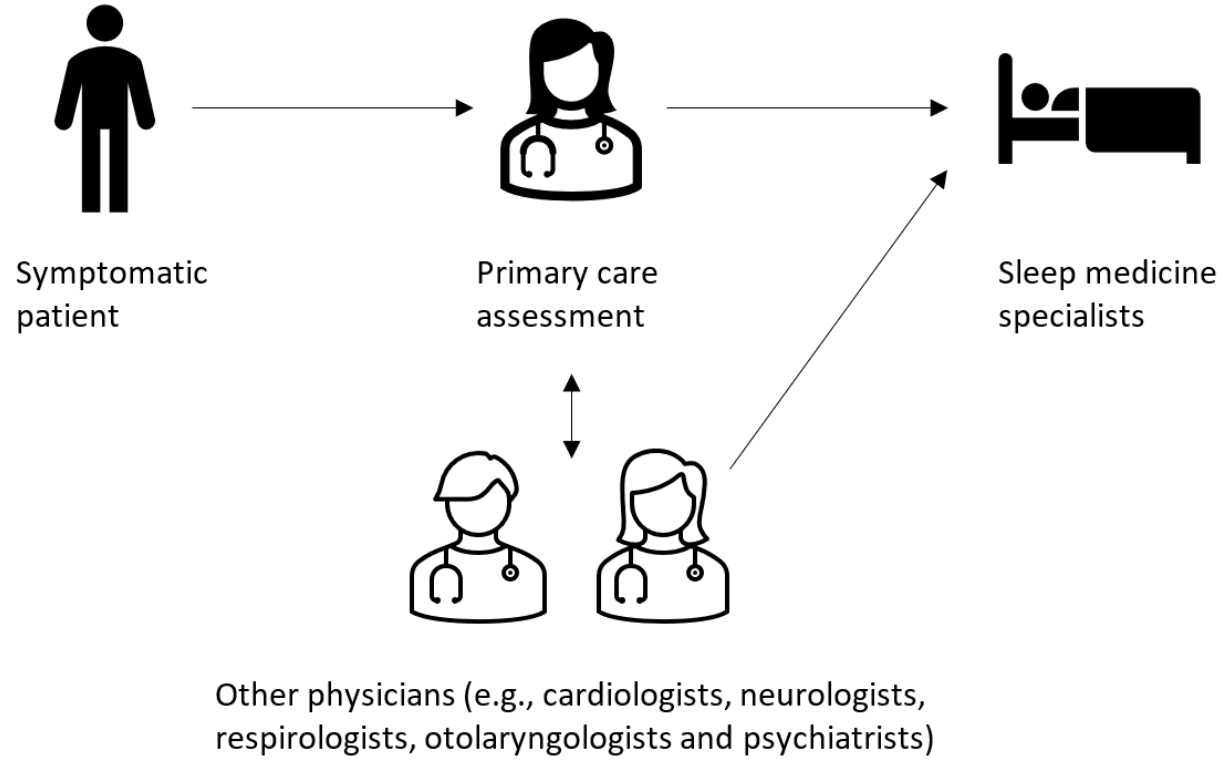

Figure 1: Simplified Clinical Pathway for the Diagnosis of Sleep Disorders in Ontario

The symptomatic patient is assessed by their primary care provider, who conducts a clinical history (which may include asking about symptoms, such as snoring) and considers the patient's clinical health factors, such as obesity, medication use, or other substance use. Adults and children for whom there is suspicion of a sleep disorder may then be referred to a sleep medicine specialist or may first be referred to other specialists (e.g., cardiologist, neurologist, respirologist, otolaryngologists, and psychiatrists) to undergo further diagnostic assessment prior to being referred to a sleep medicine specialist.

For adults, a clinician may use a validated questionnaire, such as the Athens Insomnia Scale[12] or the STOP-Bang tool,[55-57] to help them determine whether there is a risk of the patient having a sleep disorder and if referral for additional diagnostic testing is warranted.[55-58] The clinician may then refer the patient to a sleep medicine specialist to be evaluated for a suspected sleep disorder including conditions of which the patient is unaware such as obstructive sleep apnea, if the patient has hypertension, snores, or has excessive sleepiness (email communication: Murray Moffat; Dec 5, 2022). Patients may also be referred to mental health specialists to determine if there is an underlying psychiatric condition, especially if symptoms persist despite treatment[59] (also, email communication: Murray Moffat; Dec 5, 2022). Other clinical specialists (Figure 1) – commonly cardiologists, neurologists, respirologists,

otolaryngologists, and psychiatrists – may also refer patients directly to sleep medicine specialists (email communication: Murray Moffat; Mar 27, 2023; Clodagh Ryan; Dec 5, 2022).

Parents or guardians of children might first present to primary care when they notice signs of concern, such as snoring or apnea. An expert with whom we spoke (email communication: Reshma Amin, Apr 12, 2023) noted that children may present with hyperactivity or inattention, or recurrent upper respiratory tract infections or other comorbidities that may put children at risk for obstructive sleep apnea. Unlike in adults, there are no known validated clinical questionnaires for the pediatric population to support the assessment for the risk for sleep disorders (email communication: Reshma Amin; Apr 12, 2023). The primary care provider may also refer the child to an ear-nose-throat specialist if apnea is suspected or there is a history of symptoms such as snoring and gasping, if there have been witnessed episodes of apnea, or if adenotonsillar hypertrophy is suspected (email communication: Reshma Amin, Apr 12, 2023).

Adults and children for whom there is suspicion of a sleep disorder are referred to sleep specialists and may undergo further diagnostic assessments. The most common form of a sleep study is overnight sleep testing known as polysomnography. Currently, the only publicly funded option in Ontario is level 1 polysomnography, which takes place in a sleep clinic run by either a hospital or an independent health facility.

Polysomnography

Polysomnography is the most comprehensive type of sleep test used to diagnose and monitor sleep disorders. Different types of sleep studies are referred to by level, from 1 through 4 (Table 1), with level 1 being the most comprehensive. Although there are no official standard definitions for these levels,[60-62] the Ontario clinical experts with whom we consulted confirmed that the descriptions in Table 1 are generally accepted (email communications: Murray Moffat and Clodagh Ryan; Dec 5, 2022); similar descriptions of the levels have been published by the joint entity the Canadian Sleep Society/Canadian Thoracic Society.[63]

Table 1: Sleep Study Levels

Test features	Level 1	Level 2	Level 3	Level 4
Indications for use	Diagnosing, monitoring, or titrating to adjust treatment for sleep disorders	Diagnosing suspected sleep disorders in people otherwise not at risk for complex comorbidities, such as COPD or neurological disease	Diagnosing suspected obstructive sleep apnea	Screening for obstructive sleep apnea
Location and personnel	In a laboratory,[a] fully attended	At home, unattended A technician may set up the equipment	At home, unattended	At home, unattended
Number of parameters monitored	≥ 7	≥ 7	≥ 3	≥ 1
Parameters typically	Oxygen level (pulse oximetry) Airflow Respiratory effort Brain activity (via EEG) Heart activity (via ECG) Eye activity (via EOG) Muscle activity (via EMG, on the chin and leg) Other (such as synchronized video and body position)	Oxygen level (pulse oximetry) Airflow Respiratory effort Brain activity (via EEG) Heart activity (via ECG) Eye activity (via EOG) Muscle activity (EMG, on the chin or leg) Optional: synchronized video and body position	Oxygen level (pulse oximetry) Airflow Respiratory effort Heart rate	Oxygen level (pulse oximetry)

Abbreviations: COPD, chronic obstructive pulmonary disease; ECG, electrocardiography; EEG, electroencephalography; EMG, electromyography; EOG, electrooculography.

[a]At a sleep clinic within an independent health facility or hospital.

Sleep studies can be used to help identify and diagnose potential underlying causes of sleep disturbances and are required prior to beginning certain treatments, such as treatment with positive airway pressure devices for sleep apnea.[64] A level 1 sleep-study, known as polysomnography, is the current standard of care in clinical practice in Ontario today. Level 1 polysomnography captures more than 7 parameters and informs clinicians about brain activity, eye movement, muscle activity, breathing rate and depth, and oxygen levels during sleep.[60] In Ontario, level 1 polysomnography is conducted under the supervision of a sleep specialist at designated sleep clinics.[12] Some sleep clinics are run through hospitals, but most are run by independent health facilities in accordance with the College of Physician and Surgeons of Ontario Practice Parameters and Facility Standards for Sleep Medicine, with public funding through OHIP. OHIP covers the cost of an initial diagnostic level 1 sleep-study per lifetime and repeat studies every 12 months, when deemed clinically necessary, as well as a therapeutic study every 2 years[64] (email communication: Murray Moffat; Mar 27, 2023; Ontario Ministry of Health [MOH]; Aug 9, 2023).

Although level 1 polysomnography is the standard test used in clinical practice, it has many limitations, including long wait times and limited availability. People in Ontario who started treatment for obstructive sleep apnea in 2010 reported having waited approximately 1 year between their initial visit and starting treatment, and limited sleep clinic availability was reported as the primary factor.[53] Less than one-half of Ontario CPAP users underwent a sleep study within 6 months of their referral, and wait times were even longer for females, people who had been recently hospitalized, and people who

accessed testing through the hospital (as opposed to those who accessed testing through an independent health facility).[65] Sleep study wait times for children are also estimated to be between 1 and 2 years; large variations exist throughout Canada due to access to pediatric facilities and practitioner-to-children ratios[48,49] (also, email communication: Reshma Amin; Apr 12, 2023).

Some people may face challenges in accessing testing that is conducted in clinic (e.g., transportation; care partner responsibilities; patients with limited mobility, after stroke or spinal cord injury, or requiring dialysis equipment that cannot be easily brought to a sleep clinic).[66] Furthermore, not everyone is comfortable with the idea of sleeping in an unfamiliar clinical environment while being monitored, and if they undergo a sleep study nonetheless, their quality of sleep may not be representative of sleep in their home environment.

Around the world, restrictions put in place during the COVID-19 pandemic limited access to sleep testing. In parts of Asia and Europe, the number of diagnostic sleep tests performed at home overtook that of in-clinic sleep tests.[67-69] A similar pressure was felt in Ontario, intensifying the need for alternatives to in-clinic sleep testing (email communication: Murray Moffat; Dec 5, 2022). Many clinicians are finding that patients are reluctant to return to in-clinic testing and have avoided undergoing sleep tests because they do not feel comfortable in such an environment (email communication: Murray Moffat; Dec 5, 2022; Clodagh Ryan; Dec 5, 2022).

Health Technology Under Review

A level 2 polysomnography device is a portable version of the reference standard (i.e., a level 1 polysomnography device), which can offer the convenience of having testing done outside of a sleep clinic, such as in a patient's home. Level 2 polysomnography devices, like level 1 devices, evaluate 7 or more different parameters; however, because testing is conducted outside of a sleep clinic, they are conducted unattended by a clinician or technicians who would not be present during sleep.[60,70] Level 2 polysomnography differs from level 3 and level 4 testing (sometimes referred to as polygraphy), which are used as adjunct diagnostic tools for obstructive sleep apnea (for confirmation or to rule-in a diagnosis) and are not intended to be replacements for level 1 testing. American Academy of Sleep Medicine 2017 guidelines[2] state that when findings from level 3 testing do not indicate obstructive sleep apnea is present, but clinical symptoms suggest there is a high risk for apnea, then level 1 testing should be conducted to confirm the findings. These guidelines[2] do not specify when level 2 testing should be used. There have been occasions when it was suspected that the findings of a level 1 (in-clinic and attended) sleep study were falsely negative, and consequently, a level 2 (unattended, at-home) sleep study revealed findings that warranted a diagnosis.[71]

The focus of this HTA is level 2 polysomnography, for a clinically appropriate population, as an alternative option to level 1 polysomnography. Level 2 polysomnography would not be appropriate for all patients; for example, level 1 testing would still be required for people who might have comorbidities (such as seizures) that require health professional or caregiver presence or when visual confirmation of body position or movements during sleep is deemed necessary.[70]

Level 2 polysomnography devices may be set up by technicians, either in the sleep clinic that a patient visits on the day of their test or in the patient's home, or patients may be given instructions to set up the device themselves.[72] Level 2 polysomnography devices typically include a bedside digital recorder to capture data overnight, and some may include computational algorithms for diagnostic assessment. Level 2 polysomnography devices should have the capability of having their data reviewed by a sleep specialist.[73-88]

Level 2 devices have been evaluated in their capacity to measure sleep-related variables (e.g., total sleep time, rapid eye movement sleep stages) and to produce similar electroencephalography (EEG) findings compared with those produced by level 1 devices; studies have validated device measurement capabilities and have demonstrated that level 2 device capabilities are reasonably similar to those of level 1 devices.[80,85,87,88] The key criterion for a sleep study is demonstrating the capability of capturing appropriate sleep metrics that are interpretable by a sleep specialist, and thus, level 2 polysomnography is adequate.[80,85,87,88] When sleep data are not interpretable by a sleep specialist, either due to technical or other failure, patients will typically be asked to repeat the test, which ideally takes place on the following night (email communications: Murray Moffat; Mar 30, 2023; Clodagh Ryan; Mar 21, 2023).

Regulatory Information

There are 2 known sleep assessment systems for level 2 polysomnography that have active Class II Canadian medical device licences:

- The Cerebra Sleep System (Health Canada licence no. 102014), marketed as Prodigy, was first issued in November 2018 and has a related sleep monitor (Health Canada licence no. 96118). There was a recall in 2020,[89] which the manufacturer has informed us was immediately resolved (email communication, Cerebra Medical Ltd., May 8, 2023)
- The Nox A1 PSG system holds an active licence (Health Canada licence no. 95411), which was first issued in July 2015[90]

Ontario, Canadian, and International Context

Ontario

Ontario does not currently publicly fund any at-home sleep testing (e.g., level 2 polysomnography).

Level 1 polysomnography is publicly funded, and is a requirement prior to accessing public funding to prescribed positive airway pressure devices.[64] Funding assistance for positive airway pressure devices is provided by the Ministry of Health's Assistive Devices Program (ADP) for patients who meet ADP medical eligibility criteria (email communication: MOH ADP; Jul 11, 2023). The Ministry of Health's ADP assistance is applied toward the cost of a positive airway pressure device only at 75% up to a maximum fixed price set by the program (email communication: MOH ADP; Jul 11, 2023). Individuals may qualify for 100% coverage through the Ministry of Children, Community and Social Services if they are candidates for Ontario Works, Ontario Disabilities Support Program or Assistance for Children with Severe Disabilities (email communication: MOH ADP; Jul 11, 2023). A physician registered with the ADP as a prescriber for positive airway pressure systems must assess each client (email communication: MOH ADP; Feb 1, 2023). The physician must indicate a diagnosis of obstructive sleep apnea syndrome and confirm that the applicant meets all the medical eligibility criteria for a positive airway pressure device (email communication: MOH ADP; Feb 1, 2023). The assessment must include a level 1 polysomnography, performed at an ADP Registered Sleep Laboratory (email communication: MOH ADP; Feb 1, 2023). The level 1 polysomnography must show evidence of obstructive sleep apnea syndrome during sleep and the presence of significant symptoms or medical risks without treatment, and the absence of symptoms or risks with treatment (email communication: MOH ADP; Feb 1, 2023).

Canada

In Canada, there are a few independent health facilities that offer at-home testing with level 2 and 3 devices, but we were unable to determine whether this is available in Ontario as an out-of-pocket expense for patients or covered by private insurance.[91] A 2019 jurisdictional scan found that Nova Scotia, Quebec, Manitoba, Saskatchewan, Alberta, and British Columbia provide funding for level 3 sleep apnea testing, with various funding models, but Ontario does not.[92] As of February 2023, Manitoba has started a pilot project to expand the use of home testing, with a level 2 polysomnography device.[93] As of August 2023, no other province or territory offered publicly funded level 2 polysomnography.

International

College of Physicians and Surgeons of Ontario standards[64] for independent health facilities refer to American Academy of Sleep Medicine[2] and European Sleep Society guidelines[94]; all 3 consider in-clinic level 1 polysomnography to be the standard of care for sleep disorder diagnostic testing. American Academy of Sleep Medicine guidelines acknowledge that some patients may benefit from level 3 at-home testing for obstructive sleep apnea and stipulate that level 3 sleep-studies with seemingly normal findings for a person with a high-probability of obstructive sleep apnea should be confirmed with level 1 (in-clinic) polysomnography.[95] Level 3 testing, however, is not recommended for children with suspected obstructive sleep apnea.[95]

At-home testing is widely available in the United States, which includes level 2 and 3 devices. Level 2 polysomnography is available in some international health care systems: Level 2 polysomnography is used in Portugal,[96] is recommended by the Asian Pacific Society of Cardiology,[97] and is a publicly funded service for adults in Australia[71,99] (and there is a review[100] underway to support a potential funding decision about its use for children in Australia).

Equity Context

There are some differences in symptom severity[98] between sexes, and prevalences[47] of sleep disorders vary by region. One study of international data found that there were variations in sleep apnea prevalence between countries and sexes[47]: For example, rates were approximately 12.5% for men and 3.4% for women in New Zealand, 33.9% for men and 17.4% for women in the United States, 83.8% for men and 60.8% for women in Switzerland, and 13.5% for men and 6.1% for women in India; only in Singapore were rates similar for men and women (both 70.8%). Qin et al[99] surmised this variation can be attributed to differing definitions of obstructive sleep apnea, as well as genetic and hereditary variation, but likely also differences in obesity rates, which is highly correlated with obstructive sleep apnea. Additionally, another study found that geographic elevation altered diagnostic findings, thus emphasizing the importance of having testing take place in an environment similar to a person's regular sleep setting.[100]

A Canadian study found that only 5.1% of people at risk for obstructive sleep apnea were referred to a sleep clinic, with predictors for referral (beyond symptoms of sleep apnea) being male, middle age, or obese; having a chronic condition; and having a regular primary care physician.[101] There may also be inequities of access in Ontario on the basis of gender and specific setting. One study found that females with CPAP devices had to wait longer to get them compared with the males in the study and people who accessed testing through a hospital had to wait longer than people who accessed testing through a community testing centre.[65] Furthermore, access to sleep specialists and sleep testing facilities may be more difficult for people in Ontario who live in remote and rural communities. However, should at-

home testing be made available in Ontario, for some devices or some patients, technician assistance may be required (e.g., to apply the electrodes). If such an in-person visit to a sleep clinic is required of the patient, the burden of testing access would not be alleviated for people living in remote communities that lack local facilities (email communication: Clodagh Ryan; Dec 5, 2022).

Finally, there may be differences in the performance of EEG devices (which is an integral part of level 1 and level 2 sleep-studies) for people with coarse and curly hair (which includes but is not limited to people of African descent). There can be challenges in placing electrodes against the scalp in such a way that signals are captured properly when hair is thick, coarse, curly, or worn in particular styles. It is unclear to what extent such difficulties may be relevant in Ontario, but it has been reported in the United States that having some hair types or hairstyles has been a barrier to accessing EEGs.[102] Efforts are being made to develop guidance about specific types of braids and other hair styles that may support EEG use, as well as new clips to hold electrodes into place for people with coarse and curly hair.[103]

Preferences and Values

Some patients may prefer to undergo an overnight sleep study at home instead of at a sleep clinic. In a study with patients who were found to have no differences measured in general health, vitality, social functioning, and physical and mental health with testing at-home versus in-clinic testing, it was demonstrated that patients did feel better when tested at home, which led to improved adherence to treatment (e.g., CPAP).[104] Some patients preferred to have their initial assessment conducted by primary care providers but have further diagnostic testing from a sleep specialist for confirmation; there was also a strong preference for hospital-run testing centres compared with for-profit private sector centres.[105,106] Similar preferences were found in pediatric population with a study in children, where parents and guardians reported that their children slept normally during at-home sleep studies (i.e., level 2 polysomnography).[107]

In addition, because level 1 sleep-studies are fully attended and conducted in clinic, patients are required to make time in their schedule (potentially an evening, overnight, and part of the next day), which may be difficult if they have caregiver responsibilities. Patients may also have concerns about being fatigued and unable to function or work the next day.

Physicians preferences were found to be based on high expectations for diagnostic sensitivity and reliability of the equipment, with low interference with patient habits being the primary factor in physicians choosing to adopt home testing.[108]

Expert Consultation

We engaged with adult and pediatric experts in the specialty areas of adult and pediatric sleep medicine, and respirology to help inform our understanding of aspects of the health technology and our methodologies and to contextualize the evidence.

PROSPERO Registration

This health technology assessment has been registered in PROSPERO, the international prospective register of systematic reviews (CRD42023392914), available at crd.york.ac.uk/PROSPERO.

Clinical Evidence

Research Question

What is the test performance of level 2 polysomnography (unattended, at-home sleep studies) for diagnosing sleep disorders compared with level 1 polysomnography (attended, in-clinic sleep studies) for adults and children with suspected sleep disorders?

The clinical utility of level 2 polysomnography is presumed as it is being proposed as an alternative to level 1 polysomnography and thus its clinical utility would be comparable.

Methods

Clinical Literature Search

We performed a clinical literature search on January 5, 2023, to retrieve studies published from database inception until the search date. We used the Ovid interface in the following databases: MEDLINE, Embase, the Cochrane Central Register of Controlled Trials, the Cochrane Database of Systematic Reviews, the National Health Service Economic Evaluation Database (NHS EED), and APA PsycINFO.

A medical librarian developed the search strategies using controlled vocabulary (e.g., Medical Subject Headings) and relevant keywords. The final search strategy was peer-reviewed using the PRESS Checklist.[109]

We created database autoalerts in MEDLINE, Embase, and PsycINFO and monitored them until May 2023. We also performed a targeted grey literature search of the International HTA Database, HTA organizations and regulatory agencies websites, and clinical trial and systematic review registries, following a standard list of sites developed internally. (Appendix 1 contains literature search strategies, including all search terms.)

Eligibility Criteria

Studies

Inclusion Criteria

Systematic reviews and HTAs were reviewed to determine if they met inclusion criteria and were also considered comprehensive and recent enough to sufficiently address the research question in the Ontario context. Because none were considered adequate to leverage, primary studies were reviewed according to the following criteria:

- English-language full-text publications
- Diagnostic accuracy studies or comparative design primary studies

Exclusion Criteria

- Animal or in vitro studies
- Nonsystematic reviews, narrative reviews, abstracts, editorials, letters, case reports, or commentaries

Participants

Inclusion Criteria

- Adults (≥ 18 years of age) with suspected sleep disorders
- Children (< 18 years of age) with suspected sleep disorders

Exclusion Criteria

- Healthy participants (validation study)

Index Test

Inclusion Criteria

- Use of level 2 polysomnography devices (for unattended, at-home clinical sleep studies; as defined in Table 1) that are capable of monitoring a combination of the following:
  - Oxygen levels
  - Airflow
  - Respiratory effort
  - Brain activity (electroencephalography [EEG])
  - Heart activity (electrocardiography)
  - Eye activity (electrooculography)
  - Muscle activity (electromyography on the chin and/or leg)
  - Optional: synchronized video monitoring, and body position

Exclusion Criteria

- Use of level 2 polysomnography devices for any purpose other than diagnostic (such as monitoring or treatment adjustment)

Target Condition

- Any clinically diagnosed sleep disorder for which polysomnography would be indicated.

Reference Test

- Level 1 polysomnography devices (for fully attended, in-clinic sleep studies)

Outcome Measures

- Outcomes related to the diagnostic accuracy of sleep disorder diagnoses such as:
  - True positives, false positives, true negatives, and false negatives
  - Sensitivity
  - Specificity
  - Positive and negative predictive values
- Test failure rates and follow-up
- Rate of technical issues with the device that precludes the ability to get a finding (e.g., computer failure, probes fell off, device failed, insufficient total sleep time)
- Follow-up procedures, including if additional testing was repeated or other test (e.g., level 1) was required

Literature Screening

Two reviewers (SV and AS) independently screened titles and abstracts of a sample of 100 citations to validate the inclusion and exclusion criteria. All disagreements were discussed to determine if sufficient agreement (> 80%) was reached. If necessary, the exercise would have been repeated with a further sampling of 50 citations until sufficient agreement was reached. One reviewer (SV) then screened all remaining citations using Covidence systematic review management software,[110] obtained the full texts of studies that appeared to be eligible for inclusion in the review, and examined the full-text articles to identify those that met the inclusion criteria. The second reviewer (AS) was consulted, along with clinical experts, to confirm which full-text articles should be included.

During scoping, no reviews were identified that were considered sufficiently comprehensive or recent to be considered adequate to be leveraged; however, the reference lists of systematic reviews and health technology assessments identified during screening as well as included studies were also examined by 1 reviewer (SV) for any relevant studies not identified through the search.

Data Extraction

One reviewer (SV) extracted relevant data on study design and characteristics, risk-of-bias items, results, and study details such as population, index test, reference test, and outcomes.

Equity Considerations

We used PROGRESS-Plus, a health equity framework recommended by the Campbell and Cochrane Equity Methods Group,[111] to explore potential inequities for this health technology assessment. Factors that may lead to disadvantage or inequities in the framework include place of residence; race, ethnicity, culture, or language; gender or sex; disability; occupation; religion; education; socioeconomic status; social capital; and other key characteristics that stratify health opportunities and outcomes. We sought, but did not identify any equity considerations relevant to the effectiveness of level 2 polysomnography when compared with level 1 polysomnography, defined by the PROGRESS-Plus categories in the included published studies.[112] However, equity considerations may exist that were not identified as part of our analysis, such as potential differences in accuracy of EEG measures for people with coarse and curly hair.[102,103]

Statistical Analysis

Because true-positive, false-positive, true-negative, and false-negative data were not always adequately reported by the studies included in this review, we were unable to conduct a meta-analysis for diagnostic accuracy. Findings are presented as a narrative synthesis of the included studies. Planned subgroups analysis based on clinical diagnosis and method of set-up (technician-applied probe vs self-applied probe) were accounted for in the final narrative synthesis of the data, and we were unable to conduct subgroup analyses planned for comorbidities or specific device types used as the information was not sufficiently available to do so.

Critical Appraisal of Evidence

We assessed risk of bias for diagnostic test accuracy using Quality Assessment of Diagnostic Accuracy Studies (QUADAS-2).[113] We evaluated the quality of the body of evidence for each outcome according to the *Grading of Recommendations Assessment, Development, and Evaluation (GRADE) Handbook* and additional GRADE publications specific to diagnostic accuracy.[114-116] The body of evidence was assessed based on the following considerations: risk of bias, inconsistency, indirectness, imprecision, and publication bias. The overall rating reflects our certainty in the evidence.

Results

Clinical Literature Search

The database search of the clinical literature yielded 3,478 citations published from database inception to January 5, 2023, including grey literature searches and after duplicates were removed. We identified 7 systematic reviews in the literature search, and their reference lists were reviewed to identify additional studies.[60,117-122] We identified 2 additional eligible studies from other sources, including database alerts (monitored until May 2023). In total, we identified 10 diagnostic accuracy studies that met our inclusion criteria. See Appendix 2 for a list of selected studies excluded after full-text review.

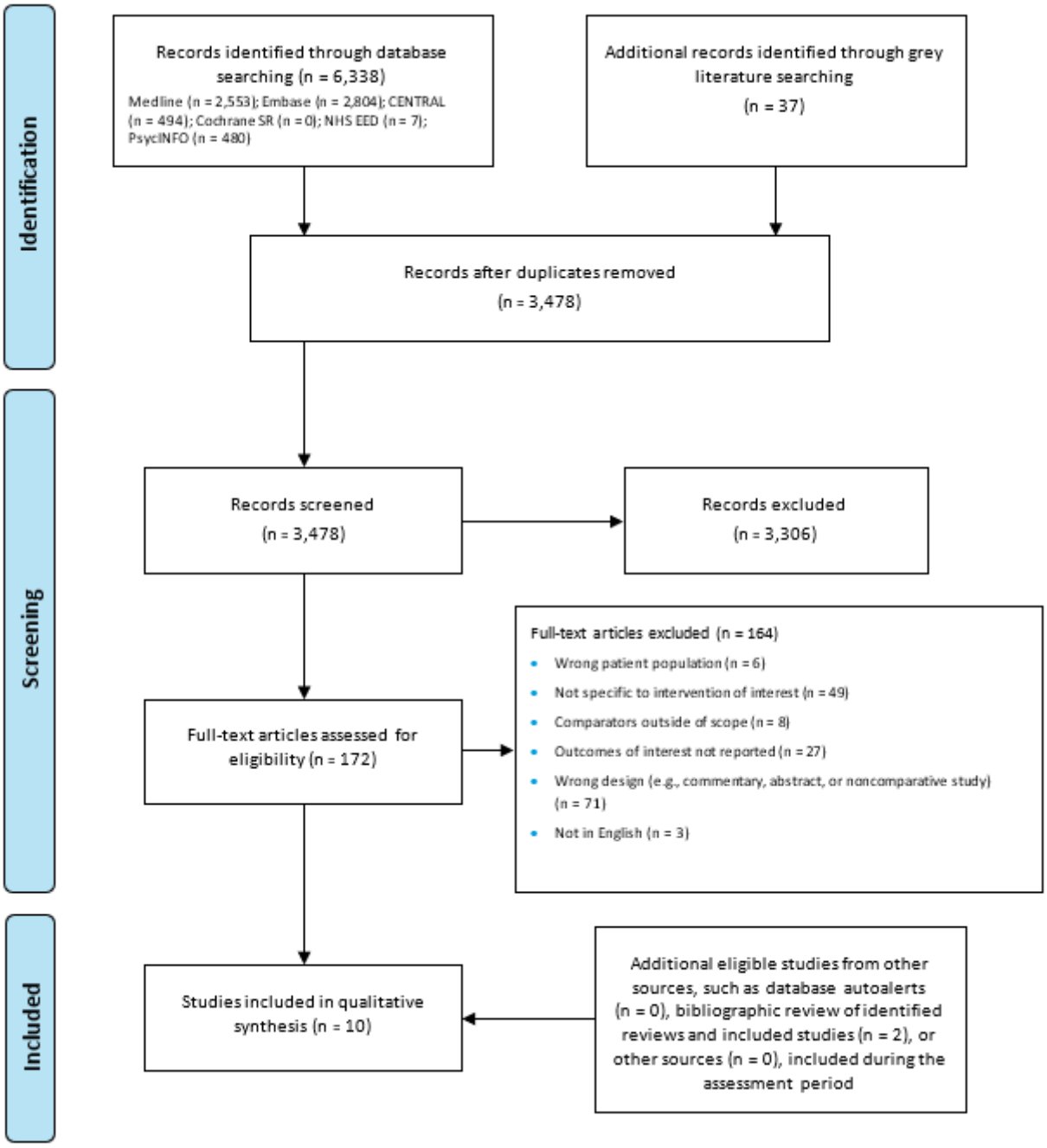

Figure 2: PRISMA Flow Diagram – Clinical Search Strategy

PRISMA flow diagram showing the clinical search strategy. The database search of the clinical literature yielded 6,338 citations published from database inception to January 5, 2023. We identified 37 records from grey literature. After removing duplicates, we screened the abstracts of 3,478 studies and excluded 3,306. We assessed the full text of 172 articles and excluded a further 164 articles. We identified 2 additional eligible studies from other sources. In the end, we included 10 articles in the qualitative synthesis and 0 in the quantitative synthesis (meta-analysis).

Abbreviation: NHS EED, National Health Service Economic Evaluation Database; PRISMA, Preferred Reporting Items for Systematic Reviews and Meta-analyses; SR, systematic review.

Source: Adapted from Page et al.[123]

Characteristics of Included Studies

In total, 10 studies met the inclusion criteria (Table 2). These studies reported the following outcomes of interest: diagnostic accuracy, failure rates, subjective measures of preference, and quality of sleep.

While polysomnography, as a testing tool, is intended to be broad in its clinical applications, all included studies were designed with a focus on a specific population of interest. There were 9 studies focused on sleep apnea (8 studies with adults[124-131] and 1 with children[132]), of which, 1 study also reported findings for periodic leg movement.[129] The final included study focused on adults with sleep bruxism.[133]

Table 2: Characteristics of Included Studies

Author, year (country)	Population (recruitment period)	N	% Male	Age, mean (SD),[a] y	BMI, mean (SD),[a] kg/m²	Study design	Test setting	
							Reference: attended (level 1 PSG)	Index test: unattended (level 2 PSG)
Abe et al, 2022[133] (Japan)	People with probable sleep bruxism, and healthy volunteers (recruited 2013–2015)	20	NR	Median 24.5 (IQR 23.3–26.8)	NR	Multisite prospective cohort Simultaneous assessment Evaluated by restricting data available for assessment Automatic and manual sleep test scoring	In clinic	In clinic
Banhiran et al, 2014[124] (Thailand)	Adults (≥ 18 y) with concerns of snoring or excessive sleepiness, excluding people who were pregnant or with significant comorbidities (recruited Sep 2011–Jan 2013)	86	56	Range 18–74	26.6 (4.0)	Single cohort, crossover 2–4-week washout after reference test	In clinic	At home, set up by technicians
Bruyneel et al, 2011[125] (Belgium)	Adults (≥ 18 y) referred by clinicians to a sleep clinic due to snoring, daytime sleepiness, and general suspicion of obstructive sleep apnea (recruitment period NR)	66	56	48.9 (13)	30.5 (7.3)	Randomized crossover trial Crossover after 2-week washout	In clinic	At home, set up by technicians
Campbell et al, 2011[126] (New Zealand)	Adults (> 18 y) with suspected obstructive sleep apnea, and who had completed 1 in-clinic sleep study successfully at start of study, excluding patients with significant psychiatric or cardiovascular comorbidities (recruitment period NR)	30	80	49.1 (13.8)	31.0 (6.1)	Randomized crossover trial All 3 sleep studies (initial assessment, reference test, index test) were conducted within a 2-week period	In clinic	At home, set up by technicians
Cunnington et al, 2009[127] (Australia)	People with high pretest probability for obstructive sleep apnea, excluding people with significant comorbidities (recruitment period NR)	37	78	42 (range 25–68)	32 (range 19–54)	Prospective cohort Simultaneous assessment Assessment was conducted by technician blinded to all study details	In clinic	In clinic
Mykytyn et al, 1999[128] (Australia)	Men, experiencing loud snoring, who were referred to sleep clinic, suspected of having obstructive sleep apnea (recruitment period NR)	20	100	46.1 (5.4)	31.5 (1.1)	Randomized trial Simultaneous assessment Half randomized to be unmonitored after hookup where technicians did not see results in real time on a laptop while the other half had results for the level 2 PSG on a laptop in real time for the technicians to view	In clinic	In clinic

Author, year (country)	Population (recruitment period)	N	% Male	Age, mean (SD),[a] y	BMI, mean (SD),[a] kg/m^2	Study design	Test setting	
							Reference: attended (level 1 PSG)	Index test: unattended (level 2 PSG)
Orr et al, 1994[129] (United States)	Patients recruited from 2 sleep clinic sites (recruitment period NR)	40	NR	NR	NR	Multisite prospective cohort Simultaneous assessment Computer assisted and manual sleep assessments	In clinic	In clinic
Portier et al, 2000[130] (France)	People referred to hospital sleep clinic (recruitment period NR)	103	82	52 (10)	31 (6.3)	Randomized crossover trial	—	—
Withers et al, 2022[132] (Australia)	Children aged 5–18 y, newly referred to clinic, with suspected obstructive sleep apnea, excluding children who may have behavioural problems at time of set-up (recruited Dec 2007–Nov 2011)	128	See rows below	See rows below[b]	See rows below[b]	Prospective cohort Home was offered based on parental preference, home environment, distance (< 30 min drive), and child size (older or larger children)		
	In-clinic group	81	60.5	Median 12.7 (SD 2.5)	Median 26.7 (SD 8.5)	Testing equipment checked at regular intervals by technicians Simultaneous assessment	In clinic	In clinic
	At-home group	47	61.7	Median 9.7 (SD 3.1)	Median 21.3 (SD 7.8)	Testing equipment checked at regular interval by parents, who were taught how to reapply leads if necessary	In clinic	At home, set up by parents
Zancanella et al, 2022[131] (Brazil)	Adults (> 18 y) with clinical symptoms that suggest high probability of obstructive sleep apnea, excluding people who are pregnant, on medications that can interfere with sleep, or people with prior PSG testing (recruited Sep 2009–Jun 2010)	40	71	40.1 (8.8)	28.2 (4.3)	Randomized crossover trial Crossover occurred within 1 night Same PSG device used for both reference and index tests	In clinic	At home, set up by technicians

Abbreviations: AHI, apnea hypopnea index; BMI, body mass index; IQR, interquartile range; NR, not reported; PSG, polysomnography; SD, standard deviation.

[a]Unless otherwise stated.

[b]Significant differences between the in-clinic and at-home groups for age ($P \leq .001$) and BMI ($P \leq .001$).

Risk of Bias in the Included Studies

There were some concerns about risk of bias among studies reporting diagnostic accuracy for sleep apnea in adults. For many of these studies, we had concerns about the administration of the polysomnography test, that is, about testing being unblinded or being conducted simultaneously with the reference standard (Appendix 3, Table A1). There was a wide range of bias across the studies; the most recently published studies – Zancanella et al, 2022,[131] for studies with adults, and Withers et al, 2022,[132] for studies with children – had the lowest risk of bias for sleep apnea assessment.

Diagnostic Accuracy

All 10 included studies report on diagnostic accuracy. While polysomnography, as a testing tool, is intended to be broad in its clinical applications, all included studies were designed with a focus on a specific population of interest. There were 9 studies focused on sleep apnea (8 studies with adults[124-131] and 1 with children[132]), of which, 1 study also reported findings for periodic leg movement.[129] The final included study focused on adults with sleep bruxism.[133]

The reference standard of level 1 polysomnography is imperfect. As demonstrated in 1 study, 11 of 25 (44%) people initially tested in clinic who were found to have apnea hypopnea index (AHI) values below the threshold value of 5 for sleep apnea had AHI values greater than 5 with home testing and were diagnosed with apnea.[124] In another study, 3 patients who were diagnosed with severe obstructive sleep apnea after in-laboratory testing were later reassessed with home testing and found to have mild and moderate apnea.[126] Similarly, Miettinen et al[134] found that, even with level 1 polysomnography that includes audio and video, some tooth grinding (i.e., sleep bruxism) may be unaccounted for. As such, herein, *accuracy* of the at-home test can be interpreted as absolute difference from, and not necessarily worse than, the reference standard.

We calculated positive and negative predictive values based on the realized prevalence rates of individual studies, as reported by the original publications unless otherwise stated. Only Bruyneel et al[125] reported prevalence; 50% of study participants were found to have moderate-to-severe sleep apnea (AHI ≥ 15).

Sleep Apnea

Adults

Of 8 studies on sleep apnea in adults, 7 were focused on the diagnosis of obstructive sleep apnea, while in 1 study, the focus was not specified, and patients were referred to as having diagnoses of sleep apnea syndrome.[130] Sleep apnea was diagnosed based on accepted AHI thresholds (AHI ≥ 5 for mild obstructive sleep apnea, AHI ≥ 15 for moderate-to-severe obstructive sleep apnea).[30] Study definitions of an episode of hypopnea varied slightly (e.g., oxygen desaturation greater than or equal to 3%[125-127] and oxygen desaturation greater than or equal to 4%[124]). Because within-study definitions of hypopnea were the same when comparing level 1 and level 2 polysomnography, this was not treated as a limitation of the review. In addition, 2 studies[129,130] reported the respiratory disturbance index, which is similar to AHI but also includes the number of arousals due to respiratory effort that may not otherwise meet hypopnea definitions.

There were insufficient data reported across the included studies to be able to calculate true-positive, false-positive, true-negative, and false-negative rates to be able to conduct meta-analyses. Across

studies with adults, reported findings for sensitivity ranged from 0.760 to 1.00, and reported findings for specificity ranged from 0.400 to 1.00 (Table 3). Overall accuracy increased with higher AHI cut-off values, (representing more severe apnea scores).

We rated the certainty in this body of evidence (GRADE) as Low, downgrading for risk of bias and imprecision (Appendix 3, Table A2).

