NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Spinal cord stimulation for chronic pain of neuropathic or ischaemic origin

Response to consultee, commentator and public comments on the Appraisal Consultation Document (ACD)

Consultee or Commentator	Comment	Institute response
Manufacturer		
Manufacturers' submission coordinated by ABHI	Thank you for the opportunity to respond to the ACD for this technology appraisal. After thorough review of the ACD and the associated Evaluation Report (ER), on behalf of the cross industry group, we would like to draw your attention to a number particular issues that we believe either have not been given due consideration further to our Assessment Report (AR) comments submitted to the Institute or do not constitute fair guidance in view of the evidence considered by the appraisal committee. These comments will be addressed under three main headings: 1. Clinical and cost-effectiveness of complex regional pain syndrome (CRPS) 2. Clinical and cost-effectiveness of refractory angina (RA) 3. RCT data inclusion for peripheral vascular disease and relevant population identification (PVD)	The Committee considered all the evidence submitted, including the manufacturers' submission. It also carefully considered the comments received from consultees and commentators in response to the Assessment Report and ACD. See responses below.
	1. Clinical and cost-effectiveness of complex regional pain syndrome (CRPS) In section 1.2 of the ACD it states that "Spinal cord stimulation is not recommended as a treatment option for adults with complex regional pain syndrome…..except in the context of research as part of a clinical trial". The rationale behind this recommendation appears to be primarily due to the Assessment Report's base case ICER of >£30,000/QALY which persuaded the committee that the use of SCS for the treatment of CRPS could currently not be considered as a cost-effective use of NHS resources. This opinion, combined with a concern that serious adverse events (SAEs) were not incorporated in the model and that 5 year follow-up data from the Kemler trial does not show a sustained difference	Comment noted. The Committee considered the recommendation for the use of SCS for CRPS- see FAD section 1.1 and responses to manufacturer comments, below.

	between SCS and CMM has, we believe, wrongly led the committee to issue inappropriate draft guidance to the NHS on the use of SCS for CRPS. To help inform the committee's next discussions, we have conducted some re-modelling using the AR acquisition cost for SCS and appropriate CRPS specific utilities, analysed SAEs reported in clinical trials and assessed the validity of the 5 year Kemler data.	Noted, see responses below.
	1.1 CRPS Re-modelling Despite our request to NICE, access to the ScHARR model was not made available. The reanalysis was therefore undertaken using the ABHI model. However, as outlined in the Overview (Section 3.2.3) the ScHARR economic model was based on the ABHI model and from the description from the ScHARR assessment report, the structure of the two models appeared identical.	The AG model included price data designated commercial in confidence. This prevented release of the AG model to consultees.
	Two inputs to ABHI CRPS model were updated a. Device cost The ABHI model device cost was updated to £9,000 as outlined in the NICE ACD (Section 4.2.8). b. Health state utility We acknowledge the comment in section 4.3.11 of the ACD i.e. "The committee noted that the models used different sources of utility data and that neither captured the utility of a person with CRPS accurately, as one source was a trial of FBSS [ABHI model] and the other a wider survey of neuropathic pain conditions [ScHARR model]." The ScHARR ICER for CRPS is based on a survey of utility values by McDermott et al sourced from neuropathic patients none of whom has CRPS. We contend this ICER is therefore invalid.	Noted. As noted, the Committee considered that neither set of data may reflect the utility of a person with CRPS – see FAD section 4.3.11.
	To overcome the limitation of previous ABHI model analysis we obtained individual patient EQ-5D data that was collected within the Kemler trial of SCS for CRPS trial (data on file). This data is the best quality utility data available for the patient group of interest and could be correlated with the health states. In accord with the FBSS cost effectiveness analysis, it was assumed that the pre-defined health states of pain relief were independent of type of treatment mechanism (i.e. how that pain relief was achieved). The proportion of patients in each health state in the first 6-months was based on the 6-month findings from the Kemler trial. The health state	The Committee considered the utility data from the CRPS trial – see FAD section 4.3.11.

values are summarised in the table below.

Table 1. Utility values for CRPS health states

Pain threshold	Health state (6 month findings from Kemler)	Utility
≥50%	Optimal pain relief	0.61
≥50%	Optimal pain relief + Complication	0.56
<50%	Sub optimal pain relief	0.23
<50%	Sub optimal pain relief + Complication	0.18
0%	SCS to CMM failure (no perceived pain reduction): assumed to be equivalent to baseline	0.16

Over the 15-year time horizon of the model, the following base case cost effectiveness results were obtained:

Table 2. Base case cost effectiveness of SCS and CRPS

CRPS	SCS + CMM	vs	CMM alone		Difference
Total cost	£92,519		£81,088		£11,431
QALYs	6.07		5.35		0.71
Cost /QALY			£16,088		

Noted, this has been reported in the evidence section - see FAD section 4.2.6

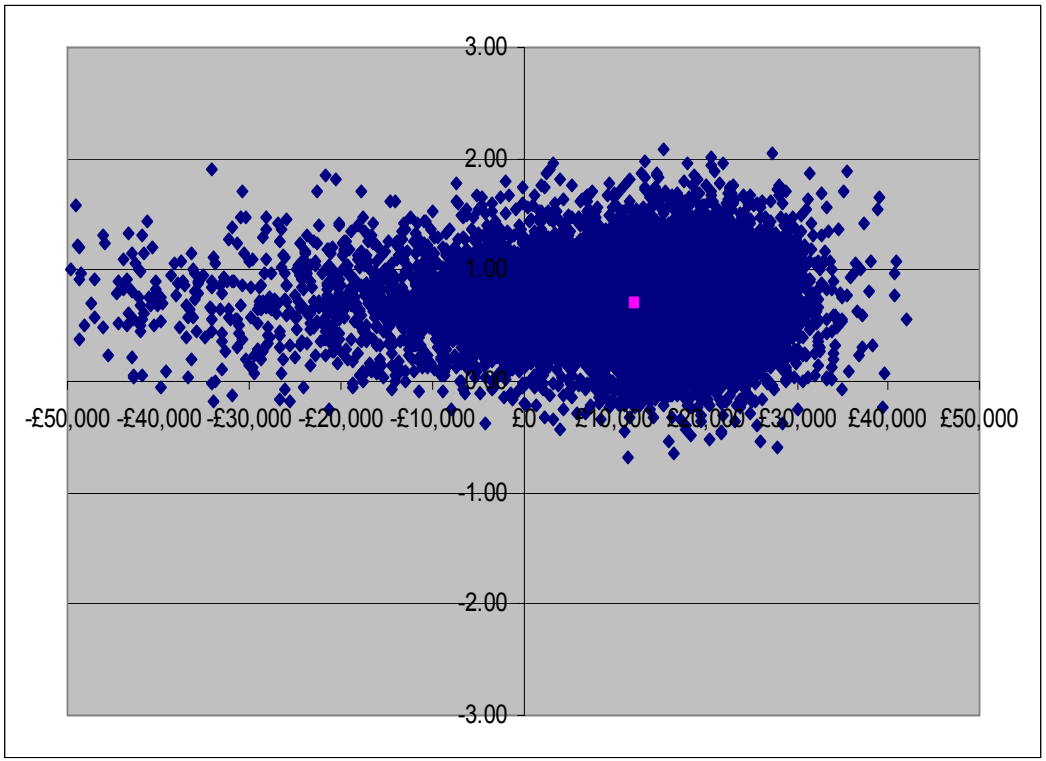
SCS produced more QALYs (0.71 per person) for relatively little extra cost (£11,431) compared to CMM, the equivalent of a cost per QALY (ICER) of £16,088. This ICER falls well below the ICER of £32,282/QALY as stated in the ACD section 4.3.11 (which is in conflict with the base case value stated in the AR and ER of £25K) and below the threshold of £20,000/QALY.

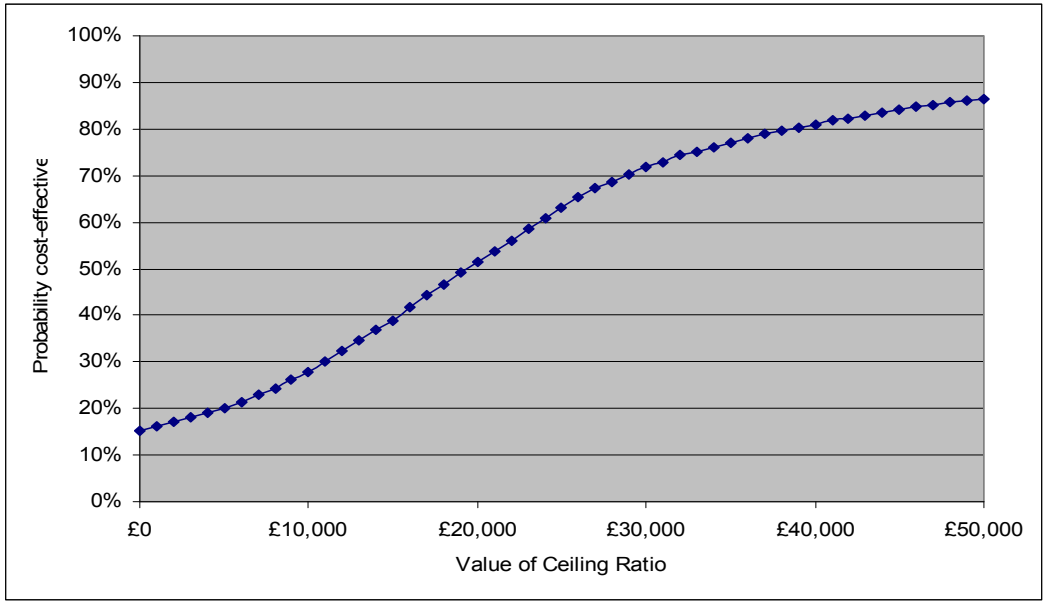
In probabilistic sensitivity analysis it was found that SCS was over 70% cost-effective at the £30,000 per QALY threshold; the probability of being cost effective at £20,000 per QALY was over 50%. The scatter plot and CEAC produced from probabilistic analysis are shown below.

Noted, the Committee considered the use of SCS for CRPS – see FAD section 4.3.11.

Figure 1. Scatter plot of incremental QALYs and costs for SCS and CRPS

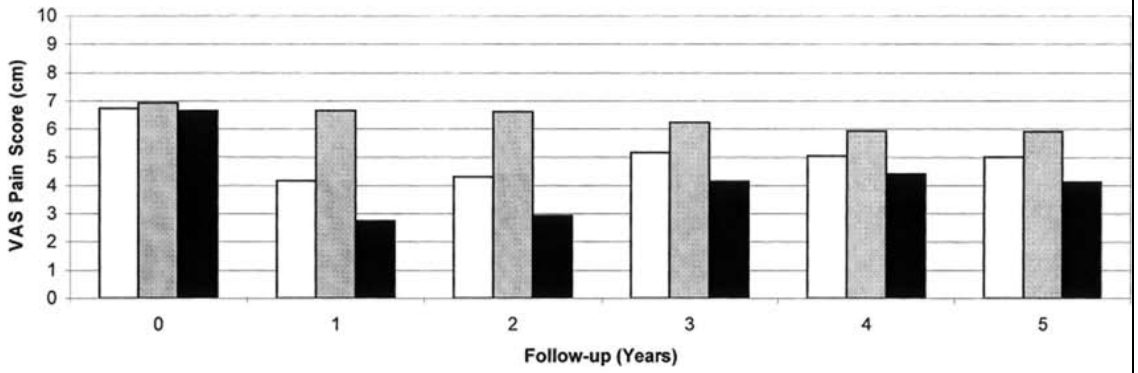
Noted, the Committee considered the use of SCS for CRPS – see FAD section 4.3.11.

		
	Figure 2. Cost effectiveness acceptability curve for SCS and CRPS	Noted, the Committee considered the use of SCS for CRPS – see FAD section 4.3.11.

		
	In summary, the ScHARR ICER for CRPS stated in the ACD is based on a survey of utility values sourced from neuropathic patients none of whom has CRPS. Although this was the best data available at the time, due to the new availability of CRPS specific utilities we believe the ScHARR ICER to be invalid. A reanalysis of the cost effectiveness of SCS for CRPS was undertaken using the ABHI model and health state utility values directly sourced from EQ-5D data collected from CRPS patients in the Kemler RCT of SCS. In this reanalysis the device cost was updated to £9,000 as stated in the ACD. Our reanalysis clearly demonstrates SCS+CMM to be a cost effective compared to CMM for CRPS with an ICER of below the threshold of £20,000/QALY. On the basis of these results, and in accord with FBSS, SCS should be recommended as a treatment option for adults with CRPS who continue to experience chronic pain (measuring at least 50 mm on a 0–100 mm visual analogue scale) for at least 6 months after surgery despite adequate standard care, and who have had a successful trial of SCS stimulation.	Noted, the Committee considered the use of SCS for CRPS – see FAD sections 1.1 and 4.3.11, and responses to comments (above).
	1.2 Trial reported SAEs It states in the ACD that the Committee noted that rare, but potentially serious, complications were not included in the model and as a consequence it is possible the	Noted. The Committee considered the frequency of serious adverse

	model may underestimate the ICER for SCS. We refute this assertion and provide trial data to show that SAEs are not relevant to the modelling. The clinical trial reports from 9 studies run in Europe since 1995, involving 443 patients (with adverse events reporting and monitoring) reported no deaths, comas or paralyses (please see attached table). We therefore believe that non inclusion of SAEs is an accurate and clinically relevant approach and that it has not caused the ICER to be underestimated. With respect to all adverse events, none are included for CMM in the model, therefore we believe the ICER to be conservative for SCS.	events associated with SCS, and the exclusion of adverse events from the CMM group. – The FAD section 4.3.8 has been amended.
	1.3 Validity of the 5 year Kemler data Unlike the six month ITT Kemler utility data used in the revised economic model, we believe that the five year data discussed by the committee has been interpreted inappropriately to conclude that there is uncertainty surrounding the long-term advantages of SCS. This is despite the committee hearing from clinical specialists that this may have been partly explained by crossover between the treatment arms of the trial. There a number of reasons why the five year Kemler data is unsuitable for determining five year relative effectiveness of CMM and SCS, these are detailed below.	The Committee noted the earlier analysis of the CRPS study and the sub group of only those patients who received their allocated treatment. The results of the sub group analysis of the CRPS trial are presented in FAD section 4.1.6 and reflected in the considerations section 4.3.6 and 4.3.8.
	a. Background on Kemler study: previously reported six- and 24-month results Patients selected for the Kemler study were enrolled between March of 1997 and July of 1998 and were randomized 2:1 to either SCS plus physical therapy (SCS+PT) (n = 36) or PT alone (n = 18). Of the 36 patients randomized to SCS+PT, 24 (67%) were implanted. At six months, in an intention-to-treat (ITT) analysis, the mean VAS score for SCS+PT patients decreased by 2.4 cm, while it increased by 0.2 cm for PT-only patients ($p < 0.001$). In an as treated analysis, the mean VAS score for SCS+PT implanted patients decreased by 3.6 cm, while it increased by 0.2 cm for PT-only patients ($p < 0.001$). In the as-treated analysis, global perceived effect (GPE) was much improved in 14 (58%) of the 24 SCS+PT implanted patients, as compared to one of the 18 (6%) PT-only patients ($p < 0.001$). SCS+PT also resulted in significant improvements in health-related quality of life (HRQoL) both for patients with an affected hand ($p = 0.02$) or foot ($p = 0.008$).	Noted, the 6 and 24 month data were included in the Assessment Report and are summarised in the FAD – see FAD sections 4.1.4, 4.1.5, 4.1.6.

	At the two-year follow-up, in an ITT analysis, mean pain intensity (VAS) decreased by 2.1 cm for SCS+PT patients compared to 0 cm for PT-only patients ($p < 0.001$). In the as-treated analysis, mean VAS score decreased by 3.0 cm for SCS+PT implanted patients compared to 0 cm for PT-only patients ($p < 0.001$). In the as-treated analysis, GPE was much improved in 15 of the 24 (63%) SCS+PT implanted patients, as compared to 1 of 11 (9%) PT-only patients ($p < 0.001$). HRQoL benefits remained the same.	
	b. Kemler study for CRPS: five-year results After five years, in the main analysis the mean pain intensity for the patients randomized to SCS+PT (n = 31) was reduced by 1.7 cm versus 1.0 cm for the patient randomized to PT only (n = 13) ($p = 0.25$). Twenty-three percent (23%) of the SCS+PT patients reported much improvement on the GPE scale, while 15% of PT-only patients reported much improvement ($p = 0.24$). HRQoL changes were not statistically different between groups. In the subgroup analysis of permanently implanted patients (n = 20) versus PT-only patients (n = 13), the average pain relief (VAS) was 2.5 cm compared to 1.0 cm ($p = 0.06$). Thirty-five percent (35%) of the SCS+PT implanted patients reported much improvement on the GPE scale, while 15% of PT-only patients reported much improvement ($p = 0.02$). HRQoL measures were not significantly different between groups. Patient satisfaction in SCS implanted patients was also very high. After five years, 90% of SCS implanted patients indicated that they had positively responded to SCS, and 95% reported that they would undergo treatment again for the same result.	Noted, the Committee considered the main and sub group analysis of the 5 year CRPS trial data - see FAD sections 1.1, 4.1.5, 4.1.6, 4.2.6, 4.2.15, 4.3.6, 4.3.8 and 4.3.11. Noted, the Committee considered the sub group analysis of the CRPS trial, - see FAD sections 1.1, 4.1.6, 4.2.6, 4.2.15, 4.3.6, 4.3.8 and 4.3.11.
	c. Pain scores at five years are moderate for SCS-implanted patients and severe for PT-only patients In the as-treated analysis of SCS+PT implanted patients versus PT-only patients, the difference in VAS pain score change approached statistical significance ($p = 0.06$) in favor of SCS and that difference was likely to be clinically meaningful to patients. As Figure 1 demonstrates, the mean VAS score for SCS implanted patients was relatively steady over years 3-5 and was still nearly two points lower than PT-only patients at year five. Furthermore, the average VAS score for SCS implanted patients was in the range of scores considered to equate to moderate pain, while the average score for PT-only patients was in the range of scores considered to equate to severe pain.	The Committee considered the sub group analysis of the CRPS trial, and the revised economic evaluation based on utility data from the CRPS trial - see FAD sections 1.1, 4.1.6, 4.2.6, 4.2.15, 4.3.6, 4.3.8 and 4.3.11.

	Figure 1: Bar graph demonstrating the mean (± SD) VAS pain scores in patients with complex CRPS-I. The groups in the main analysis are represented by white and grey bars, whereas the subgroup of patients with an implant at the final follow-up is represented by black bars.  	
	d. The nature of the analysis was unconventional Kemler's main analysis should have employed ITT analysis whereby comparisons would be made between the patients randomized to SCS+PT versus the patients randomized to PT only, regardless of what actually happened with their treatment. In fact, Kemler excludes one SCS+PT randomized patient due to a special implant and excludes four PT-only randomized patients due to SCS implant. ITT analysis is valuable because it allows the balance of known and unknown patients' characteristics to remain equal between the two treatment groups as a result of randomisation. As ITT was not employed, we cannot be sure that the two treatment groups are directly comparable or if selection bias exists.	Noted, the Committee considered available data from the CRPS trial – see FAD section 4.3.6.
	Kemler's subgroup analysis should have employed an as-treated approach whereby comparisons would be made between all patients who actually received an SCS implant (n = 27) versus all patients receiving PT only (n = 22). In fact, Kemler excludes one SCS+PT randomized patient who received a special implant, four PT-only randomized patients who received an SCS implant, and nine SCS+PT randomized patients who received PT only due to a failed SCS trial. As-treated analysis allows you to analyze the patients based upon the treatment they actually received. In the case of this study, as-treated analysis offers value because several patients randomized to SCS	Noted, the Committee considered available data from the CRPS trial – see FAD section 4.3.6.

	never received the therapy and several patients randomized to PT-only received stimulation.	
	The use of a post-randomisation baseline pain measure raises concern. As the study was not blinded, the patients' perceived baseline pain intensity may have been influenced by knowing which treatment they were about to receive. Analyzing five-year outcomes versus baseline values may no longer be a valid comparison for two reasons. First, patients may reframe their pain, meaning that the patient considers his or her pain experience from a new reference point. Treatment may allow them to increase their level of functioning. This enhanced level of activity might then become their new normal. As they push their bodies to do more, they may perceive their pain as being worse, when in fact they are performing an activity that previously was difficult or impossible due to pain. Secondly, their disease may have progressed or changed overtime to involve additional painful regions or different painful regions.	Noted, the Committee considered the maintenance of pain relief over time – see FAD sections 4.3.6, 4.3.8, 4.3.11.
	e. CRPS symptoms are heterogeneous and dynamic The character of CRPS pain evolves over time, and in 10% of patients spreads to a new region or limb. As Kemler notes, the pain may, on occasion, even resolve. Whether programming was adjusted to treat the changing nature of the patients' pain in Kemler's study is unknown. Further, the ability to adjust programming was limited for patients with the Itrel 3 and quadripolar leads compared to the systems and software available today. Significant differences in pain relief and the ability to recapture pain relief without reintervention have been reported in retrospective analysis for patients with dual lead octapolar systems versus single lead quadripolar systems.	Noted, the Committee was mindful of differences in capability between different SCS neurostimulators and components and that requirements of people assessed for SCS may differ and need to be considered by the clinician response and the patient – see FAD section 4.3.14.
	2. Clinical and cost-effectiveness of refractory angina (RA) Section 1.2 of the ACD states that "SCS is not recommended as a treatment option for patients with….. refractory angina except in the context of research as part of a clinical trial". We do not believe that this recommendation is in line with the results of the available evidence base. From analysis of the committee's deliberations it is clear that their current preliminary recommendation is based on the facts that:	The Committee considered all the evidence submitted, including the manufacturers' submission. It also carefully considered the comments received from consultees and commentators in response to the Assessment Report and ACD.

