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National Institute for Clinical Excellence

National Institute for Clinical Excellence

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Technology Appraisal Guidance - No. 44

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National Institute for Clinical Excellence

Guidance on the use of metal on metal hip resurfacing arthroplasty

June 2002

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Issue Date: June 2002
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Ordering Information:
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This guidance is written in the following context:
This guidance represents the view of the Institute, which was arrived at after careful consideration of the available evidence. Health professionals are expected to take it fully into account when exercising their clinical judgement. This guidance does not, however, override the individual responsibility of health professionals to make appropriate decisions in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

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Guidance on the use of metal on metal hip resurfacing arthroplasty

1. Guidance

1.1 Metal on metal (MoM) hip resurfacing arthroplasty is recommended as one option for people with advanced hip disease who would otherwise receive and are likely to outlive a conventional primary total hip replacement. In considering hip resurfacing arthroplasty, it is recommended that surgeons take into account activity levels of potential recipients and bear in mind that the current evidence for the clinical and cost effectiveness of MoM hip resurfacing arthroplasty is principally in individuals less than 65 years of age.

1.2 When MoM hip resurfacing arthroplasty is considered appropriate, the procedure should be performed only in the context of the ongoing collection of data on both the clinical effectiveness and cost effectiveness of this technology. Ideally, this data collection should form part of a UK national joint registry.

1.3 This guidance should be read in conjunction with the Institute's guidance on devices for total hip replacement (Guidance on the selection of prostheses for primary total hip replacement: *NICE Technology Appraisal Guidance* No 2. April 2000). In that guidance, the Institute recommended that the best prostheses (using long-term viability as the determinant) should demonstrate a 'benchmark' revision rate (the rate at which they need to be replaced) of 10% or less at 10 years or, as a minimum, a 3 year revision rate consistent with this 10-year benchmark. Establishing and confirming similar benchmarking criteria will be necessary for MoM hip resurfacing arthroplasty and will be facilitated by a UK national joint registry. In the interim, the 3 year minimum benchmark should apply to MoM hip resurfacing devices.

1.4 MoM hip resurfacing arthroplasty should be performed only by surgeons who have received training specifically in this technique.

1.5 Surgeons should ensure that patients considering MoM hip resurfacing arthroplasty understand that less is known about the medium- to long-term safety and reliability of these devices or the likely outcome of revision surgery than for conventional total hip replacements. This additional uncertainty should be weighed against the potential benefits claimed for MoM devices.

This section (Section 1) constitutes the Institute's guidance on metal on metal hip resurfacing anthroplasty. The remainder of the document is structured in the following way:

2 Clinical need and practice
3 The technology
4 Evidence and interpretation
5 Implications for the NHS
6 Recommendations for further research
7 Implementation and audit
8 Related guidance
8 Review of guidance
Appendix A: Appraisal Committee
Appendix B: Sources of evidence
Appendix C: Patient information
Appendix D: Detail on the criteria for audit

A bi-lingual summary is available from our website at www.nice.org.uk or by telephoning 0870 1555 455 and quoting the reference number N0103.

Mae crynodeb ar gael yn Gymraeg ac yn Saesneg ar ein gwefan yn www.nice.org.uk neu drwy ffonio 0870 1555 455 gan ddyfynnu cyfeirnod N0103.

2 Clinical need and practice

2.1 The main underlying causes of degenerative hip disease are rheumatoid arthritis and osteoarthrosis. The prevalence of these conditions is estimated to be 0.5% and 1–2% respectively, in England and Wales. Other conditions that cause secondary osteoarthrosis through abnormal mechanical stress on the hip include: avascular necrosis of the femoral head, hip dysplasia, Paget's disease, Perthes' disease, slipped upper femoral epiphysis, ankylosing spondylitis and trauma.

2.2 Advanced degenerative hip disease can cause prolonged pain (even during periods of rest), which may not be relieved by analgesic therapy, and significantly reduces mobility. People who are affected may be unable to carry out normal daily activities or to work and may lose their independence.

