Level 2 Polysomnography for the Diagnosis of Sleep Disorders

Recommendation

AUGUST 2024

Ontario Health

Final Recommendation

Ontario Health, based on guidance from the Ontario Health Technology Advisory Committee, recommends publicly funding level 2 polysomnography for the diagnosis of sleep disorders.

Rationale for the Recommendation

The Ontario Health Technology Advisory Committee made the above recommendation after considering the clinical, economic, and patient preferences and values evidence reported in the health technology assessment.[1]

The committee concluded that the clinical evidence showed level 2 polysomnography (unattended, at-home sleep studies) was similarly accurate when compared with level 1 polysomnography (attended, in-clinic sleep studies) – the current diagnostic approach in Ontario. The committee recognized that the availability in Ontario of a similarly accurate diagnostic approach that could be done at home may help reduce barriers in accessing sleep studies, supporting timely diagnosis and more equitably improve health outcomes for people with suspected sleep disorders.

The economic evidence showed that publicly funding level 2 polysomnography could potentially be cost saving to Ontario, with the acknowledgement that 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. Given the prospect for level 2 polysomnography to support timely diagnosis and equitable health outcomes, there was committee consensus that, although it will be important to further assess uncertainties, this ought not to delay a recommendation to publicly fund the technology. In the short-term, uptake in Ontario and risk of cost increases to the province of publicly funding level 2 polysomnography are likely constrained by current sleep medicine health human resources capacity. Capacity building of these resources will be necessary as part of implementation, and therefore, must also be accounted for planning stages, to realize the potential economic and health outcome benefits of level 2 polysomnography for people in Ontario.

The committee considered the lived experiences of people who underwent either level 1 polysomnography or an at-home sleep study (though not necessarily level 2 polysomnography). Most people expressed preference for at-home studies, citing convenience and comfort as the main reasons, and people with experience of an at-home study liked having a manual or video with instructions to aid equipment set-up. Some people expressed a preference for level 1 polysomnography, which they perceived to be more accurate; they were also concerned about setting the equipment up correctly at home. These perceptions are aligned with the findings from published studies evaluating preferences and values of people who underwent level 2 polysomnography. Reflecting on the lived experiences and published evidence, the committee supports the continued availability of level 1 polysomnography in Ontario since level 2 may not be a reasonable option for everyone. The committee also supports the decision between using level 1 or level 2 polysomnography ought to align with relevant guidelines for suitable populations.

The committee acknowledged that uncertainties about aspects of the implementation pathway exist, such as patient eligibility criteria for the use of level 2 polysomnography, cost of the technology, and

health human resource capacity, as previously noted. However, the committee recognizes level 2 polysomnography as an effective innovative technology for Ontario with potential to more equitably improve health outcomes for people with suspected sleep disorders. There was committee consensus that the managed entry of level 2 polysomnography may be guided by further assessment of the implementation considerations by the Ministry of Health.

Decision Determinants for Level 2 Polysomnography for the Diagnosis of Sleep Disorders

Overall Clinical Benefit

Effectiveness

How effective is the health technology/intervention likely to be (taking into account any variability)?

Level 2 polysomnography may have good test performance for adults and children, with adequate diagnostic test accuracy, in comparison with level 1 polysomnography.

Level 2 polysomnography is an at-home sleep study similarly accurate to level 1 polysomnography and which may be suitable in some cases to improve access and timeliness of a sleep disorder diagnosis. The identified body of evidence for level 2 polysomnography is not exhaustive of all possible sleep disorder diagnoses and because of this, the findings represent an overall diagnostic accuracy for the test.

Evidence was identified for a few diagnoses:

- For diagnosing sleep apnea in adults, based on 8 studies (*N* = 422), the sensitivity ranged from 0.760 to 1.00 (Grading of Recommendations, Assessment, Development and Evaluations [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% and 20% (GRADE: Very low).
- There was a mix of preference reported for at-home and in-clinic testing, with more people preferring at-home testing; patients reported better quality of sleep when testing was conducted at home (GRADE not conducted).

Safety

How safe is the health technology/intervention likely to be?

There are no safety concerns with respect to the use of level 2 polysomnography devices.

Burden of Illness

What is the likely size of the burden of illness pertaining to this health technology/intervention?

Half of Canadian adults are estimated to have insufficient sleep. There are over 80 sleep disorders, of which sleep apnea is one of the more commonly diagnosed disorders. The prevalence of obstructive sleep apnea among adults was estimated to be 6.4% in 2017.[2] Prevalence in children is estimated between 1% and 5%.[3,4]

Need

How large is the need for this health technology/intervention?

There is no urgent need for this health technology because there is a currently available publicly funded test (level 1 polysomnography); however, there is a need to improve accessibility, which the use of level 2 polysomnography may address.

Patient Preferences and Privacy

Patient Preferences and Values

Do patients have specific preferences, values, or needs related to the health condition, health technology/intervention, or life impact that are relevant to this assessment?

Patients highlighted that getting diagnosed for their sleep disorder helped them seek ways to manage their condition and eventually improve their lives. They viewed level 2 polysomnography favorably overall and emphasized that, for people with physical limitations, an at-home sleep study could be a challenge, due to difficulties setting up the sleep study equipment without in-person support. Participants also reported that living with a sleep disorder significantly impacted their lives.

Autonomy, Privacy, Confidentiality, and/or Other Relevant Ethical Principles as Applicable

Are there concerns regarding accepted ethical or legal standards related to patient autonomy, privacy, confidentiality, or other ethical principles that are relevant to this assessment?

