Comments on the ACD Received from the Public through the NICE Website

Name	
Role	Healthcare Other
Location	Wales
Conflict	Yes
Comments on individual sections of the ACD:	
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."
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. 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. 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.
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.
Date	9 November 2013

Name	
Role	Healthcare Other

Location	England
Conflict	yes
Notes	MatOrtho is the manufacturer of ADEPT
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	"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."
Section 3 (The technologies)	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.
Section 4 (Evidence and interpretation)	"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"
Date	8 November 2013

Name	
Role	NHS Professional
Other role	Clinical Director
Location	N Ireland
Conflict	No
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	"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. 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."
Section 3 (The technologies)	3.3 All resurfacings are NOT cemented. They are hybrid or cementless.
Date	8 November 2013

Name	
Role	NHS Professional
Other role	President British Hip Society
Location	England
Conflict	yes
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's	"1.1 Suggest clarify revision rate quoted is where indication for surgery was osteoarthritis.

preliminary recommendations)	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?."
Section 2 (Clinical need and practice)	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.
Section 3 (The technologies)	"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. 3.2 Both cemented and uncemented implants can become osseointegrated with the host skeleton."
Section 4 (Evidence and interpretation)	"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. 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."
Section 7 (Proposed date for review of guidance)	The orthopaedic specialty and surgeons specialising in hip arthroplasty do not seem to have representation on the Appraisal committee.
Date	4 November 2013

Name	
Role	NHS Professional
Location	England
Conflict	no
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	"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."
Date	28 October 2013

Name	
Role	NHS Professional
Location	England
Conflict	no
Notes	Director: The John Charnley Reseach Institute Wrightington Hospital. WN6 9EP
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	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.

Section 2 (Clinical need and practice)	Failure: clinical, radiographic or revision not defined. All findings at revision must be recorded not merely indication for revision.
Section 3 (The technologies)	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.
Section 4 (Evidence and interpretation)	Clinical results do not reflect the mechanical state of the arthroplasty. Comarison of good quality serial radiographs is essential
Section 7 (Proposed date for review of guidance)	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.
Date	27 October 2013

Name	
Role	NHS Professional
Location	Wales
Conflict	yes
Notes	"Educational courses on Hip replacement surgery. Involved in design of revision acetabular cup augments as part of an international team of surgeons with Depuy Synthes."
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	"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."

Section 2 (Clinical need and practice)	"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."
Date	25 October 2013

Name	
Role	NHS Professional
Location	England
Conflict	no
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	"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."
Section 7 (Proposed date for review of guidance)	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
Date	25 October 2013

Name	
Role	other

Other role	Professor Orthopaedic Surgery & Mech Eng
Location	US
Conflict	no
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	"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."
Section 2 (Clinical need and practice)	apart from modifying the figures in 2.4 (to agree with a 5% 10 year revision)I agree with above.
Section 3 (The technologies)	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.
Section 4 (Evidence and interpretation)	would recommend a dat after AAOS 2014, so that any new data at that meeting can be accounted for.
Section 7 (Proposed date for review of guidance)	a rep from the EORS (European Orthopaedic Research Society) or possibly EFORT should be considered. This will provide a European experience and perspective.
Date	25 October 2013

Name	
Role	NHS Professional
Location	England
Conflict	no
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	All very sensible
Section 2 (Clinical need and practice)	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
Section 4 (Evidence and interpretation)	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. 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. 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.

