NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Review Proposal Projects decision paper

Review of TA314; Implantable cardioverter defibrillators and cardiac resynchronisation therapy (biventricular pacing)

Final recommendation post consultation
The guidance will be transferred the 'static guidance' list.

1. Background

This guidance was issued in June 2014.

At the Guidance Executive (GE) meeting of 30 May 2017 it was agreed that we would consult on the recommendations made in the GE proposal paper. A four week consultation has been conducted with consultees and commentators and the responses are presented below.

2. Proposal put to consultees and commentators

The guidance should be transferred to the 'static guidance list'. That we consult on this proposal.

3. Rationale for selecting this proposal

Overall, the new evidence identified was supportive of the existing recommendation. Cardiac resynchronisation therapy in patients with intermediate QRS intervals between 120 to 149 milliseconds was identified in TA314 as an area of uncertainty and this subgroup was specifically considered when making the recommendations. New evidence relating to this group was in line with the evidence base considered for TA314 and supports the existing recommendations.

The companies have confirmed that no changes in marketing authorisation are anticipated and were not aware of any new evidence that would change the existing recommendations. There are some newer versions of these devices (for example with longer life batteries,

remote monitoring or wireless technology) that were not available at the time of TA314. Some of these are covered by NICE medical technologies guidance.

It is therefore proposed that TA314 is moved to the static list because no evidence has been identified that is likely to alter the conclusions of the guidance (that is, lead to a change in the clinical and cost effectiveness of implantable cardiac defibrillators and cardiac resynchronisation therapy).

4. Summary of consultee and commentator responses

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees.

Respondent: British Cardiovascular Society **Response to proposal:** Disagree The British Cardiovascular Society believes that several patient groups are not fully covered by the current recommendations in NICE Technology Appraisal number 314. These involve the potential implantation of CRT-D/P in preference to a standard single/dual chamber pacemaker in situations where chronic pacing of the right ventricle may worsen left ventricular systolic function. Explicitly, this may be summarised as: • Patients with left ventricular ejection fraction (LVEF) ≤35% who have narrow QRS complexes who require a pacemaker for an indication which will would result in right ventricular pacing all or most of the time. These patients should be considered for CRT. • Patients who have left ventricular systolic function which is impaired but LVEF is >35%, pacing is indicated and the intrinsic QRS is narrow. In these cases, CRT may be considered to prevent pacing- induced dysynchrony and worsening of LV function. • Patients who have a pacemaker in-situ in whom there has been a documented deterioration in LVEF yet this has not fallen below the threshold of 35% where CRT is indicated under current guidance *and* the patient is undergoing a generator or lead revision procedure. Upgrade of device to CRT may be considered in such patients.	**Comment from Technology Appraisals** Thank you for your comment. No changes have been made because: • The committee took a cautious approach when making recommendations for people with intermediate QRS (120 to 149 milliseconds) as there was a potentially harmful effect based on the available evidence (Cleland et al 2013). For more details see section 4.3.20 of the final appraisal decision (FAD) for TA314. • The committee heard that CRT devices are indicated in people who have an LVEF of 35% or less and have heart failure symptoms despite receiving optimal pharmacological therapy (see section 4.3.6 of the FAD for TA314). • The committee heard that device upgrades are not common in clinical practice (see section 4.3.12 of the FAD for TA314).

Respondent: Boston Scientific **Response to proposal:** Agree We support these proposals and are not aware of any current evidence that is likely to have a material effect on the guidance.	**Comment from Technology Appraisals** Thank you for your comment. No action required.

Respondent: British Society for Heart Failure **Response to proposal:** Disagree A point raised during the initial consultation period for TA314 was the evidence that had emerged where CRT was potentially HARMFUL in patients with a QRS of <130ms (ECHO-CRT, Ruschitzka F et al. N Engl J Med 2013. DOI: 10.1056/NEJMoa1306687). Subsequently, this has been contra-indicated in the 2016 European Society of Cardiology heart failure guidelines (Ponikowski et al. European Heart Journal. doi:10.1093/eurheartj/ehw128): *"CRT is contra-indicated in patients with a QRS duration < 130 msec."* NICE should therefore consider updating their otherwise sensible advice accordingly, as bad practice is being endorsed currently.	**Comment from Technology Appraisals** Thank you for your comment. No changes have been made because the committee took a cautious approach when making recommendations for people with intermediate QRS (120 to 149 milliseconds) as there was a potentially harmful effect based on the available evidence (Cleland et al 2013). For more details see section 4.3.20 of the FAD for TA314. The clinical experts also advised the committee for TA314 that in clinical practice, CRT devices are usually considered in patients with a QRS duration of more than 130 milliseconds and often more than 140 milliseconds. The committee also heard that for subgroups with intermediate QRS, most benefit occurs in people with LBBB (see section 4.3.20 of FAD for TA314). Therefore it is unlikely that a review will change the recommendations because the new evidence is similar to the evidence that was available at the time (Cleland et al 2013) and the recommendations were driven by the cost effectiveness results as well as the clinical data.

Respondent: Medtronic **Response to proposal:** Agree Medtronic acknowledge and support the recommendation from the Guidance Executive to transfer the guidance TA314 to the 'static guidance list'. We note in the proposal paper ''*CG108 Chronic heart failure in adults: management is currently being updated with an anticipated publication date in August 2018. The existing guideline makes a cross-reference to TA95 (updated and replaced by TA314). The scope for this update states that referral for implantable cardiac defibrillators would be removed from the final guidance''.* For consistency of approach, we seek a point of clarity, in that CG108 also references TA120 which has in addition been superseded by TA314. Medtronic believe that with a move to the static list, there is a greater importance to reinforce the option for referral for Implantable Defibrillators or Cardiac Resynchronization Therapy in line with the evidence presented in TA314. We therefore request this to be contained in the body of the clinical guideline, rather than the proposal to remove the referral statement and replace this with the generalised 'links with other NICE guidance' We politely ask if this could be discussed between the leads for the CG and TA programmes, with a view to a resolution as proposed above.	**Comment from Technology Appraisals** Thank you for your comment. The update for CG108 Chronic heart failure in adults: management will cross refer to TA314.

Paper signed off by: Melinda Goodall, 12th July 2017

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