NHS

National Institute for Clinical Excellence

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Technology Appraisal Guidance - No.2

NHS

National Institute for Clinical Excellence

Guidance on the Selection of Prostheses for Primary Total Hip Replacement

April 2000

This document has been circulated to the following:

- Health Authority Chief Executives - England and Wales
- NHS Trust Chief Executives - England and Wales
- PCG Chief Executives
- Local Health Group General Managers
- Consultant Orthopaedic Surgeons - England and Wales
- NHS Executive Regional Directors
- Special Health Authority Chief Executives
- Community Health Councils England and Wales
- Commission for Health Improvement
- Local Clinical Governance Support Team
- Chief Medical and Nursing Officers in England and Wales
- NHS Director Wales
- Chief Executive NHS
- Medical Director & Head of NHS Quality - Wales
- Clinical Effectiveness Support Unit - Wales
- Representative bodies for health services, professional organisations and statutory bodies, Royal Colleges, health advocacy groups

This Guidance is written in the following context

This guidance represents the view of the Institute's Appraisal Committee, the membership of which is set out in Appendix A, 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 in selecting prostheses for primary hip replacement. 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 Selection of Prostheses for Primary Total Hip Replacement

1 Guidance

1.1 Using the most recent available evidence of clinical effectiveness, the best prostheses (using long term viability as the determinant) demonstrate a revision rate (the rate at which they need to be replaced) of 10% or less at 10 years. This should be regarded as the current 'benchmark' in the selection of prostheses for primary Total Hip Replacement (THR).

1.2 The evidence used in support of any prosthesis, to establish whether or not it achieves this benchmark, should relate to data on 10 or more years follow up from a number of centres, obtained via adequately sized, well conducted observational studies (preferably with consecutive patients from non-selected populations) or randomised controlled trials. Such evidence should have been published or be available for peer review.

1.3 The Institute also considers it reasonable to recommend consideration of prostheses with a minimum of 3 years revision rate experience (collected as described in 1.2 above) if their performance is consistent with the benchmark of a 10% revision rate at 10 years. Prostheses that achieve this 'entry benchmark' would then need to be subject to annual review (up to 10 years) to ensure that the revision rate remains consistent with the 10 year benchmark.

1.4 Prostheses (cemented, uncemented, and hybrid) that have not been shown to achieve either of these benchmarks, should be the subject of comparative clinical evaluation before they can be recommended for routine use in the NHS.

1.5 There is currently more evidence of the long term viability of cemented prostheses, which, in many cases, occupy the lower end of the range of prostheses cost, than there is for uncemented and hybrid prosthesis.

Section 1 constitutes the Institute's Guidance on the Selection of Prostheses for Primary Total Hip Replacement. The remainder of the document provides information on the following:

1. Guidance
2. Clinical Need
3. The Technology
4. Evidence
5. Implications for the NHS
6. Further Research
7. Implementation
8. Clinical Audit Advice
9. Review of Guidance
- Appendix A: Appraisal Committee
- Appendix B: Sources of evidence
- Appendix C: Information for patients.

The full document and a summary of evidence are available from our web site at www.nice.org.uk or by contacting 0541 555 455.

Mae'r adran hon (adran 1) hefyd ar gael yn Gymraeg ar ein gwefan neu drwy gysylltu â 0541 555 455.

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2 Clinical Need

2.1 Elective THR is carried out to relieve discomfort and disability caused by arthropathies (including osteoarthritis and rheumatoid arthritis) of the hip. THR is considered to be one of the most effective orthopaedic procedures performed at the present time.

2.2 In terms of the total number of THRs performed, women outnumber men by nearly two to one and the over 65-year age group accounts for two in every three. Approximately 35,000 THRs are carried out in the NHS in England and 2,800 in Wales each year.

3 The Technology

3.1 There are more than 60 different hip prostheses, manufactured by 19 companies, currently available for THR. Figures from the National Audit Office indicate that the cost of these procedures to NHS Trusts ranges from £1,200 to £9,000, with an average of £3,686, depending on a number of factors, including the choice of prosthesis.