Table 3: Diagnostic Accuracy of Level 2 Polysomnography for Sleep Apnea in Adults, by Apnea Severity (AHI Cut-Offs)

Author, year	Index test (level 2 PSG) setting	N	Diagnostic accuracy[a]		Predictive value[a]	
			Sensitivity	Specificity	PPV	NPV
AHI ≥ 5						
Banhiran et al, 2014[124]	At home	86	0.967	0.560	0.843	0.875
Bruyneel et al, 2011[125,c]	At home	62	0.960	0.710	0.920	0.860
Campbell et al, 2011[126]	At home	28	0.880	0.500	0.877[b]	0.502[b]
AHI ≥ 10						
Campbell et al, 2011[126]	At home	62	0.905	0.889	0.905[b]	0.889[b]
Cunnington et al, 2009[127]	In clinic	37	0.967	0.400	0.912	0.654
Mykytyn et al, 1999[128]	In clinic	20	0.800	0.900	Could not be estimated	Could not be estimated
AHI ≥ 15						
Banhiran et al, 2014[124]	At home	86	0.951	0.756	0.780	0.944
Bruyneel et al, 2011[125,c]	At home	62	0.760	0.850	0.730	0.880
Campbell et al, 2011[126]	At home	28	0.937	0.769	0.935[b]	0.770[b]
Cunnington et al, 2009[127]	In clinic	37	0.960	0.833	0.923	0.909
Zancanella et al, 2022[131]	At home	34	0.800	0.830	0.910	0.670
AHI ≥ 20						
Cunnington et al, 2009[127]	In clinic	37	0.957	0.786	0.880	0.918
Mykytyn et al, 1999[128]	In clinic	20	1.00	1.00	Could not be estimated	Could not be estimated
AHI ≥ 30						
Bruyneel et al, 2011[125,c]	At home	62	0.860	1.00	1.00	0.810
Cunnington et al, 2009[127]	In clinic	37	0.867	0.909	0.867	0.909
RDI ≥ 15						
Orr et al, 1994[129]	In clinic	40	1.00[b]	0.962[b]	0.933[b]	1.00[b]
RDI ≥ 30						
Portier et al, 2000[130]	At home	78	0.967	0.851	0.811	0.976

Abbreviations: AHI, apnea hypopnea index; NPV, negative predictive value; PPV, positive predictive value; PSG, polysomnography; RDI, respiratory disturbance index.

[a]Error estimates as confidence intervals were not reported and could not be calculated.

[b]Estimates were calculated based on data available in original paper.

[c]Only this study reported prevalence: 50% of study participants were found to have moderate-to-severe sleep apnea (AHI ≥ 15).

Children

In the study[132] that reported accuracy in children (Table 4), some patients were tested with simulated unattended polysomnography while physically present in the lab, and the other patients were tested at home. Based on the findings from the home setting, we rated the certainty for the body of evidence (GRADE) for specificity estimates as Moderate, downgrading for inconsistency, and for sensitivity estimates as Low, downgrading for inconsistency and imprecision (Appendix 3, Table A2).

Table 4: Diagnostic Accuracy of Level 2 Polysomnography for Mild[a] Sleep Apnea in Children

Author, year	Index test (level 2 PSG) setting	n	Diagnostic accuracy		Predictive value	
			Sensitivity (95% CI)	Specificity (95% CI)	PPV (95% CI)	NPV (95% CI)
Withers et al, 2022[132]	In clinic	78	0.946 (0.818–0.993)[b]	0.829 (0.679–0.928)[b]	0.833 (0.686–0.930)[b]	0.944 (0.813–0.993)[b]
	At home	47	0.933 (0.681–0.998)[b]	0.969 (0.838–0.999)[b]	0.933 (0.681–0.998)[b]	0.969 (0.838–0.999)[b]

Abbreviations: CI, confidence interval; NPV, negative predictive value; PPV, positive predictive value; PSG, polysomnography.
[a]Study reported findings as "mild" but did not define apnea hypopnea index cut-off value or other descriptor.
[b]Calculated based on data available in original paper for patients reported as having at least mild apnea.

Sleep Bruxism

One study[133] reported diagnostic accuracy for the condition of sleep bruxism (Table 5); sleep bruxism was defined as having an episode index greater than 4 (per hour) and a burst index greater than 25 (per hour).[133] When recalculated using optimal cut-off values to adjust for overestimations of sleep profilers and using a burst index greater than 37, the specificity improved to 0.867 (95% CI, 0.595–0.983). The study measured findings in 2 ways: They used the standard protocol of manual scoring the various parameters captured by polysomnography, and they also assessed automated scoring by the new level 2 device to compare the results of computed findings. We rated the certainty in this body of evidence (GRADE) as Very low, downgrading for risk of bias, inconsistency, and imprecision (Appendix 3, Table A2).

Table 5: Diagnostic Accuracy of Level 2 Polysomnography for Sleep Bruxism

Author, year	Method of test scoring	n	Diagnostic accuracy		Predictive value	
			Sensitivity (95% CI)	Specificity (95% CI)	PPV (95% CI)	NPV (95% CI)
Abe et al, 2022[133]	Automatic scoring	20	1.00 (0.478–1.00)	0.467 (0.213–0.734)	0.385 (0.280–0.501)	1.00 (NR)
	Manual scoring	20	1.00 (0.478–1.00)	0.600 (0.323–0.837)	0.455 (0.310–0.608)	1.00 (NR)

Abbreviations: CI, confidence interval; NPV, negative predictive value; NR, not reported; PPV, positive predictive value.

Periodic Leg Movement

One study reported diagnostic accuracy for the condition of periodic leg movement (Table 6). We rated the certainty in this body of evidence (GRADE) for sensitivity estimates as Very low, downgrading for risk of bias, inconsistency, and imprecision and for specificity estimates as Low, downgrading for risk of bias and inconsistency(Appendix 3, Table A2).

Table 6: Diagnostic Accuracy of Level 2 Polysomnography for Periodic Leg Movement

Author, year	N	Limb movements per hour	Diagnostic accuracy		Predictive values	
			Sensitivity (95% CI)	Specificity (95% CI)	PPV (95% CI)	NPV (95% CI)
Orr et al, 1994[129]	40	≥ 20	0.889 (0.517–0.997)[a]	0.967 (0.833–0.999)[a]	0.889 (0.517–0.997)[a]	0.968 (0.833–0.999)[a]

Abbreviations: CI, confidence interval; PPV, positive predictive value; NPV, negative predictive value.

[a]Calculated based on data available in original paper.

Failure Rate

Failure rates were reported by all 10 studies (Table 7). There was heterogeneity in how failure was defined; some studies reported it as unsatisfactory data, others as excluded tests due to inadequate data, and still others simply referred to failure rates without any definition. For the purpose of this review, all data types are summarized as failure rates because the tests would not be considered adequate for clinical decision-making. We rated the certainty in this body of evidence (GRADE) as Very low, downgrading for risk of bias, inconsistency, and imprecision (Appendix 3, Table A2).

Table 7: Reported Test Failure Rates of Level 1 and Level 2 Polysomnography

Author, year	N	Index test (level 2 PSG) setting and set-up	Failure rate, %		Information provided by paper
			Reference test	Index test	
Adults, sleep apnea					
Banhiran et al, 2014[124]	86	At home, set up by technician	0	4.7	Failed tests were repeated, with 0% failure rates after second attempt Data loss (oximetry and EEG data)
Bruyneel et al, 2011[125]	66	At home, set up by technician	1.5	4.7	No significant difference between groups (P = .36) Data loss due to technical failure of sensor
Campbell et al, 2011[126]	30	At home, set up by technician	0	6.7	—
Cunnington et al, 2009[127]	37	In clinic, simultaneous assessment, set up by technician	0	0	—
Mykytyn et al, 1999[128]	20	In clinic, half simulated unattended, set up by technician	0	10	Similar failure rate observed in both the attended and unattended group (1 person represented 10% in each group)
Orr et al, 1994[129]	40	In clinic, simultaneous assessment, set up by technician	0	0	—
Portier et al, 2000[130]	103	At home, patient self set-up	5	20	Data loss due to computer error, loss of signal, and insufficient sleep time
Zancanella et al, 2022[131]	40	At home, set up by technician	0	15	Error in data was found to be due to sweating and was corrected following the crossover, and 0% error was observed in the second group
Children, sleep apnea					
Withers et al, 2022[132]	128	At home, set up by technician checked at regular intervals by parents	3.7	0	Data loss due to technical errors
Adults, sleep bruxism					
Abe et al, 2022[133]	20	In clinic, simultaneous assessment, set up by technician	0	0	—

Abbreviations: EEG, electroencephalography; PSG polysomnography.

Satisfaction

Of the included studies, 4 reported subjective measures of setting preference, and of these, 2 studies also examined sleep quality (Table 8) ; all 4 studies focused on adults with suspected sleep apnea.

We did not rate the certainty of the quality of evidence (GRADE) for these outcomes (setting preference and sleep quality) due to the narrative, descriptive, and heterogeneous nature of the reported findings.

Table 8: Summary of Subjective Measures of Setting Preference and Sleep Quality in Adults With Sleep Apnea

Author, year	N	Index test (level 2 PSG) set-up	Results	
Setting preference			**Setting**	**%**
Banhiran et al, 2014[124]	86	At home, set up by technician	Preferred home, as more convenient if all else equal	74
Bruyneel et al, 2011[125]	66	At home, set up by technician	Preferred home	67
			Preferred in clinic	16
			No preference	17
Campbell et al, 2011[126]	30	At home, set up by technician	Preferred home	50
			Preferred in clinic	25
			No preference	25
Portier et al, 2000[130]	78	At home, patient self set-up	Preferred home	28
			Preferred in clinic	48
			No preference	19
Perceived sleep quality			**Quality assessment**	***P* value**
Banhiran et al, 2014[124]	86	At home, set up by technician	More normal sleep at home, and cannot sleep in lab	.001
			Fewer awakenings at home than lab	.001
			More difficulty falling asleep in lab than at home	.005
			No difference in discomfort, unpleasant feelings	.14
			No difference in feeling insecure	.12
Portier et al, 2000[130]	78	At home, patient self set-up	More time spend in bed at home, with corresponding longer sleep evaluation time	.001[b]
			No difference in better/worse quality of sleep than usual[a]	.05

Abbreviations: PSG, polysomnography.

[a]Respondents also reported similar levels of discomfort in both home and in-clinic testing (68%–69%), with discomfort largely attributed to sensors.

Ongoing Studies

We are aware of 1 HTA and some ongoing studies that are potentially relevant to this review, including:

- Medical Services Advisory Committee (MSAC). Out-Of-Laboratory sleep studies in the diagnosis and management of sleep disordered breathing in children and adolescents 2022 April 11, 2023]. Available from: http://www.msac.gov.au/internet/msac/publishing.nsf/Content/5BA6CC81DFB1AFABCA2587FA00187650/$File/1712%20Ratified%20PICO.pdf

- Real-time Attended Home-polysomnography Through Telematic Data Transmission (sleepbox). ClinicalTrials.gov Identifier: NCT01471626. (Accessed online, May 25, 2023) Available from: https://ClinicalTrials.gov/show/NCT01471626
- Unattended In-home Sleep Recording: A Pilot Study. ClinicalTrials.gov Identifier: NCT01102842. (Accessed online, May 25, 2023) Available from: https://ClinicalTrials.gov/show/NCT01102842
- Validation of Portable Monitoring Device for Diagnosing Sleep Apnea. ClinicalTrials.gov Identifier: NCT00628511. (Accessed online, May 25, 2023) Available from: https://ClinicalTrials.gov/show/NCT00628511

Discussion

The 10 studies included in this review reported diagnostic accuracy and failure rates, and some reported patient preferences and subjective measures of sleep quality. The findings from the patient populations in these studies were considered to be reasonably generalizable to the clinical population of interest for level 2 polysomnography devices in Ontario, particularly because most studies excluded patients with multiple comorbidities, as would be in alignment with potential eligibility criteria for level 2 polysomnography in Ontario, as per advisement of our clinical experts. We assumed that the clinical context would be that of the current standard of care, in which patients must be referred to a sleep specialist and undergo a sleep study prior to being prescribed treatment with a continuous positive airway pressure (CPAP) device. However, it should be noted that in some regions outside of Ontario, a sleep specialist may conduct an initial assessment virtually and, if they consider it to be appropriate, have patients trial a CPAP at home, with follow-up virtual assessments, thus avoiding the need for a patient to make their way to a sleep clinic.

In practice, the clinical application of level 2 polysomnography is as an alternative for level 1 polysomnography testing, and thus, is not limited to any specific sleep disorder diagnosis. However, calculations for diagnostic accuracy are limited by the need for a specific diagnosis to derive true-positive, true-negative, false-positive, and false-negative metrics. For this reason, we only have evidence with respect to the accuracy of level 2 polysomnography for the diagnoses of sleep apnea in adults, sleep apnea in children, sleep bruxism in adults, and periodic leg movement in adults. Level 2 polysomnography device performance for these diagnoses was found to be reasonably similar to that of the reference standard (level 1 polysomnography), with sensitivity values from 0.760 to 1.00 and specificity values from 0.400 to 1.00. One published survey of physicians in France found a strong preference for high sensitivity, but it is uncertain if those findings could be generalized to represent the preferences of physicians in Ontario.[108] High sensitivity would mean that level 2 polysomnography devices offer good identification of patients with sleep disorders and would thus have few false-negative findings when compared with level 1 polysomnography. The lower value of the specificity range, however, indicates that there is potential for false-positive findings, but the tendency seems to disappear with higher apnea severity cut-off points and may need to be accounted for if level 2 polysomnography is adopted in Ontario.

The reference standard is also known to be imperfect and have limitations associated with interrater correlation, first-night effects, and variations in diagnosis definitions (e.g., different apnea hypopnea index thresholds)[135]; therefore, accuracy for level 2 polysomnography devices should be interpreted as being representative of absolute differences from and not necessarily worse than the reference standard.

Equity Considerations

The applications of level 2 polysomnography devices are multifold. Some patients are more comfortable sleeping in their own environment and unwilling to go to a sleep clinic. In some instances, circumstances may not allow for in-clinic testing (e.g., when patients have complex medical requirements [such as limited mobility or medical equipment like dialysis], caregiver responsibilities, during public health emergencies [such as the COVID-19 pandemic], or when patients are unable to travel to a sleep clinic [due to lack of access to transportation or distance]). Some of the included studies were designed in such a way that patients are required to have them applied by a technician prior to their overnight test and returned the next day. Having the device applied in a sleep-clinic is not possible or reasonable for all people and was reflected in the findings related to preferences; some studies explicitly stated patient preferences for in-clinic testing were based on travel difficulty[130] and other studies listed distance from clinic as an exclusion criteria.[125] In other studies, technicians drove to patients' homes to apply the polysomnography devices; however, patients were still required to live within a reasonable distance of the sleep clinic. This would, therefore, not support equity in access to those living in remote regions or without access to transportation. We are aware of one polysomnography brand that is being used in Canada that offers mailing of the devices to patients to apply themselves, and there is access to a support technician via phone as needed.[93]

We were unable to determine if study populations adequately represent the Ontario population with respect to PROGRESS-Plus criteria such as social capital or religion. Studies did report participant gender or sex, and there were more male participants across all studies.[111] Details for participant ethnicity, race, or heritage were only found in 1 study conducted in New Zealand,[126] which reported that there was an overrepresentation of New Zealand Europeans (76% of study participants) compared with the clinical population expected in their region (66%), and underrepresentation of Māori and Pacific people 3.3% of study participants) compared with 27% of the clinical population. We also recognize that EEG accuracy may be different for people with coarse and curly hair as it may require specific hair styles or clips to ensure a proper attachment of the electrodes and registration of the data.[102,103] However, the data reported in the included studies did not allow for exploration of differences in accuracy based on hair type.

Strengths and Limitations

The literature search identified 7 potentially relevant reviews,[60,117-122] and we considered whether these reviews could be leveraged. Ultimately, none were found to be recent or comprehensive enough to fully meet our scope, but their reference lists were reviewed to identify any additional potentially relevant primary studies.

Across the included studies, there was heterogeneity in the criteria for defining hypopnea; however, within each individual study, the criteria were consistent between the index test and reference group, thereby still isolating to study the impact of using unattended polysomnography at home. Similarly, each study used a different commercial brand of device for their polysomnography testing, but since we based our study inclusion criteria on the actual parameters measured by the individual devices, we were able to focus only on publications that reported utilizing devices in a way that met our inclusion criteria.

Some studies conducted in-clinic level 2 polysomnography and simulated an unattended environment where technicians were advised to not intervene with the sleep studies using level 2 polysomnography devices. This is not how devices would likely be used in clinical practice, because the clinical environment can be controlled for external noises and light and to eliminate disturbances (e.g., from

potential partners or caregiver responsibility). In the home setting, patients were generally advised to not drink alcohol, smoke, or go to sleep with the television on; however, adherence to this request could not be confirmed.

We determined it was reasonable to focus the review on test performance and presume clinical utility because level 2 polysomnography devices were being evaluated as an alternative to level 1 polysomnography for appropriate clinical populations. Therefore, clinical utility would be comparable to that of the reference tests utilized in the studies – which happens to align to usual care in Ontario as level 1 polysomnography. The anticipated benefit would be improved access and patient experience, if reasonably similar in test performance. We did not include the very large body of evidence on validation of level 2 polysomnography device metrics. Such studies generally demonstrate the comparability of individual measures captured by the sleep test devices, such as EEG leads, sleep efficiency, rapid eye movement sleep, and total sleep time.[88,107] These important metrics would have been required as baseline confirmation prior to the accuracy studies of overall test performance that were the focus of our review. Finally, while there are slight differences in the approach, reporting of outcomes, and quality assessment, overall, our findings are aligned with those of similar reviews.[122]

Summary of Findings

As level 2 polysomnography is intended as an alternative for the current available sleep test (level 1 polysomnography) it is expected to be used in a broad population. While evidence was only identified in a select few diagnoses, it may be appropriate to consider the findings as representative of the overall diagnostic accuracy.

- For diagnosing sleep apnea in adults, based on 8 studies (N = 422), the sensitivity ranged from 0.760 to 1.00 (GRADE: Low) and the specificity ranged from 0.400 to 1.00 (GRADE: Low)
- For diagnosing sleep apnea in children, based on 1 study (N = 47), sensitivity was 0.933 (GRADE: Low) and specificity was 0.969 (GRADE: Moderate)
- For diagnosing sleep bruxism in adults, based on 1 study (N = 20), sensitivity was 1.00 (GRADE: Very low) and specificity was 0.467 (GRADE: Very low)
- For diagnosing periodic leg movement in adults, based on 1 study (N = 40), sensitivity was 0.889 (GRADE: Very low) and specificity was 0.967 (GRADE: Very low)
- Failure rates were reported between 0%–20% (GRADE: Very low)
- There was a mix of preferences reported between at-home and in-clinic testing, with more people preferring at-home testing, and patients reporting better quality of sleep when testing was conducted at home (GRADE not conducted)

Conclusions

Level 2 polysomnography (unattended, at-home sleep studies) may have good test performance for adults and children, with adequate diagnostic accuracy, compared with level 1 polysomnography (attended, in-clinic).

Economic Evidence

Research Question

What is the cost-effectiveness of level 2 polysomnography (unattended, at-home sleep studies) for diagnosing sleep disorders compared with level 1 polysomnography (attended, in-clinic sleep studies) for adults and children with suspected sleep disorders?

Methods

Economic Literature Search

We performed an economic literature search on January 9, 2023, to retrieve studies published from database inception until the search date. To retrieve relevant studies, we developed a search using the clinical search strategy with an economic and costing filter applied.

We created database autoalerts in MEDLINE, Embase, and PsycINFO and monitored them until August 21, 2023. We also performed a targeted grey literature search following a standard list of websites developed internally, which includes the International HTA Database and the Tufts Cost-Effectiveness Analysis Registry. See Clinical Literature Search, above, for further details on methods used. See Appendix 1 for our literature search strategies, including all search terms.

Eligibility Criteria

Studies

Inclusion Criteria

- English-language full-text publications
- Cost–benefit analyses, cost-minimization or comparative costing analyses, and cost-effectiveness or cost–utility analyses

Exclusion Criteria

- Reviews, noncomparative (feasibility) studies, letters, editorials, case reports, commentaries, abstracts, posters, and unpublished studies

Population

Inclusion Criteria

- Adults (≥ 18 years) or children (< 18 years) with suspected sleep disorders

Exclusion Criteria

- Healthy participants (i.e., participants of validation studies)

Intervention

Inclusion Criteria

- Use of unattended (i.e., by a technician) level 2 (at-home) polysomnography for the diagnosis of clinical sleep disorders

Exclusion Criteria

Study data from the:

- Use of level 2 polysomnography for treatment (e.g., with positive airway pressure systems) monitoring or titration or for any purpose other than diagnostic testing
- Use of other types of at-home, such as level 3 or level 4 sleep studies, which are typically used to detect sleep-disordered breathing

Comparator

- Attended (which is also occasionally referred to as *fully monitored*) level 1 (in-clinic) polysomnography, which is the reference standard for diagnosing clinical sleep disorders

Outcomes

- Costs
- Health outcomes (e.g., number of people correctly diagnosed, quality-adjusted life-years [QALYs])
- Incremental costs
- Incremental effectiveness
- Incremental cost-effectiveness ratio (e.g., incremental cost per correctly diagnosed case, or per QALY) or incremental net benefit

Literature Screening

A single reviewer conducted an initial screening of titles and abstracts using Covidence[110] and then obtained the full texts of studies that appeared eligible for review according to the inclusion criteria. The same reviewer then examined the full-text articles and selected studies eligible for inclusion. The reviewer also examined reference lists for any additional relevant studies not identified through the search.

Data Extraction

We extracted relevant data on study characteristics and outcomes to collect information about the following:

- Source (e.g., citation information, study type)
- Methods (e.g., study design, analytic technique, perspective, time horizon, population, intervention[s], comparator[s])
- Outcomes (e.g., health outcomes, costs, incremental cost-effectiveness ratios)

Study Applicability and Limitations

We determined the usefulness of each identified study for decision-making by applying a modified quality appraisal checklist for economic evaluations originally developed by the National Institute for Health and Care Excellence (NICE) in the United Kingdom to inform the development of NICE clinical guidelines.[136] We modified the wording of the questions to remove references to guidelines and to make it specific to Ontario. Next, we separated the checklist into 2 sections. In the first section, we assessed the applicability of each study to the research question (directly, partially, or not applicable). In the second section, we assessed the limitations (minor, potentially serious, or very serious) of the studies that we included in the review.

Results

Economic Literature Search

The database search of the economic literature yielded 500 citations published from database inception until January 9, 2023, including grey literature searches, after duplicates were removed. We did not identify any additional eligible study from other sources, including database alerts (monitored until August 21, 2023). In total, we identified 3 studies that met our inclusion criteria. See Appendix 2 for a list of selected studies excluded after full-text review. Figure 3 presents the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) flow diagram for the economic literature search.

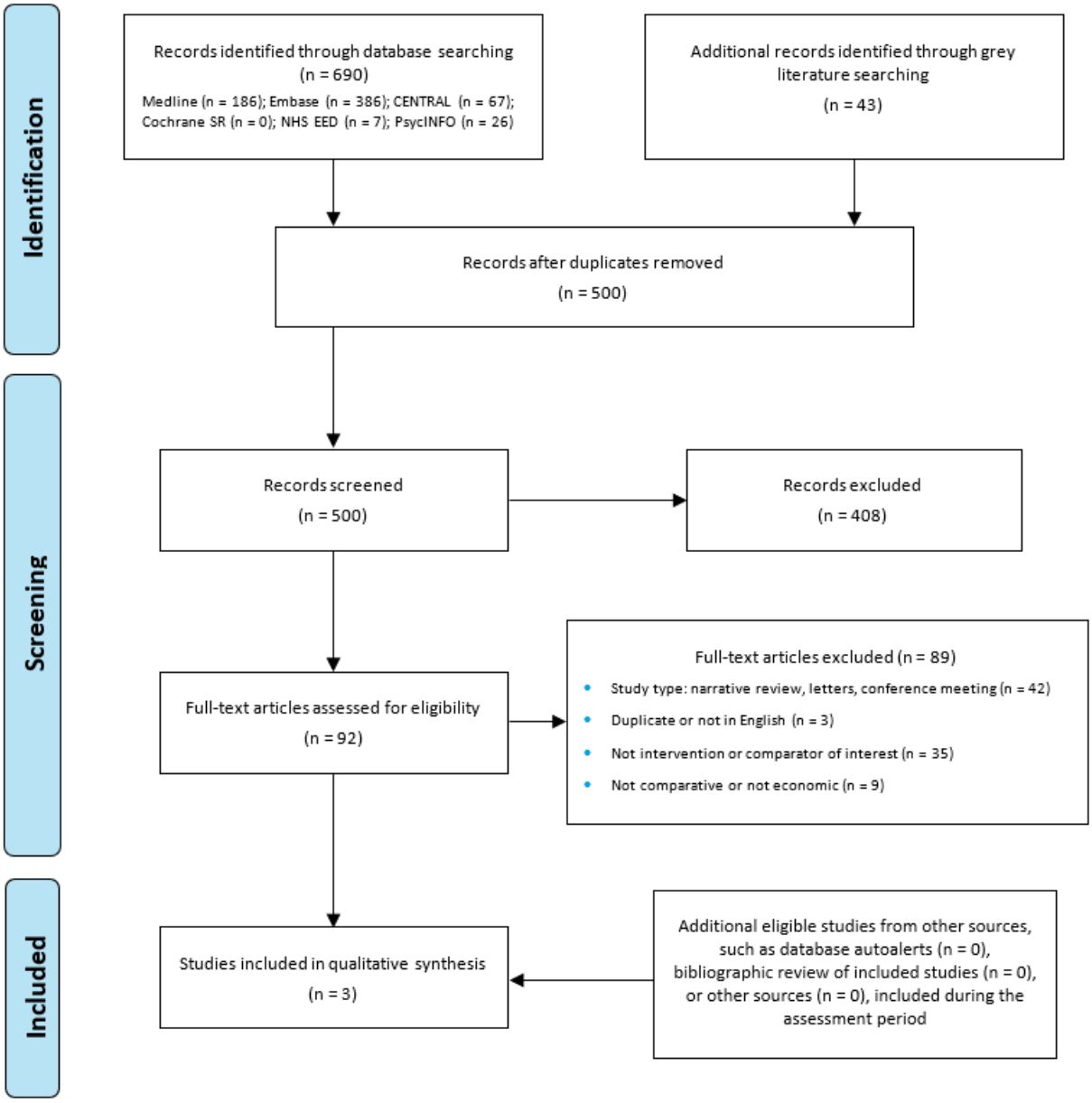

Figure 3: PRISMA Flow Diagram – Economic Search Strategy

PRISMA flow diagram showing the clinical search strategy. The database search of the clinical literature yielded 690 citations published from database inception and January 9, 2023 (monitored until August 21, 2023). We identified 43 additional eligible studies from other sources. After removing duplicates, we screened the abstracts of 500 studies and excluded 408. We assessed the full text of 92 articles and excluded a further 89. In the end, we included 3 articles in the qualitative analysis.

Abbreviations: NHS EED, National Health Service Economic Evaluation Database; PRISMA, Preferred Reporting Items for Systematic Reviews and Meta-analyses; SR, systematic review. PRISMA, Preferred Reporting Items for Systematic Reviews and Meta-analyses.

Source: Adapted from Page et al.[123]

Overview of Included Economic Studies

We included 3 studies in our qualitative synthesis (Table 9) – 2 studies[137,138] were model-based cost-minimization analyses with short time horizons, while 1 study[125] was a prospective cross-over single-blind trial that included an aggregate-level costing analysis. In all 3 studies, the study population comprised adults with clinically suspected obstructive sleep apnea, and level 2 polysomnography (either as a single test[125,138] or combined with in-clinic level 1 polysomnography[137]) was compared with level 1 polysomnography (current practice for sleep disorder diagnosis). In general, sleep study testing with level 2 (at-home) polysomnography was found to be less costly than that with level 1 (in-clinic) polysomnography.

Ayas et al[138] developed a theoretical decision-tree model to compare incremental effectiveness and cost outcomes, from a public payer perspective (in British Columbia, Canada), for several diagnostic pathways in adults with suspected obstructive sleep apnea:

- A level 1 (in-clinic) sleep study (as the only diagnostic test)
- A level 2 (at-home) sleep study, followed by a level 1 (in-clinic) sleep study, if technical failure occurs during the level 2 sleep study
- A level 3 (at-home) sleep study, followed by a level 1 (in-clinic) sleep study, if required (i.e., technical failure, negative test result, or no response to treatment [false-positive results])
- A level 3 (at-home) sleep study, followed by a level 2 (at-home) sleep study, if required (i.e., negative test result or no response to treatment [false-positive results]). If technical failure occurs during the level 2 (at-home) sleep study, a level 1 (in-clinic) sleep study would then be performed

Given the focus of our HTA, we discuss only results related to the diagnostic test pathway with level 2 polysomnography as the initial test; the decision-tree model takes into account the pretest probability of obstructive sleep apnea, and the probability of technical failure (assumed to occur 15% of the time). In addition, Ayas et al[138] assumed that level 1 and level 2 polysomnography had the same sensitivity and specificity; with this assumption, the analysis was simplified – from cost-effectiveness to cost-minimization analysis.

Because they did not specify the most clinically plausible pretest probability for the reference case, multiple iterations were run to assess how varying the pretest probability would affect the results. Ayas et al[138] did not clearly define patient eligibility criteria or indications for level 2 polysomnography use (explained by lack of empirical data); however, they offer the opinion that level 2 testing can enable better access to sleep study testing in specific situations such as COVID-19 pandemic and for some patient populations.

Ayas et al[138] estimated the cost of level 2 polysomnography to be $300 (in 2021 Canadian dollars [CAD]) per person, while the cost of level 1 polysomnography was known – $555 per person. Ayas et al[138] did not describe how the level 2 portable device was intended to be set up (e.g., whether it was necessary for patients to visit the clinic to pick-up and learn how to use the equipment, for a technician to visit patients' homes for equipment set-up, or for equipment to be mailed to patients with set-up instructions).

As a continuum of diagnostic pathways, treatment with continuous positive airway pressure (CPAP) was modelled. The cost of CPAP was assumed to be $0, because home care companies in British Columbia do

not usually charge for a CPAP trial. The model's time horizon was not directly reported; we assumed that it was short term because the model did not estimate long-term outcomes related to obstructive sleep apnea, and the use of discounting was not reported.

Using deterministic analysis, Ayas et al[138] found that when the pretest probability was less than or equal to 0.80, level 2 polysomnography (as the initial test) was the least costly diagnostic pathway of all that were compared. For example, when pretest probability was 0.5, the use of level 2 (at-home) polysomnography as the initial test for adults with suspected obstructive sleep apnea would result in cost savings of about $171 per person. The break-even cost – the cost of level 2 polysomnography at which the 2 diagnostic strategies would be equally cost-effective – was $470.

The second study included in our review was a cost-minimization analysis[137] conducted as part of a 2010 health technology assessment for the Australian Medical Services Advisory Committee to support decision-making about publicly funding unattended sleep study tests for adults and children with obstructive sleep apnea in Australia. The economic evaluation included analyses for 3 health care pathways (2 applicable to adults and 1 applicable to children):

- In nonspecialized settings (e.g., with primary care physicians)
- In referral settings (e.g., with medical specialists such as sleep medicine specialist physicians)
- In pediatric settings (e.g., with pediatricians, pediatric surgeons, and sleep medicine physicians)

While the model structure was similar for all 3 analyses, we focused on only the analysis for the referral setting pathway because this analysis incorporated inputs and provided results relevant to level 2 polysomnography. Merlin et al[137] used a cost-minimization approach because they found that there were no statistically or clinically significant differences in relevant health outcomes (e.g., number of respiratory events, sleep time, and time to commencement of treatment) between unattended (levels 2, 3, and 4) and attended (level 1) sleep studies. A time horizon of 1 month (i.e., from specialist consultation until the correct diagnosis is established) was used in the analysis.

In the analysis, an initial cohort of adults with suspected obstructive sleep apnea was stratified: 20% of people were assigned to receive at-home level 2 polysomnography, 60% of people were assigned to level 1 polysomnography, and the rest of cohort were assigned to level 3 and level 4 sleep studies (9% and 11%, respectively). As a result, this cost-minimization analysis provided an overall estimate for the cost of the combined test strategy (i.e., a potential uptake scenario if all types of sleep study are used), which was then compared with that of the existing scenario (current practice, i.e., level 1 polysomnography). The model structure included test-specific inputs related to test accuracy and technical failure rates for level 2, 3, and 4 sleep studies; for level 1 sleep studies, perfect accuracy and a technical failure rate of 0% was assumed. Also, the combined test strategy allowed for additional testing with level 1 polysomnography would be required (i.e., to account for instances in which there are uncertain findings, a false-negative result, or technical failure). It was assumed that level 1 polysomnography yielded an accurate diagnosis. To account for the impact of false-positive results on overall costs, Merlin et al[137] included the cost of obstructive sleep apnea treatment (auto-titrating positive airway pressure: $350 in 2010 Australian dollars [AUD]), followed by level 1 polysomnography. In this analysis, the cost of level 2 polysomnography was assumed to be $317 AUD per person and the cost of level 1 polysomnography was $556 AUD per person.[137]

Merlin et al[137] found that there would be cost savings, about $16 AUD per correct diagnosis per capita, for the combined-uptake scenario (with level 2 polysomnography in 20% of the eligible population). Reference case and 1-way sensitivity analyses were deterministic. Factors that substantially altered results were probability of level 1 polysomnography uptake and positive predictive value of level 2 polysomnography. When level 1 polysomnography uptake increased by only 5% (from 60% [in the reference case] to 65%) or positive predictive value of level 2 polysomnography decreased by 17% (from 97% [in the reference case] to 80%), the combined test strategy would result in cost increases ($15 AUD and $2 AUD, respectively) instead of cost savings.

The third study was a cross-over single-blind prospective study that compared sensitivity, specificity, and technical failure rate of level 1 and 2 polysomnography.[125] Adults with suspected obstructive sleep apnea underwent both types of sleep studies; the testing order (i.e., level 1 first or level 2 first) was randomly assigned. For level 2 sleep studies, a technician visited the patient's home and fit the equipment there. A second technician who was not involved in patient care reviewed all recordings independently (thus, it was a single-blind study). Although effectiveness data were reported for both strategies, Bruyneel et al[125] did not evaluate cost-effectiveness but simply estimated costs at the aggregate level using assumptions related to health resource usage. Thus, the total cost for level 2 polysomnography €268 (2008 Euro [EUR]) included the set-up technician's time, which was valued at €50 EUR, in addition to the cost of level 1 polysomnography in a Belgian hospital (€218). This simple deterministic approach yielded approximate cost savings of €790 for level 2 polysomnography when compared with level 1 polysomnography.

Table 9: Results of Economic Literature Review – Summary

Author, year, country	Study and analysis characteristics	Strategies	Population	Design information or model inputs	Results		
					Health outcomes	Costs, per person	Cost-effectiveness
Ayas et al,[138] 2021, Canada (British Columbia)	Cost-minimization analysis, decision-tree model Perspective: Case example, third-party payer Time horizon (discount rate): NR (NR)	Intervention[a]: Level 2 PSG, followed by level 1 PSG, if required Comparator: Level 1 PSG	Adults with clinically suspected OSA, referred for sleep study	Assumptions: Level 1 Sp, Sn = level 2 Sp, Sn Technical failure rate Level 2 PSG: 15% Level 1 PSG: 0% Unit cost, CAD[c] CPAP trial: $0 Level 2 PSG[b]: $300 Pretest p_{OSA} = 0.5	NA	Total mean cost, CAD[c] Level 2 PSG: $417 Level 1 PSG: $588 Mean difference: −$171	Level 2 PSG was dominant Cost savings for $p_{OSA} \leq 0.8$[a] Sensitivity analyses: Probabilistic: — Deterministic: 1-way for $0 \leq p_{OSA} < 1$; breakeven cost: $470 (for p_{OSA} = 0.5)
Merlin et al,[137] 2010, Australia	Cost-minimization analysis, decision-tree model Perspective: All costs accounted for third-party payer Time horizon (discount rate): 1 month[e] (NA)	Intervention: 60:20:9:11 patient ratio for level 1:2:3:4 sleep studies as initial test, followed by level 1 PSG, if required Comparator: Level 1 PSG	Adults with clinically suspected OSA, referred for sleep study[d]	Assumptions: Technical failure rate Level 2: 10% Level 3: 5% Level 4: 1% Unit cost, AUD (2010) Level 2 PSG: $317 Level 1 PSG: $556 Autotitrating CPAP: $350[f]	NA	Total mean costs (per correct diagnosis), AUD (2010) Level 2 PSG: $754 Level 1 PSG: $770 Mean difference: −$16	Level 2 PSG was cost-saving[g] Sensitivity analyses: Probabilistic: — Deterministic: 1-way: cost increase instead of saving if higher level 1 PSG uptake (65% vs. 60%) or lower level 2 PPV (80% vs. 97%)
Bruyneel et al,[125] 2011 Belgium	Prospective randomized crossover, single-blind clinical trial; aggregate costing analysis Perspective: NR Time horizon (discount rate): Short term (NA)	Intervention: Level 2 PSG Comparator: Level 1 PSG	Adults with clinically suspected OSA, referred for sleep study (N = 66)[h]	Both test within 2 weeks, order randomly assigned Assumptions: Unit cost, EUR (2008) Level 2 PSG: test, €218; technician labour, €50 Level 1 PSG: test, €218; hospital stay, €839	Level 2 vs Level 1 PSG AHI ≥ 5: Sn, 96%; Sp, 71% AHI ≥ 20: Sn, 76%; Sp, 85% Technical failure rate Level 2 PSG: 4.7% (95% CI, <1%–13%) Level 1 PSG: 1.5% (95%CI, <0.1%–8%); *P* = .36	Total mean costs, EUR (2008) Level 2 PSG: €268 Level 1 PSG: €1,057 Mean difference: −€789	Level 2 PSG was less costly than level 1 PSG Sensitivity analyses: —

Abbreviations: AHI, apnea-hypopnea index; AUD, Australian dollars; CAD, Canadian dollars, CPAP, continuous positive airway pressure system; EUR, euro; NA, not applicable; NR, not reported; OSA, obstructive sleep apnea; PPV, positive predictive value; PSG, polysomnography; Sn, sensitivity; Sp, specificity.

Table notes continued on next page.

[a]Information reported herein only for the intervention with index test (level 2 PSG) and versus comparator with reference test (level 1 PSG).
[b]Based on the assumption that level 2 PSG costs would likely be between those of level 3 ($167) and level 1 ($555) sleep studies.
[c]Currency year not reported (assumed to be 2021 Canadian dollars).
[d]Another model was developed for children, but no children were assigned to level 2 (80:0:10:10 patient ratio).
[e]It was assumed that, in a referral setting, it would take up to 1 month for specialist consultation, diagnostic testing, and diagnosis.
[f]Included only if subsequent level 1 PSG indicated initial finding was false positive.
[g]We were unable to determine the incremental cost-effectiveness of level 2 alone.
[h]No differences between groups (level 1 PSG first or level 2 PSG first) with respect to age (mean 50 [SD 12]; mean 48 [SD 14]; *P* = .54), sex (47% male:53% female; 69% male:31% female; *P* = .08), or body mass index (mean 31.4 [SD 9]; mean 29.7 [SD 6]; *P* = .37).

Applicability and Limitations of the Included Studies

None of the 3 included studies was directly applicable to our research question and Ontario context (Appendix 4, Table A3). Both model-based studies[137,138] were considered partially applicable and were associated with potentially serious limitations, while the third study[125] was considered to be not applicable with very serious limitations (Appendix 4, Table A4) due to the simplified approach (back-of-the-envelope–type calculations) to costing analysis.

We further discuss the study[138] in which a Canadian public-payer perspective (i.e., Ministry of Health in British Columbia) was used. We found that Ayas et al[138] considered sensible diagnostic clinical pathways that accounted for the possibility of additional testing in the case of test failure; however, the study was associated with several limitations and could not be generalizable to our research question and an Ontario context. First, the study[138] only included adults with suspected obstructive sleep apnea and did not include people with other types of sleep disorders who, in Ontario, are typically eligible for diagnostic testing with level 1 polysomnography. The model was based on the assumption that level 2 polysomnography had perfect sensitivity and specificity for confirming obstructive sleep apnea, but these inputs were not generated through a full assessment of the clinical evidence. This assumption made it impossible for the model to account for false-positive or false-negative test results, including their consequences; as a result, Ayas et al[138] likely overestimated the economic value of level 2 polysomnography. Also, the test cost for level 2 polysomnography ($300 CAD per person) was estimated based on an assumption that the cost would lie approximately midway between those of level 1 polysomnography ($555 CAD) and a level 3 sleep study ($167), which is available in British Columbia, but the cost components of level 2 test (e.g., equipment, technical fees, physician fees) were not explained; without this information, we could not determine whether these cost estimate would apply to level 2 polysomnography in Ontario.[139-141]

Discussion

All 3 economic analyses[125,137,138] suggested that level 2 polysomnography, used as the sole test method[125,138] or as an initial test in a diagnostic pathway that included other types of sleep studies,[137] is less costly than level 1 polysomnography. All studies were conducted for adults with clinically suspected obstructive sleep apnea. Thus, no economic evidence was identified for other sleep disorders or for children. The model-based studies[137,138] assumed the clinical benefits or diagnostic accuracies of level 2 polysomnography and level 1 polysomnography were equal; consequently, they focused on comparing the costs. However, the cross-over trial[125] suggested sensitivity, specificity and cost of level 2 polysomnography were all lower than those of level 1 polysomnography.

