NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Health Technology Appraisal

Total hip replacement and surface replacement for the treatment of pain resulting from end stage arthritis of the hip (Review of technology appraisal guidance 2 and 44)

Draft scope

Appraisal objective/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 resulting from end stage arthritis of the hip[*].

Background

Arthritis is a group of diseases that affect joints, leading to pain and disability. Osteoarthritis is the most common form of arthritis, where there is loss of cartilage at the end of the joints and accompanying changes in the end of the bones. Osteoarthritis is more common in women than men and the risk of developing osteoarthritis increases with age. In 2006 it was estimated that 414,900 men and 760,400 women consulted their GPs with osteoarthritis. Rheumatoid arthritis is an autoimmune disease causing inflammation of joints and is the second most common form of arthritis with approximately 400,000 people affected in the UK. Rheumatoid arthritis is approximately three times more common in women than men.

Osteoarthritis of the hip is the most common reason for having a hip replacement. In 2006/7 94% of primary hip replacements were of hips that were affected by osteoarthritis. In 2011 there were 57,745 hip procedures carried out in the NHS in England and Wales, with a further 25,138 carried out in independent hospitals.

NICE Clinical Guideline 59 on the care and management of osteoarthritis in adults says that referral for joint replacement surgery should be considered for people with osteoarthritis who experience pain, stiffness and reduced function that have a substantial impact on their quality of life and are refractory to non-surgical management such as exercise and manual therapy, and pain management.

[*] The remit of TA2 was "to provide guidance on the selection of hip prostheses for primary total hip replacement (THR)" and the remit of TA44 was "to establish the clinical and cost effectiveness of metal-on-metal hip resurfacing for younger or more active people with disease of the hip, and in particular on the factors which should determine the choice between (a) hip resurfacing, (b) total hip replacement, and (c) watchful waiting, and to produce guidance to the NHS in England and Wales".

People with arthritic damage to their hip may receive total replacement of the damaged hip with a metal alloy or ceramic prosthesis, which may include a polyethylene component and may be fixed in position using cement, be cementless or be a hybrid where one component of the prosthesis requires cement but the other does not. Surgeons may use combinations of cups and stems made by different manufacturers. Alternatively, patients may receive hip resurfacing which involves removing damaged surfaces of the bones inside the hip joint and replacement with a metal surface. Hip resurfacing is less invasive than a total hip replacement and can result in a greater range of movement after surgery, but requires the patient to have relatively strong bones, therefore tends to be used in younger, more active patients. In 2010 out of the 68,907 primary hip procedures, 36% were cemented total hip replacements (THRs), 43% were cementless THRs and 16% were hybrids, 3% were large head metal on metal THRs and 3% were resurfacing.

Currently artificial hip joints last on average for 10 to 15 years. Some hip replacements require revision surgery because of loosening of the joint, wear and tear, pain and dislocation. Current NICE guidance says that the best prostheses should demonstrate a 'benchmark' revision rate of 10% or less at 10 years or, as a minimum, a three year revision rate consistent with this benchmark.

In June 2012, the Medicines and Healthcare Regulatory Agency (MHRA) released an updated alert that Metal on Metal (MoM) implants (total hip replacements or resurfacing) may wear down at an accelerated rate in some people. The MHRA said that people with either MoM implants or resurfacing require monitoring for soft tissue damage resulting from reactions of the soft tissue to debris from these implants. For symptomatic patients with any type of MoM hip replacement or resurfacing, a blood metal measurement and imaging of the joint is recommended. In Technology Appraisals 2 and 44, further research recommendations were that long term outcomes following total hip or MoM resurfacing should be determined by compiling data in a registry. The National Joint Registry was set up by the Department of Health and Welsh Assembly Government to collect information on all hip, knee, ankle, elbow and shoulder replacement operations and to monitor the performance of joint replacement implants.

The technology

Total hip replacement is carried out to relieve discomfort and disability caused by arthritis of the hip, which cannot be managed by pain medication and physiotherapy. In total hip replacement a damaged hip joint is replaced with an artificial hip prosthesis, the prosthesis generally consists of three elements: (1) a metal or ceramic ball that replaces the original femoral head and which sits on (2) a metal stem which is inserted into the femur, and (3) a plastic, metal or ceramic cup which is inserted in the acetabulum (hip socket of the pelvis).

Hip resurfacing involves removal and replacement of the surface of the femoral head with a metal hollow hemisphere, which fits into a metal cup which locates in the acetabulum. One of the claimed advantages of the technique is that it preserves femoral bone and therefore the outcome of future replacements may be improved.

