NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Appraisal

Total hip replacement and resurfacing arthroplasty for end-stage arthritis of the hip (review of technology appraisal guidance 2 and 44)

Response to consultee, commentator and public comments on the Appraisal Consultation Document (ACD)

Definitions:

Consultees – Organisations that accept an invitation to participate in the appraisal including the manufacturer or sponsor of the technology, national professional organisations, national patient organisations, the Department of Health and the Welsh Assembly Government and relevant NHS organisations in England. Consultee organisations are invited to submit evidence and/or statements and respond to consultations. They are also have right to appeal against the Final Appraisal Determination (FAD). Consultee organisations representing patients/carers and professionals can nominate clinical specialists and patient experts to present their personal views to the Appraisal Committee.

Clinical specialists and patient experts – Nominated specialists/experts have the opportunity to make comments on the ACD separately from the organisations that nominated them. They do not have the right of appeal against the FAD other than through the nominating organisation.

Commentators – Organisations that engage in the appraisal process but that are not asked to prepare an evidence submission or statement. They are invited to respond to consultations but, unlike consultees, they do not have the right of appeal against the FAD. These organisations include manufacturers of comparator technologies, NHS Quality Improvement Scotland, the relevant National Collaborating Centre (a group commissioned by the Institute to develop clinical guidelines), other related research groups where appropriate (for example, the Medical Research Council and National Cancer Research Institute); other groups (for example, the NHS Confederation, NHS Information Authority and NHS Purchasing and Supplies Agency, and the *British National Formulary*).

Public – Members of the public have the opportunity to comment on the ACD when it is posted on the Institute's web site 5 days after it is sent to consultees and commentators. These comments are usually presented to the appraisal committee in full, but may be summarised by the Institute secretariat – for example when many letters, emails and web site comments are received and recurring themes can be identified.

Comments received from consultees

Consultee	Comment	Response
Johnson and Johnson DePuy Synthes	**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.	Comments noted. Responses are given to each issue as they are raised below.

Consultee	Comment	Response
Johnson and Johnson DePuy Synthes	**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.	Comments noted. Recommendations in NICE technology appraisal guidance do not specify how the guidance should be implemented. However the Committee was aware that the NICE Implementation Programme supports health and social care organisations to maximise the uptake and use of evidence and guidance and that ODEP, which is independent of NICE, currently provides the NHS with a list of prostheses that do or do not meet the standard for revision rates outlined in NICE technology appraisal guidance 2 and NICE technology appraisal guidance 44. See FAD sections 4.3.15 and 5.

Consultee	Comment	Response
Johnson and Johnson DePuy Synthes	**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.	Comments noted. The recommendations in section 1 have been amended. The recommendation specifying that 'If more than one type of prosthesis meeting the above criteria is suitable for a patient, the prosthesis with the lowest acquisition costs should be chosen' has been removed. See FAD section 1. Following consultation on the ACD, the Committee concluded that while the NHS should be mindful of costs, the Committee could not currently recommend selecting a prosthesis with the lowest acquisition cost when multiple prostheses demonstrated revision rates of 5% or less at 10 years. See FAD section 4.3.18. Comment noted. The Committee considered comments received in response to consultation and chose not to make recommendations by category, having concluded that this would disadvantage individual brands of prostheses with particularly low revision rates and would give an unfair advantage to individual brands with high revision rates within an overall well performing category. See FAD section 4.3.13.

Consultee	Comment	Response
Johnson and Johnson DePuy Synthes	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.	Comments noted.

Consultee	Comment	Response
Johnson and Johnson DePuy Synthes	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.	Comments noted. Comment noted. The recommendations in section 1 have been amended. The recommendation specifying that 'If more than one type of prosthesis meeting the above criteria is suitable for a patient, the prosthesis with the lowest acquisition costs should be chosen' has been removed. See FAD sections 1 and 4.3.18.

Consultee	Comment	Response
Johnson and Johnson DePuy Synthes	**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.	Comments noted. All non-manufacturer or non-sponsor consultees can nominate clinical specialists (see NICE Guide to the multiple technology appraisal process section 3.4.11) to present their personal views to the Appraisal Committee. For this appraisal no nominees were put forward by the British Orthopaedic Association or the British Hip Society to attend the appraisal committee meetings.

Consultee	Comment	Response
Johnson and Johnson DePuy Synthes	**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 not reproduced here	Comments noted. The Committee considered the comments received from consultees on the appraisal consultation document, which stated that the benefits of manufacturer support packages had not been taken into account. However, the Committee concluded that tender costs included training in the use of a prosthesis. The Committee concluded that, although the NHS should be mindful of costs, in situations where multiple prostheses with a revision rate of 5% or less at 10 years are suitable for a patient, it could not currently recommend selecting a prosthesis with the lowest acquisition cost. The Committee further concluded that the recommended standards for revision rate would encourage manufacturers to maintain training programmes to ensure the lowest revision rates possible for their products. See FAD section 4.3.18. The recommendations in section 1 have been amended. The recommendation specifying that 'If more than one type of prosthesis meeting the above criteria is suitable for a patient, the prosthesis with the lowest acquisition costs should be chosen' has been removed

Consultee	Comment	Response
JRI	1) According to the revision rates shown in table 6 and 7 in the overview and tables 67 and 68 (pages 213 and 214) in the assessment report a 10 year 5% revision rate benchmark means uncemented MoP and CoC are OK in men and women over 65 years, but not in men under 65 years and only uncemented MoP, not CoC, is OK in women under 65 years. This goes against conventional wisdom that uncemented hip implants do better in younger, more active patients and that ceramic on ceramic bearings should be used in this patient demographic because of superior wear rates.	Comment noted. The Committee considered comments received in response to consultation and reiterated that it considered making recommendations for a particular prosthesis categories based on the average revision rate of multiple brands within a category. However, the Committee chose not to make recommendations by category, having concluded that this would disadvantage individual brands of prostheses with particularly low revision rates and would give an unfair advantage to individual brands with high revision rates within an overall well performing category. See FAD section 4.3.13

<table>
<tr><th>Consultee</th><th>Comment</th><th>Response</th></tr>
<tr><td>JRI</td><td>

- Based on this and an acknowledgement that revision rates will be higher in younger patients, because of their higher activity levels and the fact that they are more likely to be fit enough (and live long enough) to have a revision should there be a 15 year revision benchmark for patients under 65 of 7%, instead of 5% at 10 years, with progression towards this benchmark as follows:

<table>
<tr><th>Year</th><th>Revision Rate</th></tr>
<tr><td>1</td><td>1.4%</td></tr>
<tr><td>2</td><td>2.1%</td></tr>
<tr><td>3</td><td>2.6%</td></tr>
<tr><td>4</td><td>3.0%</td></tr>
<tr><td>5</td><td>3.4%</td></tr>
<tr><td>6</td><td>3.8%</td></tr>
<tr><td>7</td><td>4.2%</td></tr>
<tr><td>8</td><td>4.6%</td></tr>
<tr><td>9</td><td>5.1%</td></tr>
<tr><td>10</td><td>5.5%</td></tr>
<tr><td>11</td><td>5.9%</td></tr>
<tr><td>12</td><td>6.2%</td></tr>
<tr><td>13</td><td>6.5%</td></tr>
<tr><td>14</td><td>6.8%</td></tr>
<tr><td>15</td><td>7.0%</td></tr>
</table>

</td><td>Comment noted. NICE cannot make recommendations on the basis of age as age is a protected characteristic under the equalities legislation.</td></tr>
</table>

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<tr><th>Consultee</th><th>Comment</th><th>Response</th></tr>
<tr><td>JRI</td><td>

- Based on data in the NJR, progression towards a 5% revision rate at 10 years, for patients over 65, should also be non-linear:

<table>
<tr><th>Year</th><th>Revision Rate</th></tr>
<tr><td>1</td><td>1.4%</td></tr>
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<tr><td>6</td><td>3.8%</td></tr>
<tr><td>7</td><td>4.1%</td></tr>
<tr><td>8</td><td>4.4%</td></tr>
<tr><td>9</td><td>4.7%</td></tr>
<tr><td>10</td><td>5.0%</td></tr>
</table>

</td><td>Comment noted. NICE cannot make recommendations on the basis of age as age is a protected characteristic under the equalities legislation.</td></tr>
<tr><td>JRI</td><td>

2) The price data provided by NHSSC significantly overstates the prices actually paid for all the THR implant categories. Perhaps more importantly the differences between cemented and uncemented prices are overstated. Table 11 in the overview shows uncemented MoP at almost x 2 the price of cemented MoP, with the difference being £1,458.22. We know that in reality the average price of an uncemented hip is around 30% - 40% higher than a cemented hip, and the price difference is more likely to be in the region of £400.

- There is a very large margin of error between the price and **price difference** assumptions made in the assessment and the reality of in-market pricing and price differences. This is bound to have a significant impact on the cost effectiveness model as it is acknowledged in the assessment that the difference in QALYs are negligible between THR categories A to E and that probabilistic analyses of costs and effectiveness of all categories overlapped markedly.

</td><td>Comment noted. The Committee discussed the costs of the prostheses. It understood that the Guide to the Methods of Technology Appraisal 2008 recommends using public list prices in the reference case-analysis, but noted that the NHS routinely pays a lower price for hip replacement prostheses because of volume dependent and locally negotiated discounts. The Committee was aware that the Assessment Group obtained an average of sample list price from the NHS supply chain for multiple manufacturers and that the manufacturer had presented list prices for its own brands. The Committee noted that the Assessment Group's prices were higher than the manufacturer's (with some exceptions). The Committee concluded that there was considerable uncertainty surrounding the prices of prostheses. See FAD section 4.3.11.</td></tr>
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Consultee	Comment	Response
JRI	3) The assessment concludes that cemented CoP dominates the other THR categories in terms of clinical and cost effectiveness. However, there is no uncemented CoP category included. The “ceramic bearing” comparison is therefore between cemented CoP and uncemented CoC. In table 11, the price difference between an uncemented CoC and a cemented CoP is £1,900, whereas in reality it is in the region of £500 - £600. • The failure to include uncemented ceramic on poly is a significant flaw. It has the lowest revision rate of the bearing surface combinations used with uncemented hips and the price difference between a cemented ceramic on poly hip and an uncemented hip with this bearing surface combination will be much smaller than the difference between uncemented CoC and cemented ceramic on poly. Would cemented CoP still dominate if the differences in costs and revision rates were significantly less	Comments noted. The recommendation in FAD section 1 are not made on the basis of category. The Committee chose not to make recommendations by category, having concluded that this would disadvantage individual brands of prostheses with low revision rates, and would give an unfair advantage to individual brands with high revision rates within an overall well-performing category. See FAD section 4.3.13.