We found that none of the studies was directly applicable to our research question and Ontario context. None of the studies conducted probabilistic analyses to assess assumptions related to the model structure and base case input parameter values. Also, none considered various types of sleep disorders, typically eligible for diagnostic testing with in-clinic level 1 polysomnography. Given these limitations, the cost-effectiveness of level 2 polysomnography compared with that of level 1 polysomnography, in Ontario, remains uncertain for adult populations and unknown for pediatric populations.

Equity Considerations

None of the included economic studies defined a priori factors, such as sex, access to care, obesity, income, or ethnicity, that could contribute to inequities in access to care and health outcomes.

However, Ayas et al[138] discussed that at-home level 2 polysomnography could be used to improve access to sleep study testing in situations such as the COVID-19 pandemic or in certain populations. They also discussed that eligibility and indications for this type of portable sleep study test are not clearly defined and that this area needs more empirical or implementation research. They pointed out that level 2 sleep study set up at home could be challenging for some vulnerable populations such as frail patients, patients with significant arthritic, neurologic or neuromuscular diseases, patients with cognitive impairments or those with difficulties in using technologies.[138] Likewise, it would be important to examine various scenarios related to level 2 sleep study equipment set up at home (e.g., mailing equipment with instructions to patients vs. technician attending patient's home to apply the probes) to encourage easier access to sleep study testing for eligible populations living in remote parts of Ontario that lack sleep lab facilities.

Strengths and Limitations

We only identified 3 relevant studies with adults[125,137,138] in which the cost-effectiveness of level 2 polysomnography was evaluated in comparison with level 1 polysomnography and no relevant studies with children. However, we comprehensively reviewed the economic literature and systematically searched electronic databases and grey literature sources; thus, it is unlikely that we overlooked any relevant economic literature.

Conclusions

The economic evidence suggested that diagnostic testing with level 2 polysomnography could be less costly than testing with level 1 polysomnography, when the clinical benefits of both tests were assumed to be equal; however, the methodological quality of the studies[125,137,138] was limited, and none of the studies was directly applicable to our research question or an Ontario context. As a result, the economic value of level 2 polysomnography for diagnosing sleep disorders in adults and children with suspected sleep disorders is uncertain.

Primary Economic Evaluation

We found a few published economic studies evaluating the cost-effectiveness of diagnostic testing with level 2 polysomnography in people with obstructive sleep apnea. However, none of these studies were directly applicable to the Ontario context and our research question. Therefore, we conducted a primary economic evaluation for Ontario.

Research Question

What is the cost-effectiveness of a diagnostic pathway with level 2 polysomnography (unattended, at-home sleep studies) for diagnosing sleep disorders compared with the current practice diagnostic pathway with level 1 polysomnography (attended, in-clinic sleep studies) for adults and children with suspected sleep disorders, from the perspective of the Ontario Ministry of Health?

Methods

The information presented follows the reporting standards set out by the Consolidated Health Economic Evaluation Reporting Standards (CHEERS) statement.[142,143]

Type of Analysis

For the reference case, we conducted cost-effectiveness analysis to determine the short-term costs and diagnostic outcomes of the diagnostic pathway with level 2 polysomnography in comparison with those of the diagnostic pathway with level 1 polysomnography (current practice) for adults with suspected sleep disorders. The cost-effectiveness of the diagnostic pathway with level 2 polysomnography for children was examined as a hypothetical scenario analysis.

This HTA focuses only on the diagnostic use of sleep study tests and not on their application in therapy. This is because the population of interest is highly heterogenous (i.e., people with various sleep orders) and so is the treatment pathway. To estimate the impact of level 2 polysomnography for the treatment of specific sleep-related disorders, multiple long-term cost–utility models would be required. Nevertheless, we also conducted a simplified cost–utility scenario analysis for adults with obstructive sleep apnea to address imminent economic implications of the diagnosis (e.g., costs associated with the follow-up care and use of positive airway pressure devices).

Outcomes of Interest

In this analysis, we estimated probabilities for the following effectiveness outcomes:

- Confirmed or ruled-out sleep disorders at the end of the diagnostic pathway
- Test positive or test negative after the initial diagnostic test
- Correctly diagnosed as true positive or as true negative, after the initial diagnostic test
- Incorrectly diagnosed as false positive or as false negative, after the initial diagnostic test
- Direct health care costs (total and various cost components)
- Incremental cost-effectiveness ratio (ICER) estimated from the cost and effectiveness outcomes (e.g., $ per confirmed diagnosis, $ per QALY gained)

Population of Interest

For the reference case, our population of interest was adults with a clinically suspected sleep disorder, indicated for diagnostic level 1 (in-clinic) polysomnography and no contraindications for unattended sleep study (as defined by the Ontario sleep medicine clinical guidelines[140]).

We also conducted a separate scenario analysis in children because there are many uncertainties related to different clinical diagnostic and treatment pathways for this population and we have limited understanding of the use of polysomnography for diagnostic testing of children in Ontario.

Perspective

We conducted all analyses from the perspective of the Ontario Ministry of Health.

Intervention and Comparator Diagnostic Pathways

Since level 2 polysomnography is assumed to be a replacement of in-clinic level 1 polysomnography, for pragmatic reasons, we assumed that technical failure in a level 1 or level 2 sleep study would result in reassessment with the same type of sleep study before the results are examined by a sleep medicine physician. In addition, based on guidelines[140] and expert consultations (email communication: Murray Moffat, MD and Clodagh Ryan, MD; Aug 26–28, 2023), for people who tested negative but continued to have symptoms (false-negative test results), level 1 polysomnography was used to confirm diagnostic findings. Therefore, we compared (Table 10) the following 2 diagnostic pathways:

1. ***New diagnostic pathway with level 2 polysomnography (intervention)***: Initial testing with level 2 polysomnography; repeat testing with level 2 polysomnography, if technical failure occurs for the initial test; level 1 polysomnography, if necessary
2. ***Current practice diagnostic pathway with level 1 polysomnography (comparator)***: Initial testing with level 1 polysomnography, and repeat testing with level 1 polysomnography, if technical failure occurs for the initial test

Table 10: Intervention and Comparator Evaluated in the Primary Economic Model

Intervention	Comparator	Population	Outcomes
New diagnostic pathway with level 2 polysomnography: Level 2 polysomnography; repeat testing with level 2 polysomnography, if technical failure occurs for the initial test; level 1 polysomnography, if necessary	Current practice diagnostic pathway with level 1 polysomnography: Initial testing with level 1 polysomnography, and repeat testing with level 1 polysomnography, if technical failure occurs for the initial test	Adults with A suspected sleep disorder No contraindications for unattended sleep study	Effectiveness-related Diagnosis (i.e., sleep disorder [test positive] or no sleep disorder [test negative] at Initial test End of diagnostic test pathway False positive, false negative, true positive, true negative at initial test Cost-related Direct health care costs Cost-effectiveness–related ICER[a]

Abbreviations: ICER, incremental cost-effectiveness ratio; PSG, polysomnography.

[a]ICER is estimated from cost and effectiveness outcomes.

Time Horizon and Discounting

We used a short-term (1 year) time horizon for our reference case analysis to account for costs and clinical outcomes associated with the diagnosis of a suspected sleep disorder. Consequently, we did not apply an annual discount rate of 1.5% for this analysis.[144]

Main Assumptions

The main assumptions of the reference case model (email communication: Murray Moffat and Clodagh Ryan; Aug 26–28, 2023) were:

- Valid level 1 polysomnography is the reference standard test (*valid* means tests for which an outcome, either positive or negative, can be determined); for simplicity, we assumed that it has perfect sensitivity and specificity
  (Note: This assumption was tested in sensitivity analyses)
- If technical failure occurs, then the sleep study would be repeated (second test is the same type of sleep study as the first), and technical failures would have been resolved
- In the case of false negative test results after level 2 polysomnography, level 1 polysomnography would be used to confirm the diagnosis, in line with the current standards and guidelines[140]
- A time horizon of 1 year (for diagnostic pathways) is long enough, in most cases, to establish a correct diagnosis
- We included costs incurred during diagnostic assessments as well as costs of physician follow-up visits aimed to address implications of the test results and future therapy

Model Structure: Reference Case

We developed a probabilistic decision-tree model to estimate the short-term health outcomes and costs alongside the new diagnostic pathway with level 2 polysomnography and current practice diagnostic pathway with level 1 polysomnography. This model used Bayesian approach, combining information on pretest probability of a sleep disorder (i.e., prevalence of clinically recognized, suspected disease) and test accuracy (sensitivity and specificity) to confirm sleep-disorder diagnosis (Figure 4). General sleep disorder pretest probability was based on data from our review; for the reference case, sleep disorder prevalence was estimated to be 50% (i.e., pretest probability $p = 0.50$).[125] We assumed that up until the initial test, for the referral portion of the diagnostic pathway, there is a mix of referrals from primary care physicians and specialists based on a 2019 Ontario-based administrative data study.[65,145]

The model simulated a cohort of people with suspected sleep disorders as shown in Figure 4. We accounted for the following testing and follow-up pathways:

- If technical failure occurred for the initial test, for pragmatic reasons, we assumed that the same type of sleep study was used for retesting to resolve the technical error (email communication: Murray Moffat; Aug 26, 2023)[2,140,146]
  (Note: Additional diagnostic pathway structures were examined in scenario analyses [Scenario 1: New Diagnostic Pathway Assumption – Level 1 Polysomnography is Used When Technical Failure of

Initial Level 2 Polysomnography Occurs and Scenario 2: New Diagnostic Pathway Assumption – Level 1 Polysomnography Is Used if Initial Level 2 Polysomnography Results Are Negative])

- People who tested positive (true positive or false positive) would have the same type of follow-up visit with a sleep medicine physician to discuss positive test results and treatment (in this way, we captured follow-up associated with false-positive findings)
- People who tested negative (true or false negative) would have the same type of follow-up visit to learn the test results; however, we included additional consultation and follow-up visits for people who continued to have symptoms (false-negative findings); additional level 1 polysomnography to confirm sleep disorder diagnosis is also accounted for

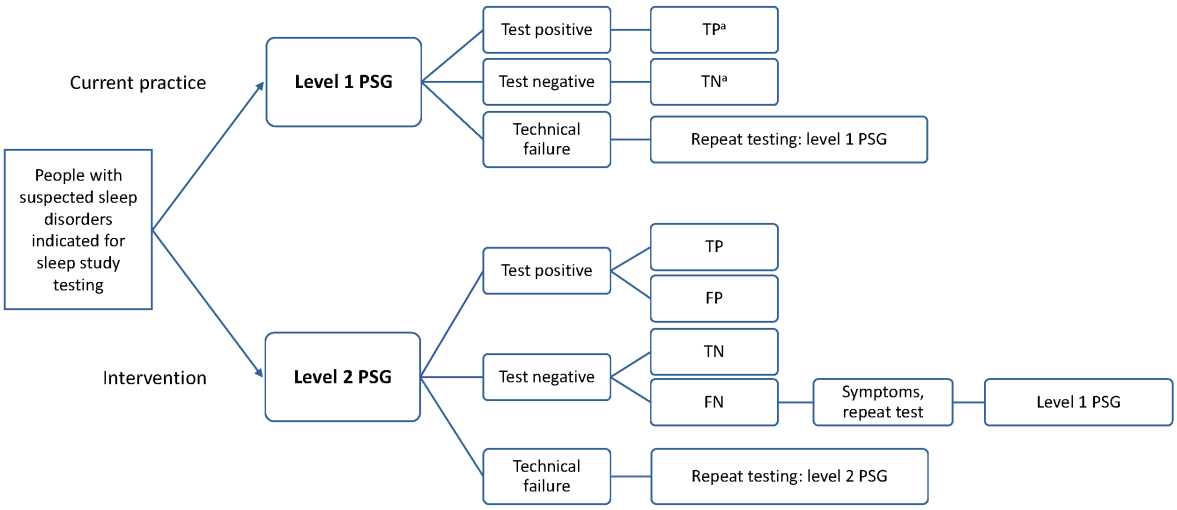

Figure 4: Simplified Model Structure, Reference Case

Abbreviations: FN, false negative; FP, false positive; PSG, polysomnography; TN, true negative; TP, true positive.
[a]Valid level 1 PSG is assumed to have perfect sensitivity and specificity in the reference case; therefore, in this figure we simplified the schematic and presented only TP and TN results for test without technical failure.

Clinical Model Parameters

We defined parameter values (Table 11) based on information from published sources (e.g., clinical evidence from our review, clinical practice guidelines, and economic evaluations from our review).

Natural History and Accuracy of Sleep Study Tests

Due to the heterogeneity of the population of interest (i.e., many possible conditions), it was difficult to accurately estimate the prior (pretest) probability (i.e., prevalence) of having a suspected sleep disorder. For the reference case, we used the midpoint pretest probability of having a sleep disorder ($p = 0.50$); this value is consistent with that estimated by Bruyneel et al, reported in our clinical review. (Note: We

tested this assumption in the sensitivity analysis [One-Way and Multiway Sensitivity Analyses and Threshold Analyses:Clinical Model Parameters].)

Diagnostic Accuracy of Sleep Study Tests

For simplicity, we assumed that the sensitivity and specificity of level 1 polysomnography (i.e., the reference standard) were 100%; this assumption is consistent with the assumptions made in other economic evaluations.[137,138] (Note: We tested this assumption in the sensitivity analysis.)

Many of the studies in our clinical review reported diagnostic test performance outcomes for adults. Overall certainty in the body of evidence (GRADE) related to level 2 polysomnography sensitivity and specificity was Low and that related to level 2 polysomnography failure rate was Very low (Appendix 3, Table A2). For the reference case analysis, we used estimates from a 2022 study[131] (Table 11) that we deemed to have the lowest risk of bias (Appendix 3, Table A1). In this study, sensitivity (0.800), specificity (0.830), and technical failure (15%) of level 2 polysomnography were reported for adults with moderate to severe sleep apnea (AHI ≥ 15), and the failure rate of in-clinic level 1 polysomnography was 0%.[131] (Note: We conducted several sensitivity analyses to address the heterogeneity of diagnostic accuracy estimates for different clinical populations [including children].)

Table 11: Inputs Related to Accuracy of Sleep Study Tests in Adults

Model parameters	Mean (SE)[a]	Source
Pretest		
Probability of having a clinical sleep disorder	0.50 (0.125)[b]	Bruyneel et al, 2011[125]
Level 1 polysomnography		
Sensitivity	1.00 (NA)	Assumption[c]
Specificity	1.00 (NA)	Assumption[c]
Technical failure	0.00 (NA)	Zancanella et al, 2022[131]
Level 2 polysomnography		
Sensitivity	0.800 (0.08)[b]	Zancanella et al, 2022[131]
Specificity	0.830 (0.08)[b]	Zancanella et al, 2022[131]
Technical failure	0.15 (0.06)[b]	Zancanella et al, 2022[131]

Abbreviation: NA, not applicable; SE, standard error.

[a]Standard errors were estimated whenever data are available. We assumed 10%–25% around the mean where data are not available.

[b]Beta distributions were assigned to the probability estimates in probabilistic analysis.

[c]This assumption was based on the fact that this test is the reference standard.

Cost Parameters

Costing Approach

We costed services related to referral to testing (initial visits), the sleep study test itself, and follow-up care (Figure 5;

Table 12) for a heterogenous population of people with suspected sleep disorders. Costs were estimated through consultations with experts and from published literature sources. We estimated all costs in 2023 Canadian dollars; when up-to-date costs were not available, we used the Consumer Price Index to adjust the values to 2023 Canadian dollars.[147] (Note: We present inputs and analysis for adults in this section and those for pediatric populations in a separate scenario analysis [Scenario 4: Pediatric Clinical Population].)

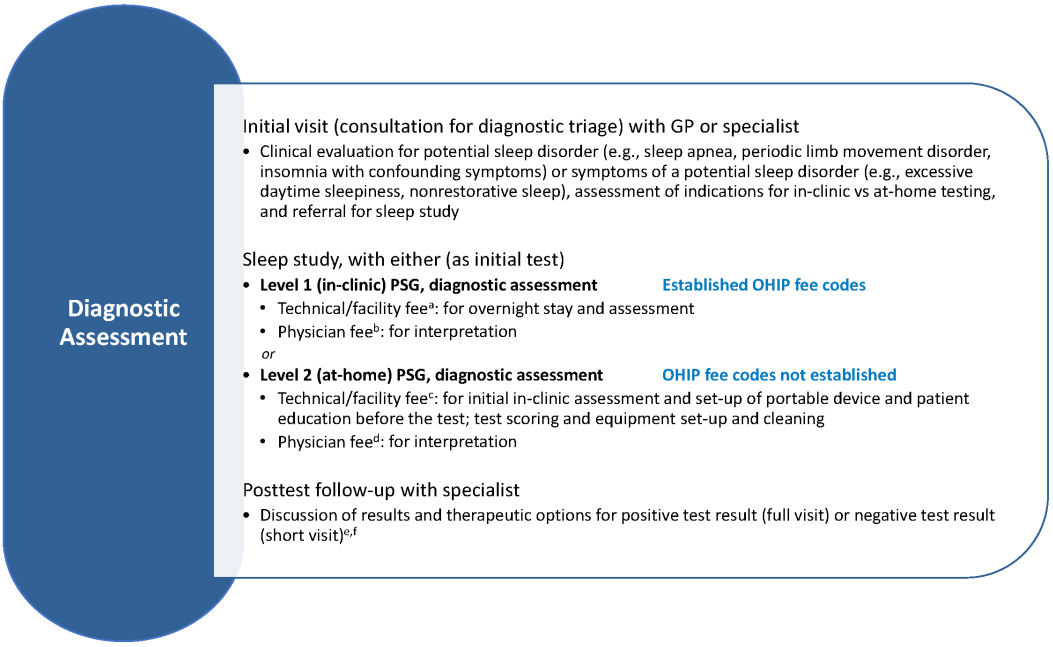

Figure 5: Simplified Costing Framework, Reference Case – Diagnostic Assessment in Adults With Level 1 or Level 2 Polysomnography

Abbreviations: GP, general practitioner; OHIP, Ontario Health Insurance Plan; PSG, polysomnography.
[a]The technical/facility fee is for the technical component of a diagnostic service to support the costs that are not physician related; this fee component includes costs related to the equipment, consumables, rentals, staffing, and overhead used at the discretion of independent health facilities[139,148] or hospitals that provide the insured service. This fee code is listed as the "H" fee in the Physician Schedule of Benefits[141] (e.g., J896, $370.75) or as the "F" fee in the Schedule of Facility Fees[149] (e.g., J896, $383.85).
[b]The physician fee is for the interpretation of the test results by a CPSO (College of Physicians and Surgeons of Ontario)–trained or a –qualified sleep medicine physician. The fee code is listed as the "P" fee code in the Physician Schedule of Benefits.[141]
[c]With level 2 PSG, we assumed that the technical/facility fee would change from the cost established for level 1 PSG and would be mostly associated with changes in sleep technologist or sleep technician labour time and equipment costs.
[d]We assumed that the fee would be the same as that for level 1 PSG.
[e]Short visit was assumed for all who test negative; this visit presupposes a previous initial full consultation (email communication: Murray Moffat and Clodagh Ryan; Aug 26–28, 2023)
[f]Additional new visits and testing were assumed to be part of additional follow-up care for those who tested false negative.

Referral for Diagnostic Polysomnography

We assumed that, regardless of the type of sleep study (level 1 [current practice] or level 2 polysomnography), the referral portion of the pathway would be the same. We used information about possible OHIP codes and referral patterns (general practitioner and specialist referral) reported in a 2019 Ontario-based study.[145] The referral of adults to diagnostic level 1 polysomnography was a mix of

the following 3 pathways: (1) 28.9% included general practitioner sleep visit (8.3 % of these were followed by a specialist sleep consultation, while 20.6% had no specialist sleep consultation); (2) 19.2 % included only a specialist sleep consultation; and (3) 51.9% included no specialist visit.[145] We estimated the weighted cost of referral using OHIP codes A947 ($37.95), for a general practitioner sleep visit; A475 ($175.55), for a specialist consultation with or without a general practitioner sleep visit; and A005 ($87.90), for referral for diagnostic polysomnography without a specialist visit. (Note: Because of uncertainty in the referral pathway, we conducted additional sensitivity analyses based on information on OHIP fee codes provided by the Ministry of Health [email communication: Ministry of Health Provider Service Branch; Aug 9, 2023].)

Testing

Initial Diagnostic Sleep Test

Current Practice Pathway: Level 1 Polysomnography

Level 1 polysomnography can be provided at sleep clinics located in independent health facilities or at hospitals.

The billing codes and fees for this test were obtained from the Ministry of Health *Schedule of Facility Fees for Independent Health Facilities*[149] and the *Schedule of Benefits for Physician Services.*[141] The cost of a sleep study test is incurred via 2 fee components – technical and professional:

- **Technical:** The "H" or "F" fee code is related to the technical components of a diagnostic service for costs that are not physician related. Technical fees include costs, related to equipment, consumables, rentals, staffing and overhead, that are at the discretion of independent health facilities[139,148] or hospitals that provide the insured service.
  - The "H" fee code, payable when level 1 polysomnography is performed in a hospital, is listed in the *Schedule of Benefits for Physician Services*[141] (e.g., J896, $370.75)
  - The "F" fee code, payable when level 1 polysomnography is performed in an independent health facility, is listed in the *Schedule of Facility Fees for Independent Health Facilities*[149] (e.g., J896, $383.85)
- **Professional:** The "P" fee code is a designated code to be used for the cost of a CPSO (College of Physicians and Surgeons of Ontario)–trained or –qualified sleep medicine physician who provides interpretation of the test results (e.g., J896: $97.50[141]). The physician fee is reimbursed in the same way regardless of where the testing is performed.

In total, the cost of an initial level 1 polysomnography test is $468.25 per person, if done at a hospital, or $481.35 per person, if done at an independent health facility. Because of the slight difference between "H" and "F" technical fee costs, we used the average cost (mean total level 1 polysomnography cost, $474.80 per person), which is based on an assumption that 50% of tests occur in hospitals and 50% occur in independent health facility. (Note: We tested this assumption in sensitivity analysis [One-Way and Multiway Sensitivity Analyses and Threshold Analyses: Market Share of Level 1 Polysomnography].)

Intervention Diagnostic Pathway: Level 2 Polysomnography

We assumed that people referred for a level 2 sleep study would go to a hospital or independent health facility, where they would learn about the test and the equipment would be set up (e.g., electrodes) by the sleep technologist or sleep technician. Patients would return home, sleep with the portable level 2 device equipment attached, and after completing the test, return (in-person or by mail [free of charge]) the device to the hospital or independent health facility. We assumed that the equipment would be returned and not lost or broken.

Because there are no billing codes for technical or professional fees for level 2 polysomnography, based on expert consultations (email communication: Murray Moffat and Clodagh Ryan; Aug 26–28, 2023), we assumed that the professional "P" fee ($97.50[141]), for interpretation of the test results, would be the same for level 2 and level 1 polysomnography because there would be no change in amount of work for the physician. (Note: We tested this assumption in sensitivity analysis [One-Way and Multiway Sensitivity Analyses and Threshold Analyses: Cost of Level 2 Polysomnography].)

We used 3 different ways to estimate the cost associated with a technical component of the level 2 sleep test ("H" or "F" fee):

- **Reference case analysis cost estimate**: We assessed various cost components to arrive at a reasonable per-person cost estimate for the level 2 sleep study test in adults (Table 12). For this purpose, we used the main components of a costing method used for a portable sleep test device in an analysis[150] done from the perspective of the health care payer in Saskatchewan (Saskatoon Health Region, Canada). With introduction of level 2 polysomnography, the only change in established billing codes would be related to the technical fee, which is mostly explained by changes in sleep technologist or sleep technician labour time and the changes in the equipment costs (Appendix 5). We arrived at an estimated cost of $338.10 for level 2 polysomnography, after summing the professional fee and the technical fee; for the technical fee – estimated to be $240.60 – we assumed that:
  - A sleep technician or sleep technologist would spend around 5 hours in total with the patient (e.g., medical history, set up, education, scoring), and have additional time for the device reset and cleaning and some administrative duties (email communication: Murray Moffat; Aug 26, 2023)
  - The device would be used about 180 times per year,[150] which would represent about 75% utilization for most sleep clinics (email communication: Murray Moffat; Aug 26, 2023)
  - The device cost would be about $14,000 (email communication Cerebra Medical Ltd; Sep 18, 2023)
  - The cost of consumables would be $14.00 (email communication: Clodagh Ryan; Aug 26–28, 2023)
  - The cost of additional administrative labour and other overhead costs would be $24.00 (email communication: Murray Moffat; Aug 26, 2023)
- **Manufacturer cost estimate:** The technical fee component was $235.02, if a sleep technician applied the device to a patient (i.e., technician-applied fee), and $213.18, if the device was patient-

applied (email communication: Nox Medical; Aug 24, 2023). For total test cost, we added the professional fee component (i.e., the physician fee for interpretation)

- **Cost estimate based on percentage adjustment of Australian Ministry of Health billing fees**: We calculated that level 2 polysomnography costs were 57% of the level 1 polysomnography, based on the billing codes of the Ministry of Health in Australia (level 1 – fee code: 12 203, $621.60 in 2023 Australian dollars [AUD][151]; level 2 – fee code: 12 250, $354.45 [2023 AUD][152]). We applied this proportion to current OHIP fees for level 1 polysomnography in Ontario and obtained corresponding level 2 polysomnography costs of $267.01 and $274.48 for independent health facility and hospital, respectively

There was large uncertainty in estimating the cost for level 2 polysomnography – because there are several components (e.g., labour cost, device cost and consumables), the cost of testing (including the cost of the device) is typically incorporated in OHIP schedule of benefits fee codes. Changes to the schedule of benefits are jointly negotiated between the Ministry of Health and the Ontario Medical Association (OMA). (Note: We conducted additional sensitivity and threshold analyses on various cost components.)

Additional Test Fees Due to Technical Failure

Currently, when a test (i.e., level 1 sleep study) must be repeated due to technical failure, the fee code for a partial level 1 sleep study is often billed (J990); the associated fee corresponds to the value of the technical fee. Therefore, we similarly assumed that only the technical fee ($240.60) would be incurred for a repeat level 2 sleep study due to technical failure. In effect, we assumed that there would be no additional cost for test interpretation (i.e., no professional physician's fee of $97.50) because the initial sleep study was not completed due to technical error, and therefore, no test interpretation took place.

Follow-Up Care After the Test

We assumed that follow-up visits with a sleep medicine physician would occur after the test, during which the test results, treatment options, and further follow-up options would be discussed as appropriate. Duration of the follow-up visit (or consult) would depend on the initial test results (email communication: Murray Moffat and Clodagh Ryan; Aug 26–28, 2023):

- A full specialist visit for positive test results (e.g., A575 [consult]: $108.95)
  (Note: We conducted sensitivity analyses to examine the effects of a reduction in this fee [One-Way and Multiway Sensitivity Analyses and Threshold Analyses: Referral and Follow-Up Costs in the Diagnostic Pathway])
- An additional follow-up visit for positive test results (e.g., A006: $45.90) later deemed to be false-positive results; this is an additional cost that accounts for incorrect initial diagnostic results (Note: In a scenario analysis [Scenario 3: Adults With Obstructive Sleep Apnea – CPAP Therapy Costs], the cost of CPAP ($554) was introduced to examine additional costs from false- positive results and to determine the trade-off in cost-effectiveness between level 2 and level 1 polysomnography)
- A short follow-up visit for negative test results (e.g., A478 [partial assessment]: $39.60)

- For patients who continue to experience symptoms (i.e., so-called *false-negative results*), additional follow-up visits, namely, general practitioner (e.g., A006: $45.90) and request for a repeat consult (e.g., A476: $108.95)

Note: We tested these assumptions in sensitivity analysis (One-Way and Multiway Sensitivity Analyses and Threshold Analyses: Referral and Follow-Up Costs in the Diagnostic Pathway).

Table 12: Per-Person Costs (Adults) Used in the Economic Model

Costs inputs	Unit cost, $[a]	Source
Referral		
Estimate for initial physician visit	104.11[b]	Weighted mean, by type of referral[c]
Level 1 PSG (initial, diagnostic test)		
Estimate used for total test cost	**474.80[b]**	Weighted mean, equal share hospital and independent health facility
Hospital, total	**468.25[b]**	
Technical fee component	370.75[b]	Physician SoB[141]: J896
Professional fee component	97.50[b]	Physician SoB[141]: J896
Independent health facility, total	**481.35[b]**	
Technical fee component	383.85[b]	Schedule of Facility Fees[149]
Professional fee component	97.50[b]	Physician SoB[141]: J896
Level 2 PSG (initial, diagnostic test)		
Reference case	**338.10[d]**	See Appendix 5
Technical fee component	240.60[d]	See Appendix 5
Professional fee component	97.50[b]	Physician SoB[141]: J896
Sensitivity analysis		
Manufacturer cost estimate, technician-applied device	**332.52[b]**	
Technical fee component	235.02[b]	Email: Nox Medical; Aug 24, 2023
Professional fee component	97.50[b]	Physician SoB[141]: J896
Manufacturer cost estimate, self-applied device	**310.68[b]**	
Technical fee component	213.18[b]	Email: Nox Medical; Aug 24, 2023
Professional fee component	97.50[b]	Physician SoB[141]: J896
Percentage adjustment based on Australian MOH fees	**270.75[d]**	Level 2 PSG costs 57% of level 1 costs, i.e., (Australian MOH cost of level 2 PSG [12 250 fee code][152]) ÷ (Australian MOH cost of level 1 PSG [12 203 fee code][151]) = ($354.45 [2023 AUD]) ÷ ($621.60 [2023 AUD])= 0.57
Hospital, total test cost	267.01[d]	0.57*$468.25 (i.e., Physician SoB[141]: J896)
Independent health facility, total test cost	274.48[d]	0.57*$481.35 (i.e., Schedule of Facility Fees[149]: J896)
Test repeat costs		
Test repeat due to technical failure		
Additional fee for level 1 PSG	377.30[b]	Weighted mean estimate, equal share (hospital [J990,[141] $370.75) and independent health facility [J990,[149] $383.85)
Additional fee for level 2 PSG	240.60[d]	See under *Level 2 PSG > Reference case > Technical fee component*
Test repeat due to false negative		
Additional total test fee for level 1 PSG	474.80[b]	See under *Level 1 PSG > Estimate used for total test cost*
Follow-up		
Posttest visit with sleep specialist, test positive	108.95[b]	Consult, respirologist (e.g., Physician SoB[141]: A575)[141]
Posttest visit with sleep specialist, test negative	39.60[b]	Short visit, partial assessment, respirologist (e.g., Physician SoB[141]: A478)
Additional visit with GP, false positive	45.90[b]	Repeat consult (e.g., Physician SoB[141]: A006)
Additional visit with GP, false negative	45.90[b]	Repeat consult (e.g., Physician SoB[141]: A006)
Additional visit with specialist, false negative	108.95[b]	Repeat consult to request level 1 PSG (e.g., Physician SoB[141]: A476)

Abbreviations: GP, general practitioner; OHIP, Ontario Health Insurance Plan; MOH, Ministry of Health; PSG, polysomnography; SoB, Schedule of Benefits. *Table notes continued on next page*

[a]All costs are in 2023 Canadian dollars.
[b]These input parameters were treated as fixed (i.e., physician fees or facility fees) and were not assigned the gamma distribution.
[c]Weighted cost = (0.52 × $87.90) + (0.21 × $37.95) + (0.08 × ($37.95 + $175.55)) + (0.19 × $175.55) = $104.11, based on data[145] (referral without specialist, 52%; GP visit only, 21%; GP visit and specialist consultation, 8%; specialist consultation only, 19%) and OHIP fee codes (referral without specialist [A005], $87.90; GP visit [A947], $37.95; specialist consultation [A475], $175.55).
[d]For these inputs, we assigned gamma or normal distributions in probabilistic analysis, depending on the type of input (Appendix 5).

Internal Validation

Formal internal validation was conducted by a secondary health economist. This included testing the mathematical logic of the model and checking for errors and accuracy of parameter inputs and equations.

Equity Considerations

Economic evaluations inherently focus on horizontal equity (i.e., people with similar characteristics are treated in a similar way). Where possible, we conducted subgroup or scenario analyses to best address vertical equity (allow for people with different characteristics to be treated differently according to their needs).

In the clinical review, we did not identify any equity considerations relevant to the effectiveness of level 2 polysomnography devices compared with devices used in current practice. However, we conducted subgroup analyses, based on the data reported in the clinical review, related to heterogeneity of diagnostic accuracy in various populations (people with obstructive sleep apnea, pediatric populations, or people with periodic leg movement). In addition, in a scenario analysis focused on adults with obstructive sleep apnea, we explored the use of CPAP after testing positive with level 2 or level 1 polysomnography, and the impact of false positive or false negative findings and conducted the short-term cost–utility analysis of level 2 polysomnography. In this way, we examined horizontal equity because the use of QALYs reflects horizontal equity because equal social value is assigned to each unit of health effect, regardless of the characteristics of the people who receive those effects or the condition being treated.

With the introduction of level 2 polysomnography, access to diagnostic testing of various sleep disorders may improve for some populations. However, the cost estimates provided in our study are of a hypothetical nature, and in general, the true estimate depends on negotiations between the Ministry and stakeholder organizations such as the Ontario Medical Association and industry. Nevertheless, we examined how changes in the cost of level 2 polysomnography affected the cost-effectiveness and budget impact estimates.

Analysis

Our reference case and sensitivity analyses adhere to CADTH guidelines when appropriate.[144] The reference case represents the analysis with the most likely set of input parameters and model assumptions. The sensitivity analysis explores how the results are affected by varying input parameters and model assumptions. All analyses were conducted using TreeAge Pro 2023.[153]

We calculated the reference case estimates by running 1,000,000 simulations in probabilistic analysis to simultaneously diminish the sample error and capture the uncertainty in all parameters that were expected to vary. Types of distributions assigned to each input parameter used in the

probabilistic analysis are stated. We calculated mean total costs and mean effectiveness outcomes with corresponding 95% credible intervals (CrI). From mean cost and effectiveness outcomes of the intervention and control) strategies, we calculated incremental values and estimated ICERs. In addition to estimating the ICER for each comparison, we also used incremental net monetary benefit to evaluate the cost-effectiveness of the included pathways. In addition, in a cost–utility scenario, we estimated the ICER using QALYs and presented the results of the probabilistic analysis using a scatter plot on a cost-effectiveness plane and/or in a cost-effectiveness acceptability curve. Although not used as a definitive willingness-to-pay (WTP) threshold, we included graphical indications of the location of the results relative to a WTP value of $50,000 per QALY to facilitate interpretation of the findings of this scenario and comparison with historical decisions.

Sensitivity Analysis

We examined uncertainty through additional sensitivity or scenario analyses to evaluate the impact of the specific parameter values or assumptions on the results of our reference case cost-effectiveness analysis. We used threshold analysis to determine the break-even points for several important factors, such as diagnostic accuracy or cost of the level 2 test. Where appropriate, we conducted 2- or multiway sensitivity analyses considering different sets of parameter values. We also conducted specific scenario analyses and describe changes in the parameter inputs, assumptions, and in the model structure for specific populations (children) or specific situations (e.g., use of CPAP) (Appendix 6 and Appendix 7). For simplicity and for meaningful sensitivity analysis results, we focused on estimating changes in the incremental costs of the level 2 polysomnography diagnostic pathway, by assuming equal effectiveness of both strategies at the end of testing pathways.

One-Way and Multiway Sensitivity Analyses and Threshold Analyses

We summarize below changes considered in various types of sensitivity analyses for important input parameters.

Clinical Model Parameters

- Pretest probability (or prevalence) of having a sleep disorder (p=0.05–1)
- Diagnostic accuracy of the reference standard (level 1 polysomnography), assuming an imperfect reference standard with a very high diagnostic test performance (sensitivity, 0.960; specificity, 0.975)[154]
- Diagnostic accuracy of level 2 polysomnography, based on data from the clinical evidence review:
  - Sensitivity, 0.760 to 1.00; specificity, 0.400 to 1.00
  - Sensitivity, specificity, and failure rate values reported for specific population subgroups for which we found clinical evidence:
    - **Obstructive sleep apnea**: One study[125] (GRADE: Low [for whole body of evidence]; Appendix 3) which was associated with low risk of bias, examined the diagnostic accuracy of level 2 polysomnography by apnea hypopnea index (AHI; where AHI ≥ 5 is suggestive of mild and AHI ≥ 15 is suggestive of moderate to severe obstructive sleep apnea). We conducted subgroup analyses using the sensitivity and specificity values for level 2 polysomnography reported for 3 patient subgroups based on AHI (AHI ≥ 5: sensitivity, 0.960; specificity, 0.710; AHI ≥ 15: sensitivity, 0.760; specificity, 0.850; AHI ≥ 30: sensitivity, 0.860; specificity, 1.00);

we also used the technical failure rates (level 2 polysomnography, 4.7%; level 1 polysomnography, 1.5%) estimated for the whole study sample[125]

  - **Sleep bruxism:** One study[133] (GRADE: Very low; Appendix 3) examined adults with sleep bruxism (level 2 polysomnography: sensitivity, 1.0; specificity, 0.60; level 1 and level 2 polysomnography technical failure rate, 0%)
  - **Periodic leg movement:** One study[129] (GRADE: Very low to Low; Appendix 3) examined adults with this condition (level 2 polysomnography: sensitivity, 0.890; specificity, 0.970; level 1 and level 2 polysomnography technical failure rate, 0%)
- Failure rate of level 2 polysomnography, ranging from 0% to 50%; this range included the lowest and the highest reported values of 0%[129,155,156] and 20%[130]; certainty in the body of evidence for this outcome was Very low (GRADE; Appendix 3)

Referral and Follow-Up Costs in the Diagnostic Pathway

Because of uncertainty in clinical care pathway costs, in these analyses, we explored how changes in the referral and follow-up portions of the diagnostic pathway would affect cost-effectiveness results:

- **Cost estimate for the referral visit:** Based on data from the MOH Provider Service Branch (email communication: Aug 9, 2023) about referrals associated with OHIP codes J895, J896, and J897, which indicate diagnostic and therapeutic use of sleep studies, we estimated a larger weighted cost based on referral from various physicians (general practitioners, psychiatrists, internal medicine physicians, and respirologists) and calculated $163.55 (in the reference case: $104.11) and was based on the published literature,[145] with the assumption that polysomnography is solely for diagnostic test purposes
- **Cost of follow-up visit after a positive test result:** We assumed a short visit (partial reassessment, A478: $39.60 per visit to represent a lower specialist visit cost (in the reference case: $108.95)

Market Share of Level 1 Polysomnography

- Assuming level 1 polysomnography would be done at independent health facilities labs solely (the level 1 study fee of about $481.35 (in the reference case: $474.80 per person)
- Assuming 70% (independent health facility) versus 30% (hospital) market share for the level 1 polysomnography based on published data[65,145]; this resulted in a slightly higher cost of level 1 polysomnography of about $477.42 per person (in the reference case: $474.80 per person)

Cost of Level 2 Polysomnography

- Technical fee component:
  - Manufacturer technical fee cost estimate per person: $235.02 for a technician-applied device and $213.18 for self-applied device (with inclusion of the professional fee, overall level 2 polysomnography costs of $332.52 [technician-applied] and $310.68 [self-applied])
  - Cost estimate based on a percentage adjustment of the Australian Ministry of Health billing fees: $270.75 per person
  - Ranging from $0 to $600.00 per person
  - Double the reference case cost estimate to $481.20 per person (in the reference case: $240.60); with inclusion of the professional fee, the total sleep study cost was about $579 (in the reference case: $338)
  - Inclusion of technician's travel time; this is counted as additional labour time (assuming additional 1 hour of labour time for travel) which resulted in an increase in technical fee component of the test to $253.10 per adult (Table A5) and to $378.10 per child (Table A6)
  - Cost of disposable per test, ranging from $5 to $50 (in the reference case: $14)
  - Number of times the device used per year, ranging from 104 to 364 times per year (in the reference case: 180)
- Professional fee component:
  - We assumed there was a 20% increase in the cost of professional fee with level 2 polysomnography (about $117.00 per test). This is a purely hypothetical scenario as the payment rates for OHIP fee codes are negotiated between the MOH, OMA, and other relevant health care partners
- Total test cost:
  - The same cost for level 1 and level 2 polysomnography

Threshold (One-Way) Sensitivity Analyses

- Pretest probability (prevalence) of having a sleep disorder
- Sensitivity and specificity of level 2 polysomnography
- Technical failure rate of level 2 polysomnography
- Various components used for estimation of the level 2 polysomnography test cost
  - Technical fee component per person
  - Disposables subcomponent cost per test
  - Device cost
  - Sleep medicine technician salary rate per hour, not including benefits
  - Sleep medicine technician labour hours
  - Administrative labour hours
  - Technician-to-patient ratio
  - Device use
- Total cost per test for level 2 polysomnography (both professional and technical components included)

Two-Way or Multiway Sensitivity Analyses

Two-way sensitivity analysis on the sensitivity estimates of level 1 and level 2 polysomnography (assuming the same values for the pretest probability and other input parameters as those for the reference case):

- Two-way sensitivity analysis on the cost of level 2 polysomnography and prevalence of sleep disorders
- Multiway sensitivity analysis varying the failure rates of the level 2 and level 1 polysomnography, with the assumption that the diagnostic accuracy of both tests is the same (perfect)

Table 13: Summary of Changes in Parameter Input Values in Sensitivity Analyses

Inputs and analyses	Assumption or basis	Value
Clinical model parameters*		
Pretest probability		
Reference	*Clinical evidence[125]*	*p = 0.05*
Sensitivity analysis	Range	$0.05 \leq p < 1$
Diagnostic accuracy		
Level 1 PSG		
Reference	*Perfect test performance*	*Sn = 1.00; Sp = 1.00*
Sensitivity analysis	Imperfect but high test performance[154]	Sn = 0.960; Sp = 0.975
Level 2 PSG		
Reference	*Clinical evidence[131]*	*Sn = 0.800; Sp = 0.830*
Sensitivity analysis	Clinical evidence range[124-131]	$0.760 \leq Sn \leq 1.00$; $0.400 \leq Sp \leq 1.00$
Sensitivity analysis	Obstructive sleep apnea – mild[125,a]	Sn = 0.960; Sp = 0.710
Sensitivity analysis	Obstructive sleep apnea – moderate[125,a]	Sn = 0.760; Sp = 0.850
Sensitivity analysis	Obstructive sleep apnea – severe[125,a]	Sn = 0.800; Sp = 1.00
Sensitivity analysis	Sleep bruxism[133,b]	Sn = 1.00; Sp = 0.600
Sensitivity analysis	Periodic leg movement[129,b]	Sn = 0.890; Sp = 0.970
Technical failure rate		
Level 1 PSG		
Reference	*Perfect test performance; clinical evidence[131]*	*0%*
Sensitivity analysis	High technical failure	5%
Level 2 PSG		
Reference	*Clinical evidence[131]*	*15%*
Sensitivity analysis	Range that exceeds reported values[c]	0.5%–50%
	*Lowest values, level 2 PSG sensitivity and specificity[d]	Sn = 0.760, Sp = 0.400; technical failure: 15%
	*Worst performance, all level 2 PSG clinical parameters[d]	Sn = 0.760, Sp = 0.400; technical failure: 20%
	*Highest values, level 2 PSG sensitivity and specificity[d]	Sn = 1.00, Sp = 1.00; technical failure: 15%
	*Low level 2 PSG technical failure[d]	Sn = 1.00, Sp = 1.00; technical failure: 4.7%
	*High technical failure[d]	Level 2 PSG – Sn = 1.00, Sp = 1.00, technical failure: 20%; Level 1 PSG – Sn = 1.00, Sp = 1.00, technical failure: 5%
Referral and follow-up costs		
Cost estimate for initial physician visit		
Reference	*Weighted mean, using published data,[145] OHIP*	*$104.11*
Sensitivity analysis	Larger cost	$163.55
Cost of consultation after positive test		
Reference	*OHIP*	*$108.95*
Sensitivity analysis	Shorter visit, OHIP	$39.60

Inputs and analyses	Assumption or basis	Value
Market share of level 1 PSG		
Reference	*Equal (50:50), OHIP*	*$474.80*
Sensitivity analysis	IHF only (100:0), OHIP	$481.35
Sensitivity analysis	Mostly IHF (70:30),[65,145] OHIP[141,149]	$477.42
Cost of level 2 PSG		
Total test		
Reference	*Estimate*	*$338.10*
Sensitivity analysis	Same as level 1 PSG cost	$474.80
Technical (total test)		
Reference	*OHIP*	*$240.50 ($338.10)*
Sensitivity analysis	Manufacturer estimate – technician-applied	$235.02 ($332.52)
Sensitivity analysis	Manufacturer estimate – patient-applied	$213.18 ($310.68)
Sensitivity analysis	Adjustment based on Australian MOH percentage	$270.75 ($368.25)
Sensitivity analysis	Range	$0.00–$600.00 ($97.50–$697.50)
Sensitivity analysis	Double the reference case	$480.00 ($570.00)
Sensitivity analysis	With technician travel time	$253.10 ($350.60)
Professional (total test)		
Reference	OHIP	$97.50 ($338.10)
Sensitivity analysis	20% increase	$117.00 ($357.50)
Other		
Disposables subcomponent of technical fee cost		
Reference	*Expert estimate*	*$14.00*
Sensitivity analysis	Range	$5.00–$50.00
Device use frequency		
Reference	*Approximately 75% utilization for most clinics[150]*	*180*
Sensitivity analysis	Range	104–364

Abbreviations: IHF, independent health facility; MOH, Ministry of Health; OHIP, Ontario Health Insurance Plan; PSG, polysomnography; Sn, sensitivity, Sp, specificity.

