

Hip replacements: Getting it right first time



Report by the
Comptroller and Auditor General

NHS Executive

Hip replacements: Getting it right first time

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John Bourn
Comptroller and Auditor General

National Audit Office
7 April 2000

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Executive summary and recommendations

Overview

1 Total hip replacement is a common elective surgical procedure, with over 30,000 performed by the NHS in England each year. It is highly effective, reducing pain and increasing mobility in almost all cases, at a cost to the NHS of some £140 million a year. The way in which the hip replacement pathway of care is managed and organised – from initial General Practitioner consultation, through to operation and discharge from hospital – has implications for the economic, efficient and effective use of the resources of NHS acute trusts, and for primary and community health services and social care. It also has a major impact on the quality of care provided to the patient.

2 Hip replacement is more common in people over 50. It involves cutting away the head of the femur and inserting a metal or ceramic ball; a cup is fixed into the socket of the pelvis and the ball is placed into it. For many older patients the hip replacement will last for their remaining lifetime; for younger patients revision surgery may be necessary. Compared to primary hip replacement, revision surgery is more complex, more expensive, and has higher failure rates.

3 While a survey carried out in 1994¹ found that 62 hip prostheses from 19 manufacturers were sold in the UK, most patients were implanted with one of a much smaller number of established designs. Procedures for approving new prostheses ensure that manufacturers have adequate systems of quality controls for both design and manufacture, and that the implants fulfil 'essential requirements' for safety and performance. Manufacturers are required to establish a system of post-market surveillance to ensure that any problems with hip prostheses are identified and any corrective action taken. These procedures cannot ensure that hip prostheses are clinically effective in the long term due to the length of testing that would be required to do so. Whilst many patients will receive a replacement hip that will perform satisfactorily for many years, there has been a proliferation of design changes to prostheses whose long term effectiveness is unknown.

¹ As reported in *Primary total hip replacement surgery: a systematic review of outcomes and modelling of cost-effectiveness associated with different prostheses*. NHS Health Technology Assessment 1998, Vol.2, No.20

4 In the context of modernising government we particularly focused on quality of service to the patient in the provision of total hip replacements, and on outcomes and performance. The report details many examples of good practice by trusts to ensure good outcomes for the patient, but there is more that trusts can do to ensure their procedures are based on good practice. Inevitably resource constraints place limits on service provision. Nonetheless, the report details initiatives taken by trusts resulting in shorter waiting lists and shorter length of stay in hospital. There are, however, areas of concern to the patient where trusts need to do more to provide a more effective service such as providing better patient information, and undertaking more effective discharge planning.

Main findings on the use and purchase of hip prostheses

5 Medical Devices Regulations require new hip prostheses to be 'CE'- marked by manufacturers before they are marketed. The Regulations are not prescriptive about details of this procedure, and while they are an improvement on the previous system, there are practical difficulties which mean that the Regulations cannot alone ensure the effective long term performance of hip prostheses. There are more steps that could be taken to improve the approval process.

6 Guidance by the Medical Devices Agency asks trusts to report specific problems with hip prostheses. Manufacturers are similarly required to notify the Agency of problems through their post-market surveillance system. In practice trusts felt that the reporting process does not work well; and we found, for example, that few trusts understand what they should be reporting. The lack of an effective reporting process limits the ability of the Medical Devices Agency to take prompt action when a hip prosthesis performs poorly.

7 Given the relatively recent development of many hip prostheses, evidence of long term effectiveness is not available for all those in current use. Around 80 per cent of consultants who responded to our survey claim to have some published evidence for the effectiveness of the prosthesis they are using, and about half mainly use one of the five prostheses identified in an NHS Health Technology Assessment report² as having good published results at 10 years or more. However, care must be taken in drawing any conclusions from this finding since two of the prostheses would have been difficult to obtain in the UK; and, more

² *Effectiveness of hip prostheses in primary total hip replacement: a critical review of evidence and an economic model.*
NHS Health Technology Assessment Report, Vol. 2, No. 6

importantly, since the Health Technology Assessment report was published, other hip prostheses commonly used in the UK have been shown to have favourable 10-year survivorship data.

8 Evidence from long term clinical trials would greatly assist in an assessment of long term performance. However, there is a difficult question as to whether it is reasonable to wait for the results of such trials before new prostheses, which might have considerable benefits to patients, are approved for use. The use and usefulness of long term trials is also complicated by the fact that hip prostheses continually evolve as manufacturers make various adjustments with the aim of improving designs, which could have an impact on performance.