3.2 The cost of prostheses varies from £400 to around £2,000. Of the prostheses available, a substantial number have been introduced in the last seven years. Although there is considerable variation in prosthesis design, the simplest and most commonly used basis for classification is whether they are cemented, uncemented or hybrid (that is, a cemented stem with a cementless cup). It is estimated that cemented prostheses make up about 90% to 95% of the current total UK THR market. In addition, different hip prostheses may undergo developmental refinements by the manufacturer over a number of years. These refinements in component design, constituents and manufacturing processes although initiated for sound theoretical reasons, are largely of unproven practical consequence. The introduction of new prostheses and in some cases, changes to existing prostheses have been associated, in the past, with early failure rates of THR in some patients.

4 Evidence

4.1 The important criteria in the assessment of the clinical effectiveness of a prosthesis are: persistence of pain and immobility, the proportion of THR's which require revision surgery within a specified period (the revision rate) and the ease with which revision can be carried out.

4.2 The experience of the whole surgical team, including physiotherapists and occupational therapists, contributes to the overall success of THR. In addition various patient factors, including age and underlying pathology, must be taken into account. So, for example, selection of a prosthesis with a long life expectancy will be important for most patients, but ease of revision will be of particular importance for younger patients.

4.3 Specific recommendations on the selection of hip prostheses for primary THR are difficult to construct because the evidence base is generally poor and difficult to interpret, for the following reasons. Few of the studies were of best design to assess clinical effectiveness and few included long term (i.e. more than 10 years) follow-up data. There are often incremental changes in specific prostheses design over time and the interaction between surgeon, hospital team and device performance has not been systematically assessed.

4.5 The available evidence, derived from randomised controlled trials and observational studies (for example hip registers) supports the use of a range of cemented prostheses for primary THR.

4.6 There is currently no cost effectiveness data, based on revision rate of 10 years or more follow up, to support the use of the generally more costly uncemented and hybrid hip prostheses.

4.7 The evidence on immediate and long term postoperative pain supports the use of cemented hip prostheses.

4.8 No reliable evidence was available to support the proposition that the potential ease of revision of a hip prostheses would outweigh its poorer revision rate, notwithstanding any evidence that cementless and hybrid prostheses may lead to less bone loss and are therefore potentially easier to revise than cemented prostheses.

4.9 A list of the source documentation and opinion, which was available to the Appraisal Committee, is set out at Appendix B.

5 Implications for the NHS

5.1 Given the wide variation in the cost of prostheses, a potential saving of up to £8 million per year would accrue if the NHS in England and Wales limited primary THR to the less expensive cemented prostheses. This estimate of saving is based on the cost of prostheses alone.

5.2 It is recognised that retraining of surgical teams may be necessary in the event that this guidance resulted in individual teams using significantly different prostheses compared with their current practice in the future.

6 Further Research

6.1 More evidence of the performance of hip prostheses over longer periods of follow-up is required. It is recognized that long-term evaluation is costly and by its very nature, may inhibit innovation. Radiosteriometric analysis (RSA) which involves the insertion of radiographic markers in order to assess prostheses movement after implantation, is a promising development. However, it is not possible, at this stage, to recommend whether this should be used either as a substitute for long term evidence or as an early warning indicator of expected poor long term revision rates. When the Institute revisits its guidance on the selection of prostheses for primary THR, it proposes to seek further evidence on the use of RSA

measurement of implant migration, together with the 'entry benchmark' referred to in para 1.3, as proxies for long term revision rates.

6.2 It is recommended that the NHS encourage the establishment of a UK hip registry and further randomised controlled trials.

7 Implementation

7.1 The NHS Purchasing and Supply Agency (working with the Welsh Health Supplies Organisation) has agreed with the Institute to work with hip prostheses manufacturers to collate and disseminate information about the performance of individual products against the 10 year full benchmark and the three year entry benchmark, in order to avoid trusts having to collect this information individually. It is anticipated that the Agency will be in a position to supply information to trusts on benchmarked products from July 2000, at the latest. They will update their database on a regular basis.

7.2 Manufacturers may seek to present data on products whose design has evolved during the period in which the data has been collected. The onus will be on manufacturers to show that performance data from the more recent versions of the product do not compromise the validity of the earlier data (In other words, that the product has not changed so significantly that it is, in effect a different prosthesis for which a new data series needs to accumulate in trial or observational study settings, or through the RSA method referred to in paragraph 6.1). This would also apply when a manufacturer seeks to present a new product as essentially the same as one with a 10 year data series.

