



Topic Exploration Report

Topic explorations are designed to provide a high-level briefing on new topics submitted for consideration by Health Technology Wales. The main objectives of this report are to:

1. Inform discussions on new topics received by HTW.
2. Determine the quantity and type of evidence available on a topic.
3. Assess the topic against HTW selection criteria.

Topic:	Sacral nerve stimulation for the treatment of faecal incontinence
Topic exploration report number	TER001
Referrer:	Julie Cornish, Consultant Surgeon, Cardiff and Vale University Health Board
Topic exploration undertaken by:	Health Technology Wales

Aim of Search

Health Technology Wales researchers searched for evidence on the clinical and cost effectiveness of sacral nerve stimulation compared to conventional therapy/no therapy for the treatment of faecal incontinence.

Summary of Findings

A Cochrane review published in 2015 assessed the clinical effectiveness of sacral nerve stimulation for faecal incontinence in adults. Based on evidence from six randomised or quasi-randomised trials, this review tentatively concludes that SNS is clinically effective, but notes that more rigorous randomised trials are needed to allow assessment with more certainty. Several other systematic reviews were identified that also included evidence from non-randomised trials. It is not clear whether all the evidence included a control group.

Several economic evaluations were identified, including one from the UK healthcare perspective, although this was published in 2008.

Systematic reviews

Seven potentially systematic reviews were identified, published between 2011 and 2017. All but one of the reviews appear to include trials of any design; a Cochrane review from 2015 included RCTs and quasi-RCTs. Two of the reviews, including the most recent published in 2017, only cover a subset of the population of interest.

Economic evaluations

Several potentially relevant economic evaluations have been published, but most are old. One from the UK perspective was published in 2008.

Other sources

NHS England published a Clinical Commissioning Policy Statement on Sacral Nerve Stimulation for Faecal Incontinence in Adults in April 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 use of a trial simulation period. This statement is based on evidence reviewed at the time this statement was issued in 2013, and this may now be out of date.

Conclusions

Evidence exists about the clinical effectiveness of SNS to treat faecal incontinence, but there may be uncertainty about the effectiveness of SNS due to the low quality of this evidence. Evidence exists about the cost effectiveness of SNS to treat faecal incontinence, but it is unclear whether this evidence is relevant and up-to-date enough to be useful for decision making.

Areas of Uncertainty

It is not clear at this stage where SNS is intended to be used in the faecal incontinence treatment pathway, or whether the evidence suggests that use in a particular subgroup of people would be most clinically and cost effective.

Feasibility of Technology Assessment

There appear to be sufficient published research findings available upon which to base a technology assessment. There is uncertainty about the clinical or cost-effectiveness of the technology: the magnitude and certainty of health benefits offered by SNS are unknown until the evidence has been fully assessed.

HTW's Assessment Group concluded to progress this topic to Evidence Appraisal. This was published as EAR003.

Brief literature search results

Resource	Results
UK guidelines and guidance	
Healthcare Improvement Scotland:	We did not identify any results on SNS from this source.
NICE	<p>Faecal incontinence pathway: https://pathways.nice.org.uk/pathways/faecal-incontinence</p> <p>NICE IPG99. Sacral nerve stimulation for faecal incontinence. 2004. https://www.nice.org.uk/guidance/ipg99 Review body report (systematic review): https://www.nice.org.uk/guidance/ipg99/evidence/systematic-review-of-the-efficacy-and-safety-of-sacral-nerve-stimulation-for-faecal-incontinence-pdf-302617261</p> <p>NICE. Faecal incontinence in adults: management. CG49. 2007. https://www.nice.org.uk/guidance/cg49 (last reviewed: 2010) Recommendations on SNS: Consider a trial of temporary sacral nerve stimulation if sphincter surgery is deemed inappropriate. This may be for patients with intact anal sphincters, or those with sphincter disruption. In those with a defect, contraindications to direct repair may include atrophy, denervation, a small defect, absence of voluntary contraction, fragmentation of the sphincter or a poor-quality muscle. Inform everyone of the potential benefits and limitations of this procedure. People should undergo a trial stimulation period of at least 2 weeks to determine if they are likely to benefit. Offer people with faecal incontinence sacral nerve stimulation on the basis of their response to percutaneous nerve evaluation during specialist assessment, which is predictive of therapy success. Assess and manage people being considered for sacral nerve stimulation at a specialist centre that has experience of performing this procedure.</p> <p>Quality standard: Faecal incontinence in adults (QS54). https://www.nice.org.uk/guidance/qs54 (makes no specific recommendations on SNS)</p>
Secondary literature and economic evaluations	
Cochrane library	<p>Cochrane reviews/other systematic reviews</p> <p>Thaha et al. Sacral nerve stimulation for faecal incontinence and constipation in adults. Cochrane Database of Systematic Reviews. 2015. DOI: 10.1002/14651858.CD004464.pub3</p> <p>Brown. Surgery for faecal incontinence in adults. Cochrane Database of Systematic Reviews. 2013. DOI: 10.1002/14651858.CD001757.pub4 (does not include SNS)</p> <p>Technology Assessments None identified</p>