2.3 The predominant surgical intervention for the treatment of degenerative hip disease in England and Wales is total hip replacement (THR), using a variety of cemented or uncemented stemmed femoral prostheses articulating with a polythene acetabular cup (Guidance on the selection of prostheses for primary total hip replacement: *NICE Technology Appraisal Guidance* No 2. April 2000). For younger patients, conventional stemmed THRs with ceramic or metal sockets are sometimes preferred to other devices. Typically patients are referred when their symptoms (for example, pain, loss of physical function) become severe and unmanageable by non-surgical means (such as analgesia and physiotherapy) and self-management programmes.

2.4 Approximately 50,000 primary total hip replacements (THRs) are performed in England and Wales each year, of which 15% are revisions. Non-UK data suggest that rheumatoid arthritis accounts for 6% of the indications for THR and moderate to severe osteoarthrosis for over 75%.

2.5 The outcomes of conventional THRs are generally considered to be good. However, problems associated with this procedure include short device survival in people who are generally more active, relatively poor outcome of revision surgery and device dislocation and loosening.

3 The technology

3.1 MoM hip resurfacing arthroplasty involves removal of the diseased or damaged surfaces of the head of the femur and the acetabulum. The femoral head is fitted with a metal surface and the acetabulum is lined with a metal cup to form a pair of metal bearings.

3.2 MoM hip resurfacing devices are considered by some surgeons to be harder wearing than conventional THRs. Having no polythene component, MoM devices cannot be subject to the loosening due to polythene degradation that affect conventional THRs. MoM devices are therefore potentially less likely to fail for these reasons than conventional THRs. In

addition if failure does occur, revision to conventional THR remains an option and is considered to be easier to perform under most circumstances and to provide better outcomes than revision of a primary THR, as less femoral bone is removed during the original procedure. However, a concern with these devices is the possibility of metal degradation products being absorbed into the body. The implications of this are presently unknown.

3.3 Currently available MoM devices include: the Cormet 2000 (Corin Medical), the Birmingham Hip (Midland Medical Technologies), Conserve Plus (Wright Cremascoli) and Wagner Resurfacing (Sulzer Limited).

3.4 Excluding value added tax, the price of the MoM resurfacing prosthesis varies between £1700 and £1900 compared with approximately £500 for a conventional cemented THR prosthesis and up to £2000 for a cementless/hybrid THR prosthesis. The types of conventional THR that more active patients are likely to receive are towards the higher end of this range.

4 Evidence and interpretation

The Appraisal Committee considered evidence from a number of sources (see Appendix B).

4.1 Clinical effectiveness

4.1.1 No randomised controlled trials of MoM hip resurfacing arthroplasty were identified. Data were available for eight observational studies, including three studies from the manufacturers of these devices. Only four of these studies have been published.

4.1.2 Most studies reported the percentage of patients who required device revisions (MoM hip resurfacing devices to THR). However, only a few studies explicitly provided information on time to device failure, and so it is difficult to make comparisons between studies of MoM devices and THRs. Comparisons were also made difficult as few details were provided on the proportions of patients with specific preoperative diagnoses and nearly all the studies examined the outcome with more than one type of prosthesis.

4.1.3 Of the eight observational studies, the highest reported mean age at the time of surgery was 51 years, suggesting that the patients in all of these studies were relatively young compared with patients who would normally receive a THR. The mean follow-up period in seven of these studies was less than 5 years.

4.1.4 The numbers of patients included in the MoM hip resurfacing studies ranged from 4 to 4424.

4.1.5 Few data were available on dislocation rates associated with MoM devices. However, the manufacturers of the Birmingham Hip stated that the rate of dislocation for this device in the year following surgery was approximately 0.05%, based on 1 dislocation in over 1700 devices. Studies suggest that the rate of dislocation in the first year following a conventional THR may be up to 5%.

4.1.6 The proportion of patients who required device revisions (from MoM hip resurfacing to THR) was reported in all but one study and ranged between 0% and 14.3%.

