DePuy Synthes
JOINT RECONSTRUCTION
COMPANIES OF Johnson & Johnson

DePuy Synthes response to the NICE appraisal consultation document on total hip replacement for end-stage arthritis of the hip (review of technology appraisal guidance 2 and 44)

DePuy Synthes requests consideration of four main issues:

1. The role of ODEP in the assessment of projected revision rate is important and should be referenced in section 1.1 of the guidance.
2. There are significant unintended consequences when section 1.2 of the guidance explicitly recommends acquisition cost as the main driver of prosthesis selection provided the benchmark revision rate has been achieved.
3. We request that the British Orthopaedic Association and/or British Hip Society are represented at the second TAC meeting on 20th November 2013.
4. Clarification that a hip prosthesis is not a commodity.

1. The role of ODEP in the assessment of projected revision rate

DePuy Synthes is supportive of the Technology Appraisal Committee's (TAC) preliminary recommendation to support the use of total hip replacement (THR) and resurfacing arthroplasty (RS) as treatment options for people with end-stage arthritis of the hip only if the prosthesis has a rate (or projected rate) of revision of less than 5% at 10 years. We are encouraged by the reference to a projected rate to allow for innovation, but unclear on how the Orthopaedic Data Evaluation Panel (ODEP) should complement and indeed be referred to within this recommendation. Section 4.3 of the ACD acknowledges the role of ODEP in advising the NHS which prostheses achieve the recommended revision rate set by NICE but we request that NICE provide guidance on how projected revision rates should be assessed and rated. In addition, our submission requested that NICE formally endorse ODEPs role to strengthen the current rating system and help signpost the NHS to purchase the most clinically effective devices and we are disappointed to see this link is missing from the ACD.

We suggest a change to recommendation 1.1 as follows:

1.1 Total hip replacement and resurfacing arthroplasty prostheses are recommended as treatment options for people with end-stage arthritis of the hip only if the prosthesis has a rate or projected rate of revision of less than 5% at 10 years. Benchmark data for new prostheses should continue to be monitored by the Orthopaedic Data Evaluation Panel.

2. The unintended consequences of recommending the selection of prosthesis on acquisition cost rather than outcome

DePuy Synthes is surprised by section 1.2 which seeks to restrict the selection of prosthesis type to the lowest acquisition cost. The cost of the surgical procedure encompasses many elements and use of the cheapest prosthesis will not necessarily result in the lowest total procedure cost to the NHS or provide the best value for money. Different operating times across the classes of prostheses and

differences in consumables needed during surgery will influence procedure costs and are not reflected in the acquisition cost of the prosthesis. A recent review of the cost of hip replacement surgery by Kallala et al. (2013) concluded that the cost of components was a small fraction of the total cost of hip replacement surgery with the major drivers of cost attributed to inpatient care and length of stay. The Committee have also recognised that the '*single most important key driver of costs and QALYs in the model'* is the revision rate (4.3.13). However, the Committee should also note that the modelling of average class revision rates by the assessment group should not be interpreted to mean there are no significant variations in revision rates between products within the class.

The preliminary recommendation to drive prosthesis choice by acquisition cost (once the revision rate criteria has been met) needs to be set within the context of a clinical decision. In our submission we included commentary on how a prosthesis is selected by the surgeon to match a proven technology to the patient's individual requirements to increase the likelihood of the best possible outcome for that patient. Surgeons make choices on which prosthesis to use based on several factors including their previous training, the class of prosthesis to be used, the quality of clinical evidence for a prosthesis and the characteristics of the patient such as age, activity levels and body mass index. They also make choices on prosthesis based on personal experience of patient outcomes observed with specific implants in their own practices (outcomes which can vary widely between surgeons). This is particularly important to surgeons in the UK given the recent requirements to publish their individual outcomes data. A surgeon should therefore not be advised to use the cheapest prosthesis if they have not achieved good clinical outcomes on previous use, or if they have not had sufficient training in its use. For THR and RS the decision is therefore more complex than one simply of lowest prosthesis acquisition cost in the short term. For hip replacement surgery it is usual practice for clinical assessment to be an important element of decision making on which type of prosthesis is most appropriate and will generate the best outcome for the patient.

It important to note that the extensive modelling carried out by the assessment group showed that revision rate and cost of revision is a far greater driver of cost effectiveness than acquisition cost of the prosthesis. It is therefore hard to reconcile the Committee's exclusive focus on acquisition cost, excluding many other important patient characteristics and surgeon training. Whilst the acquisition cost of the prosthesis of course plays a part in the decision, it should not be the sole consideration. Instead, the prosthesis which offers the most cost effective long-term solution, taking into account surgeon training and experience, would be a more appropriate recommendation for section 1.2 of the guidance.

We suggest a change to recommendation 1.2 as follows:

1.2 The decision to choose a specific prosthesis should be guided by benchmark revision rate (meeting the above criteria), maximise long term clinical outcomes, and take into account individual patient characteristics, surgeon training and experience, and low acquisition costs.

3. **In light of the lack of surgeon stakeholder representation at the September meeting, we request the British Orthopaedic Association and British Hip Society are invited by NICE to attend the November Technology Appraisal Committee meeting**

We believe these considerations would have been better articulated to the Committee had expert hip surgeons from the British Orthopaedic Association and the British Hip Society been present at the TAC meeting in September. The lack of independent clinical advice at this meeting from practicing orthopaedic surgeons who are trained and experienced in the various types of THR and RS risks leaving the Committee with a recommendation which does not take into account all the relevant clinical considerations and context. It is considered that broad and balanced surgical expertise was not afforded by the nurse specialist or the assessment group clinical lead at the meeting. We would therefore like to suggest that representatives from the British Orthopaedic Association and British Hip Society are present when the Committee is discussing comments on the ACD received at public consultation. We feel that it is essential for the opinion of surgeons with expertise in RS, cemented and uncemented THR to be heard by the Committee so that it is fully informed of the clinical context in which its recommendations are to be adopted.

4. **Clarification that a hip prosthesis is not a commodity**

DePuy Synthes does not supply technologies without also providing professional training and theatre support.

Regarding surgeon training, we consider it important to note in our response to this public consultation that professional education on the use of a prosthesis or technique is often provided by the manufacturers of those products. The quality of this training varies by manufacturer, as does the level of support provided prior to use, within the operating theatre at first use and follow-up. There is a risk that by pushing the NHS to use prostheses with the lowest acquisition cost, the training and support provided to surgeons and their teams may, in some instances, be of lesser quality or be lost completely. The provision of high-quality professional education, product training and support are important determinants of long-term clinical outcomes for patients undergoing THR and RS, and this further supports our request for change to the Committee's recommendations.

References

R. Kallala, P. Anderson, S. Morris, F.S Haddad. The cost analysis of cemented verses cementless total hip replacement operations on the NHS. *Bone Joint J* 2013;95-B:874–6.