NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

GUIDANCE EXECUTIVE (GE)

Technology Appraisal Review Proposal paper

Review of TA304; Arthritis of the hip (end stage) – hip replacement (total) and resurfacing arthroplasty

Original publication date:	January 2014
Review date	February 2017
Existing recommendations:	Optimised To see the complete existing recommendations and the original remit for TA2 & TA44, see Appendix A.

1. Proposal

The guidance should be transferred to the 'static guidance list'. That we consult on this proposal.

2. Rationale

The recommendations of Technology Appraisal 304 (TA304) focussed on the acceptable 10 year revision rate for prostheses. The search strategy from the original Assessment Group report was re-run, with modifications, on the Cochrane Library, Medline, Medline In-Process and Embase. References from November 2012 onwards were reviewed. Additional searches of clinical trials registries and other sources were also carried out.

Numerous studies investigating the revision rates associated with particular brands of prosthesis, methods of fixation or bearing surface were identified in the systematic literature review. However, the National Joint Registry (NJR) remains the most comprehensive source of data in this area. The NJR's 2016 report showed that for the whole cohort of people receiving a hip replacement between April 2013 and December 2015, the cumulative probability of revision at 10 years was 5.39%. The probability of revision was lowest for cemented prostheses (3.07% at 10 years) and a recent study using the NJR data (Jameson et al., 2015) found uncemented prostheses were associated with significantly higher risk of revision than cemented prostheses for people over 60 years old. This data is consistent with the evidence considered by the committee during TA304.

As part of TA304, the committee considered making recommendations for particular categories of prostheses based on the point estimate reflecting the average revision rate of multiple brands of prostheses within a category. However, it 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. The NJR report presents revision rates for the most frequently used brands within the different prostheses categories. This shows that there remains variation in the cumulative probability of revision at 10 years between brands within a category.

Across all types of fixation method, metal on metal bearings have a cumulative probability of revision at 10 years in excess of 5% (range 16.57%-18.75%), according to the NJR data. A number of studies associating metal on metal implants with a range of adverse events and high revision rates were identified in the systematic literature review. However, it is also noted in the NJR report that the use of metal on metal prostheses for total hip replacement has virtually ceased (n=5 in 2015) and that resurfacing arthroplasty (which only uses metal on metal components), has also declined substantially, accounting for only 0.9% of implants in 2015.

The committee recommended that research should be carried out to determine the relationship between activity and prosthesis failure. The systematic literature review did not identify any studies that attempted to directly answer this question. However, a number of studies focussed on outcomes of hip replacement in younger age groups. For example, a 2016 meta-analysis of people under 30 that received a total hip replacement found a revision rate of 5% at 8.4 years (Walker et al, 2016). This is broadly comparable to the revision rate in the general population.

The Orthopaedic Data Evaluation Panel (ODEP) registry continues to collect data on the performance of individual products against this 10 year bench mark in line with the recommendations of TA304. This means that the NHS in England is able to identify which individual brands of prostheses meet the benchmark. There have been no changes to the CE marked indications for use of any of the interventions included in TA304. Several new prostheses have been CE marked since the publication of guidance, but the current recommendations could be applied to them so the presence of new devices would not necessarily require the guidance to be updated.

Overall, no new evidence or ongoing research has been identified that is likely to alter the conclusions of the guidance (that is, lead to change in clinical and cost effectiveness of treatment).

3. Summary of new evidence and implications for review

Has there been any change to the price of the technology(ies) since the guidance was published?
Due to the large number of hip prostheses on the market and the nature of the NHS Supply Chain arrangements for procuring prostheses for use in the NHS, it is difficult to ascertain the exact prices of the technologies. However, some of the manufacturer consultees submitted prices for the most commonly used prostheses. These prices were broadly in line with those used in TA304, suggesting that there has not been any significant changes in the prices of the technologies since the guidance was published.

Are there any existing or proposed changes to the marketing authorisation that would affect the existing guidance?
There have been no changes to the CE marked indications for use of any of the interventions included in TA304 and none are anticipated.
Were any uncertainties identified in the original guidance? Is there any new evidence that might address this?
The committee concluded that there remained uncertainty surrounding the relative revision rates between different types of prostheses. While the Assessment Group's analysis had controlled for some potential confounders, it had not controlled for activity or comorbidities. The committee recommended that research should be carried out to determine the relationship between activity and prosthesis failure. The systematic literature review did not identify any studies which attempted to directly address this question. No registered and unpublished trials were identified by Information Services that may address the uncertainties in the original guidance.
Are there any related pieces of NICE guidance relevant to this appraisal? If so, what implications might this have for the existing guidance?
See Appendix C for a list of related NICE guidance.
Additional comments
None.

4. Equalities issues

No equality and diversity issues were raised in the original guidance.

GE paper sign off: **Meindert Boysen, 20 January 2017**

Contributors to this paper:

Information Specialist: Toni Shaw

Technical Analyst: Ross Dent

Technical Adviser: Martyn Burke

Associate Director: Linda Landells

Project Manager: Samantha Shannon

CCP input Rupert Franklin

Appendix A – Information from existing guidance

5. Original remit

To appraise the clinical and cost effectiveness of total hip replacement and surface replacement within their CE marked indications for the treatment of pain or disability resulting from end stage arthritis of the hip.

6. Current guidance

1.1 Prostheses for total hip replacement and resurfacing arthroplasty are recommended as treatment options for people with end-stage arthritis of the hip only if the prostheses have rates (or projected rates) of revision of 5% or less at 10 years.

