PEER REVIEW HISTORY

ARTICLE DETAILS

TITLE (PROVISIONAL)	Impact of National Institute for Health and Care Excellence (NICE) guidance on medical technology uptake: Analysis of the uptake of spinal cord stimulation in England 2008-2012
AUTHORS	Hallas, Natalie; Vyawahare, Bharati; Brookes, Morag; Taylor, Rod; Eldabe, Sam

VERSION 1 - REVIEW

REVIEWER	Hegarty, Dominic Cork University Hospital, Dept. Anaesthesia & Pain Medicine
REVIEW RETURNED	18-Oct-2013

GENERAL COMMENTS	This study sought to report the uptake of SCS since the publication of NICE guidelines in 2008. Compared to the number of cases pre-2008 they found that a similar number of “procedures” were implanted annually in 4 year window following the publication of the guidelines. There are some elements that should be noted; Firstly, retrospective database research is only as strong as the quality of the records examined and it is surprising to find the authors only consulted a single database when combining several source would have captured a more complete picture of the national activity levels. Secondly, the quality of this data itself is also uncertain given the imprecise nature of the coding structure currently in place. The authors found it difficult to classify the type of work done based on the codes. Any interpretation of this data, either within a national or international context, will merely represent a comment rather than solid fact because of this inherent weakness. Leaving these two issues aside momentarily what the results do insinuate is that if the neuromodulation community expect the publication of a set of guidelines to suddenly change implantation rates then nothing will change in the future. Why is it that the expected 10% increase in uptake annually has not happened? Why is it that even with a mandatory duty a cost-effective treatment is not being availed of in a time when cost-saving is critical? The authors propose that there are several reasons for this, however, clinical awareness of the benefits of SCS must surely be a fundamental element; unless the treatment is recommended for a greater number of patients then growth will remain stagnant. This paper highlights the need for the neuromodulation community to continue to alert all doctors who meet patients in chronic pain to the treatment options available.

REVIEWER	Nick Donaldson University College London
REVIEW RETURNED	25-Oct-2013

GENERAL COMMENTS	This is an interesting paper. Figure 3 suggests that the post-code lottery effect is strong with one PCT referring 44 patients while several others only referred one. The authors say that the reason for this is multifactorial but Figure 4 shows that PCTs had different policies on SCS. Were these policies influential in this great disparity of referrals? Given this data is available; I wonder why the authors did not look for correlation between policy and number of patients referred. The rise in the number of implantations of electrodes (A48.7 in Figure 2) is striking. This category is thought to include trials, which I take to mean implantation of electrodes which are then used with a temporary stimulator to see whether the treatment for pain is effective. One might interpret this rise as being a positive response to the NICE guidance, but as there is no corresponding rise in permanent implantations (A48.3) the treatment must have usually been ineffective. That seems rather unlikely. Anyway, if that is the correct interpretation, surely Medtronic would know that the number of electrode arrays sold is much greater than the number of stimulators (IPGs)

REVIEWER	Arthur Sherwood Baylor College of Medicine Houston, TX 77030 USA
REVIEW RETURNED	28-Oct-2013

GENERAL COMMENTS	The paper describes what appears to be a reasonable approach to the problem at hand. The authors provide a reasoned response to prior reviewer comments (some of which appear to be somewhat biased with respect to the procedure). What was not discussed was the potential efficacy of the procedure for pain. The reason trial stimulation is needed is that it is very difficult to predict the response to stimulation even in apparently identical situations. Further, if pain relief isn't 100% (and it rarely is), the subjects respond in different ways to the residual pain; some deem it sufficient to stop the trial. The reference (8) cited by Richard North does not support the contention that a high percentage go on to permanent implant; rather just the opposite "the important subset of patients who might have been implanted after a shorter trial, only to fail thereafter." This mis-statement may help explain the discrepancy in guideline compliance.

VERSION 1 – AUTHOR RESPONSE

Reviewer Name: Hegarty, Dominic
Institution and Country Cork University Hospital, Dept. Anaesthesia & Pain Medicine
Please state any competing interests or state 'None declared': None

1. This study sought to report the uptake of SCS since the publication of NICE guidelines in 2008. Compared to the number of cases pre-2008 they found that a similar number of "procedures" were implanted annually in 4 year window following the publication of the guidelines. There are some elements that should be noted;

Firstly, retrospective database research is only as strong as the quality of the records examined and it is surprising to find the authors only consulted a single database when combining several source would have captured a more complete picture of the national activity levels.

We agree with the reviewer's comment regarding the data quality. However, we do not know of an existing database that can be consulted for similar data apart from manufacturer records which will be limited to sales volume data rather than indication and procedural type. Given the number of manufacturers on the market we did not think that would be helpful. We are aware that the Neuromodulation Society of the UK and Ireland is developing a national registry for implants; this is not yet fully operational but it should allow us to revisit the impact of the NICE guidance in 1-2 years using data from both sources.