[a]Technical failure rates – level 1 PSG: 1.5%; level 2 PSG: 4.7%.

[b]Technical failure rates – level 1 PSG: 0%; level 2 PSG: 0%.

[c]Lowest and highest reported values were 0%[129,155,156] and 20%,[130] respectively.

[d]Results reported.

Scenario Analyses

Scenario 1: New Diagnostic Pathway Assumption – Level 1 Polysomnography is Used When Technical Failure of Initial Level 2 Polysomnography Occurs

This scenario included 3 diagnostic pathways and a structural change to the model to allow for 2 intervention strategies to be assessed: (1) new diagnostic pathway to use of level 1 polysomnography for people who fail initial level 2 polysomnography testing due to technical errors; this is in addition to the level 1polysomnography use for those who tested incorrectly negative; and (2) reference case diagnostic pathway (use of level 2 polysomnography after initial technical failure). Both of these strategies were compared with current practice (i.e., level 1 polysomnography). Model inputs were assumed to be the same as those described in Table 11, Table 12, and Table A7.

Scenario 2: New Diagnostic Pathway Assumption – Level 1 Polysomnography Is Used if Initial Level 2 Polysomnography Results Are Negative

This scenario included a structural change to the reference case model, namely, expansion of the level 2 arm of the diagnostic tree to enable additional costs of follow-up and testing with level 1 polysomnography for all who received test negative results after level 2 polysomnography (Table A7, Appendix 6).

Scenario 3: Adults With Obstructive Sleep Apnea – CPAP Therapy Costs

In this cost–utility analysis, we estimated the impact of providing therapy with a CPAP system to adults with suspected obstructive sleep apnea. The purpose of this analysis was to estimate imminent cost impact of funding a CPAP device for those who tested positive, and more specifically, incorrectly positive with level 2 polysomnography, rather than to examine the value of long-term treatment of obstructive sleep apnea with CPAP, which has previously been well established in several cost-effectiveness studies, including some from a Canadian health system perspective.[157,158] We described the model structure, additional assumptions and parameter inputs in Appendix 7. The cost of CPAP treatment was not considered for pediatric populations because CPAP is not the first line of treatment for sleep apnea in children.

Scenario 4: Pediatric Clinical Population

We assumed the same reference case model structure for this population subgroup and changed the effectiveness of the intervention based on the literature data from 1 study with a pediatric population.[132] This is a study of good methodological quality, associated with low risk of bias and certainty in the evidence for the outcomes sensitivity and specificity (GRADE: Moderate to High; Appendix 3). The sensitivity and specificity of level 2 polysomnography were high (0.933 and 0.969, respectively), and there was no reported technical failure. In addition to effectiveness parameter values, we changed some cost inputs based on our limited understanding of the use of sleep studies in pediatric

populations; therefore, this scenario should be considered hypothetical and needs corroboration in future studies:

- Based on our knowledge, most children are tested in designated sleep clinics in hospitals[140,141]; therefore, we assumed that the technical fee for level 1 polysomnography was $370.75, as stated in the Schedule of Benefits for code J890[140] for special populations including children
- We used a similar approach to costing of the level 2 polysomnography, but for children, we assumed that the sleep medicine technician-to-patient ratio was 1:1 instead of 1:3 (used for adults in the reference case, Appendix 5, Table A6); this resulted in a higher cost estimate of $438.10 per child
- We used the same approach to costing for referral and follow-up care but made a minor change in the cost of a follow-up visit associated with a billing code that reflects consult visits with a respirologist for children (A765: $165.50)

Results

Reference Case Analysis

Our economic analysis found that both diagnostic strategies were similarly effective at diagnosing sleep disorders, given our assumption that all false-negative results of level 2 polysomnography would be further detected with additional level 1 polysomnography (Table 14). Assuming level 1 polysomnography is a perfect reference standard, there were no false positive results or false negative results with the current practice diagnostic pathway; however, with the new diagnostic pathway with level 2 polysomnography, the probability of having an incorrect test result with level 2 polysomnography was about 19% (8.5% were false-positive test results and 10% were false-negative test results).

The new diagnostic pathway with level 2 polysomnography costs less, by about $27.20 (Table 15). This is because the cost of level 2 polysomnography was much lower than the cost of level 1 polysomnography ($344.67 vs. $474.80), but the new diagnostic pathway was also associated with additional costs when technical failure occurred during the initial test ($37.12) or when the initial test was incorrectly negative ($101.33) or incorrectly positive ($42.49). The cost difference between the two diagnostic pathways was uncertain given the wide 95% credible interval (95% CrI, −$137 to $121). Based on the mean point estimate for the main effectiveness outcome (confirmed or ruled out sleep disorder), the new pathway with level 2 polysomnography was cost-saving in comparison with current practice (i.e., the diagnostic pathway with level 1 polysomnography). In probabilistic analysis, the diagnostic pathway with level 2 polysomnography was cost-saving more often (about 70% of the time) than the current practice (30% of the time).

Table 14: Reference Case Analysis Results – Effectiveness and Cost Outcomes

Outcome	Current practice: level 1 PSG[a]	Intervention: level 2 PSG[b]
Confirmed sleep disorder at the end of pathway, *p*, mean (95% CrI)	0.50 (0.26–0.74)	0.50 (0.26–0.74)
Positive test result, *p*, mean (95% CrI)	0.50 (0.26–0.74)	0.48[c] (0.29–0.68)
True positive, *p*, mean (95% CrI)	0.50 (0.26–0.74)	0.40 (0.20–0.62)
False positive, *p*, mean (95% CrI)	0	0.085 (0.02–0.20)
True negative, *p*, mean (95% CrI)	0.50 (0.26–0.74)	0.42[c] (0.20–0.64)
False negative, *p*, mean (95% CrI)	0	0.10 (0.03–0.21)
Total cost of diagnostic pathway, $, mean (95% CrI)	653.18 (636–670)	625.99 (511–778)
Initial test cost total fee, $, mean (95% CrI)	474.80	344.67 (261–461)
Technical fee	377.30	247.16 (164–363)
Pathway cost of resolving		
False-negative diagnosis,[d] $, mean (95% CrI)	0	101.33 (29–218)
False-positive diagnosis,[e] $, mean (95% CrI)	0	42.49 (9–102)
Cost of retesting due to technical failure, $, mean (95% CrI)	0	37.12 (13–75)

Abbreviations: CrI, credible interval; *p*, probability; PSG, polysomnography.
[a]*Current practice: level 1 PSG* refers to the existing diagnostic pathway with level 1 PSG.
[b]*Intervention: level 2 PSG* refers to a new diagnostic pathway with level 2 PSG.
[c]Values may appear inexact due to rounding.
[d]The cost of the false-negative pathway includes the total cost of the initial test, costs of follow-up visits, and cost of retesting with level 1 PSG.
[e]The cost of the false-positive pathway includes the total cost of the initial test and the cost of additional follow-up visits.

Table 15: Reference Case Analysis Results – Cost-Effectiveness of Level 2 Polysomnography vs. Level 1 Polysomnography

Strategy	Average total costs (95% CrI), $	Incremental cost, mean (95% CrI), $[a,b,c]	Average total effects (95% CrI)	Incremental effect, mean (95% CrI)[c,d]	ICER[e]
Per confirmed diagnosis					
Current practice: level 1 PSG[f]	653.18 (636 to 670)	—	0.50 (0.26 to 0.74)	—	—
Intervention: level 2 PSG[g]	625.99 (511 to 778)	−27.20 (−137 to 121)	0.50 (0.26 to 0.74)	0	Dominant[h]
Per positive test case					
Current practice: level 1 PSG[f]	653.18 (636 to 670)	—	0.50 (0.26 to 0.74)	—	—
Intervention: level 2 PSG[g]	625.99 (511 to 778)	−27.20 (−137 to 121)	0.48 (0.29 to 0.68)	−0.015 (−0.16 to 0.14)	$2,720

Abbreviations: CrI, credible interval; ICER, incremental cost-effectiveness ratio.
[a]Incremental cost = average cost (level 2 PSG) − average cost (level 1 PSG).
[b]Negative costs indicate savings.
[c]Results may appear inexact due to rounding.
[d]Incremental effect = average effect (level 2 PSG) − average effect (level 1 PSG).
[e]ICER was expressed as $/confirmed diagnosis.
[f]*Current practice: level 1 PSG* refers to the existing diagnostic pathway with level 1 PSG.
[g]*Intervention: level 2 PSG* refers to a new diagnostic pathway with level 2 PSG.
[h]Dominant indicates the level 2 PSG diagnostic pathway is equally effective and less costly than the level 1 PSG diagnostic pathway.

Sensitivity Analysis

Clinical Model Parameters

Pretest Probability (or Prevalence of Having a Sleep Disorder)

As pretest probability (i.e., prevalence) increases from 0.05 to 1, savings and the incremental net benefit of the level 2 polysomnography diagnostic pathway versus the level 1 polysomnography diagnostic pathway decreases (Figure 6). At a pretest probability of approximately 0.88 (i.e., the threshold break-even point), the level 2 polysomnography diagnostic pathway was not associated with greater benefit than the level 1 polysomnography diagnostic pathway.

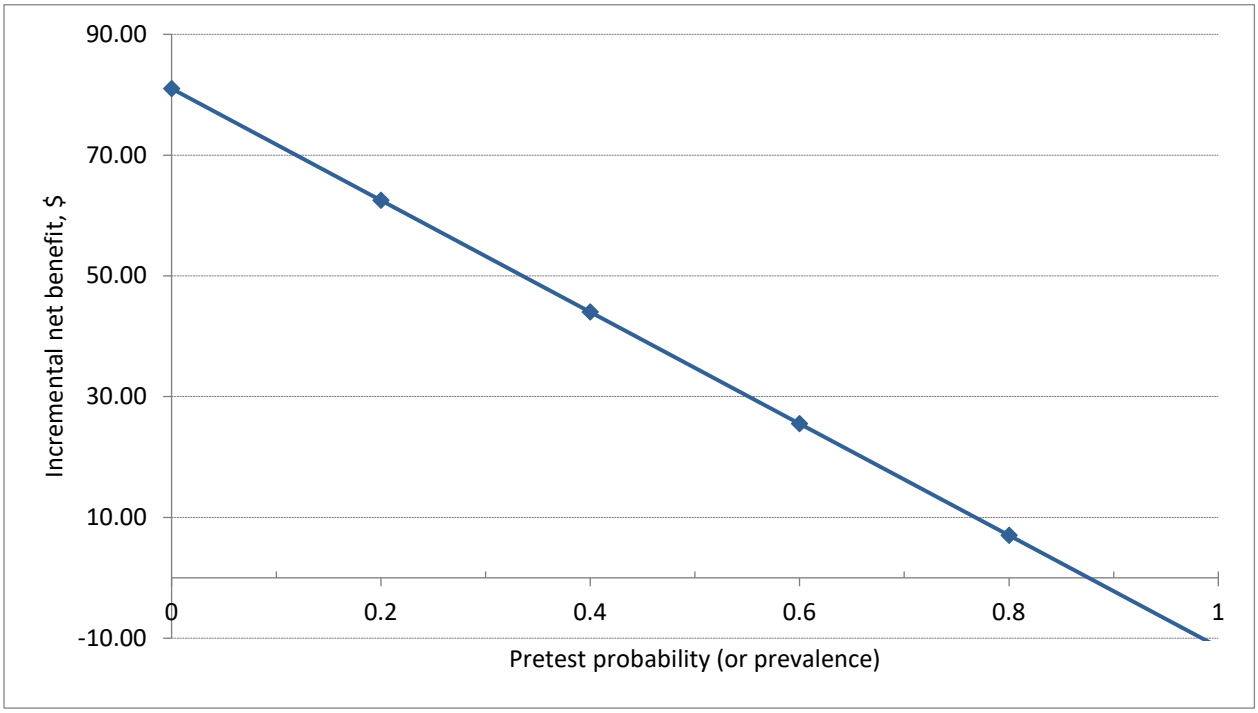

Figure 6: Change in the Cost-Effectiveness of the New Diagnostic Pathway With Level 2 Polysomnography With Change in Sleep Disorder Prevalence

Incremental net benefit is estimated using the following equation:

Incremental net benefit = Incremental effectiveness × Willingness-to-pay – Incremental costs

In our case, the *Willingness-to-pay* value does not need to be defined precisely because we assumed that both pathways had equal effectiveness.

Diagnostic Accuracy of Level 1 Polysomnography

Assuming that level 1 polysomnography had high but not perfect diagnostic test performance resulted in a higher total cost for the level 1 polysomnography diagnostic pathway ($669.60 per person) and consequently, larger per-person savings for the level 2 polysomnography diagnostic pathway ($43.54 per person). In a 2-way sensitivity analysis, we found that the level 1 polysomnography diagnostic pathway (with sensitivity 0.850) would be preferable to the level 2 polysomnography pathway only when level 2 polysomnography had a sensitivity less than 0.650.

Diagnostic Accuracy of Level 2 Polysomnography

The cost-effectiveness of the level 2 polysomnography diagnostic pathway (in comparison with level 1 polysomnography) varied with changes in the sensitivity and specificity of level 2 polysomnography. When we used the lowest published values for sensitivity and specificity, there were no cost savings, and the incremental mean cost was $21.43 (Table 16). For the best-case scenario published values, when level 2 and level 1 tests had equal sensitivity and differed only in failure rate, we found that the level 2 polysomnography diagnostic pathway was cost-saving (mean savings $92–$118) and was dominant over the level 1 polysomnography diagnostic pathway more than 90% of the time in probabilistic analysis.

- Break-even points for the sensitivity and specificity of level 2 polysomnography were 68% and 23%, respectively

Table 16: Sensitivity Analysis Results – Low and High Ranges for Sensitivity and Specificity of Level 2 Polysomnography, Adults

Strategy	Average total costs, $	Incremental cost, mean (95% CrI), $[a,b]	% Cost-effective in probabilistic analysis[c]	ICER[d]
Current practice: level 1 PSG[e]	653.19	—	—	—
Intervention: level 2 PSG[f]				
Worst performance,[g] all clinical parameters (Sn = 0.76, Sp = 0.40; technical failure: 20%)	674.62	21.43 (−88 to 169)	35% of the time	Dominated[h]
Lowest values, sensitivity and specificity (Sn = 0.76, Sp = 0.40; technical failure: 15%)	662. 23	9.04 (−98 to 155)	42% of the time	Dominated[h]
Highest values, sensitivity and specificity (Sn = 1.0, Sp = 1.0; technical failure: 15%)	560.27	−92.92 (−191 to 45)	98% of the time	Dominant[i]
Highest values, accuracy; low technical failure rate (Sn = 1.0, Sp = 1.0; technical failure: 4.7%)	534.79	−118.39 (−206 to 5)	98% of the time	Dominant[i]
Highest values, accuracy; high technical failure rates for both sleep studies				
Current practice: level 1 PSG[e] (Sn = 1.0, Sp = 1.0; technical failure: 5%)	672.06	—	—	—
Intervention: level 2 PSG[f] (Sn = 1.0, Sp = 1.0; technical failure: 20%)	572.66	−99.40 (−200 to 41)	94% of the time	Dominant[i]

Abbreviations: ICER, incremental cost-effectiveness ratio, PSG, polysomnography; Sn, sensitivity; Sp, specificity.
[a]Incremental cost = average cost (level 2 PSG) – average cost (level 1 PSG).
[b]Negative costs indicate savings.
[c]The percentages in this column indicate how often level 2 PSG was found to be more cost-effective than level 1 PSG in probabilistic analysis.
[d]ICER was expressed as $/confirmed diagnosis.
[e]*Current practice: level 1 PSG* refers to the existing diagnostic pathway with level 1 PSG.
[f]*Intervention: level 2 PSG* refers to a new diagnostic pathway with level 2 PSG.
[g]Based on published clinical evidence.
[h]Dominated indicates the level 2 PSG diagnostic pathway is equally effective but more costly than the level 1 diagnostic pathway.
[i]Dominant indicates the level 2 PSG diagnostic pathway is equally effective and less costly than the level 1 diagnostic pathway.

Obstructive sleep apnea: For sensitivity and specificity values reported for adults with mild, moderate, and severe obstructive sleep apnea,[125] the new diagnostic pathway with level 2 polysomnography was cost-saving (for all 3 severities by AHI score) when compared with current practice diagnostic pathway with level 1 polysomnography. The probability of cost-effectiveness was high, with the level 2 polysomnography diagnostic pathway being dominant 84% of the time or more.

Table 17: Sensitivity Analysis Results – Level 2 Polysomnography for Adults With Obstructive Sleep Apnea

Strategy	Average total costs, $	Incremental cost, mean (95% CrI), $[a,b]	% Cost-effective in probabilistic analysis[c]	ICER[d]
Current practice: level 1 PSG[e]	658.85	—	—	—
Intervention: level 2 PSG[f]				
Mild obstructive sleep apnea[g]	562.64	−96.21 (−192 to 49)	94% of the time	Dominant[h]
Moderate obstructive sleep apnea[i]	610.81	−48.04 (−149 to 86)	84% of the time	Dominant[f]
Severe obstructive sleep apnea[j]	573.99	−84.86 (−185 to 51)	93% of the time	Dominant[f]

Abbreviations: AHI, apnea-hypopnea index; CrI, credible interval; ICER, incremental cost-effectiveness ratio; PSG, polysomnography; Sn, sensitivity, Sp, specificity.

[a]Incremental cost = average cost (level 2 PSG) – average cost (level 1 PSG).

[b]Negative costs indicate savings.

[c]The percentages in this column indicate how often level 2 PSG was found to be more cost-effective than level 1 PSG in probabilistic analysis.

[d]ICER was expressed as $/confirmed diagnosis.

[e]*Current practice: level 1 PSG* refers to the existing diagnostic pathway with level 1 PSG.

[f]*Intervention: level 2 PSG* refers to a new diagnostic pathway with level 2 PSG.

[g]Mild AHI ≥ 5: prevalence ≥ 0.50; Sn = 0.960, Sp = 0.710; failure rate: 4.7% level 2 and 1.5% level 1 PSG.[125]

[h]Dominant indicates the level 2 PSG diagnostic pathway is equally effective and less costly than the level 1 diagnostic pathway.

[i]Moderate is AHI ≥ 15: prevalence ≥ 0.50; Sn = 0.760, Sp = 0.850; failure rate: 4.7% level 2 and 1.5% level 1 PSG.[125]

[j]Severe is AHI ≥ 30: prevalence ≥ 0.50; Sn = 0.860, Sp = 1.00; failure rate: 4.7% level 2 and 1.5% level 1 PSG.[125]

Sleep bruxism: For sensitivity and specificity values reported[133] for adults with suspected sleep bruxism,[133] the new diagnostic pathway with level 2 polysomnography was associated with mean total costs of $546.15 per person and cost savings of $107.04 per person (95% CrI, −$192 to $11) compared with the current practice diagnostic pathway with level 1 polysomnography. The new diagnostic pathway with level 2 polysomnography was dominant over the current practice diagnostic pathway more than 96% of the time in the probabilistic analysis.

Periodic leg movement: For sensitivity and specificity values reported for adults with suspected periodic leg movements,[129] the new diagnostic pathway with level 2 polysomnography was associated with mean total costs of $556.12 per person and cost savings of $97.07 per person (95% CrI, −$197 to $49) when compared with the current practice diagnostic pathway. The new diagnostic pathway with level 2 polysomnography was dominant over the current practice diagnostic pathway more than 93% of the time in the probabilistic analysis.

Technical Failure Rate of Level 2 Polysomnography

Cost savings and the incremental net monetary benefit of the level 2 polysomnography diagnostic pathway versus level 1 polysomnography diagnostic pathway decreased as the technical failure rate increased from 0%[129,155,156] to a hypothetical 50%, with the break-even point at 29%. In multiway

sensitivity analysis, the cost savings remained (Table 16) even when we used the highest reported failure rate of 20%[153] as long as the sensitivity and specificity of level 2 polysomnography were high (i.e., > 0.800).

Referral and Follow-Up Costs in the Diagnostic Pathway

A larger cost estimate for the referral visit did not have any effect on incremental cost of the level 2 polysomnography diagnostic pathway. This was because the costs associated with visits that preceded either type of testing canceled one another in the incremental cost-effectiveness analysis.

A lower follow-up consultation visit cost after testing positive had a minor effect; the incremental saving of the level 2 polysomnography diagnostic pathway slightly decreased to $26.16 from $27.20 in the reference case.

Market Share of Level 1 Polysomnography

Market share (level 1 sleep study performed in an independent health facility or hospital) did not substantially affect the cost-effectiveness of the new diagnostic pathway with level 2 polysomnography (Table 18). When we assumed that level 1 polysomnography was done at independent health facilities solely or if we assumed that 70% of level 1 polysomnography tests were done at independent health facilities,[65] we found slightly higher cost savings for the level 2 polysomnography diagnostic pathway of $33.01 (independent health facilities solely) or $29.48 per person (mostly independent health facilities) versus cost savings of $27.20 per person in the reference case (in which an equal market share was assumed).

Table 18: Sensitivity Analysis Results – Market Share of Level 1 Polysomnography, Adults

Strategy	Average total costs, $	Incremental cost, mean (95% CrI), $[a,b]	% Cost-effective in probabilistic analysis[c]	ICER[d]
Independent health facilities only				
Current practice: level 1 PSG[e]	659.74	—	—	—
Intervention: level 2 PSG[f]	626.72	−33.01 (−143 to 115)	75% of the time	Dominant[g]
Mostly independent health facilities (70:30)				
Current practice: level 1 PSG[e]	655.81	—	—	—
Intervention: level 2 PSG[f]	626.33	−29.48 (−140 to 119)	74% of the time	Dominant[g]

Abbreviations: CrI, credible interval; ICER, incremental cost-effectiveness ratio, PSG, polysomnography.

[a]Incremental cost = average cost (level 2 PSG) − average cost (level 1 PSG).

[b]Negative costs indicate savings.

[c]The percentages in this column indicate how often level 2 PSG was found to be more cost-effective than level 1 PSG in probabilistic analysis.

[d]ICER was expressed as $/confirmed diagnosis.

[e]*Current practice: level 1 PSG* refers to the existing diagnostic pathway with level 1 PSG.

[f]*Intervention: level 2 PSG* refers to a new diagnostic pathway with level 2 PSG.

[g]Dominant indicates the level 2 PSG diagnostic pathway is equally effective and less costly than the level 1 diagnostic pathway.

Cost of Level 2 Polysomnography

The cost-effectiveness of the new diagnostic pathway with level 2 polysomnography was sensitive to the cost of level 2 polysomnography test (Table 19), suggesting uncertainty around the estimation of various cost components or total cost. Compared with the reference case (an estimated $27.20 in per-person cost-savings),

- If we used the manufacturer-provided cost estimates for technician-applied and patient-applied level 2 polysomnography devices, we found cost savings between $41.20 and $66.32 with the new diagnostic pathway with level 2 polysomnography, and a very high probability of cost-effectiveness greater than 91% (> 91% for tech-applied and > 97% for self-applied devices)
- If the cost estimate was lower than the reference case ($271 per person; i.e., percentage adjustment using Australian Ministry level 1 and level 2 sleep study billing fees), per-person savings with the new diagnostic pathway with level 2 polysomnography were $97.23
- If we doubled the reference case cost estimate, the current pathway with level 1 polysomnography dominated the new diagnostic pathway with level 2 polysomnography
- If we included travel time as additional labour time, it resulted in a higher level 2 polysomnography cost which lowered savings to $12.82; the point estimate had a large 95% CrI (−$128 to $141), which suggests that there is large uncertainty in cost savings with the new diagnostic pathway with level 2 polysomnography
- If the cost of disposables (per test) increased trifold, the new diagnostic pathway with level 2 polysomnography compared with the current pathway with level 1 polysomnography was not cost saving but was associated with additional costs of $4.57 per person (95% CrI, −$108 to $156)
- The physician fee cost increase by 20% for level 2 polysomnography test resulted in a decrease in savings to $7.69 (95% CrI, −$117 to $140) with the new diagnostic pathway
- When we assumed that the cost of level 1 and level 2 polysomnography tests (i.e., no changes in the current OHIP fees for sleep studies) were the same, the new diagnostic pathway with level 2 polysomnography was associated with incremental costs of $122.43 (95% CrI, $65 to $197) compared with the current pathway with level 1 polysomnography

Table 19: Sensitivity Analysis Results – Per-Person Level 2 Polysomnography Technical Fees

Strategy	Average total costs, $	Incremental mean cost (CrI), $[a,b]	% Cost-effective in probabilistic analysis[c]	ICER[d]
Current practice: level 1 PSG[e]	653.19	—	—	—
Intervention: level 2 PSG[f]				
Manufacturer estimate, technician-applied	611.98	−41.20 (−89 to 25)	91% of the time	Dominant[g]
Manufacturer estimate, patient-applied	586.86	−66.32 (−112 to −0.32)	97.5% of the time	Dominant[g]
Adjustment based on Australian MOH percentage	555.96	−97.23 (−240 to 84)	89% of the time	Dominant[g]
Double the reference case	910.44	257.26 (53 to 537)	2% of the time	Dominated[h]

Abbreviations: CrI, credible interval; ICER, incremental cost-effectiveness ratio; MOH, Ministry of Health; PSG, polysomnography.
[a]Incremental cost = average cost (level 2 PSG) − average cost (level 1 PSG).
[b]Negative costs indicate savings.
[c]The percentages in this column indicate how often level 2 PSG was found to be more cost-effective than level 1 PSG in probabilistic analysis.
[d]ICER was calculated as $/confirmed diagnosis.
[e]*Current practice: level 1 PSG* refers to the existing diagnostic pathway with level 1 PSG.
[f]*Intervention: level 2 PSG* refers to a new diagnostic pathway with level 2 PSG.
[g]Dominant indicates the level 2 PSG diagnostic pathway is equally effective and less costly than the level 1 diagnostic pathway.
[h]Dominated indicates the level 2 PSG diagnostic pathway is equally effective but more costly than the level 1 diagnostic pathway.

Threshold (One-Way) Sensitivity Analyses

We identified the following break-even points for the new diagnostic pathway with level 2 polysomnography (assuming all other reference case input values were fixed and unchanged):

- Technical fee component (per person): approximately $300.00 (Figure 7)
- Disposables subcomponent cost (per test): $44.24
- Device cost: approximately $19,445
- Sleep medicine technician salary rate (per hour, not including benefits): approximately $37.26
- Sleep medicine technician labour: approximately 6.4 hours
- Administrative labour: approximately 1.5 hours
- Technician-to-patient ratio in a sleep clinic: approximately 2 to 1
- Device use (number of uses per year): approximately 130 (Figure 8)

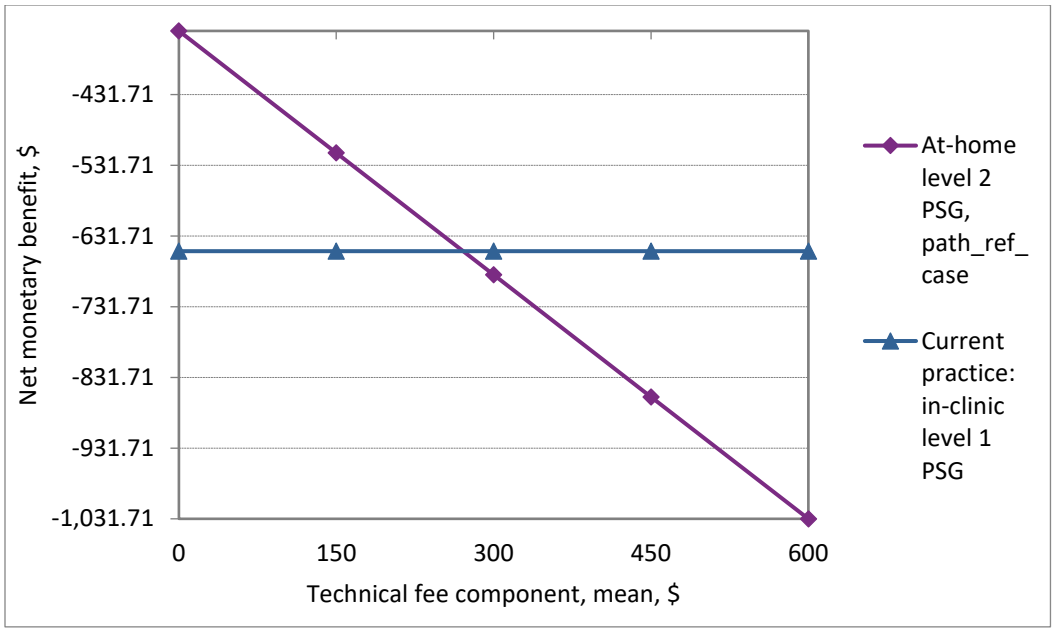

Figure 7: Technical Fee Cost Component of Level 2 Polysomnography

Abbreviation: PSG, polysomnography.

Graph showing threshold analysis and break-even point for net monetary benefit, estimated for each strategy using the following equation:

Net monetary benefit = Mean Effectiveness × Willingness-to-pay – Costs

In our case, the *Willingness-to-pay* value does not need to be precisely defined because we assumed that both pathways had equal effectiveness. The threshold is around $300 for level 2 polysomnography technical fee.

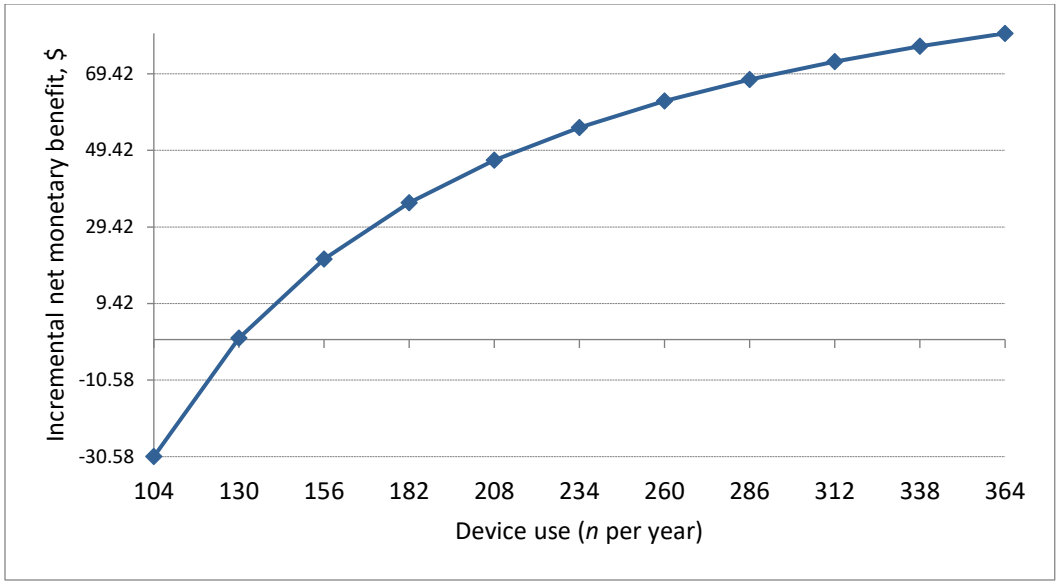

Figure 8: Changes in Frequency of Device Use and Incremental Net Benefit

Graph showing threshold analysis and break-even point for incremental net benefit for the parameter: number of times the device used over year. Threshold estimated around 130x per year vs. 180x assumed in reference case.

Two- and Multiway Sensitivity Analysis

In a 2-way sensitivity analysis related to the cost of level 2 polysomnography and prevalence of suspected sleep disorders, we found that, as the prevalence increases, the total cost of level 2 polysomnography test would have to decrease for the new diagnostic pathway with level 2 polysomnography to remain more cost-effective than the current pathway with level 1 polysomnography (Figure 9).

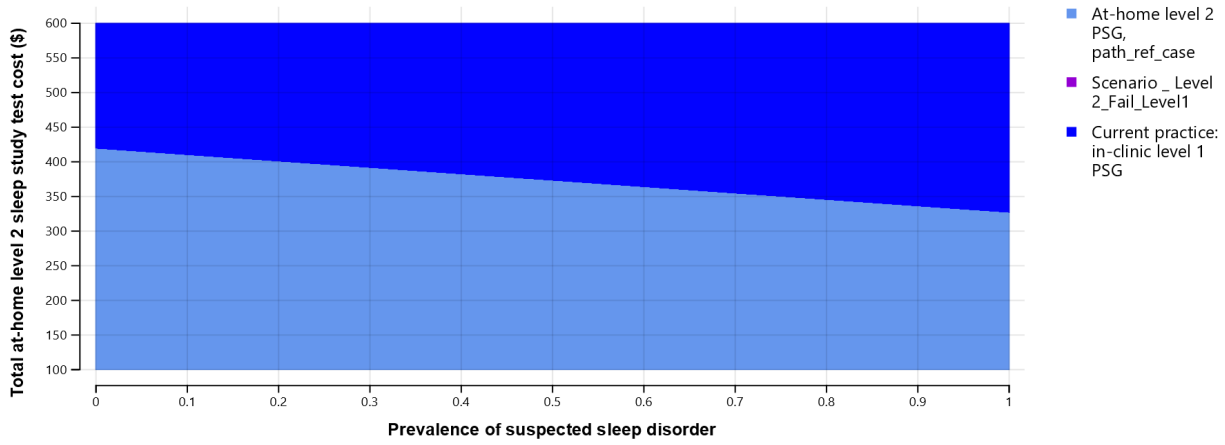

Figure 9: Changes in Prevalence of Suspected Disease and Cost of Level 2 Polysomnography and Incremental Net Benefit

Graph showing 2-way sensitivity analysis results for level 2 polysomnography test cost and pretest probability (i.e., prevalence of having a sleep disorder). The level 2 polysomnography test cost would have to decrease as prevalence increases for the level 2 polysomnography diagnostic pathway to remain more cost-effective than the level 1 polysomnography diagnostic pathway.

Scenarios

Scenario 1: New Diagnostic Pathway Assumption – Level 1 Polysomnography is Used When Technical Failure of Initial Level 2 Polysomnography Occurs

When comparing current practice with the reference case intervention pathway (i.e., repeat level 2 polysomnography when technical failure occurs during the initial test) and with an alternative intervention scenario (i.e., a diagnostic pathway in which level 1 polysomnography is used if technical failure occurs during the initial level 2 polysomnography test), the reference case intervention pathway was the least costly and most cost-effective option of all (Table 20).

Table 20: Scenario Analysis Results – Two Index Test Diagnostic Pathways with Level 2 Polysomnography

Strategy	Average total costs, $	Incremental cost, mean (95% CrI), $[a,b]	% Cost-effective in probabilistic analysis[c]	ICER[d]
Current practice: level 1 PSG	653.19	—	—	Dominated, dominated[e]
Intervention: level 2 PSG, scenario	635.59	−9.61 (−30 to 9)	58% of the time	Dominant, dominated[f]
Intervention: level 2 PSG, reference case	625.99	−27.20 (−137 to 121)	70% of the time	Dominant, dominant[g]

Abbreviations: CrI, credible interval; ICER, incremental cost-effectiveness ratio; PSG, polysomnography.
[a]Incremental cost = average cost (level 2 PSG) − average cost (level 2 PSG).
[b]Negative costs indicate savings.
[d]ICER was expressed as $/confirmed diagnosis.
[e]This diagnostic pathway was equally effective and more costly than both intervention pathways.
[f]This diagnostic pathway was equally effective and more costly than the reference case level 2 PSG diagnostic pathway but less costly than the level 1 diagnostic pathway.
[g]This diagnostic pathway was equally effective and less costly than both current practice (i.e., the level 1 PSG diagnostic pathway) and the scenario intervention pathway.

