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Journal:	*BMJ Open*
Manuscript ID:	bmjopen-2013-004182
Article Type:	Research
Date Submitted by the Author:	06-Oct-2013
Complete List of Authors:	Vyawahare, Bharati; James Cook University Hospital, Department of Pain and Anaesthesia Hallas, Natalie; Medtronic UK, Neuromodulation Brookes, Morag; James Cook University Hospital, Department of Pain and Anaesthesia Taylor, Rod; University of Exeter, Peninsula Medical School Eldabe, Sam; James Cook University Hospital, Department of Pain and Anaesthesia
Primary Subject Heading:	Health policy
Secondary Subject Heading:	Anaesthesia, Health economics, Neurology
Keywords:	Pain management < ANAESTHETICS, Health economics < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Health policy < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Neurological pain < NEUROLOGY, PAIN MANAGEMENT

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

Bharati Vyawahare[1], Natalie Hallas[2], Morag Brookes[1], Rod S Taylor[3] & Sam Eldabe[1]

1. Department of Pain and Anaesthesia, James Cook University Hospital, Middlesbrough
2. Medtronic Limited UK, Watford, Hertfordshire
3. Institute of Health Research, University of Exeter Medical School, Exeter

Abstract

Background: The National Institute for Health and Care Excellence (NICE) Technology Appraisal Guidance on spinal cord stimulation (SCS) was published in 2008 and updated in 2012 with no change. This guidance recommends SCS as a cost effective treatment for patients with neuropathic pain.

Objective: To assess the impact of NICE guidance by comparing SCS uptake in England pre- (2008-2009) and post- (2009-2012) NICE guidance. We also compared the English SCS uptake rate with Belgium, Netherlands, France and Germany.

Design: SCS implant data for England was obtained from the Hospital Episode Statistics database (HES) and compared with other European countries where comparable data were available.

Results: The HES data showed minimal increases in SCS implantation and replacement/revision procedures, and a large increase in SCS trials between 2008 and 2012. The increase in the total number of SCS procedures per million of population in England is driven primarily by revision/replacements and increased trial activity. Marked variability in SCS uptake at both health regions and primary care trust level was observed.

Conclusion: Despite the positive NICE recommendation for the routine use of SCS, we found no evidence of a significant impact on SCS uptake in England. Rates of SCS implantation in England are lower than many other European countries.

Article Summary

1. **Article Focus**
   - The NHS in England and Wales is legally obligated to fund NICE Technology Appraisal-approved technologies within 90 days. The NICE Technology Appraisal approving Spinal Cord Stimulation for Neuropathic Pain was published in 2008.
   - We examined the impact of the NICE Technology Appraisal on the overall uptake of spinal cord stimulation in England, in addition to regional variations in patient access.

2. **Key Messages**
   - The NICE Technology Appraisal publication appears to have had minimal impact on the uptake of spinal cord stimulation for new patients, and inequity of patient access remains despite clear evidence that this treatment is a cost-effective use of NHS resources.
   - Reasons for this are multifactorial and include lack of guideline awareness, commissioning variation, lack of enforcement of NICE guidance and limited capacity at implanting centres.
   - Some of these patient access barriers may be addressed with centralised commissioning of specialised services including spinal cord stimulation.

3. **Strengths/limitations**
   - This study contributes a novel data analysis in the area of spinal cord stimulation, which highlights a lack of uptake of a cost-effective technology within the NHS.
   - Our findings are based on data extracted from the Hospital Episodes Statistics database which relies on hospital coded data on procedures and indications.

Introduction

The National Institute for Health and Care Excellence (NICE) is a Department of Health funded arms-length body, established in 1999 to principally reduce 'the postcode lottery' i.e. the variation in the availability and quality of NHS treatments and care in England and Wales(1, 2). NICE publishes various types of guidance including Technology Appraisals (TA), Clinical Guidelines, Quality Standards and Interventional Procedures Guidance (2). The TA guidance is based on evaluations of clinical and cost-effectiveness of selected technologies. The NHS is legally obliged to provide funding for medicines and treatments recommended within 3 months of the guidance (1). In December 2011, The Department of Health announced in its Innovation, Health and Wealth report that commissioners are expected to provide access to new treatments within 90 days of approval (1,3).

NICE TA guidance 159 on Spinal Cord Stimulation (SCS) for chronic pain of neuropathic or ischaemic origin was published in October 2008 and reviewed in January 2012 when no changes were made (4). This TA guidance approves SCS for adults with continued chronic neuropathic pain (measuring at least 50mm on 0-100mm visual analogue score) for at least 6 months despite all standard conventional treatment and after undergoing a successful trial of SCS by a multidisciplinary team (4).

We examined the data for SCS uptake in England between 2008 and 2012 in order to assess the impact of NICE TA guidance implementation. We compared this to the SCS implant rate in other European countries. Data was also requested from all Primary Care Trusts via a Freedom of Information request with regards to their SCS commissioning policy to determine whether a policy around the implementation of NICE guidance was in place or whether Individual Funding Requests (IFR) were being used.

Methods

Data for pre- (2008-2009) and post- (2009-2010; 2010-2011; 2011-2012) NICE TA 159 publication for SCS procedural activity was obtained from the Hospital Episode Statistics (HES) database (5) , using the QUANTIS system via NHiS (6). HES is a national statistical data warehouse for England of the care provided by NHS hospitals. QUANTIS is a database of NHS and social care numerical data for the UK and NHiS is a vendor that provides subscribed access to the QUANTIS database.

We examined OPCS-4 procedure codes A48.3 (Implantation of neurostimulator adjacent to spinal cord), A48.4 (Attention to neurostimulator adjacent to spinal cord) and A48.7 (Insertion of neurostimulator electrodes into spinal cord). The OPCS code A48.3 was assumed to reflect new permanent SCS implants, code A48.4 to contain both replacements and revisions, and code A48.7 to represent trial procedures. OPCS code 48.4 does not allow for a clear differentiation between battery replacement and revisions.

The relevant SCS codes were filtered by indication to ensure that only back pain and spinal indications were included. This eliminated any inclusion of other types of neurostimulation that may have been miscoded, for example for bowel and bladder indications. SCS uptake results are expressed per million populations across each Strategic Health Authority regions in England. We also compared uptake rates across Primary Care Trusts (PCT).