Consultee	Comment	Response
Smith and Nephew	Smith & Nephew wishes to thank NICE's Appraisal Committee for this opportunity to respond to NICE's October 2013 Appraisal Consultation Document (***ACD***) concerning total hip replacement (***THR***) and resurfacing arthroplasty (***RSA***) of end-stage arthritis of the hip. In this regard, we note that the key conclusions of NICE's Appraisal Committee, as stated in the ACD(p.43), include the following: · "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 less than 5% at 10 years;If more than one type of prosthesis meeting the above criteria is suitable for a patient, the prosthesis with the lowest acquisition costs should be chosen"	Comments noted
	NICE has set out the evidence behind these and other key conclusions of its investigations (which remain provisional) in the Evaluation Report to which the ACD refers. In particular, the Evaluation Report contains a lengthy Assessment Report prepared by external consultants (the ***Warwick Report***), as well as details of the various submissions received by NICE from Smith & Nephew dated 4 February 2013 and others. However we have subsequently been informed that the submission from Smith & Nephew in support of our Birmingham Hip Resurfacing System (BHR) RSA product was unfortunately omitted from the process due to an internal error by NICE.	Comment noted. Smith and Nephew's second submission was presented to the Committee for the first Committee meeting (18th September 2013). The Committee therefore considered the contents of this submission along with evidence submitted by other consultees when discussing and agreeing the contents of the ACD.

Consultee	Comment	Response
Smith and Nephew	The Appraisal Committee has asked for comments on, among other things, the adequacy and completeness of this evidence base. We have detailed below our views on the first three questions posed at page 1 of the ACD, namely whether: 1. all the relevant evidence has been taken into account in reaching the key conclusions set out in the ACD; 2. the summaries of clinical and cost effectiveness set out in the ACD and the Evaluation Report constitute reasonable interpretations of the evidence; and 3. the key conclusions set out in the ACD are a sound and suitable basis for providing guidance to the NHS.	Comment noted. Responses are given to each issue as they are raised below.

Consultee	Comment	Response
Smith and Nephew	***1. Has all of the relevant evidence been taken into account?*** No, there are several significant omissions and errors that need to be considered for a fair assessment of RSA. These include: the lack of recognition of brand as a risk factor, no account of post-operative activity levels; enhanced QALYs and favorable cost-effectiveness as noted in the paper recently published by Heintzbergen et al. (a copy of which is sent in annex to our response). *Relevant studies were excluded and misinterpreted* In the assessment of clinical evidence selection process, the exclusion criteria were very stringent and thus failed to consider a preponderance of evidence resulting in only 16 RCTs and 8 systematic reviews being included in the assessment. A significant example of an error in the interpretation of the data within the literature cited in the assessment is the Jameson et al. study, which identifies risk factors for Hip Resurfacing Arthroplasty (RSA) (p161 of the report). The assessment report selectively presents the reported hazard ratios for gender, femoral head size, and surgeon experience but excludes prosthesis brand as a risk factor, thus failing to reveal a significant finding that was one of the main conclusions of the publication. Jameson et al., identifies BHR as the baseline standard to which other brands were compared as BHR had the lowest revision rate of the resurfacing devices tracked in the National Joint Registry for England and Wales. The results reported in the publication are presented in Figure 1. Figure 1. Independent predictors of revision following metal-on-metal hip resurfacing: A retrospective cohort study using national joint registry data (Jameson et al. The Journal of Bone and Joint Surgery 2012, 94-B:746-754). Figure not reproduced here	Comment noted. The Committee noted that the Assessment Group presented evidence from RCTs, systematic reviews, published registry studies, and its analysis of the NJR, and discussed the relevance of each source to its decision making. The Committee noted the Assessment Group's concerns that the RCTs and systematic reviews it identified had involved small numbers of patients, had relatively short follow-up, reported different outcomes either incompletely or poorly, and were underpowered to detect differences in revision.... The Committee concluded that it was appropriate to use both trial and observational data in its decision making, but that uncertainty resulting from the possibility of confounding should be taken into account. The Committee agreed that, although the NJR data had limitations, they are the most comprehensive data reflecting clinical practice in the NHS and therefore the most appropriate for decision making. See FAD section 4.3.5.

Consultee	Comment	Response
Smith and Nephew	The decision to restrict the reported analysis of registry, RCTs and publication data to RSA as a category, and to ignore the performance of individual device designs reported in peer-reviewed articles, excludes important implant survivorship data from the analysis and denies the identification of well-performing devices from the category. The conclusions drawn from the analysis are therefore incomplete and misleading for RSA and in particular BHR. Data reported from the Australian Orthopedic Association National Joint Registry, the Swedish Hip Arthroplasty Register, the National Joint Registry for England and Wales, and a study by de Steiger et al. reporting on registry data, corroborate the contention that not all RSA prostheses display similar survivorship profiles. These data sources show a marked difference in the revision incidence rate per 100 observed implant years, Figure 2. **Figure 2. RSA revision rates. (figure not reproduced here)** This lack of brand transparency is further accentuated in the report by the exclusion of brand as a risk factor in the summarized data in Table 49 (a summary table of registry studies for RSA). Noteworthy is the degree of hazard reported and the degree of hazard not reported by ignoring brand differences. The table reports a 1.3 hazard ratio (HR) difference between women and men, a 1.48 - 2.14 HR for smaller femoral head components, and a 1.36 HR for low volume surgeons. It ignores a higher HR by associated with brand, 1.43 – 2.82 for other resurfacing devices compared to BHR.	Comment noted. The Committee considered comments received in response to consultation. The Committee reiterated that it considered making recommendations for a particular prosthesis categories based on the average revision rate of multiple brands within a category. However, the Committee chose not to make recommendations by category having concluded that this would disadvantage individual brands of prostheses with particularly low revision rates and would give an unfair advantage to individual brands with high revision rates within an overall well performing category. See FAD section 4.3.13.

Consultee	Comment	Response
Smith and Nephew	*Exclusion of recent, evidence on cost-effectiveness* Smith & Nephew notes that a significant new cost-effectiveness analysis model for hip resurfacing has been published since the Warwick Report was compiled. We believe that NICE ought properly to take this more recent evidence into account in its conclusions. Heintzbergen et al. overcomes several of the limitations that the Warwick Report identified as limitations to its own methods. Furthermore, it provides significant evidence that the outcomes of BHR are unique compared to an assessment of RSA outcomes calculated from a category average. The model was developed by the Health Research Innovation Centre of Calgary, Alberta, the Department Health Technology & Services Research in the Netherlands and the Alberta Bone & Joint Health Institute. The source of outcomes data utilized in the report originated from the Alberta Hip Improvement Project (***HIP***) and the Alberta Hip and Knee Replacement Project (***AHKRP***), both of which were managed by the Alberta Bone & Joint Health Institute. The Alberta Hip Improvement Project (2012) was designed as a prospective observational cohort of patients with HRA receiving a BHR. It received support from both Alberta Health and Wellness and industry and had as its purpose to compare the patient reported functional outcomes of RSA for the first 2 years after surgery with a THA control cohort. This study demonstrated the feasibility and advantages of applying a pragmatic randomized controlled trial to ascertain comparative effectiveness (Gooch et al.). Where available, costs in the model were based on actual costs and the Regional Health Authorities provided prosthesis costs, and Alberta Health and Wellness (AHW) provided physician costs. Data was prospectively collected with the intent to analyze outcomes and comprehensive cost data, not just implant acquisition costs. This model was thus populated with data taken from study work that collectively serves as a single source of prospectively collected clinical outcomes, quality of life, and actual cost data. In contrast, the Warwick team developed their model using data elements from different sources temporal periods, patient populations and surgery types as identified on page 239 of the Assessment Report.	Comment noted. The cost effectiveness analysis undertaken by Heintzbergen et al 2013 was published after the Assessment Group's systematic review of cost-effectiveness studies was performed. NICE's Guide to the multiple technology appraisal process states that 'At the ACD consultation stage, the Centre Director must agree to accept any new evidence before it its submitted. New evidence will only be accepted if it is likely to affect the provisional recommendations in the ACD. The new evidence must be presented in a separate appendix to the comments on the ACD [3.5.33]'. The guidance on these technologies will be considered for review in February 2017. During this period, the Institute will identify any new evidence available and trials that are due for completion. The Institute will then determine whether and when a review of the guidance should be undertaken.

Consultee	Comment	Response
Smith and Nephew	The analysis model by Heintzbergen et al. reached a contradictory conclusion to the Warwick Report, reporting that “Patients with MoM hip resurfacing are expected to experience higher lifetime QALYs and have lower health care costs compared with patients with THA.” Additionally they reported that there was “a 58% probability that MoM RSA is cost-effective compared with THA” at a cost-effectiveness threshold of $50,000 per QALY. RSA was also found to be less costly and produce more QALYs in the base case (BHR) when compared to THA. Subgroup analyses revealed that RSA dominated THA in younger male patients, in particular. The authors stated that their results confirmed other peer reviewed literature concluding that, “MoM hip resurfacing could be cost-effective for patients younger than 65 years.” In the evidence review portion of the report, page 130 states that it was assessed that there was “lower grade evidence” that there was no difference between QALYs or functional scores between RSA and THA. This conclusion is not supported by Heintzbergen et al. that which reported finding net a higher QALY totals for RSA vs. THA. On page 243 of the report, it was stated that the applied prosthesis cost was an average cost. Rather, a weighted average cost would have better reflected prostheses costs for use in the model.	Comment noted. Please see response to previous comment regarding the new cost effectiveness analysis undertaken by Heintzbergen et al. 2013.

Consultee	Comment	Response
Smith and Nephew	The ACD stated that "revision rate was the single most important key driver of costs and QALYs in the model." An RSA revision rate of 17.2% was used at 10 years for hip resurfacing. The actual 10-year revision rate for BHR in the Australian and Swedish arthroplasty registers was 6.7% and 6.2%, respectively, and was 5.09% at 7 years in the NJREW. The numbers used in the Warwick model would thus significantly disadvantage BHR and could be an explanation for the difference in final assessment between the Warwick model and Heintzbergen et al. paper. Moreover, post-surgery activity levels for RSA and THR were not taken into account in the assessment in terms of both health economic arguments and the effect of higher activity on expected implant survivorship. For example, Lavigne et al. showed a significant difference in return to heavy or moderate activity levels for RSA vs. THR patients. Seventy-seven percent of RSA patients compared to 39% of THR patients returned to heavy or moderate activity at 16 months post-surgery.	Comment noted. The Committee noted that the NJR did not provide data on outcomes listed in the scope other than revision, and that it did not provide data on differences in the patient characteristics (for example, activity levels and comorbidities) that might affect both device choice and the risk for revision, and therefore cause confounding. The Committee concluded that it was appropriate to use both trial and observational data in its decision making, but that uncertainty resulting from the possibility of confounding should be taken into account. The Committee agreed that, although the NJR data had limitations, they are the most comprehensive data reflecting clinical practice in the NHS and therefore the most appropriate for decision making. See section 4.3.5 of the FAD.

