<u>Comments from the British Hip Society on</u>:

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]

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)

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*".

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.

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.

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).

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.

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.

4.3.5. Data quality for revision rates reported by the NJR has never been validated. See Comment on 4.1.16.

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.

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.