9 Most trusts did not have a policy for the introduction of prostheses into the trust for the first time. It is therefore difficult to be sure that these prostheses always offer improvements. Over a quarter of consultants we surveyed did not always tell patients when they implant such a prosthesis.

10 Trusts spent around £53 million on the purchase of hip prostheses in 1998-99. We were pleased to note that many have taken initiatives to reduce purchasing costs, and in many cases achieved substantial savings. There is scope, however, for more trusts to review their purchasing arrangements, which we estimate could result in savings of some 13 per cent, or £7 million a year. Although the NHS Executive accepts that further savings are probably possible, it does not accept the accuracy of the £7 million estimate, as the variations of the many factors affecting prices across trusts could significantly affect the potential for savings at individual trusts.

Main findings on hip replacement procedures

11 Three-quarters of consultants told us that 90 per cent or more of their patients were appropriately referred to them by General Practitioners. Fourteen per cent of consultants said that they had no inappropriate referrals, but six per cent considered that 25 per cent or more of their patients were inappropriately referred. The NHS Executive does not believe that this pattern necessarily indicates a significant problem since one purpose of referral to a specialist is to gain reassurance in cases where surgery is not necessary. Some level of “inappropriate” referrals is therefore to be expected in a properly functioning system. Consultants take a variety of actions when patients are not suitable for total hip replacement, which may be justified by casemix and clinical conditions, but there may also be scope for greater standardisation, perhaps drawing on the work of the National Institute for Clinical Excellence. Consultants also use varying criteria for age and weight above which they may not operate.

12 Currently, few trusts have integrated care pathways for hip replacements, setting out the expected course of treatment and the responsibilities of medical staff. Such pathways offer substantial potential benefits for patients, including reduced length of stay in hospital, and improved quality of care. The content and scope of integrated care pathways that are in place varies, and trusts have difficulty in obtaining information on the good practice that exists in the NHS.

13 It is important that trusts take steps to minimise delays and cancellations of operations to ensure that they make the most effective use of their resources, including more flexible use of theatre time. Across the country we estimate some 200 hours of theatre time each week are lost because of delays (some of which are unavoidable) in starting hip replacement operations. In total this is a significant resource. If theatre time could be used more effectively, for example by holding back-to-back theatre sessions, some of this time could be used to undertake additional hip replacements.

14 A primary total hip replacement costs between £384 and £7,784 (at 1998-99 prices), depending in part on the complexity of the procedure. The average cost is £3,755. Around one third of trusts have reviewed their costs, but around one third had difficulty in providing us with complete and accurate cost data. Without this basic information it is hard to see how these trusts can control costs effectively.

15 Total hip replacement is a common procedure and requires considerable surgical skill. Although at most trusts, hip replacements were sometimes carried out by unsupervised non-consultant grades, these include highly trained and competent doctors, and we have found no evidence to suggest that insufficiently trained surgeons are undertaking hip operations unsupervised. While relatively inexperienced clinicians rightly undertake hip replacement surgery under supervision in order to gain the necessary experience, the high complication rates that some studies show can arise suggest that trusts need to continue to manage carefully the risks involved.

16 On average, consultants perform around 50 primary and 12 revision hip replacements each year. Neither the Department of Health nor the British Orthopaedic Association suggest a minimum number that consultants should perform to maintain their expertise; nor is it necessarily appropriate that they do so. However eight per cent of consultants perform between one and nine primary total hip replacements a year, and some 71 per cent perform between one and nine revision hip replacements. In our view this may be insufficient to ensure outcomes of hip surgery are maximised, particularly in revision surgery.

Main findings on looking after the patient

17 Information available to consultants at an outpatient clinic varies. Good information at this stage has benefits for both staff and patients. Waiting times for hospital admission varied, and it is encouraging that most trusts have introduced initiatives to reduce waiting lists for hip replacements.

18 It is important that patients receive appropriate information about admission and their hospital stay to re-assure them about the procedures, and ensure they know what is expected of them. It is encouraging that most trusts provide patient education, though the quality varies substantially from trust to trust, and therefore in the extent to which it meets patients' needs.

