Reviewer 1

I congratulate the NICE committee on the work they have done in formulating preliminary guidelines for biventricular pacing (cardiac resynchronisation therapy, CRT) for heart failure, and recognise the difficulties faced in formulating this guidance. However, there are some major concerns about the guidance as it stands.

The primary concern is that this guidance appears to contradict the guidance on implantable cardioverter-defibrillators (ICDs) which was issued in January 2006 (NICE technology appraisal 95). In that document, ICDs were recommended for “primary prevention” in certain groups of patients, including those with prior myocardial infarction, left ventricular ejection fraction less than 30%, QRS width greater or equal to 120 ms, and NYHA functional status grade 1-3. There is a significant overlap with the indications for CRT. It would therefore seem logical that patients who fulfil the NICE criteria for an ICD and the NICE criteria for CRT should be treated with a CRT-defibrillator. Specifically, these patients are those who:

- Have had a prior myocardial infarction
- Have a left ventricular ejection fraction of less than 30%
- Have a QRS width of ≥ 150ms (or ≥ 120 ms and echocardiographic evidence of dyssynchrony AND
- Have NYHA Class 3 heart failure symptoms

However, the current ACD on CRT does not seem to take heed of the NICE ICD guidance dated January 2006, but seems only to base its ICD recommendations on the previous NICE guidance on ICDs (technology appraisal 11, September 2000).

If this ACD on CRT is ratified, there will be an anomalous (and rather ridiculous) situation that certain patients will fulfil the NICE criteria for an ICD and the NICE criteria for a CRT-pacemaker, but not the NICE criteria for a CRT-defibrillator! Is NICE suggesting that cardiologists should implant two separate devices when it is obvious that one device will do the job?

The alternative suggestion is that individual clinicians, in consultation with their patients, decide which NICE guidance to follow, either the ICD guidance or this CRT guidance.
This would entail doctors explaining to patients that, according to published guidance from NICE, the patient could have an ICD that might reduce their risk of sudden death, or a CRT pacemaker that might improve their symptoms, but not both. Such a scenario would be unacceptable to both patients and professionals.

I also take issue with the statement that approximately 10% of CRT devices will be CRT defibrillators, and 90% will be CRT pacemakers. Even if that estimate is based on the mistaken adherence to the old (September 2000) NICE ICD guidance, it is probably an underestimate of the need for CRT defibrillators. The ratio of CRT pacemakers to CRT defibrillators in the UK is currently around 40:60, and if implanting physicians were to adhere to the NICE ICD guidance it would probably be appropriate to implant CRT defibrillators in at least 50%, and perhaps 60-70%, of patients eligible for CRT. I would certainly suggest that in most centres the proportion of CRT-eligible patients receiving CRT-defibrillators should be at least 30%, and probably more than that.

At any rate, the ratio of CRT pacemakers to defibrillators will depend on local referral patterns and experience as well as national guidance. If a centre has a well-established defibrillator implantation practice but is not a major centre for the treatment of heart failure, it is likely that that centre will initially implant a preponderance of CRT defibrillators (in its defibrillator-eligible patients who also have heart failure and fulfil the CRT criteria). If national guidance from NICE then decrees that the defibrillator:pacemaker ratio should be 10:90, then that centre runs the risk of being censured by its purchasers, who might try to restrict the budget for CRT defibrillators solely on the basis of this artificial ratio which is not evidence-based. Conversely, some centres might implant exclusively CRT pacemakers and refer patients elsewhere for CRT defibrillators when appropriate.

In summary, I am happy with much of the ACD on cardiac resynchronisation therapy, but we urge the committee to amend the document in order to ensure that this technology appraisal does not contradict technology appraisal 95 on ICDs, and to amend the likely ratio of pacemakers to defibrillators accordingly. If the document is not amended, there are likely to be major sources of confusion for cardiologists, patients and purchasers.

Reviewer 2.

i) Whether you consider that all the relevant evidence has been taken into account?

Yes although I hope that the new Scottish protocol has been seen. The treatment threshold from NICE and draft SIGN CHD differ (QRS 120 onwards = Scottish proposal whilst NICE proposes 120-149 have an echo first). Also I wish to query the incidence figures used by NICE versus those gained from practice in the draft SIGN CHD Guideline.
ii) Whether 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.

I would query what was finally meant by paragraph 4.3.12 – cost-effectiveness for CRT-D.

iii) Whether 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.

Yes within the boundaries that Scotland already has a protocol and I would wish advice to refer to this.

Reviewer 3

Unavailable to participate.

21 December 2006