Date	25 October 2013

Name	McMinn Centre
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.[1] 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%[2] 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.[3] 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.[4] Hip resurfacing is for selected patients and certainly not for all patients, all centres or all surgeons. Rather than dwell on the results of BHR[5], we would ask The Committee to focus on Mortality following Hip Replacement and Resurfacing. We published on this subject in BMJ 2012.[6] 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[7] 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. 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[8] 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. [redacted] MD FRCS (Orth) [redacted] MD FRCS [redacted] BHR [1] http://www.telegraph.co.uk/health/nhs/10406198/NHS-hospitals-to-be-banned-from-fitting-metal-on-metal-hip-replacements-after-high-failure-rate.html [2] Joshi ANB, Porter ML, Trail IA, et al. Long-term results of Charnley low-friction arthroplasty in young patients. J Bone Joint Surg [Br] 1993;75-B:616-23. [3] Matharu GS, McBryde CW, Pynsent WB, Pynsent PB, Treacy RB. The outcome of the Birmingham Hip Resurfacing in patients aged < 50 years up to 14 years post-operatively. Bone Joint J. 2013 Sep;95-B(9):1172-7 [4] http://www.mcminncentre.co.uk/research-lectures-15-year-results.html [5] McMinn DJ, Daniel J, Ziaee H, Pradhan C. Indications and results of hip resurfacing. Int Orthop. 2011 Feb;35(2):231-7 [6] McMinn DJ, Snell KI, Daniel J, Treacy RB, Pynsent PB, Riley RD. Mortality and implant revision rates of hip arthroplasty in patients with osteoarthritis: registry based cohort study. BMJ. 2012 Jun 14;344:e3319 [7] A. Judge, A. Kendal, D. Prieto-Alhambra, N.K. Arden, A. Carr Mortality following elective total hip replacement and hip resurfacing. Osteoarthritis and Cartilage Volume 21, Supplement , Page S162, April 2013. [8] Hunt LP, Ben-Shlomo Y, Clark EM, Dieppe P, Judge A, MacGregor AJ, Tobias JH, Vernon K, Blom AW; National Joint Registry for England, Wales and Northern Ireland. Lancet. 2013 Sep 28;382(9898):1097-104. doi: 10.1016/S0140-6736(13)61749-3. 90-day mortality after 409,096 total hip replacements for osteoarthritis, from the National Joint Registry for England and Wales: a retrospective analysis.
Location	England
Date	7 November 2013

[1] http://www.telegraph.co.uk/health/nhs/10406198/NHS-hospitals-to-be-banned-from-fitting-metal-on-metal-hip-replacements-after-high-failure-rate.html

[2] Joshi ANB, Porter ML, Trail IA, et al. Long-term results of Charnley low-friction arthroplasty in young patients. J Bone Joint Surg [Br] 1993;75-B:616-23.

[3] Matharu GS, McBryde CW, Pynsent WB, Pynsent PB, Treacy RB. The outcome of the Birmingham Hip Resurfacing in patients aged < 50 years up to 14 years post-operatively. Bone Joint J. 2013 Sep;95-B(9):1172-7

[4] http://www.mcminncentre.co.uk/research-lectures-15-year-results.html

[5] McMinn DJ, Daniel J, Ziaee H, Pradhan C. Indications and results of hip resurfacing. Int Orthop. 2011 Feb;35(2):231-7

[6] McMinn DJ, Snell KI, Daniel J, Treacy RB, Pynsent PB, Riley RD. Mortality and implant revision rates of hip arthroplasty in patients with osteoarthritis: registry based cohort study. BMJ. 2012 Jun 14;344:e3319

[7] A. Judge, A. Kendal, D. Prieto-Alhambra, N.K. Arden, A. Carr Mortality following elective total hip replacement and hip resurfacing. Osteoarthritis and Cartilage Volume 21, Supplement , Page S162, April 2013.

[8] Hunt LP, Ben-Shlomo Y, Clark EM, Dieppe P, Judge A, MacGregor AJ, Tobias JH, Vernon K, Blom AW; National Joint Registry for England, Wales and Northern Ireland. Lancet. 2013 Sep 28;382(9898):1097-104. doi: 10.1016/S0140-6736(13)61749-3. 90-day mortality after 409,096 total hip replacements for osteoarthritis, from the National Joint Registry for England and Wales: a retrospective analysis.