4.1.7 One study relating to the use of the currently available Birmingham Hip reported 8 device failures at 4 years' follow-up. The initial cohort consisted of 1400 patients but at the time of preparing this guidance, 4 year data were available for only 21 patients. Including evidence on revision rates from the previous version of this device increased the follow-up period from 4 years to 7 years. Although only one device failure was reported over this time, the 7 year study contained fewer patients (500) than the 4 year study as the analysis was restricted to patients aged less than 55 years rather than all patients who had received the Birmingham Hip. At the time this guidance was prepared, 6 and 7 year data for this analysis were available for 40 and 20 patients respectively.

4.1.8 No other survival statistics for MoM devices were available. However, information from studies including the Swedish registry data suggests that rates of conventional THR survival in people aged less than 55 years are between 92% and 94% at 7 years.

4.1.9 Few complications were reported in any of the published studies. Little information was available on functional outcomes following MoM resurfacing and no data were available on the outcome of revisions from MoM devices to primary THRs.

4.1.10 The Assessment Group was asked to include in its review a number of alternatives to conventional THR and MoM hip resurfacing arthroplasty, including 'watchful waiting'. However, the latter option was only relevant to the extent that, if MoM devices offer (or are believed to offer) lower revision rates in younger, active patients, or better results after revision, patients and clinicians may be inclined to refer individuals for earlier consideration of hip surgery, effectively reducing the threshold for intervention.

4.2 Cost effectiveness

4.2.1 One economic evaluation from the Assessment Group and another from the manufacturers of the Birmingham Hip were available to the Committee. Both evaluations considered only the costs of treatment to the National Health Service and both expressed treatment benefits in terms of quality-adjusted life years (QALYs).

4.2.2 Neither economic evaluation incorporated data or assumptions regarding the theoretical improvement in the outcome of primary device revision associated with MoM hip resurfacing arthroplasty.

4.2.3 The economic models from the Assessment Group and the manufacturer discounted future costs at 6% and 5% per annum, respectively. Both discounted future benefits at 1.5% per annum.

4.2.4 The economic model submitted by the manufacturer of the Birmingham Hip compared MoM hip resurfacing arthroplasty with THR over a 5–20 year period for patients younger than 65 years. At 5 years, the incremental cost per QALY for the Birmingham Hip was £13,100. However lengthening the time horizon to 20 years showed MoM to be less costly and more effective than conventional THR.

4.2.5 The Assessment Group's economic model compared MoM hip resurfacing arthroplasty with conventional THR for patients aged 65 years or younger and patients older than 65 years who were considered to be relatively active. In the 5- and 20-year analyses, THR was shown to be less costly and more effective than MoM hip resurfacing arthroplasty for both patient groups at all time horizons. The main reason for the difference in results between the two economic evaluations was that the cost-effectiveness of MoM hip resurfacing devices is sensitive to the revision rate for conventional THR and the studies used different sources to estimate it.

4.3 Consideration of the evidence

4.3.1 The Committee acknowledged that there are no RCTs comparing MoM hip resurfacing arthroplasty with the main important comparator of conventional THR. It also acknowledged that there are no long-term (> 10 year) observational data on the outcomes associated with MoM hip resurfacing devices, and some of the existing short- to medium-term data relate to devices that are no longer commercially available. However, the Committee concluded that patients who are likely

to outlive conventional primary hip replacements should have the choice of receiving MoM hip resurfacing arthroplasty. This decision was made on the basis that there is sufficient short-term evidence of the effectiveness of MoM hip resurfacing devices to conclude that they are at least as effective as conventional THRs for patients younger than 55 years.

4.3.2 In making this decision, the Committee also noted that the types of conventional hip prosthesis that active patients are currently most likely to receive are similar in cost to MoM hip resurfacing devices.