Oracle (11g Database) and Excel (Microsoft Office 2010 Pro) software programmes were utilised for the data analysis. We compared English SCS uptake data from 2011-12 (code A48.3 only) with European counties where we able to source the appropriate equivalent data, i.e. France, Belgium, Germany and the Netherlands (7).

Results

The HES data analysis for year 2008-2012 showed a small increase in procedure codes 48.3 and 48.4 (Table 1a) and large increase in procedure code 48.7. Figure 2 illustrates the activity trends for each separate procedure code. On analysis of each of the procedure codes, the increase in SCS procedures appears to be driven primarily by replacements, revisions and a large increase in trial activity. There was considerable variation in the rate of SCS uptake across Strategic Health Authorities throughout this time horizon. The

breakdown of the number of SCS procedures funded by PCTs in 2011-12 is shown in Figure 3, indicating considerable inequity of patient access to this NICE-approved treatment.

Table 1b compares the available European data against procedure code 48.3, reflecting the number of new SCS implants only. In France there was a small increase in the number of SCS implants per million of population for the period 2008-2010 (Table 1b). The rate of uptake of SCS per million of population in England is the lowest compared to these other European countries (Table 1b).

Figure 4 shows requested data from all Primary Care Trusts with regards to their SCS commissioning policy via a Freedom of Information request. The response rate was 60.9%, with 40.2% of PCTs requiring individual funding requests (IFR), 18.5% following a Specialised Commissioning Group policy, 15.2% following either PCT policy or with no active policy, and only 10.8% following NICE TA Guidance allowing automatic funding.

Table 1a. Total number of SCS procedures (combined A48.3 and A48.4 OPCS procedures) from 2008-2012.

Regional SHA	Population	2008 - 2009			2009 - 2010			2010 - 2011			2011 - 2012		
		No. cases	Cases / Million	95% CI	No. cases	Cases / Million	95% CI	No. cases	Cases / Million	95% CI	No. cases	Cases / Million	95% CI
East Midlands	4,380,276	25	5.7	4 – 8	53	12.1	9 - 15	56	12.8	10 - 16	75	17.1	14 - 21
East Of England	5,714,218	137	24.0	21 - 28	175	30.6	27 - 34	205	35.9	32 - 40	170	29.8	26 - 34
London	7,757,619	83	10.7	9 - 13	60	7.7	6 - 10	81	10.4	8 - 13	73	9.4	8 - 12
North East	2,577,541	136	52.8	47 - 59	120	46.6	41 - 53	95	36.9	31 - 43	112	43.5	38 - 50
North West	6,923,825	132	19.1	16 - 22	155	22.4	19 - 26	169	24.4	21 - 28	173	25.0	22 - 28
South Central	4,069,352	20	4.9	3 - 7	39	9.6	7 - 13	44	10.8	8 -14	38	9.3	7 - 13
South East Coast	4,302,298	92	21.4	18 - 26	81	18.8	15 - 23	106	24.6	21 - 29	108	25.1	21 - 29
South West	5,181,449	109	21.0	18 - 25	99	19.1	16 - 23	88	17.0	14 - 20	116	22.4	19 - 26
West Midlands	5,421,595	50	9.2	7 - 12	53	9.8	8 - 13	45	8.3	6 - 11	43	7.9	6 - 11
Yorkshire & the Humber	5,244,956	123	23.5	20 - 27	133	25.4	22 - 29	172	32.8	29 - 37	174	33.2	29 - 37
Total	**51,573,129**	**907**	**17.6**	**17 - 19**	**968**	**18.8**	**18 - 20**	**1,061**	**20.6**	**19 - 22**	**1,082**	**21.0**	**20 - 22**

Table 1b. Comparison of new SCS implants in UK (procedure code A48.3 only) against other European countries per year

Country	Yearly SCS/ Million			
	2008	2009	2010	2011
Belgium		84.6		
France	9.19	8.17	11.35	
Netherlands				54.3
Germany			11.7	
UK(England)			11	10.7

Place Figures 1- 4 here

Discussion

The NHS has a mandatory duty to fund and provide NICE-approved treatments recommended within a NICE TA within 90 days. However, our UK data analysis from 2008 to 2012 shows that NICE TA 159 had minimal impact on uptake of SCS in neuropathic pain. Although an increase of 19.3% in SCS procedures was observed over the four year period, this figure includes battery replacements and revisions in addition to new SCS permanent implants. When new SCS implants are considered alone, an increase in uptake of only 12.4% percent was observed between 2008 and 2012 (Figure 2), despite the NICE TA 159 advocating a 10% increase in uptake each year. Interestingly the substantial rise in procedure code 48.7 (trial procedures) does not appear to convert into a comparable increase in permanent SCS procedures. Given that the conversion rate of trial to permanent SCS implants is generally consistent at around 75-80% (8), accuracy in provider coding in this instance may be questioned.

There remains considerable regional inequality in patient access to this NICE approved treatment. The Right Care (9) is one of the national work streams in the Department of Health (DH) Quality Innovation Productivity and Prevention programme (QIPP) which identifies unwarranted variation in NHS treatments based on geographical areas (9, 10). One of the Right Care objectives for 2011-2012 is to minimise this unwarranted variation and maximise value (9). Value can be increased by improving quality, optimising resource utilisation and ensuring that patients receive appropriate interventions.

Our findings are in contrast with a NICE implementation report (11) that shows a generally effective impact of guidance for surgical procedures. For example, laparoscopic colorectal surgeries occurred at higher rate than forecasted by NICE (TA 105) (12). Laparoscopic inguinal hernia repair uptake increased following guidance, but it stabilised at lower levels than NICE forecasted (TA 83) (13). In addition, there was overall increase in bariatric surgery for morbid obesity following NICE guidance (CG 43) (14). Our study provides data on the marked variability in rate of SCS uptake at both health authority and PCT level.