	a. The primary outcomes in these studies were functional rather than pain relief, and noted that no studies had demonstrated statistically significant differences for pain outcomes, hence there was considerable uncertainty about the benefits of SCS in people with RA. b. There is no definitive economic analysis on SCS in the RA population: i.e. economic analyses provided were based on a population of people for whom treatment with CABG or PCI was suitable, however these techniques are often unsuitable for people with RA.	See response to comments below.
	Whilst we concur that the evidence base for RA is less mature than that available for FBSS and CRPS, we still believe there to be enough high quality evidence available to recommend SCS in some RA patients	The Committee considered the evidence for the clinical effectiveness of SCS for the treatment of RA - see FAD section 4.3.7.
	It is important to consider that both the ESBY and SPIRIT trials showed non-inferiority of SCS vs. CABG and PMR respectively. The ESBY trial is critiqued for using CABG as the comparator. Whilst we agree that CABG is not standard treatment for RA it is important to note that CABG is known to be a highly effective treatment option in the severe angina population. Consequently, the fact that both SCS and CABG offered long lasting improvements in QoL and that the survival up to 5 years was comparable between the two groups should not be disregarded and be considered to cast "uncertainty" over the effectiveness of SCS in angina. The clinical benefits of SCS in this population also translate into economic benefits as reported by Andrell et al. in 2003. In an analysis of the 2 year follow-up data of the 104 patients in the ESBY trial it was found that "SCS proved to be a less expensive treatment modality in angina pectoris than CABG ($p < 0.01$). The SCS group had fewer hospitalisation days than CABG ($p < 0.0001$) and fewer days related to cardiac events ($p < 0.05$)…. There were also no serious complications related to the SCS treatment". We believe this to be strong supporting data in favour of the use of SCS in the angina population; non-inferiority and economic benefit despite going head to head with a challenging comparator should not be overlooked or its importance underestimated.	The Committee was aware that for some outcomes SCS had been shown to be comparable to CABG and PCI – see FAD section 4.3.7.
	In addition to the ESBY trial data, the results of the SPIRIT trial were considered. The SPIRIT trial is a UK open label, single centre, parallel group randomised trial	Noted, the SPIRIT trial was included in the Assessment Report and is

	conducted in a tertiary referral centre comparing percutaneous myocardial laser revascularisation (PMR) with SCS in patients with RA i.e. the correct, and UK specific population is being evaluated. The aim of both PMR and SCS is to relieve the disabling symptoms of RA. In the AR it is acknowledged that the design of the SPIRIT trial is robust. The method of randomisation was reported and adequate and whilst SPIRIT did not present ITT, the authors reported that ITT was carried out using last observation carried forward, but this analysis was not reported as the authors stated it did not alter conclusions although differences between groups were reduced. The power calculation (for primary outcome measure) was reported and sufficient patients randomised in the SPIRIT trial.	summarised in the FAD. The Committee recognised the importance of functional outcomes for the treatment of RA – see FAD sections 4.1.10, 4.1.12, 4.1.13, 4.1.14. 4.3.7, 4.3.13.
	The primary outcome of the SPIRIT trial assessed angina functional outcomes. The SPIRIT trial assessed change in angina class as measured by the Canadian Cardiovascular Society (CCS) angina scale. Whilst at baseline all patients were in CCS class 3 or 4, 68% of PMR and 61% were in class 3 (p 0.781). At one year more SCS patients were in CCS class 1 or 2 and the difference was marginally significant at the traditional level (p 0.059). Four PMR patients had a 2-class improvement in CCS compared to 9 SCS patients who had a 2-class and 2 who had a 3-class improvement. Again, the greater proportion with a significant improvement in CCS class in the SCS group was close to traditional levels (p 0.068). The difference at 12 months between SCS and PMR groups in an analysis treating deaths and dropouts as failures, although an analysis excluding patients without follow-up indicated the SCS group had greater improvement in CCS class (p=0.042). Whilst further research would strengthen the existing evidence base, it should not stop the use of SCS in RA outside of an RA study or trial. The optimal RA population should be discussed at the next committee meeting. It is as important to consider functional outcomes as pain outcomes. This corroborates the criticism we have with assessing angina in terms of purely pain symptoms as opposed to functional outcomes.	Noted, the SPIRIT trial was included in the Assessment Report and is summarised in the FAD. The Committee recognised the importance of functional outcomes for the treatment of RA, but considered that there was insufficient cost effectiveness evidence to support the use of SCS for RA. For both legal and bioethical reasons those undertaking technology appraisals and developing clinical guidelines must take account of economic considerations (Social Value Judgements - Principles for the development of NICE guidance; principle 2) – see FAD sections 4.1.10, 4.1.12, 4.1.13, 4.1.14. 4.3.7, 4.3.13.
	3. RCT data inclusion for peripheral vascular disease and relevant population identification (PVD) We would like to reiterate our statement from our review of the AR with respect to PVD. We fully understand that the decision of what PVD population will benefit most	The Committee considered that clinical evidence suggested that

	from treatment with SCS is problematic. We believe that the clinical review is comprehensive, however, the Cochrane review of SCS and PVD has still not been considered due to the selection criteria applied. We would advise consideration of this Cochrane review as it is a high quality systematic review of the literature PVD clinical literature: “Patients suffering from inoperable critical leg ischemia (CLI) ultimately face a major amputation”. Spinal cord stimulation (SCS) has been introduced as a possible treatment option. This paper presents the best available evidence from a systematic review on the effectiveness of SCS in these patients and discusses the indications for SCS therapy. A meta-analysis of six controlled trials, including 444 patients, showed 11% (95% confidence interval: _0.02 to _0.20) lower amputation rate after 12 months compared to those treated with optimum medical treatment. In addition, SCS patients required significantly fewer analgesics and showed a significant clinical improvement. These positive effects have to be weighed against the higher costs and (generally minor) complications of SCS. TcpO2 measurements were found to be useful in selecting the most respondent patients, yielding a 12-month limb salvage of up to 83%. Hence, SCS should be considered as a possible treatment option in patients with CLI, particularly if their foot TcpO2 is between 10 and 30 mmHg.” (J Pain Symptom Manage 2006;31:S30--S35. _ 2006) This Cochrane review, based on 6 well performed trials with 450 patients in total, concluded that the amputation free interval after 1 y was significantly lower in the SCS-patient group. We believe that the Cochrane review results should be given due consideration in determining the relevant population relevant for SCS in this guidance.	there may be benefits for SCS used for the treatment of CLI. However, it concluded that there was insufficient cost effectiveness evidence to support the use of SCS for CLI. For both legal and bioethical reasons those undertaking technology appraisals and developing clinical guidelines must take account of economic considerations (Social Value Judgements - Principles for the development of NICE guidance; principle 2).– see FAD sections 4.3.7, 4.3.13.
	Summary: *CRPS is a cost-effective treatment for use in the NHS* Due to the new availability of CRPS specific utilities we believe the ScHARR ICER to be invalid. A reanalysis using CRPS specific 6 month utilities sourced from Kemler and a device cost of £9,000 clearly demonstrates SCS+CMM to be a cost effective compared to CMM for CRPS with an ICER of below the threshold of £20,000/QALY. *No SAEs forum in clinical trial reports* Non inclusion of SAEs in the economic model is an accurate and clinically relevant approach that has not caused the ICER to be underestimated.	See above.

	Five year Kemler data is unsuitable for determining long-term relative effectiveness of CMM and SCS Due to a number of reasons detailed above, the committee has misinterpreted the data to conclude that there is uncertainty surrounding the long-term advantages of SCS in CRPS. *There is enough high quality evidence available to recommend SCS in some RA patients* The results of the ESBY and SPIRIT trials need to be reassessed. It is important to consider that both the ESBY and SPIRIT trials showed non-inferiority of SCS vs. CABG and PMR respectively. RCT data inclusion for peripheral vascular disease readily identifies the relevant population for the indication We believe that the Cochrane review results should be given due consideration in determining the relevant PVD population suitable for SCS treatment in this guidance.	
Professional and Patient Groups		
British Pain Society	The Society wishes to comment upon some of the clinical and cost effectiveness interpretations and hence some of the preliminary recommendations of the Appraisal Committee. Since the distribution of SCHARR's assessment report, new evidence is available with regard to CRPS (1). We are not aware of any equality issues.	See responses below Comment noted about equalities issues, no actions required.
	1. FBSS We note the favourable clinical and cost effectiveness interpretations for FBSS and the recommendation of SCS as a treatment option, in the important contexts of multidisciplinary assessment and a successful trial.	Comment noted, no actions required.
	2. CRPS a. Clinical effectiveness The assessment report determined that there was evidence, from good quality studies, for the clinical effectiveness of SCS in CRPS. This determination appears to have been disregarded by the Appraisal Committee on the basis of the Kemler study (1). The 5 year follow up data is reported not to be different on an intention to treat analysis. The validity of this analysis is very questionable because of significant	Noted, the Committee considered the main and sub group analysis of the 5 year CRPS trial data - see FAD sections 1.1, 4.1.5, 4.1.6, 4.2.6, 4.2.15, 4.3.6, 4.3.8 and

	crossover and non-implantation. A per treatment analysis, excluding those randomised to physical therapy who crossed over to SCS, shows a continued effect at 5 years. Compellingly, 19 of 20 patients reported they would undergo the treatment again for the same result.	4.3.11.
	b. Cost effectiveness i) We would argue that the comparator group used in the SCHARR model is no longer appropriate. Patients with general neuropathic pain are likely to include cohorts with less severe pain than patients with CRPS. The severity of pain in patients with CRPS considered for SCS in the Kemler study (1) had a pre-treatment VAS higher than patients in the PROCESS study on FBSS (2). The original Association of Healthcare Industries (ABHI) analysis using FBSS utilities produced an acceptable cost-effectiveness profile. The Society understands that a further economic analysis by the ABHI, using the new utilities for CRPS provided by Kemler (1), is even more favourable. ii) In all economic models CMM is assumed to have no complications or withdrawal rate. This is clearly not true so, in the absence of data to populate the models, leads to less favourable analyses for SCS.	[i.] The Committee considered the utility data from the CRPS trial - see FAD sections 4.2.6, 4.2.15, 4.3.11. [ii.] The Committee considered the exclusion of adverse events from the CMM group. – The FAD section 4.3.8 has been amended. The Committee considered the use of SCS for the treatment of CRPS - see FAD sections 1.1, 4.3.6, 4.3.8 and 4.3.11.
	3. Refractory Angina a. Clinical effectiveness There is some confusion with regard to terminology and definitions. However, the extant research clearly demonstrates the clinical effectiveness of SCS over no treatment and that SCS is as effective as other palliative interventions such as high-risk palliative CABG and PMR. In this context it is difficult not to conclude that SCS should be a treatment option for patients with refractory angina who are not suitable for revascularisation. b. Cost effectiveness The cost effectiveness analysis is fundamentally flawed. According to NICE's own definition, refractory angina patients are not candidates for palliative revascularisation. It is therefore illogical and unfair to use cost effective comparisons with revascularisation procedures (bypass or percutaneous coronary intervention). The proper comparators for a cost effective analysis are alternatives to SCS, such as laser revascularisation, transplantation, enhanced external counter pulsation therapy and continued medical treatment.	The Committee recognised the potential clinical benefits of SCS for the treatment of RA, but considered that there was insufficient cost effectiveness evidence to support the use of SCS for RA. For both legal and bioethical reasons those undertaking technology appraisals and developing clinical guidelines must take account of economic considerations (Social Value Judgements - Principles for the development of NICE guidance; principle 2) – see FAD sections 4.1.10, 4.1.12, 4.1.13, 4.1.14. 4.3.7, 4.3.13.

	A UK study, Murray et al (3), showed cost benefit due to decreased admission rates. Another UK study of the effectiveness of a comprehensive programme of rehabilitation, and SCS where appropriate, also demonstrated a reduction in unscheduled admissions (4). Neither study was suitable for the SCHARR model.	
	4. Critical Limb Ischaemia a. Clinical effectiveness The EPOS study (5) showed that a select group of patients with defined levels of tissue oxygenation had significantly better limb survival than unselected groups having SCS. We suggest that if pre-SCS tissue oxygenation meets EPOS entry criteria then a test for change in oxygenation with a trial of SCS should be offered. A significant improvement in oxygenation would trigger SCS implantation and greater limb survival.	The Committee considered that clinical evidence suggested that there may be benefits for SCS used for the treatment of CLI. However, it concluded that there was insufficient cost effectiveness evidence to support the use of SCS for CLI. Recognising the possible benefits of SCS for the treatment of CLI, the Committee considered that SCS should be subject to further research. For both legal and bioethical reasons those undertaking technology appraisals and developing clinical guidelines must take account of economic considerations (Social Value Judgements - Principles for the development of NICE guidance; principle 2) – see FAD sections 4.3.7, 4.3.13.
	5. Other peripheral neuropathic pain conditions a. Clinical effectiveness Apart from a small study in diabetic neuropathy all reported data comes from case studies. Nonetheless, the reports suggest that responses mirror that of FBSS and CRPS in carefully selected individuals	The Committee considered whether it was appropriate to generalise from the trial data for FBSS and CRPS to other chronic pain conditions of neuropathic origin – see FAD sections 1.1 and 4.3.12.
	Further points for consideration by the Appraisal Committee A. There are several small sub-groups of patients, particularly with critical limb ischaemia and peripheral neuropathic conditions, where the level of evidence is lower	For both legal and bioethical reasons those undertaking technology appraisals and

	than randomized controlled trials. Nonetheless, evidence exists. We are very concerned that the ACD unaltered will result in commissioning bodies applying rigid criteria for very challenging clinical problems. Currently, cost-per-case commissioning panels assess individual requests for funding. We recommend that NICE recognises the limits of its advice on cost effectiveness and acknowledges the important role of specialist commissioning teams in assessing cost effectiveness in individual cases.	developing clinical guidelines must take account of economic considerations (Social Value Judgements - Principles for the development of NICE guidance; principle 2).
	B. We agree that further research is required. Unfortunately, like many other surgical procedures, this is not always easy, and explains why data do not currently exist. We have proposed to several national bodies the establishment of a central register. Among other functions, this would enable the gathering of data to assess the utility of SCS in carefully selected cases. We remain convinced that SCS should be provided in specialist centres able to provide comprehensive multidisciplinary assessment and conventional medical management.	For both legal and bioethical reasons those undertaking technology appraisals and developing clinical guidelines must take account of economic considerations (Social Value Judgements - Principles for the development of NICE guidance; principle 2).
	C. We have some concerns with regard to the specialist advisors selected by the Appraisal Committee; these concerns relate to their authority in the use of SCS in ischaemic conditions. The contribution by Mr [redacted] of the Society of British Neurological Surgeons, contained in the Evaluation report is not acknowledged in the ACD.	The Appraisal Committee considered the full range of evidence submitted by consultees, as well as their responses to the ACD. The Assessment Group was also advised by a clinical advisor who was present at the Committee meeting. The FAD has been amended to acknowledge the clinical expertise provided to the Committee by the Clinical Specialist.
	D. Similarly, we have some concerns that ischaemic patient stakeholders have not been fully represented. Input from the British Heart Foundation is acknowledged in the ACD, but is absent in the Evaluation report.	All patient and professional consultee groups have the option to submit evidence to the appraisal. Evidence from all consultees who chose to submit was included in the evaluation report. The British Heart Foundation did not choose to submit evidence for this appraisal.

Royal College of Anaesthetists, Faculty of Pain Medicine	Response to NICE provisional recommendations by the Faculty of Pain Medicine, Royal College of Anaesthetists The Faculty of Pain Medicine, Royal College of Anaesthetists is responsible for training, assessment, professional standards and continued professional development of specialist medical practitioners involved in the treatment of pain in the UK. It supports a multidisciplinary approach to pain services and research into improving treatments. The Faculty's response to the provisional recommendations is submitted in this context. Thank you for the opportunity to comment on the above report. Our comments are listed below; we have serious concerns about some aspects of the recommendations, the emphasis of which seem to have changed compared with the last version.	Noted. There has only been one version of the Committee's preliminary recommendations circulated for consultation (the ACD).
	Specific recommendations *This guidance provides recommendations for the use of spinal cord stimulation for the following chronic pain conditions: failed back surgery syndrome, complex regional pain syndrome, critical limb ischaemia and refractory angina.* Response: We believe that it is absolutely essential that you make it clear that we are dealing with neuropathic pain after back surgery (see below). Strongly suggest inserting "neuropathic pain in" before "failed back surgery syndrome".	The Committee considered that it was appropriate to recommend SCS for the treatment of pain conditions of neuropathic origin – see FAD sections 1.1 and 4.3.12.
	1.1 Spinal cord stimulation is recommended as a treatment option for adults with failed back surgery syndrome who continue to experience chronic pain (measuring at least 50 mm on a 0–100 mm visual analogue scale) for at least 6 months after surgery despite adequate standard care, and who have had a successful trial of stimulation (as defined in recommendation 1.4). Response: Inclusion of unqualified "failed back surgery syndrome" is an unjustified extension that is not supported by the evidence. We very strongly believe you should go back to your original remit i.e. neuropathic pain after back surgery – there is only an evidence-base for this. Our views on this are such that the Faculty would not be happy to be seen to endorse this recommendation if it stands unchanged.	The remit of the appraisal was to consider the clinical and cost effectiveness of SCS for the treatment of pain of neuropathic and ischaemic origin. The Committee has made recommendations for pain of neuropathic and ischaemic origin – see FAD section 1.1 and 1.2.
	1.2 Spinal cord stimulation is not recommended as a treatment option for adults with complex regional pain syndrome, critical limb ischaemia or refractory angina except in the context of research as part of a clinical trial. Such research should be designed to	The Committee considered that clinical evidence was required that compared SCS with other

	generate robust evidence about the durability of the benefits of spinal cord stimulation (including pain relief and quality of life) compared with conventional medical management. We agree with this but possibly it is rather too limiting. Perhaps you could say “”in the context of research as part of a clinical trial or a nationally co-ordinated audit.”	alternative treatments which could then provide evidence for the cost effectiveness of SCS. See FAD section 4.3.13.
	1.3 Spinal cord stimulation should be provided only after an assessment by a multidisciplinary team skilled in chronic pain assessment and management. Response: We agree with this. Perhaps the recommendation could be made more clear if you said: “Spinal cord stimulation should be provided only after an assessment by a multidisciplinary team skilled in chronic pain assessment and management, including all conservative therapies and psychological methods.”	Consideration of the skills of the multidisciplinary team would most appropriately fit the decision problem of a clinical guideline. The Committee has formulated recommendations on the cost effectiveness of the use of SCS for the treatment of pain of neuropathic and ischaemic origin.
	1.4 For the purposes of this guidance, a trial is defined as successful if the person can tolerate the spinal cord stimulation device and stimulation sensation, and their pain is relieved (a minimum of 80% of painful areas covered and a minimum of 50% pain relief achieved in that area). Response: We agree that trialling in all its forms is accepted clinical practice. However, we believe that insisting on external trails is too proscriptive and not supported by robust evidence.	The FAD has been amended so that it does not specify that an external trial is required - see FAD sections 1.3, 4.3.3.
	1.5 When assessing the severity of pain and the trial of spinal cord stimulation, the multidisciplinary team should be aware of the need to ensure equality of access to the treatment. Tests to assess a trial of spinal cord stimulation should take into account a person’s disabilities (such as physical impairments), or linguistic or other communication difficulties, and may need to be adapted. Response: We agree with this. *1.6 If different spinal cord stimulation systems are considered to be equally suitable for a person, the least costly should be used. Assessment of cost should take into account acquisition costs for the lifetime of the device, including anticipated neurostimulator longevity, the stimulation requirements of the person with chronic pain*	Noted, no changes made to the FAD.

	and the support package offered. Response: We agree with this.	Noted, no changes made to the FAD.
	Important omission in recommendations The evidence-base underlying your recommendations arises from studies where there was a team available to advise the patients and deal with any problems on a 24-hour basis. If this is not present, then your recommendations are invalid and potentially harmful. Therefore, we strongly believe that you should recommend that a back-up service must be available to all patients receiving this device; without this, there is a danger that single handed practitioners with no commitment to backup and support will insert the devices, thereby endangering patients and wasting resources. We feel very strong about this; we would not be happy to be seen to endorse these recommendations if this point was not included in the final guidance.	Consideration of the support required following SCS would most appropriately fit the decision problem of a clinical guideline. The Committee has formulated recommendations on the cost effectiveness of the use of SCS for the treatment of pain of neuropathic and ischaemic origin. FAD section 3.8 has been amended to reflect BPS guidelines, "The ongoing care of patients is also required which includes 24 hour availability for the investigation and management of the potentially serious problems".
Neuromodulation Society UK and Ireland	Neuromodulation Society UK and Ireland Comments on the NICE Appraisal Consultation Document General Comments: i) Do you consider that all of the relevant evidence has been taken into account? 1. CRPS The Appraisal Consultation Document (ACD) has taken into account the evidence from the RCTs examined by the HTA conducted by the SCHARR group. It does not take into account the detailed new and full publication by Kemler et al (JNeurosurg 108:292–298, 2008). The ACD also comments on the uncertainty of the effects of SCS on CRPS in the long term but fails to take into consideration numerous longterm follow up case series on the subject such as the 101 case series by Bennett D, Alo K, Oakley J, et al. Spinal cord stimulation for complex regional pain syndrome I (rsd). Neuromodulation. 1999; 2:202–210. While case series type publications are open to a number of biases in the absence of any long term follow up RCTs of a large group of patients they will provide valuable data.	The Committee considered the clinical and cost effectiveness evidence available for FBSS and CRPS. The Committee also considered whether it was appropriate to generalise evidence from FBSS and CRPS to other neuropathic pain conditions – see FAD sections 4.3.6, 4.3.10, 4.3.11, 4.3.12.