Scenario 2: New Diagnostic Pathway Assumption – Level 1 Polysomnography Is Used if Initial Level 2 Polysomnography Results Are Negative

This scenario included a structural change to the reference case model; namely, expansion of the level 2 arm of the diagnostic tree to enable additional costs of follow up and testing with level 1 polysomnography for all who received test negative results after level 2 polysomnography. Table 21 shows that the current practice with level 1 polysomnography is a better option, because it is less costly than the new diagnostic pathway with level 2 polysomnography by about $234, with high 99% certainty in this estimate.

Table 21: Scenario Analysis Results – Test With Level 1 Polysomnography After Negative Level 2 Polysomnography Test

Strategy	Average total costs, $	Incremental cost, mean (95% CrI), $[a,b]	% Cost-effective in probabilistic analysis analysis[c]	ICER[d]
Current practice: level 1 PSG[e]	653.19	—	—	—
Intervention: level 2 PSG[f]	887.32	234.13 (71 to 415)	0.1% of the time	Dominated[g]

Abbreviations: CrI, credible interval; ICER, incremental cost-effectiveness ratio; PSG, polysomnography.
[a]Incremental cost = average cost (level 2 PSG) − average cost (level 1 PSG).
[b]Negative costs indicate savings.
[c]The percentages in this column indicate how often level 2 PSG was found to be more cost-effective than level 1 PSG in probabilistic analysis.
[d]ICER was expressed as $/confirmed diagnosis.
[e]*Current practice: level 1 PSG* refers to the existing diagnostic pathway with level 1 PSG.
[f]*Intervention: level 2 PSG* refers to a new diagnostic pathway with level 2 PSG.
[g]Dominated indicates the level 2 PSG diagnostic pathway is equally effective but more costly than the level 1 diagnostic pathway.

Scenario 3: Adults with Obstructive Sleep Apnea – CPAP Costs

In this short-term cost–utility analysis, we estimated the short-term economic impact of providing therapy with CPAP to people with suspected obstructive sleep apnea after level 2 or level 1 polysomnography (Appendix 7). After accounting for the costs of CPAP ($554 per device) in those who

tested positive, we found there were very small differences in QALYs between the 2 strategies, with lower costs for level 1 polysomnography (current practice) compared with those for level 2 polysomnography (Table 22).

Table 22: Scenario Analysis Results – Short-Term Cost–Utility of Level 2 Polysomnography vs. Level 1 Polysomnography in Adults With Obstructive Sleep Apnea, After Accounting for the Use of CPAP

Strategy	Average total costs, $	Incremental cost, mean, $[a,b]	Average total effects	Incremental effect[c]	ICER[d]	INB, $
Current practice: level 1 PSG[e]	930.01		0.79657	—	—	—
Intervention: level 2 PSG[f]	949.12	19	0.794686	−0.00188	Negative ICER[g]	Dominated (INB > 0)[h]

Abbreviations: ICER, incremental cost-effectiveness ratio; INB, incremental net benefit; PSG, polysomnography; WTP, willingness to pay.
[a]Incremental cost = average cost (level 2 PSG) − average cost (level 1 PSG).
[b]Negative costs indicate savings.
[c]Incremental effect = average effect (level 2 PSG) − average effect (level 1 PSG).
[d]ICER was expressed as $/QALY.
[e]*Current practice: level 1 PSG* refers to the existing diagnostic pathway with level 1 PSG.
[f]*Intervention: level 2 PSG* refers to a new diagnostic pathway with level 2 PSG.
[g]The level 2 PSG diagnostic pathway is less effective and more costly than the level 1 diagnostic pathway.
[h]INB > 0, the level 1 PSG diagnostic pathway is more cost-effective, assuming WTP of $50,000/QALY.

The results of our short-term cost–utility analysis, which did not account for long-term consequences of obstructive sleep apnea, suggested large uncertainty in the cost-effectiveness of the new diagnostic pathway with level 2 polysomnography (Figure 10). At a willingness to pay of $50,000/QALY, the new diagnostic pathway with level 2 polysomnography was more effective and less costly than the current practice pathway with level 1 polysomnography about 18% of the time only. The ICER was below $50,000/QALY about 24% of the time. The current practice with level 1 polysomnography was more cost-effective than the new diagnostic pathway with level 2 polysomnography about 58% of the time.

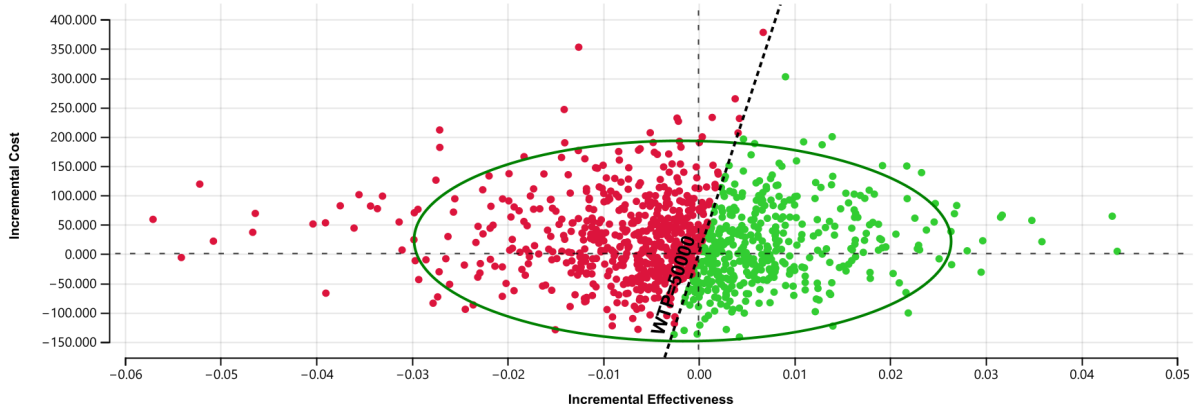

Figure 10: Probability of Cost-Effectiveness of Level 2 Polysomnography – Incremental Cost-Effectiveness Scatterplot

Abbreviation: PSG, polysomnography; QALY, quality-adjusted life-years; WTP, willingness-to-pay.
Graph showing the cost-effectiveness plane, with large uncertainty evident in the cost-effectiveness results. For the purpose of comparison, the WTP amount of $50,000/QALY is indicated by the black dashed line. The red and green dots represent values for the level 1 and 2 diagnostic pathways, respectively.

Scenario 4: Pediatric Clinical Population

We found that the cost of the new diagnostic pathway with level 2 polysomnography was slightly higher than the cost of current pathway with level 1 polysomnography for diagnosing sleep-related disorders in pediatric populations (Table 23). Nevertheless, the savings with level 1 polysomnography are highly uncertain; this is reflected by a low probability of cost-effectiveness of level 1 versus level 2 polysomnography pathways of about 51%. The results became even more uncertain when we accounted for the sleep technician's travel time for level 2 polysomnography device set-up at patients' homes; in this additional analysis, the incremental cost of new pathway with level 2 polysomnography compared with current practice with level 1 polysomnography was $48.51 (95% CrI, −$110.70 to $263.60).

Table 23: Scenario Analysis Results – New Diagnostic Pathway with Level 2 Polysomnography in Pediatric Populations

Strategy	Average total costs, $	Incremental cost, mean (95% CrI), $[a,b]	% cost-effective in probabilistic analysis[c]	ICER[d]
Current practice: level 1 PSG[e]	643.93			
Intervention: level 2 PSG[f]	653.54	9.74 (−125 to 190)	49.7% of the time	Dominated[g]

Abbreviations: CrI, credible interval; ICER, incremental cost-effectiveness ratio; PSG, polysomnography.

[a]Incremental cost = average cost (level 2 PSG) − average cost (level 1 PSG).

[b]Negative costs indicate savings.

[c]The percentages in this column indicate how often level 2 PSG was found to be more cost-effective than level 1 PSG in probabilistic analysis.

[d]ICER was calculated as $/confirmed diagnosis.

[e]*Current practice: level 1 PSG* refers to the existing diagnostic pathway with level 1 PSG.

[f]*Intervention: level 2 PSG* refers to a new diagnostic pathway with level 2 PSG.

[g]The level 2 PSG diagnostic pathway is less effective and more costly than the level 1 diagnostic pathway.

Discussion

We conducted a full economic evaluation to determine the cost-effectiveness of the new diagnostic pathway with level 2 polysomnography (unattended, at-home sleep study) compared with the current practice with level 1 polysomnography (attended, in-clinic sleep study) for diagnosing sleep disorders in adult or pediatric populations in Ontario.

Our reference case cost-effectiveness analysis examined health and cost outcomes of adults with suspected sleep disorders assuming a new diagnostic pathway starting with level 2 polysomnography, followed by level 1 polysomnography, in the case of false negative test results. The compared diagnostic strategies were similarly effective at diagnosing sleep disorder. Due to much smaller costs of testing with level 2 polysomnography, the new diagnostic pathway was associated with savings of $27.20 per person (and this took into account additional costs incurred for retesting due to technical failure of the device or false negative results). However, the 95% credible interval around this point estimate was wide, suggesting large uncertainty in the mean estimate which could further imply that level 2 polysomnography could be equal or more costly than level 1 polysomnography. Based on the probabilistic cost-effectiveness analysis results, the new diagnostic pathway with level 2 polysomnography was cost-saving more often (70% of the time) compared with current practice diagnostic pathway with level 1 polysomnography. We also estimated the ICER as cost per additional test positive result of $2,720 per additional test. However, there is no established willingness-to-pay value for the health outcomes reported in the natural units and interpretation of this value of ICER

remains unclear. Our results are aligned with previously published economic studies[125,137,138] for adults with obstructive sleep apnea that suggested cost savings with diagnostic testing with level 2 polysomnography compared with level 1 polysomnography, assuming equivalence in the sensitivity and specificity of the 2 sleep study tests.

We also conducted several subgroup analyses for people with obstructive sleep apnea, leg movement or sleep bruxism and in all 3 situations new diagnostic pathway with level 2 polysomnography was cost saving compared with the current pathway with level 1 polysomnography. However, our sensitivity analysis found some important factors that could affect the cost-effectiveness of level 2 polysomnography pathway in adult populations. For example, when we assumed the lowest reported values for sensitivity and specificity of level 2 polysomnography (0.760 and 0.400, respectively), the current pathway with level 1 polysomnography became less costly than the new pathway. If the prevalence of suspected sleep disorders was greater than 88% (indicating more severe disease at baseline), the current pathway with level 1 polysomnography is more cost efficient. Lastly, the cost of level 2 polysomnography was an important factor and if the cost of technical fee component established at around $240.60 per test, increased to about $300.00 per test then there would be no cost savings with the new diagnostic pathway. We also established some threshold values for other components used to establish the cost of the level 2 polysomnography test such as disposable cost, hours paid to sleep medicine technician or to administrative personnel, and frequency of device use per year.

In pediatric populations, we found that the cost of using new diagnostic pathway with level 2 polysomnography was slightly higher than that of level 1 polysomnography; nevertheless, these savings with level 1 polysomnography were highly uncertain because of a low probability of cost-effectiveness of the pathway with level 1 polysomnography of about 51%. To the best of our knowledge, no economic study examined the use of level 2 polysomnography in this patient subgroup.

We also conducted several scenarios to test structural model assumptions and found that if level 1 polysomnography is used for all retesting, namely in case of test failures or all test negative results, the new diagnostic pathway with level 2 polysomnography would not be more cost-effective than the current practice. Also, in a short-term cost–utility analysis for adults with obstructive sleep apnea in which we accounted for the costs of CPAP following the testing with sleep studies, we found very small differences in QALYs between the 2 strategies but smaller costs of level 1 polysomnography (current practice); the current level 1 polysomnography pathway dominated the new one with a probability of about 58%. This suggests a large uncertainty in the estimate of the ICER and in favorable results associated with the use of level 1 polysomnography. Given that long-term cost–utility analyses showed that CPAP was a cost-effective treatment for the management of people with obstructive sleep apnea,[157,158] it is possible that after accounting for large downstream costs of obstructive sleep apnea, the results of our short-term cost–utility analysis would change. Therefore, more research is needed to examine the therapeutic use and effectiveness of the new diagnostic pathway with level 2 polysomnography versus the current practice pathway with level 1 polysomnography for the management of sleep-related disorders (including obstructive sleep apnea) before making final conclusions.

Equity Considerations

Given the results of clinical review, there are some populations who would benefit from having level 2 polysomnography. We conducted several analyses for various patient subgroups and found that for people with obstructive sleep apnea or other sleep-related disorders; the new diagnostic pathway with level 2 polysomnography could be cost saving compared with the current practice. This is immensely

important to those who have limited access level 1 polysomnography or require caregivers to support their care. We also accounted in 2 scenarios time for sleep technician to travel to patient's home and hook up the equipment as this could be an enabling factor for some vulnerable populations. We conducted a cost–utility analysis and considered QALYs as an outcome, but given all modelling assumptions alongside the short-term pathway, we found very small differences in QALYs. It is unclear, whether this kind of analysis could address any issues related to inequities that mostly comes because of lack of access to portable technology. Although economic value of the new diagnostic pathway with level 2 polysomnography in adult and paediatric populations is uncertain, some patient subgroups may benefit from public funding of this new technology.

Strengths and Limitations

Our modelling study provided some new knowledge regarding the short-term benefits and costs of having level 2 polysomnography instead of level 1 polysomnography for diagnosing adult and pediatric populations with suspected sleep disorders in Ontario. As in any modelling study, our analyses are limited by assumptions related to model structure or to model parameters, but we conducted numerous sensitivity analyses to address this uncertainty.

Conclusions

Our primary economic evaluation showed that the new diagnostic pathway with level 2 polysomnography (unattended, at-home sleep studies) for adults with suspected sleep disorders was equally effective (outcome: confirmed diagnosis at the end of the pathway) as the current practice diagnostic pathway with level 1 polysomnography. With the assumption of a lower technical fee for level 2 polysomnography, the new diagnostic pathway with level 2 polysomnography was less costly than the current practice diagnostic pathway (a saving of $27 per person with a wide 95% credible interval, 95% CrI, −$137 to $121), indicating that the results are highly uncertain. For children, the new diagnostic pathway with level 2 polysomnography was associated with additional costs (mean, $9.70; 95% CrI, −$125 to $190), and similarly, this estimate was highly uncertain.

Budget Impact Analysis

Research Question

What is the potential 5-year budget impact for the Ontario Ministry of Health of publicly funding level 2 polysomnography (unattended, at-home sleep studies) for diagnosing sleep disorders in adults and children with suspected sleep disorders?

Methods

Analytic Framework

We estimated the budget impact using the cost difference between 2 scenarios: (1) current clinical practice without public funding for level 2 sleep polysomnography (the current scenario) and (2) anticipated clinical practice with introduction of public funding for level 2 polysomnography as an initial test in the diagnostic pathway (the new scenario). We determined the total costs, resource use, and budget impact associated with diagnostic use of level 1 and level 2 polysomnography. Figure 11 presents the simplified budget impact model schematic.

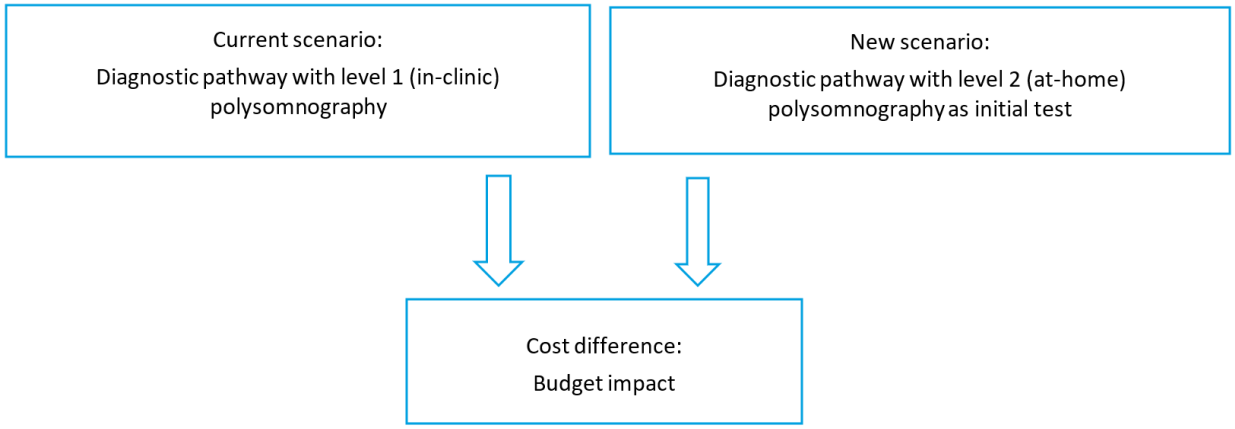

Figure 11: Simplified Schematic of Budget Impact Model

Key Assumptions

The assumptions used in our primary economic evaluation also apply to the reference case budget impact analysis. In addition, we considered the following:

- Simplifying assumptions related to the approximation and forecasting of expected target populations from available OHIP claims data[159] are reasonable
- Uptake rates over the next 5 years are expected to grow rapidly (email communication: Murray Moffat; Aug 26, 2023)

- Patient eligibility for initial testing with level 2 polysomnography is clearly defined (i.e., no expectation of the mixed use of various portable sleep study tests as initial tests for the same population)
- The type of sleep clinics (independent health facility or hospital) that currently provide OHIP-covered medical services and the respective rules related to the eligibility of patients by type of sleep clinic would not radically change with addition of level 2 polysomnography

Population of Interest

We approximated the size of population of interest based on claims data for the pre–COVID pandemic fiscal years 2014/15 to 2019/20 from the IntelliHealth Ontario Medical Services database[159] (the Medical Services data sources in IntelliHealth Ontario are obtained from OHIP Approved Claims; see Appendix 8). When level 1 polysomnography is conducted, 2 components of the sleep study fee code are rendered separately: a technical claim (using the facility or B code [OHIP], defined in the Medical Services database by the variable related to fee schedule code [FSC] combined with suffix: FSC + suffix), and a professional claim (using the H code or C code suffix). Consequently, the number of claims is much larger than the number of people who underwent diagnostic sleep studies.

For the approximation of number of adults yearly eligible for sleep studies for our reference case budget impact calculations, we made a simplifying assumption for the first point of patient entrance to sleep clinic testing. We used the number of OHIP fee schedule code (FSC) claims for an initial diagnostic sleep study (J896) related to the technical component (i.e., with the suffix "B") (Table 24). We did not include claims related to the code for a repeat diagnostic sleep study (J897), because technical failure and retesting were accounted for in our cost-effectiveness analysis. The estimated size of the adult population for diagnostic sleep studies is 111,600 to 120,500 people per year. Due to the COVID−19 pandemic, the number of tests was much lower in 2020/21 (N = 70,078); therefore, this value was not used in estimating the case volume.

Table 24: Case Volume Estimates for Number of Sleep Studies for Adults Yearly

	2015/16	2016/17	2017/18	2018/19	2019/20	2020/21	Year 1	Year 2	Year 3	Year 4	Year 5
Sleep studies, N											
Actual	99,073	103,277	106,235	108,275	107,717	70,078[a]					
Forecast[b]	—	—	—	—	—		111,601	113,830	116,058	118,287	120,516

[a]This value was not used in forecasting; due to the COVID−19 pandemic, this number was much lower than those in previous years.
[b]Forecasted using linear extrapolation from data for the fiscal year 2015–2019 for claim code J896:B.
Source: Data provided by IntelliHealth Ontario (Medical Services database).[159]

In Table 25, we provided calculations related to the size of adult population for the reference case analysis. We assumed that level 2 polysomnography would replace level 1 polysomnography for some eligible populations with suspected sleep-related disorders (e.g., no major comorbidities).[160] We assumed that there would not be an expansion of patient volumes for level 1 polysomnography over time because of current human resource constraints. We based our estimations on assumptions related to eligibility and possible diffusion of at-home sleep tests in another Canadian provinces: recently, level 2 (at-home) testing has been offered in Manitoba.[161] We assumed that about 70% of people eligible for level 1 polysomnography would also be eligible for level 2 polysomnography (email communication:

Murray Moffat; March and August 2023). We also assumed that the annual uptake of level 2 polysomnography would be 15% in year 1 and grow to 75% in year 5, which was deemed to be a more understandable and comfortable scenario for the sleep medicine community (email communication: Murray Moffat; Aug 26, 2023). (Note: These assumptions were tested in sensitivity analysis.)

We estimated that, in the first year of public funding, about 11,700 people would have a level 2 sleep study, and the annual number of people undergoing level 2 sleep studies would grow to about 63,300 by the fifth year; a total of 185,000 adults would undergo a level 2 sleep study over the next 5 years (Table 25).

Table 25: Reference Case Population Estimates – Number of Adults Eligible for Level 1 and Level 2 Polysomnography Yearly

	Year 1	Year 2	Year 3	Year 4	Year 5
Current scenario[a]					
Adults eligible for level 1 PSG, N[b]	111,601	113,830	116,058	118,287	120,516
New scenario[c]					
Adults estimated to be eligible for level 2 PSG (70%), N[b]	78,121	79,681	81,241	82,801	84,361
Uptake rate	0.15	0.30	0.45	0.60	0.75
Adults forecasted to have level 2 PSG, N[b]	11,718	23,904	36,558	49,681	63,271
Adults who would still have level 1 PSG, N[b]	99,883	89,926	79,500	68,606	57,245

Abbreviations: PSG, polysomnography.
[a]*Current scenario* refers to the existing diagnostic pathway with level 1 PSG.
[b]Some numbers may appear inexact due to rounding.
[c]*New scenario* refers to a new diagnostic pathway with level 2 PSG.
Source: Estimates are based on data provided by IntelliHealth Ontario (Medical Services database).[159]

Current Intervention Mix

Level 2 polysomnography is not publicly funded in Ontario; therefore, we assumed no intervention mix of sleep study testing in the current practice scenario.

New Scenario: Uptake of Level 2 Polysomnography

For this HTA, we were unable to establish a percentage intervention mix for various at-home sleep study tests because none of unattended portable sleep studies are currently funded in Ontario. We made a simplifying assumption of the percentage replacement of in-clinic level 1 polysomnography with the new level 2 test only and we examined this assumption in sensitivity analysis. These additional analyses with various population estimates could enable a space for the future market shares and clinical pathways given there are differences in opinion about who would be the best candidates for level 2 testing which is this project's scope.

As described in the section above and based on some recent reports from another Canadian jurisdiction,[161] we assumed that the new diagnostic pathway with level 2 polysomnography would be replacing the current practice with level 1 polysomnography with an uptake of 15% per year (i.e., year 1: 15% and year 5: 75%). Other rates of uptake (e.g., 5%–20%) were used in sensitivity analysis.

Resources and Costs

The basis for the proposed resource use and associated costs (Table 26) is described in more detail in the Primary Economic Evaluation section. Technical failure and subsequent retesting were accounted in our cost-effectiveness analysis. Budget impact was, likewise, analyzed from the perspective of the Ministry of Health, and all costs are reported in 2023 Canadian dollars.

Table 26: Reference Case – Per-Person Costs of Diagnostic Pathways with Level 1 and Level 2 Polysomnography

	Cost per person, $[a]	
	Current scenario[b] (level 1 PSG)	New scenario[c] (level 2 PSG)
Total	653.18	625.99
Initial test	474.80	344.66
Technical fee	377.30	247.16
Follow-up	74.27	92.62
Repeat test (due to technical failure)	0	37.12

Abbreviations: PSG, polysomnography.
[a]2023 Canadian dollars.
[b]*Current scenario* refers to the existing diagnostic pathway with level 1 PSG.
[c]*New scenario* refers to a new diagnostic pathway with level 2 PSG.

Internal Validation

A secondary health economist conducted formal internal validation. This process included checking for errors and ensuring the accuracy of parameter inputs and equations in the budget impact analysis.

Analysis

We conducted a reference case analysis and sensitivity analyses. Our reference case analysis represented the most likely set of input parameters and model assumptions. Our sensitivity analysis explored how the results are affected by varying input parameters and model assumptions. All budget impact analyses were conducted using Microsoft Excel for Office 365.[162]

Sensitivity Analysis

We considered a total of about 33 scenarios in sensitivity analysis; separate analyses were done for adult and pediatric populations:

Scenarios in Adult Populations

- Scenarios related to estimation of the size of the adult population for level 2 polysomnography, assuming this was initial test in the diagnostic pathway replacing in-clinic level 1 polysomnography (Figure 4):
  - Scenario that enables addition of other types of portable sleep study tests (Scenario 1A, Table 27)

    - Scenario (Scenario 1B, Table 27) that estimates the size of the adult population by accounting for additional claim codes related the use of sleep study tests (as defined by OHIP fee codes: J895, J896; Appendix 4, Table A4)
- Scenarios related to changes in the uptake rate: smaller uptakes of 1%, 5% or 10% per year or higher uptake of 20% per year (reaching 100% replacement in year 5)
- Scenario related to the type of facility (independent health facility vs hospital) where the sleep study is performed; this scenario was also used to look at the budget impact associated with the technical fee component (e.g., facility fee code)
- Scenario related to uncertainty in the fee codes used in the clinical pathway and cost of consultation after the positive test result: $39.60 vs $108.95 (reference case)
- Scenarios related to diagnostic accuracy for people with obstructive sleep apnea, by AHI and for ranges of values for sensitivity, specificity, test failure rate, and prevalence
- Scenarios related to the test failure rate:
    - Retesting with level 2 polysomnography at higher failure rate (highest value of 20% and a threshold value of 29%)
    - Structural model change: additional diagnostic pathway where level 1 polysomnography would be used for re-testing due to failures after initial level 2 polysomnography (reference case: re-testing with level 2 polysomnography, reference case failure rate of 15% for level 2 polysomnography)
- Scenarios related to the cost of level 2 polysomnography, using range of costs as reported in cost-effectiveness analysis and the break-even cost established in the threshold analysis:
    - Manufacturer cost estimates for technician-applied ($332.52) and self-applied ($310.68) level 2 polysomnography devices
    - Cost estimated by percentage adjustment of the published fees in Australia ($270.75 per person)
    - Total cost, testing for various estimates for the technical fee component including threshold value
    - Total cost estimates that considered technician's travel time: $360.50 (adults) and $475.60 (pediatric populations)
    - Cost components that affected the estimation of test price: frequency of device use per year or cost of disposables
    - Total cost estimate that included a hypothetical increase (20%) in the physician fee (OHIP code component "P"): $117.00 per test (in the reference case: $97.50)
    - Equal test cost of level 2 and level 1 polysomnography (i.e., no changes in the OHIP fee cost)
- Scenario of testing with level 1 polysomnography if received negative results with initial level 2 polysomnography (reference case: testing with level 1 polysomnography people who were false negative at the initial test)
- Scenario with inclusion of costs of CPAP for adults only (based on the results of cost–utility analysis). The underlying assumption of this scenario is that level 2 polysomnography diagnostic test results

would be sufficient to receive a prescription for an ADP-funded device (i.e., currently devices can be prescribed only with test results from level 1 polysomnography).[140] The cost of CPAP treatment was not considered for pediatric populations because that treatment is not the first line treatment for sleep apnea in children and is not often prescribed or used

Table 27: Sensitivity Analysis – Adult Population Size Estimation for Scenario 1

	Year 1	Year 2	Year 3	Year 4	Year 5
Reference case					
Adults receiving level 2 PSG (15% uptake), N[a]	11,718	23,904	36,558	49,681	63,271
Scenario 1A					
People eligible (J896B) for diagnostic level 1 PSG, N[a]	111,601	113,830	116,058	118,287	120,516
People estimated to be eligible for level 2 PSG (10%), N[a]	11,160	11,383	11,606	11,829	12,052
Uptake rate of level 2 PSG	0.15	0.3	0.45	0.6	0.75
People receiving diagnostic level 2 PSG, N[a]	1,674	3,415	5,223	7,097	9,039
Scenario 1B					
People eligible (J895, J896) for level 1 PSG, N[a]	174,028	176,469	178,910	181,352	183,793
People estimated to be eligible for level 2 PSG (70%), N[a]	121,819	123,528	125,237	126,946	128,655
Uptake rate of level 2 PSG	0.15	0.3	0.45	0.6	0.75
People receiving diagnostic level 2 PSG, N[a]	18,273	37,058	56,357	76,168	96,491

Abbreviations: PSG, polysomnography.
[a]Some numbers may appear inexact due to rounding. They represent approximations and not exact numbers of possible future cases.
Source: Estimates based on data provided by Ontario IntelliHealth (Medical Services database).[159]

Scenario for Eligible Pediatric Populations

One hypothetical analysis was focused on the use of the level 2 polysomnography in eligible children. We had very limited information who could be eligible and tested in this way but we used the OHIP code J890, that is related to testing of children in designated hospital sleep labs[140] to estimate the population size (Table 28).

Table 28: Case Volumes and Predictions, Pediatric Populations

	2015/16	2016/17	2017/18	2018/19	2019/20	2020/21	Year 1	Year 2	Year 3	Year 4	Year 5
Sleep studies, N											
Actual	1,186	1,258	1,226	1,358	1,319	—[a]					
Forecast[b]	—	—	—	—	—		1,379	1,416	1,452	1,489	1,526

[a]Data from 2020/21 were not used in forecasting; due to the COVID−19 pandemic, this number was much lower than those in previous years.
[b]Forecasted using linear extrapolation from data from fiscal years 2015–2019 for claim code J890:B.
Source: Data provided by IntelliHealth Ontario (Medical Services database).[159]

Using predicted volumes, we assumed that the size of pediatric population would be about 50% of the estimate and calculated overall total population for level 2 polysomnography of about 554 people by assuming the slow uptake of the new diagnostic pathway with level 2 polysomnography (an increase

of 5% annually). This was because of limited capacities of sleep clinics for younger people in Ontario (Table 29).

Table 29: Scenario Analysis – Estimate of Pediatric Volumes for Budget Impact Analysis, Level 2 Polysomnography and Level 1 Polysomnography

	Year 1	Year 2	Year 3	Year 4	Year 5
Current scenario[a]					
Children eligible (OHIP J890) for level 1 PSG, N[b]	1,379	1,416	1,452	1,489	1,526
New scenario[c]					
Children estimated to be eligible for level 2 PSG (50%), N[b]	690	708	726	745	763
Uptake rate	0.05	0.1	0.15	0.2	0.25
Children forecasted to have level 2 PSG, N[b]	34	71	109	149	191
Children who would still have level 1 PSG, N[b]	1,345	1,345	1,343	1,340	1,335

Abbreviations: PSG, polysomnography.
[a]*Current scenario* refers to the existing diagnostic pathway with level 1 PSG.
[b]Some numbers may appear inexact due to rounding.
[c]*New scenario* refers to a new diagnostic pathway with level 2 PSG.
Source: Estimates are based on data provided by IntelliHealth Ontario.[159]

Results

Reference Case

Table 30 presents the budget impact of publicly funding the new diagnostic pathway with level 2 polysomnography for diagnosing sleep disorders. With the current scenario, the total costs of the current practice with level 1 polysomnography ranged from $72.90 million in year 1 to about 78.72 million in year 5, with a total 5-year cost of $379.04 million. In the new scenario, assuming replacement of level 1 polysomnography and the rate of uptake of 15% per year, the total costs associated with the new diagnostic pathway with level 2 polysomnography, ranged from $72.58 million in year 1 (with about 11,700 adults receiving this test) to 77 million in year 5 (with about 63,300 receiving this test), with a total 5-year cost of $374 million (about 185,000 received level 2 polysomnography). Therefore, we can expect cost-savings with the new diagnostic pathway with level 2 polysomnography of 5.03 million over the next 5 years. These cost savings are largely explained by savings in the test cost (of $24.09 million over 5 years).

Table 30: Budget Impact Analysis Results – Reference Case

Scenario	Budget impact, $ million[a]					
	Year 1	Year 2	Year 3	Year 4	Year 5	Total[b,c]
Current scenario,[d] total costs	**72.90**	**74.35**	**75.81**	**77.26**	**78.72**	**379.04**
Costs of initial testing (total: technical and professional fees)	52.99	54.05	55.10	56.16	57.22	275.52
Costs of test failure (test repeat)	0.00	0.00	0.00	0.00	0.00	0.00
Costs, healthcare, other (visits, follow-up)	19.91	20.31	20.70	21.10	21.50	103.51
New scenario,[e] total costs	**72.58**	**73.70**	**74.81**	**75.91**	**77.00**	**374.00**
Costs of initial testing (total: technical and professional fees)	51.46	50.94	50.35	49.70	48.99	251.43
Costs of test failure (test repeat)	0.44	0.89	1.36	1.84	2.35	6.87
Costs, healthcare, other (visits, follow-up)	20.68	21.88	23.11	24.37	25.66	115.70
Budget impact, total[b,c]	**−0.32**	**−0.65**	**−0.99**	**−1.35**	**−1.72**	**−5.03**
Budget impact: testing (due to the decrease in technical fee)	−1.52	−3.11	−4.76	−6.47	−8.23	−24.09
Budget impact: costs of test failures (test repeats)	0.44	0.89	1.36	1.84	2.35	6.87
Budget impact: other than testing (e.g., initial visits, follow-up)	0.77	1.57	2.41	3.27	4.16	12.19

[a]In 2023 Canadian dollars. All costs were calculated using the mean cost from the Primary Economic Evaluation's probabilistic results.
[b]Negative costs indicate savings.
[c]Results may appear inexact due to rounding.
[d]*Current scenario* refers to the existing diagnostic pathway with level 1 PSG.
[e]*New scenario* refers to a new diagnostic pathway with level 2 PSG.

Sensitivity Analysis

In general, the budget impact estimate in adult populations was uncertain and depended on many factors (Table 32). The estimate was sensitive to changes in the assumptions related to the diagnostic accuracy of level 2 polysomnography and related parameters (pretest probability), rate of uptake of level 2 polysomnography, parameters used to estimate the cost of the level 2 polysomnography, for example:

- Smaller cost-savings than those seen in the reference case were found with reduction of overall test population to about 10%, with smaller uptake rates of the new diagnostic pathway with level 2 polysomnography, with assuming increases in the physician component of the fee code, if accounted time for technician's travel to patient's home, and with using level 1 polysomnography in case for level 2 polysomnography test failures due to technical errors
- Higher cost-savings than those seen in the reference case were found with the following: use of level 2 polysomnography for diagnostic and therapeutic testing, very high uptake of level 2 polysomnography of 20% per year, delivering level 2 polysomnography in independent health facility sleep labs only, using level 2 polysomnography in people with obstructive sleep apnea regardless of AHI score (due to higher sensitivity and specificity of the test), with the best case assumptions related to equal diagnostic accuracy of level 2 polysomnography as that of level 1 polysomnography, with a smaller test cost: lower than $300 per person (threshold analysis) or with using manufacturer's estimates of the cost for a self-applied level 2 polysomnography device
- Switch in the total budget impact estimate and additional costs with the new diagnostic pathway with level 2 polysomnography ranging between $0.94 million and to about $6.21 million over 5

years were seen for the following: very high failure rate of level 2 polysomnography of 29%, combination of the lowest (unfavourable) estimates for diagnostic accuracy of level 2 polysomnography, very high prevalence of suspected sleep disorder (about 88%), the cost of level 2 polysomnography of over $300 per person, high cost of disposable or occasional use of level 2 polysomnography device. In addition:

- When we estimated imminent cost associated with the use of CPAP, we showed the budget impact increase to about $3.54 million (170% change in reference case estimate; Table 32 and Appendix 9); in some additional scenarios associated with extreme savings or extremely large additional costs, the addition of the cost of CPAP substantially affected the estimate (Appendix 9, Table A11B)
- Some other examples of extreme findings where the additional budget changed more than 800% (Table 32):
  - Test cost of about $550 per person (technical fee of $450), was associated with additional costs of $38.14 million (858% change from the reference case)
  - Scenario where all people who tested negative with level 2 polysomnography would undergo level 1 polysomnography, the cost increase was $43.35 million (962% change from the reference case)

The budget impact for pediatric populations was higher compared with the one estimated for adult populations; over 5 years, we could expect additional costs of about $0.005 million (Table 31 and Table 32). When we accounted for technician travel time, the budget slightly increased to $0.03 million over 5 years.

Table 31: Budget Impact Scenario Results – Pediatric Populations

Scenario	Budget impact, $ million[a]					
	Year 1	Year 2	Year 3	Year 4	Year 5	Total[b,c]
Current scenario,[d] total cost	**0.89**	**0.91**	**0.94**	**0.96**	**0.98**	**4.68**
Costs of initial testing (total: technical and professional fees)	0.65	0.66	0.68	0.70	0.71	3.40
Costs of test failure (test repeat)	0.00	0.00	0.00	0.00	0.00	0.00
Costs other than testing (e.g., initial visits, follow-up)	0.24	0.25	0.26	0.26	0.27	1.28
New scenario,[e] total cost	**0.89**	**0.91**	**0.94**	**0.96**	**0.98**	**4.68**
Costs of initial testing (total: technical and professional fees)	0.65	0.66	0.68	0.69	0.71	3.39
Costs of test failure (test repeat)	0.00	0.00	0.00	0.00	0.00	0.01
Costs other than testing (e.g., initial visits, follow-up)	0.24	0.25	0.26	0.26	0.27	1.29
Budget impact, total[b,c]	**0.0003**	**0.0007**	**0.0010**	**0.0014**	**0.0018**	**0.0053**
Budget impact: initial testing costs	−0.0008	−0.0017	−0.0026	−0.0035	−0.0045	−0.0130
Budget impact: costs of test failures (test repeats)	0.0004	0.0009	0.0014	0.0019	0.0024	0.0071
Budget impact: other healthcare costs (e.g., initial visits, follow-up)	0.0007	0.0014	0.0022	0.0030	0.0039	0.0112

[a]In 2023 Canadian dollars. All costs were calculated using the mean cost from the Primary Economic Evaluation's probabilistic results.
[b]Negative costs indicate savings.
[c]Results may appear inexact due to rounding.
[d]*Current scenario* refers to the existing diagnostic pathway with level 1 PSG.
[e]*New scenario* refers to a new diagnostic pathway with level 2 PSG.

Table 32: Budget Impact Sensitivity Analysis Results – Scenarios

Scenario	Total 5-year budget impact, $ million[a,b]	% Change[c]
Reference case, adults (uptake 15% per year)	−5.03	NA
Adult population scenarios		
Reduction in the population size (eligibility to 10%) account for additional types of sleep study tests (Table A10, methods)	−0.72	86%
Expansion of the population size to account for diagnostic and therapeutic sleep study codes (Table A11, methods)	−7.73	54%
Changes in uptake of level 2 PSG compared to ref case		
Uptake of 1% per year	−0.34	−93%
Uptake of 5% per year	−1.68	−67%
Uptake of 10% per year	−3.36	−33%
Uptake of 20% per year (100% in year 5)	−6.71	33%
Type of sleep lab facility: level 2 done in independent health facility only	−6.11	22%
Clinical pathway – reimbursed smaller physician visit fee for test positive ($39.80 vs. $108.95, ref case)	−4.84	−4%
Failure rate		
High failure rate of level 2 PSG, threshold value of 29% (vs. 15%)	1.60	−132%
Structural change: additional diagnostic pathway, use of level 1 PSG for all who fail initial level 2 polysomnography due to technical errors	−3.26	−35%
Diagnostic accuracy of level 2 PSG, various parameters combined: sensitivity, specificity, failure rates, prevalence		
OSA, AHI ≥ 5 (Bruyneel et al, 2011)[125]: Sn = 0.960; Sp = 0.710; failure rates: 4.7% (level 2) and 1.5% (level 1), *p* = 0.5	−17.81	254%
OSA, AHI ≥ 15 (Bruyneel et al, 2011) [125]: Sn = 0.760; Sp = 0.850; failure rates:4.7% (level 2) and 1.5% (level 1), *p* = 0.5	−8.89	77%
OSA, AHI ≥ 30 (Bruyneel et al, 2011)[125]: Sn = 0.860; Sp = 1.00; failure rates:4.7% (level 2) and 1.5% (level 1), *p* = 0.5	−15.71	212%
Worst published values: Sn = 0.760 (Bruyneel, 2011; AHI ≥ 15); Sp = 0.400 (Cunnington, 2009), failure rates: 20% (level 2); 0% (level 1)	3.97	−179%
Best published values: Sn = 1.00; Sp = 1.00, failure rates: 4.7% (level 2); 0% (level 1)	−21.92	336%
Highest diagnostic accuracy and high failure rates: Sn = 1.00; Sp = 1.00, failure rates: 20% (level 2) and 5% (level 1)	−18.40	266%
Prevalence: 88% threshold value (vs. 50%, ref case)	1.40	−128%
Diagnostic accuracy of level 1 PSG (imperfect reference standard): Sn = 0.960, Sn = 0.975, failure rate: 1%	−8.06	60%
Cost of level 2 PSG		
Manufacturer's cost estimates for tech-applied device ($332.50 vs. $338, ref case)	−7.63	52%
Manufacturer's cost estimates for self-applied device ($310.68 vs. $338, ref case)	−12.28	144%
Test cost estimated based on assumptions about % adjust of Australian MOH fee codes ($271 vs. $338, ref case)	−18.00	258%
Test cost at a threshold value for the technical fee of about $300 (total test cost ≥ $397.50)	6.21	−223%
Test cost at $450, technical fee (total test cost ≥ $547.50)	38.14	−858%
Test cost at $150, technical fee (total test cost≥$297.50)	−25.73	412%

Scenario	Total 5-year budget impact, $ million[a,b]	% Change[c]
Test cost including travel time ($350.60 vs. $338, ref case)	−2.37	−53%
Cost of disposables, 3 times higher ($42)	0.94	−119%
Use of device: 104 times per year (vs. 180x/y, ref case)	5.64	−212%
Use of device: 260 times per year	−11.55	130%
Test cost including 20% increase in physician fee ($117 vs. $97.50, ref case)	−1.42	−72%
Same overall test cost of level 1 and level 2 PSG	22.67	−551%
Scenario, structural change: Level 1 PSG used for all who tested negative at initial level 2 PSG	43.35	−962%
Scenario, structural change: Cost of CPAP (Appendix 9)	3.54	−170%
Pediatric population scenarios		
Scenario for children (Table 31)	0.00533	−100%
Scenario for children with test cost that included travel time cost ($475.60 vs. $438, ref case in children)	0.03	−101%

Note: Negative sign for the cost suggests cost savings, negative sign for % change suggest a change in budget impact, and when it is negative and ≥ 100% then there is a switch in budget impact estimated from cost saving to cost spending (additional costs).

