29th August 2007

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Dear Reetan

Abbott response to: Ischemic heart disease – coronary artery stents: appraisal consultation document. Review of Guidance No. 71

Thank you for the opportunity to comment on the Appraisal Consultation Document, (ACD).

Abbott acknowledges and supports all the statements and objections made in the British Cardiac Industry Association (BCIA) submission. In addition we would like to express our concern for patients with cardiovascular disease for whom access to treatment might be adversely affected by a final appraisal decision based upon insufficient independent clinically robust data and contemporary pricing practice. Our concerns are as follows:

Has all the evidence been taken into account? Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence and are the preliminary views on the resource impact and implications for the NHS appropriate?

1. Clinical data referenced to Randomised Controlled Trials

   We support the comprehensively referenced data that British Cardiac Interventional Society (BCIS) have previously submitted to define the endpoints, including:

   - Bare Metal Stent (BMS) Absolute Revascularisation Risk of 13% 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 acute and non acute coronary syndromes to define the absolute risk of revascularization for the unselected population it is 14.5%.

   - 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.

- Using a price delta of £300 between DES and BMS, which reflects current UK market prices.

We would advise that the Appraisal Committee insists that data derived from Randomised Controlled Trials (RCT) is used in the modelling as this follows the Institute's own Guide to the Methods of Technology Appraisal (section 3.2.2.1), which states ".....RCTs are therefore ranked first in the hierarchy of evidence for measures of relative treatment effect." If the Appraisal Committee deviates from this we would like to understand why.

2. Deviation from modelling data used in 2003 guidance

We question why the current appraisal deviates from the clinical data that formed the basis for the October 2003 guidance in terms of Absolute Risk of 12.7% & Risk Reduction of 79% and which is supported by a growing body of Randomised Controlled Trial data. By making unreferenced or unsupported changes the appraisal would be suggesting that the model used in the previous guidance was not robust. The use of RCT data combined with the reality of a lowering price delta between Drug Eluting and Bare Metal Stents would have a significant impact, and shows DES to be more cost-effective than 4 years ago when the original guidance was issued. We would appreciate the references for the trials used to define the risks in the current appraisal and to understand why these have been selected in preference to the data in the 2003 model as well as a read only copy of the economic model.

3. Use of contemporary data

Due to the length of time this appraisal has taken, (the original submission was made in 2006) reliable trial data and pricing information from the last 2 years are not included.

The SPIRIT III trial compares the Xience V Everolimus eluting stent to the Taxus stent and is the first RCT, which shows clinical superiority of one DES over another on the clinical end point of MACE (major adverse clinical event). The Xience V stent is on the VISION chromium cobalt BMS platform, which is sited by LRiG for having low restenosis rates in the Basket trial. It should therefore be important to look at the risk reduction and cost effectiveness of second generation DES, which due to the timing this appraisal has been unable to do.

Are the provisional recommendations of the Appraisal Committee sound and constitute a suitable basis for the preparation of guidance to the NHS?

4. Comprehensive Clinical and Budget Impact and Patient Choice

Abbott is of opinion that the present appraisal has not considered the true impact of withdrawing DES as a treatment option in the UK. There has been an assumption that the use of BMS and DES are interchangeable, when this is clearly not the case. A significant number of patients will not get the best clinical outcome from a BMS procedure and would receive more invasive and expensive Coronary Artery Bypass Graft (CABG) surgery in the absence of DES. The true budget, logistical and social impact of this transfer of treatment was not considered, neither the patients loss of choice to receive a more conservative treatment.

The BCIS audit data has reported procedure numbers for England and Wales as 58,576 for 2005, we have seen 11% growth during 2006 and 9% growth in 2007 leading to over 70,000 procedures being carried out in 2007. The last reported CABG figures were 22,724 procedures, so a switch of patients from PCI to Surgery with longer procedure times and the increased patient stay, would impact on surgical capacity and bed availability. This would be expected to lead to unacceptable waiting periods for patients, probably exceeding the Government recommendation of less than 18 weeks. The NHS does not have the capacity to provide sufficient alternative treatment to PCI with significantly curtailed DES usage.

5. Code of Practice for Declaring and Dealing with Conflicts of Interest

In the Code of Practice for Declaring and Dealing with Conflicts of Interest published by NICE in April 2007, section 3.5 states if:

A personal non-pecuniary interest in a topic under consideration might include, but is not limited to:

i) a clear opinion, reached as the conclusion of a research project, about the clinical and/or cost effectiveness of an intervention under review
ii) a public statement in which an individual covered by this Code has expressed a clear opinion about the matter under consideration, which could reasonably be interpreted as prejudicial to an objective interpretation of the evidence

As such we consider that the prior publication by Professor Bagust and Professor Walley in the Jan 2006 issue of The Heart on cost effectiveness of coronary artery stenting in a UK setting, contravenes this code.

Summary

The body of clinical evidence supporting the safety and effectiveness of drug-eluting stents for treating patients with diseased coronary arteries and chest pain is vast and growing. Drug-eluting stents were designed to reduce vessel renarrowing and to treat chest pain, which they have proven to do. Limiting reimbursement for drug-eluting stenting would reduce patient access to an important treatment option and increase the number of re-interventions or major open heart surgery that patients would undergo.

Abbott will not support a NICE drug-eluting stent reimbursement recommendation based on non-randomised data from only one treatment center in the UK. Abbott would support a determination based on the most recent randomised clinical trial data available, taking into account the outcomes of patients treated with drug eluting stents across a broad sampling of physicians and treatment centers.

We therefore call for the appraisal to be restarted with an independent economic modelling group employing the most up to date clinical and pricing data. We would be concerned by a referral to the Decision Support Unit as this will be starting from the premise of reviewing the existing LRiG model which we believe is inherently biased.

Yours Sincerely

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