Implantable cardioverter defibrillators for the treatment of arrhythmias and cardiac resynchronisation therapy for the treatment of heart failure (review of TA95 and TA 120)

Personal perspective: [redacted]

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An update and amalgamation of the two technology appraisals is somewhat timely. In particular, the lack of guidance on patients with non-ischaemic cardiomyopathies was always a glaring omission in the previous TA95, and should be addressed in this current review.

Since the 2-volume, 654-page, tome landed on my desk a week ago, it has proven a challenge to get through it all in the short time allowed. However, although it is clear that a lot of work has gone into this document, there are number of fundamental issues:

i) I find this document very repetitive and poorly written in places. The heart failure sections in particular are an example of the latter. There are also a large number of typographical errors

ii) The categorisation of the patient populations into the 3 groups is not clinically helpful and is somewhat artificial. This is a fundamental flaw. I would have preferred to categorise patients with severe LVSD (LVEF≤35%) into:
   a. Ischaemic/non-ischaemic aetiology
   b. NYHA class
   c. LBBB and Non-LBBB, with appropriate cut-offs for QRS duration
   d. Presence or absence of atrial fibrillation (particularly for CRT)

iii) The repeated use of the term "cardiac dyssynchrony", rather than "the presence of left bundle branch block". Echo assessment of dyssynchrony has largely been discredited (Hawkins NM. J Am Coll Cardiol. 2009 May 26;53(21):1944-59. Selecting patients for cardiac resynchronization therapy: the fallacy of echocardiographic dyssynchrony.). The vast majority of CRT trials recruited on the basis of QRS duration/LBBB

iv) What clinicians *want* to know is:
   a. Who should I implant an ICD in?
   b. Who should I not implant an ICD in?
   c. Should I implant CRT-P or CRT-D?
   d. Does CRT work in non-LBBB?
   e. Above what QRS duration is CRT effective?
   f. Does CRT work in atrial fibrillation?
   g. Which NYHA classes of patient should be considered for CRT?
   h. What about broad paced rhythms – should they be *upgraded* to CRT?
   i. Which is more cost effective – CRT-P or CRT-D?

v) **Heart failure.** It is clear that the author(s) are not aware of modern heart failure management, nor are they familiar with cardiac physiology. Examples include:

a. Inotropes and "short term VADs" are not relevant in this patient population.
b. Statins have been shown in 2 large RCT's not to alter outcome in patients with heart failure.
c. Aldosterone antagonists (now termed mineralocorticoid receptor antagonists – MRA's) are not "for people resistant to other drug therapy" (p33). They have replaced ARBs as 3rd line treatments (after ACE inhibitors and beta-blockers). They are indicated in NYHA II-IV heart failure.
d. ACE inhibitors "should not be initiated in haemodynamically significant valve disease". What about mitral regurgitation?? Presumably the authors refer to critical aortic stenosis. (p37)
e. Milrinone and enoximone??? (p37). Phosphodiesterase inhibitors have been shown to increase mortality in CHF!
f. Amiodarone is not part of "optimal medical therapy" for heart failure. SCD-HeFT – the largest amiodarone study in heart failure – showed no impact on mortality
g. There is no evidence for the use of aspirin in CHF
h. The UK does not use the term "*congestive* heart failure"
i. Calcium antagonists (except amlodipine) are contra-indicated in heart failure
j. "Other causes of heart failure include LVSD…" the LVSD is a consequence of the underlying aetiology
k. "Other causes of heart failure include….cardiomyopathy (either hypertrophic or restrictive)". What about dilated cardiomyopathy? Or ARVC? As far as I am aware there is no large RCT of device therapy in restrictive cardiomyopathy!
l. cardiac catheterisation is not performed "if blood samples from the heart are required" (p32)

vi) **Arrhythmias and device therapy.** The sections on arrhythmias and device therapy are similarly flawed. Examples include:

a. A lack of understanding of the terms "pacing", "cardioversion" and "defibrillation"
b. "Modern ICDs provide the functionality of standard pacemaker". I am not aware of ICDs that do not, except of course for S-ICDs. This is not highlighted here (p28)
c. "CRT-P is appropriate for patients with less serious cardiac arrhythmias" (p29) – what on earth does that mean?
d. I cannot imagine when a "CRT-P would be … upgraded to an ICD"
e. S-ICDs are not pectoral devices
f. Modern devices do not deliver resynchronisation shocks
g. ICDs do not "provide cardioversion and/or defibrillation ….for asystole"!!! (p28)

vii) Patients with congenital heart disease are not included in this document