NICE assessed SCS as a highly cost-effective treatment for failed back surgery syndrome with an incremental £10,480 per quality adjusted life year (QALY) ratio compared with

conventional medical management alone, and £9219 per QALY gained when compared with repeat back operation (4). These ratios are considerably below the UK willingness to pay threshold of £20,000 to 30,000 per QALY.

Despite mandatory TA guidance on SCS, the majority of PCTs required Individual Funding Requests (IFR) for each patient (Figure 4). Some PCTs rated SCS as a low priority procedure. The reasons for the barriers to funding are multifactorial and include lack of awareness of SCS referral guidelines, lack of NICE TAG enforcement at regional and national level, as well as a limitation of clinical capacity at implanting centres. Due to the limitations of the available data it is not possible to disentangle the factors responsible for the continuing inequity of funding for SCS implants. Yet we can comment that there has been no significant increase in the number of implanting centres. The capacity within existing centres is not showing a growth curve as expected in response to the NICE guidance. Only 10.8% of PCTs implemented NICE guidance as a funding policy (Figure 4). It is possible that piecemeal funding and the difficulties associated with such an approach, as well as the impact of the marked regional variations, have prevented the expansion of current providers. The reported incidence of failed back surgery syndrome is estimated as 10-40% of patients undergoing back surgery (15). In recent survey of the United Kingdom, 53% of pain clinics estimated 10% of their referrals comprised of failed back surgery syndrome patients and the remaining 47% of pain clinics estimated it as 20-30% of their referrals, therefore lack of candidates is unlikely (16).

In a comparison to France, Germany, Belgium and the Netherlands, England has the lowest rate of implants per million of the population. Smaller countries show a much higher rate of SCS implants (7), with Belgium and the Netherlands implanting 84.6 and 54.3 per million of population respectively. Nevertheless, for Belgium and the Netherlands only one year of data is available therefore we are unable to comment on trends. Data for France was available for the last three years (Table 1b) and shows no significant increase in SCS implants. The main indications for SCS are similar across the four countries i.e. failed back surgery syndrome or radicular pain, phantom pain, peripheral nerve injury, traumatic brachial plexus injury, spinal lesion, diabetic polyneuropathy and post herpetic neuralgia (7). Focusing on the most common indication for SCS of failed back surgery syndrome, it is estimated that 10-40% of patients undergoing spinal surgery will develop neuropathic pain (15). According to HES database, the number of spinal surgery procedures in England

in 2009-2010 was 117,803 (17). Assuming that one third of these procedures is being carried out for pain, the annual estimate will be 78,533 procedures of which 10% to 40 % (7,853 to 31,414) would be expected to be eligible for SCS treatment (16). Based on this data, less than 2% of the eligible population of neuropathic patients in England are currently receiving SCS treatment.

Conclusion

Our study shows that NICE TA 159 has had minimal impact on the uptake of SCS for new patients, and rates of SCS implantation were highly variable across Strategic Health Authorities and PCTs. The reasons for the lack of impact appear to be multifactorial. Within the new arrangements of NHS England, where SCS is deemed to be a prescribed specialised service that will be commissioned centrally, some of these barriers may be addressed including a shift towards more equitable access to this technology, and elimination of the use of Individual Funding Requests. Future implementation of NICE Innovation Scorecards to track compliance with NICE Technology Appraisals and other NICE compliance initiatives may further help to reinforce and track the implementation of NICE guidance.

Figure Legends

Figure 1. No. of SCS implanting centres year on year

Figure 2. Breakdown of SCS procedural activity trends (procedure codes A48.3, A48.4, and A48.7)

Figure 3. Number of total SCS procedures per PCT in 2011-12

Figure 4. Data from Freedom of Information request regarding PCT policies on SCS (data accessed 2011)

Contributorship Statement:

All authors had an integral role in producing this manuscript and have made substantial contributions to the analysis and interpretation of data; drafting and revision of the article; and approving the final version of the manuscript.

Funding statement: Access to the QUANTIS database to extract the relevant Hospital Episode Statistics data was funded by Medtronic UK. The planning, conduct and conclusions of this report are those of the authors and not the company.

Competing interests statement: Rod Taylor is a paid consultant for Medtronic Inc. Sam Eldabe has previously undertaken consulting work for Medtronic Inc.

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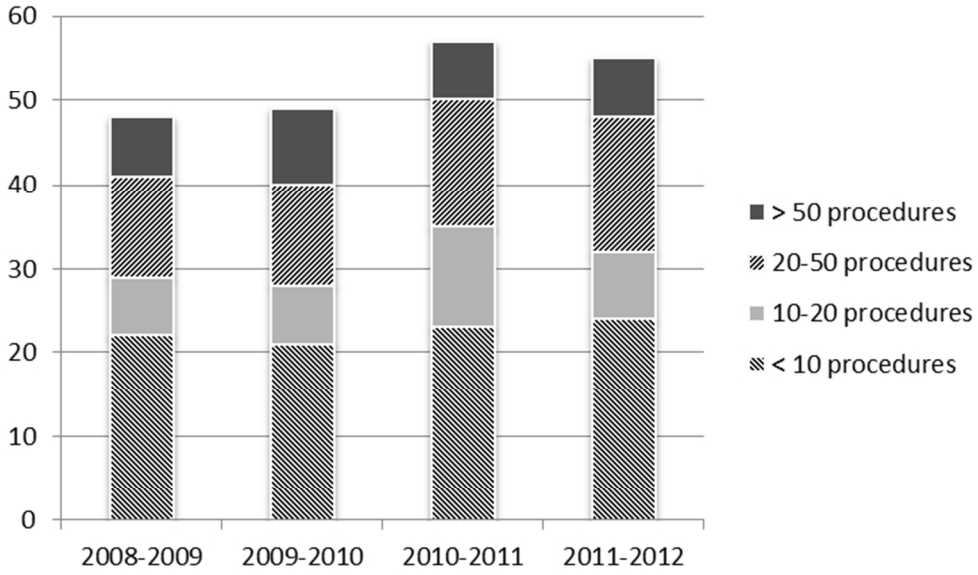