	While the ACD acknowledges that both FBSS and CRPS are neuropathic pain conditions and recommends SCS for FBSS, it fails to address SCS in other causes of neuropathic pain where a large number of case series show efficacy for SCS in this group of patients where 50% are refractory to drug therapy (EFNS guidelines on pharmacological treatment of neuropathic pain Attal et al. European Journal of Neurology 2006, 13: 1153–1169). As a group of physicians with long expertise in the use SCS we feel that this particular group of patients will be particularly disadvantaged by the current ACD recommendations. While no RCT exists for this group of patients a lack of RCTs does not equate to a lack of effectiveness and the literature on SCS should be considered as a body rather than RCTs in isolation.	
	2. CLI The study conducted by Amann, W. Spinal cord stimulation in the treatment of nonreconstructable stable critical leg ischaemia: results of the European Peripheral Vascular Disease Outcome Study (SCS-EPOS). European Journal of Vascular & Endovascular Surgery 2003; 26 280-286). Is alluded to briefly both in the ACD and the HTA. The study is not an RCT but explores adequate selection criteria for candidates for SCS in CLI. The study shows clearly that the SCS group with selection criteria applied (SCS match group) has better limb survival than patients with SCS and no selection criteria or patients with no SCS. The paper was not analyzed in the HTA as it is not an RCT. It has been alluded to in the HTA document .	The Committee considered that clinical evidence suggested that there may be benefits for SCS used for the treatment of CLI. However, it concluded that there was insufficient cost effectiveness evidence to support the use of SCS for CLI. Recognising the possible benefits of SCS for the treatment of CLI, the Committee considered that SCS should be subject to further research. For both legal and bioethical reasons those undertaking technology appraisals and developing clinical guidelines must take account of economic considerations (Social Value Judgements - Principles for the development of NICE guidance; principle 2) – see FAD sections 4.3.7, 4.3.13.
	ii) Do you consider that the summaries of clinical and cost effectiveness are reasonable interpretations of the evidence and that the preliminary views on the resource impact and implications for the NHS are appropriate? 1. CRPS	

	The summaries of cost effectiveness on CRPS is a skewed interpretation of the literature. This is based largely on the fact that the 5-year analysis of SCS+PT vs. PT alone had not been published fully by Kemler (JNeurosurg 108:292–298, 2008) We have a number of comments relating to this study	Noted, the Committee considered the main and sub group (per treatment) analysis of the 5 year CRPS trial data - see FAD sections 1.1, 4.1.5, 4.1.6, 4.2.6, 4.2.15, 4.3.6, 4.3.8 and 4.3.11.
	a) The ACD acknowledges that the study was a small study (54 patients) with a large crossover 4/18 patients of the PT group received an SCS implant and 12/36 in the SCS group did not receive an SCS because of failed test stimulation. Under those conditions the groups at 5 years where no longer representative of the groups	Noted, the Committee considered the main and sub group (per treatment) analysis of the 5 year CRPS trial data - see FAD sections 1.1, 4.1.5, 4.1.6, 4.2.6, 4.2.15, 4.3.6, 4.3.8 and 4.3.11.
	b) Kemler does not conduct an ITT analysis of the original randomized groups but chooses to exclude some of the randomized patients (4 in the PT group because of SCS implant and 1 in the SCS+PT Group because of a special implant). This is no longer a conventional ITT analysis but is taken as such without question in the ACD document.	Noted, the Committee considered the main and sub group (per treatment) analysis of the 5 year CRPS trial data - see FAD sections 1.1, 4.1.5, 4.1.6, 4.2.6, 4.2.15, 4.3.6, 4.3.8 and 4.3.11.
	c) In the ACD, the committee concludes that there is considerable uncertainty regarding the long term effects of SCS in CRPS but takes little account of the fact that in the Kemler study at 5 years. Among patients (90%) of 20 patients with an SCS indicated that they had positively responded to the treatment, and 19 patients (95%) reported that they would undergo the treatment again for the same result.	As above.
	d) The same study conducted an unconventional per treatment analysis, which excluded 4 patients who were randomized to PT but actually received a stimulator and one patient in the stimulator group who received a special SCS implant. This per treatment analysis shows a continued effectiveness of SCS at 5 years.	As above.
	e) The Kemler study population had suffered with CRPS for an average of more than 3 years at baseline. The patients had an average baseline VAS score of 7. This is a high score when 5.4 is considered as severe and the committee is recommending SCS for patients with VAS scores above 5 in FBSS	The Committee carefully considered the comments received from consultees and commentators in response to the Assessment Report and ACD, including these data from the CRPS trial - see FAD sections 1.1, 4.3.6, 4.3.8 and 4.3.11.

	f) The committee concludes that SCS is cost effective at IPG life longer than 4 years. It is important to note that the technology used by Kemler et al is now outdated. In our experience this would have a profound effect on battery life as well as the number of SCS trail failures	In considering recommendations for pain of neuropathic origin the Committee was mindful of consultee comments that device longevity may be greater than the 4 year period - see FAD section 4.3.11.
	In the economic analysis for the CRPS group of patients different ICERs are arrived at in the ABHI submission vs. the SCHARR HTA analysis. This is dependent on the estimation of the baseline utilities value for that group of patients. In the ABHI submission a similar group of patients (FBSS patients with severe pain) derived from the PROCESS trial (an RCT) are used. THE SCHARR HTA group derived the baseline utilities value from the Mc Dermott et al paper (Mc Dermott et al. European Journal of Pain 10 (2006) 127–135). This is not an RCT but a cross sectional observational survey. Furthermore the Mc Dermott group of patients is far from representative of patients with severe CRPS seen in a hospital setting as the patients are sampled from GP surgeries. As a matter of fact the authors comment on their sample choice " We limited sampling to non-pain specialists in order to evaluate a broad range of neuropathic pain severity, including patients with milder forms that may not have been evaluated by a specialist". The utilities for this group, even the severe pain range, will clearly not represent the severe pain CRPS patients for which SCS is clinically appropriate.	The Committee recognised that the utility data in the McDermott paper may not reflect the utility of a person with CRPS. The Committee considered the utility data from the CRPS trial – see FAD sections 4.2.6, 4.2.15, 4.3.11.
	International Guidelines for the treatment of CRPS developed under the auspices of the International Association for the Study of Pain (IASP), recommends SCS for CRPS at 12-16 weeks. This guideline was developed by a panel of internationally recognized experts in the care of CRPS patients (Stanton-Hicks M. et al .An updated interdisciplinary clinical pathway for CRPS: report of an expert panel. Pain Pract. 2002;2(1):1-16). The Kemler study population had suffered with CRPS on average for more than three years. SCS should be recommended severe CRPS where conventional medical management has failed to achieve a result or facilitate physiotherapy	The Committee considered the use of SCS for CRPS - see FAD sections 1.1, 4.3.4, 4.3.11.
	Refractory Angina: 1. In The ESBY study SCS vs. CABG, the SCS group show a similar effectiveness to the CABG group at 5 years and a non significant tendency towards improved survival. The HTA concludes that SCS dominates CABG.	The Committee recognised the potential clinical benefits of SCS for the treatment of RA, but considered that there was insufficient cost

	The committee considers that as this group of patients could undergo CABG they are not true RA patients and therefore the study is unrepresentative of the patient group. 2. In the SPiRiT trial SCS was shown to be as effective as PMR in patients regarded as being truly RA. The patients receiving SCS were drawn from all over the UK and had poor follow up arrangements for reprogramming. The trial design insisted upon using an outmoded electrode technique for stimulation. Both the studies show that SCS is equivalent to the gold standard in Angina and Refractory Angina patients. Murray et al "Spinal cord stimulation significantly decreases the need for acute hospital admission for chest pain in patients with refractory angina pectoris" Heart 1999;82:89-92 a UK study of costs before and after SCS in 19 consecutive patients provides UK data of cost benefit. This is in an RA population. Cost savings are due to the fall in annual admission rates. In light of the above evidence SCS should be available to patients who are suitable for CABG but are unable to undergo the procedure because of high clinical risk. As well those who are unsuitable for reoperation. (True RA) In the UK clinical context SCS is only considered as an option following referral from a cardiology team consideration of other pain management techniques as per the Guidelines created by the Cheshire and Merseyside Cardiac Network on "Diagnosis and Management of Stable Angina" can be found at the link below – http://www.cmcn.nhs.uk/guidelines/stable_angina.html	effectiveness evidence to support the use of SCS for RA. Recognising the potential benefits, it recommended that SCS use in these people be restricted to research. For both legal and bioethical reasons those undertaking technology appraisals and developing clinical guidelines must take account of economic considerations (Social Value Judgements - Principles for the development of NICE guidance; principle 2) – see FAD sections 4.1.10, 4.1.12, 4.1.13, 4.1.14. 4.3.7, 4.3.13.
	3. Critical Limb Ischaemia: The study conducted by Amann, W. Spinal cord stimulation in the treatment of nonreconstructable stable critical leg ischaemia: results of the European Peripheral Vascular Disease Outcome Study (SCS-EPOS). European Journal of Vascular & Endovascular Surgery 2003; 26 280-286). Is alluded to briefly both in the ACD and the HTA. The study is not an RCT but explores the effects of adequate selection criteria on candidates for SCS in CLI. In our experience the number of candidates with CLI who would be inappropriate for reconstructive surgery and would match the Amann selection criteria represents a small subgroup of CLI sufferers as a whole. The study shows clearly that the SCS group with selection criteria applied (SCS match	The Committee considered that clinical evidence suggested that there may be benefits for SCS used for the treatment of CLI. However, it concluded that there was insufficient cost effectiveness evidence to support the use of SCS for CLI. Recognising the possible benefits of SCS for the treatment of CLI, the Committee considered that SCS should be subject to further research in this group of people. For

	group) has better limb survival than patients with SCS and no selection criteria or patients with no SCS. The paper was not analyzed in the HTA as it is not an RCT. However in issuing guidance to the NHS the committee should consider in full the clinical implications of the results of the study on a small group of patients who would otherwise go on to loose their limbs as a result of guidance restricting the use of SCS to research. Burger' s disease also represents a small subgroup of young patients where an RCT does not exist but clinical experience confirms effectiveness of SCS. Condemning this group to an assured amputation in their 3rd decade would not constitute sound clinical guidance	both legal and bioethical reasons those undertaking technology appraisals and developing clinical guidelines must take account of economic considerations (Social Value Judgements - Principles for the development of NICE guidance; principle 2) – see FAD sections 4.3.7, 4.3.13.
	iii) Do you consider that the provisional recommendations of the Appraisal Committee are sound and constitute a suitable basis for the preparation of guidance to the NHS? FBSS: On the subject of FBSS the ACD provides sound guidance in line with the evidence, the recommendation however should be broadened to include SCS for other clear aetiologies of neuropathic pain that have not responded to conventional medical management, as the ACD document agrees that both FBSS and CRPS are neuropathic pain conditions. Clinical effectiveness has been demonstrated for both conditions, which are taken to represent a wider spectrum of neuropathic pain conditions. On the subject of the necessity of a trial of spinal cord stimulation prior to implant. The ACD recommends that a trial must be carried out as in the studies. Clinical practice differs from randomized studies and as there is no evidence that a trial of SCS improves outcome, a trial should be recommended but not be a mandatory requirement. Payers may well interpret the guidance as mandating a trial in every patient. This can be counterproductive in the immunocompromised patient.	The Committee considered whether evidence of benefit and cost effectiveness could be generalised to other chronic pain conditions of neuropathic origin – see FAD sections 1.1 and 4.3.12. The Committee considered the comments received from consultees and commentators about the use of trial stimulation. The needs of special groups of patients may not be specifically addressed in the technology appraisal guidance. Guidance does not override the responsibility to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer – see FAD section 4.3.3.

	CRPS: On the subject of CRPS the guidance provided is unfortunately a poor conclusion based on misinterpretation of the evidence and poor reading of the 5 year Kemler study as well as poor choice of sample for baseline utilities . The guidance as it stands would disadvantage a group of patients who have very little in the way of treatment options. SCS and other pain relieving methods are employed in CRPS to enable physiotherapy. In case of failure of other interventions (as outlined in the international guidelines) SCS should be recommended in this group of patients in line with the available evidence and international guidelines. In our experience as a group of clinical experts CRPS patients respond well to early intervention with SCS. Also their battery life with current technology far exceeds the 4 years quoted by the research using outdated SCS models.	The Committee recognised that the utility data in the McDermott paper and the FBSS trial may not reflect the utility of a person with CRPS. The Committee considered the utility data from the CRPS trial – see FAD sections 4.2.6, 4.2.15, 4.3.11. The Committee considered the main and sub group analysis of the 5 year CRPS trial data - see FAD sections 1.1, 4.1.5, 4.1.6, 4.2.6, 4.2.15, 4.3.6, 4.3.8 and 4.3.11.
	Angina: The evidence quoted has shown SCS to be equivalent to the current gold standard for the treatment of angina i.e CABG. SCS is also equivalent to PMR (Percutaneous myocardial revascularization) the ACD states" All four trials recruited people with RA for whom revascularisation procedures were unsuitable or for whom it was considered that revascularisation would not improve prognosis" (4.1.9) The committee however proceeds with a different interpretation of the evidence based on the groups of patients recruited for the trial. We have used SCS in angina for more than 15 years have found it to be an effective treatment in line with the evidence from the studies.. We find the committee's recommendations on this subject difficult to comprehend in a group of patients who, in our experience respond extremely well and rarely require battery replacements. We find that RA is one of the best indications for SCS. SCS should remain an option for RA and Angina with significant co-morbidity. SCS should be available to those that manage patients with Refractory angina in a multidisciplinary setting with clear clinical pathways. Multidisciplinary pain management has been shown by NRAC to achieve best results.	The Committee recognised the potential clinical benefits of SCS for the treatment of RA, but considered that there was insufficient cost effectiveness evidence to support the use of SCS for RA. Recognising the potential benefits, it recommended that SCS use in these people be restricted to research. For both legal and bioethical reasons those undertaking technology appraisals and developing clinical guidelines must take account of economic considerations (Social Value Judgements - Principles for the development of NICE guidance; principle 2) – see FAD sections 4.1.10, 4.1.12, 4.1.13, 4.1.14. 4.3.7, 4.3.13.

	CLI: The ACD alludes to the Amman study but makes no comment on it. We feel that the guidance as it stands would disadvantage the group of patients who match the Amann study selection criteria and who again in our experience benefit significantly from SCS Another group that would be tragically disadvantaged from this guidance would be patients with Buerger's disease and vasospastic disorders, who again, in our clinical experience respond extremely well to SCS. It is clear that the therapy makes a huge impact on the Quality of life of this group of patients. ON CLI as well the other indications we feel that the restrictions imposed by the HTA in considering only RCTs should be lifted at this stage and the committee should be considering a larger body of evidence including case series and non randomized trials.	The Committee considered that clinical evidence suggested that there may be benefits for SCS used for the treatment of CLI. However, it concluded that there was insufficient cost effectiveness evidence to support the use of SCS for CLI. Recognising the possible benefits of SCS for the treatment of CLI, the Committee considered that SCS should be subject to further research in this group of people. For both legal and bioethical reasons those undertaking technology appraisals and developing clinical guidelines must take account of economic considerations (Social Value Judgements - Principles for the development of NICE guidance; principle 2) – see FAD sections 4.3.7, 4.3.13.
	Implementation: Implementation SCS as a therapy area has survived in the UK due to the interest of clinicians from functional neurosurgery and pain anaesthesia. There are approximately 30 implanting centres within the UK. A few perform up to 60 new patient procedures per year and some less than 10. Clinical networks: Best practice with SCS is achieved where SCS is carried out in high volume centres within the context of a multidisciplinary team. It will be essential to develop care pathways in order to support successful commissioning. Existing centres will need to expand; it's possible that a few other centres will need to be established	Noted, no changes required to the FAD.
	Clinical Training: There is a deficit in training facilities for SCS. NSUKI, St Thomas's, Walton centre and the industry partners provide training. A few receive limited training as part of their	Noted, no changes required to the FAD.

	CCST. The Faculty of pain medicine is responsible for over seeing SCS training for anaesthetists within the arrangements for specialist training of anaesthetists in pain medicine. SBNS is responsible for neurosurgical training. Device registration, audit, governance and research Throughout the appraisal process we have mentioned the need for device registration, clinical audit and governance and a coordinated approach to future research. The professional societies believe there is a good case for a web-based registry to capture all implant activity throughout the UK. NSUKI is currently running a pilot national registry for pain implant devices. This effort is coordinated by [redacted].	Noted, no changes required to the FAD.
	Specific comments on the ACD document: 1.1 Should be changed to express clearly that a trial stimulation is desirable but not mandatory and that in line with the evidence from PROCESS and North study this group of patients should not have to exhaust all avenues of standard care before they are considered for SCS 1.2 The recommendations for SCS in CRPS, RA and CLI should be revised in line with the evidence presented by the HTA, other evidence as case series and non randomized trials etc.. See general comments above 1.4 & 4.3.3. Trials should be desirable but not mandatory especially in the immunocompromised group.	The Committee considered the use of trial stimulation as part of the assessment for SCS – See FAD section 1.3, 4.3.3. The Committee considered the use of SCS for people with RA, CLI and CRPS – See FAD section 1.1, 1.2, 4.3.5, 4.3.6, 4.3.7, 4.3.11, 4.3.13. The needs of special groups of patients may not be specifically addressed in the technology appraisal guidance. Guidance does not override the responsibility to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer – see FAD section 4.3.3.
	2.4 The term pain management program is used in error in this context. A Pain Management Program (in the context of chronic pain management) implies a specific cognitive behavioral group therapy. We believe the term" multidisciplinary approach" would serve the meaning better and allay any confusion.	This has been amended in the FAD – see FAD section 2.4.

	4.1.10 RA patients find pain ratings very difficult to express as their pain is usually described as severe and intermittent. Use of Nitrates hospital admissions and frequency of angina attacks are better clinical indicators	Noted, the FAD summarises both pain and functional outcomes, no changes made to the FAD.
	4.2.7 An annual withdrawal rate of 3.24% per annum, is assumed to be because of gradual loss of pain control for the SCS group in the model. No withdrawal rate is assumed to occur for the CMM group in both models this does not reflect clinical reality as tolerance to drugs, injection techniques and psychological and physical rehabtechniques are well documented. Why was no withdrawal rate assumed for CMM? Why are no complications assumed in the CMM group? This again bears no resemblance to clinical reality.	The economic analyses assume that people will continue to receive some form of conventional medical management even if the specific type of treatment changes. Therefore the model assumes no withdrawal from the CMM arm. The Committee noted that adverse events were not included in the CMM group when considering the cost effectiveness analyses– see FAD section 4.3.8
	4.2.9 The cross sectional survey of McDermott et al is not representative of patients with severe CRPS who would be candidate for SCS implant, even the severe pain group. Both the HTA and the ACD are mistaken on this assumption. While the patients included CRPS patients they were recruited from GP surgeries, which is by definition a different population from the hospital CRPS population. Why was this survey (not RCT) allowed? And how can it be safely assumed that these patients represent the refractory group of CRPS patients referred for SCS?	The Committee recognised that the utility data in the McDermott paper may not reflect the utility of a person with CRPS. The Committee considered the utility data from the CRPS trial – see FAD sections 4.2.6, 4.2.15, 4.3.11.
	4.2.13 If device longevity becomes the deciding factor in the ICER, a trial of SCS would help the clinician decide on estimated device longevity based on the current usage during the trial. CPRPS patients with a successful trial and low current requirements should be allowed to proceed with a final implant	The Committee considered device longevity - see FAD section 4.3.9, 4.3.11.
	4.3.5 The Committee therefore recognizes that price and longevity were not independent and that longevity varies depending on an individual's pain characteristics. Does the committee realize that some devices allow the clinician to estimate device longevity based on trial data?	The Committee considered device longevity - see FAD section 4.3.9, 4.3.11.
	4.3.6 The committee's conclusions on its specific guidance would disadvantage a group of patients with rare causes of neuropathic pain for whom an RCT will never be possible as FBSS and CRPS are both neuropathic pain conditions. The final guidance	The Committee considered whether it was appropriate to generalise evidence from FBSS and CRPS to

	should therefore recommend SCS for severe neuropathic pain of clear aetiology that has not responded to CMM. 4.3.7 Neither the committee nor the experts had access to the Kemler 5 year full data. The comments above on the conduct of the ITT in this paper lead to different conclusions nevertheless the committee's conclusions on long term results of CRPS are bizarre given the comments from the experts.	other neuropathic pain conditions – see FAD sections 4.3.6, 4.3.10, 4.3.11, 4.3.12. The Committee considered the main and sub group (per treatment) analysis of the 5 year CRPS trial data - see FAD sections 1.1, 4.1.5, 4.1.6, 4.2.6, 4.2.15, 4.3.6, 4.3.8 and 4.3.11.
	4.3.8 Pain outcomes are difficult for RA patients to rate as their pain is intermittent and severe, in CLI pain ratings are very different at rest from on movement hence patients have great difficulty in providing pain ratings 4.3.9 Reduction in the effects of the comparator are not taken into account by the committee. The rare but serious complications of SCS are overemphasized as they relate mainly to surgical lead implant and are no different from complications of a laminectomy procedure (standard practice in the NHS)	Noted, no changes required to the FAD. The Committee noted that adverse events were not included in the CMM group when considering the cost effectiveness analyses. It also considered the frequency of serious adverse events - see FAD section 4.3.8.
	4.3.11 accurate utility data for CRPS is now available 4.3.12 from a clinical perspective RA patients are the best indication for SCS we therefore find the committee's interpretation of the available evidence at odds with the clinical reality. As the RA population respond to implant with simple devices have low current requirements and rarely require battery replacement. The interpretation of the data should not hinge entirely on the question of refractoriness of the population in the studies	The Committee considered the utility data from the CRPS trial – see FAD sections 4.2.6, 4.2.15, 4.3.11. The Committee recognised the potential clinical benefits of SCS for the treatment of RA, but considered that there was insufficient cost effectiveness evidence to support the use of SCS for RA. Recognising the potential benefits, it recommended that SCS use in these people be restricted to research. For both legal and bioethical reasons those undertaking technology appraisals

		and developing clinical guidelines must take account of economic considerations (Social Value Judgements - Principles for the development of NICE guidance; principle 2) – see FAD sections 4.1.10, 4.1.12, 4.1.13, 4.1.14. 4.3.7, 4.3.13.
Royal College of Nursing	The Royal College of Nursing welcomes the opportunity to review the Appraisal Consultation Document (ACD) of the technology appraisal of Spinal cord stimulation for chronic pain of neuropathic or ischaemic origin. The document is comprehensive and has covered all aspects very well. Sound recommendations have been made on how to implement the guidance. We consider that effective recommendations on further research is an area that does need more work.	Noted, no changes required to the FAD. Noted, no changes required to the FAD. Noted, no changes required to the FAD.
	The only fact that perhaps relates to the equality question is in regards to access to pain clinics as this obviously acts as a 'gatekeeper' to the treatment. The point is well made in the document that this option needs to be considered as part of the process within MDT pain management arrangements and not as an isolated event thus the availability of pain clinic is pivotal.	Noted, local providers have a responsibility to implement the guidance, in their local context, in light of their duties to avoid unlawful discrimination and with due regard to promoting equality of opportunity.
Society of British Neurological Surgeons	I am a member of the Clinical Advisory Group, representing the Society of British Neurological Surgeons and endorsed by the Welsh Assembly Government.	Noted, no changes required to the FAD.
	Spinal cord stimulation (SCS) was introduced in 1967 and I have been actively involved in its use since 1980 – 28 years – in London and Cardiff. As a consultant neurosurgeon since 1988 I have implanted spinal cord stimulators in 328 patients. Over the last 5 years I have implanted an average of 25 new units per annum, including in that period 45 (36%) for "Failed Back Surgery Syndrome" (FBSS); 41 (33%) for Complex Regional Pain Syndrome (CRPS), 31 (25%) for other neuropathic pain syndromes and a smaller number for ischaemic conditions. Some patients continue to enjoy effective stimulation for neuropathic syndromes after more than 15 years.	Noted, no changes required to the FAD.

