National Institute for Health and Clinical Excellence

Implantable cardioverter defibrillators for the treatment of arrhythmias and cardiac resynchronisation therapy for the treatment of heart failure (review of TA95 and TA120)

Comment 1: the draft remit

Section	Consultees	Comments	Action
Appropriateness	SADS UK	No comments	Comment noted.
	Boston scientific	No comments	Comment noted.
	British Nuclear Cardiology Society / British Nuclear Medicine Society	No comments	Comment noted.
	NCGC acute and chronic	No comments	Comment noted.
	Royal college of physicians	No comments	Comment noted.
Wording	SADS UK	No comments	Comment noted.
	Boston scientific	No comments	Comment noted.
	British Nuclear Cardiology Society / British Nuclear Medicine Society British Association of Urological Surgeons	No comments	Comment noted.
	NCGC acute and chronic	No comments	Comment noted

Section	Consultees	Comments	Action
Timing Issues	SADS UK	No comments	Comment noted.
	Boston scientific	No comments	Comment noted.
	British Nuclear Cardiology Society / British Nuclear Medicine Society	No comments	Comment noted.

Comment 2: the draft scope

Section	Consultees	Comments	Action
Background information	SADS UK	The background information covered seems reasonable	Comment noted.
	Boston Scientific	No comments	Comment noted.
	British Nuclear Cardiology Society / British Nuclear Medicine Society	No comments	Comment noted.
	NCGC acute and chronic conditions	The information is good, but some alterations and corrections are needed, as follows: Under (Arrhythmias): Paragraph 1, Lines 1-3: [Arrhythmias are caused by an abnormality in the electrical conduction system resulting in a reduction in cardiac efficiency.]. This should read: {Arrhythmias are caused by an abnormality in the myocardial tissue of the atria or ventricles, or in the electrical conduction system. Arrhythmias can result in a reduction in cardiac efficiency.}. Under (Heart Failure): Paragraph 1, Lines 3-5: [In a healthy heart, the lower chambers (ventricles) pump at the same time in and in synchrony with the upper chambers (atria).]. This should read: {In a healthy heart, the lower chambers (ventricles) pump at the same time and in sequential synchrony following the upper chambers (atria).]	Commented noted. Amended accordingly.. Commented noted. Amended accordingly.

Section	Consultees	Comments	Action
	NCGC acute and chronic conditions	Under (Heart Failure): Paragraph 1, Lines 7-12: [Some patients have heart failure as a result of left ventricular systolic dysfunction (LVSD) in which the left ventricle does not pump in synchrony with some or all of the other chambers of the heart. LVSD is associated with a reduced left ventricular ejection fraction (the fraction of blood pumped out of the left ventricle with each heart beat expressed as a percentage of the total volume).] This should read: {Many patients with heart failure have left ventricular systolic dysfunction (LVSD). LVSD is associated with a reduced left ventricular ejection fraction (the fraction of blood pumped out of the left ventricle with each heart beat expressed as a percentage of the total volume). Some patients with LVSD do not have synchrony within the left ventricle, between the left and the right ventricles, or between the atria and the left ventricle}.	Commented noted. Amended accordingly.
	Heart Rhythm UK/ Arrhythmia Alliance/ British Society for Heart Failure	This section contains a significant number of inaccuracies. In the light of recent advances in the understanding and management of arrhythmias, we suggest rewording this section to ensure that the document accurately reflects the current clinical context. Please see appendix for detailed comments: Appendix reproduced below)	Comment noted. The background of the scope is only intended to provide a brief overview of the disease and its current clinical management and is written in a style that is consistent with NICE technology appraisal documentation.