4.3.3 The Committee recognised that safety in clinical use is one of the main issues in evaluating this technology and that device survival rates are a useful method of establishing safety. As there are no data on the long-term safety of these devices, the Committee recommended ongoing data collection, ideally through a UK national joint registry, and that surgeons should ensure that patients considering this type of surgery are made aware that less is known about the long-term safety (and reliability) of MoM devices than for conventional THRs.

4.3.4 It is difficult to compare MoM with THR because most studies relating to conventional THRs have considered patients older than 65 years and have not differentiated between patients who were considered to be more active and those who were not.

4.3.5 No data were presented to the Appraisal Committee on the clinical effectiveness of MoM hip resurfacing devices for active, more elderly patients. Although age might be considered a factor in deciding whether or not a patient might outlive a device, the Committee believed that the suitability of hip resurfacing should be based on patients' activity levels rather than age alone.

4.3.6 Although the two economic evaluations produced different results, this was largely because the models used different rates of revision for conventional THR. Sensitivity analysis showed that inputting different revision rates drastically altered the cost effectiveness of MoM resurfacing. On the balance of probabilities, the Appraisal Committee believed that MoM hip resurfacing arthroplasty was likely to be of similar cost effectiveness to conventional THRs in people who were expected to outlive the device. Moreover, the possible improvement in the outcome of primary revisions for MoM resurfacing compared with revisions for conventional THR, further favoured its use for patients who were expected to outlive the device.

4.3.7 The benchmark revision rate in the Institute's guidance for conventional THRs is 10% or less at 10 years or, as a minimum, a 3 year revision rate consistent with this 10 year benchmark (Guidance on the selection of prostheses for primary total hip replacement: *NICE Technology Appraisal Guidance* No 2. April 2000). The Committee recognised that for MoM devices there is currently no evidence to confirm that intermediate (3- to 7-year) device survival rates are predictive of the 10-year rates as is the case for conventional THRs. The Committee nevertheless noted that where evidence was available for MoM devices revision rates appeared to be consistent with this 3-year minimum benchmark. The Committee considered it essential to establish a benchmark for MoM hip resurfacing arthroplasty in order to properly inform the choice of device made by patients and clinicians. This is best established through ongoing audit of practice of the use of MoM hip resurfacing arthroplasty via a UK national joint registry. However, until this is established, the minimum 3 year benchmark for conventional THRs to MoM hip resurfacing devices is considered to be an appropriate interim measure.

4.3.8 Although no data were available on the likelihood or clinical consequence of systemic absorption of metal degradation products, the Appraisal Committee recognised that this issue may be important in determining the long-term safety of these devices.

5 Recommendations for further research

5.1 Further information on the long-term use of MoM hip resurfacing arthroplasty is required if the present understanding of the clinical and cost effectiveness of these devices is to be confirmed.

5.2 It is recommended that data relating to the use of MoM hip resurfacing arthroplasty are submitted to a UK national joint registry as soon as this is possible. These data should include the date of revision, details of predisposing disease, age, activity level, surgeon identification and reason for and outcome of revision surgery.

5.3 Research is required to investigate the likelihood and possible clinical consequence of the potential for systemic absorption of metal degradation products from the MoM resurfacing arthroplasty.

5.4 Future studies assessing the reliability of MoM hip resurfacing prostheses should report appropriate device survival (e.g. Kaplan-Meier) statistics, which were infrequently reported in existing studies.

6 Implications for the NHS

6.1 When it is assumed that purchasing a more expensive MoM prosthesis (£1800 excluding value added tax) is the only difference in the cost of performing a MoM hip resurfacing arthroplasty compared with a conventional THR (prosthesis cost: £500 to £2000 excluding value added tax) and that 4500 people each year will undergo MoM hip resurfacing instead of conventional THRs, the total budget impact is estimated to be between an increase of £5.9 million per annum (if MoM devices are used instead of conventional THRs costing £500) and a reduction of £0.9 million per annum (if MoM devices are used instead of conventional THRs costing £2000). However, as patients considered to be suitable for MoM hip resurfacing arthroplasty (as indicated in Section 1.1) are more likely to have been considered for a THR approaching £2000, the budget impact is more likely to be at the lower end of this range.

