Abbott HE Model ResponseFrom: [redacted] (c) ([redacted])
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Sent: 01 October 2007 14:51
To: Natalie Bemrose
Cc: [redacted] ([redacted]); [redacted] ([redacted])
Subject: Abbott HE Model Response

Follow Up Flag: Follow up
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Attachments: Abbott NICE Economic Model Response.doc; BCIA Comments on Economic Model v2 (4).doc

Natalie

Please can you confirm receipt of this email as acceptance that you have received the Abbott Health Economic Model response on Review of Guidance No. 71. In addition we have attached a copy of the British Cardiac Industry Association response as confirmation of our acceptance of this joint industry document and endorsement of it's content.

<<Abbott NICE Economic Model Response.doc>> <<BCIA Comments on Economic Model v2 (4).doc>>

Best Regards

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1st October 2007

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Dear Natalie

Abbott response to: Ischemic heart disease – coronary artery stents: Consultation on Economic Model. Review of Guidance No. 71

Thank you for the opportunity to comment on the Economic Model.

Abbott acknowledges and supports all the statements and objections made in the British Cardiac Industry Association (BCIA) submission.

1. Model Structure

The model is decision tree based, using probabilities of events (i.e. revascularisation) to determine the overall expected outcomes. In this analysis Drug Eluting Stents, DES, were compared against Bare Metal Stents, BMS, over a 1 year time horizon.

Since the spreadsheet is non-executable, this restricts our ability to explore the formulae and cell-linkage in the model to asses for calculation errors. We are also unable to comment on the consistency of the model with the Technology Appraisal Report, TAR.

Abbott would consider the limitations of the model are:

1.1 Time Horizon

There is a restricted time horizon and Abbott believes this should be modelled to 2 years in order to fully assess the cost effectiveness of DES versus BMS. This is particularly important given that repeat revascularisations accrue beyond year 1 and the AMI utility gain will also persist into each subsequent year.

1.2 Budget Impact

By only considering DES compared against BMS the assessment does not take into account the budget impact from those patients who physicians would refer to surgery because the clinical outcome from stenting with BMS would be unsatisfactory.

2. Clinical Data Inputs

2.1 Acute Coronary Syndromes

In the assessment model the data input for Acute Coronary Syndromes, ACS, and therefore those patients who would receive dual anti-platelet therapy for 12 months regardless of stent type was 44%. Recently presented data (Ludman 2007) on the BCIS audit returns for year ending 2006 shows this has risen to 48.5%, we request that the most up to date figures should be employed in the model.

2.2 Absolute and Relative Risk Reduction

The main driver of effectiveness is the absolute and percentage risk reduction in the need for revascularisation procedures. Abbott considers this is a suitable measure of effectiveness provided the inputs are based on clearly referenced multi-centre audited data.

2.2.1 Absolute Risk

For Absolute Risk the model uses 10% for elective patients and 13% for non-elective, but it is unclear how these figures have been derived.

Abbott recommends using the data below from a multi-centre audited database, rather than a single centre source:

BMS Absolute Revascularisation Risk of 13% is taken from the Scottish registry prior to DES (year 2000-2001, Pell & Slack 2004). In addition if the data takes into consideration the relative number of patients with ACS, 48.5% for 2006, the Absolute Revascularisation Risk for the unselected population is 14.7%.

2.2.2 Relative Risk

For Relative Risk the model presents 2 scenarios 55% and 65%, Abbott believes that 65% is more representative of the Randomised Controlled Trial, RCT, data. It is of note that in the assessment model diabetics have an unusually low relative risk based on the CTC database. This is because non-elective diabetic patients are portrayed to have a relative risk of 0.9, which is combined with 1.38 for elective patients. It would be perverse for a known risk factor, repeatedly identified in Randomised Clinical Trials to have a Relative Risk of less than 1 in non-elective patients.

Abbott recommends using the data below previously submitted by clinical experts from BCIS and derived from RCT rather single centre data:

Relative Risk for the following independent risk factors: Small Vessels 1.75, Long Lesions 1.35, Diabetes 1.52. This would lead to a Risk Reduction gain from DES of: 69% Small Vessels, 70% Long Lesions, 61% Diabetes.

2.3 Number of Stents

There appears to be a discrepancy in the Assessment Model on the number of stents per procedure used in the combined Table A of Addendum 6 and that displayed in the separate elective and non-elective datasets of Addendum 5. Abbott seeks clarification of the correct value.

2.4 Re-treatment for Revascularisation

In the model the following data is used for re-treatment, however it is unclear what the source is for this data.

