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Reetan Patel
Technology Appraisal Project Manager
The National Institute for Health and Clinical Excellence
MidCity Place
71 High Holborn
London
WC1V 6NA

Dear Reetan

Response to Assessment Report Addenda 3'' and 4': Coronary Artery Stents for the Treatment of Ischaemic Heart Disease (Update to Guidance No. 71).

Thank you for the opportunity to comment on these two further Addenda to the Assessment Report. Although some concerns raised in the original Assessment Report have been resolved there are several key issues raised by the Appraisal Committee after the February 2006 meeting which are still not addressed by the Assessment Group and one additional point raised by the new latest economic analysis:

1. **Risk Factors for Repeat Revascularisation**
   The Appraisal Committee's reque[redacted]include long [redacted]s, small vessels and diabetes in the economic model h[redacted]However, the Assessment Group is still using the relative risks risks for these groups from the CTC audit dataset, which the Appraisal Committee has already concluded is not representative of repeat revascularisation rates (and by implication to the relative risks that are derived from that dataset).
2. **Absolute Risk of Repeat Revascularisation with Bare Metal Stents**
   The Assessment Group continue to use the absolute risks from the CTC registry despite the Appraisal Committee's request to use the absolute risk of repeat revascularisation from the Scottish registry as the base-case scenario.
   The 12-month repeat revascularisation rate from the Scottish registry is approximately 13%, thus this number should form the base-case in the economic model so that it reflects realistic repeat revascularisation rates.
3. **Risk Reduction Associated with Drug-eluting Stents**
   The cost-effectiveness results presented in Addenda 3'' and 4' are still biased against drug-eluting stents because the Assessment Group continue to use a 41% relative risk reduction due to DES from the BASKET trial 6-month results (Addendum 3', page 38). This underestimates the DES treatment effect at 12 months and consequently biases against the cost-effectiveness of DES.

   We are aware that the Appraisal Committee is concerned that protocol-mandated angiographic follow up in the randomised trials may cause the treatment effect of DES to be overstated. However, we would point out three important pieces of information that do not feature in the Assessment Report or Addenda:
   - In the small vessel sub-group of BASKET, the risk reduction associated with DES at 12 months was approximately **61%** (Kaiser et al 2006).
   - In the real-world RESEARCH registry, the risk reduction associated with sirolimus-eluting stents at 12 months was **67%** (Lemos et al 2004).

- In the TAXUS IV cohort of patients who did not receive angiographic follow up, the risk reduction associated with the use of paclitaxel-eluting stents at 12 months was **65%** (Pinto et al 2006).

4. **Impact of Additional Clopidogrel**

Addendum 4' applies the incremental cost of 9-months additional Clopidogrel to all DES patients. However patients presenting with acute coronary syndromes (ACS) already receive at least 12 months of Clopidogrel, even if they are treated with a bare metal stent. This cost should only be applied to the proportion not already receiving 12-months Clopidogrel therapy (approximately 56%, according to current BCIS audit data).

5. **Summary**

We propose that the economic model be re-run using:

- Relative risks for the independent risk factors of small vessel, long lesions and diabetes representative of the trials and wider clinical databases.
- A base-case repeat revascularisation rate of 13% from the Scottish registry.
- 12-month DES risk reductions derived from the trials and wider clinical databases, particularly the risk reductions pertaining to higher-risk sub-groups.
- Applying and additional 9-months Clopidogrel costs to only 56% of patients.

Yours sincerely

[redacted]

DR CHRISTA ROBERTS
General Manager
Abbott Vascular UK
[redacted]

References

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BCIS audit data. www.bcis.org.uk