7 Implementation and audit

7.1 Orthopaedic surgeons who perform hip replacement surgery should consider the guidance set out in Section 1.

7.2 NHS trusts, primary care trusts and local health groups should ensure that referring clinicians are aware of the MoM hip resurfacing arthroplasty technology, as they consider treatment options for patients with advanced hip disease and particularly for younger patients who might otherwise face the possibility of repeat THR procedures.

7.3 Local guidelines or care pathways on the multi-professional care of patients having hip replacement surgery should incorporate the guidance set out in Section 1 when orthopaedic surgeons working at local level have decided to offer MoM hip resurfacing arthroplasty as one option for people with advanced hip disease who would otherwise receive a conventional primary THR.

7.4 When the decision has been made to use MoM, surgeons should ensure that data are collected on an ongoing basis to confirm the clinical effectiveness and cost effectiveness of this technology, ideally as part of a UK national joint registry.

7.5 To measure compliance locally with the guidance set out in Section 1, the following criteria should be used. Further details on audit criteria are presented in Appendix D.

7.5.1 MoM hip resurfacing arthroplasty is considered as an option for people with advanced hip disease who would otherwise receive and are likely to outlive a conventional primary THR, particularly for younger patients who wish to be reasonably active.

7.5.2 MoM hip resurfacing arthroplasty is performed only by a surgeon who has received training specifically in this technique.

7.5.3 For a patient having MoM hip resurfacing arthroplasty, the patient's informed consent refers specifically to current evidence on the medium- to long-term safety and reliability of MoM devices and the likely outcome of revision surgery in comparison with conventional THRs.

8 Related guidance

8.1 The Institute issued guidance on the selection of prostheses for primary hip replacement in April 2000: National Institute for Clinical Excellence (2000) Guidance on the selection of prostheses for primary hip replacement. *NICE Technology Appraisal Guidance* No. 2. London: National Institute for Clinical Excellence. Available from www.nice.org.uk.

9 Review of guidance

9.1 The guidance on this technology will be reviewed in February 2005.

Andrew Dillon
Chief Executive

June 2002

APPENDIX A

Appraisal Committee members

The Appraisal Committee is a standing advisory committee of the Institute. Its members are appointed for a 3-year term. A list of the Committee members appears below. The Appraisal Committee meets twice a month other than in December, when there are no meetings. The Committee membership is split into two branches, with the chairman, vice chairman and a number of other members attending meetings of both branches. Each branch considers its own list of technologies and topics are not moved between the branches.

Committee members are asked to declare any interests in the technology to be appraised. If there is a conflict of interest, the member is excluded from participating further in that appraisal.

The minutes of each Appraisal Committee meeting, which include the names of the members who attended and their declaration of interests, are posted on the NICE website.

Dr Jane Adam
Radiologist, St. George's Hospital
London

Professor RL Akehurst
Dean, School of Health Related
Research
Sheffield University

Dr Sunil Angris
General Practitioner
Waterhouses Medical Practice

Professor David Barnett
(Chairman)
Professor of Clinical Pharmacology
University of Leicester

Professor Sir Colin Berry
Professor of Morbid Anatomy
St Bartholomew's and Royal London
School of Medicine

Dr Sheila Bird
MRC Biostatistics Unit
Cambridge

Professor Carol Black
Consultant Physician,
Royal Free Hospital & UCL, London

Professor John Brazier
Health Economist, University of
Sheffield

Professor Martin Buxton
Director of Health Economics
Research Group
Brunel University

Professor Bruce Campbell
Consultant Surgeon
Royal Devon & Exeter Hospital

Professor Mike Campbell
Statistician
Institute of General Practice & Primary
Care, Sheffield

Dr Karl Claxton
Health Economist
University of York

Professor Sarah Cowley
Professor of Community Practice
Development
Kings College, London

Professor Nicky Cullum
Reader in Health Studies
Centre for Evidence Based Nursing,
University of York