Comments received from clinical specialists and patient experts

Nominating organisation	Comment	Response
Smith and Nephew	***2. Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?*** No, significant gaps in data and limitations of the analysis do not allow for an accurate cost effectiveness conclusion. The Warwick analysis is flawed because RSA was evaluated only as a category. Implant brand, reported by Jameson, et al., is a significant predictor of revision risk, however was not differentiated within model. Rather, all RSA brands were assumed to have the same risk of revision. The Alberta model, discussed in detail above, reports a contradictory conclusion to the Warwick model. This cost-effectiveness evaluation similarly compared RSA to THA, but, contrary to the Warwick model, the Alberta model found that in the base case RSA dominated THA because it had lower total costs and more QALYs generated. (Heintzbergen et al.). A key difference of the Alberta model compared to the Warwick model was that BHR alone was reported to be the hip resurfacing device used by the Hip Improvement Project, which was a key data source for its model. Specifically, costs reflected in the Warwick model represent implant acquisition only. The true cost of a procedure includes the implant but also ancillary products (such as cement), theater time, QALYs, etc. The study by Heintzbergen et al. was specifically designed to evaluate cost effectiveness and reached a contradictory conclusion to the Warwick analysis. Heintzbergen et al. reported a cost-effectiveness evaluation of RSA (all BHR) and THA. Contrary to the Warwick model, they found that in the RSA dominated THA because it was found to have lower total costs and more QALYs generated.	Comment noted. The Committee chose not to make recommendations by category, having concluded that this would disadvantage individual brands of prostheses with particularly low revision rates and would give an unfair advantage to individual brands with high revision rates within an overall well performing category. In addition the Committee considered that it was appropriate to recommend that a prosthesis (for either resurfacing arthroplasty or THR) should meet a revision rate of 5% or less at 10 years. See FAD sections 4.3.13 and 4.3.14.

Nominating organisation	Comment	Response
Smith and Nephew	The Warwick analysis is also flawed because brand was not differentiated in the RSA segment, rather all RSA brands have been assumed to have the same risk of revision. Moreover in section 6.2.5, there are only 3 RCTs that have been analyzed and stated to have been the foundation of the comparison between RSA and THA. In two of these studies, the RSA product evaluated was Durom (Zimmer), which was subject to a recall in 2008 due to higher than anticipated revision rates. The other RCT did not specify which products were used as the brand selection as the choice was left to surgeon discretion.	Comment noted. The Committee chose not to make recommendations by category, having concluded that this would disadvantage individual brands of prostheses with particularly low revision rates and would give an unfair advantage to individual brands with high revision rates within an overall well performing category. In addition the Committee considered that it was appropriate to recommend that a prosthesis (for either resurfacing arthroplasty or THR) should meet a revision rate of 5% or less at 10 years. See FAD sections 4.3.13 and 4.3.14
	The lack of consideration of brand in the selection of RCT data makes these studies questionable in relevance and strength of the overall conclusions. Furthermore, the data used in the systematic reviews and the inclusion of several products in the RSA group which have subsequently been withdrawn from the market due to having high failure rates, bring into question the strength of any conclusions made in the Evaluation Report.	Comment noted. The revision rate estimates were based on data from the National Joint Registry. See FAD sections 4.3.6 and 4.3.8.

Nominating organisation	Comment	Response
Smith and Nephew	***3. Are the provisional recommendations sound and a suitable basis for guidance to the NHS?*** We support the objectives of NICE, namely to ensure that the NHS has access to the most clinically effective and cost effective hip prostheses. However, we do not support the recommendations as they currently stand. The proposed guidance first recommends the choice of implants only meeting the recommendation of less than 5% revision rate at 10 years. As regards **THA**, this recommendation may be applicable for the current products, however the second part of the recommendation being to select the least expensive implant within that group which falls below 5%, could lead to an increased cost burden to the NHS. This is because the Warwick report has viewed cost to only include implant acquisition and omitted many other important contributors to the cost (ancillary products, theater time, QALYs, etc.). We cannot support the proposed recommendation of that implant cost acquisition solely as the determining cost factor in implant choice. It must be recognized that an implant meeting the guidance but performing better than another lower cost implant may in fact result in a total cost that is lower than the less expensive implant. This assertion is supported by our review of the paper by Heintzbergen et al. which performed a rigorous cost effective analysis in comparison to the Warwick report. In fact, the Appraisal Consultation Document itself seems conflicted in that a key conclusion that "Revision rate was the single most important key driver of costs and QALYs in the model" appears contradictory to a finding reported on page 303 "…that the cost of the prosthesis is the most important factor…". As such, we feel that the second proposed guidance of choosing the lowest cost implant, while well intentioned, is very incomplete and may perversely impact in an effort to assist the NHS in reducing their overall cost burden without further qualification.	Comments noted. The recommendations in section 1 have been amended. The recommendation specifying that 'If more than one type of prosthesis meeting the above criteria is suitable for a patient, the prosthesis with the lowest acquisition costs should be chosen' has been removed. See FAD section 1. The Committee concluded that although the NHS should be mindful of costs, in situations where multiple prostheses with a revision rate of 5% or less at 10 years are suitable for a patient, it could not currently recommend selecting a prosthesis with the lowest acquisition cost. See FAD section 4.3.18.

Nominating organisation	Comment	Response
Smith and Nephew	Finally, we do not believe that the data, or analysis of the data in its current form, can support any meaningful conclusions relative to RSA. We highlighted significant shortcomings in the analysis performed for RSA including the lack of recognition of brand as a risk factor, no account of postoperative activity levels, enhanced QALYs and favorable cost-effectiveness as noted in the paper by Heintzbergen et al. Moreover, we have established that there is strong evidence contradicting the conclusion of the Warwick report that BHR is more cost effective than THA. Finally, the evidence submitted by Smith & Nephew to NICE on 4 February 2013 for the purpose of the current technology appraisal was unfortunately not taken into account in a timely manner. In light of these shortcomings it would be appropriate to perform an additional review of the RSA data with a view to assess appropriate benchmarks for RSA in this younger more active patient population.	Comment noted. Please see responses to previous comments regarding the analyses undertaken by the Assessment Group and the comparison of the Assessment Groups with Heintzbergen et al. 2013 Comment noted. Please see response to previous comment on evidence submitted by Smith and Nephew on February 2013.

Nominating organisation	Comment	Response
Stryker	Stryker supports the points outlined in the response from ABHI (below): In response to the NICE consultation on its preliminary recommendations for total hip replacement and resurfacing arthroplasty for end-stage arthritis of the hip (review of TA guidance 2 and 44), the ABHI Orthopaedic Special Interest Section would like to make the following comments to the Technology Appraisal Committee (TAC) for their consideration. Firstly we were disappointed to note the absence of any practicing surgeon members of the British Orthopaedic Association (BOA) or British Hip Society (BHS) at the TAC meeting on 18th September 2013 when the Committee made its preliminary recommendations. It is critical that recommendations be appropriately informed through professional input across the range of clinical experience across different types of fixation and technology. To that end we feel strongly that the BOA and BHS should provide the TAC with independent expert opinion and very much hope the second committee meeting will take account of this point. In addition, the ABHI believe NICE's preliminary recommendations do not account for the importance of surgeon training and experience when choosing types of prostheses. The provision of training, education and support by the manufacturer is an important component of the decision to select a particular prosthesis to ensure long-term clinical outcomes for the patient and we do not consider that sufficient emphasis has been placed on this. We request that the Committee carefully consider this important aspect as context against which section 1.2 must be balanced when making its final recommendations to ensure the outcome is pragmatic and relevant to the NHS. Section 1.2 of the draft guidance currently recommends use of the prosthesis with the lowest acquisition cost. We believe that whilst this is one important factor for the NHS, patient characteristics, surgeon training and experience with a particular prosthesis and non-implant procedure costs (e.g. consumables and theatre time) should be taken into account in the guidance.	Comment noted. Comments noted. All non-manufacturer or non-sponsor consultees can nominate clinical specialists (see NICE Guide to the multiple technology appraisal process section 3.4.11) to present their personal views to the Appraisal Committee. For this appraisal no nominees were put forward by the British Orthopaedic Association or the British Hip Society to attend the appraisal committee meetings.However, the British Hip Society and the British Orthopaedic Association have provided responses to the appraisal consultation document and these were taken into account by the Committee in the second Committee meeting. Comments noted. Section 1 has been amended. The recommendation specifying that 'If more than one type of prosthesis meeting the above criteria is suitable for a patient, the prosthesis with the lowest acquisition costs should be chosen' has been removed. Following consultation on the ACD,:the Committee concluded that although the NHS should be mindful of costs, in situations where multiple prostheses with a revision rate of 5% or less at 10 years are suitable for a patient, it could not currently recommend selecting a prosthesis with the lowest acquisition cost (see FAD section 4.3.18).

Nominating organisation	Comment	Response
Stryker	In Addition Stryker would like the Committee to address the following questions/concerns: 2.4 How will ODEP define the different categories in light of the reduction of the 10 year revision rate to 5%? Will this impact on the failure rates at other time points e.g. 3, 5, 7 years?	Comment noted. 4.3.15 of the FAD states: The Committee was aware that NICE Technology Appraisal guidance recommends on the cost-effective use of NHS resources but does not specify how to implement guidance; it was also aware that the NICE Implementation Programme supports health and social care organisations to maximise the uptake and use of evidence and guidance.
	4.3.15 **Furthermore, the Committee agreed that there should be a 'stopping rule' –** how will this be managed? There will be a number of Contracts/Tenders with lengthy timelines that do not meet this criteria.	Comment noted. The Committee agreed that prostheses that currently have at least 3 years of data which estimate a higher than 5% revision rate at 10 years when projected, should not continue to be offered to patients. See FAD section 4.3.15.
	4.3.16 The recommendations do not refer to the causes for revision which may influence the revision rate. Also, the combination of different manufacturers product and the variety therin may influence revision rates, and affect the rate of different components. It is also unclear how products with revision rates lower than 5% will be preferenced.	Comment noted. After consultation on the appraisal consultation document, the committee further considered revisions that result from prostheses failing and revisions that result from complications during surgery or errors in prosthesis insertion (early revision). The Committee heard from the manufacturers that they expected the proportions of revisions not directly related to device failures to be similar across classes of hip replacement prostheses. See FAD section 4.3.7

Nominating organisation	Comment	Response
Wright Medical	The "Appraisal consultation document – Arthritis of the hip (end-stage) hip replacement (total and resurfacing arthroplasty (Rev TA2, TA 44)," released in October 2013, posed the following questions to consultees: 1) Has all of the relevant evidence been taken into account? 2) Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence? 3) Are the provisional recommendations sound and a suitable basis for guidance to the NHS? Wright Medical's response: 1) Has all of the relevant evidence been taken into account? **It appears that key pieces of clinical evidence for Wright Medical's CONSERVE® Plus resurfacing device, PROFEMUR® and ANCA-FIT™ total hip Arthroplasty (THA) devices were not considered. Please refer to the "Clinical Results" section below.** 2) Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence? **Refer to the "Clinical Results" section below.** 3) Are the provisional recommendations sound and a suitable basis for guidance to the NHS? **One of the preliminary recommendations reported in the ACD is that THA and resurfacing are recommended if the devices have an established 95% survivorship at 10 years follow-up. This value may not be appropriate in all clinical studies or patient populations, as a variety of non-device related factors can affect survivorship. These factors include infection, improper patient selection, surgical technique, brand mismatch, patient compliance, contraindications, etc. Furthermore, it remains unclear whether 95% survivorship applies to all evidence, taken as an average or can be applied selectively to specific pieces of evidence.**	Comments noted The NICE Guide to the multiple technology appraisal process states that 'At the ACD consultation stage, the Centre Director must agree to accept any new evidence before it its submitted. New evidence will only be accepted if it is likely to affect the provisional recommendations in the ACD. The new evidence must be presented in a separate appendix to the comments on the ACD [3.5.33]'. Comment noted. The Committee appreciated that the underlying reason for why a patient needed revision surgery may be difficult to identify and is not routinely recorded in NJR. In addition, the Committee was told that there is no system that collects data about the prevalence of people living with a failed prosthesis who are unable to, or chose not to, have revision surgery, and no representative data on the proportion of revisions that are a result of failing prostheses. The Committee accepted that, while revision rates may not fully reflect prosthesis failure, revision was an important outcome both from the patients' perspective and in terms of its cost and the resources needed. See FAD section 4.3.7.

