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Electrical Stimulation for Drug-Resistant Epilepsy: OHTAC Recommendation

Ontario Health Technology Advisory Committee

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Conflict of Interest Statement

All reports prepared by the Evidence Development and Standards branch at Health Quality Ontario are impartial. There are no competing interests or conflicts of interest to declare.

About Health Quality Ontario

Health Quality Ontario (HQO) is an arms-length agency of the Ontario government. It is a partner and leader in transforming Ontario's health care system so that it can deliver a better experience of care, better outcomes for Ontarians, and better value for money.

Health Quality Ontario strives to promote health care that is supported by the best available scientific evidence. The Evidence Development and Standards branch works with advisory panels, clinical experts, developers of health technologies, scientific collaborators, and field evaluation partners to provide evidence about the effectiveness and cost-effectiveness of health interventions in Ontario.

To conduct its systematic reviews of health interventions, the Evidence Development and Standards branch examines the available scientific literature, making every effort to consider all relevant national and international research. If there is insufficient evidence on the safety, effectiveness, and/or cost-effectiveness of a health intervention, HQO may request that its scientific collaborators conduct economic evaluations and field evaluations related to the reviews. Field evaluation partners are research institutes focused on multicentred clinical trials and economic evaluation, as well as institutes engaged in evaluating the safety and usability of health technologies.

About the Ontario Health Technology Advisory Committee

The Ontario Health Technology Advisory Committee (OHTAC) is a standing advisory subcommittee of the Board of Directors of Health Quality Ontario. Based on the evidence provided by Evidence Development and Standards and its partners, OTHAC makes recommendations about the uptake, diffusion, distribution, or removal of health interventions within the provincial health system. When making its recommendations, OHTAC applies a unique decision-determinants framework that takes into account overall clinical benefit, value for money, societal and ethical considerations, and the economic and organizational feasibility of the health care intervention in Ontario.

Publishing Health Quality Ontario Research

When the evidence development process is nearly completed, draft reviews, reports, and OHTAC recommendations are posted on HQO's website for 21 days for public and professional comment. For more information, please visit: http://www.hqontario.ca/evidence/evidence-process/evidence-review-process/professional-and-public-engagement-and-consultation.

Once finalized and approved by the Board of Directors of Health Quality Ontario, the research is published as part of the *Ontario Health Technology Assessment Series*, which is indexed in MEDLINE/PubMed, Excerpta Medica/Embase, and the Centre for Reviews and Dissemination database. Corresponding OHTAC recommendations and associated reports are also published on the HQO website. Visit http://www.hqontario.ca for more information.

When sufficient data are available, OHTAC tracks the ongoing use of select interventions it has previously reviewed, compiling data by time period and region. The results are published in the Ontario Health Technology Maps Project Report.

Disclaimer

This report was prepared by Health Quality Ontario or one of its research partners for the *Ontario Health Technology Advisory Committee* and was developed from analysis, interpretation, and comparison of scientific research. It also incorporates, when available, Ontario data and information provided by experts and applicants to Health Quality Ontario. It is possible that relevant scientific findings may have been reported since the development of this recommendation. This report may be superseded by an updated publication on the same topic. Please check the Health Quality Ontario website for a list of all publications: http://www.hqontario.ca/evidence/publications-and-ohtac-recommendations.

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Background

An evidence-based analysis was conducted by Health Quality Ontario to answer the following research questions:

1. What is the effectiveness of electrical stimulation in reducing the frequency of seizures in patients with drug-resistant epilepsy who are not surgical candidates?
2. Does electrical stimulation in patients with drug-resistant epilepsy reduce health resource utilization, specifically hospitalizations and/or emergency department (ED) visits?
3. What adverse events are associated with electrical stimulation?
4. What is the provincial budgetary impact of DBS and VNS in Ontario?

Conclusions

Both deep brain stimulation (DBS) and vagus nerve stimulation (VNS) have been used to treat patients with drug-resistant epilepsy who are not surgical candidates. In adults, both DBS and VNS seem to reduce seizure frequency, although the evidence on DBS is limited to 1 randomized controlled trial with substantial limitations. No significant reduction in seizure frequency was observed in the evidence for VNS in children. However, there were significant decreases in health resource utilization in children after VNS implantation, suggesting that children had fewer and/or less severe seizures following VNS. Although there are considerable risks associated with the invasive stimulation procedures, the long-term adverse events associated with the procedures appear to be limited based on the evidence reviewed.

Decision Determinants

OHTAC has developed a decision-making framework that consists of 7 guiding principles for decision making and a decision determinants tool. When making a decision, OHTAC considers 4 explicit main criteria: overall clinical benefit, consistency with expected societal and ethical values, value for money, and feasibility of adoption into the health system. For more information on the decision-making framework, please refer to the *Decision Determinants Guidance Document* available at: http://www.hqontario.ca/evidence/evidence-process/evidence-review-process/decision-making-framework.