7.3 Trusts should aim to achieve best value, through normal tendering procedures, in their purchasing of those prostheses which achieve the benchmark.

7.4 Existing prostheses supply contracts will need to be honoured, but trusts should consider whether there is flexibility within such contracts to orientate their buying towards prostheses which meet the benchmark.

7.5 Manufacturers with products which do not yet meet the entry benchmark will want to consider how sufficient data on their product(s) can be accumulated. They will be familiar with the processes for establishing clinical trials and constructing robust observational studies and if established, should consider the role of the hip register in the collection of trial or study data. The primary responsibility for organising and funding clinical trials and other research of this kind rests with manufacturers. Where they consider that the NHS may be able to help them in doing so, they should consider contacting the NHS Research and Development Programme.

8 Clinical Audit Advice

8.1 Trusts will need to establish systems to record the number and type of prostheses used.

8.2 As part of clinical activity in support of this guidance, it is recommended that the NHS encourage the establishment of a UK hip registry and further randomised controlled trials. A registry based on the experience in Sweden and in the UK (the Trent Registry) was supported by all consultees in the appraisal. The registry would aid in the important process of audit of THRs and the establishment of 'best practice' in the performance of the surgical and support teams including rehabilitation and physiotherapy undertaking these procedures. Matching the correct hip prosthesis to a specific clinical situation is also considered to be important. Factors likely to affect the outcome of THR (for example, age of the recipient) need to be incorporated into the registry database and associated randomised, controlled trials.

8.3 The British Orthopaedic Association has set out detailed recommendations on the possible design of a UK national hip register and their recommendations, along with the experience of the Trent and other registries should form the basis of detailed discussions by the parties concerned.

8.4 As the expertise of the surgical team is a major factor in the success of THR, it is recommended that all clinicians and all orthopaedic departments participate in a comparative clinical audit programme. Such programmes are likely to be more effective in improving patient care when they form part of the organisation's formal clinical governance arrangements and where they are linked to specific post-graduate activities.

9 Review of Guidance

9.1 This guidance will be reviewed in April 2003.

Andrew Dillon
Chief Executive

April 2000

APPENDIX A

Appraisal Committee Members

Professor R. L.Akehurst
Dean, School of Health Related Research
Sheffield University

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

Professor Sir Colin Berry
Professor of Morbid Anatomy
London Hospital Medical College

Dr Sheila Bird
MRC Biostatistics Unit, Cambridge

Professor Martin Buxton
Director of Health Economics Research Group
Brunel University

Professor Yvonne Carter
Professor of General Practice and Primary Care
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Dr Karl Claxton
Lecturer in Economics
University of York

Professor Duncan Colin-Jones
Professor of Gastroenterology
University of Southampton

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

Dr Nicky Cullum
Reader in Health Studies
University of York

Mr Chris Evennett
Chief Executive
Mid-Hampshire Primary Care Group

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
International Medical Operations Director
Glaxo-Wellcome R&D Ltd

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

Professor Philip Home
Professor of Diabetes Medicine
University of Newcastle

Dr Terry John
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Dr Mayur Lakhani
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Mr M Mughal
Consultant Surgeon
Chorley and South Ribble NHS Trust

Mr James Partridge
Chief Executive
Changing Faces

Dr L.J. Patterson
Consultant Physician and Medical Director

Professor Philip Routledge
Professor of Clinical Pharmacology
University of Wales

Professor Andrew Stevens
Professor of Public Health
University of Birmingham

APPENDIX B

Documentation and Opinion Available to the Appraisal Committee

i) The following documentation was made available to the Appraisal Committee:

a) Assessment Report
The effectiveness and cost effectiveness for total hip replacement; National Institute for Clinical Excellence

b) Manufacturer/Sponsor submissions:

- B.Braum Medical Ltd.
- Biomet Merck Ltd.
- Corin Group Ltd.
- Cremascoli Fry Ortho Ltd.
- DePuy UK
- Endo-Plus (UK) Ltd.
- Joint Replacement Instrumentation
- Midland Medical Technologies
- Orthodesign Ltd.
- Smith & Nephew
- STRATEC Medical Ltd.
- Stryker UK Ltd.
- Sulzer Orthopaedics (UK) Ltd.
- Zimmer Ltd.

c) Professional/Specialist/patient and carer group submissions;