Nominating organisation	Comment	Response
Wright Medical	**Clinical Results** *Clinical Results for CONSERVE® PLUS Resurfacing*: The published survivorship data for the CONSERVE® PLUS resurfacing device is summarized in Table 1 below. The values highlighted in bold fall beneath the NICE benchmark of 90% survivorship at 10 years follow-up. Table 1: CONSERVE® PLUS resurfacing survivorship (table not reproduced here). Two studies presented survivorship values less than 90% at 10 years follow-up. Amstutz et al. reported 88.5% survival for their first 100 CONSERVE® Plus resurfacings. It should be noted that these patients were implanted during the surgeon's "learning curve" phase and prior to the creation of the strict patient selection criteria now used for resurfacing. Additionally, the 88.5% survival at 10 years is greater than the survivorship reported for all hip resurfacings in the 10th Annual Report of the National Joint Registry of England and Wales (NJR). The second study with survivorship less than 90% at 10 years follow-up was also published by Amstutz et al. The patients in this study were considered "risk factor" patients as they had small femoral head sizes (<46 mm) and femoral head defects greater than 1 cm. The authors described ideal patients as having femoral heads greater than 46 mm and femoral head defects less than 1 cm. *Clinical Results for Wright Total Hip Arthroplasty (Mid to Long-Term Follow-Up)* The published mid to long-term survivorship data for the PROFEMUR® and ANCA-FIT™ total hip THA devices is summarized in Table 2 below. Table 2: PROFEMUR® and ANCA-FIT™ THA survivorship (table not reproduced here) References not reproduced here	Comments noted.

Nominating organisation	Comment	Response
Zimmer	we are aware of your formal process for comments on the guidance. Nevertheless, we would thake the opportunity to comment on the NICE draft proposal "*Total hip replacement and resurfacing arthroplasty for end-stage arthritis of the hip" (review of TA guidance 2 and 44).* First of all Zimmer is concerned about the absence of members of the British Orthopaedic Association (BOA) or British Hip Society (BHS) at the TAC meeting on 18th September 2013. Secondly, since patient reported experiences and outcomes (i.e. PROMs) have increased in importance in the UK we are wondering why patient groups were not present at the TAC meeting. Specifically in regard to the draft proposal, and importantly in our view, two main factors have to be considered by NICE while defining success benchmark: 1- Non-linearity of revision in THA: given known revision rates early after the procedures that are non-device related (infection, dislocation). 2- Device vs. non-device-related revisions: benchmark should consider only device-related revisions, and those parameters should be well defined	All non-manufacturer or non-sponsor consultees can nominate clinical specialists (see NICE Guide to the multiple technology appraisal process section 3.4.11) to present their personal views to the Appraisal Committee. For this appraisal no nominees were put forward by the British Orthopaedic Association or the British Hip Society to attend the appraisal committee meetings. However, the British Hip Society and the British Orthopaedic Association have provided responses to the appraisal consultation document and these were taken into account by the Committee in the second Committee meeting. Comment noted.The Committee agreed that, while other appropriate distributions may exist, the analysis of revision rates presented by the Assessment Group for this appraisal had shown it was reasonable to extrapolate using the bathtub function for prostheses with a follow-up shorter than 10 years. Furthermore, the bathtub model accounted for a higher rate of early revisions, which may reflect surgical complications or other factors unrelated to the prosthesis. See FAD section 4.3.15.

Nominating organisation	Comment	Response
Zimmer	Below is some additional information outlining our key concerns: • It is important to note that Hip and Knee arthroplasty survivorship is NOT entirely controlled by design of implant. One could argue that the majority of a permissible 5% ten-year revision rate will be consumed by issues/complications beyond the manufacturer's control. • Reasons for failure of THA procedures are multifactorial. Most of the time the reasons in fact are not implant-related (infection, dislocation, intra-op fractures) and can also be due to surgical technique, surgeon's experience, comorbidities and/or patient incompliance. Globally, there persists more that 1% incidence of revision due to infection, which is not due to the implant itself. There is also more than 1.5% incidence of revision due to instability/dislocation. The majority of dislocation cases are due either to surgeon technique in mal-positioning of implants, patient soft tissue conditions or implant selection. Some facts and remarks: o **Indications**: different patient populations may have different risks and failure modes and rates after THA, examples: ▪ Revision THA: especially difficult revisions with insufficient bone stock. ▪ Dysplastic hips: some manufacturers have specific hip implants for this category of patients. ▪ Fractured necks: different treatment modalities recommended with different success rates (unipolar, bipolar, THA, cemented, uncemented, hybrid). ▪ Young active patients may have a higher revision rate.	Comment noted. See FAD section 4.3.7 After consultation on the appraisal consultation document, the Committee further considered revisions that result from prostheses failing compared with revisions that resulted from complications during surgery or errors in implantation of the prosthesis (early revision). The Committee heard from the manufacturers that they expected the proportions of revisions not directly related to device failures to be similar across classes of hip replacement prostheses.

Nominating organisation	Comment	Response
Zimmer	o **Surgeon's experience**: more experienced surgeons may have a lower rate of revision. This can be important in teaching hospitals where residents, who are less experienced, perform THAs. o **New hip implants**: as a revision is not linear with time and specific revisions occur shortly after the procedure (infection, dislocation), new implants when introduced will show a higher revision rate early after the product introduction. This could be interpreted as a failure as the implant will not meet the benchmark. This is the case already with the NICE 90% benchmark. o **Survival of a system (cup and stem) vs. a single component (cup or stem)**: in some circumstances during a revision surgery, there is a preference and/or an indication to revise all components. This impacts the results of the non-loosened component and can result in artificially lowering the survival rate.	Section 4.3.7 of the FAD states: After consultation on the appraisal consultation document, the Committee further considered revisions that result from prostheses failing compared with revisions that resulted from complications during surgery or errors in implantation of the prosthesis (early revision). The Committee heard from the manufacturers that they expected the proportions of revisions not directly related to device failures to be similar across classes of hip replacement prostheses.
	• There needs to be a strong definition of revision/survival rate: o The criteria used for the revision must be clearly defined. Survival rate must be defined according to a well-established methodology (i.e., survival rate according to Kaplan-Meier with mentioning of a confidence interval and the end-point).	Comment noted. See FAD section 4.3.15: The Committee was further aware that ODEP, which is independent of NICE, currently provides the NHS with a list of prostheses that do or do not meet the standard for revision rates outlined in NICE technology appraisal guidance 2 and NICE technology appraisal guidance 44, and that there are initiatives to improve collecting and disseminating information on revision rates.

Nominating organisation	Comment	Response
Zimmer	Overall, we have a concern about setting this level of reduction in revision performance criteria, without having all of the other issues and questions outlined above addressed. With regard to 1.2, we suggest that this language be amended. For many patient indications and disease states, as well as physician training and preference, there could be specific reasons why the lowest cost product would not be the appropriate choice. Mandating such could negatively impact patient outcomes. Lastly, there does not appear to be a clear mechanism for how products with less than ten year performance or adequate time on the market would be able to be utilized if these are best for patient indications. This could potentially hamper the introduction or use of new technologies that could benefit patients.	Comments noted. Following consultation on the preliminary recommendations in the ACD, recommendation 1.2 has been removed: The Committee concluded that although the NHS should be mindful of costs, in situations where multiple prostheses with a revision rate of 5% or less at 10 years are suitable for a patient, it could not currently recommend selecting a prosthesis with the lowest acquisition cost. See FAD section 4.3.18. Comment noted. See FAD section 4.3.15: The Committee concluded that it would be reasonable to recommend prostheses with less than 10 years of data, provided that the revision rate was consistent with 5% or less at 10 years and that the recommendation could be implemented within the current support framework provided by ODEP.

Nominating organisation	Comment	Response
British Orthopaedic Association	Comments from BOA's lay representative 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.	Comment noted. New revision rate standards have been recommended in this review of NICE technology appraisal guidance 2 and NICE technology appraisal guidance 44. FAD Section 4.3.14 states: The Committee agreed that the current standard was too high for both populations and the Committee was aware that prostheses become more cost effective the lower the revision rates.
	This would appear to be contrary to NICE guidance of 'less than 10% at 10 years'. I have difficulty with 'or projected rate' of revision. Early experience with a particular device usually provides a greater failure rate in the first year or two – it would not be reasonable to extrapolate such to the 10 years expectation. Both Charnley and Exeter hips had many failures at the start of their useage. Also, this may well preclude many of the combinations (including from differing producers) preferred by the operating surgeon. Not all hybrid combinations have track records.	Comment noted. FAD section 4.3.15 states: The Committee agreed that, while other appropriate distributions may exist, the analysis of revision rates presented by the Assessment Group for this appraisal had shown it was reasonable to extrapolate using the bathtub function for prostheses with a follow-up shorter than 10 years. Furthermore, the bath-tub model accounted for a higher rate of early revisions, which may reflect surgical complications or other factors unrelated to the prosthesis.
	1.2 If more than one type of prosthesis meeting the above criteria is suitable for a patient, the prosthesis with the lowest acquisition costs should be chosen. Should the surgeon, and support team's, experience with a particular device not be also taken into account. Further, it is common practice for there to be discounts available according to the number of devices ordered.	Comment noted. Section 1 has been amended. The recommendation specifying that 'If more than one type of prosthesis meeting the above criteria is suitable for a patient, the prosthesis with the lowest acquisition costs should be chosen' has been removed. The Committee concluded that, although the NHS should be mindful of costs, in situations where multiple prostheses with a revision rate of 5% or less at 10 years are suitable for a patient, it could not currently recommend selecting a prosthesis with the lowest acquisition cost (see FAD section 4.3.18).