No concerns related to patient autonomy, privacy or confidentiality were identified. Participants reported that at-home sleep studies were more comfortable, convenient, and better able to reflect their normal sleep pattern. This is consistent with principles of independence and empowerment as at-home sleep study devices can, in most cases, be set up by patients themselves or their care partners unattended, at the home setting.

Equity and Patient Care

Equity of Access or Outcomes

Are there disadvantaged populations or populations in need whose access to care or health outcomes might be improved or worsened that are relevant to this assessment?

Currently, only level 1 polysomnography is publicly funded. Level 2 polysomnography, as an alternative option, may support people who have a preference for at-home testing, for example, people with care partner responsibilities, who are unable to travel, or with comorbidities, or who require equipment (e.g., dialysis) that make going to an overnight sleep test difficult.

However, it is recognized that there may be ongoing barriers in accessing polysomnography, even if level 2 polysomnography were to be offered. Particularly, internet access may not be consistent across the province and if a level 2 device requires good internet access to conduct the test, it may limit its applicability to remote regions in the province. Additionally, people with coarse and curly hair (including but not limited to people of African descent) may face barriers with electroencephalography, which requires that a network of electrodes placed on the scalp to capture brain activity and is an integral component of polysomnography testing (level 1 and level 2). Specifically, if patients are required to remove their preferred hair styles (such as braids),[5] they may opt to delay or not undergo testing.

Patient Care

Are there challenges in the coordination of care for patients or other system-level aspects of patient care (e.g., timeliness of care, care setting) that might be improved or worsened that are relevant to this assessment?

While some areas in Ontario report reasonable wait times, overall, wait times in Ontario for access to sleep specialists in clinics for adults and children is currently estimated to be close to 1 year, which is longer than the Canadian Thoracic Society recommendation that all patients be seen within 6 months of referral to a sleep specialist.[6-8] Level 2 polysomnography may improve access to testing, which in turn might help reduce current wait times.

Cost-Effectiveness

Economic Evaluation

How efficient is the health technology/intervention likely to be?

Based on economic modelling, for adults with suspected sleep disorders, using level 2 polysomnography as an initial test was equally effective (outcome: confirmed diagnosis at the end of the pathway) as the current practice with level 1 polysomnography. With the assumption of a lower technical fee for level 2 polysomnography, using level 2 polysomnography as an initial test was less costly than the current practice with level 1 polysomnography, but this result was highly uncertain (mean: −$27.20; 95% credible interval [CrI]: −$137 to $121). For children, using level 2 polysomnography as an initial test was associated with additional costs (mean: $9.70; 95% CrI: −$125 to $190), and similarly, this estimate was highly uncertain.

Feasibility of Adoption Into Health System

Economic Feasibility

How economically feasible is the health technology/intervention?

The estimated cost of a level 2 polysomnography test (unattended, at home sleep study) is approximately $345 (95% CrI: $261 to $461), with a technical fee component of $247 (95% CrI: $164 to $363). The total budget impact of publicly funding level 2 polysomnography for adults with suspected sleep disorders in Ontario is uncertain, ranging from savings (−$22 million) to additional costs ($43 million over 5 years), depending on various assumptions. Publicly funding level 2 polysomnography for children could be associated with additional costs of about $0.005 million over 5 years.

Organizational Feasibility

How organizationally feasible is it to implement the health technology/intervention?

There is a well-established clinical pathway for level 1 polysomnography testing within existing sleep clinics (both hospitals and independent health facilities) in Ontario. The implementation of level 2 polysomnography into Ontario's health care system is uncertain. Its implementation would likely require changes to the current reimbursement approach of in-clinic level 1 polysomnography (e.g., changes to the OHIP fee codes), which are jointly negotiated between the Ministry of Health and the Ontario Medical Association.

References

1. Ontario Health. Level 2 polysomnography for the diagnosis of sleep disorders: a health technology assessment. Ont Health Technol Assess Ser [Internet]. 2024 Aug;24(7):1–157. Available from: https://www.hqontario.ca/evidence-to-improve-care/health-technology-assessment/reviews-and-recommendations/level-2-polysomnography-for-the-diagnosis-of-sleep-disorders
2. Sleep apnea in Canada, 2016 and 2017. Ottawa (ON): Statistics Canada; 2018.
3. Katz SL, Witmans M, Barrowman N, Hoey L, Su S, Reddy D, et al. Paediatric sleep resources in Canada: the scope of the problem. Paediatr Child Health. 2014;19(7):367–72
4. Marcus CL, Brooks LJ, Draper KA, Gozal D, Halbower AC, Jones J, et al. Diagnosis and management of childhood obstructive sleep apnea syndrome. Pediatrics. 2012;130(3):576–84
5. Lofton T. How one patient's textured hair nearly kept her from a needed EEG. KFF Health News [Internet]. 2023 Jun 13. Available from: https://kffhealthnews.org/news/article/black-textured-hair-eeg-racial-barriers/
6. Fleetham J, Ayas N, Bradley D, Fitzpatrick M, Oliver TK, Morrison D, et al. Canadian Thoracic Society 2011 guideline update: diagnosis and treatment of sleep disordered breathing. Can Respir J. 2011;18(1):25–47.
7. Rotenberg B, George C, Sullivan K, Wong E. Wait times for sleep apnea care in Ontario: a multidisciplinary assessment. Can Respir J. 2010;17(4):170–4.
8. Povitz M, Bray Jenkyn K, Kendzerska T, Allen B, Pendharkar SR, Ouedraogo A, et al. Clinical pathways and wait times for OSA care in Ontario, Canada: a population cohort study. Can J Respir Crit Care Sleep Med. 2019;3(2):91–9.

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