19 Planning discharge from hospital ensures patients do not remain in hospital longer than necessary, and that any post-operative support is in place when needed. Effective discharge planning requires an early assessment of the patient's needs, and may require a home visit to assess domestic circumstances. It is good practice that discharge planning should begin prior to patient admission. At one third of trusts, post-operative discharge planning was undertaken only after admission to hospital ³

20 The average length of stay in hospital for a primary total hip replacement was 11 days, and at most hospitals is decreasing. Shorter length of stay improves patient satisfaction, reduces cost, lowers risk of hospital acquired infection, and makes more effective use of NHS trust resources. Many trusts and consultants believe that length of stay could be further reduced, though most trusts have no plans to do so. We estimate that a reduction of between 2 and 6 days could lead to a cost saving for NHS Trusts of between £15.5 and £46.5 million each year and release resources. This estimate does not, however, accurately represent the overall saving to the health system as earlier discharge from hospital could be dependent on hospital outpatient, community health and social care that could incur additional costs.

³ A number of these issues are covered more broadly in the National Audit Office's report on *Inpatient Admissions and Bed Management in NHS acute hospitals*, HC 254, Session 1999-2000, February 2000

21 Deep infection following total hip replacement can have serious consequences for the patient, significantly increase length of stay, and may require revision surgery. The British Orthopaedic Association has noted that trusts should aim for infection rates of between one and two per cent. Infection rates at trusts which record the data are, on average, less than one per cent, but vary up to eight per cent. However around half of trusts do not have complete and accurate data on their infection rates.⁴

22 Follow-up of patients after hip surgery is important to enable consultants to assess the results of surgery, and identify the possible need for revision in a timely way. Lack of effective follow-up may result in making any necessary surgery more difficult and potentially less successful. Sixty per cent of consultants believe that patients should be followed up regularly for life, though less than a quarter of consultants do so, they claim mainly because of pressure of work and lack of funds.

23 Measuring outcomes of hip replacement is important to determine the success of the operation and the prosthesis. Fewer than half of consultants measured outcomes, and even fewer did so regularly. The lack of comprehensive outcome information is a matter for concern, particularly with consultants using a wide range of hip prostheses, most with limited evidence of long term effectiveness.

Overall conclusions

24 Our examination has identified many examples of trusts and consultants applying good practice in total hip replacement. We were particularly impressed by the skill and dedication of many consultants, nurses and other NHS staff in caring for patients with hip pain. Patients we spoke to universally praised the service they received. There is scope for this good practice to be spread more widely, which will bring substantial benefits to the patient and the NHS, including cost savings and improvements in quality of patient care.

25 We are concerned, however, about the lack of evidence of effectiveness of hip prostheses in use, and weaknesses in the process for introducing new prostheses. One solution to this and other problems highlighted in this report would be to undertake controlled trials on new hip prostheses, and to carry out the majority of revision hip replacements at existing centres of excellence. We are also

4 See also the National Audit Office's report on *The Management and Control of Hospital Acquired Infection in Acute NHS Trusts in England, HC 230, Session 1999-2000, February 2000.*

concerned about variations in such areas as the length and duration of the follow up of patients following hip replacement, and supervision of hip replacement surgery.

26 A common theme we found is a lack of relevant information available to clinicians and others. Trusts and consultants were in many cases unable to provide accurate information on, for example, outcomes for hip surgery, infection rates or the cost of hip replacement. Some trusts were unable to provide us with information on the number of delays to and cancellations of operations, length of stay or even the price of hip prostheses. Accurate information is needed to ensure that trusts make further improvements in the service provided to patients, and that they effectively manage the resources devoted to hip replacements.

27 Most patients requiring a hip replacement receive an excellent service from the NHS. Many of the issues we have identified in this report are common to other areas of care in the NHS and have been clearly recognised by the government's White Paper "The new NHS". The government's quality agenda "A First Class Service" has set in train wide ranging reforms to tackle these issues, for example: the National Institute for Clinical Excellence, National Service Frameworks, clinical governance, professional self-regulation, life-long learning, the Commission for Health Improvement and the National Survey of patients. Our recommendations should be viewed in the context of this work, including guidance by the National Institute for Clinical Excellence on the choice of hip prostheses. We hope our recommendations will contribute to taking forward these reforms as well as help to improve service to the hip replacement patient.