	My publications on SCS (selected references appended chronologically, 1-23; other references are listed in the order in which they appear) include an early case series(2), and the first comprehensive literature review(4), both of which contributed to the recognition that SCS is effective in neuropathic and ischaemic pain but not in nociceptive pain. At the invitation of Prof. Patrick Wall I wrote the chapter on neurostimulation for the 4th edition of Wall and Melzack's Textbook of Pain(8) and co-wrote the chapter in the 5th edition(14). It was his suggestion that I edited a book on neurostimulation for pain(9) and I have also co-edited a further, 2 volume, textbook on neurostimulation/ neuromodulation(18,19).	Noted, no changes required to the FAD.
	I was a member of the panel which published the UK guidelines for SCS in 2005(24), a member of the recent European Federation of Neurological Societies Task Force on neurostimulation for pain(8) and am European representative on the neuromodulation committee of the World Federation of Neurosurgical Societies. I was president of the International Neuromodulation Society (INS) 2000 – 2003.	Noted, no changes required to the FAD.
	I would not have persisted with these clinical and academic endeavours over a long period if SCS was not effective in a variety of chronic, intensely painful and disabling conditions. Various reviews of my case series have revealed very significant, often dramatic, benefit in approximately 60% of patients with a range of otherwise intractable neuropathic syndromes and a moderate but worthwhile benefit in a further 20%. In my experience more than 80% of patients with CRPS gain considerable benefit from SCS. Outcomes are improving with technological advances in the equipment.	Noted, the Committee considered the clinical effectiveness of SCS for the treatment of pain of neuropathic and ischaemic origin – see FAD section 4.3.5, 4.3.6, 4.3.7.
	Contextural comments 1) A very large body of RCT evidence indicates that drug therapy gives effective relief for less than 50% of patients with neuropathic pain.(25) 2) SCS is a long-term treatment for long-term conditions and therefore not appropriately assessed in the same way as acute treatments for short-term conditions (e.g postoperative analgesia).	Noted, no changes required to the FAD. Noted, no changes required to the FAD.
	3) The impossibility of blinding (evoked paraesthesia are essential), surgical considerations and the long time-course militate against acquisition of the highest level evidence in this field. Thus the paucity of RCTs contrasts with the position in, say, acute drug trials, which are comparatively straightforward. There is, however, a large body of lower level positive evidence as acknowledged by the EFNS Task	The Appraisal Committee considers evidence submitted to the Institute and that retrieved from the published literature by the Assessment Group.

	Force(22). 4) Patients treated with SCS have generally failed to respond to all other treatment, physical, pharmacological, psychological and invasive, often over long periods.	 The Committee was mindful that SCS was used after other therapies have failed to provide a response – see FAD sections 1.1, 4.3.4.
	5) These patients have, obviously, not recovered spontaneously, also over a long period of time. 6) Lower level evidence (e.g uncontrolled case series) is strengthened by, and should be given greater recognition for, the length of history prior to SCS combined with the duration of the response which are both typically measured in years, sometimes more than 20 years. This effectively eliminates placebo responses. The number and range of previous, ineffective, therapies are also relevant to this point.	Noted, no changes required to the FAD Noted, no changes required to the FAD.
	7) A majority of patients not only return for pulse generator replacement and because of other equipment failures, but also typically demand urgent attention, thereby acting as their own controls. Illustrative case: I have a patient with severe Raynaud's disease (vasospastic disease) affecting all 4 extremities. Over 15 years prior to implantation she had had four vascular operations and had almost lost the use of her hands, as well as suffering severe pain and blistering. She has enjoyed spectacular control with SCS, both of pain and functionally, for 12 years. The relief is immediately lost when her pulse generators deplete and is restored when they are replaced (she has 2 systems). This "N of one trial" provides compelling evidence.	To determine the effect of a treatment relative to standard care. The Institute has a strong preference for evidence collected from head to head RCTs. See Guide to the Methods of Technology Appraisal (April 2004) section 3.2
	8) Critical limb ischaemia (CLI) Illustrative case: A 51 year old lady presented with severe rest pain and a deep ischaemic ulcer on one toe despite having undergone surgical sympathectomy and two bypass grafts in the previous two years. She was using a wheelchair. After a failed prostacyclin trial she was scheduled for above-knee amputation but decided to try SCS. After implantation in 1990 the foot immediately became warm, the rest pain was completely relieved, the ulcer healed and her walking distance increased to more than a mile. She took her granddaughters all round the world. The only time the pain returned was when a technical fault developed with the stimulator and it resolved when it was replaced. When she died from lung cancer 13 years later she had two comfortable legs and was still walking long distances. 9) I suspect that, almost paradoxically, the wealth of dramatically positive clinical	The Committee considered that clinical evidence suggested that there may be benefits for SCS used for the treatment of CLI. However, it concluded that there was insufficient cost effectiveness evidence to support the use of SCS for CLI. Recognising the possible benefits of SCS for the treatment of CLI, the Committee considered that SCS should be subject to further research in this group of people. For both legal and bioethical reasons

	experience, where nothing else works, is partly responsible for the relative paucity of RCTs, in the same way that nobody has invested in RCTs for fire extinguishers, parachutes and laparotomy for ruptured spleen.	those undertaking technology appraisals and developing clinical guidelines must take account of economic considerations (Social Value Judgements - Principles for the development of NICE guidance; principle 2) – see FAD sections 4.3.7, 4.3.13
	10) Outcome assessment in patients with chronically painful neuropathic conditions is problematic and "50% pain relief", although almost universally used, is simplistic and misleading in this context.(10,26) Pain is inherently non-quantitative and the VAS is a subjective abstraction, not an objective measure. It is subject to many influences when used in the long term. Some patients who consistently report considerable degrees of pain relief yield percentage changes on VAS scores lower than 50%. (12, 27, 28) Illustrative case: One patient, a professional man with a young family who was disabled by FBSS, reported to me that his reduction in pain intensity was no more than 25% but SCS made the quality of the pain very different and much more bearable and that it made an enormous difference to his life. Such reports are not unusual.	The Committee considered the use of trial stimulation. The FAD does not specify how the trial should be conducted or 'success criteria' of any SCS trial – see FAD sections 1.1, 1.3, 4.3.3.
	More holistic outcome measures have been appearing in the literature only very recently. 11) In our study where the stimulator was switched off for a period (12), 34 out of 63 declined to take part. Ten (16%) explicitly did not wish to be without their stimulator even for one week and 15 (24%) gave no reason. The others declined for various reasons.	The Committee considered the clinical effectiveness of SCS – see FAD section 4.3.5, 4.3.6, 4.3.7.
	12) FBSS is just one representative or cause of neuropathic pain of peripheral origin (cf. spinal cord injury or stroke: central origin). The Assessment should be made in this context, i.e as assessing neuropathic pain of peripheral origin where the available published evidence happens to be mainly about the exemplar FBSS. Approval should logically be generalised to other cases including "Failed Neck Surgery Syndrome", amputation pain, post thoracotomy pain, various other post surgical peripheral syndromes, diabetic peripheral neuropathy etc.	The Committee considered whether it was appropriate to generalise evidence from FBSS and CRPS to other neuropathic pain conditions – see FAD sections 4.3.6, 4.3.10, 4.3.11, 4.3.12.

	13) With regard to angina pectoris, the question is not whether SCS is better than any comparator. It is whether SCS is at least as good as coronary artery bypass grafting (CABG), but with the advantage of being a much smaller procedure not requiring ITU/coronary unit admission etc, in high risk/unsuitable cases, and is it effective in patients unsuitable for stenting? You have the evidence for reduced hospital admission and improved cardiac function.	The Committee recognised the potential clinical benefits of SCS for the treatment of RA, but considered that there was insufficient cost effectiveness evidence to support the use of SCS for RA. Recognising the potential benefits, it recommended that SCS use in these people be restricted to research. For both legal and bioethical reasons those undertaking technology appraisals and developing clinical guidelines must take account of economic considerations (Social Value Judgements - Principles for the development of NICE guidance; principle 2) – see FAD sections 4.1.10, 4.1.12, 4.1.13, 4.1.14. 4.3.7, 4.3.13.
	14) Trial stimulation. I am extremely uneasy about the recommendation that there should be a preliminary trial. This is advocated simply because that is what happened to be done in the RCTs being relied upon. You recommend trial stimulation with no comparative evidence, controlled or otherwise, which contrasts vividly with your general dependence upon RCTs. The efficacy of trial stimulation has never been tested in an appropriately constructed trial, so how do you justify supporting it?	The Committee specifically considered the use of trial stimulation in the clinical and cost effectiveness evidence submitted and consultee comments – see FAD sections 1.1, 1.3, 4.3.3.
	Although trial stimulation may certainly detect the very small proportion of patients who do not like the sensation or whose pain is exacerbated by stimulation, overall it is a poor predictor of long-term success, leading to a failure rate of around 30% on average. See for example Van Buyten et al (29) whose long term success rate was 68% after a very thorough preliminary trial in a large series. Possible reasons for this include: - it depends on percutaneous wire or “catheter” electrodes; surgically implanted	The Committee specifically considered the use of trial stimulation in the clinical and cost effectiveness evidence submitted and consultee comments. The selection criteria for a successful trial have been removed from the FAD – see FAD sections 1.1, 1.3,

	paddle electrodes perform better(30, 31) and may work where percutaneous leads do not, but cannot be used for a trial. - the biggest failure rate occurs early, suggesting a placebo response(see De la Porte and Van de Kelft(32): 95% immediate success, 80% at one month, 58% at one year in FBSS). In the Tesfaye RCT on diabetic neuropathy (33) a dummy trial stimulator significantly improved the pain scores. - most patients see this as their last hope and are desperate to "qualify". This will bias the outcome of the trial. - selecting patients on the basis of a 50% change in VAS is completely unsatisfactory. A VAS score of 10/10 dropping to 5/10 is not the same as a score of 5/10 dropping to 2.5/10. It is 100% different! This is absurd. The worst cases have to score the biggest responses to proceed; a less severe case is more likely to get a stimulator. - although the false positive rate of selecting cases IN is as high as 30% or more, little is known about the false negative rate, i.e patients who are wrongly rejected. There is some published evidence, however, indicating that patients who fail a trial can certainly benefit in the long term (34, 35). - in some people the response increases over time, which would not be detected by a trial. I have not used trial stimulation for several years yet my outcomes are comparable to those where a trial is used.	4.3.3.
	General 1) I have not raised specific points from the RCTs which are being relied upon but I refer to Dr [redacted] comments on these, and those of NSUKI, which I fully endorse. 2) As Dr [redacted] explains in his submission, new calculations indicate that the ICER for CRPS is substantially less than £30,000 per QALY	Noted, no changes required to the FAD. The Committee considered the use of SCS for the treatment of people with CRPS – see FAD sections 1.1, 4.3.6, 4.3.11.
	3) The extent of the dependence upon published RCTs appears excessive. I was very disturbed to read in the Technology Assessment Report produced for NICE by ScHARR, at pp22/23: "Data from non-randomised studies were not included as evidence was available from RCTs." The EFNS Task Force on stimulation for pain acknowledged that there was positive evidence for SCS in a range of neuropathic pain	To determine the effect of a treatment relative to standard care. The Institute has a strong preference for evidence collected from head to head RCTs where

	conditions, whilst acknowledging that further comparative trials were needed before SCS could be unreservedly recommended for these conditions (22).	these are available. See Guide to the Methods of Technology Appraisal (April 2004) section 3.2.
	4) A lack of published high level evidence is not, of course, evidence for lack of efficacy. The clinical evidence, both published and unpublished, relates to tens of thousands of cases implanted and sometimes reimplanted over several decades.	Noted, no changes required to the FAD.
	5) Many suitable patients have their conditions as a result of hospital treatment.	Noted, no changes required to the FAD.
	6) There is a cohort of patients with CRPS and various neuropathic and ischaemic conditions in whom the sustained response is dramatic and life-changing for them and their families.	The Committee considered the clinical effectiveness evidence for CRPS, RA and CLI – see FAD sections 4.3.5, 4.3.6, 4.3.7.
	7) The extent and duration of the unremitting suffering of people who may be greatly helped by SCS is generally not appreciated, including by the medical profession. It is dangerous and unconscionable to condemn many of these people to continue with their suffering because relatively few RCTs have been published, in a field in which there are barriers to obtaining the highest level evidence	For both legal and bioethical reasons those undertaking technology appraisals and developing clinical guidelines must take account of economic considerations (Social Value Judgements - Principles for the development of NICE guidance; principle 2).
	8) Whilst strongly endorsing the call for further research, I fear the proposal, that apart from FBSS SCS should be employed only as part of a research programme, is too restrictive and exclusive and will deny deserving patients appropriate therapy.	The Committee considered the clinical and cost effectiveness of SCS for the treatment of pain of neuropathic and ischaemic origin – see FAD sections 4.3.5, 4.3.6, 4.3.7, 4.3.11, 4.3.12, 4.3.13.
	9) I have spent many years using SCS to treat patients with CRPS, a range of neuropathic pain aetiologies and vasospastic disease, very successfully and without a preliminary trial. Is NICE going to opine that most of my practice is invalid and should not continue and that these patients did not, or should not, have had years of pain relief and improved function?	For both legal and bioethical reasons those undertaking technology appraisals and developing clinical guidelines must take account of economic considerations (Social Value Judgements - Principles for the development of NICE guidance; principle 2).

Association of British Neurologists	The Appraisal Committee has produced a comprehensive and detailed document on the use spinal cord stimulation in four different clinical conditions: Failed Back Surgery Syndrome (FBSS), Complex Regional Pain Syndrome (CRPS), Refractory Angina (RA) and Critical Limb Ischaemia (CLI). In the present statement the focus is on the two first conditions, with a brief comment made on RA and CLI only.	Noted, no changes required to the FAD.
	General comments Spinal cord stimulation (SCS) has been used in clinical practice for 40 years but controlled trials are few. This is not unique in the surgical management of chronic pain in which only recently has evidence based medicine gained support. As an example, large decisive trials on the surgical management of sciatica have only been published in the last few years. There remain a large number of treatments for chronic pain for which no appropriate controlled trials have been published (e.g., microvascular decompression and ganglion-level procedures in trigeminal neuralgia and total hip replacement in advanced osteoarthritis). In these conditions, the weight of evidence supporting the use of the technology appears so overwhelming that few voices have been raised to demand a controlled trial to prove efficacy. As regards SCS, much of the current evidence has been gathered before evidence-based medicine made its breakthrough, in the form of poorly controlled case series and a limited follow-up. Despite these weaknesses, spinal cord stimulation is steadily gaining popularity with an ever-increasing number of patients provided with the treatment. Given the long period of time over which has happened, and the fact that there are no signs of the treatment being surpassed or replaced by a more effective or popular one, SCS should be seen as an advanced clinical practice that has established its position in the armamentarium of pain clinics, despite lack of controlled trials. One has to welcome the recommendation from the Appraisal Committee that more research is needed, not the least in the form of controlled trials, but until that has been achieved, the needs of the patients must also be considered. The particular group of patients whose ongoing treatment should not be threatened are those who have enjoyed significant subjective benefit from SCS but who need a revision or battery change. To not carry out such a procedure in the light of lack of properly controlled trials would be clinically unjustifiable and ethically questionable.	Noted, no changes required to the FAD. NICE guidance is prospective. People who are currently using SCS for chronic pain should have the option to continue treatment until they and their clinicians consider it appropriate to stop. The FAD has been amended to make to state this – see FAD section 1.6.

	SCS requires a percutaneous trial and internalisation of the system, or a separate surgical procedure (laminotomy or laminectomy), neither of which are a major operation. Reported serious adverse effects associated with SCS are very rare. Its use is limited to chronic pain, and the general acceptance on the part of the patient is excellent because it provides a drug-free alternative. Advancement of SCS, and neuromodulation therapies in general, has led to a decrease of previously common use of repeated nerve blocks and neurodestructive procedures which are not evidence based. Curtailing the use of SCS in the management of refractory pain brings about the risk of obsolete therapies being reintroduced by perplexed doctors and accepted by desperate patients. The Appraisal Committee recommends multidisciplinary assessment of the patient's suitability for SCS and a percutaneous trial to establish efficacy before implantation of the permanent system. This is common practice and has obvious benefits. In some highly specialised centres led by very experienced clinicians this may seem superfluous. However, as SCS is becoming more technically advanced and is being adopted by an increasing number of neurosurgical and pain departments it is imperative for the maintenance of the clinical standards that patient selection and treatment choice are based on comprehensive assessment and best advice available. The consultation document discusses two neuropathic pain conditions, FBSS and CRPS.	Noted, no changes required to the FAD.
	(1) Failed back surgery syndrome (FBSS) The Committee has evaluated the two RCTs so far published (North et al 2005, Kumar 2007). These two studies were rated Class II by the European Federation of Neurological Sciences Task Force in 2007 (Cruccu et al 2007). Both RCTs showed superiority of SCS over either reoperation or conventional medical management, CMM. The PROCESS study (Kumar et al 2007) showed that SCS was superior to CMM at both 6 months (>50% pain relief obtained in 48% randomised to SCS and 9% randomised to CMM, respectively) and 12 months (34% and 7%, respectively). In the North study, 50% or more of pain relief was obtained by 39% of patients who received SCCS as opposed to 12% who underwent a reoperation. The number of patients in the PROCESS study was 100, and in the North study 60. Cost effectiveness analyses carried out by the Appraisal Committee supported the use of SCS in this indication. These two studies are of a reasonably good quality and reach similar conclusions. By and large they corroborate the suggestive evidence from a large number of case series in this indication. Cruccu et al (2007) report of pooled data of 3307 patients with FBSS, with a response rate of 62% (Class IV evidence). For a comparator trial, both	Noted, both the PROCESS and North trials were considered by the Committee, no changes required to the FAD.

	studies can be commended on the long end point (12 months for the PROCESS study and 4 months for the North study).	
	(2) CRPS The appraisal was based on the single Class II (EFNS Task Force definition) study by Kemler et al, with a two-year comparison of SCS with physiotherapy (PT), followed on by a non-randomised follow up for a further 3 years during which some patients received SCS (Kemler et al 2000, Kemler et al 2008). The conclusion reached by the investigators was that while at 24 months SCS is superior in pain relief to physiotherapy, this effect was lost from the 3rd year onwards. The Appraisal Committee acknowledge the treatment effect but question the use of SCS in CRPS on the basis of its cost effectiveness. It is unfortunate that only one serious attempt at a controlled trial has been published on this indication. The conclusions that can be reached from this study are hampered by methodological flaws. One relates to power calculations that were inadequate and led to the study becoming underpowered. The authors based their calculations on a previous pilot data (Kemler et al 1999). In that uncontrolled study, 18/23 (78%) patients went on to have a permanent stimulator implanted following a successful percutaneous trial. At one month, the baseline mean of 7.9 (range 6.5-1.0) on a visual analogue scale (VAS) of 0-10 had dropped to 4.2 (range 1-7) (Kemler et al 1999). This large treatment effect (~3.7) appears to be the basis of their power calculations. However, from the same report it appears that at a follow up of a (mean of) 32 months (range 6-79 months) the mean VAS score was 5.4 (range 1.0-8.4) in the 15 patients in whom the data were available where as in the 23 who did not have a SCS implanted the score had come down from 7.3(baseline) to 6.8 (2.3-9.3). The authors do not present the figure for the adjusted mean difference (between pain scores in the implanted vs. non-implanted groups) but it is likely to be around 2, still a very substantial difference in comparison with any approved pharmacological agent in neuropathic pain. It should be noted that the authors specify a target of 3.5 (3.5 cm on a 10 cm visual analogue scale presumably) at six months for the basis of their power calculations regarding the RCT, which is extraordinarily large. It of course allows far fewer patients to be recruited into the study, a sensible aim if one is concerned about shot term efficacy. It should be noted that the above-mentioned power calculations were based on a 6 month perspective (Kemler et al 1999). If the authors had planned a long-term follow-up study from the outset they would have been compelled to consider entering far more patients, the estimate based on their own 32 month data from the pilot study (Kemler et al 1999). Taking these data at face value one would predict that 22% of patients allocated to the SCS+PT group fail the percutaneous trial	Noted, the Committee considered the main and sub group analysis of the 5 year CRPS trial data – see FAD sections 1.1, 4.1.5, 4.1.6, 4.2.6, 4.2.15, 4.3.6, 4.3.8 and 4.3.11.

	(based on their pilot study), and aim at a treatment difference of 2.0. In this way one would get a more realistic target for the group difference of 1.6. Using their reported SD of 2.34 (with alpha 0.05 and beta 0.90) one would need 90 patients to enter. It should be also noted that the power calculations did not include drop-outs. In the five-year follow-up study (Kemler et al 2008) the completed patients totalled 31 in the SCS+PT group and 13 in the PT group (less than the 34 +17 needed based on their original calculations). An attrition percentage of 15 would increase the sample size to over 100.	
	The five-year assessment also suffers from methodological ambiguity (Kemler et al 2008). The ITT evaluation was not pursued rigorously throughout the study, and a patient with a special implant was excluded from the SCS+PT group analysis. No data are given as to any confounding factors during the 3 years of extended study, other than SCS provided for 4 patients in the PT group, such as other interventions that might alter the course of the pain problem (e.g. use of medication). This is especially pertinent to the PT group. These flaws withstanding, there was no statistical group-wise difference detected in any measures. As is customary in studies in which crossing over to another treatment modality is allowed, a sub group analysis of the 5-year pain status was carried out between the patients with SCS versus those who were offered PT in the first place, had no trial, and no SCS. Such an analysis led to a significant group difference of approximately 1.5 in favour of SCS (P=0.06) – an impressive result from an underpowered study and compatible with results from 12-week only drug trials in neuropathic pain. Despite some post hoc analyses based on LOCF values (no data shown), the authors appear not to have compared two further groups, those who actually received SCS and were not lost to follow up (20 in the randomised and 4 who crossed over) versus those who received PT alone (13 in the group assigned to PT at the outset and 9 who failed the trial). Such a comparison would better reflect clinical practice and inform the clinician what additional value to the management of CRPS to conventional treatment available SCS could provide.	Noted, the Committee considered the main and sub group analysis of the 5 year CRPS trial data – see FAD sections 1.1, 4.1.5, 4.1.6, 4.2.6, 4.2.15, 4.3.6, 4.3.8 and 4.3.11.
	Further scrutiny of the results show that there was limited increase in reported pain scores form year 2 to 5 so in the SCS+PT group and reduction of pain levels in the PT group during the same period. Because 4(22%) of 18 patients randomised to this group actually received SCS and were excluded from the analysis, this may have caused a significant bias, not captured by the LOCF analysis.	Noted, the Committee considered the main and sub group analysis of the 5 year CRPS trial data – see FAD sections 1.1, 4.1.5, 4.1.6, 4.2.6, 4.2.15, 4.3.6, 4.3.8 and 4.3.11.