Nominating organisation	Comment	Response
British Orthopaedic Association	The British Orthopaedic Association wishes to endorse the response from the British Hip Society in relation to this consultation, and provides a replicate of this response below (see comments from British Hip Society)	Comment noted.
British Hip Society	1.1 It is not stated what is acceptable as a source for this evidence. If it is NJR data then please see Comment on 4.1.16 below concerning data quality. If the NJR data is to be accepted then we suggest NICE clarify that the revision rate quoted should be where the indication for surgery is osteoarthritis so that case-mix is not a confounding issue. As you will be aware, NICE commissioned PASA (now NHS supply chain) to set up the Orthopaedic Devices Evaluation Panel (ODEP). If the advice refers to ODEP analyses, then ODEP considers results in consecutive series of patients from peer-reviewed sources to apply a rating. They also consider data submitted by Manufacturers. We suggest the Appraisal Committee liaises with ODEP about the decision they have made to develop their system for rating devices. We have been told that there has been little communication between NICE and ODEP during compilation of this Guidance. ODEP is planning to introduce a new rating of 10* where a cohort of at least 500 consecutive patients have been reviewed beyond 10 years. This NICE Guidance should refer to the system of ratings defined by ODEP. Implants with follow-up less than 10 years should have acceptable revision rates defined using ODEP methodology if this is the source of acceptable data referred to in the Guidance. Surgeons should be advised to use implants that have not yet achieved a 3 year ODEP rating only if patients are enrolled in the Beyond Compliance initiative driven by BOA/MHRA. (http://www.beyondcompliance.org.uk)	Comment noted. FAD section 4.3.15 states: The Committee was aware that NICE technology appraisal guidance makes recommendations on the most cost-effective use of NHS resources but does not specify how to implement the guidance. It was also aware that the NICE Implementation Programme supports health and social care organisations to maximise the uptake and use of evidence and guidance. The Committee was further aware that ODEP, which is independent of NICE, currently provides the NHS with a list of prostheses that do or do not meet the standard for revision rates outlined in NICE technology appraisal guidance 2 and NICE technology appraisal guidance 44, and that there are initiatives to improve collecting and disseminating information on revision rates…. The Committee concluded that it would be reasonable to recommend prostheses with less than 10 years of data, provided that the revision rate was consistent with 5% or less at 10 years and that the recommendation could be implemented within the current support framework provided by ODEP. See also FAD section 5.

Nominating organisation	Comment	Response
British Hip Society	1.2 This recommendation is too naïve to be workable, would not necessarily lead to the lowest overall cost of arthroplasty for an institution, may reduce quality of service and ultimately patient safety. • Implants are modular and different combinations of stem/head/shell/liner are possible making comparisons extremely problematic. • Implant sale price usually includes provision of the instruments required to implant the prostheses; these are provided by companies on consignment. The cost also covers essential support, training and education. • Different brands of implants are not equally comprehensive in covering the needs of all patient groups. Where the range of implants offered is inadequate institutions will need to purchase outside the core contract with additional expense to hire instruments and buy implants. • There will be a significant cost to an institution in lost productivity when staff need training with a new device. We suggest the wording should be changed to: "*If more than one implant meets the above criteria the lowest price for implant usage for the whole range of implants required should be sought, this price to include identical specification in terms of instrument provision, training and institutional support*".	Comment noted. Section 1 has been amended. The recommendation specifying that 'If more than one type of prosthesis meeting the above criteria is suitable for a patient, the prosthesis with the lowest acquisition costs should be chosen' has been removed. The Committee concluded that, although the NHS should be mindful of costs, in situations where multiple prostheses with a revision rate of 5% or less at 10 years are suitable for a patient, it could not currently recommend selecting a prosthesis with the lowest acquisition cost (see FAD section 4.3.18).

Nominating organisation	Comment	Response
British Hip Society	2.2 A document called "Commissioning Guidance for Adult Hip Pain" is being prepared using NICE approved methodology by a collaboration between the BOA, BHS, RightCare, RCS England, CSP, BSR and RCGP. The document has been through public consultation and peer review and is to be signed off imminently by NHS England and the Royal College of Surgeons. This document defines best practice in investigation and treatment of adults with hip pain and should be referred to in this section.	Comment noted.
British Hip Society	3. Use of hip resurfacing implants has fallen to 1% of patients undergoing arthroplasty in 2012. Most orthopaedic surgeons carrying out arthroplasty have already abandoned use of resurfacing implants. Excellent results are reported from specialist centres in young and truly active patients, particularly males with large femoral heads.	Comment noted.
British Hip Society	4.1.14. There are publications refuting this finding on mortality (Hunt et al. 90-day mortality after 409 096 total hip replacements for osteoarthritis, from the National Joint Registry for England and Wales: a retrospective analysis. The Lancet, Volume 382, Issue 9898, Pages 1097 - 1104, 28 September 2013).	Comment noted. The Assessment Group did not assume a different mortality rate for people receiving resurfacing arthroplasty or THR in its cost effectiveness model. The Assessment Group used data from the Office for National Statistics on death rates in England and Wales to determine all-cause mortality by age (see FAD section 4.2.4)

Nominating organisation	Comment	Response
British Hip Society	4.1.16. Although data has been collected on the NJR since 2003 there were significant problems with compliance and incomplete data entry in the early years. There is still a problem of capturing revision data and accurate linkage with HES data. The magnitude of the problem is unknown. Recommending a 95% survival at 10 years may be too high and be shown to be unachievable as data capture in the NJR becomes more complete. **To-date the quality of NJR data collected in key areas has never been validated and the British Hip Society is profoundly concerned that NJR data should be used to define acceptable revision rates when the quality of the source data is simply not known.**	Comments noted. FAD section 4.3.5 states: The Committee noted the comments received on the appraisal consultation document, stating that there is a problem with an accurate link with Hospital Episode Statistics data, and that data on revision rates from the NJR had not been validated. The Committee concluded that it was appropriate to use both trial and observational data in its decision making, but that uncertainty resulting from the possibility of confounding should be taken into account. The Committee agreed that, although the NJR data had limitations, they are the most comprehensive data reflecting clinical practice in the NHS and therefore the most appropriate for decision making.
	4.1.22 Extrapolating revision rates beyond 9 years using NJR data is extremely problematic not only because the quality of the NJR data is unknown, but also because the mechanisms for failure of devices change with increasing follow-up; some mechanisms are unexpected and they cannot be predicted using early data (Exempli Grati: re-operation for problems with first generation polyethylene uncemented cups). 4.1.29 Existing NJR data are inadequate to predict revision rates and modes of failure into the second decade. 4.2. There are very many assumptions in these models particularly on costs of follow-up/ treatment of complications over the lifetime of the patient.	Comments noted. The Committee noted that the bathtub model, which it understood was widely used in manufacturing to describe device failure, assumed that risk of revision would decrease initially and then increase over time, whereas the log-normal and Weibull models assumed an increasing risk of revision over time. The Committee concluded that, of the 3 models presented to extrapolate revision rates beyond the 9-year follow-up of the NJR, the Assessment Group's bathtub extrapolation was the most plausible (FAD section 4.3.8). The bathtub model accounted for a higher rate of early revisions, which may reflect surgical complications or other factors unrelated to the prosthesis (FAD section 4.3.15).

Nominating organisation	Comment	Response
British Hip Society	4.3.5. Data quality for revision rates reported by the NJR has never been validated. See Comment on 4.1.16.	Comment noted. The Committee agreed that, although the NJR data had limitations, they are the most comprehensive data reflecting clinical practice in the NHS and therefore the most appropriate for decision making (FAD section 4.3.5).
	4.3.10 The clinical outcome in terms of PROM, complication rate and revision rate and the cost of revision surgery will be different depending on what type of hip replacement is revised and the indication for revision.	Comment noted. FAD section 4.3.10 states: The Committee concluded that it was plausible that people who had revision surgery would have a lower quality of life than people who had a successful primary hip replacement. It further concluded that, given the available evidence, it was not possible to determine how use of different types of hip replacement prostheses would affect quality of life.

Nominating organisation	Comment	Response
British Hip Society	4.3.11. See Comments in section 1.2. Empirical use of the list price of implants will be of almost no value in calculating the real cost to an institution of providing implants to fulfill all clinical needs. 4.3.15. New implants to the market should now be introduced according to the Beyond Compliance initiative driven by BOA/MHRA. (http://www.beyondcompliance.org.uk) 4.3.16 See comments on section 1.2.	Section 1 has been amended. The recommendation specifying that 'If more than one type of prosthesis meeting the above criteria is suitable for a patient, the prosthesis with the lowest acquisition costs should be chosen' has been removed. The Committee concluded that, although the NHS should be mindful of costs, in situations where multiple prostheses with a revision rate of 5% or less at 10 years are suitable for a patient, it could not currently recommend selecting a prosthesis with the lowest acquisition cost (see FAD section 4.3.18). Comment noted see FAD section 5 Comment noted see response to previous comments on section 1.2
Biomet (submitted via web comments)	Section 1 (Appraisal Committee's preliminary recommendations) "Biomet recognises the importance of NICE's role in improving outcomes for patients treated by the NHS and other public health and social care services. Biomet therefore agrees with the principle of the review that was undertaken by the Technology Appraisal Committee relating to total hip replacement and resurfacing arthroplasty in the NHS in England and Wales. Biomet welcomes the opportunity to provide comments on the preliminary recommendations and as a member of the Association of British Healthcare Industries (ABHI), Biomet supports the comments provided by ABHI on behalf of the industry. However, Biomet would like to take this opportunity to reinforce certain aspects of the ABHI response and provide additional commentary to the committee for consideration."	Comment noted. Comment noted.

Nominating organisation	Comment	Response
Biomet (submitted via web comments)	Section 4 (evidence and interpretation) The recommendations do not take into account confounding factors such as surgical technique, surgeon training and experience when choosing types of implants. Biomet takes its responsibility seriously to provide training, education and support on the safe and effective usage of its products. Biomet does not believe these have been adequately taken into consideration as a factor in the decision to select a particular prosthesis to ensure long-term dependable clinical outcomes for the patient.	Comments noted. FAD section 4.3.18 states: The Committee further concluded that the recommended standards for revision rate would encourage manufacturers to maintain training programmes to ensure the lowest revision rates possible for their products.
	Also absent are factors that would elicit information on the additional benefits of THR such as bone conservation and lower infection rate, these should not be ignored as they provide valuable insights on the quality of outcome for patients.	Comment noted. FAD section 4.3.10 states: [The Committee] further concluded that, given the available evidence, it was not possible to determine how use of different types of hip replacement prostheses would affect quality of life.
	We would like to highlight that while confounding factors including those mentioned above are not recorded in the NJR they can have a significant effect on the long-term clinical outcome for the patient. One particular confounding factor namely the practice of mixing and matching implants from different manufacturers might also lead to higher revision rates. We believe greater emphasis should be placed on analysis and management of confounding factors.	The Committee recognised that there was a need for further analysis of potential confounding factors (See FAD section 6 for further details of the Committee's research recommendations).