2. Secondly, the quality of this data itself is also uncertain given the imprecise nature of the coding structure currently in place. The authors found it difficult to classify the type of work done based on the codes. Any interpretation of this data, either within a national or international context, will merely represent a comment rather than solid fact because of this inherent weakness.

We agree, and we have acknowledged and commented on this limitation of the data within the Methods section (paragraph 2).

3. Leaving these two issues aside momentarily what the results do insinuate is that if the neuromodulation community expect the publication of a set of guidelines to suddenly change implantation rates then nothing will change in the future. Why is it that the expected 10% increase in uptake annually has not happened? Why is it that even with a mandatory duty a cost-effective treatment is not being availed of in a time when cost-saving is critical? The authors propose that there are several reasons for this, however, clinical awareness of the benefits of SCS must surely be a fundamental element; unless the treatment is recommended for a greater number of patients then growth will remain stagnant. This paper highlights the need for the neuromodulation community to continue to alert all doctors who meet patients in chronic pain to the treatment options available.

Again we are in full agreement with the reviewer on this important point. We have amended our manuscript within the discussion and conclusion sections appropriately (p.10). These additions highlight that the lack of clinical awareness amongst the wider referral base is a key factor in the limited uptake of SCS. We have also alluded to the need for more pro-active engagement by the neuromodulation community to initiate these changes and raise the profile of SCS as a treatment option.

Reviewer: Reviewer Name Nick Donaldson
Institution and Country University College London
Please state any competing interests or state 'None declared': None declared

1. Table 1b has a cell in grey that should be white (I guess). Authors use "minimal" when they mean "small".

We have amended the manuscript accordingly to correct these issues.

2. This is an interesting paper. Figure 3 suggests that the post-code lottery effect is strong with one PCT referring 44 patients while several others only referred one. The authors say that the reason for this is multifactorial but Figure 4 shows that PCTs had different policies on SCS. Were these policies influential in this great disparity of referrals? Given this data is available; I wonder why the authors did not look for correlation between policy and number of patients referred.

This is a good suggestion, and whilst the level of data does not allow for a formal statistical analysis of the correlation between policy status and the number of patient referred, we have revisited the data to investigate whether a qualitative correlation can be ascertained. We have found evidence of some correlation at a regional level, and we have incorporated these additional observations into the manuscript (Results, p.5).

3. The rise in the number of implantations of electrodes (A48.7 in Figure 2) is striking. This category is thought to include trials, which I take to mean implantation of electrodes which are then used with a temporary stimulator to see whether the treatment for pain is effective. One might interpret this rise as being a positive response to the NICE guidance, but as there is no corresponding rise in permanent implantations (A48.3) the treatment must have usually been ineffective. That seems rather unlikely. Anyway, if that is the correct interpretation, surely Medtronic would know that the number of electrode arrays sold is much greater than the number of stimulators (IPGs).

There are at least three different manufacturers in the SCS market hence it is not possible to ascertain the sales volume correlating to trials/implants for all manufacturers. Collecting data from only one manufacturer would return incomplete and inaccurate data therefore we do not feel that this is a viable option. The explanation we have offered to explain the large increase in trial procedures, namely miscoding (Discussion, p.8), is reasonable as we agree that ineffective trials to this extent seem unlikely.

Reviewer: Reviewer Name Arthur Sherwood
Institution and Country Baylor College of Medicine
Houston, TX 77030 USA
Please state any competing interests or state ‘None declared’: none declared

1. The paper describes what appears to be a reasonable approach to the problem at hand. The authors provide a reasoned response to prior reviewer comments (some of which appear to be somewhat biased with respect to the procedure).

What was not discussed was the potential efficacy of the procedure for pain. The reason trial stimulation is needed is that it is very difficult to predict the response to stimulation even in apparently identical situations. Further, if pain relief isn’t 100% (and it rarely is), the subjects respond in different ways to the residual pain; some deem it sufficient to stop the trial.

We believe that the nature and extent of the response to the trial of SCS is not within the scope of our article, but generally most authors cite around an 80% conversion rate from trial to final implant, with 50% of patients expressing long term pain relief of over 50%. The three key randomised controlled trials on SCS for neuropathic pain reviewed within the Health Technology Assessment on

SCS had conversion rates ranging from 71-83% (Simpson et al., 2009; Health Technology Assessment 2009, Vol. 13, No. 17).

2. The reference (8) cited by Richard North does not support the contention that a high percentage go on to permanent implant; rather just the opposite “the important subset of patients who might have been implanted after a shorter trial, only to fail thereafter.” This mis-statement may help explain the discrepancy in guideline compliance.

We feel that the article supports a high conversion rate form trial to final implants in SCS. Indeed, North states "A decade ago, we reviewed a 20-year experience with SCS at our institution; we reported a 78% rate of “successful” SCS trials proceeding to permanent implant". Whilst this is less than the 96% conversion figure that the article is commenting on, North does agree that a high percentage of trials proceed to final stage implants.