	It would seem premature to conclude anything definitive on the long-term (5-year) effectiveness of SCS on the basis of this single small study. In discussing the long term effect of SCS the Committee expressed unease about the uncertainty of the duration of effect of SCS. However, several long-term follow up studies have been published that by and large are in agreement with a sustained effect of SCS, especially in the CRPS group. Kumar et al reported a case series spanning over 22 years of 410 patients, 328 of whom received a permanent implant, and reported a long term success rate of 74%. The mean follow-up in this case series was 96 months. Of the 32 patients with CRPS (both types) 23(72%) benefited long-term. Similar results were reported by Quigley et al in 21 patients with CRPS and a mean follow-up of 4.2 years. For their cost effectiveness analysis, the Appraisal Committee estimated the device longevity at 4 years. It is not clear that this is based on the actual longevity of the devices implanted today observing the best clinical practice. Although Kumar et al report in their last case series that on average, the internal pulse generator (IPG) had to be changed in the fourth year (Kumar et al 2006), the results were biased because of use of the now discontinued Pisces-Sigma in the early part of the case series, and limited use of the new multichannel and multipolar electrode systems that have a longer survival time (Kumar et al 2006). In Kemler's study (2008) in half of the patients the IPG was replaced in the fifth year. As rechargeable IPGs are appearing with a claimed life span of 7-10 years (Kumar et al 2006), the chosen longevity of 4 years for the cost effectiveness analyses seems unduly short. As was acknowledged by the Committee, the clinical specialists made the point in this regard and also highlighted the role of the individual's pain characteristics.	The Committee considered the maintenance of effect over time – see FAD sections 4.3.6, 4.3.8. The Committee was mindful of consultee comments that device longevity may be greater than the 4-year period used in the economic modelling – see FAD sections 4.3.9, 4.3.11.
	The Committee also recognised (page 23) that the economic modelling based on the assumption that the effect of SCS is stable over 15 years may be overoptimistic with subsequent underestimation of ICERs. However, it must be emphasised that there are no data suggesting that over such a very long period of time patients with disabling neuropathic pain conditions such as CRPS would not experience deterioration of their condition when undergoing alternative treatment. (It should be noted that Kemler's study does not qualify for evaluation of long-term natural course and as the PT group did not remain intact and 4 patients actually received an implant). Therefore, ICERs may have been equally well over estimated. The Committee also noted that serious complications were not included in the models. In fact such serious complications, although anecdotally reported, are quite rare, and it is doubtful whether their inclusion in the economic models would change the overall conclusions. As an example, the	The Committee considered the maintenance of effect over time – see FAD sections 4.3.6, 4.3.8. The Committee considered the frequency of serious adverse events associated with SCS, and the exclusion of adverse events from the CMM group – FAD section 4.3.8 has been amended.

	recent systematic review and guidelines paper (Cruccu et al 2007) registered no serious complications in altogether 4724 patients (number obtained from Table 2, pp 957-960). Although anecdotal reports do appear in the literature, exploration of the literature reveals less than 10 cases, mostly from the early era of the therapy. Professor Nurmikko who is the first author of this report is aware of 3 serious and 3 moderately serious unreported complications (mainly neurological) collected over 15 years from several large practices, constituting to much less than 1% of all implanted cases.	
	3. Ischaemic pain (RA and CLI) There is an unfortunate lack of high-quality studies addressing this issue. While the first studies in RA suggested comparable efficacy with CABG and PCI, the decisive Phase III efficacy study (STARTSTIM) has been suspended since 2006. In this trial the primary outcome measure was to be total exercise time on a treadmill, while secondary outcome measure included exercise time to angina onset, improvement of angina symptoms and cardiovascular function (www.clinicaltrials.gov id: NCT00200070). There are therefore currently insufficient data available for firm conclusions, and the non-committal stance of the Appraisal Committee is appreciated. Similarly, data on pain in relation to CLI appears too limited for firm conclusions and recommendations. There is obviously a need for high quality research in sufficiently large populations to settle the matter conclusively, and the recommendation in this regard given by the Committee is to be supported. The Committee have a difficult task in appraising the use of SCS in chronic pain despite the limited decisive evidence for its wide spread use in clinical practice. The four conditions addressed in the consultation process probably constitute no more than 50% of all indications for SCS in the clinic as practised today. Other pains for which SCS is considered are mostly those in which neuropathic pain mechanisms dominate. While it is reasonable to assume that in these conditions the response rate is not significantly different from those in FBSS and CRPS, the hard data are lacking. The evidence regarding these conditions (e.g., peripheral nerve injury, diabetic neuropathy, PHN, brachial plexus lesion, stump and phantom limb pain and spinal cord injury) is Class IV and only comes from case series. It is obvious that well-designed controlled trials must be conducted before the issue of ultimate effectiveness of SCS in neuropathic pain can be considered. However, for those patients already with a successfully implanted stimulator for any such alternative (neuropathic) pain who require revision of the system should be allowed to be assessed sympathetically and the fact that they report excellent pain relief (and as many patients do) improved	Noted, no changes required to the FAD. The Committee considered whether it was appropriate to generalise evidence from FBSS and CRPS to other neuropathic pain conditions – see FAD sections 4.3.6, 4.3.10, 4.3.11, 4.3.12. NICE guidance is prospective. People who are currently using SCS for chronic pain should have the option to continue treatment until they and their clinicians consider it appropriate to stop. The FAD has

	quality of life and improved functional status should be taken into consideration as significant factors. *References included but not replicated in this table*	been amended to make to state this – see FAD section 1.6.
Herpes Viruses Association and Shingles Support Society	[Edited] ….I do not have any observations to make. I had hoped that I would find shingles / postherpetic neuralgia in the documents - but clearly this is not used in those cases. [Edited]…..I wished to comment on the jargon here: "adequately powered trials". "Power" with electricity or gas? (Ironic!) I am sure that 10 years ago there was a satisfactory way of saying this. Perhaps "large enough trials" ? Would that express it? I am guessing because I don't know what the jargon means and cannot imagine what other factors would be involved 2.4 Results Eleven randomised controlled trials were included in the clinical effectiveness review, three of neuropathic pain, and eight ischaemic pain. Comparators were relevant to UK practice. Good quality, adequately powered trials were available for neuropathic conditions FBSS and CRPS type I, and suggested SCS was more effective than CMM in reducing pain.	The Committee considered the use if SCS for pain conditions of neuropathic and ischaemic origin. It also considered whether it was appropriate to generalise the evidence available for CRPS, FBSS, CLI and RA to other pain conditions – see FAD section 4.3.5. The term statistical 'power' is omitted from section 4.2 of the FAD.
Pain Relief Foundation and the Walton Centre for Neurology and Neurosurgery	The comments contained in this document have been made on behalf of the Pain Relief Foundation (PRF) and the Walton Centre for Neurology and Neurosurgery (WCNN) in Liverpool. The PRF is a charitable organisation set up to facilitate research into the causes and treatment of chronic pain. It is closely associated with the Pain Clinic at WCNN and the team are directly involved in the work of the PRF.	Noted, no changes to the FAD required.
	i) Do you consider that all of the relevant evidence has been taken into account? We have grave concerns that the international wealth of clinical experience in this area is not being given enough weight in the decision making process. Surely when there is not enough RCT evidence available it is appropriate to use clinical experience and non-RCT evidence to support the existing RCT evidence. It is appropriate to	The Committee considered all the evidence submitted, including evidence from clinical trials, patient and clinical experts, the Assessment Group's economic analysis and the

	recommend further research, but we strongly believe that patient care will be compromised if the HTA concludes that SCS cannot be used for any condition, except FBSS, unless it is in the context of research as part of a clinical trial. The evidence for SCS, as a surgical procedure for the treatment of a range of pain conditions, is actually very good. There are few other surgical procedures that are supported by several well designed RCTs.	manufacturers' submission. It also carefully considered the comments received from consultees and commentators in response to the Assessment Report and ACD. For both legal and bioethical reasons those undertaking technology appraisals and developing clinical guidelines must take account of economic considerations (Social Value Judgements - Principles for the development of NICE guidance; principle 2).
	As discussed in our original submission, it is essential that the full range of evidence is taken into consideration and that treatment with SCS is not reserved solely for those conditions with RCT evidence. It is reasonable that further research is recommended, as long as treatment with SCS is not withheld from the wider range of neuropathic pain conditions known to respond to it in clinical practice. RCTs are not straightforward for this type of therapy and it is extremely difficult to provide any reasonable type of placebo control. However, comparison to standard treatment is not unreasonable; although this in itself proves a problem in many cases. For example, in the case of phantom limb pain there is no consensus as to the standard treatment and a wide range of therapies have been advocated over the years. A survey in 1980 identified 68 different methods, of which 50 were still in use (Sherman et al, 1980). As with pharmacological research, it may be that the results of RCTs in certain key conditions are then extrapolated to other similar conditions. For example, many of the studies of the newer anticonvulsant drugs were focussed on the treatment of painful diabetic neuropathy and post-herpetic neuralgia, but the drugs are licensed for the general treatment of neuropathic pain. Therefore, it could also be argued that if SCS has been demonstrated to be effective in certain key neuropathic pain conditions, the results could be extrapolated to other similar neuropathic pain conditions. This again strengthens the argument for carrying out trials of SCS before permanent implant, especially in those conditions without RCT evidence.	The Committee considered whether it was appropriate to generalise from the trial data for FBSS and CRPS to other chronic pain conditions of neuropathic origin – see FAD sections 1.1 and 4.3.12.
	ii) Do you consider that the summaries of clinical and cost effectiveness are reasonable interpretations of the evidence and that the preliminary views on	

	the resource impact and implications for the NHS are appropriate? We would strongly support the view that individual patients' battery usage can vary greatly in relation to the area of pain distribution and the complexity of the pain condition. We would also agree with the general consensus that there are significant statistical flaws in the Kemler (2006) paper in relation to the five year follow up outcomes, which may lead to an underestimate of the long term outcomes. This loss of effect does not reflect our own clinical experience of the long term effectiveness of SCS in CRPS patients.	The Committee was persuaded by consultee comments that device longevity may be greater than the 4-year period used in the economic modeling – see FAD section 4.3.11. The Committee considered the main and sub group analysis of the 5 year CRPS trial data - see FAD sections 1.1, 4.1.5, 4.1.6, 4.2.6, 4.2.15, 4.3.6, 4.3.8 and 4.3.11.
	iii) Do you consider that the provisional recommendations of the Appraisal Committee are sound and constitute a suitable basis for the preparation of guidance to the NHS? No, we have grave concerns that provisional recommendations on the guidance for the NHS would have a significant and detrimental impact on patient care.	Noted, see responses below.
	As stated in our original submission, in the NHS chronic neuropathic pain is currently primarily treated using a pharmacological approach. Despite a considerable increase in randomised placebo-controlled trials in neuropathic pain over recent years, the medical treatment of neuropathic pain is still far from satisfactory, with less than half of the patients achieving significant benefit with any pharmacological drug (Attal et al, 2006). Efficacy is limited in the drugs used to treat chronic neuropathic pain. Drug-related adverse effects are common, not only because of the specific medications used, but also because many of the patients with this condition are older, take multiple medications, and have co-morbid illnesses (Dworkin et al, 2003). Many patients fail pharmacotherapy because they are unable to tolerate the side effects	The Committee considered whether it was appropriate to generalise from the trial data for FBSS and CRPS to other chronic pain conditions of neuropathic origin - see FAD sections 1.1 and 4.3.12.
	At the WCNN, SCS has been used since the early 1990s and approximately 600 - 700 patients have been implanted since that time. The WCNN has successfully treated a large number of patients with SCS for some of the conditions identified in the RCTs, but also for other conditions that do not have RCT evidence. These conditions include: neuropathic pain secondary to peripheral nerve damage (related to trauma or surgery), traumatic brachial plexopathy: (partial, not avulsion), post-amputation pain (stump and phantom pain), diabetic neuropathy, facial pain, neuropathic pain associated with MS, and post-herpetic neuralgia. It is essential that such patients are	The Committee considered whether it was appropriate to generalise from the trial data for FBSS and CRPS to other chronic pain conditions of neuropathic origin – see FAD sections 1.1 and 4.3.12.

	not denied treatment with SCS purely on the basis that an RCT has not been carried out for a particular condition, when there is strong clinical evidence to support its use.	
	We are also extremely concerned about the potential reaction from PCTs if the guidance is released with its current conclusions and how this would impact on patients who currently have SCS for conditions other than FBSS. If funding for revision surgery or IPG replacements is then refused, a huge number of patients who are currently being successfully treated with SCS on a long term basis could be denied ongoing pain relief. This has serious ethical and humanitarian implications.	NICE guidance is prospective. People who are currently using SCS for chronic pain should have the option to continue treatment until they and their clinicians consider it appropriate to stop – see FAD section 1.6.
	In a recent WCNN audit (2006) a large number of the successful SCS trials that were carried out were for CRPS and post surgical neuropathic pain. In fact, the success rate of the trials for CRPS was actually slightly higher than for FBSS (90.9% vs 90%). The WCNN has successfully managed a large case load of patients with SCS for a range of conditions for over 15 years. Surely this huge wealth of clinical experience must count for something. We plan to carry out further research on the other conditions that respond to SCS. However, we sincerely hope that our ongoing and future treatment of patients with SCS for complex pain problems (that have often been refractory to an array of other treatments) is not curtailed by the outcome of the HTA, when SCS has been shown to be so effective in our hands for so many years.	The Committee considered the clinical and cost effectiveness of the use of SCS for the treatment of CRPS. The Committee considered whether it was appropriate to generalise from the trial data for FBSS and CRPS to other chronic pain conditions of neuropathic origin – see FAD sections 1.1 and 4.3.12.
	FBSS and CRPS are two examples of neuropathic pain conditions. We believe that if NICE conclude that there is a good evidence base for the use of SCS in the treatment of FBSS, then the results should be extrapolated to other neuropathic pain conditions. This is seen to be appropriate in many pharmacological studies, as stated earlier in the text. Such drugs are licensed for the treatment of neuropathic pain in general and not restricted to solely the conditions studied in the RCTs. Surely it is appropriate for NICE to adopt the same approach for SCS when there is significant RCT evidence for two neuropathic pain conditions.	The Committee considered whether it was appropriate to generalise from the trial data for FBSS and CRPS to other chronic pain conditions of neuropathic origin – see FAD sections 1.1 and 4.3.12.
	iv) Are there any equality related issues that may need special consideration? No specific comments. *References included but not replicated in this table.*	Noted, no changes required to the FAD.
Pelvic Pain Support Network	See response to Expert 4	

National Refractory Angina Centre	The National Refractory Angina Centre was the first and remains the largest specialist refractory angina service provider in the UK. We were very surprised to see the definition of refractory angina used by NICE. As experts in the field we do not recognise the definition used. We believe that this is the result of NICE's failure to seek advice from the acknowledged national experts in refractory angina. The problem is that, having used the wrong definition, the recommendations can only be relevant to patients who fulfil that definition. This cannot be resolved by retrospectively changing the inaccurate and clumsily worded definition used in the consultation.	The background section of the FAD provides a brief overview of the clinical condition. The description of refractory angina in the FAD is that used in the submission from the manufacturers'. The boundaries of the appraisal are defined by the remit provided by the Department of Health and by the scope document issued by NICE, and not by the background section of the FAD.
	The premise of the appraisal is flawed. The question NICE should have addressed is whether SCS is justified in the appropriate subset of refractory angina sufferers. SCS is no more indicated for all refractory angina patients, than revascularisation is indicated for all patients with stable angina. In our view SCS is only indicated when non-invasive, evidence based alternatives recommended by accepted guidelines, such as the SIGN 2007 stable angina guidelines, have demonstrably failed. To be clear, spinal cord stimulation should only be considered after the patient has received comprehensive education and rehabilitation programme, optimisation of medication and Cognitive Behavioural Therapy (CBT) where appropriate and then following extensive assessment by a multidisciplinary team.	The boundaries of the appraisal are defined by the remit referred by the DH and by the scope document issued by NICE. This does not preclude the identification of subgroups of people for whom SCS may be more clinically or cost effective.
	We have been implanting spinal cord stimulators for over ten years for the management of refractory angina. It continues to be an effective treatment in the small group of patients who continue to have poor control of their symptoms, despite cognitive reframing of their condition, optimal medical therapy and other pain management strategies. Our decade long experience of using SCS according to accepted guidelines convinces us that SCS has an extremely important role in this small subset of refractory angina patients. In the largest published series to date we demonstrated that fewer than 3% of 433 consecutive RA patients referred to NRAC required SCS implantation. We agree that limited research has been undertaken to demonstrate cost	The Committee recognised the potential clinical benefits of SCS for the treatment of RA, but considered that the cost effectiveness evidence was not sufficiently robust to support the use of SCS for RA. Recognising the potential clinical benefits, the Committee recommended that SCS use in these people be restricted to

	effectiveness of SCS. However the decision to conduct a cost effectiveness analysis of SCS using the alternative of revascularisation is bizarre, given the fact that NICE's own definition precludes revascularisation as an option. The proper comparator should have been the medical management costs or the costs of alternative strategies such as external enhanced counter pulsation therapy, implantable opioid delivery devices, 'heroic' redo redo bypass, transmyocardial laser, transplantation. Presently the decision to fund SCS (as opposed to these expensive and dubious invasive alternatives) is correctly made on an individual basis by a properly informed specialist commissioning group who are tasked to make this sort of difficult funding decision. They are able to take into account the potential cost effectiveness of SCS in the context of the individual patient. SCS is an effective therapy that has reduced pharmacological costs and the number of hospital re-admissions. Pharmacological cost can be significant in the treatment of chronic refractory angina. Opiate costs alone can reach £30,000 per annum per patient. Spinal cord stimulation should remain an available option for patients with chronic refractory angina as defined above	research in order to gain evidence that could be used in cost effectiveness analysis. For both legal and bioethical reasons those undertaking technology appraisals and developing clinical guidelines must take account of economic considerations" (Social Value Judgements - Principles for the development of NICE guidance; principle 2) – see FAD sections 4.1.10, 4.1.12, 4.1.13, 4.1.14. 4.3.7, 4.3.13.
Experts		
Expert 1: Clinical specialist	General Comment: Although at the meeting I attended everything was very fairly represented, the summary seems to contain some inaccuracies- and a misunderstanding appears to have arisen regarding the process of pain management in general and a Pain Management Program in particular. With regards to the questions to which I have been asked to respond- I do so as follows. i) Do you consider that all of the relevant evidence has been taken into account? <u>Response:</u> While I believe that all the relevant evidence in terms of clinical trials has	The Committee carefully considered evidence submitted, the comments received from consultees and commentators and advice offered by clinical specialists and patient experts. The term Pain Management Program has been amended in the FAD – see FAD section 2.4. The Committee considered whether it was appropriate to generalise from the trial data for FBSS and CRPS to

	been considered, I also believe that patients with other forms of neuropathic pain (whose pain would be equally responsive to SCS as the neuropathic pain of FBSS), will, as a result of the absence of evidence concerning their pain, be relatively disenfranchised if this absence of evidence is taken to indicate that SCS is not effective in neuropathic pain of other origin.	other chronic pain conditions of neuropathic origin – see FAD sections 1.1 and 4.3.12.
	ii) Do you consider that the summaries of clinical and cost effectiveness are reasonable interpretations of the evidence and that the preliminary views on the resource impact and implications for the NHS are appropriate?	
	Response: As far as I am able to interpret the summaries of clinical and cost effectiveness are reasonable interpretations of the evidence.	Noted, no changes required to the FAD.
	As far as I could see there was no real view on the future resource impact and implications for the NHS. This reflects the difficulty of assessing alternative expenditure. What is certain is that patients will continue to request that something is done and the medical fraternity will continue to attempt to do something even if it not implantation of SCS. Some of the things they will do may be more expensive and have greater morbidity than the implantation of SCS (eg Coronary angioplasty).	The Committee does not consider the affordability, that is costs alone, of new technologies but rather their cost effectiveness in terms of how its advice may enable the more efficient use of available healthcare resources (NICE Guide to the Methods of Technology Appraisal (April 2004), paragraphs 6.2.6.1 – 6.2.6.3). A costing report and template will, however, be available when the guidance is published.
	iii) Do you consider that the provisional recommendations of the Appraisal Committee are sound and constitute a suitable basis for the preparation of guidance to the NHS?	
	Response: I believe that the provisional recommendations of the Appraisal Committee are sound with regard to SCS in FBSS. I believe that the failure to approve SCS for use in CRPS will disadvantage a vulnerable group of patients. A better solution would be to allow its use provided that yearly outcome data was collected on all the patients in whom SCS was used. At the same time other research	The Committee considered the clinical and cost effectiveness of the use of SCS for the treatment of CRPS – see FAD sections 1.1, 4.3.6, 4.3.11.