Section	Consultees	Comments	Action
	Heart Rhythm UK/ Arrhythmia Alliance/ British Society for Heart Failure (cont.)	**Background information** **Arrhythmias** Normal heart function requires optimal electrical coordination of contraction. Any abnormal cardiac rhythm, or arrhythmia, which disturbs normal physiological sinus rhythm, reduces cardiac efficiency. Arrhythmias arising in the ventricles, ventricular tachycardia and ventricular fibrillation, can result in insufficient blood being pumped by the heart to sustain life. This is the mechanism of over 80% of sudden cardiac deaths, killing 90,000 people in the UK each year. The most common risk factor for sudden cardiac death is ischaemic heart disease but other causes of reduced cardiac function such as cardiomyopathy also result in increased risk. There are also many inherited conditions which increase the risk of ventricular arrhythmias and sudden death. The most effective way to prevent cardiac arrhythmias is to the treat the underlying heart condition with medications and other interventions. Prevention is an essential part of every patient's management, but the only effective treatment of life-threatening ventricular arrhythmias is electrical defibrillation. This can be performed with an external defibrillator but unfortunately, because of the short time window before irreversible brain damage, only 5% of people survive a cardiac arrest outside a hospital. The alternative is the implantation of an automatic device, an implantable cardioverter defibrillator (ICD), in people at increased risk of cardiac arrest. This detects and treats any ventricular arrhythmia within a few seconds and is much more effective, successfully defibrillating 99% of patients. This technology is recommended in NICE technology appraisal 95 which states that ICD implantation is indicated in primary (no previous cardiac arrest) and secondary (resuscitated cardiac arrest) prevention.	Please see response above.

Section	Consultees	Comments	Action
	Heart Rhythm UK/ Arrhythmia Alliance/ British Society for Heart Failure (cont.)	**Heart failure** Heart failure is a complex syndrome of signs and symptoms which results from the heart's inability to supply the circulatory requirements of the body. Heart failure is common, affecting around 900,000 people in the UK with almost as many again having asymptomatic left ventricular dysfunction. The incidence and prevalence of heart failure increase steeply with age, so our ageing population, improvements in the survival of people with ischaemic heart disease and more effective medical and interventional treatments, mean that the number of people affected will continue to increase. Heart failure has a worse prognosis than many cancers with up to 40% of patients dying within a year of diagnosis, and a greater effect on quality of life than many other chronic diseases such as chronic lung disease and arthritis. The medical management of heart failure is described in the NICE clinical guideline 108 Chronic heart failure Management of chronic heart failure in adults in primary and secondary care published August 2010. People with normal cardiac function have considerable cardiovascular reserve and can tolerate significant physiological and pathological cardiovascular stresses. People with reduced cardiac function have greatly reduced reserve and anything which reduces cardiac efficiency further can have a dramatic effect on their symptoms and quality of life. Approximately 30% of patients with heart failure due to left ventricular systolic dysfunction have atrio-ventricular and/or inter-ventricular dyssynchrony which is seen on the 12-lead ECG as a prolonged PR interval and/or increased QRS complex duration.	Please see response above.

Section	Consultees	Comments	Action
	Heart Rhythm UK/ Arrhythmia Alliance/ British Society for Heart Failure (cont.)	Synchronisation of cardiac contraction may be improved by the implantation of a cardiac rhythm device which can sense and stimulate the atria, right and left ventricles independently – a cardiac resynchronisation pacemaker (CRT-P) or defibrillator (CRT-D) which can improve cardiac function and reduce heart failure symptoms. NICE technology appraisal guidance 120 (May 2007) recommends CRT-P for people who: • are currently experiencing or have recently experienced breathlessness at rest or on minimal exertion (NYHA III-IV) despite optimal pharmacological therapy • which is associated with left ventricular dysfunction (LVEF ≤35%) • and in whom dyssynchrony (QRS duration ≥150ms or 120–149 ms with evidence of mechanical dyssynchrony) is implicated. It also recommends cardiac resynchronisation therapy with a device capable of defibrillation (CRT-D) for people who fulfil the criteria for implantation of a CRT-P device and the criteria for the use of an ICD device as recommended in NICE technology appraisal guidance 95.	Please see response above.

Section	Consultees	Comments	Action
	Heart Rhythm UK/ Arrhythmia Alliance/ British Society for Heart Failure (cont.)	**Implantable cardioverter defibrillators (ICDs)** An ICD is an electronic device implanted in a patient at increased risk of life-threatening arrhythmias. It monitors cardiac rhythm continuously and automatically delivers therapy in the form of rapid low-voltage pacing and/or high voltage defibrillation shocks when a dangerous ventricular arrhythmia is detected. The majority of devices implanted in the UK comprise one or more leads connecting the heart via the central venous system to a device implanted beneath the skin of the chest. These devices are all capable of pacing functions to treat slow heart rhythms (bradycardia). A recently developed subcutaneous ICD is able to detect arrhythmias and deliver defibrillation using a lead which is placed under the skin of the chest but does not enter the heart. Subcutaneous ICDs are not directly interchangeable with standard ICDs as they have specific indications and limitations. We suggest that this requires separate consideration.	Please see response above.

