COMMENTS ON

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Health Technology Appraisal: Coronary artery stents for the prevention of ischaemic heart disease (review of guidance No. 71) – Additional analyses and evidence requested by Appraisal committee

The Royal College of Physicians of Edinburgh is pleased to respond to NICE on the additional evidence and analyses requested by the Appraisal Committee in relation to this Health Technology Appraisal.

The College has the following comments on Addendum 3′:

1 The College considers that the original LRiG report was flawed and is not convinced that this addendum addresses the shortcomings of the first review.

2 The CTC model is essentially a local audit, which seems inappropriate as a basis for shaping national policy. Although the in-hospital and short-term data are probably reliable, there has been no systematic follow-up of these patients and many potentially important events may have been missed. The DoH is investing significant resources in the National Audit project (UKCCAD), which will allow linking of the BCIS, MINAP, Cardiothoracic Surgery and ONS registries, because this is the only reliable way of tracking the complete patient journey. Until this is fully operational, it would seem unwise to base national policy on local and time limited audit data.

3 There is also considerable potential for systematic bias in this sort of audit. The chosen method of revascularisation is influenced by many factors including knowledge of the published literature, and it is easy to argue that the PCI population in this audit is not representative of the overall CHD population.

4 Only one of the 12 papers quoted in the data sources for this addendum is based on a randomised trial; the other 11 are all registries and are therefore of doubtful quality. National policy should be based on robust analysis of high quality randomised controlled trials. The evidence put forward by the LRiG does not fall into this category, and there is therefore no strong evidence to change the current NICE guidance for using a DES.

5 The College believes there is wide agreement that PCI in general, and the comparison of DES vs BMS in particular, does not alter life expectancy but mainly leads to symptomatic relief. Therefore, discussion of the trend towards an increase in non-fatal AMIs in the BMS patients is of limited value. There is no reason why DES should

result in such reductions and, as mentioned, the hypothetical cost implications are minimal.

6 The College is not convinced that diabetes is not an independent predictor of restenosis. It may not have reached significance in the risk models studied, but there is a large body of randomised and observational data which has consistently shown that diabetes is a risk factor for restenosis.

All College responses are published on the College website www.rcpe.ac.uk.

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