Nominating organisation	Comment	Response
Biomet (submitted via web comments)	Section 7 (proposed date for review of guidance) We were very disappointed by the fact that there were no practicing surgeon members of the BOA or BHS at the TAC meeting on the 18th September 2013. We support the ABHI in its suggestion for an independent expert opinion to be provided by these parties for the second committee meeting.	Comments noted. All non-manufacturer or non-sponsor consultees can nominate clinical specialists (see NICE Guide to the multiple technology appraisal process section 3.4.11) to present their personal views to the Appraisal Committee. For this appraisal no nominees were put forward by the British Orthopaedic Association or the British Hip Society to attend the appraisal committee meetings. However, the British Hip Society and the British Orthopaedic Association have provided responses to the appraisal consultation document and these were taken into account by the Committee in the second Committee meeting.

Comments received from commentators

Commentator	Comment	Response
ABHI	**ABHI Industry response to:** NICE Total hip replacement and resurfacing arthroplasty for the treatment of pain or disability resulting from end stage arthritis of the hip (Review of technology appraisal guidance 2 and 44) [ID540] ACD In response to the NICE consultation on its preliminary recommendations for total hip replacement and resurfacing arthroplasty for end-stage arthritis of the hip (review of TA guidance 2 and 44), the ABHI Orthopaedic Special Interest Section would like to make the following comments to the Technology Appraisal Committee (TAC) for their consideration. Firstly we were disappointed to note the absence of any practicing surgeon members of the British Orthopaedic Association (BOA) or British Hip Society (BHS) at the TAC meeting on 18th September 2013 when the Committee made its preliminary recommendations. It is critical that recommendations be appropriately informed through professional input across the range of clinical experience across different types of fixation and technology. To that end we feel strongly that the BOA and BHS should provide the TAC with independent expert opinion and very much hope the second committee meeting will take account of this point.	Comments noted: Comments noted. All non-manufacturer or non-sponsor consultees can nominate clinical specialists (see NICE Guide to the multiple technology appraisal process section 3.4.11) to present their personal views to the Appraisal Committee. For this appraisal no nominees were put forward by the British Orthopaedic Association or the British Hip Society to attend the appraisal committee meetings. However, the British Hip Society and the British Orthopaedic Association have provided responses to the appraisal consultation document and these were taken into account by the Committee in the second Committee meeting.

Commentator	Comment	Response
ABHI	In addition, the ABHI believe NICE's preliminary recommendations do not account for the importance of surgeon training and experience when choosing types of prostheses. The provision of training, education and support by the manufacturer is an important component of the decision to select a particular prosthesis to ensure long-term clinical outcomes for the patient and we do not consider that sufficient emphasis has been placed on this. We request that the Committee carefully consider this important aspect as context against which section 1.2 must be balanced when making its final recommendations to ensure the outcome is pragmatic and relevant to the NHS. Section 1.2 of the draft guidance currently recommends use of the prosthesis with the lowest acquisition cost. We believe that whilst this is one important factor for the NHS, patient characteristics, surgeon training and experience with a particular prosthesis and non-implant procedure costs (e.g. consumables and theatre time) should be taken into account in the guidance.	Comments noted. Section 1 has been amended. The recommendation specifying that 'If more than one type of prosthesis meeting the above criteria is suitable for a patient, the prosthesis with the lowest acquisition costs should be chosen' has been removed. The Committee concluded that, although the NHS should be mindful of costs, in situations where multiple prostheses with a revision rate of 5% or less at 10 years are suitable for a patient, it could not currently recommend selecting a prosthesis with the lowest acquisition cost (see FAD section 4.3.18).

Commentator	Comment	Response
MHRA	3. Technologies 3.1.– page 5 Text: *The head of the femur (thigh bone) is replaced with either a singlepiece* *metal stem and head or a modular component consisting of a* *metal stem with a metal, ceramic or ceramicised metal head.* **Comments:** Metal stems are available in various degrees of modularity and some text could be added to reflect this: The head of the femur (thigh bone) is replaced with either a singlepiece metal stem and head or a modular component consisting of a metal stem **(which may consist of more than one pieces)**, with a metal, ceramic or ceramicised metal head.	Comment noted. FAD section 3.1 has been updated to read: The head of the femur (thigh bone) is replaced with either a single-piece metal stem and head, or a modular component consisting of a metal stem (which may consist of more than 1 piece), with a metal, ceramic or ceramicised metal head.
MHRA	3. Technologies 3.2.– page 5 Text: *THRs may also vary by femoral head size, with a large head defined as being greater than, or equal to 36 mm.* **Comments:** The 36mm relates to the diameter of the femoral head. Therefore suggesting: THRs may also vary by femoral head size, with a large head defined as being greater than, or equal to 36 mm **in diameter.**	Comment noted. FAD section 3.2 has been updated to read: THRs may also vary by femoral head size, with a large head defined as being 36 mm or more in diameter.

Commentator	Comment	Response
MHRA	3. Technologies 3.8.– page 7 Text: *The average list prices for THRs across the manufacturers were: £1557 for cemented polyethylene-on-metal; £3016 for cementless polyethylene-on-metal; £3869 for cementless ceramic-on-ceramic; £2650 for hybrid polyethylene-on-metal and £1996 for cemented polyethylene-on-ceramic.* *Comments:* Current conventional description of the type of the THRs is head material/cup, not the other way around. Therefore suggesting changes as follows: The average list prices for THRs across the manufacturers were: £1557 for cemented **metal-on-polyethylene**; £3016 for cementless **metal-on-polyethylene**; £3869 for cementless ceramic-on-ceramic; £2650 for hybrid **metal-on-polyethylene** and £1996 for cemented ceramic-on-polyethylene.	Comment noted by the Committee. In the preparation of this FAD acronyms have not been used and the materials of the different components within the categories of total hip replacement considered by the assessment group have been detailed in full to avoid confusion.

Commentator	Comment	Response
Orthopaedic data evaluation panel	The comments from ODEP are summarised below, I believe a technical response has been received by the British hip society hence comments have been restricted to those relating to ODEP only. 1) Uncertainty regarding the reported figures on numbers of hips with ODEP rating that NICE have provided in section 1.7 of evaluation report. I have included a file detailing the numbers of hip products used according the latest NJR figures. 2) We would like to state that the NICE guidance is for Primary hips and hence ODEP ratings are for Primary hip stems and cups (or those where the main function is for primary hips) 3) ODEP would like more understanding regarding the 5% revision rate at 10 years as this appears to have been based upon extrapolated data from the NJR of England and Wales. 4) Understanding how re-evaluation is anticipated for all current 10A rated products (those meeting the current NICE standard) and how the committee would envisage ensuring end user confusion was minimised. ODEP are happy to discuss options for the introduction of a reduced revision rate benchmark and scoring requirements for achieving this rating. 5) The benchmarks for the current guidance as provided by ODEP relates to a benchmark for the femoral stem and acetabular cup as individual items, i.e. each gains a separate benchmark. It's uncertain if the committee's recommendations are requesting benchmarks for full systems or if the benchmark remains for individual items. Section 1.1.	Comments noted. FAD section 4.3.16: The Committee confirmed that the revision rate should apply to the prosthetic components as a whole in THR or resurfacing arthroplasty.

Comments received from members of the public

Role*	Section	Comment	Response
Healthcare other	1	"RS should not be treated as THR. RS should keep the current 10% @ 10 years. • NJR Data for RS is severely depleted by changes in clinical practise and by the devices that are currently available. • K-M CIs are wide and @ risk numbers are low. • Dislocation for THR are not reported as revisions, early neck fracture are for RS. • RS can and will be revised to THR and hence will always get a higher revision rate than THR. Activity levels can be higher with RS because it is expected to be revised. The complexity of revision has not been established for current clinical reviews as advised by NHRA/BOA. • Some RS revisions are due to adverse publicity surrounding MoM implants rather than clinical necessity. • The 10 years benchmark is arbitrary and does not predict behaviour past that point. All current polys have little more than 10 years clinical use. RS has the potential to outlast MoP and the best surviving MoM implants have 40+ years implantation. The 10 years experience of RS to today has been severely clouded by a large number of poor implants, poor surgery and patient selection and risks being judged unfairly with Conventional hips for the reasons given here. If 5% at 10 years is imposed RS will cease and the real test of time will be destroyed."	Comments noted. The Committee considered that, because all of the categories of THR prostheses for both populations had a predicted revision rate of less than 5% at 10 years, the value reflecting the new standard for THRs should be no higher than 5%. Additionally it considered that as the predicted revision rate of THR was less than 5% at 10 years in the population for whom both THR and resurfacing arthroplasty was suitable, the revision rate standard for resurfacing arthroplasty should be the same as that for THRs. See FAD section 4.3.14

* When comments are submitted via the Institute's web site, individuals are asked to identify their role by choosing from a list as follows: 'patent', 'carer', 'general public', 'health professional (within NHS)', 'health professional (private sector)', 'healthcare industry (pharmaceutical)', 'healthcare industry'(other)', 'local government professional' or, if none of these categories apply, 'other' with a separate box to enter a description.

Role*	Section	Comment	Response
	3	It is important, in informing the public, to clearly distinguish between large diameter MoM THR devices and MoM RS. Whilst the two types of device share some similarities, their performance is quite different. For example in general, revision rates increase with increasing head diameter for MoM THR whilst the inverse is seen with MoM RS.	Comments noted.

Role*	Section	Comment	Response
	4	"There is a lack of data for RS. Referenced papers compared products which do not meet the current NICE guidance. Follow-up was short on all studies. No data was reviewed (because it is not available) for the successful RS devices. All studies were conducted prior to the current follow-up guidance. Indications for RS have changed and we are aware of some well documented failures. The analysis does not compare RS to THR using current practice. Whilst the different demographic between RS and THR are included comparing the RS group to the THR by matching introduces bias because the high demand RS patients were not included in the THR cohort. The data is not available to make these comparisons at this time. Data (Benjamin-Lang et al, Bone Joint J 2013 vol. 95-B no. SUPP 15 13) is starting to emerge that RS has advantages over THR for some indications. Revision costs do not reflect less complex revisions associated with successful RS. Lifetime predications are impossible for these complex systems. We do not know the failure mode, the time to failure, the indications of failure, and the optimal time to revise. We do not know how current RS and newer THR devices compare because they have not had extended clinical use. Clinical audit was not mentioned. Similarly, increased levels of transparency are not evident. Uncertainties generated by the guidance are noted but are not manifest in the proposed guidance. 4.3.6"	Comment noted. The Committee noted the Assessment Group's concerns that the RCTs and systematic reviews it had identified involved small numbers of patients, had relatively short follow-up, reported different outcomes either incompletely or poorly, and were underpowered to detect differences in rates of revision (see FAD section 4.3.5). Comment noted. The Assessment Group modelled revision rates for both total hip replacement and resurfacing arthroplasty using data from the National Joint Registry. It performed additional analysis in which the revision rates were presented for men only and excluding the DePuy ASR resurfacing prosthesis which is no longer used (see FAD section 4.1.21). Comment on potential differences between people who receive total hip replacement and resurfacing arthroplasty noted. Section 4.3.6 of the FAD states: The Committee concluded that the Assessment Group's analysis of revision rates were consistent with published systematic reviews of trials, and controlled for some, but not all, potential confounders, notably activity level and comorbidities, and therefore uncertainty remained surrounding the relative revision rates between different types of prostheses. Comments on other uncertainties noted.