Section	Consultees	Comments	Action
	Heart Rhythm UK/ Arrhythmia Alliance/ British Society for Heart Failure (cont.)	**Cardiac resynchronisation therapy (CRT)** Conventional bradycardia pacemakers comprise leads connecting the right atrium and/or ventricle to a device implanted beneath the skin of the chest. They monitor heart rhythm continuously and deliver electrical stimulation to induce myocardial contraction when the heart falls below a pre-specified rate or ventricular contraction does not follow atrial contraction after a pre-specified interval. In this way, they can prevent bradycardia and restore synchronisation between atrial and ventricular contraction. In heart failure, around 1 in 3 patients have impaired electrical synchronisation which is seen on the ECG as delayed atrio-ventricular conduction and/or bundle branch block. This can further reduce the efficiency of systolic function. Synchronisation can be improved by the implantation of a device which can sense and stimulate the right atrium and/or ventricle as in a conventional pacemaker but with the addition of a lead directly pacing the left ventricle. This is usually placed in a branch of the coronary sinus, the vein draining the muscle of the left ventricle into the right atrium. This CRT functionality can be added to a pacemaker (CRT-P) or an ICD (CRT-D	Please see response above.
The technology/ intervention	SADS UK	Yes	Commented noted.

Section	Consultees	Comments	Action
	Boston Scientific	Interventions as described in the provisional scope and from comments at the workshop, would more appropriately read: ICD, CRT-P and CRT-D The interventions as listed above being roughly associated to the populations as listed in the points below: *ICD- People at increased risk of sudden cardiac death due to ventricular arrhythmias despite optimal pharmacological treatment* *CRT-P-People with heart failure as a result of left ventricular systolic dysfunction and cardiac dyssynchrony despite optimal pharmacological treatment* *CRT-D* *People with both conditions described to the left*	• *People at increased risk of sudden cardiac death due to ventricular arrhythmias despiteoptimal pharmacological treatment (column 1)*: – Comment noted. • *People with heart failure as a result of left ventricular systolic dysfunction and cardiac dyssynchrony despite optimal pharmacological treatment (column 2)*::- Comment noted. The decision to include both CRT-P and CRT-D as interventions for the population with heart failure was based on the '2010 Focused Update of ESC Guideline on device therapy in heart failure' and the comparisons within the COMPANION study (randomised people to receive CRT-P or CRT-D after excluding people with conventional ICD indications) • *People with both conditions described to the left*: (column 3): - Comment noted

Section	Consultees	Comments	Action
	British Nuclear Cardiology Society / British Nuclear Medicine Society	No comments	Comment noted.
	NCGC acute and chronic conditions	Yes, but there are two typing errors, as follows: Under (Implantable Cardioverter Defibrillator): Paragraph 1, line 2: [*shoulder, with leads into the heart to pace, sense and defibrillate.. Dual-*] This should read: {shoulder, with leads into the heart to pace, sense and defibrillate. Dual-} Under (Cardiac Resynchronisation Therapy): Paragraph 2, Last line: [*this the device is known as a CRT-D device.*] This should read: {this device is known as a CRT-D device.}	Comment noted. Amended accordingly. Comment noted. Amended accordingly.
Population	SADS UK	Yes	Comment noted.

Section	Consultees	Comments	Action
	Boston Scientific	People at risk of increased risk of sudden cardiac death as a result of ventricular arrhythmias despite optimal pharmacological treatment includes a significant proportion of 'Secondary Prevention' patients as indicated in TA 95. Previously consultee's have advised NICE of the lack of new evidence in this indication since the previous review and hence it is our belief that the current guidance in this patient population does not require review. Whilst we understood the feedback from NICE at the scoping workshop that your preference would be to have all current guidance contained within one document, we re-emphasize that a review of this indication will add no further insight and it would be economical to exclude this indication given the complexity of the remaining populations in this review in the ICD Primary Prevention and Heart Failure indications. We wish to draw attention to the fact that the populations as defined in the scope are not as discrete as the segmentation in the scope would seem – simply, there is a huge amount of overlap in the patient populations at risk of SCD and HF death. Given the aim of this review is to support cost effective decision making, the way Industry approach is to use the existing evidence base to create an algorithm for optimal device selection (based on cost effectiveness criteria) using thresholds for commonly used patient parameters.	Comment noted.. Comment noted. This is beyond the scope of an appraisal.
	British Nuclear Cardiology Society / British Nuclear Medicine Society	No comments	Comment noted.