No. of SCS implanting centres year on year
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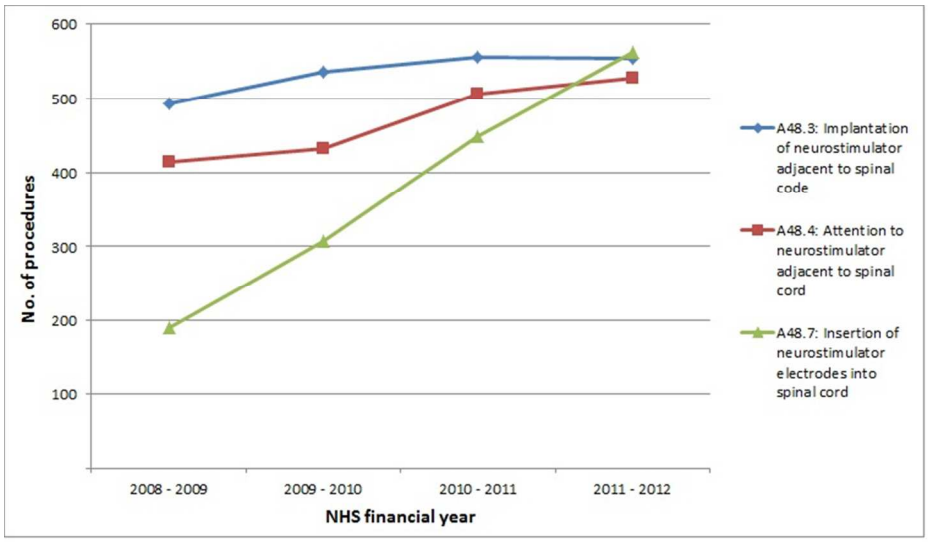

Breakdown of SCS procedural activity trends (procedure codes A48.3, A48.4, and A48.7)
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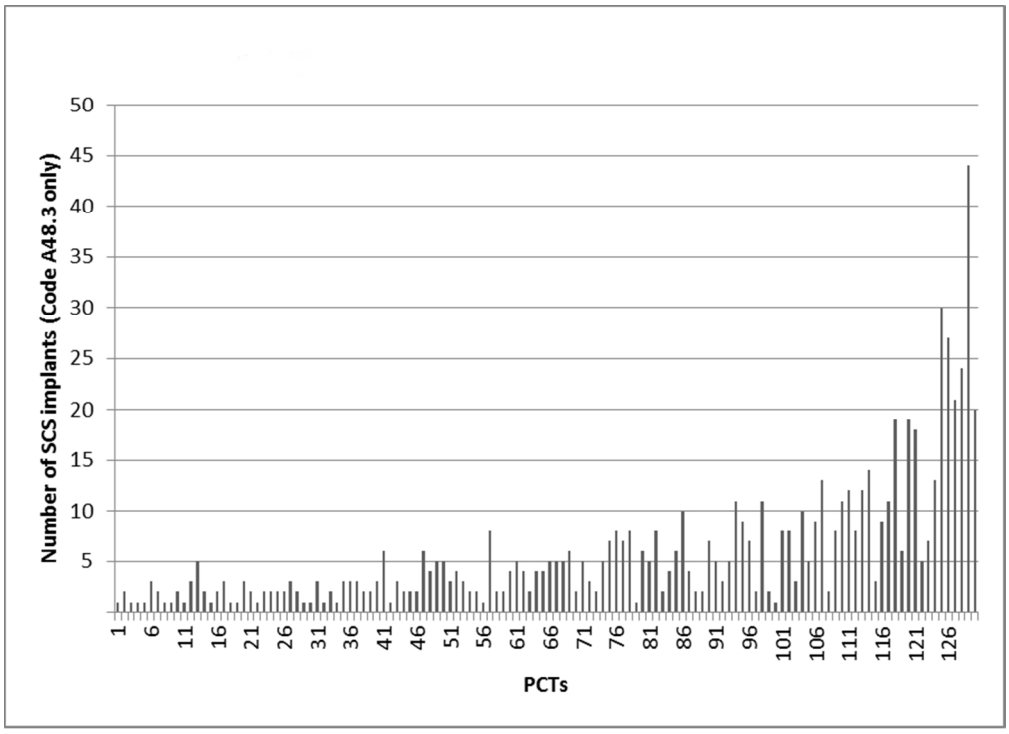

Number of total SCS procedures per PCT in 2011-12
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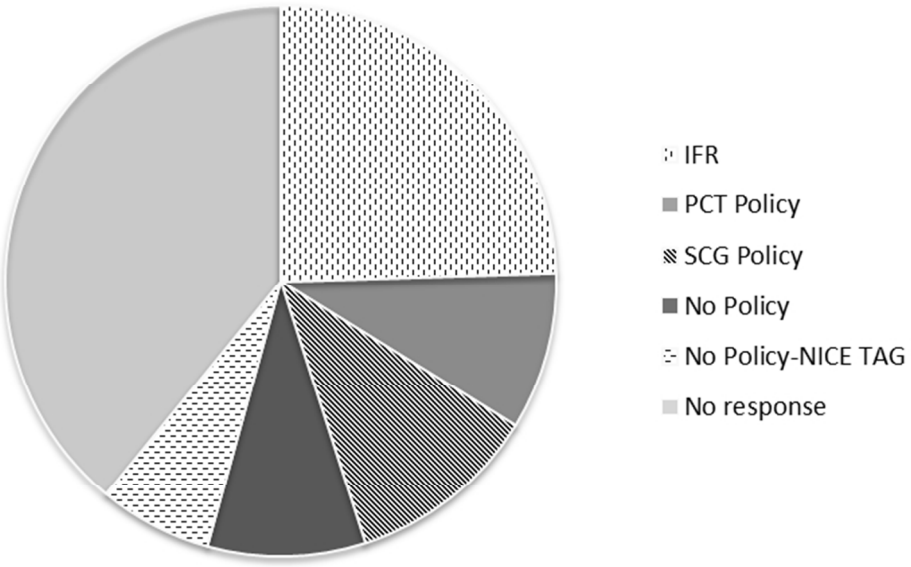

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BMJ open

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Table 1a. Total number of SCS procedures (combined A48.3 and A48.4 OPCS procedures) from 2008-2012.

