



The clinical and cost effectiveness of sacral nerve stimulation to treat faecal incontinence that cannot be controlled with conservative management

**Guidance Number:**

003 (June 2018)

**FIELD:** Incontinence

**TYPE:** Treatment



## HEALTH TECHNOLOGY WALES (HTW) GUIDANCE 003 (June 2018)

### Sacral nerve stimulation for the treatment of faecal incontinence

#### Why did Health Technology Wales (HTW) appraise this topic?

Sacral nerve stimulation (SNS) is a treatment for faecal incontinence that involves direct, chronic, low-voltage electrical stimulation of the sacral nerve roots. It is available via the NHS in some other parts of the UK, but not in NHS Wales. SNS is intended to be used in people who cannot manage their faecal incontinence by more conservative methods. In these cases, alternatives such as stoma or sphincter repair are associated with significant costs and morbidity rates, and do not always provide adequate relief to the patient.

HTW guidance is that the available evidence supports the use of sacral nerve stimulation to treat faecal incontinence, only where the condition has not responded to conservative management.

Sacral nerve stimulation should only be offered to people with faecal incontinence in line with the criteria outlined in the [National Institute for Health and Care Excellence Clinical Guideline 49](#) (Faecal incontinence in adults: management).

#### Evidence:

- Evidence from three randomised controlled trials and four crossover studies consistently demonstrates that sacral nerve stimulation reduces the number of faecal incontinence episodes experienced by patients.
- There is evidence that sacral nerve stimulation has the potential to be cost effective compared with conservative treatment in people who have failed to benefit from conservative treatment. This finding is based on the assumption that the clinical benefit of sacral nerve stimulation is sustained in the long term.

*The status of HTW guidance is that NHS Wales should adopt this guidance or justify why it has not been followed. HTW will evaluate the impact of its guidance.*

## SUMMARY OF EVIDENCE APPRAISAL REPORT<sup>1</sup>

### Context

Faecal incontinence (FI) is the involuntary loss of solid or liquid faeces. It is a disabling and socially embarrassing condition. Damage to the anal sphincter mechanism or its nerve supply, age-related degeneration of the sphincter, spinal injury, or other neurological causes can all lead to chronic FI. FI is at first treated by conservative management, with a range of nonsurgical, non-invasive interventions. Where conservative managements fails to control FI, surgical treatment can be used. SNS is a surgical technique that involves insertion of an electrode through a sacral foramen (usually S3), which then stimulates the nerve roots via a battery-powered pulse generator. All patients undergo a trial period to determine whether they will be responsive to SNS (usually a threshold of at least 50% reduction in FI episodes is used). In NHS Wales, commonly used surgical treatments in this scenario are the injection of bulking agents or creation of a stoma. People with FI due to sphincter defect may be offered sphincter repair or replacement initially; if this treatment fails, these people may also be candidates for SNS.

Two SNS devices are commercially available in the UK: the Medtronic Interstim system, which obtained CE marking in 2004, and the Axonics r-SNM system, which received CE marking in 2016. All of the clinical and cost-effectiveness evidence considered in this appraisal relates to the Medtronic Interstim system. SNS devices cost between £8,336 and £8,610.

In NHS England, SNS is offered to some adult patients with FI in line with a Clinical Commissioning Policy Statement (NHS Commissioning Board, 2013). This states that this treatment should only be offered to patients who meet all of a number of criteria, including disease that is severe and life-limiting, has not responded to conservative management, sphincter surgery is deemed inappropriate, and has improved after a trial simulation period. However, no equivalent policy exists in NHS Wales.

### Evidence on clinical effectiveness, safety, economic analysis and patient issues

Three randomised trials compared SNS to optimal medical therapy, PTNS or bulking agent injection. In each trial, SNS was more beneficial than the control treatment in reducing the frequency of FI episodes. Better quality of life (measured using FI-specific scales) was also reported by patients receiving SNS in each of the trials.