Section	Consultees	Comments	Action
	NCGC acute and chronic conditions	Yes, although this is difficult, we need to take a hard look at: 1. The not infrequent tendency of some clinicians to extend evidence-based indications beyond the evidence (time, NYHA class). 2. The use of ICD in NYHA class IV, and within class IV whether we should try and identify those patients in whom the window of opportunity might have been missed and thus the intervention is either inappropriate or not cost-effective. 3. The use of CRT in patients with NYHA class II, and the implications of the RAFT study. I also wonder whether the appraisal could also stipulate that the clinician should explain at the time of consent for devices the implications of having the device on the mode of death in heart failure patients, and a frank discussion about the possibility at some stage (in the terminal phase of life) of switching off the device.	1. Comment noted. 2. Comment noted. 3. Comment noted. The populations within the scope are not defined by NYHA class Therefore the populations are sufficiently broad to capture evidence submitted regarding NYHA class II. Comment noted. This is beyond the scope of an appraisal.
	Cardiomyopathy Association	We are pleased to see that people with dilated cardiomyopathy are not excluded.	.Comment noted.

<table>
<tr><th>Section</th><th>Consultees</th><th>Comments</th><th>Action</th></tr>
<tr>
<td></td>
<td>Heart Rhythm UK/ Arrhythmia Alliance/ British Society for Heart Failure</td>
<td>
Have the three populations in this scope been defined correctly?

We recommend that the clearest way to define the populations and their comparators is in a 2x2 matrix
<table>
<tr><td></td><td>People at increased risk of sudden cardiac death as a result of ventricular arrhythmias despite optimal pharmacological treatment (OPT)</td><td>People without this characteristic</td></tr>
<tr><td>People with heart failure as a result of left ventricular systolic dysfunction and cardiac dyssynchrony despite optimal pharmacological treatment (OPT)</td><td>Intervention: CRT-D +OPT

Comparator: OPT alone</td><td>Intervention: CRT-P +OPT

Comparator: OPT alone</td></tr>
<tr><td>People without this characteristic</td><td>Intervention: ICD +OPT

Comparator: OPT alone</td><td>Intervention: OPT alone</td></tr>
</table>
</td>
<td>Comment noted. The population and technologies described in the draft scope have been presented n a style that is consistent with NICE technology appraisal documentation.</td>
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Section	Consultees	Comments	Action
	Heart Rhythm UK/ Arrhythmia Alliance/ British Society for Heart Failure (cont.)	The evidence strongly supports the use of ICDs in patients at increased risk of ventricular arrhythmias (primary prevention) as well as those who have been resuscitated from a cardiac arrest (secondary prevention) as described in NICE TA 95. This includes people with ischaemic heart disease, cardiomyopathy, congenital heart disease and primary arrhythmic conditions. Recent evidence demonstrates the efficacy of CRT in patients with less severe heart failure symptoms and we suggest that this population be included in the analysis. Although there are groups of patients where greater and lesser benefit from device therapy would be anticipated, we recommend that they are included in the main appraisal process.	Comment noted. The populations within the draft t scope are not defined by NYHA class. Therefore the populations are sufficiently broad to capture evidence submitted regarding NYHA class II.
Comparators	SADS UK	No comments	Comment noted.

Section	Consultees	Comments	Action
	Boston Scientific	The intervention in column 2 should be CRT-P and the comparator should be optimal pharmacological treatment. The ICD element of the CRT-D is indicated in patients with an associated risk of sudden cardiac death (see column 3). For those that have both conditions to the left as described above, the intervention should be CRT-D and the comparator should be ICD, CRT-P or OPT.	Comment noted. The decision to include both CRT-P and CRT-D as interventions for the population with heart failure (column 2) was based on the '2010 Focused Update of ESC Guideline on device therapy in heart failure' and the comparisons within the COMPANION study ((randomised people to receive CRT-P or CRT-D after excluding people with conventional ICD indications). Comment noted. The comparators for the patient population with heart failure and conventional indication for an ICD have been amended to include CRT-P.
	British Nuclear Cardiology Society / British Nuclear Medicine Society	No comments	Comment noted.