	Elective	Non-Elective
Proportion as unstented PCI	36.60%	27.40%
Proportion as stented PCI	54.50%	54.70%
Proportion as CABG	9.00%	17.90%

Abbott has concerns over the high percentage of unstented PCI employed in the model, which is double the rate we would expect. In the meta-analysis of SPIRIT II and III, only 14% of Target Lesion Revascularisations were retreated with balloon angioplasty alone.

Abbott is also concerned that there is no transparency on whether the stent, and therefore the costs associated, for the stented PCI is in fact DES or BMS. We seek clarification on what percentage of the stented PCI patients received DES and what percentage BMS.

3. Cost Data Inputs

The cost of DES is offset against the cost savings associated with fewer revascularisation procedures (e.g. reduced number of PCI, CABG, outpatient visits, etc.) It is therefore critical for the Appraisal Committee to ensure the assessment model is run with accurate up to date cost data.

3.1 Reference Costs

The model uses reference costs from 2003-04, which have now been superseded by the 2005-06 data. Abbott would recommend these new costs are used as the default in the model.

Item	2003-04 Reference Cost	2005-06 Reference Cost
Cardiology 1st out-patient attendance	£134	£148
Cardiac surgery 1st out-patient attendance	£208	£274
Cardiology out-patient follow up	£94	£104
Cardiac surgery out-patient follow up	£156	£182
Angiography	£724	£838
PCI (elective)	£2609	£3093
Unstented PCI	£1453	£1937
CABG (elective)	£7066	£8172

3.2 Price Delta DES and BMS

In addition Abbott assesses the relative premium of a DES over a BMS in 2007 to be £300, not the £600 considered in the model. Abbott would recommend that in view of the length of time this assessment has taken that a new independent price survey is conducted.

3.3 QALY Loss Awaiting Repeat Revascularisation

For QALY loss awaiting repeat revascularisation the assessment model employs NHS wait time statistics for Quarter 4 2004-05, PCI 16 weeks and CABG 9 weeks with 4 week wait prior to joining the list. Again due to the length of time this appraisal has taken these are out of date. Abbott would recommend the methodology from the attached BCIA report based on the Hawkins formulae. This consists of 3 elements: 6 week wait to first out-patient attendance (waiting time statistics Q4 2006) 11.1 week wait for

angiography (HES 2005-06) 8 week wait PCI and 9.3 week wait CABG (HES 2005-06)

4. Cost Effectiveness

4.1 Weighted Distribution of Risk Factors

The authors appear to have calculated the 'weighted' distribution of patients with each permutation of the risk factors based on the assumption that the respective likelihoods of experiencing each of the risk factors are independent of one another. In reality, it is possible that the existence of one risk factor is also lined with the probability of experiencing one or more others.

This would imply that the probability of a patient experiencing all three (i.e. the highest risk) group are underrepresented in the analysis. As such, the weighted results are likely to underestimate the true cost-effectiveness of DES.

Summary

Abbott believes it would be unsound to issue guidance based on the current assessment model without making the following changes:

The model should be based on a 2 year time horizon.

The data inputs should be changed to reflect that 48.5% of UK patients are non-elective.

The Absolute Risk of revascularisation should be input at 14.7%, based on the Scottish Registry and adjustment for the 2006, 48.5%, ACS rate.

The Relative Risk should take into account the following independent risk factors: Small Vessels 1.75, Long Lesions 1.35, Diabetes 1.52. This would lead to a Risk Reduction gain from DES of: 69% Small Vessels, 70% Long Lesions, 61% Diabetes.

The number of stents used in the combined data sets for Addendum 5 and 6 are clarified and applied consistently in the model.

The Re-treatment of Revascularisations should be adjusted to reflect a 14% re-treatment with balloon only PCI and clarification of what percentage of stented PCI includes DES.

The procedural costs should be taken from the NHS reference costs 2005-06.

A new independent survey should be conducted to determine the price delta between DES and BMS to ensure that costs are representative of 2007.

The QALY Loss Awaiting Repeat Revascularisation is rerun using the Hawkins formulae consisting of the following three elements: 6 week wait to first out-patient attendance (waiting time statistics Q4 2006) 11.1 week wait for angiography (HES 2005-06) 8 week wait PCI and 9.3 week wait CABG (HES 2005-06).

Correct the 'weighted' distribution of patients with multiple risk factors.

The Appraisal Committee should consider the budget, logistical and social impact of restricting DES usage, which would increase the rate of Coronary Artery Bypass Surgery, and remove patient choice for a less invasive procedure.

Yours Sincerely

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