Regional SHA	Population	2008 - 2009			2009 - 2010			2010 - 2011			2011 - 2012		
		No. cases	Cases / Million	95% CI	No. cases	Cases / Million	95% CI	No. cases	Cases / Million	95% CI	No. cases	Cases / Million	95% CI
East Midlands	4,380,276	25	5.7	4 – 8	53	12.1	9 - 15	56	12.8	10 - 16	75	17.1	14 - 21
East Of England	5,714,218	137	24.0	21 - 28	175	30.6	27 - 34	205	35.9	32 - 40	170	29.8	26 - 34
London	7,757,619	83	10.7	9 - 13	60	7.7	6 - 10	81	10.4	8 - 13	73	9.4	8 - 12
North East	2,577,541	136	52.8	47 - 59	120	46.6	41 - 53	95	36.9	31 - 43	112	43.5	38 - 50
North West	6,923,825	132	19.1	16 - 22	155	22.4	19 - 26	169	24.4	21 - 28	173	25.0	22 - 28
South Central	4,069,352	20	4.9	3 - 7	39	9.6	7 - 13	44	10.8	8 -14	38	9.3	7 - 13
South East Coast	4,302,298	92	21.4	18 - 26	81	18.8	15 - 23	106	24.6	21 - 29	108	25.1	21 - 29
South West	5,181,449	109	21.0	18 - 25	99	19.1	16 - 23	88	17.0	14 - 20	116	22.4	19 - 26
West Midlands	5,421,595	50	9.2	7 - 12	53	9.8	8 - 13	45	8.3	6 - 11	43	7.9	6 - 11
Yorkshire & the Humber	5,244,956	123	23.5	20 - 27	133	25.4	22 - 29	172	32.8	29 - 37	174	33.2	29 - 37
Total	**51,573,129**	**907**	**17.6**	**17 - 19**	**968**	**18.8**	**18 - 20**	**1,061**	**20.6**	**19 - 22**	**1,082**	**21.0**	**20 - 22**

Table 1b. Comparison of new SCS implants in UK (procedure code A48.3 only) against other European countries per year

Country	Yearly SCS/ Million			
	2008	2009	2010	2011
Belgium		84.6		
France	9.19	8.17	11.35	
Netherlands				54.3
Germany			11.7	
UK(England)			11	10.7

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Discussion

The NHS has a mandatory duty to fund and provide NICE-approved treatments recommended within a NICE TA within 90 days. However, our UK data analysis from 2008 to 2012 shows that NICE TA 159 had a small impact on uptake of SCS in neuropathic pain. Although an increase of 19.3% in SCS procedures was observed over the four year period, this figure 1 includes battery replacements and revisions in addition to new SCS permanent implants. When new SCS implants are considered alone, an increase in uptake of only 12.4% percent was observed between 2008 and 2012 (Figure 2), despite the NICE TA 159 advocating a 10% increase in uptake each year. Interestingly the substantial rise in procedure code 48.7 (trial procedures) does not appear to convert into a comparable increase in permanent SCS procedures. Given that the conversion rate of trial to permanent SCS implants is generally consistent at around 75-80% (8), accuracy in provider coding in this instance may be questioned.

There remains considerable regional inequality in patient access to this NICE approved treatment. The Right Care (9) is one of the national work streams in the Department of Health (DH) Quality Innovation Productivity and Prevention programme (QIPP) which identifies unwarranted variation in NHS treatments based on geographical areas (9, 10). One of the Right Care objectives for 2011-2012 is to minimise this unwarranted variation and maximise value (9). Value can be increased by improving quality, optimising resource utilisation and ensuring that patients receive appropriate interventions.

Our findings are in contrast with a NICE implementation report (11) that shows a generally effective impact of guidance for surgical procedures. For example, laparoscopic colorectal surgeries occurred at higher rate than forecasted by NICE (TA 105) (12). Laparoscopic inguinal hernia repair uptake increased following guidance, but it stabilised at lower levels than NICE forecasted (TA 83) (13). In addition, there was overall increase in bariatric surgery for morbid obesity following NICE guidance (CG 43) (14). Our study provides data on the marked variability in rate of SCS uptake at both health authority and PCT level.

NICE assessed SCS as a highly cost-effective treatment for failed back surgery syndrome with an incremental £10,480 per quality adjusted life year (QALY) ratio compared with

conventional medical management alone, and £9219 per QALY gained when compared with repeat back operation (4). These ratios are considerably below the UK willingness to pay threshold of £20,000 to 30,000 per QALY.

Despite mandatory TA guidance on SCS, the majority of PCTs required Individual Funding Requests (IFR) for each patient (Figure 4). Some PCTs rated SCS as a low priority procedure. The reasons for the barriers to funding are multifactorial and include lack of awareness of SCS referral guidelines, lack of NICE TAG enforcement at regional and national level, as well as a limitation of clinical capacity at implanting centres. Due to the limitations of the available data it is not possible to disentangle the factors responsible for the continuing inequity of funding for SCS implants. Yet we can comment that there has been no significant increase in the number of implanting centres. The capacity within existing centres is not showing a growth curve as expected in response to the NICE guidance. Only 10.8% of PCTs implemented NICE guidance as a funding policy (Figure 4). It is possible that piecemeal funding and the difficulties associated with such an approach, as well as the impact of the marked regional variations, have prevented the expansion of current providers. The reported incidence of failed back surgery syndrome is estimated as 10-40% of patients undergoing back surgery (15). In recent survey of the United Kingdom, 53% of pain clinics estimated 10% of their referrals comprised of failed back surgery syndrome patients and the remaining 47% of pain clinics estimated it as 20-30% of their referrals, therefore lack of candidates is unlikely (16).