Recommendation 1: Improving control over hip prostheses

28 We consider that there are weaknesses in the procedures for introducing, purchasing and monitoring the use of hip prostheses in NHS trusts. To remedy this we recommend that:

- The NHS Executive and the Medical Devices Agency should take further action to ensure the effectiveness of new hip prostheses. In particular we recommend that consideration be given to requiring that hip prostheses are subject to appropriate trials before they enter into general use in the NHS. The Agency should issue guidance on manufacturers' post-market surveillance systems to ensure consistency;

- The Medical Devices Agency and the NHS Executive should review the procedures for adverse incident reporting. The NHS Executive should encourage trusts to comply with reporting guidance issued by the Medical Devices Agency;
- Trusts should consider restricting the prostheses available to consultants to those with long term evidence of effectiveness and make appropriate arrangements for controlling the exceptional use of other prostheses;
- Trusts should develop a formal policy covering the introduction of hip prostheses into the trust for the first time;
- In the light of best practice we observed, trusts should review the scope for improving their prosthesis purchasing procedures to save costs, while maintaining quality standards.

Recommendation 2: Spreading good practice to ensure successful outcomes

29 We found examples of good practice by trusts in ensuring that patients with hip pain receive cost-effective treatment that results in a successful outcome. If spread more widely, this good practice would have significant benefits for trusts and patients alike. We therefore recommend that:

- The NHS Executive should assess the extent to which there is inequity in offering patients hip replacement surgery;
- Trusts should use integrated care pathways for hip replacement patients. The NHS Executive should arrange the production of guidelines to enable trusts to institute care pathways cost-effectively. We welcome the recent announcement that the National Institute for Clinical Excellence is to produce referral guidance on osteoarthritis for hips and knees;
- Trusts should review the extent to which there are avoidable delays and cancellations of surgery that result in lost theatre time. Where appropriate, and taking account of any impact on safety, they should prepare and implement an improvement action plan;

- Trusts should ensure their financial information systems enable them to identify the costs of procedures including hip replacements. Trusts should benchmark their performance against the National Schedule of Reference Costs, and take action where costs are high in relation to others;
- Trusts should measure the outcome of hip replacements regularly. The Department of Health should complete its consideration of the case for a national Hip Registry as quickly as possible;
- Trusts should check their arrangements to ensure that where operations are carried out by non-consultant grades without consultant supervision, there are effective risk management assessments and procedures in place;
- The NHS Executive, in consultation with the National Institute of Clinical Excellence and the British Orthopaedic Association, should explore whether a consultant should perform a minimum number of primary and revision hip replacements to maintain their expertise, and consider issuing guidance. They should also consider the merits of further development of centres of excellence to undertake, in particular, revision hip replacements.

Recommendation 3: Improving the quality of patient care

30 On issues of patient care we again found many examples of good practice which we believe would benefit from being spread more widely. We recommend that:

- For planned admissions trusts should draw on best practice to reduce, within available resources, the length of time that patients wait for hip replacements. Trusts should ensure that the re-prioritisation of patients on waiting lists is undertaken solely on clinical grounds;
- Consultants should discuss with Primary Care Groups what information should be available at the outpatient clinic. This could usefully be included in General Practitioner referral guidelines to be produced by the National Institute for Clinical Excellence;

- Better quality patient information on hip replacements should be developed. Trusts should consider designating a senior member of staff to ensure patient information meets high quality standards;
- As for other planned admissions, trusts should ensure that discharge planning is agreed or underway prior to hospital admission. Health and Social Services professionals should also consider home visits to patients prior to admission where it is cost-effective to do so;
- Consistent with maintaining standards of care, and in line with guidance in “The New NHS 1999 Reference Costs”, trusts should take steps to prevent unnecessary length of stay in hospital for hip replacement patients;
- Trusts should accurately monitor infection rates and take cost-effective action to reduce them;
- The NHS Executive, in consultation with the British Orthopaedic Association, should ask the National Institute of Clinical Excellence to issue guidance on the frequency and duration of follow up of hip replacement patients. Trusts should consider options for providing cost-effective follow-up;
- The NHS Executive should issue guidance to ensure consistent and well-designed patient satisfaction surveys. Trusts should undertake such surveys on a regular basis, using the results to improve patient services.