Section	Consultees	Comments	Action
	NCGC acute and chronic conditions	Yes. However, it would be helpful to add in the third section on CRT-D, another comparator namely CRT-P. This is despite the fact that CRT-P and CRT-D are compared in the second section. In some of the cases, yes. However, a modality could be regarded by the clinician to be the best alternative care in a particular patient, but not in another.	Comment noted. The comparators for the patient population with heart failure and conventional indication for an ICD (column 3) have been amended to include CRT-P. Comment noted.
	Heart Rhythm UK/ Arrhythmia Alliance/ British Society for Heart Failure	Standard NHS care is represented by optimal pharmacological therapy (OPT), which all patients should receive. The intervention is device implantation. The appropriate comparison for “people with heart failure as a result of left ventricular systolic dysfunction and cardiac dyssynchrony despite optimal pharmacological treatment” is cardiac resynchronisation therapy (CRT) with OPT against OPT alone. CRT may be delivered as a CRT-P (pacemaker) or CRT-D (defibrillator) depending on whether or not the patient has a requirement for ICD therapy.	Comment noted. 1. The decision to include both CRT-P and CRT-D as interventions for the population with heart failure (column 2) was based on the ‘2010 Focused Update of ESC Guideline on device therapy in heart failure’ and the comparisons within the COMPANION study (randomised people to receive CRT-P or CRT-D after excluding people with conventional ICD indications).

Section	Consultees	Comments	Action
		The appropriate comparison for "people at increased risk of sudden cardiac death as a result of ventricular arrhythmias despite optimal pharmacological treatment" is a defibrillator with OPT against OPT alone. Defibrillator therapy may be delivered as ICD or CRT-D depending on whether or not the patient has a requirement for CRT	2. The comparators for the patient population with heart failure and conventional indication for an ICD (column 3) have been amended to include CRT-P. The decision to include CRT-P was based on the '2010 Focused Update of ESC Guideline on device therapy in heart failure' and the comparisons within the REVERSE study.
Outcomes	SADS UK	Yes	Comment noted.
	Boston Scientific	No comments	Comment noted.
	British Nuclear Cardiology Society / British Nuclear Medicine Society	No comments	Comment noted.
	NCGC acute and chronic conditions	Yes	Comment noted.

Section	Consultees	Comments	Action
	Heart Rhythm UK/ Arrhythmia Alliance/ British Society for Heart Failure	**Have the most appropriate outcomes for implantable cardioverter defibrillators and cardiac resynchronisation therapy been included in the scope? In particular should exercise capacity be included given that it was an outcome measure in Technology Appraisal no.120?** • mortality • adverse effects of treatment • health related quality of life • symptoms and complications related to tachyarrhythmias • heart failure hospitalisations • change in NYHA class • change in left ventricular ejection fraction In addition to the measures above, we would suggest appropriate outcome measures include: • sudden cardiac death • symptoms and complications associated with heart failure • exercise capacity (e.g. 6-minute walk distance	Comment noted. The outcomes listed in the draft scope have been amended to include sudden cardiac death and symptoms and complications associated with heart failure. Exercise capacity has not been included in the list of outcomes as it will be captured by the outcome measure 'symptoms and complications associated with heart failure.'
		We suggest that these analyses should, as far as possible, take into account improvements in technology since the pivotal trials. These have mitigated some of the adverse effects of treatment on quality of life (e.g. improved algorithms to avoid unnecessary defibrillation shocks, remote monitoring which reduces patients' travel burden, smaller devices) and improved clinical effectiveness (e.g. improved left ventricular lead technology, algorithms for early detection of heart failure decompensation).	Comment noted.
Economic analysis	SADS UK	No comments	Comment noted.
	Boston Scientific	No comments	Comment noted.

