BCIS President

Personal Statement for NICE review of Drug eluting stents.

The UK has made enormous progress in the treatment of coronary artery disease (CAD) over the last 10 years. It is now portrayed throughout Europe as an example of how "appropriate" investment can restore a healthcare system that was failing its patients.

I believe the credit for this extra-ordinary change in the perception of UK Cardiology throughout the world can be equally divided between clinicians and managers (government).

The UK is widely recognised as having one of the most "evidence based" healthcare systems in the western world. Systems within the UK ensure interventional cardiologists in the UK maintain their continued professional development and follow evidence-based medicine. The "NICE" process has reinforced this. The original stent guidance, the Drug eluting stent (DES) guidance and the IIb/IIIa guidance have all reported positively (based on the randomised literature) and allowed the UK to practice evidence-based medicine, often in advance of the rest of Europe.

"Delivering" the National Service Framework (NSF) for coronary artery disease required a huge increase in revascularisation in a relatively short time frame. It was assumed that this would be in the form of a 1:1 ratio between percutaneous coronary intervention (PCI) and coronary artery bypass grafting (CABG), with 750 per million being performed for both, resulting in a revacularisation rate of 1500 per million.

Over the last 10 years creditable scientific international randomised trials, peer reviewed, and published in reputable journals have persuaded clinicians that a greater proportion of patients can be treated reliably and robustly by PCI.

Recently the "ARTS 2" trial (multi-vessel DES versus an historical surgical control group) has persuaded clinicians that PCI with DES is now close to equivalent to CABG in a patient with multivessel CAD. This "evidence based" approach to revascularisation has led to the "delivery" of the NSF targets, not by CABG but by a rapid expansion of PCI. The latest data available suggests the ratio of PCI:CABG is now 2.5:1.

This change of policy in the mode of treatment of coronary artery disease (based on well performed randomised trials) has dramatically changed the waiting times for revascularisation procedures. Only 5 years ago the UK was the laughing stock of Europe as many patients had to wait over a year for their revascularisation therapy. Now, all patients are treated within 3 months, and by 2008 all patients will have to receive a diagnosis and treatment within 18 weeks of referral from their GP. The recent shift in revascularisation strategy there is a reasonable chance this could be delivered for CAD.

Managers and the government have acknowledged the above changes. There has been a major capital investment in cardiac catheter labs within this country and this has been widely perceived as "appropriate" within the cardiac community. At the same

time there has been a slowing and, in some cases, reconsideration or reversal of decisions for capital investment in cardiothoracic surgical centres. In addition, cardiothoracic surgical training numbers have been frozen and indeed the deaneries have been advising a career change in those surgeons at an early stage of their cardiothoracic training.

It is important to recognise that this is the strategic framework under which current revascularisation is being performed in the UK and the current NICE review being held. It is also important to appreciate that these changes are mirrored in healthcare systems throughout the world.

In my opinion ratification of the original NICE guidelines (which continue to be supported by the randomised literature), with the addition of diabetes as an indication for a DES, will allow the extra-ordinary progress in the treatment of CAD within the NHS to continue. I believe we will be able to deliver acceptable European levels of revascularisation without major capital investment and achieving the 18 week wait in 2008. This is simply because interventionalists will perform evidence based medicine.

There is an alternative scenario! If for some reason the current NICE review concludes that DES are indicated in only a small (<5%) number of patients and the majority should receive bare metal stents then interventionalists will, once more, return to evidence based practice. We believe the ARTS 1 trial (BMS versus CABG in multivessel CAD) shows an advantage to surgery in these patients, wholly related to repeat interventions required in the BMS stent arm, (this advantage of surgery is negated in ARTS 2 by the reduced restenosis rate of the DES arm). In addition interventionalists would return to the randomised data and conclude that, in general, patients with long lesions, small vessels (previously criteria for DES under NICE guidance) and diabetes would be better served with CABG if they could not receive a DES.

In my own practice it would have an extra-ordinary effect. In my experience 50%+ of PCI patients have one or more of these risk factors. My centre currently performs 1500 PCIs per year and 700 CABGs. Under any “new” arrangement I would refer hundreds of patients back to CABG. The consequence of this approach as a whole would be devastating clinically and politically. Importantly, I do not believe it would be clinically appropriate. There is currently no infrastructure to reverse the “slow down” of CABG. Waiting lists for revasularisation procedures would quickly breach the 3 month wait and there would be no prospect of reaching the 18 week target in 2008 as there would not be enough surgical trainees to deliver the surgery.

I should stress the reasons for the above would be that the UK ***DOES*** follow evidence based practices and any guideline which restricts the use of DES would force us to review the data on restonosis with BMS and its relationship to CABG.

Over the last 10 years I have felt increasingly proud to be able to talk about the delivery of cardiac services in the UK within the NHS to my European colleagues. This is because we have been allowed to practice evidence based medicine and the NICE process has been pivotal to this. I am confident that the current review of the use of DES will continue to allow me to do this.