Comparative clinical evidence is available for a relatively short follow-up period (minimum 4 weeks; maximum 12 months). In a multicentre European study that followed patients up for a median of 84 months after SNS implantation, 194 out of 237 recruited patients had at least 50% reduction in FI frequency at last follow up, and 136 (57.3%) achieved full continence.

Published cost-effectiveness results and additional analyses by HTW suggest that SNS is more effective but also more costly than conservative management. The most relevant analysis was published in 2008; an updated analysis using a structure offered by the literature resulted in a similar incremental cost effectiveness ratio to the published results (in the range of £20,000 to £30,000 per quality-adjusted life-year (QALY) gained. Extending the model time horizon to a plausible longer term would improve the ICER and could be argued to be a more accurate estimate. Patients who experienced large improvements to their QALYs would theoretically result in lower ICERs even following device replacement.

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<sup>1</sup>Summary of Evidence Appraisal Report intended for use by decision-makers in NHS Wales.

## Organisational issues

Based on estimated incidence in NHS England, approximately 30 patients per year in NHS Wales have FI that may be suitable for treatment with SNS (that is, they have FI that cannot be managed conservatively, and meets the criteria outlined in NICE Clinical Guideline 49). A pilot scheme, in approximately 10 patients, is planned in NHS Wales which will give access to SNS (using the Medtronic Interstim device) via Value Based Procurement.

The permanent stimulator is battery-operated; batteries last for several years but this may vary according to factors such as stimulation parameters. For the Medtronic Interstim II device, the manufacturer estimates the battery life to be 4 to 7 years; experts report that from clinical experience, batteries last between 5 and 10 years. Once the battery is depleted, replacement is required: the device incorporates a battery indicator to allow judgement on when replacement is needed.

## Further research

Research into the long-term effectiveness of sacral nerve stimulation is recommended. This should capture outcomes including changes in frequency of faecal continence, quality of life, patient satisfaction, adverse events (particularly those that lead to device removal) and time to battery depletion/replacement.

## Responsibilities for consideration of this Guidance

Health Technology Wales (HTW) was established by Ministerial recommendation<sup>1,2</sup> to support a strategic, national approach to the identification, appraisal and adoption of non-medicine health technologies into health and care settings. The HTW Appraisal Panel comprises senior representation from all Welsh boards with delegated authority to produce guidance 'from NHS Wales, for NHS Wales'. The status of HTW guidance is 'adopt or justify'. There is an expectation from Welsh Government that HTW guidance is implemented with adoption regularly audited by HTW.<sup>3</sup>

The guidance in this document is intended to assist Welsh care system decision makers to make evidence-informed decisions when determining the place of health technologies and thereby improve the quality of care services.

The content of this HTW guidance was based upon the evidence and factors available at the time of publication. An international evidence base was reviewed and external topic experts and HTW committee members consulted to contextualise available evidence to Wales. Readers are asked to consider the generalisability of the evidence reviewed to NHS Wales and that new trials and technologies may have emerged since first publication and the evidence presented may no longer be current. It is acknowledged that evidence constitutes only one of the sources needed for decision making and planning.

This guidance does not override the individual responsibility of health professionals to make decisions in the exercise of their clinical judgment in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

No part of this guidance may be used without the whole of the guidance being quoted in full. This guidance represents the view of HTW at the date noted. HTW guidance is not routinely updated. It may, however, be considered for review if requested by stakeholders, based upon the availability of new published evidence which is likely to materially change the guidance given.

Standard operating procedures outlining HTWs evidence review methods and framework for producing its guidance are available from the HTW website.

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Declarations of interest were sought from all reviewers. All contributions from reviewers were considered by HTWs Assessment Group. However, reviewers had no role in authorship or editorial control and the views expressed are those of Health Technology Wales.

Chair, Health Technology Wales Appraisal Panel

1. National Assembly for Wales, Health and Social Care Committee. Access to medical technologies in Wales. December 2014.
2. Response to Recommendations from the Health & Social Care Committee: Inquiry into Access to Medical Technologies in Wales. February 2015.
3. Gething, V. Letter to all Health Board Chairs re Funding for Sacral Nerve Stimulation in Wales. VG\_01655\_17. September 2017.



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