- British Orthopaedic Association
- British Institute of Musculoskeletal Medicine
- Chartered Society of Physiotherapy
- British Geriatrics Society
- Arthritis Care
- Royal Association for Disability and Rehabilitation (RADAR)
- The Association of British Health-Care Industries
- EUCOMED
- College of Occupational Therapists
- British Medical Association

ii) The following experts were invited to make submissions to the Committee:

a) Professor Paul Gregg,Professor of Trauma and Orthopaedic Surgery, The Medical School, Newcastle-upon-Tyne

b) Mr Richard Field, Consultant Orthopaedic Surgeon, Epsom & St. Helier NHS Trust

APPENDIX C

Guidance on the Selection of Artificial Joints for Primary Total Hip Replacement– Patient Notes

The patient information in this appendix has been designed to support the production of your own information leaflets; you can download it from our web site (www.nice.org.uk) it is available in English and Welsh. A printed version of this text is available in English/Welsh or English alone. If you would like copies of the leaflet please contact 0541 555 455, and ask for " Guidance on the Selection of Artificial Joints for Primary Total Hip Replacement – Information for Patients".

What is NICE Guidance?

The National Institute for Clinical Excellence (NICE) is a part of the NHS. It has a team of experts who produce guidance for both the NHS and patients on medicines, medical equipment and clinical procedures.

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 technology, patient groups and professional organisations.

NICE was asked to look at artificial hips (prostheses) and provide guidance to the NHS about which ones work best and represent value for money.

What are artificial hip joints and when are they used?

Artificial hip joints are also known as '*replacement hip joints*' or '*hip prostheses.*'

They are inserted surgically into the hip to replace diseased or damaged joints. The operation is called a Total Hip Replacement (*THR*). *THR*s are often carried out to relieve discomfort and disability caused by joint disease (including osteoarthritis and rheumatoid arthritis of the hip). At present, *THR* is thought to be one of the most effective operations.

Approximately 35,000 *THRs* are carried out in the NHS in England and 2,800 in Wales each year. Between 10 to 15% of these have to be revised. Revised means that the operation has to be repeated. This could be because the replacement hip has worn out or because there was a problem following the operation.

There are more than 60 different artificial hips available for *THR* but they can be split into 3 groups: cemented, uncemented or hybrid. Which group an artificial hip is placed in depends on the way it is put in during the *THR* operation.

What do NICE recommend?

Based on the evidence, NICE has recommended to the NHS that:

1. Wherever possible, the NHS should use artificial hip joints that can show they last for 10 years or more. This is called a benchmark.

2. Sometimes a surgeon might need to use an artificial hip that does not meet this benchmark. If this is the case, the hip should have at least 3 years evidence. This evidence should show that the artificial hip is on target to meet the 10-year benchmark.

3. Artificial hips that do not meet the standards 1 and 2 above should only be used in the NHS as part of a clinical trial. If you need one of these hips, then your surgeon will discuss the details of the clinical trial with you before you agree to have the operation.

4. Artificial hips are described in one of three ways: cemented, uncemented or hybrid. It depends on the design of the artificial hip and how it is fixed into the bone, during the operation.

   There is more evidence that cemented artificial hips meet the 10-year benchmark (described in point 1) and produce the least pain and discomfort.

5. To help the NHS establish and do the best for their *THR* patients more evidence on the performance of artificial hip joints and *THRs* is needed. Therefore, NICE has recommended that the NHS should set up a *hip registry* and should encourage more research. This may mean that the NHS and your surgeon will collect information about your hip operation and how well you have progressed.

What should I do?

If you, a member of your family, or someone you care for is going to have a *THR* you should discuss this advice with your GP or surgeon.

If I have already had a HIP replacement – what does the NICE guidance mean to me?

If you have already had a hip replacement please do not worry. This guidance does not mean that your hip joint is not safe or should not have been used.

This guidance means that, in the future, no matter where you live in England and Wales, your surgeon has access to the same information on the best performing hip joints.

Will NICE review its guidance?

Yes. The guidance will be reviewed in April 2003.

Further Information

Further information on NICE, and the full guidance issued to the NHS is available on the NICE web site (www.nice.org.uk). It can also be requested from 0541 555 455.

Mae'r daflen hon hefyd ar gael yn Gymraeg.