Abbreviations: AHI, apnea hypopnea index; CPAP, continuous positive airway pressure; OSA, obstructive sleep apnea; PSG, polysomnography; Sn, sensitivity; Sp, specificity.

[a]In 2023 Canadian dollars.

[b]Results may appear inexact due to rounding.

[c]Percentage change calculated as the total budget impact of the scenario analysis divided by the total budget impact of the reference case.

Discussion

We conducted model-based budget impact analyses to estimate the range of investments needed to publicly fund the new diagnostic pathway with level 2 polysomnography for diagnosing sleep disorders in adult or pediatric populations in Ontario.

In the reference case that assumed adult populations only and a high rate of uptake of the new diagnostic pathway with level 2 polysomnography ranging from 15% in year 1 to 75% in year 5, we found cost savings of about $5 million over the next 5 years (for testing about 185,000 people). These cost savings were largely explained by savings in the test cost (of about $24 million over 5 years), namely savings related to the technical component of the OHIP fee code.

We conducted a scenario for children, which is limited by many assumptions and lack of knowledge of implementation pathway for pediatric populations in Ontario. In this analysis, we calculated that the new diagnostic pathway with level 2 polysomnography would be associated with additional costs of about $0.005 million over the next 5 years (for about 550 people tested with the new technology).

We also conducted over 30 scenarios for adult populations to examine uncertainty in the reference case estimates. In sensitivity analysis, the 5-year budget impact ranged from savings of $22 million to additional costs of $43 million, depending on the assumptions related to the diagnostic test accuracy, test cost, cost the follow-up, etc. We found that smaller cost savings could be expected if the uptake or overall eligible population for level 2 polysomnography were smaller, or if level 1 polysomnography were used for retesting of those who fail initially level 2 polysomnography due to technical failure.

We found that additional costs – thus increase in the budget (instead of cost savings) – could be expected for very high failure rates, high prevalence of the disease (> 88%) or a cost increase of the technical fee for about $60 (from $240 in the reference case to about $300 in a scenario). When we accounted for the cost of CPAP (assuming the population of people with obstructive sleep apnea), the budget increased 170% and was about $3.54 million over the 5 years.

In summary, a new level 2 polysomnography diagnostic pathway was found to result in a substantial budget impact for scenarios in which (1) the level 2 polysomnography test cost was estimated as being higher than the cost of the level 1 test; (2) the cost of CPAP was included in the estimation of level 2 diagnostic pathway cost for people who test positive with an initial level 2 test, and (3) the level 1 test was used for retesting in the level 2 polysomnography diagnostic pathway (a) after technical failure of the initial level 2 test or (b) for people with negative level 2 test results.

Equity Considerations

We explored various assumptions related to the uptake of level 2 polysomnography that is in general related to access of people with suspected sleep disorders to sleep study testing. We assumed high uptake rates in the reference case scenario to estimate the budget of level 2 polysomnography when access to sleep study testing is facilitated properly by the province. We also thoroughly examined the cost of the level 2 polysomnography device as this factor could be also connected with equity issues (e.g., the cost of device for those who can come to the clinic to get hooked up to level 2 polysomnography and an increase in the cost for those who need technicians coming to their homes). Due to limited published information, we were not able to examine specific vulnerable patient subgroups including children and young people.

Strengths and Limitations

Our analyses are restricted by our assumptions and uncertainty in the parameter inputs that informed the model, but we conducted several scenario analyses to examine factors that could affect changes in the overall budget. One possible limitation is that we underestimated the budget because we did not assume an expansion of patient volumes for level 1 polysomnography over the next 5 years with the introduction of level 2 polysomnography. However, large expansion of level 1 polysomnography testing is an unrealistic assumption because of the current health human resource constraints and limited capacity.

Conclusions

The total budget impact of publicly funding the new diagnostic pathway with level 2 polysomnography (unattended, at-home sleep studies) for diagnosing sleep disorders in Ontario is uncertain, from savings to additional costs, depending on various assumptions. In adults, the estimate of 5-year budget impact ranged from savings of $22 million to additional costs of $43 million, depending on the assumptions related to the diagnostic test accuracy, test cost, cost of the follow-up, or use of CPAP. In children, publicly funding the new diagnostic pathway with level 2 polysomnography would require additional costs.

Preferences and Values Evidence

Objective

The objective of this analysis was to explore the underlying values, needs, and priorities of those who have lived experience with sleep disorders. In addition, this analysis aimed to examine patient, family, and caregiver preferences and perceptions of level 2 polysomnography (unattended, at-home sleep studies).

Background

Exploring patient preferences and values provides a unique source of information about people's experiences of a health condition and the health technologies used to manage or treat that health condition. It includes the impact of the condition and its treatment on the person with the health condition, their family and other caregivers, and the person's personal environment. Engagement also provides insight into how a health condition is managed by the province's health system.

Information shared from lived experience can also identify gaps or limitations in published research (e.g., outcomes important to those with lived experience that are not reflected in the literature). Additionally, lived experience can provide information and perspectives on the ethical and social values implications of health technologies.

Because the needs, preferences, priorities, and values of those with lived experience in Ontario are important to consider understanding the impact of the technology in people's lives, we may speak directly with people who live with a given health condition, including those with experience of the technology we are exploring.

For this analysis, the preferences, and values of people with lived experience with sleep disorders were examined via direct engagement. The initiative was led by the Patient and Public Partnering team at Ontario Health, and direct engagement with eligible participants was completed through telephone interviews and online survey.

Direct Patient Engagement

Methods

Partnership Plan

The partnership plan for this health technology assessment focused on consultation to examine the experiences of people with sleep disorders and their family members or caregivers. We engaged with participants via telephone interviews and an online survey.

We conducted qualitative interviews, as this method of engagement allowed us to explore the meaning of central themes in the experiences of people with sleep disorders, their diagnosis journey as well as the experiences of their families and caregivers. The sensitive nature of exploring people's experiences of a health condition and their quality of life further supported our choice of methodology. We conducted a supplementary online survey to extend the opportunity to interested participants who contacted us after recruitment for the interviews was closed.

Participant Outreach

We used an approach called purposive sampling, which involves actively reaching out to people with direct experience of the health condition and health technology being reviewed. We approached a variety of community organizations (Sleep On It Canada, The Canadian Sleep and Circadian Network, the Canadian Sleep Society, Fondation Sommeil, and Wake-up Narcolepsy Canada), clinical experts, and community-based health programs in Ontario that support people with sleep disorders in an effort to increase the public's awareness of our engagement activity and to connect with people who would like to share their lived experiences.

Inclusion Criteria

We sought to speak with adults with lived experience with sleep disorders who underwent or may undergo a sleep study. Participants did not have to have direct experience with level 1 or 2 polysomnography in order to participate.

Exclusion Criteria

We did not set exclusion criteria for participants who otherwise met the inclusion criteria.

Participants

For this project, we spoke with 15 people with a sleep disorder living in Ontario, as well as 2 caregivers. Of the 17 participants who were interviewed, 12 had experience with in-clinic (level 1) polysomnography, 4 had experience with at-home sleep studies (participants were not aware if it was level 2 or level 3), and 3 had no experience with sleep studies. In addition, 11 participants completed the online survey: 7 had experience with level 1 polysomnography, 1 had experience with level 2 polysomnography, 3 had no experience with sleep studies.

Approach

At the beginning of the interview, we explained the role of our organization, the purpose of this health technology assessment, the risks of participation, and how participants' personal health information would be protected. We gave this information to participants both verbally and in a letter of information (Appendix 10) if requested. We then obtained participants' verbal consent before starting the interview. With the participants' consent, we audio-recorded and then transcribed the interviews.

Interviews lasted approximately 30 to 60 minutes. The interview was semistructured and consisted of a series of open-ended questions. Questions were based on a list developed by the Health Technology Assessment International Interest Group on Patient and Citizen Involvement in Health Technology Assessment.[163] Questions focused on the impact of sleep disorder on quality of life, journey to getting diagnosed, experiences with polysomnography, and perceptions of the benefits or limitations of polysomnography. Please see Appendix 11 for the interview guide.

The online survey questions (Appendix 12) were developed to be similar to the interview questions. At the beginning of the survey, we explained the role of our organization, the purpose of this health technology assessment, the risks of participation, and how participants' personal health information would be protected. Participants gave consent when they chose to participate in the survey.

Data Extraction and Analysis

We used a modified version of a grounded-theory methodology to analyze interview transcripts and survey responses. This approach allowed us to organize and compare experiences across participants. This method consists of a repetitive process of obtaining, documenting, and analyzing responses while simultaneously collecting, analyzing, and comparing information. We used the qualitative data analysis software program NVivo[164] to identify and interpret patterns in the data. The patterns we identified allowed us to describe the impact of sleep disorders and decision-making factors for polysomnography.

Results

Living With a Sleep Disorder

Participants had a wide variety of sleep disorders and neurological conditions, including sleep apnea, narcolepsy, and congenital central hypoventilation syndrome. Participants reported that they experienced multiple symptoms because of their sleep disorder, including the lack of quality sleep, difficulty falling asleep, difficulty staying asleep, excessive snoring, shortness of breath, and severe fatigue during the day. These symptoms were persistent and impacted different aspects of their lives:

> *My partner has really bad apnea, very interrupted breathing, which would sort of cause him to wake up…they get 20 minutes in and just be woken up again.*
>
> *I had a lot of trouble falling asleep…I would wake up during the night and have trouble falling back asleep.*
>
> *I slept out in a friend's house who heard me snoring and suggested I consult my family physician and I did, and I was sent for a sleep test…and it was confirmed that I had a mild sleep disorder.*
>
> *For years, I've been going to see my specialist doctor and complaining of fatigue.*

Impact on Day-to-Day Life

Participants described the effect that the lack of quality sleep had on their day-to-day life, including reduced quality of life, chronic exhaustion, difficulty maintaining an active lifestyle, and difficulty performing day-to-day duties. For people with chronic pain, lack of sleep exacerbated their condition:

> *It has an impact on my quality of life (ability to function, socialize, exercise, it negatively affects my mood, my ability to participate in activities because of exhaustion).*
>
> *[I experience] Chronic fatigue and chronic lethargy…having to take 1 or 2 naps every day reduced my quality of life.*
>
> *It's a vicious cycle when you're too tired to exercise. Exercise can help you get your energy levels up for sure, but if you don't have the energy to start exercising, or the kind of mental fortitude to stick with it.*
>
> *I live with chronic pain and sleep disruption really exacerbates that.*

Some participants spoke about the impact their sleep disorder had on their driving ability. They mentioned feeling unsafe while driving due to a lack of alertness. One participant commented on their sleep disorder leading to their driver's license being revoked:

> *I used to drive when I worked, and I would feel less than alert on the road, which always concerns me.*
>
> *This disorder led to the revocation of my driver's license (muscle weakness) and limited my ability to work to my full potential; it kept me from driving.*

Impact on Work

Some explained their sleep disorder contributed to decreased productivity and performance at work which had repercussions on their career trajectory. In addition, their sleep disorder led to an increase in number of days of work missed. They reflected on missed professional opportunities, if they didn't experience continuous fatigue because of their sleep disorder. Participants also commented on how their sleep disorder set them back and limited them from achieving their full potential at work. They also noted that they had trouble with short-term memory at work:

> *Exhaustion during the day makes it hard to complete work duties. Massive debilitating headaches in the morning often led to needing to take half a day off work.*
>
> *We have to be very choosy about what we do career wise because of the extent to which this sleep disorder has really impacted our lives.*
>
> *Sometimes I look back on the last 40 years and think how different my life would have been, as far as career goes, and outside interests that I might have pursued if I had been a better-rested person.*
>
> *At work, I always had trouble with short-term memory.*

Impact on Social Life

Social life and family relationships were also impacted by their sleep disorder. Participants explained that they had reduced social interactions due to low energy levels during the day. Lack of sleep also affected their mood and patience, making them irritable toward family members which, in turn, strained their relationships. Some reported their family members had a negative impression of them due to them experiencing constant fatigue:

> *It completely impacted my social life, because I never had the energy levels to play any sports or go out. I was always tired and wanted to spend any days off resting or sleeping at home.*
>
> *You're just not as patient and you have a lot of anxiety and you're quicker to react to a certain situation and just not be patient about it, which can impact family functioning and positive parenting as well.*

I have strained relationships with friends and family. Most of them saw me as lazy and a nuisance.

Impact on Mental Health

Mental health was another aspect that was emphasized as being substantially impacted by lack of sleep. Patients reported that their mental health disorders, including anxiety and depression, were associated or exacerbated by their lack of sleep. Caregivers also reported that the extensive caregiving responsibility had a toll on their mental health. Some participants struggled with a negative self-image caused by the perception that being overweight led to their sleep disorder:

It definitely affects my mood on the days when I don't get some sleep…I have a lot of issues with depression and anxiety. But not getting sleep exacerbate that.

In terms of our son, there is like a lot of caregiving responsibility...So, it's really impacted his [husband] mental health along with my mental health as well.

...embarrassment at all this, and self-loathing, because of perception that only fat people have apnea.

Challenges Navigating the Health Care System

Participants spoke about struggling with sleep issues for multiple years before seeking care. They noted that navigating the health care system to receive a diagnosis for their sleep disorder was a challenge, partly due to patients' lack of awareness about sleep studies. Some participants had to advocate for themselves to get a referral for a sleep study. Others noted that dismissive actions from their health care providers delayed their diagnosis. Some even described how discrimination and negative perceptions of body weight deterred them from pursuing care at a sleep clinic:

So, I've been experiencing this [sleep issue] since I was pretty young. Realizing that all these symptoms were attributed to the condition, but I had no way of really knowing just because awareness wasn't there.

You don't really have the mental energy to gather all the data or your symptoms. You just want your doctor to look into it and you trust that they can help you along. You really have to advocate for yourself.

He [doctor] brushed it off. He's like, oh, no, you don't have narcolepsy...so I went to my family physician, and I did a lot of research ahead of time just to make sure I knew which tests needed to be done.

One of the reasons I left [the sleep clinic] was because of the fat shaming. Every single person that got diagnosed with sleep apnea that was overweight got fat shamed and like, there is a way to tell somebody that their weight is a factor. But I had numerous women come out of that office crying after they saw the doctor and because he was saying that if they just lose weight, they wouldn't have any more sleep apnea.

Experience With In-Clinic (Level 1) Polysomnography

Participants spoke about their experience with level 1 polysomnography at a sleep clinic or hospital setting. A majority spoke about having a negative experience due to the unfamiliar environment, which impacted their sleep quality and made it difficult for the sleep during their sleep study to reflect their normal sleeping habits. The wires associated with the polysomnography equipment made movement difficult for some patients who are used to moving around in their normal sleep setting:

> *It was a pretty awful experience…bed was super uncomfortable, and clinic was noisy – could hear construction noise from outside. Impossible to sleep with so many wires all over me. I felt it wasn't at all a reflection of "normal" sleeping habits or patterns.*

> *I had all these cords, and I couldn't move. And I move around a lot at the best of time. So, I'm not surprised that they diagnosed me with mild to moderate sleep apnea, because I don't think I slept very well.*

Caregivers mentioned that the lack of accommodation is a significant barrier, especially for parents with disability who care for their children. They commented on the hospital setting not being attuned to caregivers who may have health issues of their own and require assistive devices. One participant who had previously worked at a sleep clinic reported that patients with special needs who require assistance had a challenging experience with in-clinic (level 1) polysomnography:

> *We literally don't sleep because you're given chairs. [I sleep] with a ventilator every night because I stop breathing whenever I sleep, so I literally just pull an all-nighter…it's especially not set up for disabled parents to support their kids getting sleep studies done.*

> *For folks with special needs, I had very ill and disabled patients that we were not able to manage [level 1 polysomnography].*

Participants reported that undergoing in-clinic (level 1) polysomnography required multiple arrangements including taking time off from work and childcare. Some explained that they would have to take the whole day off from work following their sleep study because they would be too tired to go to work the next morning. Others noted that they had to arrange for childcare while they were away from home to be able to undergo their sleep study:

> *It's just getting like the morning off work. That's the barrier because you don't sleep well during a sleep study. I literally just take the next day off.*

> *My husband stays home with my son, and we have nightly nursing to support my son at nighttime. If I was a single parent, it would be impossible for me to go take care of my own sleep studies because that would mean there would be too many childcare barriers for my son.*

Some participants noted that transportation and associated travel costs were barriers to accessing in-clinic (level 1) polysomnography. The logistics of planning an overnight stay at the sleep clinic was burdensome for some patients:

There is travel costs associated with that, because I lived 1 hour and 20 minutes away from the sleep clinic.

His sleep studies create a lot of planning that's involved because we have other kids at home. We have to child plan for other kids when our son has his sleep studies done. And the money involved for traveling to and from the hospital.

Some mentioned negative interactions with the clinic staff that made their experience worse:

It was not a good experience the people on the front desk were awful. They just want to get you into the room, hooked up [to the polysomnography equipment] and move on. [There was] no patient friendliness.

They were extremely upset with me because I kept getting up. I'm not used to going to bed that early. They want me to be in bed by 8–9 o'clock and I don't go to bed that early ever.

Experience With At-Home Sleep Studies

Participants talked about their experience with at-home sleep studies. We could not confirm if this was a level 2 or level 3 because participants were not aware of the terminology for different types of sleep studies. Overall, those who did their sleep studies at home reported a positive experience. Convenience and comfort were highlighted as the greatest strengths of at home sleep studies. Some mentioned that setting up the equipment was easy and attuned to the end user:

I had no difficulties at all with it. It was very well thought out and the equipment they sent you is well labeled, and everything just seemed to have been attuned to the end user.

I had the experience of having a sleep study at home and I found it really convenient. It had everything I needed to have a quality sleep study.

Most patients mentioned that they did not have any out-of-pocket costs associated with their at-home sleep study. However, they were not sure how the cost of the testing was covered. Some participants noted that they would not have been able to afford an at-home sleep study if it involved out-of-pocket expenses. One participant, in particular, mentioned that they had to pay out-of-pocket for their at-home sleep test:

No, I didn't pay for that. I have no idea [how it was covered]. The doctor just told me to go pick up the machine and do the study, so I did.

My husband and I are both disabled. We've lived in poverty our whole lives. It would never have happened if it wasn't covered.

I also did a couple home sleep tests that I paid privately for, just to try out the difference.

For people with physical limitations, setting up equipment for an at-home sleep study was a challenge:

> *I did have a little bit of trouble because I do have a congenital deformity of, particularly, [on one of my] hand and arm. So, I had to be a little ingenious about how to get the pieces together, but it all worked.*

> *We had challenges getting it set up because I'm not a professional…it was uncomfortable for an individual who can't use their hands to readjust.*

Participants reported that they would prefer to have support in the form of an instruction manual or video to set up at-home sleep study equipment. Most were comfortable with a help center that offers technical assistance:

> *Maybe clear instructions or a teaching video step by step to be able to put the home sleep test on myself.*

> *I would like [there] to be a help center that you could call text or email.*

> *I would say [a] YouTube video or manual instructions would be fine as long as they're not complicated.*

> *I'm very technical and so is my husband, so as long as they had the manual and they had the information, I'm sure we could do it.*

Preferences and Decision-Making

Participants were asked about their preference regarding in-clinic (level 1) and at-home (level 2) polysomnography. The majority of patients said they would prefer level 2 polysomnography, citing comfort and convenience as their main reasons. Patients also reported that they perceive level 2 polysomnography was or would be more representative of their actual sleep patterns, because it is conducted in a familiar setting (i.e., the home). Some mentioned that at-home sleep studies are more convenient when managing other chronic conditions:

> *It would certainly be more practical as it'll better represent my actual sleep patterns, I'll be more comfortable in my space. No disruptions to my routine and I'll still be able to care for my dependents.*

> *In the comfort of familiar surroundings is the best place for me to at least attempt to fall asleep. In an unfamiliar setting, I would not be able to follow my sleep routine nor have my timing. It simply would be more convenient.*

> *I've got rheumatoid arthritis and it requires a certain level of care, some of it taking place at bedtime or when I get up in the morning…I have to keep my other health problems in check and under control, so I'm very reluctant to go out…I found that then having a sleep study at home was so much more convenient because it didn't interrupt my routine and my care for my other diseases at all.*

Although most participants with whom we spoke preferred at-home polysomnography, there were some patients who preferred in-clinic (level 1) polysomnography because they have physical limitations

and need assistance to set up the sleep study equipment or because of concerns regarding the reliability of at-home polysomnography results:

> *I would choose the hospital setting because I care very much about the quality of results.*

> *I might have been able to fix it or do a little reposition and roll, but I think within the context of a patient with spinal cord injury, it [level 2 polysomnography] didn't really work.*

Impact of Having a Sleep Disorder Diagnosis

Participants reported that getting diagnosed for their sleep disorder helped them seek ways to manage their condition and eventually improve their lives. Some reflected that early diagnosis would have been better. Others noted that their mental health improved after diagnosis and treatment. In addition, patients had experiences with different treatments for their sleep disorder ranging from using a CPAP machine, lifestyle modification, medication, and dental appliance. The effectiveness of these treatments varied from patient to patient, but overall participants reported improved life after diagnosis:

> *I wish I had been diagnosed sooner…but I'm glad that I was able to get the sleep study done.*

> *I'm much more productive than I was pre diagnosis and pre therapy.*

> *My mental health has improved as far as depression and anxiety just because the medications that I'm on… and they [medication] help me get more consistent sleep during the night.*

CPAP machines were prescribed to most patients after their diagnosis:

> *Now I have my CPAP machine, when I use it, it improves my life.*

Patients described modifying their lifestyle after getting a diagnosis. Losing weight and following proper sleep hygiene (e.g., staying off electronic devices before bed, sleeping in a dark and quiet room, using relaxation and breathing techniques) were the most common lifestyle changes:

> *I do find that strict sleep hygiene really helps, getting enough sunshine and some activity during the day…practicing some relaxation and stretching techniques. I find that most helpful.*

> *I was 45 pounds overweight at both sleep tests…and since I lost weight, things have improved.*

Others noted that medications and dental appliance was prescribed to them to help with their sleep disorder:

> *I was trying the melatonin for a while. Every now and then, I'll use magnesium as a both muscle relaxer and it does help at times with the sleep stuff.*
>
> *He [doctor] had me on melatonin and gabapentin, and it worked for a long time. And then, it just quit working.*
>
> *The prescription was a dental appliance, so [it's] an overnight appliance that does something with the jaw.*

Preferences and Values Evidence Discussion

All participants had lived experience with a sleep disorder or were a family or caregiver to someone with a sleep disorder. Participants reported negative impacts that it had on their day-to-day, mental health, social and family relationships, and work.

Participants spoke about the journey to manage their condition. They were able to speak extensively of their experience with in-clinic (level 1) polysomnography and at-home sleep studies. Participants also highlighted the importance of getting a diagnosis to seek proper treatment and improve their lives.

In terms of limitations, there was a lack of geographic representation among participants, all of whom lived in southern Ontario; however, both urban and rural perspectives were provided. There were no participants with direct experience with level 2 polysomnography which we attribute to the fact that there is limited access to and availability of level 2 polysomnography across Ontario. In addition, participants were not aware of the different terminologies for at home sleep studies, hence, could not differentiate between level 2 and level 3 sleep studies.

Preferences and Values Evidence Conclusions

Participants spoke about the impact of living with a sleep disorder. They reflected on their experience undergoing in-clinic (level 1) and at-home sleep studies to get a proper diagnosis for their condition. Most participants who had experience with in-clinic (level 1) polysomnography commented on their negative experience at a sleep clinic or hospital. Those who had experience with at-home sleep studies viewed them favorably overall, mainly due to comfort and convenience. However, participants emphasized that for people with mobility issues, at-home sleep studies could be a challenge. Getting an early diagnosis was important to participants; however, they noted that navigating the health care system to get a diagnosis for their sleep disorder was a challenge, partly due to patients' lack of awareness about sleep studies.

Equity Considerations

Currently, only level 1 (in-clinic) polysomnography is publicly funded. Having an at-home alternative may support those who may have a preference, care partner responsibilities, inability to travel, or other circumstances that may make it difficult to prevent them from undergoing a sleep study in clinic.

Conclusions of the Health Technology Assessment

Level 2 polysomnography (unattended, at-home sleep studies) may have good test performance for adults and children, with adequate diagnostic accuracy, compared with level 1 polysomnography (attended, in-clinic sleep studies).

Economic analysis showed that the cost-effectiveness of level 2 polysomnography for adults with suspected sleep disorders is highly uncertain due to uncertainty in the estimated costs. Given limited information, the cost-effectiveness of level 2 polysomnography is uncertain for children and young adults. The budget impact of publicly funding level 2 polysomnography for adults is uncertain and could range from savings of $22 million to additional costs of $43 million, depending on various assumptions (e.g., diagnostic test accuracy, test cost, cost of follow-up, or use of CPAP). Publicly funding the new diagnostic pathway with level 2 polysomnography for children would require additional costs (0.005 million or around $5,000 over 5 years).

Patients highlighted the the importance of getting a diagnosis to be able to seek proper treatment for their sleep disorder. People who had experience with at-home sleep studies viewed them favorably overall, finding them to be more comfortable and convenient. However, participants emphasized that for people with physical limitations, setting up the equipment for an at-home sleep study could be a challenge.

Abbreviations

ADP: Assistive Devices Program

AHI: apnea hypopnea index

AUD: Australian dollars

CAD: Canadian dollars

CADTH: Canadian Agency for Drugs and Technologies in Health

CI: confidence interval

CPAP: continuous positive airway pressure

CrI: credible interval

EEG: electroencephalography

GRADE: Grading of Recommendations Assessment, Development, and Evaluation

ICER: incremental cost-effectiveness ratio

MOH: Ministry of Health

NHS EED: National Health Service Economic Evaluation Database

NICE: National Institute for Health and Care Excellence

NIH: National Institutes of Health

OHIP: Ontario Health Insurance Plan

OMA: Ontario Medical Association

QALY: quality-adjusted life-year

SD: standard deviation

SE: standard error

WTP: willingness-to-pay

Glossary

Budget impact analysis: A budget impact analysis estimates the financial impact of adopting a new health care intervention on the current budget (i.e., the affordability of the new intervention). It is based on predictions of how changes in the intervention mix will impact the level of health care spending for a specific population. Budget impact analyses are typically conducted for a short-term period (e.g., 5 years). The budget impact, sometimes referred to as the net budget impact, is the estimated cost difference between the current scenario (i.e., the anticipated amount of spending for a specific population without using the new intervention) and the new scenario (i.e., the anticipated amount of spending for a specific population following the introduction of the new intervention).

Cost–benefit analysis: A cost–benefit analysis is a type of economic evaluation that expresses the effects of a health care intervention in terms of a monetary value so that these effects can be compared with costs. Results can be reported either as a ratio of costs to benefits or as a simple sum that represents the net benefit (or net loss) of one intervention over another. The monetary valuation of the different intervention effects is based on either prices that are revealed by markets or an individual or societal willingness-to-pay value.

Cost-effective: A health care intervention is considered cost-effective when it provides additional benefits, compared with relevant alternatives, at an additional cost that is acceptable to a decision-maker based on the maximum willingness-to-pay value.

Cost-effectiveness acceptability curve: In economic evaluations, a cost-effectiveness acceptability curve is a graphical representation of the results of a probabilistic analysis. It illustrates the probability of health care interventions being cost-effective over a range of willingness-to-pay values. Willingness-to-pay values are plotted on the horizontal axis of the graph, and the probability of the intervention of interest and its comparator(s) being cost-effective at corresponding willingness-to-pay values is plotted on the vertical axis.

Cost-effectiveness acceptability frontier: In economic evaluations, a cost-effectiveness acceptability frontier is a graph summarizing the probability of a number of health care interventions being cost-effective over a range of willingness-to-pay values. Like cost-effectiveness acceptability curves, cost-effectiveness acceptability frontiers plot willingness-to-pay values on the horizontal axis and the probability of the interventions being cost-effective at particular willingness-to-pay values on the vertical axis.

Cost-effectiveness analysis: Used broadly, “cost-effectiveness analysis” may refer to an economic evaluation used to compare the benefits of two or more health care interventions with their costs. It may encompass several types of analysis (e.g., cost-effectiveness analysis, cost–utility analysis). Used more specifically, “cost-effectiveness analysis” may refer to a type of economic evaluation in which the main outcome measure is the incremental cost per natural unit of health (e.g., life-year, symptom-free day) gained.

Cost-effectiveness plane: In economic evaluations, a cost-effectiveness plane is a graph used to show the differences in cost and effectiveness between a health care intervention and its comparator(s). Differences in effects are plotted on the horizontal axis, and differences in costs are plotted on the vertical axis.

Cost-minimization analysis: In economic evaluations, a cost-minimization analysis compares the costs of two or more health care interventions. It is used when the intervention of interest and its relevant alternative(s) are determined to be equally effective.

Cost–utility analysis: A cost–utility analysis is a type of economic evaluation used to compare the benefits of two or more health care interventions with their costs. The benefits are measured using quality-adjusted life-years, which capture both the quality and quantity of life. In a cost–utility analysis, the main outcome measure is the incremental cost per quality-adjusted life-year gained.

Decision tree: A decision tree is a type of economic model used to assess the costs and benefits of two or more alternative health care interventions. Each intervention may be associated with different outcomes, which are represented by distinct branches in the tree. Each outcome may have a different probability of occurring and may lead to different costs and benefits.

Deterministic sensitivity analysis: Deterministic sensitivity analysis is an approach used to explore uncertainty in the results of an economic evaluation by varying parameter values to observe the potential impact on the cost-effectiveness of the health care intervention of interest. One-way sensitivity analysis accounts for uncertainty in parameter values one at a time, whereas multiway sensitivity analysis accounts for uncertainty in a combination of parameter values simultaneously.

Discounting: Discounting is a method used in economic evaluations to adjust for the differential timing of the costs incurred and the benefits generated by a health care intervention over time. Discounting reflects the concept of positive time preference, whereby future costs and benefits are reduced to reflect their present value. The health technology assessments conducted by Ontario Health use an annual discount rate of 1.5% for both future costs and future benefits.

Dominant: A health care intervention is considered dominant when it is more effective and less costly than its comparator(s).

Equity: Unlike the notion of equality, equity is not about treating everyone the same way.[165] It denotes fairness and justice in process and in results. Equitable outcomes often require differential treatment and resource redistribution to achieve a level playing field among all individuals and communities. This requires recognizing and addressing barriers to opportunities for all to thrive in our society.

Equity-deserving groups: Those who exhibit the socially stratifying characteristics identified in the PROGRESS-Plus framework.[166] These characteristics involve:

- Place of residence (e.g., rural and remote populations)
- Race/ethnicity/culture (e.g., First Nations, Métis, and Inuit populations, immigrant populations, and linguistic minority populations)
- Occupation or labour-market experiences more generally (e.g., those in “precarious work” arrangements like minimum-wage, seasonal, or part-time work)
- Gender
- Religion
- Educational level (e.g., health literacy)
- Socioeconomic status (e.g., economically disadvantaged populations)

- Social capital/social exclusion (e.g., citizenship/residence)
- Personal characteristics associated with discrimination (e.g., age, disability, sexual orientation)
- Time-dependent relationships (e.g., leaving the hospital, in respite care)

Health inequity: Health inequities are avoidable inequalities in health between groups of people within countries and between countries.[167] These inequities arise from inequalities within and between societies. Social and economic conditions and their effects on people's lives determine their risk of illness and the actions taken to prevent them becoming ill or treat illness when it occurs.

Horizontal equity: Horizontal equity requires that people with like characteristics (of ethical relevance) be treated the same.

Incremental cost: The incremental cost is the additional cost, typically per person, of a health care intervention versus a comparator.

Incremental cost-effectiveness ratio (ICER): The incremental cost-effectiveness ratio (ICER) is a summary measure that indicates, for a given health care intervention, how much more a health care consumer must pay to get an additional unit of benefit relative to an alternative intervention. It is obtained by dividing the incremental cost by the incremental effectiveness. Incremental cost-effectiveness ratios are typically presented as the cost per life-year gained or the cost per quality-adjusted life-year gained.

Incremental net benefit: Incremental net benefit is a summary measure of cost-effectiveness. It incorporates the differences in cost and effect between two health care interventions and the willingness-to-pay value. Net health benefit is calculated as the difference in effect minus the difference in cost divided by the willingness-to-pay value. Net monetary benefit is calculated as the willingness-to-pay value multiplied by the difference in effect minus the difference in cost. An intervention can be considered cost-effective if either the net health or net monetary benefit is greater than zero.

Market distribution: When evaluating more than two technologies, the market distribution is the proportion of the population that uses each technology.

Ministry of Health perspective: The perspective adopted in economic evaluations determines the types of costs and health benefits to include. Ontario Health develops health technology assessment reports from the perspective of the Ontario Ministry of Health. This perspective includes all costs and health benefits attributable to the Ministry of Health, such as treatment costs (e.g., drugs, administration, monitoring, hospital stays) and costs associated with managing adverse events caused by treatments. This perspective does not include out-of-pocket costs incurred by patients related to obtaining care (e.g., transportation) or loss of productivity (e.g., absenteeism).

Multiway sensitivity analysis: A multiway sensitivity analysis is used to explore uncertainty in the results of an economic evaluation. It is done by varying a combination of model input (i.e., parameter) values simultaneously between plausible extremes to observe the potential impact on the cost-effectiveness of the health care intervention of interest.

Natural history of a disease: The natural history of a disease is the progression of a disease over time in the absence of any health care intervention.

One-way sensitivity analysis: A one-way sensitivity analysis is used to explore uncertainty in the results of an economic evaluation. It is done by varying one model input (i.e., a parameter) at a time between its minimum and maximum values to observe the potential impact on the cost-effectiveness of the health care intervention of interest.

Probabilistic analysis: A probabilistic analysis (also known as a probabilistic sensitivity analysis) is used in economic models to explore uncertainty in several parameters simultaneously and is done using Monte Carlo simulation. Model inputs are defined as a distribution of possible values. In each iteration, model inputs are obtained by randomly sampling from each distribution, and a single estimate of cost and effectiveness is generated. This process is repeated many times (e.g., 10,000 times) to estimate the number of times (i.e., the probability) that the health care intervention of interest is cost-effective.

Quality-adjusted life-year (QALY): The quality-adjusted life-year is a generic health outcome measure commonly used in cost–utility analyses to reflect the quantity and quality of life-years lived. The life-years lived are adjusted for quality of life using individual or societal preferences (i.e., utility values) for being in a particular health state. One year of perfect health is represented by one quality-adjusted life-year.

Reference case: The reference case is a preferred set of methods and principles that provide the guidelines for economic evaluations. Its purpose is to standardize the approach of conducting and reporting economic evaluations, so that results can be compared across studies.

Scenario analysis: A scenario analysis is used to explore uncertainty in the results of an economic evaluation. It is done by observing the potential impact of different scenarios on the cost-effectiveness of a health care intervention. Scenario analyses include varying structural assumptions from the reference case.

Sensitivity analysis: Every economic evaluation contains some degree of uncertainty, and results can vary depending on the values taken by key parameters and the assumptions made. Sensitivity analysis allows these factors to be varied and shows the impact of these variations on the results of the evaluation. There are various types of sensitivity analysis, including deterministic, probabilistic, and scenario.

Societal perspective: The perspective adopted in an economic evaluation determines the types of costs and health benefits to include. The societal perspective reflects the broader economy and is the aggregation of all perspectives (e.g., health care payer and patient perspectives). It considers the full effect of a health condition on society, including all costs (regardless of who pays) and all benefits (regardless of who benefits).

Time horizon: In economic evaluations, the time horizon is the time frame over which costs and benefits are examined and calculated. The relevant time horizon is chosen based on the nature of the disease and health care intervention being assessed, as well as the purpose of the analysis. For instance, a lifetime horizon would be chosen to capture the long-term health and cost consequences over a patient's lifetime.

Uptake rate: In instances where two technologies are being compared, the uptake rate is the rate at which a new technology is adopted. When a new technology is adopted, it may be used in addition to an existing technology, or it may replace an existing technology.

Vertical equity: Vertical equity allows for people with different characteristics (of ethical relevance) to be treated differently.

Willingness-to-pay value: A willingness-to-pay value is the monetary value a health care consumer is willing to pay for added health benefits. When conducting a cost–utility analysis, the willingness-to-pay value represents the cost a consumer is willing to pay for an additional quality-adjusted life-year. If the incremental cost-effectiveness ratio is less than the willingness-to-pay value, the health care intervention of interest is considered cost-effective. If the incremental cost-effectiveness ratio is more than the willingness-to-pay value, the intervention is considered not to be cost-effective.