Total hip replacement manufacturers include: Amplitude, Biomet, B Braun/ Aesculap, Comis Orthopaedics, Corin, DePuy, Exactech, Finsbury, JRI (Joint Replacement Instrumentation), Implantcast , Implants International, Lima WG Healthcare, Mathys Orthopaedics , Medacta UK, Othodynamics, Peter Brehm, SERF dedienne santé, Smith & Nephew, Stanmore Implants Worldwide, Stryker, Symbios SA, Waldemar Link, Wright Medical UK, Zimmer

Resurfacing head and cup manufacturers include: Biomet, Corin, Finsbury, JRI, Implantcast, Smith & Nephew, Stryker, Symbios SA, Wright Medical UK, Zimmer

Intervention(s)	1. Elective total hip replacement 2. Hip resurfacing
Population(s)	People with pain resulting from end stage arthritis of the hip for which non-surgical management has failed.
Comparators	Total hip replacement and surface replacement will be compared with each other for people in whom both procedures are suitable. Total hip replacement will be compared to best supportive care for people who are not suitable for hip resurfacing.

Outcomes	The outcome measures to be considered include: • Functional result • Pain • Bone conservation • Revision rates • Radiosteriometric analysis to asses prosthesis movement • Adverse effects of treatment • Health-related quality of life • Metal degradation products (metal prostheses)
Economic analysis	The reference case stipulates that the cost effectiveness of treatments should be expressed in terms of incremental cost per quality-adjusted life year. The reference case stipulates that the time horizon for estimating clinical and cost effectiveness should be sufficiently long to reflect any differences in costs or outcomes between the technologies being compared. Costs will be considered from an NHS and Personal Social Services perspective.
Other considerations	If the evidence allows subgroups based on activity levels will be compared. If the evidence allows different types of hip prostheses will be considered separately such as: • Hip replacements with components made from different materials (metal, ceramic, polyethylene). • Cemented, cementless or hybrid prostheses. • Prostheses with differing femoral head size. Guidance will only be issued in accordance with CE marking If the recommendations remain based on long term performance (revision rates), the collection and monitoring of performance data and arrangements for the effective implementation of such recommendations should be considered.

Related NICE recommendations	Related Technology Appraisals: Technology Appraisal No. 2, Apr 2000, 'Hip disease-replacement prostheses' Technology Appraisal No. 44, Jun 2002, 'Hip disease-metal on metal hip resurfacing' Related Guidelines: Clinical Guideline No. 79, Nov 2004, 'Rheumatoid arthritis: the management of rheumatoid arthritis in adults' Clinical Guideline No. 59, Feb 2008, 'Osteoarthritis: The care and management of osteoarthritis in adults CG 59. Review in progress, earliest anticipated date of publication Nov 2013. Related Interventional Procedures: Intervention Procedure Guidance No. 112, Feb 2005 'Minimally invasive two-incision surgery for total hip replacement' Intervention Procedure Guidance No. 408, Sept 2011 'Arthroscopic femoro-acetabular surgery for hip impingement syndrome'

Questions for consultation

Have the most appropriate comparators for the treatment of hip disease been included in the scope? Should management without the use of hip replacement or resurfacing (best supportive care) be included as a comparator for people who are only suitable for one type of implant (total hip replacement or resurfacing)?

If included as a comparator, how should management without the use of hip replacement or resurfacing (best supportive care) be defined?

Are the subgroups suggested in 'other considerations' appropriate? Are there any other subgroups of people in whom the technology is expected to be more clinically effective and cost effective or other groups that should be examined separately? Should different types or brands of hip prostheses be considered separately? If so, how should different types of prostheses be grouped?

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. Please let us know if you think that the

proposed remit and scope may need changing in order to meet these aims. In particular, please tell us if the proposed remit and scope:

- could exclude from full consideration any people protected by the equality legislation who fall within the patient population for which total hip replacement or hip resurfacing are indicated

- could lead to recommendations that have a different impact on people protected by the equality legislation than on the wider population, e.g. by making it more difficult in practice for a specific group to access the technology;

- could have any adverse impact on people with a particular disability or disabilities.

Please tell us what evidence should be obtained to enable the Committee to identify and consider such impacts.

Do you consider the technology to be innovative in its potential to make a significant and substantial impact on health-related benefits and how it might improve the way that current need is met (is this a 'step-change' in the management of the condition)?

Do you consider that the use of the technology can result in any potential significant and substantial health-related benefits that are unlikely to be included in the QALY calculation?

Please identify the nature of the data which you understand to be available to enable the Appraisal Committee to take account of these benefits.