Professor Jack Dowie
Health Economist
London School of Hygiene & Tropical Medicine, London

Mr Chris Evennett
Chief Executive
Mid-Hampshire Primary Care Group

Dr Paul Ewings
Statistician
Taunton & Somerset NHS Trust

Professor Terry Feest
Clinical Director and Consultant Nephrologist
Richard Bright Renal Unit, and Chairman of the UK Renal Registry

Professor Gary A Ford
Professor of Pharmacology of Old Age/Consultant Physician
University of Newcastle

Ms Jean Gaffin
Formerly Executive Director
National Council for Hospice and Specialist Palliative Care Service

Mrs Sue Gallagher
Chief Executive
Merton, Sutton and Wandsworth Health Authority

Dr Trevor Gibbs
Head, Global Clinical Safety & Pharmacovigilance
GlaxoSmithKline

Sally Gooch
Director of Nursing
Mid-Essex Hospital Services Trust

Mr John Goulston
Director of Finance
The Royal Free Hampstead NHS Trust

Professor Trisha Greenhalgh
Professor of Primary Health Care
University College London

Liz Heyer
Chief Executive
Barnet & Chase Farm Hospitals NHS Trust

Professor Philip Home
Professor of Diabetes Medicine
University of Newcastle

Dr Terry John,
General Practitioner
The Firs, London

Dr Diane Ketley
Research into Practice Programme Leader
NHS Modernisation Agency

Dr Mayur Lakhani
General Practitioner
Highgate Surgery, Leicester,
and Lecturer, University of Leicester

Ruth Lesirge
Lay Representative; Director
Mental Health Foundation

Dr George Levvy
Lay Representative; Chief Executive
Motor Neurone Disease Association

Dr Gill Morgan
CEO, North & East Devon Health Authority

Professor Miranda Mugford
Health Economist
University of East Anglia

Mr M Mughal
Consultant Surgeon
Chorley and South Ribble NHS Trust

Mr James Partridge
Chief Executive, Changing Faces

Siân Richards
General Manager
Cardiff Local Health Group

Professor Philip Routledge
Professor of Clinical Pharmacology
University of Wales College of Medicine

Dr Rhiannon Rowsell
Pharmaceutical Physician AstraZeneca UK Ltd

Dr Stephen Saltissi
Consultant Cardiologist
Royal Liverpool University Hospital

Professor Andrew Stevens (Vice-Chairman)
Professor of Public Health
University of Birmingham

Professor Ray Tallis
Consultant Physician
Hope Hospital, Salford

Dr Cathryn Thomas
General Practitioner, and Senior Lecturer, Department of Primary Care and General Practice
University of Birmingham

Professor Mary Watkins
Head of Institute of Health Studies
University of Plymouth

Dr Norman Waugh
Public Health Consultant
University of Southampton

APPENDIX B

Sources of evidence considered by the Committee

The following documents were made available to the Committee in their appraisal of the use of metal on metal hip resurfacing.

- **Overview** prepared by the NICE Appraisal Team

- **Evaluation report** consisting of

  Assessment report prepared by the Health Economics Research Unit and Health Services Research Unit, University of Aberdeen (Systematic review of the effectiveness and cost-effectiveness of metal on metal hip resurfacing arthroplasty for treatment of hip disease, November 2001).

  Comments on the assessment report received from:
  - ABHI
  - British Orthopaedic Association
  - Chartered Society of Physiotherapy
  - Corin Group Ltd
  - Health Technology Board for Scotland
  - Midland Medical Technologies Ltd

Professional/specialist,patient and trade group submissions from:
- ABHI
- Arthritis Care
- British Orthopaedic Association
- Chartered Society of Physiotherapy
- Department of Health
- Health Technology Board for Scotland
- South Essex Health Authority

Manufacturer/sponsor submissions from:
- Corin Group Ltd
- Midland Medical Technologies Ltd
- Wright Medical Technologies

Expert submissions from:
- Mr Steve Krikler, Consultant Orthopaedic Surgeon, University Hospitals Coventry & Warwickshire NHS Trust

APPENDIX C

Patient information

Guidance on the use of metal on metal hip resurfacing

The patient information in this appendix has been designed to support the production of your own information leaflets. You can download it from our website at www.nice.org.uk where it is available in English and Welsh. If you would like printed copies of the leaflets please ring the NHS Response Line on 0870 1555 455 and quote reference number N0104 for the English patient leaflet and N0105 for the bi-lingual patient leaflet.