	<p>Economic evaluations</p> <p>Dudding T C, Lee E M, Faiz O, Pares D, Vaizey C J, McGuire A, Kamm M A. Economic evaluation of sacral nerve stimulation for faecal incontinence. <i>British Journal of Surgery</i> 2008; 95(9): 1155-1163 (UK perspective)</p> <p>Munoz-Duyos A, Navarro-Luna A, Brosa M, Pando JA, Sitges-Serra A, Marco-Molina C. Clinical and cost effectiveness of sacral nerve stimulation for faecal incontinence. <i>British Journal of Surgery</i> 2008; 95(8): 1037-1043 (Spanish perspective)</p> <p>NETSCC. A randomised comparison of the Fenix® magnetic anal sphincter versus sacral nerve stimulation for adult faecal incontinence. <i>Health Technology Assessment</i> (ongoing study) http://www.crd.york.ac.uk/crdweb/ShowRecord.asp?LinkFrom=OAI&ID=32014000344 https://www.journalslibrary.nihr.ac.uk/programmes/hta/123507#/</p> <p>van Wunnik BP, Visschers RG, van Asselt AD, Baeten CG. Cost-effectiveness analysis of sacral neuromodulation for faecal incontinence in the Netherlands. <i>Colorectal Disease</i>.2012;14(12):e807-e814</p>
Evidence.nhs.uk	<p>Systematic reviews</p> <p>Kong E. A systematic review of sacral nerve stimulation for faecal incontinence following ileal pouch anal anastomosis. <i>Updates Surg</i>. 2017 Oct 30. doi: 10.1007/s13304-017-0496-y. [Epub ahead of print] (covers a subset of causes of faecal incontinence only. Includes all study types)</p> <p>Mirbagheri N. Systematic review of the impact of sacral neuromodulation on clinical symptoms and gastrointestinal physiology. <i>ANZ J Surg</i>. 2016 Apr;86(4):232-6. doi: 10.1111/ans.13257. (includes all study types)</p> <p>Thaha et al. Sacral nerve stimulation for faecal incontinence and constipation in adults. <i>Cochrane Database of Systematic Reviews</i>. 2015. DOI: 10.1002/14651858.CD004464.pub3 (RCTs and quasi-RCTs. Tentatively supports the use of SNS, but notes that more rigorous trials are needed to allow assessment with more certainty)</p> <p>Ramage L. A systematic review of sacral nerve stimulation for low anterior resection syndrome. <i>Colorectal Dis</i>. 2015 Sep;17(9):762-71. doi: 10.1111/codi.12968. (this covers a subset of causes of faecal incontinence only)</p> <p>Ratto C, Litta F, Parello A, Donisi L, De Simone V, Zaccone G. Sacral nerve stimulation in faecal incontinence associated with an anal sphincter lesion: a systematic review. <i>Colorectal Disease</i> 2012; 14(6): e297-e304. https://www.ncbi.nlm.nih.gov/pubmed/22356165 (any study design)</p>

Tan E, Ngo NT, Darzi A, Shenouda M, Tekkis PP. Meta-analysis: sacral nerve stimulation versus conservative therapy in the treatment of faecal incontinence. *International Journal of Colorectal Disease* 2011; 26(3): 275-294. <https://www.ncbi.nlm.nih.gov/pubmed/21279370> (any study design)

Maeda Y, Matzel K, Lundby L, Buntzen S, Laurberg S. Postoperative issues of sacral nerve stimulation for fecal incontinence and constipation: a systematic literature review and treatment guideline. *Diseases of the Colon and Rectum* 2011; 54(11): 1443-1460. PubMedID: 21979192 (older than other reviews, but may contain some safety-focussed outcomes)

NICE IPG99. Review body report (systematic review). 2004:
<https://www.nice.org.uk/guidance/ipg99/evidence/systematic-review-of-the-efficacy-and-safety-of-sacral-nerve-stimulation-for-faecal-incontinence-pdf-302617261>