Appendices

Appendix 1: Literature Search Strategies

Clinical Evidence Search

Search date: January 05, 2023

Databases searched: Ovid MEDLINE, Embase, Cochrane Database of Systematic Reviews, Cochrane Central Register of Controlled Trials, NHS Economic Evaluation Database, APA PsycINFO

Database: EBM Reviews—Cochrane Central Register of Controlled Trials <December 2022>, EBM Reviews—Cochrane Database of Systematic Reviews <2005 to January 4, 2023>, EBM Reviews—NHS Economic Evaluation Database <1st Quarter 2016>, Embase <1980 to 2022 Week 52>, Ovid MEDLINE(R) ALL <1946 to January 04, 2023>, APA PsycINFO <1967 to December Week 4 2022>
Search Strategy:
---
1 exp Sleep Disorders, Intrinsic/ (360223)
2 exp Parasomnias/ (19850)
3 ((sleep* and (apn?e* or hypopn?a*)) or OSA or OSAS or OSAH or OSAHS or CSA or MSA or (sleep adj3 disorder*) or SDB or sleep disturbance* or insomnia* or narcolep* or parasomni*).ti,ab,kf. (442251)
4 (hypersomn* or hyper-somn* or ((daytime* or excessive*) adj1 (sleepiness* or tiredness* or somnolen*))).ti,ab,kf. (42442)
5 Sleep Disorders, Circadian Rhythm/ (3742)
6 (((circadi* rhythm* or nyctohemeral rhythm* or sleep-wake schedule* or sleep-wake cycle* or shift-work) adj3 (disturbance* or disorder*)) or delayed sleep phase*).ti,ab,kf. (8819)
7 Snoring/ (19339)
8 (snore* or snoring).ti,ab,kf. (23319)
9 or/1-8 (620827)
10 Polysomnography/ and (Monitoring, Physiologic/ or Monitoring, Ambulatory/ or Telemedicine/ or Wireless Technology/ or Home Care Services, Hospital-Based/) (1456)
11 ((home* or at-home* or in-home* or non-lab* or unattended or unsupervi* or unstaff* or outpatient* or unmonitored or un-monitored or parent-attended or ambulatory or ambulant or portable or comprehensive or multi-paramet* or wireless* or wire-less* or out-of-cent* or OOC) adj5 (polysomnogra* or PSG*)).ti,ab,kf. (4872)
12 (((home* or at-home* or in-home* or non-lab* or unattended or unsupervi* or unstaff* or outpatient* or unmonitored or un-monitored or parent-attended or ambulatory or ambulant or portable or comprehensive or multi-paramet* or wireless* or wire-less* or out-of-cent* or OOC) adj5 (sleep* or nocturnal* or overnight* or over-night* or night*) adj2 (test* or monitor* or stud* or evaluation* or analys#s or analy#e*)) or OCST or home PM or (automated sleep* adj3 system*)).ti,ab,kf. (6507)
13 ((sleep* or nocturnal* or overnight* or over-night* or night*) adj2 (test* or monitor* or stud* or evaluation* or analys#s or analy#e*) adj5 (home* or at-home* or in-home* or non-lab* or unattended or unsupervi* or unstaff* or outpatient* or unmonitored or un-monitored or parent-attended or

ambulatory or ambulant or portable or comprehensive or multi-paramet* or wireless* or wire-less* or out-of-cent* or OOC)).ti,ab,kf. (5428)
14 ((level* or type*) adj5 (II or "2" or two) adj5 (polysomnogra* or PSG*)).ti,ab,kf. (326)
15 ((level* or type*) adj5 (II or "2" or two) adj5 ((sleep* or nocturnal* or overnight* or over-night* or night*) adj2 (test* or monitor* or stud* or evaluation* or analys#s or analy#e*))).ti,ab,kf. (195)
16 (H-PSG or HPSG or T2PSG* or T2-PSG*).ti,ab,kf. (182)
17 (prodigy* sleep* or nox* a1* or nox medical* or sleep profiler* or sleepstudy* or octave* dreem* or embletta* or somnomedics* or sleepview* or trex* home* or alice* pdx* or easy II psg* or trackit* or medipalm* or embletta* or onera* or zmachine*).ti,ab,kf. (893)
18 or/10-17 (12569)
19 9 and 18 (9543)
20 19 use medall (2835)
21 exp Animals/ not Humans/ (16485565)
22 20 not 21 (2826)
23 Case Reports/ or Comment.pt. or Editorial.pt. or (Letter not (Letter and Randomized Controlled Trial)).pt. or Congress.pt. (6236869)
24 22 not 23 (2707)
25 limit 24 to english language [Limit not valid in CDSR; records were retained] (2553)
26 19 use cleed (7)
27 19 use cctr,coch (668)
28 ((Letter not (Letter and Randomized Controlled Trial)) or Conference Proceeding or Editorial or Comment).pt. (4303862)
29 27 not 28 (494)
30 exp sleep disorder/ (423373)
31 ((sleep* and (apn?e* or hypopn?a*)) or OSA or OSAS or OSAH or OSAHS or CSA or MSA or (sleep adj3 disorder*) or SDB or sleep disturbance* or insomnia* or narcolep* or parasomni*).tw,kw,kf. (447742)
32 (hypersomn* or hyper-somn* or ((daytime* or excessive*) adj1 (sleepiness* or tiredness* or somnolen*))).tw,kw,kf. (42937)
33 (((circadi* rhythm* or nyctohemeral rhythm* or sleep-wake schedule* or sleep-wake cycle* or shift-work) adj3 (disturbance* or disorder*)) or delayed sleep phase*).tw,kw,kf. (9016)
34 snoring/ (19339)
35 (snore* or snoring).tw,kw,kf. (23429)
36 or/30-35 (648964)
37 (polysomnograph/ or polysomnography/) and (physiologic monitoring/ or ambulatory monitoring/ or telemedicine/ or wireless communication/ or home monitoring/) (1449)
38 ((home* or at-home* or in-home* or non-lab* or unattended or unsupervi* or unstaff* or outpatient* or unmonitored or un-monitored or parent-attended or ambulatory or ambulant or portable or comprehensive or multi-paramet* or wireless* or wire-less* or out-of-cent* or OOC) adj5 (polysomnogra* or PSG*)).tw,kw,kf,dv. (5034)
39 (((home* or at-home* or in-home* or non-lab* or unattended or unsupervi* or unstaff* or outpatient* or unmonitored or un-monitored or parent-attended or ambulatory or ambulant or portable or comprehensive or multi-paramet* or wireless* or wire-less* or out-of-cent* or OOC) adj5 (sleep* or nocturnal* or overnight* or over-night* or night*) adj2 (test* or monitor* or stud* or evaluation* or analys#s or analy#e*)) or OCST or home PM or (automated sleep* adj3 system*)).tw,kw,kf,dv. (6617)
40 ((sleep* or nocturnal* or overnight* or over-night* or night*) adj2 (test* or monitor* or stud* or evaluation* or analys#s or analy#e*) adj5 (home* or at-home* or in-home* or non-lab* or unattended

or unsupervi* or unstaff* or outpatient* or unmonitored or un-monitored or parent-attended or ambulatory or ambulant or portable or comprehensive or multi-paramet* or wireless* or wire-less* or out-of-cent* or OOC)).tw,kw,kf,dv. (5509)
41 ((level* or type*) adj5 (II or "2" or two) adj5 (polysomnogra* or PSG*)).tw,kw,kf,dv. (329)
42 ((level* or type*) adj5 (II or "2" or two) adj5 ((sleep* or nocturnal* or overnight* or over-night* or night*) adj2 (test* or monitor* or stud* or evaluation* or analys#s or analy#e*))).tw,kw,kf,dv. (197)
43 (H-PSG or HPSG or T2PSG* or T2-PSG*).tw,kw,kf,dv. (182)
44 (prodigy* sleep* or nox* a1* or nox medical* or sleep profiler* or sleepstudy* or octave* dreem* or embletta* or somnomedics* or sleepview* or trex* home* or alice* pdx* or easy II psg* or trackit* or medipalm* or embletta* or onera* or zmachine*).tw,kw,kf,dv. (1237)
45 or/37-44 (12981)
46 36 and 45 (10014)
47 46 use emez (5793)
48 (exp animal/ or nonhuman/) not exp human/ (11645173)
49 47 not 48 (5746)
50 Case Report/ or Comment/ or Editorial/ or (letter.pt. not (letter.pt. and randomized controlled trial/)) or conference abstract.pt. or conference review.pt. (12986155)
51 49 not 50 (2994)
52 limit 51 to english language [Limit not valid in CDSR; records were retained] (2804)
53 exp sleep wake disorders/ (423373)
54 ((sleep* and (apn?e* or hypopn?a*)) or OSA or OSAS or OSAH or OSAHS or CSA or MSA or (sleep adj3 disorder*) or SDB or sleep disturbance* or insomnia* or narcolep* or parasomni*).ti,ab,id. (436036)
55 (hypersomn* or hyper-somn* or ((daytime* or excessive*) adj1 (sleepiness* or tiredness* or somnolen*))).ti,ab,id. (41841)
56 (((circadi* rhythm* or nyctohemeral rhythm* or sleep-wake schedule* or sleep-wake cycle* or shift-work) adj3 (disturbance* or disorder*)) or delayed sleep phase*).ti,ab,id. (8616)
57 snoring/ (19339)
58 (snore* or snoring).ti,ab,id. (22855)
59 or/53-58 (640692)
60 polysomnography/ and (outpatient treatment/ or home care/ or outpatients/ or wearable devices/ or telemedicine/ or home environment/) (1110)
61 ((home* or at-home* or in-home* or non-lab* or unattended or unsupervi* or unstaff* or outpatient* or unmonitored or un-monitored or parent-attended or ambulatory or ambulant or portable or comprehensive or multi-paramet* or wireless* or wire-less* or out-of-cent* or OOC) adj5 (polysomnogra* or PSG*)).ti,ab,id. (4799)
62 (((home* or at-home* or in-home* or non-lab* or unattended or unsupervi* or unstaff* or outpatient* or unmonitored or un-monitored or parent-attended or ambulatory or ambulant or portable or comprehensive or multi-paramet* or wireless* or wire-less* or out-of-cent* or OOC) adj5 (sleep* or nocturnal* or overnight* or over-night* or night*) adj2 (test* or monitor* or stud* or evaluation* or analys#s or analy#e*)) or OCST or home PM or (automated sleep* adj3 system*)).ti,ab,id. (6393)
63 ((sleep* or nocturnal* or overnight* or over-night* or night*) adj2 (test* or monitor* or stud* or evaluation* or analys#s or analy#e*) adj5 (home* or at-home* or in-home* or non-lab* or unattended or unsupervi* or unstaff* or outpatient* or unmonitored or un-monitored or parent-attended or ambulatory or ambulant or portable or comprehensive or multi-paramet* or wireless* or wire-less* or out-of-cent* or OOC)).ti,ab,id. (5302)
64 ((level* or type*) adj5 (II or "2" or two) adj5 (polysomnogra* or PSG*)).ti,ab,id. (319)

65 ((level* or type*) adj5 (II or "2" or two) adj5 ((sleep* or nocturnal* or overnight* or over-night* or night*) adj2 (test* or monitor* or stud* or evaluation* or analys#s or analy#e*))).ti,ab,id. (196)
66 (H-PSG or HPSG or T2PSG* or T2-PSG*).ti,ab,id. (182)
67 (prodigy* sleep* or nox* a1* or nox medical* or sleep profiler* or sleepstudy* or octave* dreem* or embletta* or somnomedics* or sleepview* or trex* home* or alice* pdx* or easy II psg* or trackit* or medipalm* or embletta* or onera* or zmachine*).ti,ab,id. (892)
68 or/60-67 (12188)
69 59 and 68 (9397)
70 69 use psyb (514)
71 (animal not human).po. (371999)
72 70 not 71 (510)
73 case report/ or editorial.dt. or comment reply.dt. or letter.dt. (5253620)
74 72 not 73 (491)
75 limit 74 to english language [Limit not valid in CDSR; records were retained] (480)
76 25 or 26 or 29 or 52 or 75 (6338)
77 76 use medall (2553)
78 76 use emez (2804)
79 76 use coch (0)
80 76 use cctr (494)
81 76 use cleed (7)
82 76 use psyb (480)
83 limit 76 to yr="1967 - 2015" (3045)
84 remove duplicates from 83 (1675)
85 limit 76 to yr="2016 -Current" (3289)
86 remove duplicates from 85 (1882)
87 84 or 86 (3557)

Economic Evidence Search

Search date: January 09, 2023

Databases searched: Ovid MEDLINE, Embase, Cochrane Database of Systematic Reviews, Cochrane Central Register of Controlled Trials, NHS Economic Evaluation Database, APA PsycInfo

Database: EBM Reviews—Cochrane Central Register of Controlled Trials <December 2022>, EBM Reviews—Cochrane Database of Systematic Reviews <2005 to January 4, 2023>, EBM Reviews—NHS Economic Evaluation Database <1st Quarter 2016>, Embase <1980 to 2023 Week 01>, Ovid MEDLINE(R) ALL <1946 to January 06, 2023>, APA PsycInfo <1967 to January Week 1 2023>

Search Strategy:

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1 exp Sleep Disorders, Intrinsic/ (360761)
2 exp Parasomnias/ (19886)
3 ((sleep* and (apn?e* or hypopn?a*)) or OSA or OSAS or OSAH or OSAHS or CSA or MSA or (sleep adj3 disorder*) or SDB or sleep disturbance* or insomnia* or narcolep* or parasomni*).ti,ab,kf. (442736)

4 (hypersomn* or hyper-somn* or ((daytime* or excessive*) adj1 (sleepiness* or tiredness* or somnolen*))).ti,ab,kf. (42491)
5 Sleep Disorders, Circadian Rhythm/ (3742)
6 (((circadi* rhythm* or nyctohemeral rhythm* or sleep-wake schedule* or sleep-wake cycle* or shift-work) adj3 (disturbance* or disorder*)) or delayed sleep phase*).ti,ab,kf. (8831)
7 Snoring/ (19358)
8 (snore* or snoring).ti,ab,kf. (23329)
9 or/1-8 (621567)
10 Polysomnography/ and (Monitoring, Physiologic/ or Monitoring, Ambulatory/ or Telemedicine/ or Wireless Technology/ or Home Care Services, Hospital-Based/) (1456)
11 ((home* or at-home* or in-home* or non-lab* or unattended or unsupervi* or unstaff* or outpatient* or unmonitored or un-monitored or parent-attended or ambulatory or ambulant or portable or comprehensive or multi-paramet* or wireless* or wire-less* or out-of-cent* or OOC) adj5 (polysomnogra* or PSG*)).ti,ab,kf. (4880)
12 (((home* or at-home* or in-home* or non-lab* or unattended or unsupervi* or unstaff* or outpatient* or unmonitored or un-monitored or parent-attended or ambulatory or ambulant or portable or comprehensive or multi-paramet* or wireless* or wire-less* or out-of-cent* or OOC) adj5 (sleep* or nocturnal* or overnight* or over-night* or night*) adj2 (test* or monitor* or stud* or evaluation* or analys#s or analy#e*)) or OCST or home PM or (automated sleep* adj3 system*)).ti,ab,kf. (6514)
13 ((sleep* or nocturnal* or overnight* or over-night* or night*) adj2 (test* or monitor* or stud* or evaluation* or analys#s or analy#e*) adj5 (home* or at-home* or in-home* or non-lab* or unattended or unsupervi* or unstaff* or outpatient* or unmonitored or un-monitored or parent-attended or ambulatory or ambulant or portable or comprehensive or multi-paramet* or wireless* or wire-less* or out-of-cent* or OOC)).ti,ab,kf. (5433)
14 ((level* or type*) adj5 (II or "2" or two) adj5 (polysomnogra* or PSG*)).ti,ab,kf. (326)
15 ((level* or type*) adj5 (II or "2" or two) adj5 ((sleep* or nocturnal* or overnight* or over-night* or night*) adj2 (test* or monitor* or stud* or evaluation* or analys#s or analy#e*))).ti,ab,kf. (196)
16 (H-PSG or HPSG or T2PSG* or T2-PSG*).ti,ab,kf. (182)
17 (prodigy* sleep* or nox* a1* or nox medical* or sleep profiler* or sleepstudy* or octave* dreem* or embletta* or somnomedics* or sleepview* or trex* home* or alice* pdx* or easy II psg* or trackit* or medipalm* or embletta* or onera* or zmachine*).ti,ab,kf. (893)
18 or/10-17 (12584)
19 9 and 18 (9556)
20 exp Animals/ not Humans/ (16489026)
21 19 not 20 (7795)
22 Case Reports/ (2311160)
23 21 not 22 (7747)
24 19 use coch,cleed (7)
25 economics/ (290359)
26 economics, medical/ or economics, pharmaceutical/ or exp economics, hospital/ or economics, nursing/ or economics, dental/ (1018307)
27 economics.fs. (467212)
28 (econom* or price or prices or pricing or priced or discount* or expenditure* or budget* or pharmacoeconomic* or pharmaco-economic*).ti,ab,kf. (1401216)
29 exp "costs and cost analysis"/ (719013)
30 (cost or costs or costing or costly).ti. (338208)
31 cost effective*.ti,ab,kf. (449328)

32 (cost* adj2 (util* or efficacy* or benefit* or minimi* or analy* or saving* or estimate* or allocation or control or sharing or instrument* or technolog* or increment*)).ab,kf. (318046)
33 models, economic/ (15611)
34 markov chains/ or monte carlo method/ (105618)
35 (decision adj1 (tree* or analy* or model*)).ti,ab,kf. (68069)
36 (markov or markow or monte carlo).ti,ab,kf. (180773)
37 quality-adjusted life years/ (53310)
38 (QOLY or QOLYs or HRQOL or HRQOLs or QALY or QALYs or QALE or QALEs).ti,ab,kf. (113503)
39 ((adjusted adj1 (quality or life)) or (willing* adj2 pay) or sensitivity analys*s).ti,ab,kf. (190755)
40 or/25-39 (3511547)
41 23 and 40 (603)
42 41 use medall,cctr (259)
43 exp sleep disorder/ (423940)
44 ((sleep* and (apn?e* or hypopn?a*)) or OSA or OSAS or OSAH or OSAHS or CSA or MSA or (sleep adj3 disorder*) or SDB or sleep disturbance* or insomnia* or narcolep* or parasomni*).tw,kw,kf. (448227)
45 (hypersomn* or hyper-somn* or ((daytime* or excessive*) adj1 (sleepiness* or tiredness* or somnolen*))).tw,kw,kf. (42986)
46 (((circadi* rhythm* or nyctohemeral rhythm* or sleep-wake schedule* or sleep-wake cycle* or shift-work) adj3 (disturbance* or disorder*)) or delayed sleep phase*).tw,kw,kf. (9028)
47 snoring/ (19358)
48 (snore* or snoring).tw,kw,kf. (23439)
49 or/43-48 (649713)
50 (polysomnograph/ or polysomnography/) and (physiologic monitoring/ or ambulatory monitoring/ or telemedicine/ or wireless communication/ or home monitoring/) (1450)
51 ((home* or at-home* or in-home* or non-lab* or unattended or unsupervi* or unstaff* or outpatient* or unmonitored or un-monitored or parent-attended or ambulatory or ambulant or portable or comprehensive or multi-paramet* or wireless* or wire-less* or out-of-cent* or OOC) adj5 (polysomnogra* or PSG*)).tw,kw,kf,dv. (5042)
52 (((home* or at-home* or in-home* or non-lab* or unattended or unsupervi* or unstaff* or outpatient* or unmonitored or un-monitored or parent-attended or ambulatory or ambulant or portable or comprehensive or multi-paramet* or wireless* or wire-less* or out-of-cent* or OOC) adj5 (sleep* or nocturnal* or overnight* or over-night* or night*) adj2 (test* or monitor* or stud* or evaluation* or analys#s or analy#e*)) or OCST or home PM or (automated sleep* adj3 system*)).tw,kw,kf,dv. (6624)
53 ((sleep* or nocturnal* or overnight* or over-night* or night*) adj2 (test* or monitor* or stud* or evaluation* or analys#s or analy#e*) adj5 (home* or at-home* or in-home* or non-lab* or unattended or unsupervi* or unstaff* or outpatient* or unmonitored or un-monitored or parent-attended or ambulatory or ambulant or portable or comprehensive or multi-paramet* or wireless* or wire-less* or out-of-cent* or OOC)).tw,kw,kf,dv. (5514)
54 ((level* or type*) adj5 (II or "2" or two) adj5 (polysomnogra* or PSG*)).tw,kw,kf,dv. (329)
55 ((level* or type*) adj5 (II or "2" or two) adj5 ((sleep* or nocturnal* or overnight* or over-night* or night*) adj2 (test* or monitor* or stud* or evaluation* or analys#s or analy#e*))).tw,kw,kf,dv. (198)
56 (H-PSG or HPSG or T2PSG* or T2-PSG*).tw,kw,kf,dv. (182)
57 (prodigy* sleep* or nox* a1* or nox medical* or sleep profiler* or sleepstudy* or octave* dreem* or embletta* or somnomedics* or sleepview* or trex* home* or alice* pdx* or easy II psg* or trackit* or medipalm* or embletta* or onera* or zmachine*).tw,kw,kf,dv. (1238)
58 or/50-57 (12997)

59 49 and 58 (10028)
60 (exp animal/ or nonhuman/) not exp human/ (11650058)
61 59 not 60 (9955)
62 Case Report/ (5056052)
63 61 not 62 (9725)
64 Economics/ (290359)
65 Health Economics/ or Pharmacoeconomics/ or Drug Cost/ or Drug Formulary/ (146441)
66 Economic Aspect/ or exp Economic Evaluation/ (537857)
67 (econom* or price or prices or pricing or priced or discount* or expenditure* or budget* or pharmacoeconomic* or pharmaco-economic*).tw,kw,kf. (1427662)
68 exp "Cost"/ (671454)
69 (cost or costs or costing or costly).ti. (338208)
70 cost effective*.tw,kw,kf. (458643)
71 (cost* adj2 (util* or efficac* or benefit* or minimi* or analy* or saving* or estimate* or allocation or control or sharing or instrument* or technolog* or increment*)).ab,kw,kf. (327478)
72 Monte Carlo Method/ (80674)
73 (decision adj1 (tree* or analy* or model*)).tw,kw,kf. (71879)
74 (markov or markow or monte carlo).tw,kw,kf. (184728)
75 Quality-Adjusted Life Years/ (53310)
76 (QOLY or QOLYs or HRQOL or HRQOLs or QALY or QALYs or QALE or QALEs).tw,kw,kf. (116942)
77 ((adjusted adj1 (quality or life)) or (willing* adj2 pay) or sensitivity analys*s).tw,kw,kf. (211555)
78 or/64-77 (3033684)
79 63 and 78 (700)
80 79 use emez (395)
81 exp sleep wake disorders/ (423940)
82 ((sleep* and (apn?e* or hypopn?a*)) or OSA or OSAS or OSAH or OSAHS or CSA or MSA or (sleep adj3 disorder*) or SDB or sleep disturbance* or insomnia* or narcolep* or parasomni*).ti,ab,id. (436515)
83 (hypersomn* or hyper-somn* or ((daytime* or excessive*) adj1 (sleepiness* or tiredness* or somnolen*))).ti,ab,id. (41890)
84 (((circadi* rhythm* or nyctohemeral rhythm* or sleep-wake schedule* or sleep-wake cycle* or shift-work) adj3 (disturbance* or disorder*)) or delayed sleep phase*).ti,ab,id. (8628)
85 snoring/ (19358)
86 (snore* or snoring).ti,ab,id. (22865)
87 or/81-86 (641436)
88 polysomnography/ and (outpatient treatment/ or home care/ or outpatients/ or wearable devices/ or telemedicine/ or home environment/) (1111)
89 ((home* or at-home* or in-home* or non-lab* or unattended or unsupervi* or unstaff* or outpatient* or unmonitored or un-monitored or parent-attended or ambulatory or ambulant or portable or comprehensive or multi-paramet* or wireless* or wire-less* or out-of-cent* or OOC) adj5 (polysomnogra* or PSG*)).ti,ab,id. (4807)
90 (((home* or at-home* or in-home* or non-lab* or unattended or unsupervi* or unstaff* or outpatient* or unmonitored or un-monitored or parent-attended or ambulatory or ambulant or portable or comprehensive or multi-paramet* or wireless* or wire-less* or out-of-cent* or OOC) adj5 (sleep* or nocturnal* or overnight* or over-night* or night*) adj2 (test* or monitor* or stud* or evaluation* or analys#s or analy#e*)) or OCST or home PM or (automated sleep* adj3 system*)).ti,ab,id. (6400)

91 ((sleep* or nocturnal* or overnight* or over-night* or night*) adj2 (test* or monitor* or stud* or evaluation* or analys#s or analy#e*) adj5 (home* or at-home* or in-home* or non-lab* or unattended or unsupervi* or unstaff* or outpatient* or unmonitored or un-monitored or parent-attended or ambulatory or ambulant or portable or comprehensive or multi-paramet* or wireless* or wire-less* or out-of-cent* or OOC)).ti,ab,id. (5307)
92 ((level* or type*) adj5 (II or "2" or two) adj5 (polysomnogra* or PSG*)).ti,ab,id. (319)
93 ((level* or type*) adj5 (II or "2" or two) adj5 ((sleep* or nocturnal* or overnight* or over-night* or night*) adj2 (test* or monitor* or stud* or evaluation* or analys#s or analy#e*))).ti,ab,id. (197)
94 (H-PSG or HPSG or T2PSG* or T2-PSG*).ti,ab,id. (182)
95 (prodigy* sleep* or nox* a1* or nox medical* or sleep profiler* or sleepstudy* or octave* dreem* or embletta* or somnomedics* or sleepview* or trex* home* or alice* pdx* or easy II psg* or trackit* or medipalm* or embletta* or onera* or zmachine*).ti,ab,id. (892)
96 or/88-95 (12203)
97 87 and 96 (9410)
98 (animal not human).po. (372034)
99 97 not 98 (9406)
100 case report/ (5056052)
101 99 not 100 (9177)
102 economics/ or economy/ (401239)
103 pharmacoeconomics/ or health care economics/ (228751)
104 (econom* or price or prices or pricing or priced or discount* or expenditure* or budget* or pharmacoeconomic* or pharmaco-economic*).tw. (1387622)
105 exp "costs and cost analysis"/ (719013)
106 cost*.ti. (362763)
107 cost effective*.tw. (451674)
108 (cost* adj2 (util* or efficacy* or benefit* or minimi* or analy* or saving* or estimate* or allocation or control or sharing or instrument* or technolog* or increment*)).ab. (308667)
109 markov chains/ (29265)
110 (decision adj1 (tree* or analy* or model*)).tw. (69463)
111 (markov or markow or monte carlo).tw. (179070)
112 (QOLY or QOLYs or HRQOL or HRQOLs or QALY or QALYs or QALE or QALEs).tw. (115558)
113 ((adjusted adj1 (quality or life)) or (willing* adj2 pay) or sensitivity analys*s).tw. (207461)
114 or/102-113 (2934975)
115 101 and 114 (640)
116 115 use psyb (29)
117 24 or 42 or 80 or 116 (690)
118 limit 117 to english language [Limit not valid in CDSR; records were retained] (672)
119 118 use medall (186)
120 118 use emez (386)
121 118 use coch (0)
122 118 use cctr (67)
123 118 use cleed (7)
124 118 use psyb (26)
125 remove duplicates from 118 (470)

Health State Utilities Search

Search date: January 25, 2023

Databases searched: Ovid MEDLINE

Database: Ovid MEDLINE(R) ALL <1946 to January 24, 2023>

Search Strategy:

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1 Polysomnography/ and (Monitoring, Physiologic/ or Monitoring, Ambulatory/ or Telemedicine/ or Wireless Technology/ or Home Care Services, Hospital-Based/) (779)
2 ((home* or at-home* or in-home* or non-lab* or unattended or unsupervi* or unstaff* or outpatient* or unmonitored or un-monitored or parent-attended or ambulatory or ambulant or portable or comprehensive or multi-paramet* or wireless* or wire-less* or out-of-cent* or OOC) adj5 (polysomnogra* or PSG*)).ti,ab,kf. (1378)
3 (((home* or at-home* or in-home* or non-lab* or unattended or unsupervi* or unstaff* or outpatient* or unmonitored or un-monitored or parent-attended or ambulatory or ambulant or portable or comprehensive or multi-paramet* or wireless* or wire-less* or out-of-cent* or OOC) adj5 (sleep* or nocturnal* or overnight* or over-night* or night*) adj2 (test* or monitor* or stud* or evaluation* or analys#s or analy#e*)) or OCST or home PM or (automated sleep* adj3 system*)).ti,ab,kf. (1960)
4 ((sleep* or nocturnal* or overnight* or over-night* or night*) adj2 (test* or monitor* or stud* or evaluation* or analys#s or analy#e*) adj5 (home* or at-home* or in-home* or non-lab* or unattended or unsupervi* or unstaff* or outpatient* or unmonitored or un-monitored or parent-attended or ambulatory or ambulant or portable or comprehensive or multi-paramet* or wireless* or wire-less* or out-of-cent* or OOC)).ti,ab,kf. (1603)
5 ((level* or type*) adj5 (II or "2" or two) adj5 (polysomnogra* or PSG*)).ti,ab,kf. (81)
6 ((level* or type*) adj5 (II or "2" or two) adj5 ((sleep* or nocturnal* or overnight* or over-night* or night*) adj2 (test* or monitor* or stud* or evaluation* or analys#s or analy#e*))).ti,ab,kf. (55)
7 (H-PSG or HPSG or T2PSG* or T2-PSG*).ti,ab,kf. (40)
8 (prodigy* sleep* or nox* a1* or nox medical* or sleep profiler* or sleepstudy* or octave* dreem* or embletta* or somnomedics* or sleepview* or trex* home* or alice* pdx* or easy II psg* or trackit* or medipalm* or embletta* or onera* or zmachine*).ti,ab,kf. (166)
9 or/1-8 (3877)
10 Quality-Adjusted Life Years/ (15360)
11 (quality adjusted or adjusted life year*).ti,ab,kf. (22392)
12 (qaly* or qald* or qale* or qtime*).ti,ab,kf. (14051)
13 (illness state$1 or health state$1).ti,ab,kf. (8093)
14 (hui or hui1 or hui2 or hui3).ti,ab,kf. (1906)
15 (multiattribute* or multi attribute*).ti,ab,kf. (1261)
16 (utility adj3 (score$1 or valu* or health* or cost* or measure* or disease* or mean or gain or gains or index*)).ti,ab,kf. (18694)
17 utilities.ti,ab,kf. (9063)
18 (eq-5d or eq5d or eq-5 or eq5 or euro qual or euroqual or euro qual5d or euroqual5d or euro qol or euroqol or euro qol5d or euroqol5d or euro quol or euroquol or euro quol5d or euroquol5d or eur qol or

eurqol or eur qol5d or eurqol5d or euro?qul or eur?qul5d or euro* quality of life or European qol).ti,ab,kf. (16462)
19 (euro* adj3 (5 d or 5d or 5 dimension* or 5dimension* or 5 domain* or 5domain*)).ti,ab,kf. (5701)
20 (sf36* or sf 36* or sf thirtysix or sf thirty six).ti,ab,kf. (25985)
21 (time trade off$1 or time tradeoff$1 or tto or timetradeoff$1).ti,ab,kf. (2310)
22 ((qol or hrqol or quality of life).ti. or *quality of life/) and ((qol or hrqol* or quality of life) adj2 (increas* or decreas* or improve* or declin* or reduc* or high* or low* or effect or effects of worse or score or scores or change$1 or impact$1 or impacted or deteriorate$)).ab. (42744)
23 Cost-Benefit Analysis/ and (cost effectiveness ratio* and (perspective* or life expectanc*)).ti,ab,kf. (5000)
24 *quality of life/ and (quality of life or qol).ti. (63281)
25 quality of life/ and ((quality of life or qol) adj3 (improve* or chang*)).ti,ab,kf. (35084)
26 quality of life/ and ((quality of life or qol) adj (score$1 or measure$1)).ti,ab,kf. (15030)
27 quality of life/ and health-related quality of life.ti,ab,kf. (42979)
28 quality of life/ and ec.fs. (10873)
29 quality of life/ and (health adj3 status).ti,ab,kf. (11379)
30 (quality of life or qol).ti,ab,kf. and cost-benefit analysis/ (16408)
31 models, economic/ (11047)
32 or/10-31 (206678)
33 9 and 32 (79)
34 limit 33 to english language (78)

Grey Literature Search

Search dates: January 10–13, 2023

Websites searched: Alberta Health Evidence Reviews, BC Health Technology Assessments, Canadian Agency for Drugs and Technologies in Health (CADTH), Institut national d'excellence en santé et en services sociaux (INESSS), Institute of Health Economics (IHE), University Of Calgary Health Technology Assessment Unit, Ontario Health Technology Assessment Committee (OHTAC), McGill University Health Centre Health Technology Assessment Unit, Centre Hospitalier de l'Universite de Quebec-Universite Laval, Contextualized Health Research Synthesis Program of Newfoundland (CHRSP), Health Canada Medical Device Database, International HTA Database (INAHTA), Agency for Healthcare Research and Quality (AHRQ) Evidence-based Practice Centers, Centers for Medicare & Medicaid Services Technology Assessments, Veterans Affairs Health Services Research and Development, Institute for Clinical and Economic Review, Oregon Health Authority Health Evidence Review Commission, Washington State Health Care Authority Health Technology Reviews, National Institute for Health and Care Excellence (NICE), National Health Service England (NHS), Healthcare Improvement Scotland, Health Technology Wales, Ireland Health Information and Quality Authority Health Technology Assessments, Australian Government Medical Services Advisory Committee, Australian Safety and Efficacy Register of New Interventional Procedures -Surgical (ASERNIP-S), Italian National Agency for Regional Health Services, Belgian Health Care Knowledge Centre, Ludwig Boltzmann Institute for Health Technology Assessment, Swedish Agency for Health Technology Assessment and Assessment of Social Services, Ministry of Health Malaysia Health Technology Assessment Section, Tuft's Cost-Effectiveness Analysis Registry, PROSPERO, EUnetHTA, clinicaltrials.gov

Keywords used: sleep, polysomnography, polysomnographies, polysomnogram, PSG, insomnia, parasomnia, circadian, hypersomnia, snoring, ((polysomnography or psg or polysomnogram) AND (level II or level two or level 2 or home or in-home or at-home or type II or type two or type 2)), (sleep AND (unattended or unmonitored or unsupervised or outpatient test or outpatient study or unstaffed or parent-attended))
Clinical results (included in PRISMA): 37
Economic results (included in PRISMA): 43
Ongoing HTAs (PROSPERO/EUnetHTA): 8
Ongoing clinical trials: 79

Appendix 2: Select Excluded Studies

Clinical Evidence

For transparency, we provide a list of studies that readers might have expected to see but that did not meet the inclusion criteria, along with the primary reason for exclusion.

Citation	Primary reason for exclusion
Bruyneel M, Libert W, Ameye L, Ninane V. Comparison between home and hospital set-up for unattended home-based polysomnography: a prospective randomized study. Sleep Med. 2015;16(11):1434–38	Wrong comparator. Evaluated unattended polysomnography that were connected to the patients at different locations (home vs. sleep lab).
Edinger JD, Ulmer CS, Means MK. Sensitivity and specificity of polysomnographic criteria for defining insomnia. J Clin Sleep Med. 2013;9(5):481–91	Validation study (validating criteria for polysomnography metrics to define insomnia used home diary as reference standard)
Iber C, Redline S, Kaplan Gilpin AM, Quan SF, Zhang L, Gottlieb DJ, et al. Polysomnography performed in the unattended home versus the attended laboratory setting--Sleep Heart Health Study methodology. Sleep. 2004;27(3):536–40	Validation study (reported correlation statistics for laboratory and home testing)
Griffiths A, Mukushi A, Adams AM. Telehealth-supported level 2 pediatric home polysomnography. J Clin Sleep Med. 2022;18(7):1815–21	Wrong comparator. Proof-of-concept study with no comparator.
Marrone O, Salvaggio A, Insalaco G, Bonsignore MR, Bonsignore G. Evaluation of the POLYMESAM system in the diagnosis of obstructive sleep apnea syndrome. Monaldi Arch Chest Dis. 2001;56(6):486–90	Wrong index test (does not include EEG)
Nilius G, Domanski U, Schroeder M, Franke KJ, Hogrebe A, Margarit L, et al. A randomized controlled trial to validate the Alice PDX ambulatory device. Nat Sci Sleep. 2017;9:171–80	Wrong index test while the Alice device can include sufficient channels to function as a level 2 device, that is not how it was utilized in this publication, and it was only measuring cardiorespiratory metrics (therefore, as a level 3 device)
Miettinen T, Myllymaa K, Muraja-Murro A, Westeren-Punnonen S, Hukkanen T, Toyras J, et al. Polysomnographic scoring of sleep bruxism events is accurate even in the absence of video recording but unreliable with EMG-only setups. Sleep Breathing. 2020;24(3):893–904	Outcomes of interest not reported (only reported event detection sensitivity and specificity, not diagnostic accuracy)
Younes M, Soiferman M, Thompson W, Giannouli E. Performance of a new portable wireless sleep monitor. J Clin Sleep Med. 2017;13(2):245–58	Validation study (reported correlation statistics for in-clinic and home testing)

Abbreviations: EEG, electroencephalography; PSG, polysomnography.

Economic Evidence Review

For transparency, as an example, we provide a list of studies that readers might have expected to see but that did not meet the inclusion criteria, along with the primary reason for exclusion.

Citation	Primary reason for exclusion
Nakase-Richardson R, Dismuke-Greer C, Jeanne H, Drashser-Phillips L, Schwartz D, Calero K, et al. Cost effectiveness of diagnostic approaches to sleep apnea evaluation during inpatient rehabilitation for moderate to severe TBI. Sleep; 2020: 43(1):A449–50	Intervention: at-home level 3 sleep study
Withers A, Maul J, Rosenheim E, O'Donnell A, Wilson A, Stick S. Comparison of home ambulatory type 2 polysomnography with a portable monitoring device and in-laboratory type 1 polysomnography for the diagnosis of obstructive sleep apnea in children. J Clin Sleep Med. 2022;18(2):393–402.	Not comparative economic evaluation (provided data for resource utilization and qualitative statements about cost savings but no direct monetary assessment)
Kim RD, Kapur VK, Redline bruch J, Rueschman M, Rosen CL, Redline S, et al. Cost minimization analysis of a multi-site randomized clinical trial of home-based versus laboratory-based testing for the diagnosis and treatment of obstructive sleep apnea (HomePAP Study). Value in Health. 2012;15(4):PA68–69	Intervention: at-home level 3 sleep study
Reuven H, Schweitzer E, Tarasiuk A. A cost-effectiveness analysis of alternative at-home or in-laboratory technologies for the diagnosis of obstructive sleep apnea syndrome. Med Decis Making. 2001;21(6):451–58	Unclear which type of unattended sleep study
Deutsch PA, Simmons MS, Wallace JM. Cost-effectiveness of split-night polysomnography and home studies in the evaluation of obstructive sleep apnea syndrome. J Clin Sleep Med. 2006;2(2):145–153	Unclear which type of unattended sleep study and based on CPT code this could be level 3; study focused on therapy (CPAP for titration)
Duran-Cantolla J et al. Validity and cost-effectiveness analysis of pediatric home respiratory polygraphy for the diagnosis of obstructive sleep apnea: rationale, design, and methodology. Sleep Med. 2017;40:e84–e85	Intervention: at-home level 3 sleep study and also this is abstract - conference meeting
Pelletier-Fleury N, Gagnadoux F, Philippe C, Rakotonanahary D, Lanöe JL, Fleury B. A cost-minimization study of telemedicine. The case of telemonitored polysomnography to diagnose obstructive sleep apnea syndrome. Int J Tech Assess Health Care. 2001;17:604–11	Comparator is telemedicine PSG and not in-lab PSG and at-home PSG is not defined by number of channels (unclear if it is level 2 PSG)
Carpentier N, Jonas J, Schaff JL, Koessler L, Maillard L, Vespignani H. The feasibility of home polysomnographic recordings prescribed for sleep-related neurological disorders: a prospective observational study. Neurophysiol Clin. 2014;44(3):251–255	Feasibility study for level 2, not comparative assessment (level 1 PSG vs. level 2 PSG)
Miettinen T, Myllymaa K, Westeren-Punnonen S, et al. Success rate and technical quality of home polysomnography with self-applicable electrode set in subjects with possible sleep bruxism. IEEE J Biomed Health Inform. 2018;22(4):1124–32	Not an economic evaluation

Abbreviations: CPAP, continuous positive airway pressure; CPT, Current Procedural Terminology code; PSG, polysomnography.

Appendix 3: Critical Appraisal of Clinical Evidence

Table A1: Risk of Bias[a] Among Diagnostic Accuracy Studies (QUADAS-2 Tool)

	Risk of bias				Applicability concerns		
Author, year	Patient selection	Index test	Reference standard	Flow and timing	Patient selection	Index test	Reference standard
Abe et al, 2022[133]	High[b]	Low	Low	Low[c]	High[a]	Low[d]	Low
Banhiran et al, 2014[124]	Low	Low	Low	Low	High[e]	Low[d]	Low
Bruyneel et al, 2011[125]	Low	Low	Low	Low	Low	Low[d]	Low
Campbell et al, 2011[126]	Low	High[f]	High[f]	Low	Low	Low[d]	Low
Cunnington et al, 2009[127]	Low	Unclear[g]	Low	Low[c]	Low	Low[d]	Low
Mykytyn et al, 1999[128]	Low	High[h]	Unclear[i]	Low[c]	High[j]	High[k]	Low
Orr et al, 1994[129]	High[l]	Unclear[m]	Low	Low[c]	Unclear[n]	Low[d]	Low
Portier et al 2000[130]	Low	Low	Low	Low	Unclear[o]	Low	Low
Withers et al, 2022[132]	Low	Low	Low	Low	Low	Low[d]	Low
Zancanella et al, 2022[131]	Low	Low	Low	Low	Low	Low[d]	Low

Abbreviations: QUADAS, Quality Assessment of Diagnostic Accuracy Studies.

[a]Possible risk-of-bias levels: low, high, unclear.

[b]Half of the patients were a convenience sample of healthy people from the same dental office, and it was unclear how or why they were selected, making it also unclear if the findings would be generalizable to the potential patient population in Ontario.

[c]The index test (level 2 polysomnography) and reference standard (level 1 polysomnography) were conducted simultaneously; however, we felt that this was not a source for a risk of bias with respect to flow and timing as there would be no risk for having a different sleep experience when one test was conducted over the other.

[d]Technicians applied the index test (level 2) polysomnography device. We had low concerns about applicability, assuming similar implementation methodology would occur in Ontario.

[e]Patients were excluded if they were considered to have insufficient sleep during reference testing (in-clinic polysomnography), which might be the exact target population for home-testing in real-world conditions.

[f]The assessment was not blinded to location (home/lab)

[g]Details were unclear about how the index test (level 2 polysomnography) was conducted and if it was free of technician support, which would represent true unattended real-world testing.

[h]The findings for diagnostic accuracy do not distinguish the unattended group from the half patients with real-time data shared with technicians.

[i]There was a technical malfunction that affected the EMG data, which the study authors explained as going unnoticed, and may have impacted the findings.

[j]The study population was limited to men.

[k]Half of the study group had attended index testing (level 2 polysomnography).

[l]Patients were recruited from 2 sleep lab sites, but it was unclear how they were selected, and if bias was incidentally introduced.