Section	Consultees	Comments	Action
	British Nuclear Cardiology Society / British Nuclear Medicine Society	No comments	Comment noted.
	NCGC acute and chronic conditions	Appropriate	Comment noted.
	Heart Rhythm UK/ Arrhythmia Alliance/ British Society for Heart Failure	Because the lifetime cost of ICD therapy is highly sensitive to device longevity, we would suggest that the characteristics of currently implanted devices should be used in cost effectiveness modelling, rather than historical data from devices with previous generations of battery technology. The costs associated with subcutaneous ICDs will need specific review.	Commented noted. The 'other considerations' section of the scope has been amended to include the following: 'If evidence allows the clinical and cost-effectiveness of subcutaneous ICDs will be considered separately'
Equality and Diversity	SADS UK	No comments	Comment noted.
	Boston Scientific	No comments	Comment noted.
	British Nuclear Cardiology Society / British Nuclear Medicine Society	No comments	Comment noted.
	NCGC acute and chronic conditions	None	Comment noted

Section	Consultees	Comments	Action
	Cardiomyopathy Association	Latest figures show there are widespread regional differences in the use of both devices (Heart Rhythm Devices: UK National Clinical Audit 2009). This is a concern that needs to be addressed	Comment noted. Implementation is outside the remit of a NICE appraisal committee. NICE produces a number of tools (e.g. costing and audit tools) to aide implementation of its guidance and reduce barriers to access to technologies..
	Heart Rhythm UK/ Arrhythmia Alliance/ British Society for Heart Failure	National audit data collected by the national pacemaker and ICD database (www.devicesurvey.com) has demonstrated significant disparity in ICD and CRT implantation rates across the UK which cannot be explained by disease prevalence. The cause of this apparent inequality of access is unknown and requires further research. We suggest that the guidance should require each implanting centre to submit complete and timely audit data to the national database with a minimum data set including aetiology, NYHA functional class, left ventricular ejection fraction, QRS duration, and history of ventricular arrhythmias (primary or secondary prevention). Expected implant rates for ICD and CRT have been very helpful in planning services and we would welcome revised rates in the new guidance.	Comment noted.
Other considerations	SADS UK	No comments	Comment noted.

Section	Consultees	Comments	Action
	British Nuclear Cardiology Society / British Nuclear Medicine Society	Consider the role of nuclear techniques in (1) assessing LV function, (2) looking for lateral wall scar pre CRT, (3) assessing dyssynchrony with MUGA or gated SPECT, and (4) assessing sympathetic innervation	Comment noted. The role of nuclear techniques is outside the remit of the appraisal.
	NCGC acute and chronic conditions	See comments in population section	Comment noted.
	Cardiomyopathy association	It is important that people having these devices are given psychological support both before and after implantation. Fear of having such devices, especially ICDs, is common and can deter patients who need them from accepting them and/or being able to live successfully with them. Patients also need advice on care of their devices, details about downloading of data options, battery life and changes, follow-up (such as how often reviews are, where they are and by whom, and how to access clinic in between appointments if problems arise), and general advice on travel, insurance, occupational issues (such as avoiding electrical fields). They should also be given information about charities, such as the Cardiomyopathy Association, that supports these patients. Our impression is that patients get a very variable experience of information and support at this time.	Comment noted.

Section	Consultees	Comments	Action
	Heart Rhythm UK/ Arrhythmia Alliance/ British Society for Heart Failure	**Reassessment** When a patient is assessed and found not to fulfil NICE guidance criteria for device implantation, a recommendation on when this assessment should be repeated would be welcome. **Device programming** ICDs and CRT devices are complex and require expert programming to maximise clinical benefits and minimise the risk of inappropriate therapy. A recommendation on the process of optimising therapy would be welcome.	Comment noted. Comment noted.
		Life expectancy We recognise that patients with very limited life expectancy may not benefit from device implantation or replacement. A recommendation on how to identify such patients would be welcome. **Atrial fibrillation** There is significant evidence that patients with atrial fibrillation benefit from CRT when a high proportion of ventricular beats are biventricularly paced. We suggest that these data should be included in the analysis with a recommendation on achieving optimal clinical response. This may require atrio-ventricular node ablation.	Comment noted. Comment noted.