Appendix 1 provides a summary of the decision determinants for this recommendation.

Based on the Decision Determinants criteria, OHTAC weighted in favour of the limited but promising evidence for DBS which indicates that more research is needed before recommending expanded use for this procedure. The recommendation for VNS was based on the fact that VNS is in use in the province and that patients who are candidates for VNS have limited treatment alternatives. However, the lower quality of evidence led OHTAC to recommend the prospective tracking of outcomes.

OHTAC Recommendations

- OHTAC recommends the use of VNS for children and adults with drug-resistant epilepsy who are not candidates for surgical resection, provisional on the following:
  - VNS is incorporated into the Provincial Strategy for Epilepsy Care
  - Appropriate criteria for using VNS are established
  - Outcomes of VNS procedures are tracked prospectively
  - The use of VNS is limited to institutions with demonstrated expertise

- While the initial evidence on DBS is promising, there is insufficient evidence for OHTAC to make a recommendation on the use of DBS in adults or children with drug-resistant epilepsy at this time.

Appendix 1 – Decision Determinants

Table A1: Decision Determinants for Electrical Stimulation for Drug-Resistant Epilepsy

Decision Criteria	Subcriteria	Decision Determinants Considerations
Overall clinical benefit How likely is the health technology/intervention to result in high, moderate, or low overall benefit?	**Effectiveness** How effective is the health technology/intervention likely to be (taking into account any variability)?	**Research Questions** 1. What is the effectiveness of electrical stimulation in reducing the frequency of seizures in patients with drug-resistant epilepsy who are not surgical candidates? 2. Does electrical stimulation in patients with drug-resistant epilepsy reduce health resource utilization, specifically hospitalizations and/or emergency department (ED) visits? 3. What adverse events are associated with electrical stimulation? 4. What is the provincial budgetary impact of DBS and VNS in Ontario? <u>Seizure Frequency:</u> DBS in adults: There was a significant reduction in seizure frequency between treatment and control groups. **(GRADE: LOW)** VNS in adults: There was a significant reduction in seizure frequency between treatment and control groups. **(GRADE: MODERATE-LOW)** VNS in children: There was no significant reduction in seizure frequency between treatment and control groups. **(GRADE: LOW)** <u>Health Resource Utilization</u> There was a significant reduction in hospitalizations and ED visits in adults and children after VNS implantation. **(GRADE: LOW)** *No DBS studies were found on utilization.
	Safety How safe is the health technology/intervention likely to be?	Both the VNS and DBS procedures are invasive (DBS is more invasive) and involve risk. However, neither is associated with long-term adverse events. No deaths related to the implantation of the device were reported in any of the studies .
	Burden of illness What is the likely size of the burden of illness pertaining to this health technology/intervention?	An estimated 30% of adults and children with epilepsy are drug-resistant (21,000 in Ontario). Of these, about two-thirds are also not suitable candidates for surgical resection (about 14,000 people in Ontario).
	Need How large is the need for this health technology/intervention?	Adults and children with drug-resistant epilepsy who are not candidates for surgical resection have limited treatment alternatives.
Consistency with expected societal and ethical values[a] How likely is adoption of the health	**Societal values** How likely is the adoption of the health technology/intervention to be congruent with expected societal values?	Adults and children with uncontrolled epilepsy suffer from frequent seizures limiting their participation in society. It impacts work, education, social interactions, and relationships.
	Ethical values	

Decision Criteria	Subcriteria	Decision Determinants Considerations
technology/intervention to be congruent with societal and ethical values?	How likely is the adoption of the health technology/intervention to be congruent with expected ethical values?	
Value for money How efficient is the health technology likely to be?	**Economic evaluation** How efficient is the health technology/intervention likely to be?	The initial epilepsy assessment (to determine candidacy for surgical resection or other treatment alternatives) costs an estimated $11,700, and the actual VNS procedure costs about $28,000. The DBS procedure would cost more than the VNS procedure because the device is more expensive and the operating room time is longer.
Feasibility of adoption into health system How feasible is it to adopt the health technology/intervention into the Ontario health care system?	**Economic feasibility** How economically feasible is the health technology/intervention?	VNS has been given special funding in the province.
	Organizational feasibility How organizationally feasible is it to implement the health technology/intervention?	The Provincial Strategy on Epilepsy Care would identify patients who are not surgical candidates and refer them to consider treatment alternatives, including electrical stimulation.

Abbreviations: DBS, deep brain stimulation; ED, emergency department; GRADE, Grading of Recommendations Assessment, Development and Evaluation; VNS, vagus nerve stimulation.

[a]The anticipated or assumed common ethical and societal values held in regard to the target condition, target population, and/or treatment options. Unless there is evidence from scientific sources to corroborate the true nature of the ethical and societal values, the expected values are considered.

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