



## Aim

To analyze the available published evidence on the long-term use of VNS for refractory epilepsy.

The intent was to provide an update to the health policy makers, medical practitioners, and the public on the current status of the use of VNS for this indication in both adults and children and on its use and coverage in Canada.

## **Conclusions and results**

The reviewed literature suggests that VNS therapy is safe, well tolerated, and effective when used as adjunctive therapy in patients (<sup>3</sup>12 years of age) with partial-onset seizures refractory to medication and who are not candidates for epilepsy surgery or failed surgery. Limited followup evidence reported by uncontrolled studies suggests that its benefits and safety do not diminish over time for those who continue to use it. However, VNS therapy is not a cure for refractory epilepsy and should be used only as a last resort after an extensive and thorough patient evaluation. The safety and efficacy of VNS in children with refractory epilepsy has yet to be established.

Eleven of the twelve Ministries of Health across Canada responding to the survey provide coverage for this procedure and the device through their medical insurance programs and hospital budgets. VNS therapy is available in seven provinces, while three provinces and one territory provide coverage for the procedure to be performed in other provinces.

## Recommendations

Further research is needed to determine the mode of action of VNS; which patients are likely to respond; its effect in less severely afflicted patients and in different syndromes of epilepsy; the quality of life of treated patients and their caregivers; and the details of stimulation paradigms.

Patients considering VNS and their caregivers should be aware that:

- VNS appears to have a moderate initial efficacy that may increase over time, but it is not a cure for epilepsy.
- VNS should only be used as a last resort after an extensive and thorough patient evaluation to rule out non-epileptic conditions and exclude patients who may benefit from conventional therapy.
- VNS does not work for everyone.
- The safety and efficacy of VNS in children with refractory epilepsy has yet to be established.
- VNS appears to have a favorable safety profile when compared to conventional therapies, but the possibility of unknown adverse effects associated with its use still exists.

## **Methods**

Systematic review of the research published from 1998 to September 2000 and a survey of the provincial/territorial Medical Directors from Health Ministries across Canada were conducted.

The following databases were searched: MEDLINE, PubMed, HealthSTAR, EMBASE, ECRI database, The Cochrane database of Systematic Reviews, Best Evidence database, and the NHS (UK) Centre for Reviews and Dissemination databases.

Two well renowned experts externally reviewed this report.