Role*	Section	Comment	Response
NHS Professional 1	1	"1.1 I am concerned with the proposal for allowing a projected rate of less than 5% at 10 years. If 10 year data is not available, I believe devices should only be considered as part of a proper trial, not for general use.	Comment noted. Section 4.3.15 of the FAD states: The Committee was aware that NICE technology appraisal guidance 2 and NICE technology appraisal guidance 44 considered it reasonable to recommend prostheses with a minimum of 3 years of experience, provided the projected revision rate was consistent with the standard recommended at that time; the Committee considered that this remained appropriate.
		1.2 The NJR has demonstrated that outlying surgeons are often those who frequently change from one device to another. Better results are undeniability achieved by repetition, that is using the same devices frequently and over a long time period. this proposal will lead to annual changes of implants and stock in hospitals due to small changes in the relative costs of implants. It does not take into account the complexities of cost banding for implants under National Procurement. Moreover, this proposal would favour a (cheaper) implant with a 4.9% failure rate over a (more expensive) one with a 1% failure rate at 10 years, even if the latter was only slightly more expensive. A more appropriate statement would be ""If more than one type of prosthesis meeting the above criteria is suitable for a patient, prostheses with the lowest acquisition costs should be considered, in the absence of any demonstrable advantage to using the more expensive."	Comments noted. Section 1 has been amended. The recommendation specifying that 'If more than one type of prosthesis meeting the above criteria is suitable for a patient, the prosthesis with the lowest acquisition costs should be chosen' has been removed. The Committee concluded that, although the NHS should be mindful of costs, in situations where multiple prostheses with a revision rate of 5% or less at 10 years are suitable for a patient, it could not currently recommend selecting a prosthesis with the lowest acquisition cost (see FAD section 4.3.18).

Role*	Section	Comment	Response
	3	3.3 All resurfacings are NOT cemented. They are hybrid or cementless.	Comment noted. FAD section 3.3 has been updated to read: All resurfacing arthroplasty prostheses currently on the market are metal-on-metal (MoM), and can be hybrid or cementless. As with THR prostheses, resurfacing arthroplasty prostheses may also vary by femoral head size.
NHS professional 2	1	"1.1 Suggest clarify revision rate quoted is where indication for surgery was osteoarthritis. 1.2 This recommendation is unworkable and, in any case, would not necessarily lead to the lowest overall cost of arthroplasty for an institution and may reduce quality of service and ultimately patient safety. Implants are modular and different combinations are possible with a vast array of expense making comparisons extremely problematic. Sale cost usually sponsors provision of instruments required on consignment, essential support, training and education . Different brands of implants are not equally comprehensive in covering the needs of all patient groups. Where the range of implants offered is inadequate institutions will need to purchase outside the core contract with additional expense. Suggest the wording should be changed to: ?If more than one implant meets the above criteria the lowest price for implant usage for the range of implants required should be sought, this price to include identical specification in terms of instrument provision, training and institutional support?."	Comment noted. The indication for surgery (end-stage arthritis) is included in recommendation 1.1 Comments noted. Section 1 has been amended. The recommendation specifying that 'If more than one type of prosthesis meeting the above criteria is suitable for a patient, the prosthesis with the lowest acquisition costs should be chosen' has been removed. The Committee concluded that, although the NHS should be mindful of costs, in situations where multiple prostheses with a revision rate of 5% or less at 10 years are suitable for a patient, it could not currently recommend selecting a prosthesis with the lowest acquisition cost (see FAD section 4.3.18).

Role*	Section	Comment	Response
	2	2.2 A document called 'Commissioning guidance for adult hip pain' is being prepared using NICE approved methodology by a collaboration between the BOA, BHS, RightCare, RCS England, CSP, BSR and RCGP. The document has been through public consultation and peer review and is to be signed off imminently by NHS England and the Royal College of Surgeons. This document defines best practice in investigation and treatment of adults with hip pain and should be referred to in this section.	Comment noted.
	3	"3. There is over-emphasis on the option of hip resurfacing in this guidance document. Use of hip resurfacing implants has fallen to 1% of patients undergoing arthroplasty in 2012. Most orthopaedic surgeons carrying out arthroplasty have already abandoned use of resurfacing implants.	Comments noted. As this guidance is a review of NICE technology appraisal guidance 2 and NICE technology appraisal guidance 44 (Hip disease- metal on metal resurfacing) the cost effectiveness of resurfacing arthroplasty was assessed. FAD section 4.3.2 states: The Committee heard from the Assessment Group's clinical adviser that the use of resurfacing prostheses has declined over the past few years, noting the Medicines and Healthcare products Regulatory Agency's alerts to recall some resurfacing prostheses and to monitor patients with metal-on-metal prostheses.
		3.2 Both cemented and uncemented implants can become osseointegrated with the host skeleton."	Comment noted.

Role*	Section	Comment	Response
	4	"4.1.14. The finding of the McMinn paper have been discredited and this citation should be removed (Hunt et al. 90-day mortality after 409 096 total hip replacements for osteoarthritis, from the National Joint Registry for England and Wales: a retrospective analysis. The Lancet, Volume 382, Issue 9898, Pages 1097 - 1104, 28 September 2013). 4.1.18. It is the clinical opinion of the British Hip Society that conventional THRs are suitable for all age groups of all activity levels when the operation is clinically indicated. 4.3.5. Data quality for revision rates reported by the NJR have never been validated.	Comment noted. The Assessment Group did not assume a different mortality rate for people receiving resurfacing arthroplasty or THR in its cost effectiveness model. The Assessment Group used data from the Office for National Statistics on death rates in England and Wales to determine all-cause mortality by age (see FAD section 4.2.4) Comment noted. Comments on NJR data noted. FAD section 4.3.5 states: The Committee noted the comments received during the consultation on the appraisal consultation document, stating that there is a problem with an accurate link with Hospital Episode Statistics data, and that data on revision rates from the NJR had not been validated. The Committee concluded that it was appropriate to use both trial and observational data in its decision making, but that uncertainty resulting from the possibility of confounding should be taken into account. The Committee agreed that, although the NJR data had limitations, they are the most comprehensive data reflecting clinical practice in the NHS and are therefore the most appropriate for decision making.

Role*	Section	Comment	Response
	4 continued	4.3.10 The clinical outcome in terms of PROM, complication rate and revision rate and the cost of revision surgery will be different depending on what type of hip replacement is revised and the indication for revision. Results of revision of resurfacing implants for Adverse Reaction to Metal Debris (ARMD) can be very poor. 4.3.11. See comments in section 1.2. Empirical use of the list price of implants will be of very limited value in calculating the real cost to an institution of providing implants to fulfill all clinical needs."	Comments noted. The Committee heard from the manufacturers that they expected the proportions of revisions not directly related to device failures to be similar across classes of hip replacement prostheses…. The Committee appreciated that the underlying reason for why a patient needed revision surgery may be difficult to identify and is not routinely recorded in the NJR(FAD section 4.3.7). FAD section 4.3.10 states: [The Committee] further concluded that, given the available evidence, it was not possible to determine how use of different types of hip replacement prostheses would affect quality of life. Comment noted please see response to comments on section 1.2 above.
	7	The orthopaedic specialty and surgeons specialising in hip arthroplasty do not seem to have representation on the Appraisal committee.	Comments noted. All non-manufacturer or non-sponsor consultees can nominate clinical specialists (see NICE Guide to the multiple technology appraisal process section 3.4.11) to present their personal views to the Appraisal Committee. For this appraisal no nominees were put forward by the British Orthopaedic Association or the British Hip Society to attend the appraisal committee meetings. However, the British Hip Society and the British Orthopaedic Association have provided responses to the appraisal consultation document and these were taken into account by the Committee in the second Committee meeting.

Role*	Section	Comment	Response
NHS professional 3	1	"I read with interest the appraisal consultation document on hip replacement. The second conclusion of the document states ""If more than one type of prosthesis meeting the above criteria is suitable for a patient, the prosthesis with the lowest acquisition costs should be chosen.""" In the current climate this tends to favour cemented rather than uncemented implants since generally they have lower costs. As a surgeon who performs not only primary but revision hip surgery, I recognise that my revision hip practice uses almost entirely uncemented prostheses (which reflects the pattern of surgery in the UK and abroad). I am concerned that if we outlaw the use of uncemented implants in primary hip surgery, which have an entirely different technique for implantation that this may have an implication for me keeping my skills for revision surgery to a high standard, and also has implications for the training of registrars. Presumably to learn to use uncemented implants for the purposes of revision surgery trainees will be forced to go abroad? There is already considerable pressure to drive down costs associated with all aspects of hip surgery. I am not sure it is necessary for NICE to dictate how much is spent on a hip implant."	Comments noted. Section 1 has been amended. The recommendation specifying that 'If more than one type of prosthesis meeting the above criteria is suitable for a patient, the prosthesis with the lowest acquisition costs should be chosen' has been removed. The Committee concluded that, although the NHS should be mindful of costs, in situations where multiple prostheses with a revision rate of 5% or less at 10 years are suitable for a patient, it could not currently recommend selecting a prosthesis with the lowest acquisition cost (see FAD section 4.3.18).
NHS professional 4	1	The term: end stage arthritis is inappropriate, emotional, probably taken from management of malignant disease. It gives no indication of pathology, radiographic morphology or the clinical problem. It merely appears to justify hip replacement.	Comment noted. During scoping for this appraisal the definition of end-stage was discussed after comments from consultees. It was agreed that for the purpose of this appraisal end stage arthritis of the hip should be defined as arthritis of the hip for which non-surgical management has failed.

Role*	Section	Comment	Response
	2	Failure: clinical, radiographic or revision not defined. All findings at revision must be recorded not merely indication for revision.	Comment noted. FAD section 6 details the Committee's research recommendations. FAD section 6.2 states: The Committee recommended the collection of data on prosthesis failure or on the prevalence of people living with a failed hip but for whom revision surgery is not suitable or who choose not to have revision surgery. The Committee further recommended that nomenclature for hip replacement failure needs to be established to allow demarcation of prosthesis-dependent and prosthesis-independent hip replacement failure. Furthermore, patient reported outcome measures collected as part of the National Joint Registry should allow for reporting of hip replacement failure in people who cannot or chose not to have revision surgery.
	3	Metal on metal articulation, anywhere, demands lubrication it also generates hard, abrasive metal wear particles. Ingress into the articulation and ejection under load bearing generates abrasive water jet with prssures twice the normal systolic blood pressure. The immediate effects are local and depend on severity and frequency of ejection episodes: approx 1.41 million per year. Higher incidence of problems in female patients explained by shorter stride for equivalent distance walked about 27% higher. Established in 1985 by comparing clinical and experimental wear rates in the Charnley LFA.	Comments noted.