What is NICE guidance?

The National Institute for Clinical Excellence (NICE) is a part of the NHS. It produces guidance for both the NHS and patients on medicines, medical equipment, diagnostic tests and clinical and surgical procedures and where they should be used.

When the Institute evaluates these things, it is called an appraisal. Each appraisal takes around 12 months to complete and involves the manufacturers of the drug or device, the professional organisations and the groups who represent patients.

NICE was asked to look at the available evidence on metal on metal hip resurfacing and provide guidance that would help the NHS in England and Wales decide where it should be used to treat people with hip disease.

What are artificial hip joints and why are they used?

Artificial hip joints can be fitted to relieve the pain and disability associated with hip joint disease, including osteoarthritis and rheumatoid arthritis of the hip. In conventional total hip replacement operations (THRs), the hip joint is replaced with an artificial 'ball and cup' joint. The cup fits into the socket of the hip joint, and the ball replaces the head of the thigh bone. The cups are usually made of polythene (plastic), but sometimes they are made of metal or a ceramic material. The ball is usually made of metal.

Approximately 50,000 first-time, or primary, THRs are performed in England and Wales each year.

THRs are generally successful operations, although sometimes wear or other problems with the artificial joint mean that it has to be replaced. This replacement is called a 'revision'. A revision to replace an existing artificial hip joint may be less successful than the first THR. Artificial hip joints are likely to wear out more quickly in people who are active.

What is metal on metal hip resurfacing?

Metal on metal (often referred to as MoM) hip resurfacing involves replacing the diseased or damaged surfaces in the hip joint (that is at the top of the thigh bone and inside the socket of the hip bone) with metal surfaces. Less bone has to be removed for MoM resurfacing than to fit a conventional cup and ball artificial hip joint.

Some surgeons think that MoM hip resurfacing devices are harder wearing than conventional THRs because they do not contain polythene, which can become worn down as the joint is used. If a MoM hip joint does stop working, a revision can be carried out to replace it with a conventional cup and ball THR device. It is thought that it may be easier to carry out a revision for a MoM device than for a conventional THR. However, there is concern that substances from the metal surfaces might be absorbed into the body, although at the moment there have been no reported cases of this happening.

What has NICE recommended about the use of MoM hip resurfacing?

NICE has made the following recommendations about the use of MoM hip resurfacing.

- MoM hip resurfacing is recommended as an option for people with advanced hip disease who would otherwise receive a conventional primary THR and are likely to live longer than the device is likely to last.
- When considering MoM hip resurfacing surgeons should bear in mind:
  - how active the individual is
  - that the evidence available at the moment for the clinical effectiveness and cost effectiveness of MoM hip resurfacing comes mainly from studies that have involved people less than 65 years of age. ('Clinical effectiveness' means how well MoM hip resurfacing works, and 'cost effectiveness' mean how well it works in relation to how much it costs.)
- Information on MoM resurfacing operations carried out should be collected as part of a UK national joint registry. The information collected will help the NHS to gather evidence on both the clinical effectiveness and cost effectiveness of MoM hip resurfacing.
- The data from the national joint registry will allow researchers to find out how long MoM hip resurfacing devices last before they need to be replaced. Until more long-term evidence is available, NICE recommends that surgeons should choose a device for MoM resurfacing for which there is at least 3 years' evidence. This evidence should show that the device is likely to meet a target of less than 1 in 10 devices needing replacing over 10 years.
- MoM hip resurfacing should be performed only by surgeons who have received training in the technique.
- Surgeons should make sure that people considering having MoM hip resurfacing understand all the risks and benefits associated with it, and are aware that less is known about the safety and reliability of MoM devices than about conventional cup and ball THR devices.

