Health Technology Appraisal: Coronary artery stents for the prevention of ischaemic heart disease (review of guidance No 71) Assessment Report	
To: NICE	**FROM: NHS QIS**

Comments on NICE Technology Appraisal (TAR 04/42); Drug-eluting stents: a systematic review and economic evaluation – prepared by NHS QIS nominated expert.

In summary, the above appraisal, prepared by the Liverpool Reviews and Implementation Group concludes that DES are only cost–effective in a very small minority of patient undergoing PCI as part of the management of CHD (<4%). I have no expertise in health economics and cannot comment specifically on the LRiG's conclusions in this regard. I do however have extensive experience of treating patients with DES both within the context of clinical trials and in routine practice. I am also an elected council member of the British Cardiovascular Intervention Society and would add my support to the comments contained in their submission to NICE. I would however hope that the following points contribute usefully to the discussion about this TAR.

1. The clinical and resource data informing the "independent" cost–effectiveness analysis in this NICE TAR are derived from an analysis of audit data from a single PCI centre in Liverpool, the CTC.

2. **Relevance and quality of dataset from CTC:** The quality of this dataset is unknown but is likely to be significantly inferior to the data quality of the numerous published randomised controlled trials comparing DES against BMS. It is not known if the patient and lesion specific characteristics of this population are typical of the rest of the UK. Indeed, the PCI centre in question is atypical in that it is not associated with either an A&E department or an acute receiving medical unit. This will potentially modify the case-mix towards fewer acute cases with a potentially lower risk of repeat revascularisation.

3. **Predictors of repeat revascularisation at CTC (8.2.3):** The risk factors identified as being predictive of repeat revascularisation within 12 months are atypical, inconsistent with almost all previously published data and do not include either of the predictors identified by the LRiG themselves in their first report on DES. There is also no biological reason why a particular lesion-specific criteria should be predictive in an elective patient group but not so in a non-elective group.

4. **Frequency of repeat revascularisation at CTC(8.2.3):** I have received a personal communication from a senior consultant at CTC indicating that time delays in repeat angiography and/or PCI at CTC are such that a proportion of patients with a clinical indication for repeat

PCI have not undergone their procedure within 12 months of the date of their index PCI. As such the repeat revascularisation rates at 12 months used in the LRiG analysis may underestimate the true incidence. The Scottish Coronary Revascularisation Register Report for 2003-04 reports a repeat revascularisation rate at 12 months of 12.9% (95%CI 12.1-13.7; n=6525 vs 7.79% in Liverpool) for patients undergoing elective PCI and 16.6% (15.7-17.6; n=5921 vs 10.15% in Liverpool) for patients undergoing PCI for unstable coronary syndromes. DES use as a proportion of total stents in the year 03-04 was 9.6% in elective PCI and 4.2% in urgent PCI. This absolute 5% increment in the risk of repeat revascularisation in the Scottish population compared to Liverpool, despite some existing use of DES would substantially increase the cost-effectiveness of DES.

5. **Price premiums for DES (8.4.1):** the price premium quoted in the report greater than in our own unit: £537 (VAT excluded) for Taxus at CTC vs £255 (VAT excluded) in North Glasgow. This is a critical component of the C/E analysis and any reduction in the price premium used in the calculations will improve the ICER.

6. **Wastage rate of DES (8.4.1):** this is quoted at 5% and is effectively an additional price premium. Even with first generation DES our own experience was that wastage rates were never more than 1-2%. With 2nd generation DES e.g. Taxus Liberte wastage rates are now less than 1 %.

7. **DES use per lesion:** obviously a stent:lesion ratio of 1 would maximise the contribution of this parameter to an improved ICER. One of the reasons why this has not been achievable so far is the limited range of DES sizes available from either of the main manufacturers. For example the maximum available length of 2.25mm and 2.5mm diameter Taxus Liberte stents is 24mm. A lesion of length 30mm in a vessel of 2.5mm diameter therefore requires 2 DES. As longer stents become available the stent:lesion ration will decline improving ICER. NB – stents of different size are of equal cost.

8. **Duration of clopidogrel therapy (8.4.3) :** The LRiG report that it is now common to prescribe clopidogrel for 12 months following DES but this is not the case in the West of Scotland where there is an agreed policy of discontinuing clopidogrel at 6 months. Clearly this will reduce costs and further improve the ICER against a policy of 12 months therapy.

9. **Health related quality of life (8.4.4):** The LRiG report that there is no difference between PCI and CABG in quality of life from 6 weeks post procedure until 12 months. This is not consistent with my own experience over 20 years of practice. However, setting anecdote aside, it is patently disingenuous to ignore the first 6 weeks after each procedure during which time there is an obvious and major difference in favour of PCI.

10. **Multi-vessel disease:** almost all of the RCT data and most of the CTC data quoted in the report describe the outcomes of DES used for single vessel PCI. By definition the risk of repeat revascularisation in patients with single vessel PCI is lower than the cumulative risk of repeat revascularisation in patients undergoing 2 or 3 vessel PCI +/- treatment of left main stenosis. It is in this latter group that the benefits of DES will be greatest and yet there is no mention of the outcomes of the recently published ARTSII study in which over 600 patients with 2 or 3 vessel disease were treated with multiple DES with a 12 month event free survival rate higher than the CABG arm of ARTSI. A C/E analysis of this study is pending.

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