Role*	Section	Comment	Response
	4	Clinical results do not reflect the mechanical state of the arthroplasty. Comparison of good quality serial radiographs is essential	Comments noted.
	7	Thank you very much for the opportunity to make some comments on the topic of hip replacement. Would be happy to offer information on the Charnley hip replacement spanning 50 years and a follow up past 40years.Results of research on M/M hip resurfacing: Bone &Joint Research Vol 1 No3 March 2012 p25-30.	Comments noted.
NHS Professional 5	1	"1. When recommending a specific implant the bearing combination and patient demographics should also be taken into account. Cemented hips do better in the elderly or poor quality bone but cementless implants do better in patients who will live more than 10 years (Swedish Hip Joint Registry). 2. Dislocation is the commonest complication in the elderly. Whilst a cemented implant will be cheaper than a hybrid (equivalent survivorship), the operation complication rate will be lower with a hybrid as larger articulating heads, dual mobility and constrained liner options will be available to prevent dislocation. 3. When comparing cemented with cementless implants the extra cost of cement, mixing system, femoral tamp, femoral cement restrictor, disposable cement pressurisers, cement gun,lavage system and extra time in theatre for cemented implants should be taken into account as these items are not used in cementless implants. Whilst an isolated cemented prosthesis may be cheaper than a cementless one the total cost of the operation will be the same or even more expensive. It is the cost of the whole operation that is important not the isolated implants."	Comments noted. FAD section 4.3.2 states: The Committee concluded that both THR and resurfacing arthroplasty are options for treatment of end-stage arthritis of the hip, and that clinicians consider together with patients the factors associated with the risk of revision when choosing the most appropriate procedure. FAD section 4.3.3 states: The Committee understood that surgeons tend to choose not only the type but also the brand of hip prosthesis which a patient receives, and that this is driven by factors including the surgeon’s training, perception of which prostheses perform best, clinical data and experience using different prostheses, among other factors.

Role*	Section	Comment	Response
	2	"The National Joint Registry only provides data up to 9 years and does not go into as much detail on specific implants as the Swedish, Norwegian or Australian Regsitries. The data from these registries should be taken into account as they are relevant to UK practice and contain information that the UK NJR does not cover. Manufacturers are able to submit internal data with no transparency or peer review of their data. This is open to concealment on the part of manufacturers and compromises ODEP credibility. All manufacturer submitted data should be available for scrutiny openly."	Comments on implementation noted.
NHS Professional 6	1	"Whilst I do practice what is being proposed, I do not believe that it is appropriate for the whole of the NHS or UK. If the use of implants is restricted to those with a revision rate of better than 5% at 10 years, there will be no way to adopt new procedures within the UK, stifling both clinical advances and industrial development. It would be better to allow new implants to be used, but in clinical trials, probably sponsored by, but independent of the industry. With regards the choice of implant, surgeon familiarity with the implant needs to be accounted for. The small difference in cost of one implant to another (of similar types) is quickly negated if one implant is more difficult to implant, takes longer, or a complication has to be treated (such as fracture, of malalignment). Current registry data does not take into account what was intended to be implanted, but what was implanted, skewing some data."	The recommendation in section 1 of the FAD allows for prostheses with less than 10 years of data on revision rates to be used as long if the projected rates of revision are 5% or less at 10 years. Comments noted on additional potential confounding factors. FAD section 4.3.6 states: The Committee concluded that the Assessment Group's analysis of revision rates were consistent with published systematic reviews of trials, and controlled for some, but not all, potential confounders, notably activity level and comorbidities, and therefore uncertainty remained surrounding the relative revision rates between different types of prostheses.

Role*	Section	Comment	Response
	7	With a lack of orthopaedic representation, and minimal surgical guidance, I hope that the technical aspects of the operation have been appreciated. While the cost of the implant is easy to see, and outcomes as measured by registries or clinical trials can allow for some form of measurement, many other factors are taken into account by the surgeon in choosing an implant. For instance, many trials do not look at infection as a failure, yet may be lower with cemented vs uncemented implants. Also many of my colleagues tell me that one kind of implant is quicker to insert than another, allowing greater productivity, and therefore income for the hospital. Therefore while I am an advocate of costs being controlled, (and have a reputation in the hospitals where I work of caring about such things) it needs to take account of local factors as well.	Comments noted. The Assessment Group received advice from its clinical adviser during preparation of the assessment report. FAD section 4.3.3 states: The Committee understood that surgeons tend to choose not only the type but also the brand of hip prosthesis a patient receives, and that this is driven by factors including the surgeon's training, perception of which prostheses perform best, clinical data and experience using different prostheses, among other factors. Comments on cost noted.The Committee noted that the Assessment Group had used published literature to determine surgical costs and had assumed that these would be the same for resurfacing arthroplasty and THR. The Committee also noted that 1 manufacturer (DePuy Synthes) had carried out a costing study to estimate time in surgery and consumables, and that the manufacturer stated that procedure costs differed for resurfacing arthroplasty and for THR, and between various types of THR. The Committee heard from the manufacturers that the cost of a prosthesis may be a small proportion of the tariff paid by the NHS for a hip replacement. The Committee noted that the cost of a prosthesis is included in the fixed NHS tariff… Where multiple prostheses with a revision rate of 5% or less at 10 years are suitable for a patient, [the Committee] could not currently recommend selecting a prosthesis with the lowest acquisition cost (see FAD section 4.3.18).

Role*	Section	Comment	Response
Other 1	1	"1.1. I would add: 'when used in a normal population, in primary cases'. This would allow for different designs to be used in, for example, risk of dislocation, or series where a high proportion of unusual cases (eg CDH) were carried out. 1.2 I would add: within a 10% margin (this allows for habitual use of a particular design with surgeon experience or preference for a specific clinical reason."	Comment noted. The definition of end-stage used in this appraisal is arthritis for which non-surgical management has failed therefore it is implicit that the recommendation refers to primary prostheses. Comment noted. After consultation on the preliminary recommendations in the appraisal consulation document recommendation 1.2 was removed.
	2	apart from modifying the figures in 2.4 (to agree with a 5% 10 year revision)I agree with above.	Comment noted. The figures in 2.4 refer to the standards recommended in NICE technology appraisal guidance 2 and NICE technology appraisal guidance 44; the revision rate standard has been updated in this MTA review
	3	Item 3.6 does not make sense, because Surface Replacements are likely to have a higher failure rate than standard designs. There are better 'conservative' options than surface replacement. My suggestion is that surface replacements be put on some special clinical trial regime, because of their unpredictability.	Comment noted. Resurfacing arthroplasty prostheses which have the clinical evidence to support a revision rate of predicted revision rate of 5% or less at 10 years are recommended.
	4	would recommend a date after AAOS 2014, so that any new data at that meeting can be accounted for.	The guidance on this technology will be considered for review in February 2017.
	7	a rep from the EORS (European Orthopaedic Research Society) or possibly EFORT should be considered. This will provide a European experience and perspective.	Comment noted.
NHS	1	All very sensible	Comment noted.

Role*	Section	Comment	Response
Professional 7	2	ODEP is probably too generous for historical reasons as the times record a failure rate of 1% per annum or 10% at 10 years. It is not logical to recommend a device with a 7% failure at 7 years when the general recommendation is 5% at 10	Comment noted. ODEP's revision rate standards are based on the standards recommended in NICE technology appraisal guidance 2 and NICE technology appraisal guidance 44; The revision rate standard has been updated in this appraisal (see FAD section 1).. It is anticipated that ODEP will review its entry benchmarks following the updated recommendations (see section 5 of the FAD)
	4	The Swedish Hip Registry is empirical data and probably more relaible than modelling or extrapolating from 9 year NJR and Australian data. There is no mention of Scottish Arthroplasty Project data of which is current and more consistent with practice in England and Wales than Scandinavian or Antipodean. Cemented and uncemented stems are comparable in the Swedish Hip Registry at 15 years but the higher rate of failure of uncemented cups with polyethylene liners is not mentioned.	Comments noted.
		There seems to be an overemphasis on resurfacing which is now a very rare procedure and little on other harder bearing tribology such as ceramic and cross linked polyethylene.	Comment noted. This guidance is a review of NICE technology appraisal guidance 2: hip disease- replacement prostheses and NICE technology appraisal guidance 44: hip disease-metal on metal resurfacing.
		The use of uncemented devices in the elderly is growing and there is good evidence that in the over 70s, any late benefit will be negated by death of the patient.	Comment noted.

Role*	Section	Comment	Response
Other 2	notes	As designers of the Birmingham Hip Resurfacing, we have read the consultation document with interest. Whilst the aims of the consultation are laudable we are concerned that the interests of our young active adult patients have not been adequately represented and through no fault of The Committee have in fact been misrepresented in the popular Press.	Comments noted.
		When we embarked upon designing a hip resurfacing in 1989, even in the best hands the 20 year implant survival of THR in younger patients with OA was 50% and the best hip resurfacing system survival was only 50% at 5 years. In 2013 males under the age of 65 implanted with a BHR have a 96% 10-yr survival in The Australian Registry and recently published 100% survival has been seen in designer hands at 14 years.	Comment noted.
		The indications, technique and contraindications for BHR have now been clearly defined and there is no reason to suppose that in competent trained hands that a less than 5% failure at 10 years should be expected. Hip resurfacing is for selected patients and certainly not for all patients, all centres or all surgeons.	Comment noted.
		Rather than dwell on the results of BHR we would ask The Committee to focus on Mortality following Hip Replacement and Resurfacing. We published on this subject in BMJ 2012. This made uncomfortable reading for some sectors of our profession as one of the conclusions it drew was that cemented THR may carry a significant mortality burden compared with hip resurfacing. As we acknowledged in our paper, we were constrained by a limited number of variables and residual confounding may have remained. However recently another more detailed study from an independent institution has provided external validation of our work and will shortly be published but not perhaps before the deadline of the Committee's deliberations.	Comments noted. Safety is outside the remit of a NICE technology appraisal. Guidance can only be issued in accordance with CE markings.

Role*	Section	Comment	Response
	notes	The covariables studied in the mortality papers are more numerous and detailed than those used for adjustment of implant survival outcomes. If we are to be led to believe that unrecognised confounders nullify a Hazard Ratio of 1.8 for mortality of THR compared to BHR, then we cannot be seriously expected to accept 2-3% differences in implant survival based on weaker data. Whilst the recent Lancet article provides some reassurance to patients in the short term, it does not address concerns about the longer term. In view of the potential gravity of the situation, we have taken the unusual step of contacting the members of The Committee directly to avoid the possibility of overenthusiastic censoring of information they may receive. It would be more than unfortunate if only days after their deliberations, no doubt endorsing the cheaper and admittedly comparatively revision-free cemented hip, it transpired that the NICE recommendations were in fact sending prospective patients to an unnecessarily early grave We urge the Committee to take into account the terrible social and economic toll associated with premature death when performing cemented THR instead of resurfacing in younger patients. Reference list not reproduced here	Comments noted. Safety is outside the remit of a NICE technology appraisal. Guidance can only be issued in accordance with CE markings.