What should I do?

If you have, or someone you care for has, hip disease then you can discuss this advice with your doctor at your next appointment. If you have already had a THR, do not worry. This guidance does not mean that your hip joint is not safe or should not have been used.

Will NICE review its guidance?

Yes. In February 2005 NICE will consider any new evidence on MoM hip resurfacing and decide if the guidance should be reviewed.

Further information

Further information on NICE, and the full guidance issued to the NHS is available on the NICE website (www.nice.org.uk). The guidance can also be requested from 0870 555 455, quoting reference N0102.

NICE issued guidance on conventional THRs in April 2000, this is also available on the website or by telephoning 0870 555 455, quoting reference 21382.

If you have access to the Internet and would like to find out more about hip disease visit the NHS Direct website: www.nhsdirect.nhs.uk. If you would like to speak to NHS Direct, please phone 0845 46 47.

APPENDIX D

Detail on the criteria for audit of the use of metal on metal hip resurfacing arthroplasty

Possible objectives for an audit

An audit on the appropriateness and effectiveness of the use of MoM hip resurfacing arthroplasty could be carried out to ensure the following.

- MoM hip resurfacing arthroplasty is considered as an option for people with advanced hip disease who would otherwise receive and are likely to outlive a conventional primary total hip replacement.
- MoM hip resurfacing arthroplasty is performed only by a surgeon who is trained specifically in this technique.
- The informed consent by a patient who receives MoM hip resurfacing arthroplasty includes information about the safety and reliability of these devices and the likely outcome of revision surgery in comparison to conventional total hip replacements.

In addition, because of the need to gather clinical (and cost) effectiveness data on the use of this technology, data agreed for submission to a UK national joint registry, when available, should be collected on a continuous basis and analysed at reasonable intervals depending on the number of procedures performed.

Patients to be included in an audit and time period for selection

An audit on the first objective above would be carried out on all patients with advanced hip disease who are referred for surgery.

An audit on the second and third objectives would be carried out an all patients undergoing MoM hip resurfacing arthroplasty.

Measures to be used as a basis for the audit

The measure that can be used in an audit of the appropriateness of the use of MoM hip resurfacing arthroplasty to confirm that MoM hip resurfacing arthroplasty is being considered for patients with advanced hip disease is as follows.

Criterion	Standard
1. MoM hip resurfacing arthroplasty is considered as an option for a patient with advanced hip disease who is referred for surgery and is likely to outlive a conventional total hip replacement	100% of patients with advanced hip disease who are referred for surgery

The measures that can be used in an audit of the effectiveness of the use of MoM hip resurfacing arthroplasty to confirm that the procedure is being carried out the right way are as follows.

1. Surgery is performed by a surgeon who has received training specifically in MoM	100% of patients having MoM
2. The patient's informed consent refers specifically to current evidence on the medium-to long-term safety and reliability of MoM devices and the likely outcome of revision surgery in comparison to conventional total hip replacement	100% of patients having MoM

Calculation of compliance with the measure

Compliance with each measure described in the table is calculated as follows:

$$\frac{\text{Number of patients whose care is consistent with the } \textbf{Criterion} \textit{ plus } \text{number of patients who meet any locally agreed } \textbf{Exception}}{\text{Number of patients to whom the } \textbf{Measure applies}} \times \mathbf{100}$$

Clinicians should review the findings of measurement, identify if practice can be improved, agree on a plan to achieve any desired improvement and repeat the measurement of actual practice to confirm that the desired improvement is being achieved.

Exception	Definition of Terms
None	Surgeons should agree locally on how to record that MoM hip resurfacing arthroplasty has been considered for each patient, for audit purposes
None	Surgeons should agree on what constitutes appropriate training in the use of the MoM technique
None	Surgeons should agree locally on how this information will be reflected in the signed informed consent form. Failure rates are cited in this document.