Level 2 Polysomnography for the Diagnosis of Sleep Disorders

Recommendation

MONTH 20XX

Ontario Health

Draft 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 the clinical evidence showed that level 2 polysomnography (for unattended, at-home sleep studies) was similarly accurate when compared with level 1 polysomnography (for attended, in-clinic sleep studies) – currently the standard of care – and could be used as an option that would improve access to diagnostic testing for people with suspected sleep disorders who may find undergoing in-clinic sleep studies a challenge.

The primary economic evaluation suggested that the new diagnostic pathway with level 2 polysomnography can be considered cost-effective because it may lead to cost savings in adults and small cost increases in children, although there is uncertainty in these results, with total cost depending on how level 2 polysomnography is implemented. The committee also discussed that there could be a cost increase for the Province if the new diagnostic pathway with level 2 polysomnography leads to more sleep studies taking place (i.e., an increase in total patient volume). However, they recognized that the budget may be constrained by the health human resources needed to support level 2 polysomnography in the near future (i.e., capacity limitations).

The committee also took into account the lived experiences of people who have undergone sleep studies and recognized the need for publicly funding a valid at-home sleep study to improve equity in access to sleep study testing in Ontario.

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.

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

Safety

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

There are no safety concerns with respect to the administration of this diagnostic test.

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 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?

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?

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 with level 1 polysomnography, but this result was highly uncertain (mean −$27.20; 95% credible interval [CrI], −$137 to $121). 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.

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 the new diagnostic pathway with level 2 polysomnography in Ontario is uncertain, ranging from savings (−$22 million) to additional costs ($43 million), depending on various assumptions. In the reference case, with the assumption of a lower cost for the level 2 test than that for the level 1 test and high uptake (15% per year), we estimated there would be savings of about $5 million over 5 years for adults with suspected sleep disorders. Publicly funding the new diagnostic pathway with 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?

Level 2 polysomnography may be well incorporated into the well-established clinical pathway within existing sleep clinics (both hospitals and independent health facilities). A recommendation to publicly fund the new diagnostic pathway with level 2 polysomnography would necessitate changes to the eligibility for publicly funded access to treatment for obstructive sleep apnea of positive airway pressure devices (e.g., continuous positive airway pressure [CPAP]); current criteria from the Ontario Assistive Devices Program require a diagnosis by means of level 1 polysomnography.

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ISBN TBD (PDF)

Citation

TBD