[m]It was unclear if the index testing (level 2 polysomnography) was considered adequately unattended to represent intended real-world use of the devices.

[n]Insufficient information was provided to determine the applicability of the population included.

[o]It was unclear if inclusion and exclusion criteria would be applicable to the intended use of the index test (level 2 polysomnography) in Ontario today.

Table A2: GRADE Evidence Profile for the Comparison of Level 2 Polysomnography Devices (Unattended) and Level 1 (In-Clinic) Polysomnography

Outcome	Number of studies (N)	Risk of bias[a]	Inconsistency	Indirectness	Imprecision	Publication bias	Upgrade considerations	Quality
Diagnostic accuracy for apnea – in adults								
Sensitivity	8 (422)	Serious limitations (−1)	No serious limitations	No serious limitations	Serious limitations (−1)[b]	Undetected	None	⨁⨁ Low
Specificity	8 (422)	Serious limitations (−1)	No serious limitations	No serious limitations	Serious limitations (−1)[b]	Undetected	None	⨁⨁ Low
Diagnostic accuracy for apnea – in children[c]								
Sensitivity	1 (128)	No serious limitations	Serious limitations (−1)[d]	No serious limitations	Serious limitations (−1)[e]	Undetected	None	⨁⨁ Low
Specificity	1 (128)	No serious limitations	Serious limitations (−1)[d]	No serious limitations	No serious limitations	Undetected	None	⨁⨁⨁ Moderate
Diagnostic accuracy for sleep bruxism								
Sensitivity	1 (20)	Serious limitations (−1)	Serious limitations (−1)[d]	No serious limitations	Serious limitations (−1)[f]	Undetected	None	⨁ Very low
Specificity	1 (20)	Serious limitations (−1)	Serious limitations (−1)[d]	No serious limitations	Serious limitations (−1)[f]	Undetected	None	⨁ Very low
Diagnostic accuracy for periodic leg movement								
Sensitivity	1 (40)	Serious limitations (−1)	Serious limitations (−1)[d]	No serious limitations	Serious limitations (−1)[e]	Undetected	None	⨁ Very low
Specificity	1 (40)	Serious limitations (−1)	Serious limitations (−1)[d]	No serious limitations	No serious limitations	Undetected	None	⨁⨁ Low
Failure rates								
	10 (570)	Serious limitations (−1)	Serious limitations (−1)[d]	Serious limitations (−1)[g]	Not estimable	None detected	None	⨁ Very low

Abbreviations: GRADE, Grading of Recommendations Assessment, Development, and Evaluation; RCT, randomized controlled trial.

[a]See risk of bias table, A# and figure # demonstrates that there is similar risk of bias observed across the various apnea hypopnea index severity cut-offs.

[b]Confidence intervals or other measure of precision was not estimable in most studies and cannot be pooled from the included studies.

[c]GRADE was conducted for the subgroup of patients where index test was conducted in the home.

[d]Not applicable as there is only 1 study.

[e]Confidence interval was considered to be sufficiently wide that the lower end would yield a different clinical decision than the upper end.

[f]Considered to be inadequately powered due to small sample size.

[g]Among the studies that conducted level 2 polysomnography simulated in a clinic, there were 0 failures observed.

Appendix 4: Results of Applicability and Limitation Checklists for Studies Included in the Economic Literature Review

Table A3: Assessment of the Applicability of Studies Evaluating the Cost-Effectiveness of At-Home Level 2 Sleep Study Polysomnography vs. In-Clinic Level 1 Sleep Study Polysomnography

Author, year, country	Is the study population similar to the question?	Are the interventions similar to the question?	Is the health care system studied sufficiently similar to Ontario?	Were the perspectives clearly stated? If yes, what were they?	Are all direct effects included? Are all other effects included where they are material?	Are all future costs and outcomes discounted? If yes, at what rate?	Is the value of health effects expressed in terms of quality-adjusted life-years?	Are costs and outcomes from other sectors fully and appropriately measured and valued?	Overall judgment[a]
Ayas et al,[138] 2021, Canada	Partially	Yes	Partially (example of British Columbia)	Unclear	Partially	No, duration of time horizon unclear	No	Partially	Partially applicable
Merlin et al,[137] 2010, Australia	Partially	Partially	No	Yes (Australian society and Australian third-party payer)	Partially	No, short duration of time horizon	No	Partially	Partially applicable
Bruyneel et al,[125] 2011, Belgium	Partially	Yes	No	No	No	No, duration of study short	No	No	Not applicable

Abbreviations: PSG, polysomnography.

Note: Response options for all items were "yes," "partially," "no," "unclear," and "NA" (not applicable).

[a]Overall judgment may be "directly applicable," "partially applicable," or "not applicable."

Table A4: Assessment of the Limitations of Studies Evaluating the Cost-Effectiveness of At-Home Level 2 Sleep Study Polysomnography vs. In-Clinic Level 1 Sleep Study Polysomnography

Author, year, country	Does the model structure adequately reflect the nature of the health condition under evaluation?	Is the time horizon sufficiently long to reflect all important differences in costs and outcomes?	Are all important and relevant health outcomes included?	Are the clinical inputs[a] obtained from the best available sources?	Do the clinical inputs[a] match the estimates contained in the clinical sources?	Are all important and relevant (direct) costs included in the analysis?	Are the estimates of resource use obtained from the best available sources?	Are the unit costs of resources obtained from the best available sources?	Is an appropriate incremental analysis presented, or can it be calculated from the reported data?	Are all important and uncertain parameters subjected to appropriate sensitivity analysis?	Is there a potential conflict of interest?	Overall judgment[b]
Ayas et al,[138] 2021, Canada	Partially	Unclear	Partially	Unclear	Unclear	Unclear	Unclear	Unclear	No	Partially	Partially	Potentially serious limitations
Merlin et al,[137] 2010, Australia	Partially	No	Partially	Unclear	Unclear	Yes	Yes	Yes	Partially	Partially	Unclear	Potentially serious limitations
Bruyneel et al,[125] 2011, Belgium	NA	No	No	No	No	Partially	No	No	No	No	Unclear	Very serious limitations

Abbreviations: PSG, polysomnography.

Note: Response options for all items were "yes," "partially," "no," "unclear," and "NA" (not applicable).

[a]Clinical inputs could include relative treatment effects, natural history, and utilities.

[b]Overall judgment may be "minor limitations," "potentially serious limitations," or "very serious limitations."

Appendix 5: Costing of At-Home Level 2 Polysomnography Sleep Study, Adult and Pediatric Populations

Table A5: Costing At-Home Level 2 Polysomnography Sleep Study Fee, Adults

Cost components and subcomponents	Total per unit, $ (2023 CAD)	Subcomponent cost, mean (SE), $	Frequency, mean (SE) and distribution	Hours, mean (SE)	Hourly rate, mean (SE),[a] $/h	Benefits	Description
Level 2 polysomnography, total	**338.10**						
Professional fee component, subtotal	97.50						Physician SoB: J896, J897, J895, J890
Technical fee component, subtotal	**240.60**						
Technologist/technician labour							
Consult, initial visit, device set-up, medical history, education	50.00	37.50	3	4[b] (4*0.25) normal dist.	30 (30*0.25) gamma dist.	0.25	Salary: $37.5/h [$30/h plus benefits]; 3 patients per technician; 4 h
Device removal and sanitization	18.75	37.50	1	0.5 (0.5*0.25) normal	30 (30*0.25) gamma dist.	0.25	Salary: $37.5/h [$30/h plus benefits]; 0.5 h
Scoring	56.25	37.50	1	1.5 (1.5*0.25) normal	30 (30*0.25) gamma dist.	0.25	Salary: $37.5/h [$30/h plus benefits]; 1.5 h
Disposables	14.00	14.00 (14*0.25) gamma dist	1	NA	NA	NA	$14 per patient (email: C. Ryan; Aug 28, 2023)
Device	77.78	14,000 (14,000*0.25) gamma dist	180 (180*0.25) normal dist	NA	NA	NA	$14,000 per device (email: Cerebra Medical Ltd, Sep 18, 2023); assumed to be used 180 times per year
Administrative	14.38	28.75	1	0.5 (0.5*0.25) normal dist.	23 (23*0.25) gamma dist.	0.25	Salary: $28.75/h [$23/h plus benefits]; 0.5 h
Additional	9.45	9.45	1	NA	9.45 (9.45*0.25) gamma dist.	NA	e.g., Office rent costs after equipment amortization (email: M. Moffat; Aug 26, 2023)

Abbreviations: CAD, Canadian dollars; h, hour; NA, not applicable; SE, standard error; SoB, Schedule of Benefits.

[a]Hourly rate with benefits or cost.

[b]In sensitivity analysis, we accounted for an additional 1 hour of labour (i.e., 5 hours) for travel and this resulted in an increase in the technical fee to $253.10 and total test cost to $350.60.

Table A6: Costing At-Home Level 2 Polysomnography Sleep Study Fee, Eligible Pediatric Populations

Cost components and subcomponents	Total per unit, $ (2023 CAD)	Subcomponent[a] cost, mean (SE), $	Frequency, mean (SE) and distribution	Hours, mean (SE)	Hourly rate, mean (SE),[a] $/h	Benefits	Description
Level 2 polysomnography, total	**438.10**						
Professional fee component, subtotal	97.50						Physician SoB: J890; special populations including children
Technical fee component, subtotal	**340.60**						
Technologist/technician labour[b]							
Consult, initial visit, device set-up, medical history, education	150.00	37.50	3	4[b] (4*0.25) normal dist.	30 (30*0.25) gamma dist.	0.25	Salary: $37.5/h [$30/h plus benefits]; 1 patient per technician; 4 h
Device removal and sanitization	18.75	37.50	1	0.5 (0.5*0.25) normal	30 (30*0.25) gamma dist.	0.25	Salary: $37.5/h [$30/h plus benefits]; 0.5 h
Scoring	56.25	37.50	1	1.5 (1.5*0.25) normal	30 (30*0.25) gamma dist.	0.25	Salary: $37.5/h [$30/h plus benefits]; 1.5 h
Disposables	14.00	14.00 (14*0.25) gamma dist	1	NA	NA	NA	$14 per patient (email: C. Ryan; Aug 28, 2023)
Device	77.78	14,000 (14,000*0.25) gamma dist	180 (180*0.25) normal dist	NA	NA	NA	$14,000 per device (email: Cerebra Medical Ltd., Sep 18, 2023); assumed to be used 180 times per year
Administrative	14.38	28.75	1	0.5 (0.5*0.25) normal dist.	23 (23*0.25) gamma dist.	0.25	Salary: $28.75/h [$23/h plus benefits]; 0.5 h
Additional	9.45	9.45	1	NA	9.45 (9.45*0.25) gamma dist.	NA	e.g., Office rent costs after equipment amortization (email: M. Moffat; Aug 26, 2023)

Abbreviations: CAD, Canadian dollars; NA, not applicable; h, hour; SE, standard error; SoB, Schedule of Benefits.

[a]Hourly rate with benefits or cost.

[b]In sensitivity analysis, we accounted for an additional 1 hour of labour for travel and this resulted in increase in the technical fee to $378.10 and total test cost to $475.60.

Appendix 6: Additional Information, Sensitivity Analysis

Table A7: Summary of Changes in Parameters and Assumptions in Scenarios

Scenario	Reference case	Description of changes
Use of level 1 PSG in case of technical failures after initial level 2 PSG	Single intervention pathway: use of level 2 PSG in case of technical failures after initial level 2 PSG	Structural change in the reference case tree and development of 2 intervention pathways (following technical failure with level 2 PSG) that were compared with current practice (level 1 PSG): 1. In case of technical failure with initial level 2 PSG apply level 2 PSG for the second time (reference case) 2. In case of technical failure with initial level 2 PSG apply level 1 PSG (additional arm) 3. Level 1 PSG (current practice)
Use of level 1 PSG for people who tested negative with initial level 2 PSG	Use of level 1 PSG after receiving false negative results from level 2 PSG (this was detected as the patient continued to experience symptoms and requested further care)	Structural change to the reference case model with using level 1 PSG for all who received test negative results after level 2 PSG
Accommodation of therapy with CPAP in people with OSA	Cost-effectiveness analysis for a heterogenous group of people with sleep disorders	Cost–utility analysis focused on a group of people with OSA that would require a PAP therapy (at a CPAP cost of $554 per person) for those who tested positive, further assumptions are described in Appendix 7
Scenario for a subgroup of youth and children potentially eligible for level 2 PSG	Reference case population: adults with sleep disorders	Population: Children and youth. Estimates of diagnostic accuracy sourced from Withers et al, 2022.[132] Clinical pathway and fee codes for this population uncertain, minor changes made to the pathway. The cost of the test was adjusted to allow for a 1:1 technician to patient ratio.

Abbreviations: CPAP, continuous positive airway pressure; PSG; polysomnography.

Appendix 7: Scenario in Adults – Short-Term Cost–Utility Analysis Including the Use of CPAP

In this scenario, we estimated the impact of providing therapy with a PAP system using the previously described decision-tree model. Given the diagnostic scope of our HTA and heterogeneity of study populations eligible for sleep study in-clinic testing, for this scenario, we conducted a simplified cost–utility analysis assuming that a population of interest was adults with suspected obstructive sleep apnea. Below, we describe additional modelling assumptions and estimation of additional cost and utility parameter values for this analysis.

We used the same reference case model structure and made additional modeling assumptions:

- Level 2 polysomnography diagnostic test results would be enough to receive prescription for the Assistive Device Program (ADP)-funded PAP device (i.e., currently PAP devices could be prescribed only with results from level 1 polysomnography)
- Diagnostic assessment and the management of obstructive sleep apnea with CPAP would be done within 1 year
- People who tested true positive were provided treatment with CPAP (incurred the cost of the device) and were assigned the utility of "treated obstructive sleep apnea" (Table A8)
- People who tested false positive were provided treatment with CPAP (incurred the cost of the device) and were assigned the utility of not having obstructive sleep apnea (healthy)
- People who tested true negative received no CPAP (no costs incurred) and were assigned the utility of not having obstructive sleep apnea (healthy)
- People who tested false negative were followed up and were late for the treatment with CPAP, but received it (incurred the cost of the device); because of the later start of the treatment and short time horizon, we made a simplifying assumption that an increase in the utility from "untreated obstructive sleep apnea" to "treated obstructive sleep apnea" would be twice smaller than the expected (0.02 vs. 0.04 at 3 months; Table A8)

Additional Cost Inputs and Assumptions

We made a simplifying assumption that after a follow-up visit to review positive test results and treatment for obstructive sleep apnea, there would be no separate titration visits using level 1 or level 2 polysomnography. We also made simplifying assumptions about the type of a PAP device used for the treatment of obstructive sleep apnea and assumed the ADP-approved cost of CPAP of $554 (75% of the full CPAP cost),[168,169] as this is the most commonly used PAP system in Ontario.[65,145] The same cost is estimated for APAP (autotitrating PAP) system.[168,169] No data for yearly maintenance cost for the device over time can be found in the ADP manual; therefore, we did not account for this type of cost; we also assumed that a PAP device has a service life of about 10 years (although this assumption would not affect our analysis given the short time horizon). In another analysis (data not shown), we considered the cost of other PAP devices (i.e., bilevel PAP, $950).[168,169]

Health Utilities

A health utility represents a person's preference for a certain health state or an outcome, such as the state of living with untreated obstructive sleep apnea. Utilities are often measured by different tools, on a scale ranging from 0 (death) to 1 (full health). We performed a targeted literature search in MEDLINE for health utility values on January 25, 2023, to retrieve studies published from database inception until the search date. We used a similar search strategy to that used for the clinical search but with a methodologic filter[170] applied to limit retrieval to health state utility values. See Appendix 1 for our literature search strategies, including all search terms. We screened 78 retrieved citations and reviewed in full ten studies that were deemed eligible including the sources of utilities reported in those studies. We also examined inputs of the economic studies from our economic evidence review and searched citations in the reference lists of other economic studies that were deemed ineligible because of the type of index test (i.e., portable level 3 sleep study test or CPAP).

Table A8 presents utility data that are used to populate the cost–utility model in the scenario analysis. We assumed that the population with clinically suspected obstructive sleep apnea indicated for diagnostic testing and possible PAP treatment was on average 53 years old, about 64% being male.[65,145] For people living without obstructive sleep apnea, we used data from a study by Guertin et al[171] to adjust the utility values reported in the literature with the age- and sex-specific Canadian (Ontario) utility norms for the age range 50 to 54 years. We used data from a randomized controlled trial conducted by Chakravorty et al. that measured utilities associated with treated and untreated and treated obstructive sleep apnea by the EQ-5D quality of life assessment tool.[172] These utilities were also estimated by several observational studies,[173-177] which estimated different baseline utility values for untreated obstructive sleep apnea (ranging between 0.65,[176,177] 0.79[173] and 0.81[174]) and utility change with CPAP treatment (ranging from 0.005 to 0.08).[173-175,178,179] Our review identified a study by Andrade et al[104] that showed no statistically significant differences in health-related quality of life (as measured by SF-36) between in-clinic level 1 and at-home level 2 sleep study tests for people diagnosed with obstructive sleep apnea and treated with PAP. Therefore, we did not assign any health utility difference due to the type of sleep study device.

Table A8: Utilities Used in the Cost–Utility Analysis

Outcomes or health state	HSU, mean (SD)[a,b]	Distribution	Source
Healthy, living without OSA in Ontario, age 50–54 years[b]		Beta	Guertin et al, 2018[171]
Female (36%)	0.832 (0.808–0.855)		
Male (64%)	0.841 (0.809–0.872)		
Living with OSA no PAP treatment (untreated OSA)	0.73 (± 0.18)	Beta	Chakravorty et al, 2002[172]
Living with OSA on CPAP treatment (treated OSA), utility increase at 3 months	0.04 (0.04)	Beta	Chakravorty et al, 2002 [172](similar estimate found by; Schmidlin, 2010;[180] Kim et al, CADTH HTA, 2017,[157] Walia, 2017[174])

Abbreviations: CPAP, continuous positive airway pressure; HSU, health state utility; OSA, obstructive sleep apnea; PAP, positive airway pressure; SD, standard deviation.

[a]Beta distributions are assigned in probabilistic analysis. Two parameters of the beta distribution (α, β) are derived from the mean and SE. Standard error is assumed to be 10% of the mean where it is not reported. Standard errors are calculated from SDs based on the reported study sample size (N = 32 in the Chakravorty study[172]; N = 95, with n = 57 for a subset of those who were compliant, in the Rizzi et al study[178])

[b]As measured by Health Utility Index 3 (HUI3) and reported in the Guertin studies. [171]The estimates were adjusted using the published EQ-5D-HUI3 mapping algorithm: EQ5D Utility = 0.7202142 ×HUI3 − 0.0420107×HUI32 + 0.2491915. The Chakravorty study[172] measured utilities by EQ-5D quality of life assessment tool.

Appendix 8: Estimation of Population of Interest for Budget Impact Analyses

Table A9: Sleep Study Claims, Fiscal Years 2015/16–2020/21, IntelliHealth Ontario (Medical Services Database)

Description	2015/16	2016/17	2017/18	2018/19	2019/20	2020/21
Sleep study – therapeutic (J895: both B and C suffix)	119,406	124,302	124,358	122,798	123,347	44,036
Sleep study – diagnostic, unspecified level 1 overnight (J890, both B and C suffix)	2,427	2,587	2,541	2,794	2,725	1,812
Sleep study – diagnostic, initial testing (J896, both B and C suffix)	194,900	204,509	211,606	214,563	213,938	135,647
Sleep study – diagnostic, repeat testing (J897, both B and C suffix)	29,857	33,681	36,342	38,862	40,610	28,930

Note: The drop in the number of claims in 2020/21 was as a result of the COVID pandemic.

Source: Data estimated based on data provided by Ontario IntelliHealth (Medical Services database).[159]

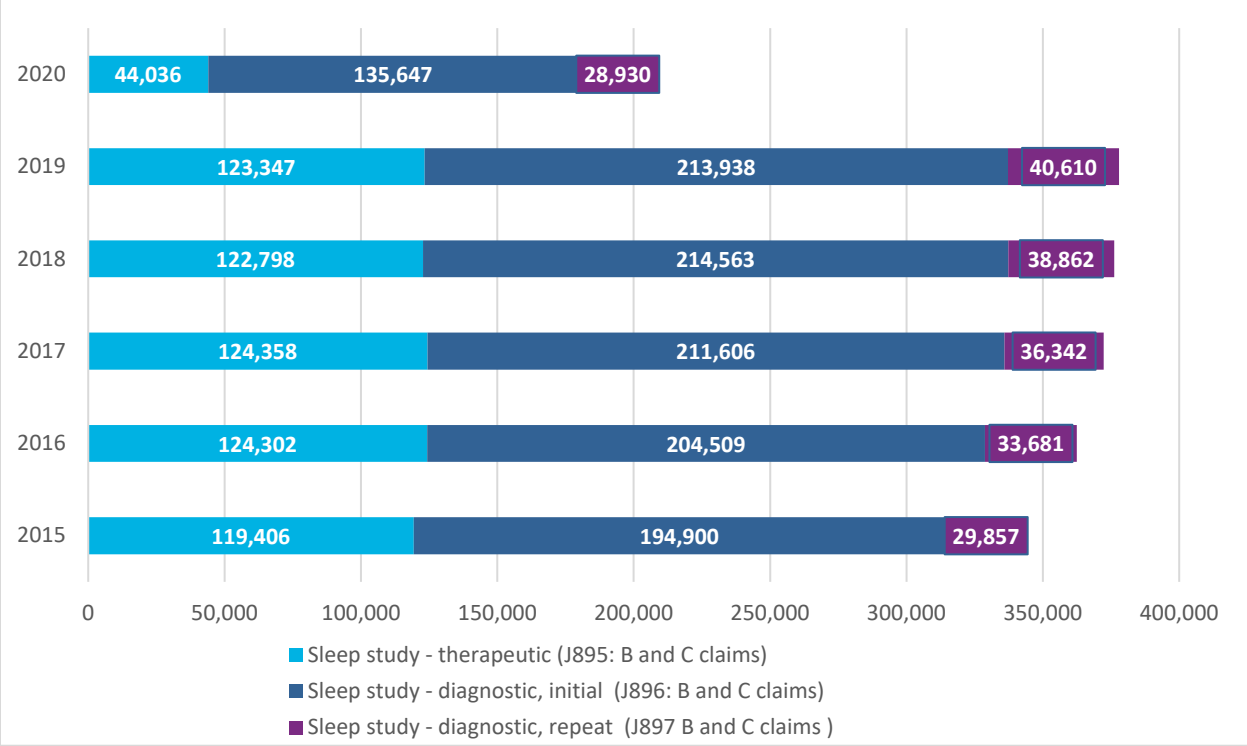

Figure A1: Level 1 Sleep Study Claims (2015–2020): Diagnostic and Therapeutic Use

Source: Estimates based on data provided by Ontario IntelliHealth (Medical Services database).[159]

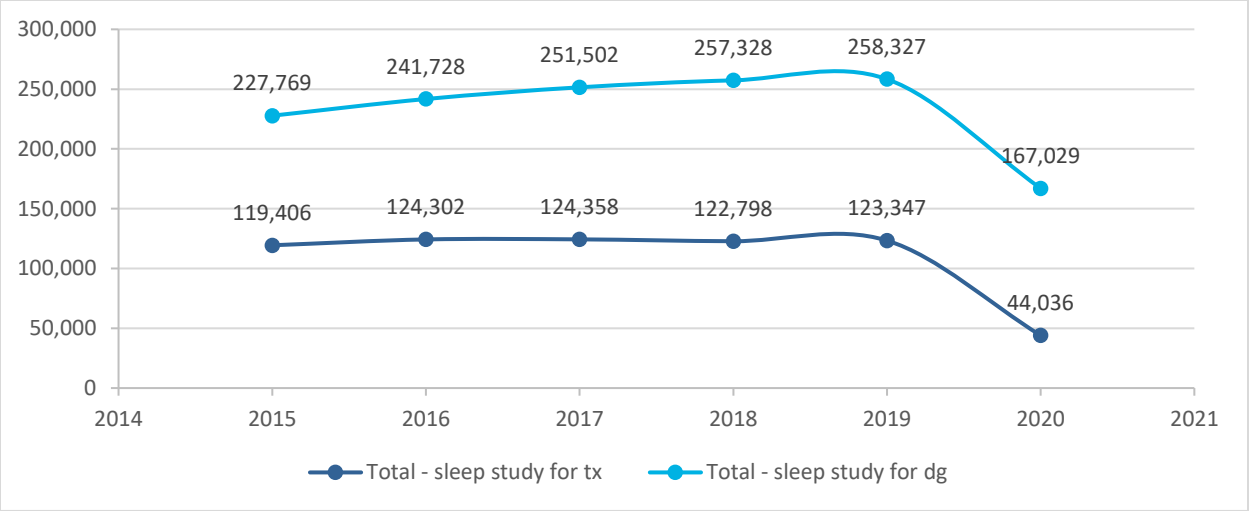

Figure A2: Total Claim Volumes: Level 1 Sleep Study (2015/16–2020/21), Diagnostic and Therapeutic Use

Note: The drop in the number of claims in 2020/21 was as a result of the COVID pandemic.

Source: Data estimated based on data provided by Ontario IntelliHealth (Medical Services database).[159]

Table A10: Expansion of Case Volume Estimates and Predictions (Based on OHIP Medical Services Claims Data)

Number of cases	**Years**					
Number of cases, fiscal years 2015–2020 (OHIP codes: sleep study FSC combined with suffix[a])	**2015/16**	**2016/17**	**2017/18**	**2018/19**	**2019/20**	**2020/21[b]**
Total number of cases, level 1 PSG, 2015/16–2020/21 (J890 and J896, B suffix claim)	100,259	104,535	107,461	109,633	109,036	70,939
Total number of cases, level 1 PSG, 2015/16–2020/21 (J895, B suffix claim)	60,563	62,458	62,269	61,588	62,062	22,849
Forecasted case volumes[b]	**Year 1**	**Year 2**	**Year 3**	**Year 4**	**Year 5**	**NA**
Predicted total number of cases, OHIP codes J890 and J896	112,980	115,246	117,511	119,776	122,041	NA
Predicted total number of cases, OHIP codes J895	62,426	62,639	62,852	63,065	63,278	NA
Total number of predicted cases (OHIP codes J890, J896, J895)	175,407	177,885	180,363	182,841	185,319	NA

Abbreviations: FSC, fee schedule code; NA, not applicable; OHIP, Ontario Health Insurance Plan, PSG, polysomnography.

Note: We are not including the FSC related to repeat diagnostic visits (e.g., J897) because the failure rate associated with the sleep study test and subsequent chance of re-testing will be accounted and calculated from our cost-effectiveness models.

[a]Based on data from the IntelliHealth Ontario Medical Services database (data obtained from the OHIP Approved Claims)[159]; the claim variable is defined by fee-schedule-code [FSC] combined with suffix: FSC + suffix.

[b]Based on pre-COVID sleep study test data, approximated from Ontario IntelliHealth data, as provided, for the fiscal years 2015 to 2019.[159]

Appendix 9: Budget Impact Scenarios in Adults – Inclusion of CPAP Costs

As noted in the main text of the report, we conducted budget impact scenarios that included the costs of CPAP ($554 per person) in adult populations only to address imminent costs to the Ministry that could be associated with the use of CPAP. This analysis was based on the outputs from our cost–utility model (described in Appendix 7 and in the report section Results, Sensitivity Analysis). The cost of PAP treatment was not considered for pediatric populations because that treatment is not the first-line treatment for sleep apnea in children. The underlying assumption of this scenario is that level 2 polysomnography diagnostic test results would be sufficient to receive a prescription for an ADP-funded PAP device (i.e., currently PAP devices could be prescribed only with test results from level 1 polysomnography).[140]

As shown in Table A11A, when we included the cost of CPAP, we showed the total 5-year budget would increase to about $3.54 million (170% change in reference case estimate [Table 32]). At a cost of $554 per CPAP system and using the budget impact estimates related to CPAP costs only (e.g., $8.72 million over 5 years), we estimated additional 997 CPAP systems in year 1 to about additional 5,380 CPAP systems in year 5, with a total of additional 15,745 CPAP systems over the next 5 years.

Table A11A: Budget Impact Scenario Results: Inclusion of Costs of CPAP, Adults

Scenario	Budget impact, $ million[a]					
	Year 1	Year 2	Year 3	Year 4	Year 5	Total[b,c]
Current scenario,[d] total costs	**103.79**	**105.86**	**107.94**	**110.01**	**112.08**	**539.68**
Costs of initial testing (total: technical and professional fees)	52.99	54.05	55.10	56.16	57.22	275.52
Costs of test failure (test repeat)	0.00	0.00	0.00	0.00	0.00	0.00
Costs of CPAP	30.90	31.51	32.13	32.75	33.36	160.65
Costs, other than testing (e.g., initial visits, follow-up, etc.)	19.91	20.30	20.70	21.10	21.50	103.51
New scenario,[e] total costs	**104.01**	**106.32**	**108.63**	**110.96**	**113.29**	**543.22**
Costs of initial testing (total: technical and professional fees)	51.46	50.93	50.33	49.68	48.96	251.36
Costs of test failure (test repeat)	0.43	0.88	1.35	1.84	2.34	6.84
Costs of CPAP	31.45	32.64	33.85	35.09	36.35	169.38
Costs, other than testing (e.g., initial visits, follow-up, etc.)	20.67	21.87	23.10	24.36	25.64	115.64
Budget impact, total[b,c]	**0.22**	**0.46**	**0.70**	**0.95**	**1.21**	**3.54**
Budget impact: initial testing costs (total)	−1.53	−3.12	−4.77	−6.48	−8.26	−24.16
Budget impact: costs of test failures (test repeats)	0.43	0.88	1.35	1.84	2.34	6.84
Budget impact: costs of CPAP	0.55	1.13	1.72	2.34	2.98	8.72
Budget impact: other healthcare costs (initial visits, follow-up)	0.77	1.57	2.40	3.26	4.15	12.14

Abbreviations: CPAP, continuous positive airway pressure.

[a]In 2023 Canadian dollars. All costs were calculated using the mean cost from the Primary Economic Evaluation's probabilistic results.

[b]Negative costs indicate savings.

[c]Results may appear inexact due to rounding.

[d]*Current scenario* refers to the existing diagnostic pathway with level 1 PSG.

[e]*New scenario* refers to a new diagnostic pathway with level 2 PSG.

We also conducted additional scenarios related to CPAP use, see results in Table A11B (Scenarios 2 to 4):

- If we expanded the modelling of our extreme scenario with all people who received test negative results with level 2 polysomnography to be retested with level 1 polysomnography, and included the cost of CPAP, then the total budget required was about $51.96 million (compared with $43.35 million in Table 32)
- If we used another set of parameters reported in the Bruyneel study,[125] and included the costs of CPAP then the total savings would be smaller and would decrease from about $17.81 million to about $3.00 million
- If we considered the uptake of 100% at year 5 and the cost of CPAP then the overall (total) budget would change from savings of $6.71 million to additional costs of about $4.71 million.

Table A11B: Budget Impact Sensitivity Analysis Results – Additional CPAP Cost-Related Scenarios

Additional CPAP cost-related scenarios in adults	Total 5-year budget impact, $ million[a,b]	Portion of BI associated with CPAP treatment, $ million	% Change, compared with reference case[c]
Reference case, adults (uptake 15% per year)	−5.03	NA	NA
1. Scenario, structural change: Inclusion of the cost of CPAP of $554/person (see also Appendix 7 for the description of the CUA in adults with OSA)	3.54	8.72	−170%
2A. Scenario structural changes (Table 32): Level 1 PSG in all who tested negative on level 2 PSG without inclusion of the cost of CPAP	43.35	NA	−962%
2B. Scenario structural changes (extreme example): Level 1 PSG in all who tested negative on level 2 PSG with inclusion of the cost of CPAP	51.96	8.72	−1,132%
3A. Scenario parameter changes (Table 32): Change in sensitivity and specificity of level 2 PSG for adults with OSA, AHI>=5 (Bruyneel et al, 2011[125]: Sn = 0.960; Sp = 0.710; failure rates: 4.7% [level 2] and 1.5% [level 1], prevalence = 0.5) without inclusion of the cost of CPAP	−17.81	NA	254%
3B. Scenario parameter and structural changes (extreme example): Change in sensitivity and specificity of level 2 PSG (data from Bruyneel et al, 2011[125]) with inclusion of the cost of CPAP	−3.00	14.87	−41%
4A. Scenario parameter changes (Table 32): Change in the rate of uptake, reaching 100% in year 5, without inclusion of the cost of CPAP	−6.71	NA	33%
4B. Scenario parameter and changes structural changes (extreme example): Change in the rate of uptake, reaching 100% in year 5, with inclusion of the cost of CPAP	4.71	11.63	−194%

Abbreviations: BI, budget impact, CPAP, continuous positive airway pressure; OHIP, Ontario Health Insurance Plan, OSA, obstructive sleep apnea; PSG, polysomnography.

Note: Negative sign for the cost suggests cost savings; negative sign for % change suggests a change in BI, and when it is negative and ≥100% then there is a switch in BI estimated from cost saving to cost spending (additional costs).

[a]In 2023 Canadian dollars.

[b]Results may appear inexact due to rounding.

[c]Percentage change calculated as the total budget impact of the scenario analysis divided by the total budget impact of the reference case.

Appendix 10: Letter of Information

LETTER OF INFORMATION

Ontario Health

Ontario Health is conducting a review of **at-home portable sleep study devices for people with sleep disorders for public funding**.

An important part of this review involves gathering perspectives of patients and caregivers of those who have been diagnosed with a sleep disorder who may or may not have experience with sleep study.

WHAT DO YOU NEED FROM ME

- ✓ Willingness to share your story
- ✓ 30-40 minutes of your time for a phone
- ✓ Permission to audio- (not video-) record the interview

WHAT YOUR PARTICIPATION INVOLVES

If you agree to share your experiences, you will be asked to have an interview with Ontario Health staff. The interview will last about 30-40 minutes. It will be held over the telephone and with your permission, the interview will be audio-taped. The interviewer will ask you questions about your or your loved one's condition and your perspectives on bariatric surgery in Ontario.

Participation is voluntary. You may refuse to participate, refuse to answer any questions or withdraw before or at any point during your interview. Withdrawal will in no way affect the care you receive.

CONFIDENTIALITY

Please ensure to avoid providing any identifiable information throughout the interview as there may be opportunity for inadvertent collection personal health information via our auto-recording and transcription process.

All information you share will be kept confidential and your privacy will be protected except as required by law. The results of this review will be published, however, no identifying information will be released or published. Any records containing information from your interview will be stored securely until project completion. After the project's completion, the records will be destroyed.

If you are sending us personal information by email, please be aware that electronic communication is not always secure and can be vulnerable to interception.

RISKS TO PARTICIPATION

There are no known physical risks to participating. Some participants may experience discomfort or anxiety after speaking about their experiences.

Appendix 11: Interview Guide

HTA Interview Script

Consent to record:
I would like your permission to have an audio recording of this conversation so I can use your direct quotes and other information from this conversation to make a case for the decision makers. Your name or any other identifiers will not be placed in the report or the presentation and your privacy and your confidentiality will be protected. So do I have your permission to audio record this conversation?

Explanation of Health Technology Assessments:
What I'm doing is called a Health Technology Assessment. This is where we review different technologies or interventions to be publicly funded. There are 3 main components. The first one is a clinical review, this is where we speak to clinical experts and look at the research around the technology. The second section is the economic review. This is where we look at the cost of technology on the healthcare system. And the third section, which is what you're taking part in is the patient preferences and values. This is where we speak to patients or caregivers about their lived experience with the condition the technology addresses and ask about their experience with the technology or their opinion on the technology if they haven't used it.
Once we gathered our evidence, we develop a report and presentation to a committee called the Ontario Health Technology Advisory committee. This committee based on the evidence we prepare for them makes a recommendation to publicly fund or not public fund the technology. This recommendation gets sent to the Ministry of Health and they decide whether to uphold the decision. Even if the committee makes a recommendation for public funding, it does not guarantee the Ministry will fund the technology.

For this HTA we are looking at portable sleep study devices that can be used at home to diagnose sleep disorders. An at-home sleep study device is a portable wireless sleep monitor system that is used to diagnose sleep disorders.

Do you have any questions before we get started?

End of interview: Next Steps
In terms of next steps, we are planning to present to the committee in the fall. Once the committee makes a decision, we go through an internal review process. After that, we post the decision for public comment. That's the next time you'll hear back from me. I'll email you with the decision and the link where you can comment on the committee's decision.

<u>Sleep HTA Interview Questions</u>

Impact of living with a sleep disorder

1. **What type of sleep disorder were you diagnosed with?**

2. **Can you describe your experience living with the condition and its impact on your quality of life?**

   - Describe the symptoms of your sleep disorder?
   - How long have you been experiencing these?
   - What was your experience with sleep disorder?
   - Was there an impact on your quality of life? (Social, emotional, financial, mental health, work, family, other day to day)

   Diagnosis journey:

3. **Can you describe your diagnosis journey? Including what intervention was used for your diagnosis: in-lab or at-home sleep test?**
   -What have you tried to manage your sleep disorder?

- How was your experience with the intervention used? In-lab or at-home sleep test

  For in-lab sleep test:
  - What arrangements had to be made for you to have the in-lab sleep test (childcare, transportation etc)?
  - Time going to clinic, was it in sync with your regular sleep schedule
  - How long did you have to take time off work to do the sleep clinic? Any out-of pocket costs re: transportation?
  - 3-4k
  - How long did you stay in the clinic?
  - How was your overall experience in the sleep clinic?
  - Were you able to sleep?
  - Were there any barriers to you accessing the test?

  For at-home sleep test:
  - What arrangements had to be made for you to have the in-lab sleep test (childcare, picking up sleep test device etc)
  - How was your overall experience with the at-home sleep test?
  - Were you able to sleep?
  - Were you given enough information on how to setup the equipment?
  - Did you have support from the healthcare team, family members, caregivers?

- What is your preference on in-lab vs at-home sleep test options?
- Were there any barriers to you accessing the test?
- What information were you given prior to sleep test? Re: discharge summery, post intervention monitoring… etc?
- At-home sleep study: what assistance would you need?

Impact

- What was the accuracy of your diagnosis after the test?
- What was your experience with treatment after diagnosis?
- Did this have an impact on loved ones/caregivers?

Appendix 12: Survey Questions

Thank you for participating in Ontario Health's Health Technology Assessment (HTA) on *"At-Home, Level-2 Sleep Study Polysomnography Devices"*.

What is a Health Technology Assessment?

An HTA is a review of scientific evidence about health care services and interventions. This includes speaking with patients and family members to find out about the perceived benefits and disadvantages of health interventions and technologies.

Our review will conclude in a recommendation about public funding of the intervention in Ontario.

What is this survey about?

We would like to know your lived experience with a sleep disorder, experience with undergoing a sleep study and your opinion on at home sleep study devices being available in Ontario .

A sleep study is used to diagnosed sleep disorders by monitoring a patient while they sleep.

In Ontario, there is currently no standardized funding or access to the use of at home sleep study devices.

The last day to participate in this assessment is August 18th, 2023.

Important note

Your participation in this HTA is completely voluntary. You are under no obligation to participate, and you can withdraw from the HTA at any time and/or refuse to answer any questions without any negative consequences.

If you choose to participate, please note that all information collected from participants will be kept confidential and your privacy will be protected, except as required by law. The overall findings from this survey will be published, however, we will not use your name or any personally identifiable information (e.g., names of clinics or doctors) in any presentations or publications related to this HTA.

If you have any questions about the survey or would like to submit your feedback in another format, please contact:

[Contact information field]

Thank you for your time and input! Your experience is valued and appreciated.

Sleep HTA Survey Questions

1. Can you share a little bit about your symptoms with your sleep disorder and the impact it has on your quality of life (social, emotional, financial, mental health, work, family, other day to day)?

2. If you have experience with a sleep study, did it take place at home, at a private sleep clinic, in a community sleep clinic or at a hospital (check all that apply)
    a. At Home
    b. Community Sleep Clinic
    c. In Hospital Sleep Clinic
    d. Private Sleep Clinic
    e. I don't have experience with a sleep study
    f. I don't know
    g. Other
3. (*if applicable)* What was your overall experience with the sleep study?

    Did you have to make arrangements to be able to do the sleep study (childcare, time off work, transportation)?

4. What was your experience during the sleep study?

    Think of the below themes when answering the question:
    -Comfort
    -Ability to sleep
    -Sleep routine
    -Sleep timing
    -Convenience

5. What is your opinion on having at home sleep studies available to you? Would you prefer this option over the in hospital/clinic sleep studies?

    Think of the below themes when answering the question:
    -Comfort
    -Ability to sleep
    -Sleep routine
    -Sleep timing
    -Convenience

6. Is there anything else you feel would be important for us to know about sleep studies (at home/clinic)?

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