Title:	**Sacral nerve stimulation implant (SNSI) for refractory lower urinary tract dysfunction of the following types: urge incontinence, urgency-frequency, and retention/overflow - May 2002**
Agency:	Medical Services Advisory Committee (MSAC) Commonwealth Department of Health and Ageing GPO Box 9848 Canberra ACT 2601 Australia **http://www.msac.gov.au**
Reference:	**MSAC application 1046.**

Aim

To assess the safety, effectiveness and cost effectiveness of the procedure and the circumstances under which public funding should be supported for the procedure.

Conclusions and results

Safety Published results of a multicentre randomised controlled trial (MDT-103) showed that the incidence of adverse events was relatively high. In 518 patients undergoing screening tests to identify suitable patients, approximately one in four patients experienced an adverse event, most often device related (i.e. lead migration). Among 219 patients treated with SNSI, 52 per cent experienced at least one adverse event, most often due to pain. Of patients experiencing at least one adverse event, approximately 65% required hospitalisation or surgical intervention.

Effectiveness The randomised controlled trial indicated that, for patients passing a screening test, more patients treated with SNSI achieved a full response than those treated with standard care: urge incontinence - risk difference (RD) 30.8 per cent (95% CI 18.2%, 43.3%); urgency frequency - 23.7 per cent (95% CI 8.3%, 39.1%); retention/overflow - 47.6% (29.4%, 65.8%). Treatment response appeared to be maintained over time however 50 per cent of patients had 12 months or less follow-up data reported. Impact on quality of life is uncertain.

Cost-effectiveness Cost effectiveness ratios are commercial-in-confidence as unpublished data were used in computing them. The incremental cost per additional patient with a full response was sensitive to assumed duration of sustained response.

Recommendation

MSAC recommended that public funding should not be supported for this technology at this time as insufficient additional evidence of safety, effectiveness or cost-effectiveness has emerged since it was previously considered (February 2000) by the MSAC.

Method

MSAC conducted a systematic review of the medical literature from 1966 to March 2002 accessed via Medline, PreMedline, Embase, Current Contents and the Cochrane Library. Health technology assessment websites were also searched. Safety and effectiveness were assessed in a randomised controlled trial of 260 patients that compared SNSI with standard care in patients with refractory lower urinary tract incontinence: urge incontinence, urgency-frequency and retention/overflow. Cost effectiveness was assessed using an economic model that incorporated costs of urinary incontinence associated with standard care versus SNSI and QALYs derived from the literature.