In a comparison to France, Germany, Belgium and the Netherlands, England has the lowest rate of implants per million of the population. Smaller countries show a much higher rate of SCS implants (7), with Belgium and the Netherlands implanting 84.6 and 54.3 per million of population respectively. Nevertheless, for Belgium and the Netherlands only one year of data is available therefore we are unable to comment on trends. Data for France was available for the last three years (Table 1b) and shows no significant increase in SCS implants. The main indications for SCS are similar across the four countries i.e. failed back surgery syndrome or radicular pain, phantom pain, peripheral nerve injury, traumatic brachial plexus injury, spinal lesion, diabetic polyneuropathy and post herpetic neuralgia (7). Focusing on the most common indication for SCS of failed back surgery syndrome, it is estimated that 10-40% of patients undergoing spinal surgery will develop neuropathic pain (15). According to HES database, the number of spinal surgery procedures in England

in 2009-2010 was 117,803 (17). Assuming that one third of these procedures is being carried out for pain, the annual estimate will be 78,533 procedures of which 10% to 40 % (7,853 to 31,414) would be expected to be eligible for SCS treatment (16). Based on this data, less than 2% of the eligible population of neuropathic patients in England are currently receiving SCS treatment. A lack of awareness of SCS as a clinical and cost-effective treatment option amongst referring physicians may be hindering the uptake of this NICE-approved technology. More constructive engagement with the wider population of patients and referring physicians by the neuromodulation community is warranted to ensure appropriate and early referral for SCS therapy.

Conclusion

Our study shows that NICE TA 159 has had negligible impact on the uptake of SCS for new patients, and rates of SCS implantation were highly variable across Strategic Health Authorities and PCTs. The reasons for the lack of impact appear to be multifactorial and may include limited awareness of SCS as an clinical and cost-effective treatment option amongst the wider referral community. Within the new arrangements of NHS England, where SCS is deemed to be a prescribed specialised service that will be commissioned centrally, some of these barriers may be addressed including a shift towards more equitable access to this technology, and elimination of the use of Individual Funding Requests. Future implementation of NICE Innovation Scorecards to track compliance with NICE Technology Appraisals and other NICE compliance initiatives may further help to reinforce and track the implementation of NICE guidance.

Figure Legends

Figure 1. No. of SCS implanting centres year on year

Figure 2. Breakdown of SCS procedural activity trends (procedure codes A48.3, A48.4, and A48.7)

Figure 3. Number of total SCS procedures per PCT in 2011-12

Figure 4. Data from Freedom of Information request regarding PCT policies on SCS (data accessed 2011)

Contributorship Statement: All authors had an integral role in producing this manuscript and have made substantial contributions to the analysis and interpretation of data; drafting and revision of the article; and approving the final version of the manuscript.

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Competing interests statement: Rod Taylor is a paid consultant for Medtronic Inc. Sam Eldabe has previously undertaken consulting work for Medtronic Inc.

Data sharing: Readers are invited to contact the corresponding author, Natalie Hallas, if they wish to request any raw unpublished Hospital Episodes Statistics data pertaining to the manuscript.

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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

Bharati Vyawahare[1], Natalie Hallas[2], Morag Brookes[1], Rod S Taylor[3] & Sam Eldabe[1]

1. Department of Pain and Anaesthesia, James Cook University Hospital, Middlesbrough
2. Medtronic Limited UK, Watford, Hertfordshire
3. Institute of Health Research, University of Exeter Medical School, Exeter

Abstract

Background: The National Institute for Health and Care Excellence (NICE) Technology Appraisal Guidance on spinal cord stimulation (SCS) was published in 2008 and updated in 2012 with no change. This guidance recommends SCS as a cost effective treatment for patients with neuropathic pain. **Objective:** To assess the impact of NICE guidance by comparing SCS uptake in England pre- (2008-2009) and post- (2009-2012) NICE guidance. We also compared the English SCS uptake rate with Belgium, Netherlands, France and Germany. **Design:** SCS implant data for England was obtained from the Hospital Episode Statistics database (HES) and compared with other European countries where comparable data were available. **Results:** The HES data showed ~~minimal~~ small increases in SCS implantation and replacement/revision procedures, and a large increase in SCS trials between 2008 and 2012. The increase in the total number of SCS procedures per million of population in England is driven primarily by revision/replacements and increased trial activity. Marked variability in SCS uptake at both health regions and primary care trust level was observed. **Conclusion:** Despite the positive NICE recommendation for the routine use of SCS, we found no evidence of a significant impact on SCS uptake in England. Rates of SCS implantation in England are lower than many other European countries.

Article Summary

1. **Article Focus**
    - The NHS in England and Wales is legally obligated to fund NICE Technology Appraisal-approved technologies within 90 days. The NICE

Technology Appraisal approving Spinal Cord Stimulation for Neuropathic Pain was published in 2008.

- We examined the impact of the NICE Technology Appraisal on the overall uptake of spinal cord stimulation in England, in addition to regional variations in patient access.

2. **Key Messages**

- The NICE Technology Appraisal publication appears to have had ~~minimal~~ negligible impact on the uptake of spinal cord stimulation for new patients, and inequity of patient access remains despite clear evidence that this treatment is a cost-effective use of NHS resources.
- Reasons for this are multifactorial and include lack of guideline awareness, commissioning variation, lack of enforcement of NICE guidance and limited capacity at implanting centres.
- Some of these patient access barriers may be addressed with centralised commissioning of specialised services including spinal cord stimulation.

3. **Strengths/limitations**

- This study contributes a novel data analysis in the area of spinal cord stimulation, which highlights a lack of uptake of a cost-effective technology within the NHS.
- Our findings are based on data extracted from the Hospital Episodes Statistics database which relies on hospital coded data on procedures and indications.

Introduction

The National Institute for Health and Care Excellence (NICE) is a Department of Health funded arms-length body, established in 1999 to principally reduce 'the postcode lottery' i.e. the variation in the availability and quality of NHS treatments and care in England and Wales(1, 2). NICE publishes various types of guidance including Technology Appraisals (TA), Clinical Guidelines, Quality Standards and Interventional Procedures Guidance (2). The TA guidance is based on evaluations of clinical and cost-effectiveness of selected technologies. The NHS is legally obliged to provide funding for medicines and treatments recommended within 3 months of the guidance (1). In December 2011, The Department of Health announced in its Innovation, Health and Wealth report that commissioners are expected to provide access to new treatments within 90 days of approval (1,3).