	projects could be set up. While I appreciate that NICE does not have the funds to support research projects on other uses of SCS, the NICE recommendation that research is undertaken on the use of SCS in CRPS, Refractory angina and ischaemic limb pain should carry the same weight as the positive NICE recommendation for the use of SCS in FBSS. iii) Are there any equality related issues that may need special consideration? Response: The ACD does touch on certain aspects of inequality especially regarding a patient's ability to communicate. I can only add that a significant number of chronic pain patients are poorly able to represent their interests even where they are not from ethnic minorities. In some cases this appears to be related to their socio-economic status. In addition in some patients there are psychological problems.	The Committee agreed that consideration should be made to ensure equality of access to the treatment – see FAD sections 1.4 and 4.3.4.
Expert 2: Clinical specialist	Thank-you for asking for my comment on the ACD. I will keep my comment short as I entirely agree with the content of the response sent by [redacted] on behalf of the International Neuromodulation Society (INS) which has been circulated to members of the INS.	Noted, no changes required to the FAD.
	The evidence selected (RCTs) is only a tiny proportion of the clinical experience with SCS and it has to be remembered that the patients selected for this treatment are often, by the very nature of the cost and the surgery involved, at the end of the pharmacological pathway. An allowance must be made for the large amount of non-RCT data which are available. The data for CRPS which was considered by the Committee did not include the latest follow-up data from Kemler et al (J Neurosurg 2008, 108(2):292-8 which has shown that 19 of 20 patients who underwent SCS thought it worthwhile 5 years post implant. I think the draft advice is too restrictive for SCS in pain states other than "failed back syndrome" and this will potentially deny a large group of patients for which there are no alternative therapies for their pain.	The Appraisal Committee relies on the available evidence submitted to the Institute and that retrieved from the published literature by the assessment group. It also carefully considered the comments received from consultees and commentators in response to the Assessment Report and ACD. The Committee considered the clinical and cost effectiveness of SCS for the treatment of people with CRPS. It also considered whether the evidence could be generalised to other pain conditions – see FAD

		sections 1.1, 4.3.5, 4.3.6, 4.3.11, 4.3.12.
Expert 3: Clinical specialist	I would like to make a number of observations regarding the SCS appraisal. I welcome the conclusion that SCS can be supported as a therapy for neuropathic pain consequent upon failed back surgery syndrome. However I think that the result obtained from the RCT evidence for this specific indication can be extrapolated to other neuropathic pain conditions, given that there is much other evidence that corroborates this finding in other neuropathic pain conditions. An almost identical situation pertains in respect of "failed neck syndrome", as well as a number of other conditions. Evidence is to be found in the various papers listed in the literature search performed by SCHARR. I would therefore ask that the committee allow extrapolation of the recommendation in respect of FBSS to all neuropathic pain. It will be unrealistic to attempt RCT for each individual category of neuropathic pain.	The Committee considered whether it was appropriate to generalise from the trial data for FBSS and CRPS to other chronic pain conditions of neuropathic origin – see FAD sections 1.1 and 4.3.12.
	The recommendation regarding CRPS be re-examined. The 5 year Kemler results are not readily interpreted, and only the 2 year data represents an RCT. I am aware of many criticisms of this and to be fair these were aired at the appraisal committee meeting. I am also aware of submitted critique of the cost effectiveness. Again I think the committee should give more weight to the evidence that exists outwith RCTs. Perhaps there should be some consideration as to how the different levels of evidence can be quantified relative to each other; if this cannot be done then I cannot see good justification for discarding large volumes of lower levels of evidence, especially in the circumstance – as here - that it is consistent with RCT based evidence. You have asked specifically whether all relevant evidence has been taken into account; I would contend that it has not because of the decision to discard non RCT evidence. The solution should be to devise a quantification of the levels of evidence relative to each other – though to be fair it is most difficult to see how this might be done. The practical effect of this is that it will be almost impossible to design a trial (consider how patient information document would need to appear) that could recruit patients as the majority would refuse randomisation or demand cross-over if randomised to the stimulator negative arm of the trial, remembering that all such patients would have filed other treatments.	The Committee considered the clinical and cost effectiveness of the use of SCS for the treatment of CRPS – see FAD sections 1.1, 4.3.6, 4.3.11.
	The area I think is contentious is that of trial stimulation. I do not think the false positive and false negative rates are established for this, as I commented to the appraisal committee. In particular a false negative may arise because the technology	The Committee considered the comments received from consultees and commentators about the use of

	used for the trial is not as sophisticated a may be	trial stimulation – see FAD section 4.3.3.
	I do not have sufficient experience of the indications wrt angina or critical limb ischaemia to contribute too much to this aspect of the debate but would observe that pain responses for vascular claudication were extremely good in the small number that were done in Liverpool for this indication.	For both legal and bioethical reasons those undertaking technology appraisals and developing clinical guidelines must take account of economic considerations (Social Value Judgements - Principles for the development of NICE guidance; principle 2).
	Another area for research is the issue of back pain; controversy exists as to whether SCS might be effective for this indication – for example when treating FBSS the usual recommendation is that SCS will be very likely to improve the neuropathic leg pain component, but success for the low back pain may or may not be relieved. Again this is an issue that might be affected by the introduction of newer technologies.	The Committee considered whether it was appropriate to generalise from the trial data for FBSS and CRPS to other chronic pain conditions of neuropathic origin – see FAD sections 1.1 and 4.3.12.
Expert 4: Patient expert	I would like to make the following comments with regard to the above HTA ACD and Evaluation Report under the general heading: Do you consider that all of the relevant evidence has been taken into account ? I was disappointed that there was no mention of spinal cord stimulation for neuropathic pain of pelvic origin. There have been studies carried out in this field but they were not mentioned in any of the documentation.. What I said at the meeting appeared to fall on deaf ears. I fear that patients who are suffering intolerable pain and who could potentially benefit form such a treatment will be denied the opportunity.	The Committee considered whether it was appropriate to generalise from the trial data for FBSS and CRPS to other chronic pain conditions of neuropathic origin – see FAD sections 1.1 and 4.3.12.
Other		
Department of Health	Thank you for the opportunity to comment on the Appraisal Consultation Document and Evaluation Report for the above appraisal. I wish to confirm that the Department of Health has no substantive comments to make, regarding this consultation.	Noted, no changes required to the FAD.

Comments received from public consultation (such as email or letters):

Consultee or Commentator	Section of ACD (if specified) - Comment	Institute Response
NHS Professional 1	General The ACD recognises that SCS in FBSS (a neuropathic pain syndrome) offers both clinical and cost effectiveness. Apart from implementation I will not discuss FBSS and SCS further.	Noted.
	The NICE appraisal process has a specific methodology. The review of literature necessitates the finding of RCT evidence in order to populate the clinical and cost effectiveness model. Some of this evidence is incomplete and so the HTA gives a misleadingly incomplete version of the clinical benefits of this therapy area. However there is 40 years of clinical experience as well as investigational research of specific aspects of mechanism of action which when taken in the whole produces a most compelling case for SCS. The task is to try and demonstrate what RCT evidence there is and to use the non RCT and clinical experience evidence to help the assumptions made to support the RCT evidence.	The Appraisal Committee relies on the available evidence submitted to the Institute and that retrieved from the published literature by the assessment group
	Clinical experience from around the world must count for something in this process. Evidence based medicine is important in order to make sure that best practice and value for money is achieved. EBM for SCS, a surgical procedure, for a variety of conditions, is actually surprisingly good. Few other surgical procedures can boast several well designed RCT's. Furthermore, in the case of FBSS the clinical efficacy of SCS far exceeds what is usually achieved by new pharmaceutical products introduced to the market.	The Committee considered all the evidence submitted, including evidence from clinical trials, patient and clinical experts, the Assessment Group's economic analysis and the manufacturers' submissions. It also carefully considered the comments received from consultees and commentators in response to the Assessment Report and ACD
	The professional community of SCS implanters understand the need for continuing data collection. We recommend the creation of a device registry. This will give future data on patient numbers, equity of access, device longevity, and complications.	Noted, no changes to the FAD required.
	Further RCT evidence is required particularly when considering SCS as a treatment alternative earlier in the severe chronic pain condition and where gaps in the evidence cannot be filled with intelligent assumption and modelling.	Noted, no changes to the FAD required.

	When NICE publishes its guidance and recommends treatment the uptake of this advice by commissioners is often less than eager. However if NICE publishes guidance that does not recommend routine use then we can be sure that commissioners will be only too happy to withdraw funding.	For both legal and bioethical reasons those undertaking technology appraisals and developing clinical guidelines must take account of economic considerations (Social Value Judgements - Principles for the development of NICE guidance; principle 2).
	CRPS General New utility data specifically relating to CRPS has reached the public domain and was included in the publication , Kemler et al J Neurosurg 2008 Feb;108(2):292-8 Effect of spinal cord stimulation for chronic complex regional pain syndrome Type I: five-year final follow-up of patients in a randomized controlled trial. This data when passed through the economic model changes from that published in the HTA and discussed at the appraisal committee meeting. The Cost per QALY is now significantly below the £30,000.	The Committee considered the clinical and cost effectiveness of the use of SCS for the treatment of CRPS – see FAD sections 1.1, 4.3.6, 4.3.11
	The long term efficacy of SCS versus CMM is also addressed in this paper. This series of papers demonstrated SCS effectiveness as measured by reduction in VAS to about 3 years duration. This is a significant achievement in itself. These patients were experiencing severe pain (mean VASPI at entry was 7/10 whereas 5.4/10 is equated as a clinically meaningful severe pain threshold), they had also been suffering the condition for a mean of 3 years. Although at 5 years the reduction in VASPI reduction was not statistically significant it was clearly clinically significant since 19 of the 20 analysed at 5 years would have the same procedure done for the same result and 18/20 reported a clinically positive effect. The SCS patients also reported significantly improved global perceived effect.	The Committee considered the clinical and cost effectiveness of the use of SCS for the treatment of CRPS – see FAD sections 1.1, 4.3.6, 4.3.11

	The authors have tried to maintain statistical credibility throughout the trial. However we should note that of those patients randomised to SCS and PT, 12/36 had failed the SCS trial and never received an implant and indeed 3/12 were not included in follow up due to 2 lost to follow up and 1 implanted with a “special device”. At 5 year follow up 5/18 were excluded from the PT group due to lost to FU and 4 had been subsequently implanted with SCS. This left 13 patients of which 2 made a spontaneous complete improvement. The statistical effects on such a small group may artificially bias the benefits of PT alone. The statistical management and presentation of the data is flawed as he did not use ITT throughout and should have used an as treated analysis as part of the sub group analysis. The results of this RCT series must be looked at in the whole. Pain intensity scoring is just one parameter of outcome assessment. Health related quality of life, global perceived effect and patient satisfaction are also just a relevant and were all shown to be significantly improved.	Noted, the Committee considered the main and sub group analysis of the 5 year CRPS trial data - see FAD sections 1.1, 4.1.5, 4.1.6, 4.2.6, 4.2.15, 4.3.6, 4.3.8 and 4.3.11.
	CRPS - Clinical considerations CRPS is a disabling, long lasting condition with less than complete understanding of its pathophysiology. In the early acute stage it is possible that the dominating mechanism is that of neurogenic inflammation with severe pain (greater than 5/10). Early management involves early recognition, tailored pain control (using anti neuropathic medication and analgesics), cognitive therapy (important education about the condition and prevention of unhelpful coping styles), sympathetic nerve bocks and physical therapy.	Noted, no changes to the FAD requested.
	However if this is not successful or if the patient presents later in the course of the process, then these patients present to the pain clinician for consideration of SCS. It is likely that at this stage the dominant pain mechanism will be neuropathic as well as all the other psychological effects of unrelieved pain. The Kemler papers have included this latter group. Any improvement from therapy is clinically significant. Further research needs to be done to determine if early application of SCS in the first 3 months would offer benefits above CMM and reduce the progression into the more chronic phase. However the medical community experience recommends earlier use of SCS as suggested in the guideline below. Delaying treatment merely exacerbates the problem. Stanton-Hicks MD, Burton AW, Bruehl SP, Carr DB, Harden RN, Hassenbusch SJ, Lubenow TR, Oakley JC, Racz GB, Raj PP, Rauck RL, Rezai AR. An updated interdisciplinary clinical pathway for CRPS: report of an expert panel. Pain Pract. 2002;2(1):1-16.	For both legal and bioethical reasons those undertaking technology appraisals and developing clinical guidelines must take account of economic considerations (Social Value Judgements - Principles for the development of NICE guidance; principle 2).

	CRPS - Conclusions SCS is more effective than CMM alone as measured by pain intensity, HrQol, patient satisfaction, global perceived effect up to 3 years following initiation of SCS treatment. SCS is more effective than CMM alone as measured by HrQol, patient satisfaction, global perceived effect up to 5 years following initiation of SCS treatment. SCS is cost effective once the appropriate health utilities are used and indeed the assumptions made by the ABHI submission for using PROCESS/FBSS utilities for the CRPS model have been borne out Prevention of the patient from receiving SCS will be detrimental to this group of patients. SCS should be recommended earlier for use in CRPS when a coordinated pain management and physical approach has not succeeded See Stanton Hicks guidelines Other Neuropathic pain states General The clinical consensus is that SCS is used in medically refractory neuropathic pain of peripheral origin. FBSS and CRPS are regarded as examples of Neu pain. The NICE appraisal process apparently wishes to look at each diagnosis in turn rather than accepting that the same clinical effect seen with 2 neu pain diagnoses might be the same for all neu pain of peripheral origin. The "other neu pain" diagnoses in clinical practice are conditions such as Diabetic neuropathic pain, viral induced neuropathic pain (eg post herpetic neuralgia), post traumatic or surgical peripheral neuropathy. For diabetic neuropathy there has been an RCT published in Lancet 1996 Watt J et al Electrical spinal-cord stimulation for painful diabetic peripheral neuropathy" from the Liverpool group which demonstrated efficacy although the follow up was short. Apart from this these other neu pains have not been studied in isolation in an RCT design. Case series data often includes mixed series data such as May et al Neuromodulation 2002 in which a personal series of long term follow up in the UK of 100 consecutive patients treated with SCS was published. The majority of patients had FBSS, but the result in patients with "other neu pain" conditions was not dissimilar.	The Committee considered the clinical and cost effectiveness of the use of SCS for the treatment of CRPS – see FAD sections 1.1, 4.3.6, 4.3.11 The Committee considered whether it was appropriate to generalise from the trial data for FBSS and CRPS to other chronic pain conditions of neuropathic origin - see FAD sections 1.1 and 4.3.12.

	Other neu pain Clinical considerations In practice it is the patients with the post traumatic or post surgical peripheral neuropathic pain that present to the pain clinician. Some of these have evidence of neu pain being complicated by development of spreading pain with vasomotor instability and is in fact CRPS type 2. EG after knee surgery where there is neu pain from the infrapatellar nerves. These patients respond extremely well to SCS Medical management of diabetic neuropathic pain has improved but this modality should be available for refractory cases Other neu pain Conclusions The committee should accept that evidence from 2 neu pain states of peripheral origin and the data from case series and clinical experience should be sufficient to broaden the recommendation to include all medically refractory neu pain of peripheral origin.	The Committee considered whether it was appropriate to generalise from the trial data for FBSS and CRPS to other chronic pain conditions of neuropathic origin - see FAD sections 1.1 and 4.3.12.
	Refractory Angina General The work done on this appraisal has suffered from a lack of agreement on the definition of Refractory angina. Most understand RA to be chest pains caused by ischaemia in patients who are receiving optimal medical therapy and where further angioplasty or CABG is not feasible.	Noted, no changes to the FAD required.
	Now that we understand that interventional vascular management confers no prognostic benefit on patients unless there is LMS or triple vessel disease then the definition should also include aspects of risk of complications as well as potential benefits.	Noted, no changes to the FAD required.
	Once patients have been defined as having RA they are in a relatively low cost treatment group. Their costs are pharmacological and a heavy dependency on acute medical admission services. However if the cardiology team do not change their mind then these patients are not further investigated with angiography nor offered expensive managements such as CABG or PCI.	Noted, the Assessment Group were able to only provide exploratory cost effectiveness analyses due to the paucity of data on utility gain and survival in this group of people.
	Sadly this group has been very poorly managed throughout the UK with a “sweetbox” of potential therapies. It is only SCS where there has been sufficiently robust research.	Noted, no changes required to the FAD.

	The National Refractory Angina Centre recommends a more pragmatic approach based upon what evidence there is as well as a patient centred model of care. This rationalised model includes SCS but only after thorough assessment and cognitive reconceptualisation of the condition coupled with the adoption of pain management strategies.	Noted, no changes required to the FAD.
	SCS in ischaemia is not simply a method to “block” pain messages to the brain. Collective work by Foreman B, De Jongste M and Linderoth B have demonstrated in animal models and in human that SCS has a beneficial effect on myocardial blood distribution, cardiac myoprotection and is anti-dysrhythmogenic	Noted, no changes required to the FAD.
	RA – clinical considerations The ESBY study series includes a 5 year follow up and a cost benefit analysis. ESBY did not look at true RA patients since they were eligible for CABG. However since they had significant co-morbidity they were at risk of CABG. Indeed the cardiac and cerebral morbidity and indeed mortality seen after CABG in this series bears this risk out. The ESBY study demonstrates that SCS is AS GOOD AS CABG in controlling symptoms and that this effect is maintained at 5 years. There is a non statistical tendency to better survival in the SCS treated group. The cost benefit analysis is favourable to SCS The SPiRiT trial showed that SCS was AS GOOD AS PMR in patients regarded as being truly RA. The patients receiving SCS were drawn from all over the UK and had poor follow up arrangements for reprogramming. The trial design insisted upon using an outmoded electrode technique for stimulation. Murray et al Heart 1999;82:89-92 (July) “Spinal cord stimulation significantly decreases the need for acute hospital admission for chest pain in patients with refractory angina pectoris” a UK study of costs before and after SCS in 19 consecutive patients provides UK data of cost benefit. This is in an RA population. Cost savings are due to the fall in annual admission rates. P. Andréll et al Cardiology volume 99 no. 1 2003 vol Cost-Effectiveness of Spinal Cord Stimulation versus Coronary Artery Bypass Grafting in Patients with Severe Angina Pectoris - Long-Term Results from the ESBY Study demonstrate the cost benefits of SCS at 2 years of SCS versus CABG . The cost savings were due to a shorter hospital stay and reduced cardiac admissions.	The Committee recognised the potential clinical benefits of SCS for the treatment of RA, but considered that there was insufficient cost effectiveness evidence to support the use of SCS for RA. Recognising the potential benefits, it recommended that SCS use in these people be restricted to research. For both legal and bioethical reasons those undertaking technology appraisals and developing clinical guidelines must take account of economic considerations (Social Value Judgements - Principles for the development of NICE guidance; principle 2) – see FAD sections 4.1.10, 4.1.12, 4.1.13, 4.1.14. 4.3.7, 4.3.13.

	RA - Conclusions SCS should remain an option for RA and Angina with significant co-morbidity. SCS should be available to those that manage patients with Refractory angina in a multidisciplinary setting with clear clinical pathways. This allows patients to receive optimised care rather than a “sweetbox” approach. Multidisciplinary pain management has been shown by NRAC to achieve best results. Guidelines created by the Cheshire and Merseyside Cardiac Network on “Diagnosis and Management of Stable Angina” can be found at the link below – http://www.cmcn.nhs.uk/guidelines/stable_angina.html Pages 41 to 47 refer to RA management and specifically include the use of SCS. Future study design will need to look at the base population after they have completed an angina management programme. Those that remain symptomatic would then be the base population. Study design may then include a randomised RCT of SCS vs standard medical care with crossover. Or it could compare SCS to other RA therapies such as external counter pulsation (technique for which there is some evidence of benefit in RA associated with heart failure).	See responses above.
	Critical limb ischaemia General Critical limb ischaemia that is refractory to surgical management or angioplasty is managed conservatively. Pain is severe and tissue viability is under threat. Pain may also be refractory to conventional pain therapies. Unrelieved pain results in amputation of the limb in the UK. SCS offers the chance of relief of pain. This is a prize so precious alongside the permanent loss of limb that all efforts should be directed to prevent any loss of limb due to pain alone. SCS has also been found to have a limb tissue preserving effect. Progression tissue destruction is reversed and ulcers heal. The three main aetiologies of CLI are atherosclerosis (peripheral arterial occlusive disease PAOD), thromboangiitis obliterans (Buerger’s disease), and vasospastic disorders.	The Committee considered all the evidence submitted, including evidence from clinical trials, patient and clinical experts, the Assessment Group’s economic analysis and the manufacturers’ submissions. It also carefully considered the comments received from consultees and commentators in response to the Assessment Report and ACD.

	CLI - evidence Much of the RCT evidence includes patients with PAOD. Many of the early studies included patients with severe end stage disease. The EPOS group, of which I was a co-worker, deliberately investigated the premise that specific criteria, including adequateTpO2 rise to SCS, would predict long term success. It was not ethical to demonstrate this response in a patient and then withdraw the SCS device in order to have a CMM group. Loss of limb due to pain and/or tissue loss is not reversible. Since the Klomp study (ESES) with the Ubbink sub analysis had showed that this intermediate group very nearly reached statistical significance it was felt that studying this cohort and comparing to historical controls was all that could ethically be done. CLI - Clinical considerations My vascular surgeon colleagues and I see SCS as an essential part of CLI management. To date I have not had a patient loose a target limb due to CLI in Buerger's disease. These were 4 men in their 40's who would have been prematurely disabled. This is a condition where the prognosis is usually grim. CLI - Conclusions Existing RCT evidence does demonstrate pain reduction but just fail to confirm prevention of tissue loss. In PAOD Refined selection criteria appear to show high rates of pain reduction, ulcer healing and prevention of limb amputation. Clinical experience in other conditions such as Buerger's disease and vasospastic disorders suggest that SCS should be available.	The Committee considered that clinical evidence suggested that there may be benefits for SCS used for the treatment of CLI. However, it concluded that there was insufficient cost effectiveness evidence to support the use of SCS for CLI. Recognising the possible benefits of SCS for the treatment of CLI, the Committee considered that SCS should be subject to further research in this group of people. For both legal and bioethical reasons those undertaking technology appraisals and developing clinical guidelines must take account of economic considerations (Social Value Judgements - Principles for the development of NICE guidance; principle 2).– see FAD sections 4.3.7, 4.3.13 See response above

	Implementation SCS as a therapy area has survived in the UK due to the interest of clinicians from functional neurosurgery and pain anaesthesia. There are approximately 30 implanting centres within the UK. A few perform up to 60 new patient procedures per year and some less than 10. Many of the conditions have high prevalence since they are long lasting conditions. Any planning for development of an SCS service must take the existing patients into account. RA will be a growing condition for as long as the numbers of CABG grow since by definition some post CABG will become RA.	Noted, implementation is not the responsibility of NICE, however, costing and audit tools will be made available after publication of the guidance.
	The incidence of FBSS is dependent upon the incidence of spinal surgery much like the incidence of “other neu pain” is dependent upon the incidence of trauma and limb and body surgery.	Noted, no changes required to the FAD.
	Clinical networks Best practice with SCS is achieved where SCS is carried out in high volume centres within the context of a multidisciplinary team. It will be essential to develop care pathways in order to support successful commissioning Existing centres will need to expand; it’s possible that a few other centres will need to be established	Noted, implementation is not the responsibility of NICE, however, costing and audit tools will be made available after publication of the guidance.
	Clinical Training There is a deficit in training facilities for SCS. NSUKI, St Thomas’s, Walton centre and the industry partners provide training. A few receive limited training as part of their CCST. The Faculty of pain medicine sees is responsible for over seeing SCS training for anaesthetists within the arrangements for specialist training of anaesthetists in pain medicine. Presumably SBNS is responsible for neurosurgical training	Noted, implementation is not the responsibility of NICE, however, costing and audit tools will be made available after publication of the guidance.
	Device registration, audit, governance and research Throughout the appraisal process we have mentioned the need for device registration, clinical audit and governance and a coordinated approach to future research. The professional societies believe there is a good case for a web based registry to capture all implant activity. To date there is limitation on funding. This effort is being coordinated by Dr [redacted].	Noted, no changes required to the FAD.