Section	Consultees	Comments	Action
		Measures of dys-synchrony QRS duration has been shown to predict dys-synchrony and thus clinical response to CRT. We would welcome an analysis of the methods used to assess mechanical dys-synchrony.	Comment noted.
		Arrhythmia risk stratification The tests currently used to stratify the risk of ventricular arrhythmias were based on the entry criteria to the pivotal ICD clinical trials. The positive and negative predictive accuracy of non-sustained ventricular tachycardia on Holter recording and sustained ventricular tachycardia induced during a stimulation study have been questioned in more recent analyses. We would welcome a reassessment of the continuing utility of these tests and whether other non-invasive tests would be more appropriate in targeting of device therapy.	Comment noted.
		Right ventricular pacing Patients with atrio-ventricular heart block require ventricular pacing to maintain atrio-ventricular synchrony and an appropriate pulse rate. This induces similar ventricular dyssynchrony to that seen in native bundle-branch block. If patients with left ventricular impairment require ventricular pacing, they should be treated as equivalent to those with native bundle branch block.	Comment noted.
Questions for consultation Should ICDs be included as a comparator to CRT-D given that the MIRACLE ICD trial	SADS UK	No comments	Comment noted.
	Boston Scientific	ICD's should be included as a comparator. MIRACLE ICD is not the only study where this comparator was used, see also MADIT-CRT, REVERSE and RAFT for example.	Comment noted. ICDs are included as a comparator to CRT-D for patients with heart failure and conventional indication for an ICD

Section	Consultees	Comments	Action
(referenced in the ESC Guidelines 2010 on device therapy in heart failure) compared CRT-D with ICD in patients with heart failure in NYHA class III-IV and with a conventional indication for an ICD?	British Nuclear Cardiology Society / British Nuclear Medicine Society	No comments	Comment noted.
Questions for consultation Should standard care (optimal pharmacological treatment without CRTD) be included as comparator to CRT-D?	SADS UK	No comments	Comment noted.
	Boston Scientific	OPT should be included as a comparator, in support of the inclusion of this comparator please see the COMPANION study.	Comment noted.
Questions for consultation Do you consider the technologies to be innovative in their potential to make a significant and substantial impact on health-related benefits and how it might improve the way that current need is met (is this a 'step-change' in the management of the condition?	Heart Rhythm UK/ Arrhythmia Alliance/ British Society for Heart Failure	The use of implantable cardiac rhythm devices has transformed the treatment of patients, improving quality of life and reducing sudden death. Significant new evidence has been published since these technologies were last considered by NICE and we support the development of new joint guidance for ICDs and CRT.	Comment noted.

Section	Consultees	Comments	Action
Questions for consultation Do you consider that the use of these technologies can result in any potential significant and substantial health-related benefits that are unlikely to be included in the QALY calculation?	Heart Rhythm UK/ Arrhythmia Alliance/ British Society for Heart Failure	We agree that the health-related benefits of these treatments are likely to be captured by the proposed outcome measures and QALY calculations	Comment noted.
Any additional comments on the draft scope	Heart Rhythm UK/ Arrhythmia Alliance/ British Society for Heart Failure	Since the preparation of NICE guidance 95 in 2006, the body of evidence supporting the use of ICDs for secondary prevention and for primary prevention in people with a familial cardiac condition with a high risk of sudden death has not changed significantly and we do not feel that there is any need to amend the current guidance	Comment noted.

The following consultees/commentators indicated that they had no comments on the draft remit and/or the draft scope:

Southampton Health Technology Assessment centre

Cochrane peripheral vascular diseases review group

Royal College of Nursing

Welsh Government

Department of Health

Sanofi Aventis

Medtronic UK

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Single Technology Appraisal (STA)

Implantable cardioverter defibrillators for the treatment of arrhythmias and cardiac resynchronisation therapy for the treatment of heart failure (review of TA95 and TA120)

Response to consultee and commentator comments on the provisional matrix of consultees and commentators (pre-referral)

Version of matrix of consultees and commentators reviewed: Provisional matrix of consultees and commentators sent for consultation					
Summary of comments, action taken, and justification of action:					
	Proposal:	*Proposal made by:*		*Action taken:* Removed/Added/Not included/Noted	*Justification:*
1.	The Cochrane Peripheral Vascular Diseases review group does not wish to be involved in this consultation on implantable cardioverter defibrillators.	Cochrane Peripheral Vascular Diseases review group		Removed	