NICE TA guidance 159 on Spinal Cord Stimulation (SCS) for chronic pain of neuropathic or ischaemic origin was published in October 2008 and reviewed in January 2012 when no changes were made (4). This TA guidance approves SCS for adults with continued chronic neuropathic pain (measuring at least 50mm on 0-100mm visual analogue score) for at least 6 months despite all standard conventional treatment and after undergoing a successful trial of SCS by a multidisciplinary team (4).

We examined the data for SCS uptake in England between 2008 and 2012 in order to assess the impact of NICE TA guidance implementation. We compared this to the SCS implant rate in other European countries. Data was also requested from all Primary Care Trusts via a Freedom of Information request with regards to their SCS commissioning policy to determine whether a policy around the implementation of NICE guidance was in place or whether Individual Funding Requests (IFR) were being used.

Methods

Data for pre- (2008-2009) and post- (2009-2010; 2010-2011; 2011-2012) NICE TA 159 publication for SCS procedural activity was obtained from the Hospital Episode Statistics (HES) database (5) , using the QUANTIS system via NHiS (6). HES is a national statistical data warehouse for England of the care provided by NHS hospitals. QUANTIS is a database of NHS and social care numerical data for the UK and NHiS is a vendor that provides subscribed access to the QUANTIS database.

We examined OPCS-4 procedure codes A48.3 (Implantation of neurostimulator adjacent to spinal cord), A48.4 (Attention to neurostimulator adjacent to spinal cord) and A48.7 (Insertion of neurostimulator electrodes into spinal cord). The OPCS code A48.3 was assumed to reflect new permanent SCS implants, code A48.4 to contain both replacements and revisions, and code A48.7 to represent trial procedures. OPCS code 48.4 does not allow for a clear differentiation between battery replacement and revisions.

The relevant SCS codes were filtered by indication to ensure that only back pain and spinal indications were included. This eliminated any inclusion of other types of neurostimulation that may have been miscoded, for example for bowel and bladder indications. SCS uptake results are expressed per million populations across each Strategic Health Authority regions in England. We also compared uptake rates across Primary Care Trusts (PCT).

Oracle (11g Database) and Excel (Microsoft Office 2010 Pro) software programmes were utilised for the data analysis. We compared English SCS uptake data from 2011-12 (code A48.3 only) with European counties where we able to source the appropriate equivalent data, i.e. France, Belgium, Germany and the Netherlands (7).

Results

The HES data analysis for year 2008-2012 showed a small increase in procedure codes 48.3 and 48.4 (Table 1a) and large increase in procedure code 48.7. Figure 2 illustrates the activity trends for each separate procedure code. On analysis of each of the procedure codes, the increase in SCS procedures appears to be driven primarily by replacements, revisions and a large increase in trial activity. There was considerable variation in the rate of SCS uptake across Strategic Health Authorities throughout this time horizon. The

breakdown of the number of SCS procedures funded by PCTs in 2011-12 is shown in Figure 3, indicating considerable inequity of patient access to this NICE-approved treatment.

Table 1b compares the available European data against procedure code 48.3, reflecting the number of new SCS implants only. In France there was a small increase in the number of SCS implants per million of population for the period 2008-2010 (Table 1b). The rate of uptake of SCS per million of population in England is the lowest compared to these other European countries (Table 1b).

Figure 4 shows requested data from all Primary Care Trusts with regards to their SCS commissioning policy via a Freedom of Information request. The response rate was 60.9%, with 40.2% of PCTs requiring individual funding requests (IFR), 18.5% following a Specialised Commissioning Group (SCG) policy, 15.2% following either PCT policy or with no active policy, and only 10.8% following NICE TA Guidance allowing automatic funding. Whilst the level of data did not allow a statistical analysis of the correlation between the PCT policy status and the number of SCS procedures funded, some evidence of an association ~~correlation~~ between regions with an existing policy and the number of patients being funded for SCS was apparent. For example, across Yorkshire and the Humber, where a clear SCG policy was being followed by the collective PCTs, a high rate of SCS procedures was observed at 33.2 cases per million (Table 1a). This was also evident with the East of England (29.8 procedures per million). Conversely, the lowest rates of SCS referrals were reported in regions with no PCT or SCG policy in place, such as the West Midlands and London (7.9 and 9.4 procedures per million, respectively).

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Table 1a. Total number of SCS procedures (combined A48.3 and A48.4 OPCS procedures) from 2008-2012.