NHS professional 2	I have worked within the NHS for the past 36 years and for the past 11 years I have worked as the lead in neuromodulation at the National Refractory Angina Centre (NRAC) Liverpool and have played a major roll in the development of this service especially Spinal Cord Implants (SCS) for stable angina pain management. The service was developed to specifically treat and manage the pain of angina using simple none invasive treatments first and invasive treatments last, all of which have been proven to improve the quality of life of the suffers and their carers which intern dramatically reducing hospital admissions within this patient group. I am seen as a national expert in the use of spinal cord stimulators for angina pain management and have been successfully treating patients with SCS for ten years.	The Committee recognised the potential clinical benefits of SCS for the treatment of RA, but considered that there was insufficient cost effectiveness evidence to support the use of SCS for RA. Recognising the potential benefits, it recommended that SCS use in these people be restricted to research. – see FAD sections 4.1.10, 4.1.12, 4.1.13, 4.1.14. 4.3.7, 4.3.13.
	As an advisor to NICE I am therefore appalled at the very negative approach NICE have taken in the formulation of these proposed guidelines. As the national centre for angina management we were not approached to take part in this important debate and when application by myself and Dr [redacted] Consultant pain specialist was made for panel members its seems to have been ignored.	The National Refractory Angina Centre has been invited to participate as a Consultee, in accordance with the technology appraisal process – see NRAC comments in table above. The Committee considered all the evidence submitted, including evidence from clinical trials, patient and clinical experts, the Assessment Group's economic analysis and the manufacturers' submissions. It also carefully considered the comments received from consultees and commentators in response to the Assessment Report and ACD.
	I cannot believe that these guidelines which will have a major impact on Primary Care Trust's and their specialist funding for SCS and its use for angina are to be published with out NRAC's involvement in any of the consultation. I would draw your attention to new guidelines published in November 2007 by the Cheshire and Merseyside Cardiac Network on the management of stable angina which actually supports the use of SCS for angina pain management, please visit their web site for further information:- http://www.cmcn.nhs.uk/document_uploads/Stable%20Angina/Stable%20Angina.pdf	For both legal and bioethical reasons those undertaking technology appraisals and developing clinical guidelines must take account of economic considerations (Social Value Judgements - Principles for the development of NICE guidance;

	These guidelines are presently in use throughout Cheshire, Merseyside and North Wales with other authorities taking interest in them as the treat for refractory angina is now being developed throughout the United Kingdom. I seriously believe that if NICE do not revise these guidelines to include refractory angina patients they will be committing a serious injustice to all stable angina suffers who may otherwise benefit from its use.	principle 2).– see FAD sections 4.1.10, 4.1.12, 4.1.13, 4.1.14. 4.3.7, 4.3.13.
NHS professional 3	[redacted] Consultant in Anaesthesia and Pain Management [redacted] UK Background: I am a consultant anaesthetist with an interest in pain management. I have been practicing neurostimulation particularly spinal cord stimulation for the last 12 years. I have a series of 150 spinal stimulators. I am co-author of the PROCESS study and Honorary Secretary of Neuromodulation Society UK and Ireland. I have acted as a Clinical Advisor to The SCHARR HTA on SCS Comments on the Appraisal Consultation Document i) Do you consider that all of the relevant evidence has been taken into account? The full publication of the 5 years results of the Kemler study (Kemler et al .J Neurosurg 108:292–298, 2008) should be considered in greater detail particularly the contrast between the ITT analysis and the per treatment group analysis. The per treatment group analysis shows a continuing patients satisfaction with SCS and a continuing drop in VAS rate of the order of 2.5 for the treatment group. The ITT analysis is not a conventional one as a number of patients are excluded due to cross over or special implant. The groups are no longer representatives of the original randomized patients The same study has shown a tendency to spontaneous improvement in the PT group. This is not my experience with C RPS patients over the last 15 years. This is confirmed by the recent publication by Vaneker M,. et al. Impairments as measured by ISS do not greatly change between one and eight years after CRPS 1 diagnosis European Journal of Pain 10 (2006) 639–644) which followed up 45 CRPS sufferers for 8 years. The study concluded that considerable impairments were still present over 8 years after the initial CRPS diagnosis and that the impairments including VAS scores did not change much between one and eight years post-diagnosis. This would lead me to believe that the PT sample of	Noted, no changes required to the FAD. Noted, the Committee considered the main and sub group (per treatment) analysis of the 5 year CRPS trial data - see FAD sections 1.1, 4.1.5, 4.1.6, 4.2.6, 4.2.15, 4.3.6, 4.3.8 and 4.3.11.

	the Kemler study of 13 patients is not representative of the CRPS population as a whole. CLI.	
	The study by Amann et al. Spinal cord stimulation in the treatment of non-reconstructable stable critical leg ischaemia: results of the European Peripheral Vascular Disease Outcome Study (SCS-EPOS). European Journal of Vascular & Endovascular Surgery 2003; 26 280-286). Should be considered in greater detail. This is a controlled but nonrandomized study and therefore was not part of the evaluation report. The results of this particular study together with the Cochrane review by Ubbink et al. should be considered before final guidance is issued.	The Committee considered all the evidence submitted, including evidence from clinical trials, patient and clinical experts, the Assessment Group's economic analysis and the manufacturers' submissions. It also carefully considered the comments received from consultees and commentators in response to the Assessment Report and ACD – see FAD section 4.3.7.
	ii) Do you consider that the summaries of clinical and cost effectiveness are reasonable interpretations of the evidence and that the preliminary views on the resource impact and implications for the NHS are appropriate?	
	FBSS: The recommendation of a universal requirement for a trial prior to a final SCS implant is difficult to understand from a clinical view point as some patients will have a compromised immune system thereby making an on table trial the only possibility. This is not feasible in the case of surgical electrodes. It would be more sensible to recommend trials but acknowledge that this will not be possible in some patients.	The Committee considered the comments received from consultees and commentators about the use of trial stimulation – see FAD section 4.3.3.
	The effectiveness of SCS in FBSS is clear from the evidence the effectiveness in CRPS is also clear. The committee should therefore make the logical step in concluding that SCS is effective in neuropathic pain. Assuming that different neuropathic pain conditions respond differently is contrary to all clinical facts.	The Committee considered whether it was appropriate to generalise from the trial data for FBSS and CRPS to other chronic pain conditions of neuropathic origin - see FAD sections 1.1 and 4.3.12.
	CRPS: The summary of clinical and cost effectiveness suffers from a lack of in-depth	Noted, the Committee considered

	reading of the details of full 5 year results, which was only published in February 2008 The summary interpretation that the long-term results of SCS in CRPS are unclear relies on the interpretation of the 5-year results, which presents an unconventional ITT analysis of 2 groups with several patients excluded. These s are no longer representatives of the original groups. Another unconventional per treatment analysis with several patients excluded concludes that 90% of patients reported positive effectiveness of SCS therapy at 5 years and 95% felt they would undergo the same treatment again for the same results. Furthermore the drop on the VAS scale of 2.5 at 5 years may fall just short of statistical significance, it is a highly significant result clinically, in a group of patients who have suffered severe pain for 8 years. Finally the improvement in the PT group is clinically unusual and should be interpreted with caution in light of the publication of Vaeneker et al (vide supra)	the main and sub group (per treatment) analysis of the 5 year CRPS trial data - see FAD sections 1.1, 4.1.5, 4.1.6, 4.2.6, 4.2.15, 4.3.6, 4.3.8 and 4.3.11.
	The cost effectiveness evaluation suffers from a number of flaws that do not mirror real life: 1. A gradual decrease in the effects of SCS is correctly assumed but no gradual decrease of the effects of CMM is assumed in all analyses. This does not accurately mirror real life costs where costs of CMM will escalate because of gradual development of tolerance to CMM therapy modalities	The economic analyses do not assume that treatment benefits gradually decrease in either the SCS or CMM arms. The economic analyses assume that in both arms the treatment effect is maintained.
	2. Complications of CMM are not taken into consideration in the calculation of CMM costs. This again bears no resemblance to clinical practice	Noted. The Committee considered the frequency of serious adverse events associated with SCS, and the exclusion of adverse events from the CMM group. – The FAD section 4.3.8 has been amended.
	3. The paper used to for the value of the baseline utilities of CRPS patients is the McDermott et al. publication which is a cross sectional survey rather than an RCT. The subjects of the survey are a GP practice sample of neuropathic pain patients. These patients will differ considerably from the refractory patients with CRPS referred into an implant centre for SCS consideration. I would consider the assumption that the utilities of these patients to be equivalent to those with CRPS to be grossly unsafe.	The Committee recognised that the utility data in the McDermott paper may not reflect the utility of a person with CRPS. The Committee considered the utility data from the CRPS trial – see FAD sections 4.2.6, 4.2.15, 4.3.11.

	4. The issue of IPG (battery) longevity seems to be paramount to the economic analysis. The committee should take into account the fact that the device used in the Kemler study is outdated and current batteries are likely to easily outlast 5 year	In considering recommendations for pain of neuropathic origin the Committee was mindful of consultee comments that device longevity may be greater than the 4 year period - see FAD section 4.3.11.
	Angina: The studies conducted on angina patients have shown that SCS is equivalent to CABG and PMR the threshold analysis shows that SCS dominates CABG. The committee's provisional recommendations are largely based on a lack of agreement of the definition of the term Refractory Angina. In clinical practice the definition of the tem RA will always rest with the referring cardiology team rather than the implanting pain/neurosurgery team. While guidelines should be formulated to clarify a pathway of therapy for this group of patients, failure to recommend a therapy that is equivalent to the current gold standard and more economical in some cases is surprising. A number of patients who are unable to undergo CABG/PCI because of other clinical issues would suffer. The National Refractory Angina Centre NRAC guidelines have provided a reasonable pathway that most UK clinicians have followed.	The Committee recognised the potential clinical benefits of SCS for the treatment of RA, but considered that there was insufficient cost effectiveness evidence to support the use of SCS for RA. Recognising the potential benefits, it recommended that SCS use in these people be restricted to research. For both legal and bioethical reasons those undertaking technology appraisals and developing clinical guidelines must take account of economic considerations (Social Value Judgements - Principles for the development of NICE guidance; principle 2) – see FAD sections 4.1.10, 4.1.12, 4.1.13, 4.1.14. 4.3.7, 4.3.13.
	CLI: In considering only RCT evidence the committee has missed out on a crucial piece of the evidence, namely the Amann study (vide supra) that provides clear selection criteria for patients with CLI and improves the limb survival significantly when compared to CMM or to patients implanted without attention to selection criteria. My experience with SCS in CLI that consists of a series of 25 patients confirms that following the Amann et al criteria has resulted in only one major amputation over the last 6 years. The Cochrane review by Ubbink et al confirms that application of selection criteria improves the outcomes.	The Committee considered that clinical evidence suggested that there may be benefits for SCS used for the treatment of CLI. However, it concluded that there was insufficient cost effectiveness evidence to support the use of SCS for CLI. Recognising the possible benefits of SCS for the treatment of CLI, the Committee

		considered that SCS should be subject to further research in this group of people. For both legal and bioethical reasons those undertaking technology appraisals and developing clinical guidelines must take account of economic considerations (Social Value Judgements - Principles for the development of NICE guidance; principle 2) – see FAD sections 4.3.7, 4.3.13
	iii) Do you consider that the provisional recommendations of the Appraisal Committee are sound and constitute a suitable basis for the preparation of guidance to the NHS? FBSS: The recommendation should be broadened to encompass other causes of neuropathic pain of clear clinical aetiology. As a number of patients who suffer from neuropathic pain of rare clinical aetiologies will be disadvantaged in the long term without any potential for access to SCS therapy as a result of this guidance. In some cases the rarity of the condition would make future RCTs almost impossible. CRPS: The guidance is based entirely on the results of one RCT available in the field of CRPS. It surprising that this guidance and the clinical effectiveness report ignore the major body of literature relating to the use of SCS in CRPS because the majority of the work consists of case series. While these are a weaker level of evidence they should not be ignored. The guidance also fails to take into account the fact that 50% of the patients with neuropathic pain fail to respond to drug therapy (EFNS guidelines on pharmacological drug therapy for neuropathic pain Attal et al. European Journal of Neurology 2006, 13: 1153–1169. The same paper highlights the fact that the evidence available for all pharmacotherapy in RCT format is limited to a follow- up period of 12 weeks when we are debating 5 year results for SCS. The guidance as it stands deprives 50% of the CRPS patients in the UK of access to an effective and cost effective option. Indeed my experience of a total of 35 cases of CRPS where 78% continue to describe an excellent or a very good response (Rodriguez et al Neuromodulation 2007). Of the 35 cases implanted over the last 12 years only 3 have	The Committee considered whether it was appropriate to generalise from the trial data for FBSS and CRPS to other chronic pain conditions of neuropathic origin – see FAD sections 1.1 and 4.3.12. The Committee considered the use of SCS for the treatment of people with CRPS – see FAD sections 1.1, 4.3.6, 4.3.11.

	required battery replacements. The guidance should consider that it is now possible to estimate battery life based on trial data.	
	Refractory Angina: The guidance here is at stark odds with clinical practice, where most clinicians have recognised for the last decade that RA is the best indication for SCS. As the patients receive the simplest SCS system respond the best and rarely require battery replacements because of low current requirements and short duration of usage per day. In a series of 32 patients Implanted over the last 10 years we have replaced only 1 battery. The position of the electrode at top of the non mobile portion of the thoracic spine make electrode migration less common in this group of patients. Despite these results the numbers of RA patients receiving SCS in the UK has remained low because of adherence to the clinical guidelines of NRAC.	The Committee recognised the potential clinical benefits of SCS for the treatment of RA, but considered that there was insufficient cost effectiveness evidence to support the use of SCS for RA. Recognising the potential benefits, it recommended that SCS use in these people be restricted to research. For both legal and bioethical reasons those undertaking technology appraisals and developing clinical guidelines must take account of economic considerations (Social Value Judgements - Principles for the development of NICE guidance; principle 2) – see FAD sections 4.1.10, 4.1.12, 4.1.13, 4.1.14. 4.3.7, 4.3.13.
	CLI: The guidance should allow SCS in subgroups of CLI disease where the response is most effective. Consideration has not been given to other vascular disorders such as vasospastic disorders and Buerger's disease where clinicians have reported excellent responses to SCS with little else in the way of therapeutic options apart from amputation.	The Committee considered that clinical evidence suggested that there may be benefits for SCS used for the treatment of CLI. However, it concluded that there was insufficient cost effectiveness evidence to support the use of SCS for CLI. Recognising the possible benefits of SCS for the treatment of CLI, the Committee considered that SCS should be subject to further research in this

		group of people. For both legal and bioethical reasons those undertaking technology appraisals and developing clinical guidelines must take account of economic considerations (Social Value Judgements - Principles for the development of NICE guidance; principle 2) – see FAD sections 4.3.7, 4.3.13.
	iv) Are there any equality related issues that may need special consideration? None	Noted, no changes required to the FAD.
	General Comment: It is clear from the effectiveness report that the number of RCTs in the field of SCS is limited. Spinal cord stimulation has been in clinical practice from 1967 onwards and has been used in it early years for numerous indications. In the last 2 decades the use of spinal cord stimulation has concentrated on the areas of neuropathic and ischaemic pain. During this period a large number of pain treatment intervention have disappeared from practice due to lack of efficacy. The survival of SCS as a therapy tells its own story about its clinical effectiveness. The failure, until recently, to produce high quality research is a failure of our clinical and academic communities coupled with difficulty in obtaining funding for pain research in general. The sufferers of neuropathic and ischaemic pain should not be deprived of this therapy based on our failure to produce the evidence. In considering its final guidance I would urge the committee to examine not only the effectiveness of SCS but also the poor record of the alternative therapies available to this unfortunate group of patients [redacted] 2/7/08	See responses above. For both legal and bioethical reasons those undertaking technology appraisals and developing clinical guidelines must take account of economic considerations (Social Value Judgements - Principles for the development of NICE guidance; principle 2).
Patient 1	Having attended Hospital on numerous occasions with various symptoms which had been affecting my vision. In December 1997 whilst attending [redacted] Eye Hospital for a biopsy of my right eye, I was taken ill. I was diagnosed with having Bechets. The illness also brought on Transverse Myelitis which left me paralysed and desensitised from the T6 region together with bowel and bladder problems.	The views of clinical experts and patient/carer representatives were considered by the Appraisal Committee when formulating its recommendations. It carefully

	I then subsequently suffered from constantly excruciating pain that would not only make me feel physically sick but had me literally rolling on the floor in an effort to try and ease the discomfort. As well as the cocktail of medication I was taking and still am for the Bechets I was prescribed various other medication to try and help deal with this constant pain. To give you an indication of this, I was started on a dose of 100mg of Gabapentin which within a short period of time was increased to 3000mg. Nothing worked to relieve the constant chronic pain I was in. I like to think that I have a very high pain threshold but the consistency of the pain was starting to take its toll on me. Had it not been for me being referred to Mr. [redacted] at the UHW who offered some hope of alleviating the chronic pain by implanting a spinal cord stimulator, then I have no doubt I would have contemplated ending my life. In October 2006, Mr. [redacted] and his team carried out the operation to implant the stimulator, which was very successful. Neither myself or my wife can begin to tell you how much of a difference it made to both our lives. I use the stimulator everyday for between 12/14 hrs. It has helped to reduce the pain by approximately 75%. Although it hasn't stopped the pain completely it's reduced it to a level which is both tolerable and manageable. The only down side to having the stimulator on for so long is that it further affects my mobility and stability. But to me, that's a small price to pay for it helping to relieve the chronic pain that I'm suffering with. I'm still attending Hospital on a regular basis in relation to the Bechets and eye condition. In December 2007, I also underwent a clam cystoplassy operation as a result of the problems caused by the Transverse Myelitis. To conclude, chronic pain is such a personal issue, no one but the person affected by it really knows how bad the suffering is. Sure, Doctors and other people can be empathetic and in a lot of cases prescribed drugs can help. But I believe there is some pain that prescribed drugs can't alleviate and to this both my wife and I are eternally grateful to Mr. [redacted] and his team who not only listened but helped Having been a recipient of the stimulator implant, I can without doubt tell you that it works and having helped me it is important that this type of operation is allowed to continue to go on to help other people who may be suffering.	considered the comments received from consultees and commentators in response to the Assessment Report. For both legal and bioethical reasons those undertaking technology appraisals and developing clinical guidelines must take account of economic considerations (Social Value Judgements - Principles for the development of NICE guidance; principle 2).
Patient 2	I had a spinal cord stimulator implanted in January 2007 having been diagnosed with Chronic Regional Pain Syndrome due to a car accident in July 2000.	The views of clinical experts and patient/carer representatives were

	The symptoms were gradual over a period of two years from tingling fingers, dropping items, burning sensation in both the left arm and hand which progressed to swelling in the left hand and arm, discolouration, severe burning pain in the left upper limb which could be described as if a bone was broken in the forearm area. It became very difficult to hold objects and to function normally on a day to day basis. I attended the Pain Clinic under Dr [redacted] having already received several modules of physiotherapy, acupuncture and the usage of a Tens machine. Dr [redacted] treated the condition with Stellate Ganglion Blocks, Botox injections (for the neck pain) and in November 2004 I underwent a Thorascopic Sympathectamy The medication I was taking on a daily basis was :- Gabapentin 300mg x 12 Codeine Phosphate 60mg x 4 Laprozamol 1 x 15mg Diazepam 5mg as required I was on Living Disability Allowance for mobility (was unable to drive) and for the preparation / cooking of food. After having the spinal cord stimulator implant, my life changed quite drastically. I am no longer on Living Disability Allowance. Medication taken on a daily basis is :- Codeine Phosphate 3 x 60mg (Chronic Regional Pain Syndrome in left lower limb - foot) I am able to drive and there is no evidence of swelling, discolouration in the left upper limb or severe burning pain. I am able to hold objects in the left hand and grip. I have started swimming to build and strengthen and are able to carry out daily household chores i.e. cooking, ironing which had been so difficult to do before. Furthermore, I must add that all times, mentally, I have tried to continue to do as much as possible. I have always tried to have a positive attitude even though there were days when the pain was so severe and uncomfortable it was difficult. I consider myself very lucky to have bee offered by Mr [redacted] the spinal cord stimulator and to have been given another opportunity to lead a normal, pain free life.	considered by the Appraisal Committee when formulating its recommendations. It carefully considered the comments received from consultees and commentators in response to the Assessment Report. For both legal and bioethical reasons those undertaking technology appraisals and developing clinical guidelines must take account of economic considerations (Social Value Judgements - Principles for the development of NICE guidance; principle 2).

Patient 3	I was just 15 when I was diagnosed with RSD / CRPS. That meant that I had severe pain in certain parts of my body. There was no reason for this; I had had no fall or anything to trigger it. It just happened one day at school. Then a few months later the pain in my foot mirrored itself into my left foot. The pain was something I had never experienced before. Like knives being shoved up through my heels into my legs. It was a constant pulsating pain that resulted me unable to walk and in a wheelchair. Then the condition mirrored itself into my right shoulder so that I was in a wheelchair permanently and was now unable to even push myself. All my independency was taken away from me. Things got worse when because the pain was so extreme I suffered from nausea. This resulted in me being unable to attend school and staying at home in bed most of the time. I stopped seeing my friends as I wasn't coping and felt like I turned almost robotic in a sense that I was just doing what I had to do to get through the day. Then there was talk about me having the stimulator. I went and saw Mr [redacted] in Cardiff and he gave me some hope again. After doctors had said that I would not walk again he said there was a chance. I knew it was a small one but there were also other benefits that could be made, even if I could not walk, like just some of the pain being taken away. That seemed amazing enough for someone feeling what I was feeling that I decided right away it was the right move for me. There was worry about my age as I was 16 when I had the operation. But to me it was a light at the end of the tunnel, which I hadn't seen in a long time. And then I got the most amazing gift of all, a true miracle on my 17th birthday, I walked for the first time in 2 years. Since then I am now studying at 6th form college, celebrated my 18th with my friends, I go out shopping and just doing normal teenage things which I haven't been able to do for years. True I still have my condition but having the stimulator has given me my life back and given me my control back. The stimulator has let me appear normal which I know sounds very strange but for people like me is all we want to be, someone whose life is simple and easy and ordinary. Even though the pain isn't gone I can now cope with my life better then I could ever imagine back when I was at my worst. I won't say its easy having a stimulator in you but it's a lot better then suffering in pain all day everyday with no breaks what so ever.	The views of clinical specialists and patient experts were considered by the Appraisal Committee when formulating its recommendations. The Committee carefully considered the comments received from consultees and commentators in response to the Assessment Report. The Committee considered the use of SCS for the treatment of people with CRPS – see FAD sections 1.1, 4.3.6, 4.3.11.