Economic evaluations

Dudding T C, Lee E M, Faiz O, Pares D, Vaizey C J, McGuire A, Kamm M A. Economic evaluation of sacral nerve stimulation for faecal incontinence. *British Journal of Surgery* 2008; 95(9): 1155-1163 (UK perspective)

Munoz-Duyos A, Navarro-Luna A, Brosa M, Pando JA, Sitges-Serra A, Marco-Molina C. Clinical and cost effectiveness of sacral nerve stimulation for faecal incontinence. *British Journal of Surgery* 2008; 95(8): 1037-1043 (Spanish perspective)

HAYES, Inc.. Staged approach to sacral nerve stimulation for treatment of fecal incontinence. Lansdale: HAYES, Inc.. Directory Publication. 2015. <http://www.hayesinc.com/hayes/crd/?crd=35706>

NETSCC. A randomised comparison of the Fenix® magnetic anal sphincter versus sacral nerve stimulation for adult faecal incontinence. Health Technology Assessment (ongoing study)
<http://www.crd.york.ac.uk/crdweb/ShowRecord.asp?LinkFrom=OAI&ID=32014000344>
<https://www.journalslibrary.nihr.ac.uk/programmes/hta/123507#/>

Leroi A-M, Lenne X, Dervaux B, Chartier-Kastler E, Mauroy B, Normand LL, Grise P, Faucheron JL, Parc Y, Lehur PA, Mion F, Damon H, Barth X, Leriche A, Saussine C, Guy L, Haab F, Bresler L, Sarramon JP, Bensadoun H, Rullier E, Slim K, Sielezneff I, Mourey E, Ballanger P, Michot F. Outcome and cost analysis of sacral nerve modulation for treating urinary and/or fecal incontinence. *Annals of Surgery* 2011; 253(4): 720-732 (health system unclear - France?)

	<p>Indinnimeo M, Ratto C, Moschella CM, Fiore A, Brosa M, Giardina S. Sacral neuromodulation for the treatment of fecal incontinence: analysis of cost-effectiveness. <i>Diseases of the Colon and Rectum</i> 2010; 53(12): 1661-1669 (Italian healthcare system)</p> <p>Guidelines</p> <p>NICE. Faecal incontinence in adults: management. CG49. 2007. https://www.nice.org.uk/guidance/cg49 (last reviewed: 2010)</p> <p>American Society of Colon and Rectal Surgeons' Clinical Practice Guideline for the Treatment of Fecal Incontinence. <i>Dis Colon Rectum</i> 2015; 58: 623-636. DOI: 10.1097/DCR.0000000000000397 (clinical guideline based on systematic review. Includes some recommendations on SNS based on <i>Thin NN, Horrocks EJ, Hotouras A, et al. Systematic review of the clinical effectiveness of neuromodulation in the treatment of faecal incontinence. Br J Surg. 2013;100:1430-1447</i>).</p> <p>Other sources</p> <p>NHS England. Clinical Commissioning Policy Statement: Sacral Nerve Stimulation (SNS) for Faecal Incontinence in Adults. April 2013. Policy Statement: https://www.england.nhs.uk/wp-content/uploads/2013/04/a08-ps-b.pdf Supporting report: https://www.england.nhs.uk/commissioning/wp-content/uploads/sites/12/2013/08/a08-p-b.pdf</p> <p>NICE Shared Learning Database. The insertion of temporary sacral nerve stimulator can be carried out under local anaesthetic without compromising outcome and with positive effect on cost. 2009. https://www.nice.org.uk/sharedlearning/the-insertion-of-temporary-sacral-nerve-stimulator-can-be-carried-out-under-local-anaesthetic-without-compromising-outcome-and-with-positive-effect-on-cost</p> <p>Bielefeldt K. Adverse events of sacral neuromodulation for fecal incontinence reported to the federal drug administration. <i>World J Gastrointest Pharmacol Ther.</i> 2016 May 6;7(2):294-305. doi: 10.4292/wjgpt.v7.i2.294.</p> <p>Royal College of Surgeons. 2017. Commissioning guide: Faecal Incontinence. (“The commissioning of Sacral Nerve Stimulation (SNS) sits outside of this guide as it is commissioned nationally by NHS England.”)</p>
<p>Other</p> <p>Evidence identified by topic proposer</p>	<p>Zhu Y. [Meta-analysis of sacral nerve stimulation for fecal incontinence]. [Article in Chinese]. <i>Zhonghua Wei Chang Wai Ke Za Zhi.</i> 2017 Dec 25;20(12):1417-1421.</p>

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Concepts used:	Sacral nerve stimulation, sacral neuromodulation, faecal incontinence, fecal incontince, anal continence