Shaun Minehan
Project Manager
NICE
Mid-City Place
71 High Holborn
London WC1V 6NA

1 October 2007

Dear Shaun,

Boston Scientific comments on LRiG economic model for review of TA71

Please find comments from Boston Scientific on the LRiG model. Boston Scientific also is a party to the response from the BCIA which is attached to this letter and will also have been sent separately to NICE.

If you have any questions regarding this letter please contact me at:

[redacted]

or on [redacted]

Yours sincerely,

[redacted]
Boston Scientific UK and Ireland

Introductory Comments

Whilst we welcome the opportunity to analyse the Assessment Group's model our view remains, as stated in our previous submissions, that many of the key inputs to the model are not substantiated by the body of clinical evidence on DES. As such, the design quality or otherwise of this model is entirely secondary to the input data which has led to the potentially perverse draft guidance.

Application of relative risk

The LRiG model applies the same risk reduction across the total population and the sub-groups (small vessels, diabetes, and long lesions). This is an unrealistic approach as there is overwhelming evidence from RCTs and registries that that DES are particularly effective in certain high-risk subgroups sub-groups.

We would urge the Committee to draw from a meta-analysis of RCTs a distinct risk reduction for each high-risk subgroup.

Diabetes as a risk factor

In the LRiG model the overall risk factor for Diabetics is 1.19 – a very low number resulting from the combination of elective and non-elective groups. In the non-elective group, Diabetics are shown as having a lower risk factor (0.9) than the general population. This is at odds with the bulk of published evidence which shows diabetes as a significant risk factor. We recommend that the model use a meta-analysis of available RCTs to derive the appropriate figure.

Service Costs

The cost inputs used for the model are NHS reference costs 2003/4. These should be updated with the latest published NHS reference costs (2005/6) as there have been substantial changes in this period making the original inputs outdated.

Device Costs

The current prices of DES and BMS in the NHS should be gathered to properly identify the true delta between these products. The NHS PaSA survey of prices will be 4 years out of date by the time this guidance is issued and is unlikely to reflect current prices.

Average number of stents

There is an attempt to show a differentiated average number of stents across all of the sub-groups and between elective and non-elective cases. The problem with this approach is that some of the sub-groups represent only 0.1% of the CTC database. As such this cannot be meaningful and we believe that the analysis should be re-run using the overall mean number of stents for all subgroups.

Conclusion

The specific issues shown above relate directly to the opportunity to analyse the Liverpool model at close quarters. We refer you to our consultation response to the ACD to reiterate that LRiGs reliance on single centre non-randomised data and the selective use of literature evidence such as BASKET mean that the inputs to this model regarding absolute risk and relative risk reduction do not reflect the breadth of evidence on DES and as such the results from the model will be perverse.

We would therefore recommend to the Committee to refer this Appraisal to the Decision Support Unit.