Comments received from website consultation:

Consultee or Commentator	Section of ACD (if specified)		Institute response
Public	**Section 1** (Appraisal Committee's preliminary recommendations)	As the mother of a daughter with CRPS, I cannot begin to tell you of the improvements in her life since being fitted with a spinal cord stimulator 4 years ago. Prior to the fitting my daughter was bed ridden for the majority of the time and was taking many very strong drugs which impaired her quality of life without giving her the pain relief she needed. She was unable to sleep and needed help with all she did. My daughter had no social life, and had to forgo her place at university to read law. Since being fitted with the stimulator my daughter has had physiotherapy and hydrotherapy, she has learnt how to walk again and is able to be much more self-sufficient. Although not completely pain free my daughter is no longer living in a drugged haze, in excruciating pain. She has reclaimed her life and is looking forward to being able to work, socialise with her friends, generally to live her life as a 20 something should. Without the stimulator my daughter would still be lying in bed, unable to move without terrible pain, watching her life pass by. I would urge you to reconsider your decision not to allow the spinal cord stimulator to be used as pain control in the case of CRPS.	The views of clinical experts and patient/carer representatives were considered by the Appraisal Committee when formulating its recommendations. It carefully considered the comments received from consultees and commentators in response to the Assessment Report and ACD. The Committee considered the clinical and cost effectiveness of the use of SCS for the treatment of CRPS – see FAD sections 1.1, 4.3.6, 4.3.11
Carer	**Notes**	CRPS is a disabling illness. The sufferer is in constant pain and the drugs only dull the edge. On bad days they are bed ridden and in excruciating pain, even the touch of the bed sheet causes pain. On good days perhaps they can get up and move around a few feet, not leave the house or walk, but with help make it to a wheelchair. They cannot bath, dress, or go to the toilet alone. They are disabled and in pain. Depression is also a massive factor, the constant pain and the knowledge that the drugs do not really work can turn even the strongest mind towards depression. With SCS CRPS sufferer have a life, maybe not a normal one but they are not disabled or depressed. Walking with crutches is possible, taking a shower is possible, the normal things we all take for granted and that really make a difference to the quality of life can be accomplished. Your preliminary recommendation not to give SCS as a treatment for CRPS is, in my view wrong. The difference in quality of life from being disabled to reasonably normal, after fitting SCS is massive. I understand that you have	The views of clinical experts and patient/carer representatives were considered by the Appraisal Committee when formulating its recommendations. It carefully considered the comments received from consultees and commentators in response to the Assessment Report and ACD. Pain and quality of life data were included in the report by the independent Assessment Group and considered by the Committee when formulation its recommendations. The Committee considered the clinical and cost effectiveness of

Consultee or Commentator	Section of ACD (if specified)		Institute response
		to value all treatments and SCS is no miracle cure, but you have made a mistake and undervalued the difference SCS makes to CRPS sufferers.	the use of SCS for the treatment of CRPS – see FAD sections 1.1, 4.3.6, 4.3.11.
Carer	**Section 1** (Appraisal Committee's preliminary recommendations)	As the parent of a CRPS sufferer I find it incredible that you would even contemplate denying such a life changing treatment to other sufferers. Since receiving a stim implant my daughters whole life has been transformed for the better. She is now able to lead an almost normal life. Whilst she will never be free of the pain this has been significantly reduced by the stim and she is now in control of her own life. Please reconsider your decision since this has obviously been made without a full appreciation of the benefits of this treatment for CRPS sufferers.	The Committee considered the clinical and cost effectiveness of the use of SCS for the treatment of CRPS – see FAD sections 1.1, 4.3.6, 4.3.11.
Public	**Section 1** (Appraisal Committee's preliminary recommendations)	I have a close friend who suffers from CRPS. She has recently had a stim implanted to help with her condition. Before this operation she was unable to leave the house due to the amount pain she felt. Since having the stim implanted her condition, and therefore quality of life, has improved greatly. The amount of pain she suffers has lessened significantly, so much so that she is now able to walk with the aid of a crutch and is no longer reliant upon the use of a wheelchair. She can bend her leg and can frequent places with lots of vibration without the worry that her condition will be exaccerbated and her being left unable to get it under control. If it were not for the stim she would still be confined to a wheelchair and not able to venture outside for long periods of time, if at all. The stim has given her a new lease of life which she did not have before. Because of this, I believe that this implant should be made available to all sufferers of CRPS as it will greatly ease their suffering and improve their quality of life.	The views of clinical experts and patient/carer representatives were considered by the Appraisal Committee when formulating its recommendations. It carefully considered the comments received from consultees and commentators in response to the Assessment Report and ACD. The Committee considered the clinical and cost effectiveness of the use of SCS for the treatment of CRPS – see FAD sections 1.1, 4.3.6, 4.3.11.
Patient	**Section 1** (Appraisal Committee's preliminary recommendations)	I suffer from CRPS Type I in my left leg and have been lucky enough to have a spinal cord stimulator for the past 4&1/2 years. The pain relief I have gained has been almost unbelieveable. Before my stim I could not walk, could not bend my leg, had trouble sleeping,had great difficulty leaving the house due to the exacerbation of pain caused by vibrations of travelling, in a car or wheelchair. I tried accupuncture, physiotherapy and spinal blocks and was taking a combination of medicines but nothing was effective enough for me to have any quality of life. Once my stim was implanted my quality of life was drastically improved. Ive started to live my life again and become more self-reliant gaining more self-respect and independence. The physio and	The views of clinical experts and patient/carer representatives were considered by the Appraisal Committee when formulating its recommendations. It carefully considered the comments received from consultees and commentators in response to the Assessment Report and ACD.

Consultee or Commentator	Section of ACD (if specified)		Institute response
		hydrotherapy I received after my stim was implanted were of great benefit but without the use of the stim I would not have been able to get the pain controlled enough to be able to try them. I would encourage any sufferer of CRPS to have this treatment, it has the potential to turn their life around, it did mine! Please do not deny others this opportunity, it may not be a cure in your eyes but to a CRPS sufferer it feels like one.	The Committee considered the clinical and cost effectiveness of the use of SCS for the treatment of CRPS – see FAD sections 1.1, 4.3.6, 4.3.11 For both legal and bioethical reasons those undertaking technology appraisals and developing clinical guidelines must take account of economic considerations (Social Value Judgements - Principles for the development of NICE guidance; principle 2).
Public	**Notes**	My friend has had a stim fitted and basically it has completely changed her life for the better. Before she had it fitted she was in extreme amounts of pain, her parents had to convert the conservatory into a bedroom for her as she was unable to use the stairs, she was unable to bathe herself unaided, she could only go outside if she was in her wheelchair but at the lowest point of all this she couldnt even go out in her wheelchair or take a car ride as the vibrations (as little as they would be for you and me) would cause her extreme pain. Since she has had the stim fitted she is a completely different person, shes still not 100% and still has her off days but she is slowly and surely on the mend, she is now able to socialise with friends again, drive her car (automatic), go shopping and lead a more normal life.	The views of clinical experts and patient/carer representatives were considered by the Appraisal Committee when formulating its recommendations. It carefully considered the comments received from consultees and commentators in response to the Assessment Report and ACD.
Public	**Section 1** (Appraisal Committee's preliminary recommendations)	I have a friend who had the spinal cord stim fitted earlier this year. Before this was fitted she was in constant pain,unable to leave the house and even unable to put on shoes and socks. Now she is able to drive her car on short journeys and make short trips to the shops etc. Without the NHS funding for this device she would have had no quality of life. Taking the funding away from others like my friend would be criminal. the NHS have helped her so much please let them help others with similar conditions.	The views of clinical experts and patient/carer representatives were considered by the Appraisal Committee when formulating its recommendations. It carefully considered the comments received from consultees and commentators in response to the Assessment Report and ACD.

Consultee or Commentator	Section of ACD (if specified)		Institute response
			For both legal and bioethical reasons those undertaking technology appraisals and developing clinical guidelines must take account of economic considerations (Social Value Judgements - Principles for the development of NICE guidance; principle 2) – see FAD sections 4.3.7, 4.3.13.
Public	**Section 1** (Appraisal Committee's preliminary recommendations)	Whilst the crps will probably never go away the spinal cord stimulator has made a huge difference to the quality of life. prior to having the spinal stim fitted she was bed ridden and on enormous quantities of drugs which did nothing to reduce the pain with no quality of life. having had the stim fitted she is once again able to have a	The views of clinical experts and patient/carer representatives were considered by the Appraisal Committee when formulating its recommendations. It carefully considered the comments received from consultees and commentators in response to the Assessment Report and ACD. The Committee considered the clinical and cost effectiveness of the use of SCS for the treatment of CRPS – see FAD sections 1.1, 4.3.6, 4.3.11.
Public	**Notes**	Since the stim was implanted iyou can see significant improvements - I would easily recommend anyone who is looking into this surgery to go ahead with it.	For both legal and bioethical reasons those undertaking technology appraisals and developing clinical guidelines must take account of economic considerations (Social Value Judgements - Principles for the development of NICE guidance; principle 2) – see FAD sections 4.3.7, 4.3.13.

Consultee or Commentator	Section of ACD (if specified)		Institute response
			Before implantation of an SCS device a person should have a successful trial of stimulation – see FAD section 1.3
NHS Professional	**Section 1** (Appraisal Committee's preliminary recommendations)	There have been vast clinical experience in SCs therapy over the 40years. I am surprised SCS in Refractory angina is deemed experimental / in research stages when there is good quality evidence for its efficacy. In relation to CRPS, the longterm follow up data has been misinterpreted and there has been signinfiacnt flaws in the intention to treat analaysis in a small number of cases skewing the results significantly. While SCS (a surgical procedure) has limited RCT evidence compared to a pharmacological intervention, it has ahead compared to other surgical interventions frequently institued in an MDT setting. Moreover SCS is one of the rare surgical intervention which can be tried for its eficacy before proceeding to full system implantation. If the current recommendation are implemented, i am afraid a signifcant proportion of CRPS patients (economically productive) would be to deemed to a life of significant disability without the potential to undergo physical therapy due to their symptoms.	The Committee considered that clinical evidence suggested that there may be benefits for SCS used for the treatment of RA. However, it concluded that there was insufficient cost effectiveness evidence to support the use of SCS for RA. Recognising the possible benefits of SCS for the treatment of RA, the Committee considered that SCS should be subject to further research in this group of people in order to inform the evidence of cost effectiveness. For both legal and bioethical reasons those undertaking technology appraisals and developing clinical guidelines must take account of economic considerations (Social Value Judgements - Principles for the development of NICE guidance; principle 2) – see FAD sections 4.3.7, 4.3.13. The Committee considered the clinical and cost effectiveness of the use of SCS for the treatment of CRPS – see FAD sections 1.1, 4.3.6, 4.3.11.

Consultee or Commentator	Section of ACD (if specified)		Institute response
NHS Professional	**Section 1** (Appraisal Committee's preliminary recommendations)	I believe that 1.2 is too restrictive. The evidence shown alter points to good benefits in refractory angina but this is excluded. There is nothing about radicular pain except in the context of failed back surgery. This technology is last line for patients who have exhausted all other options.	The Committee considered that clinical evidence suggested that there may be benefits for SCS used for the treatment of RA. However, it concluded that there was insufficient cost effectiveness evidence to support the use of SCS for RA. Recognising the possible benefits of SCS for the treatment of RA, the Committee considered that SCS should be subject to further research in this group of people. For both legal and bioethical reasons those undertaking technology appraisals and developing clinical guidelines must take account of economic considerations (Social Value Judgements - Principles for the development of NICE guidance; principle 2) – see FAD sections 4.3.7, 4.3.13. The Committee considered whether it was appropriate to generalise from the trial data for FBSS and CRPS to other chronic pain conditions of neuropathic origin – see FAD sections 1.1 and 4.3.12.
	Section 4 (Evidence and interpretation)	There appears to be increased limb survival on your own data using SCS but this is felt not to be economically significant. I feel this underestimates the value to the patient when all other options have been exhausted.	The Committee considered that clinical evidence suggested that there may be benefits for SCS used for the treatment of CLI. However, it concluded that there was insufficient cost effectiveness

Consultee or Commentator	Section of ACD (if specified)		Institute response
			evidence to support the use of SCS for CLI. Recognising the possible benefits of SCS for the treatment of CLI, the Committee considered that SCS should be subject to further research in this group of people. For both legal and bioethical reasons those undertaking technology appraisals and developing clinical guidelines must take account of economic considerations (Social Value Judgements - Principles for the development of NICE guidance; principle 2) – see FAD sections 4.3.7, 4.3.13.
NHS Professional	**Notes**	I have been working with spinal cord stimulation in Scotland for over 12 years.	Noted.
	Section 1 (Appraisal Committee's preliminary recommendations)	1.1 Failed back syndrome could be caused by recurrent disc etc and should be defined in the recommendation. For example a patient who continues to have pain after back surgery might still have residual disc or developed a recurrent disc. The guidance should affirm the definition of failed back surgery syndrome. The mere reduction of pain severity by 50% is not sufficient justification for SCS, there should be improvement in the quality of life. In my experience that spans over a decade in this area, the mere reduction in pain scores is not a good surrogate of benefit in the long run. The role of preimplanation trail is not as yet defined as there is no class I evidence to support the use of such trial. In fact several patients who pass a trial fail later on because of the placebo effect and several patients who fail the trail do get a very useful benefit because of poorly administered trial	The Committee considered whether it was appropriate to generalise from the trial data for FBSS and CRPS to other chronic pain conditions of neuropathic origin – see FAD sections 1.1 and 4.3.12. The Committee specifically considered the use of trial stimulation in the clinical and cost effectiveness evidence submitted and consultee comments. The selection criteria for a successful trial have been removed from the FAD – see FAD sections 1.1, 1.3, 4.3.3.

Consultee or Commentator	Section of ACD (if specified)		Institute response
NHS Professional	**Section 1** (Appraisal Committee's preliminary recommendations)	The nature of angina means that it is extremely difficult to achieve full coverage of the painful areas. The committee do not appear to have understood that the mechanism of ischaemic cardiac pain is different from other chronic pain states. This lack of insight is best explained by the committees failure to take advice from clinicians with current relevant expertise.	The Committee considered all the evidence submitted, including evidence from clinical trials, patient and clinical experts, the Assessment Group's economic analysis and the manufacturers' submissions. It also carefully considered the comments received from consultees and commentators in response to the Assessment Report and ACD – see FAD section 4.3.7, 4.3.13.
	Section 2 (clinical need and practice)	As an expert in RA and responsible in large part for generating a consensus view of the definition of chronic refractory angina I do not accept (or even understand) the definition used here. It is not one I have even come across previously. It raises questions about the expertise of your clinical specialist in RA	The background section of the FAD provides a brief overview of the clinical condition and is not meant to be comprehensive. The description of refractory angina in the FAD is that used in the submission from the manufacturers'.
	Section 4 (Evidence and interpretation)	The use of the term clinical specialists (4.3.1) suggests clinians with special knowledge of refractory angina management. It is not clear who was the clinical specialist in RA. I specialise exclusively in the management of refractory angina and was only contacted for comments a few days before the document was to be finalised. I explained that I could not be expected to give a considered opinion at such late notice and in the time available. Briefly, the cost effectiveness analysis does not appear to take account of the special clinical circumstances that pertains in RA patients. Nor does it appear to be based on a proper consideration of the data on the safety and effectiveness of revascularisation in RA patients who might be candidates for SCS	The Committee appraised the use of SCS for pain of neuropathic and ischaemic origin. Consultees involved in the appraisal had a range of backgrounds. Committee concluded that there was insufficient cost effectiveness evidence to support the use of SCS for RA. Recognising the possible benefits of SCS for the treatment of RA, the Committee considered that SCS should be subject to further research in this

Consultee or Commentator	Section of ACD (if specified)		Institute response
			group of people in order to inform the cost effectiveness evidence. For both legal and bioethical reasons those undertaking technology appraisals and developing clinical guidelines must take account of economic considerations (Social Value Judgements - Principles for the development of NICE guidance; principle 2) – see FAD sections 4.3.7, 4.3.13.
	Section 6 (proposed recommendations for further research)	SIGN, the ESC refractory angina study group and NRAC all agree that conventional medical management should be education, comprehensive rehabilitation including cognitive behavioural intervention and a review of medication before any other intervention is considered. None of the studies cited in evidence, treated RA patients according to these conventional principles. It is noteworthy that at NRAC this approach resulted in only 2% of 433 consecutive RA patients progressing to SCS.	The Committee did not consider that the cost effectiveness evidence available was sufficient to recommend the use of SCS for the treatment of RA – see FAD section 4.3.7, 4.3.13.
NHS Professional	**Notes**	1.1: Simple use of the Visual Analogue Scale is over-simplistic. The effect of the pain on the patients FUNCTION is far more important. Any number of functional scores are available and are of much greater importance than a simple pain score. 1.2 This is somewhat restrictive. There is evidence in carefully selected angina / ischaemia patients - possibly better than FBBS - although I accept that careful selection is necessary. The same applies for CRPS patients who are a very diverse group and, with careful selection (ie much better than simple VAS) can do well. General: The approach of the recommendations feels a little too	The Committee recognised the importance of functional outcomes for the treatment of chronic pain – see FAD sections 4.1.10, 4.1.12, 4.1.13, 4.1.14. 4.3.7, 4.3.13. The Committee concluded that there was insufficient cost effectiveness evidence to support the use of SCS for CLI and RA. Recognising the possible benefits of SCS for the treatment of CLI and RA, the Committee considered that SCS should be subject to further research in this group of people.

Consultee or Commentator	Section of ACD (if specified)		Institute response
			The Committee considered the clinical and cost effectiveness of the use of SCS for the treatment of CRPS – see FAD sections 1.1, 4.3.6, 4.3.11
	Section 1 (Appraisal Committee's preliminary recommendations)	1.1: Simple use of the Visual Analogue Scale is over-simplistic. The effect of the pain on the patients function is far more important. This concept is brought in later in the document, but (IMHO) functional limitation is as important (?more) as pain. In any event such a simple marker as a VAS of 5/10 for 6 months is very blunt and I suggest not useful. 1.2 This is somewhat restrictive. I accept that careful selection is necessary, but I am not convinced that the (in effect) denial of these options for a significant number of patients is appropriate on the grounds of evidence given... your determination seemingly being based on absence of evidence rather than evidence of absence. Agree that trials necessary - but this should be the emphasis, rather than denial outside of trials. Of course ALL clinicians should be collecting data on outcomes for ALL procedures... which is a bit different from being part of a clinical trial, but just as important.	See response above. The Committee concluded that as the clinical trials included people who indicated that there was pain 50/100mm on a VAS scale, the Committee's recommendations should reflect this – see FAD section 4.3.4. The Committee considered that clinical evidence suggested that there may be benefits for SCS used for the treatment of ischaemic pain. However, it concluded that there was insufficient cost effectiveness evidence to support the use of SCS for ischaemic pain. Recognising the possible benefits of SCS for the treatment of ischaemic pain, the Committee considered that SCS should be subject to further research in this group of people.– see FAD sections 4.3.7, 4.3.13.
	Section 2 (clinical need and practice)	2.1 has good elements, but I think starting with defining the condition by chronology rather than complexity sends slightly the wrong message. Excellent that there are elements of supported self-management in here. If possible to beef this up, please do!	Section 2 provides a brief overview to the condition and its management. It does not provide a comprehensive guide to

Consultee or Commentator	Section of ACD (if specified)		Institute response
			treatment. No changes made to the FAD.
	Section 3 (The technology)	3.8 Although you have not capitalised, I suggest drop the term	It is unclear the context of this comment to section 3.8. No changes made to the FAD
	Section 4 (Evidence and interpretation)	Accept that this is an interpretation of the evidence base. I would like to see (have I missed it?) an emphasis on the need to collect outcomes data in a form that can be shared with other centres. I think this is possibly more important at this stage than full-blown RCTs (important though these are).	The Committee considered that clinical evidence suggested that there may be benefits for SCS used for the treatment of ischaemic pain. However, it concluded that there was insufficient cost effectiveness evidence to support the use of SCS for ischaemic pain. Recognising the possible benefits of SCS for the treatment of ischaemic pain, the Committee considered that SCS should be subject to further comparative research in this group of people. For both legal and bioethical reasons those undertaking technology appraisals and developing clinical guidelines must take account of economic considerations" (Social Value Judgements - Principles for the development of NICE guidance; principle 2) – see FAD sections 4.3.7, 4.3.13.
	Section 6 (proposed recommendations for further research)	There are centres with excellent clinical outcomes that are simply not in a position (NHS Trust limitations) to be doing RCTs. Data outcomes are vital in all centres, and being able to combine / compare data from a number of centres just as important. I think this is just as valid (for permitting continuing	Recommendations for further research are prioritised using processes and criteria agreed by the Institute's research and

Consultee or Commentator	Section of ACD (if specified)		Institute response
		practice) as being involved in RCTs... possibly more so. Sir Bruce Keogh (medical director NHS, D-CMO) has been robust in his views on the above.	development advisory committee. The Institute promotes research recommendations to organisations that fund research, such as the NHS National Institute for Health Research.
	Section 8 (proposed date of review of guidance)	Given the rationale for	Consultees may request an earlier review date once the guidance is published, if they consider that there is evidence which change the current recommendations. No changes made to the review date.
NHS Professional	**Section 1** (Appraisal Committee's preliminary recommendations)	Spinal cord stimulation is not recommended as a treatment option for adults with complex regional pain syndrome. I find this satement suprising as many of the best results that I have had have been inpatienst with CRPS. Anecdotally, I implanted a ptient thsi week who came in to hospital wearing a rocker boot and walking on tiptoes with an elbow crutch unable to care for her daughter. She had a successful trial, and has walked out leaving her boot etc. behind. Who is going to run the trial you suggest ?	The Committee considered the clinical and cost effectiveness of the use of SCS for the treatment of CRPS – see FAD sections 1.1, 4.3.6, 4.3.11.