Regional SHA	Population	2008 - 2009			2009 - 2010			2010 - 2011			2011 - 2012		
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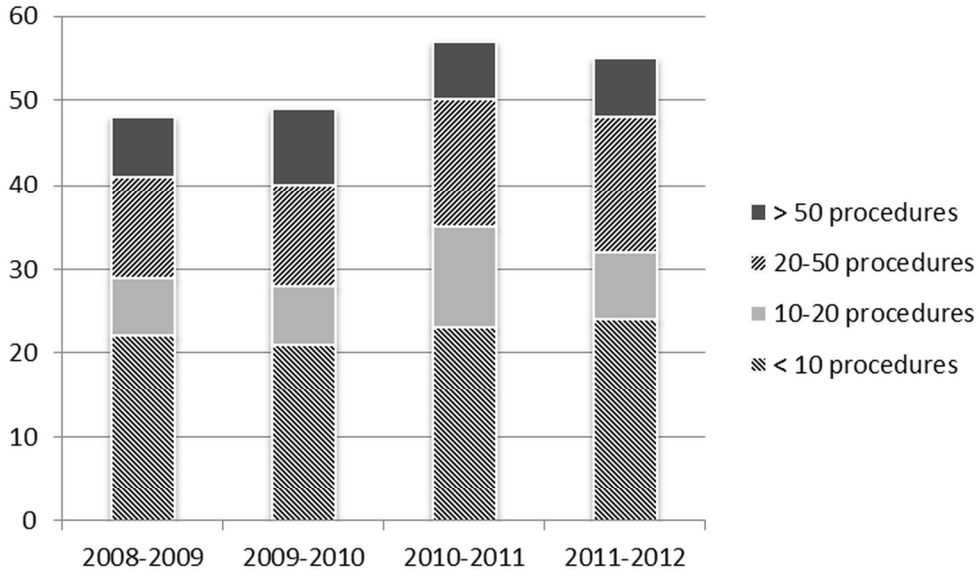
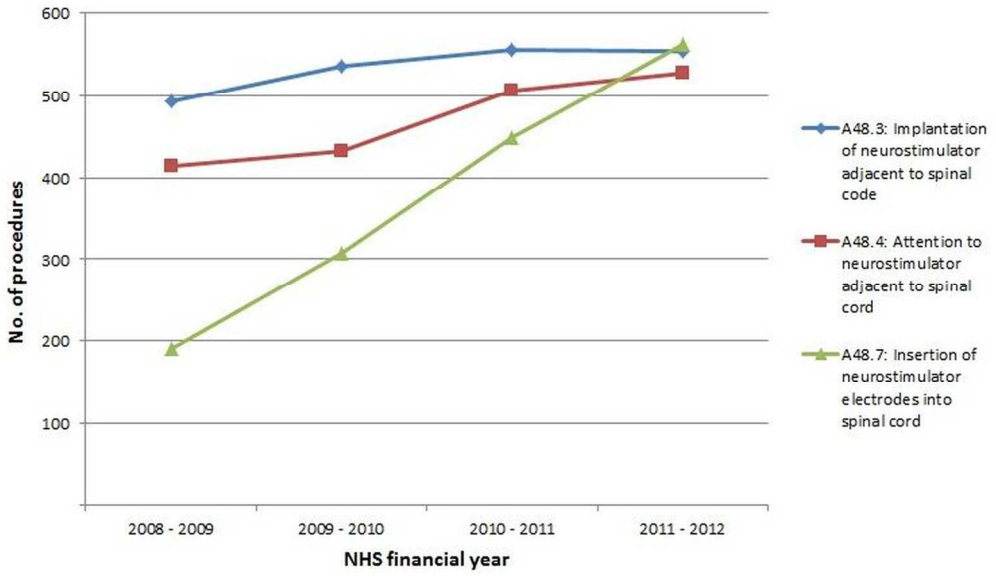
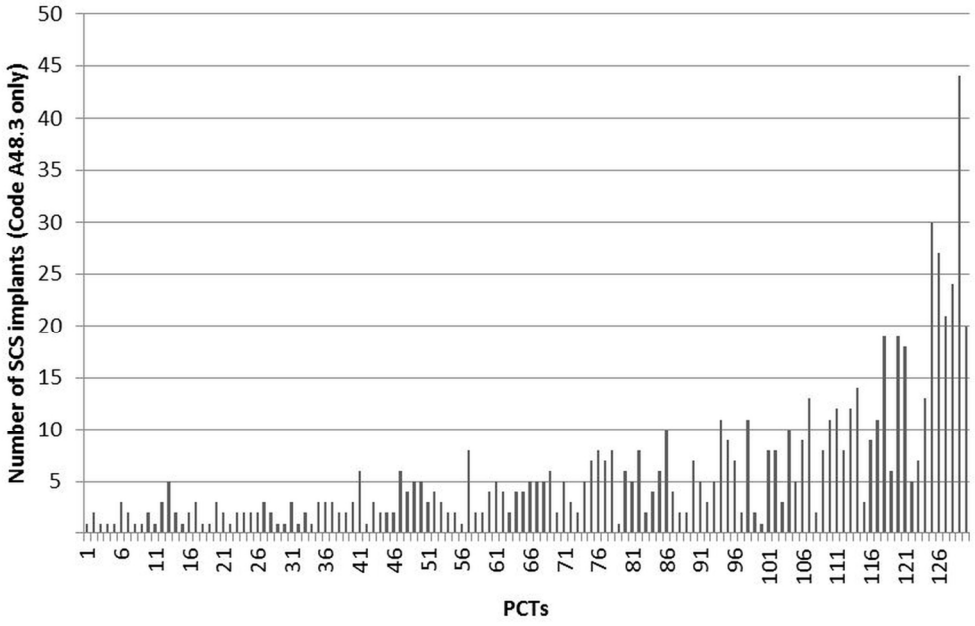


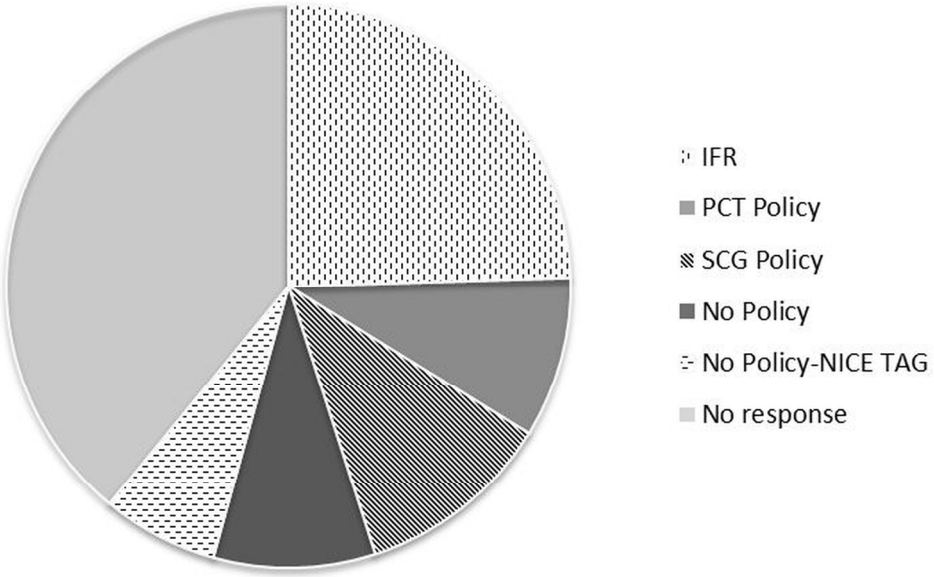
No. of SCS implanting centres year on year
151x90mm (300 x 300 DPI)



Breakdown of SCS procedural activity trends (procedure codes A48.3, A48.4, and A48.7)
156x90mm (300 x 300 DPI)



Number of total SCS procedures per PCT in 2011-12
129x90mm (300 x 300 DPI)



Data from Freedom of Information request regarding PCT policies on SCS (data accessed 2011)
152x90mm (300 x 300 DPI)