7. Research recommendations from original guidance

6.1 The Committee recommended that research should be carried out to determine the relationship between activity and prosthesis failure.

6.2 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 choose not to have revision surgery.

8. Cost information from original guidance

“The average list prices for THRs across the manufacturers were: £1557 for a cemented polyethylene cup plus a metal head; £3016 for a cementless metal cup with a polyethylene liner plus a metal head (cementless stem); £3869 for a cementless metal cup with a ceramic liner plus a ceramic head (cementless stem); £2650 for hybrid cementless metal cup with a polyethylene liner plus a metal head (cemented stem); and £1996 for cemented polyethylene cup with ceramic head (cemented stem). The average list price for resurfacing arthroplasty prostheses across the manufacturers was £2672. Typically, the price of hip replacement prostheses depends on the volume ordered and locally negotiated discounts, so the prices paid by the NHS are routinely lower than the list prices listed above.”

Appendix B – Explanation of options

When considering whether to review one of its Technology Appraisals NICE must select one of the options in the table below:

Options	Consequence	Selected – 'Yes/No'
A review of the guidance should be planned into the appraisal work programme. The review will be conducted through the specify STA or MTA process.	A review of the appraisal will be planned into the NICE's work programme.	No
The decision to review the guidance should be deferred to specify date or trial.	NICE will reconsider whether a review is necessary at the specified date.	No
A review of the guidance should be combined with a review of a related technology appraisal. The review will be conducted through the MTA process.	A review of the appraisal(s) will be planned into NICE's work programme as a Multiple Technology Appraisal, alongside the specified related technology.	No
A review of the guidance should be combined with a new technology appraisal that has recently been referred to NICE. The review will be conducted through the MTA process.	A review of the appraisal(s) will be planned into NICE's work programme as a Multiple Technology Appraisal, alongside the newly referred technology.	No
The guidance should be incorporated into an on-going clinical guideline.	The on-going guideline will include the recommendations of the technology appraisal. The technology appraisal will remain extant alongside the guideline. Normally it will also be recommended that the technology appraisal guidance is moved to the static list until such time as the clinical guideline is considered for review. This option has the effect of preserving the funding direction associated with a positive recommendation in a NICE technology appraisal.	No

Appendix B

Options	Consequence	Selected – 'Yes/No'
The guidance should be updated in an on-going clinical guideline[1].	Responsibility for the updating the technology appraisal passes to the NICE Clinical Guidelines programme. Once the guideline is published the technology appraisal will be withdrawn. Note that this option does not preserve the funding direction associated with a positive recommendation in a NICE Technology Appraisal. However, if the recommendations are unchanged from the technology appraisal, the technology appraisal can be left in place (effectively the same as incorporation).	No
The guidance should be transferred to the 'static guidance list'.	The guidance will remain in place, in its current form, unless NICE becomes aware of substantive information which would make it reconsider. Literature searches are carried out every 5 years to check whether any of the Appraisals on the static list should be flagged for review.	Yes
The guidance should be withdrawn	The guidance is no longer relevant and an update of the existing recommendations would not add value to the NHS. The guidance will be stood down and any funding direction associated with a positive recommendation will not be preserved.	No

[1] Information on the criteria for NICE allowing a technology appraisal in an ongoing clinical guideline can be found in section 6.20 of the guide to the processes of technology appraisal.

1. Appendix C – other relevant information Relevant Institute work

Published

Hip fracture: management (2011, last updated 2014) NICE guideline CG124. A partial update is in progress, expected April 2017.

Hip fracture in adults (2012) NICE quality standard 16. An update is in progress, expected November 2016.

Minimally invasive total hip replacement (2010) NICE interventional procedures guidance 363.

Osteoarthritis: care and management (2014) NICE guideline CG177.

2. Details of new products

Below is a list of manufacturers who have products found in the Supply Chain Catalogue or on the National Joint Registry and were not listed in the original guidance set of consultees and commentators:

- Adler Ortho
- Arthrex
- Aquilant orthopaedics
- Matortho
- Microport orthopaedics
- Orthimo
- Sheffield Medical Products
- Evolutis
- FH orthopaedics
- Van Straten Medical

3. Registered and unpublished trials

Trial name and registration number	Details
None	

4. Relevant services covered by NHS England specialised commissioning

The NHS England Manual for Prescribed Specialised Services 2016/17 says the following is classed as 'specialist commissioning':

> *Hip – secondary or tertiary referred revisions; primary revision (all stages); infected revision; replacement requiring modular prosthesis; massive acetabular defects requiring bone grafting or metal augmentation; complex femoral reconstructive segmental reconstruction.*

NHS England does not routinely commission resurfacing, although as this is stated in a 2013 document still live on the website this may no longer be applicable:

Hip resurfacing is regarded as a procedure of low clinical priority and therefore not routinely funded by the Commissioner.

Appendix D – References

Jameson S et al. (2015) Implant optimisation for primary hip replacement in patients over 60 years old with osteoarthritis: A cohort study of clinical outcomes and implant costs using data from England and Wales. *PLoS ONE.* 10 (11): e0140309

National Joint Registry (2016) National Joint Registry for England, Wales, Northern Ireland and the Isle of Man: 13th Annual Report.

Walker RP et al. (2016) Functional outcomes of total hip arthroplasty in patients aged 30 years or less: A systematic review and meta-analysis. *HIP International.* 26 (5): 424-431