Part 1: Background and Introduction

1.1 Around 8 million people in the UK suffer hip pain from a wide range of hip disorders, though osteoarthritis is the most common. For many, the most appropriate treatment will be a total hip replacement. Over 30,000 hip replacements are performed in the UK each year at a cost of £139 million, and it is a highly effective procedure, producing immediate and dramatic benefits in almost all cases.

Case Study 1:

“At the age of 70, having enjoyed a few years of productive and healthy retirement, I developed an arthritic hip with severe pain, unsteadiness and a tendency to fall over. I had a hip replacement operation and was restored to my previous good health. Five years later I had similar symptoms in the other hip. That too was replaced.

At 77, I may not be able to walk fast, but I am very mobile and totally free of pain in my hips. I can do most gardening jobs, fish from the river bank and swim. Crossing fences, previously avoided, is no longer a problem. Without the operations I am convinced I would have become wheelchair-bound very soon after the symptoms started.”

The hip

1.2 The hip is a ball and socket joint, linking the pelvis and leg (Figure 1). The rounded head of the thigh bone (femur) sits in the socket (acetabulum) of the pelvis; and to prevent the bones rubbing together they are separated by cartilage, and the joint lubricated by synovial fluid. The hip joint allows backwards and forwards movement, inward/outward swing and some degree of rotation.

A hip joint

Figure 1



Source: James Stevenson,
Science Photo Library

1.3 Problems with hips are broadly of two types, both more common in older people. Arthritis and other hip joint diseases cause pain, stiffness and deformity, and may need treatment with medication, rehabilitation or surgery. Hip fractures usually result from a fall and require emergency treatment.

Hip replacement

1.4 Primary hip replacement involves replacing the femoral head and the acetabulum with an artificial prosthesis. The rounded head of the femur is cut away and replaced with a metal or ceramic ball joint, which is usually fixed in place with bone cement. A cup is fixed into the acetabulum, and the ball joint inserted (Figure 2).

X ray showing hip prosthesis inside hip joint

Figure 2

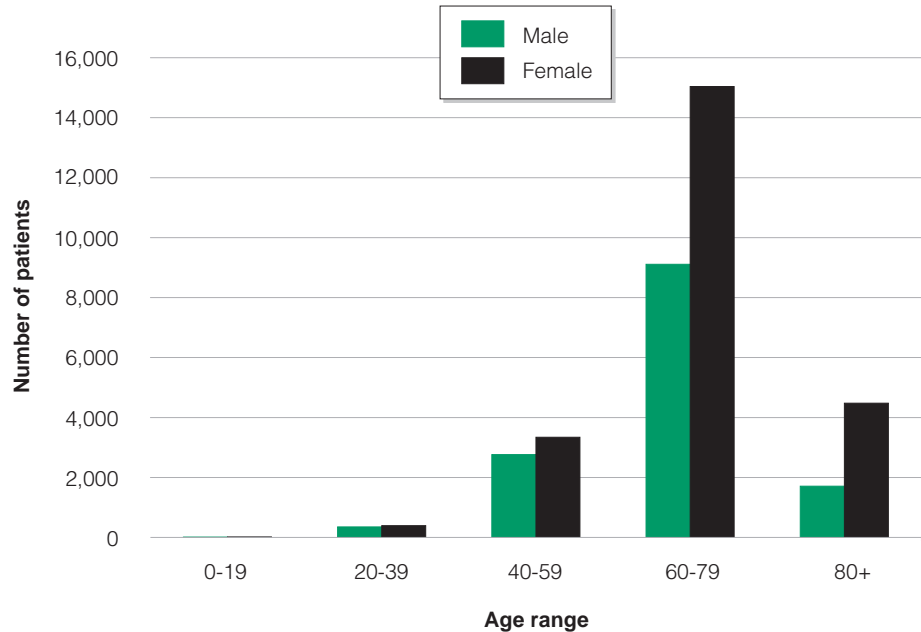


Source: Dr P. Marazzi,
Science Photo Library

1.5 Primary hip replacement is most commonly undertaken on patients aged between 60 and 79, and is more common in women than men (Figure 3). However, the average age of patients is decreasing as younger patients receive implants. The cost to NHS trusts of a primary hip replacement varies from about £384 to £7,784 (an average of £3,755), depending on a range of factors, including choice of prosthesis. The cost of the prosthesis itself varies from £300 to around £2,000 depending on function. The general process through which patients with hip pain go is shown in Figure 4.

Age and gender of primary hip replacement patients in 1998-99

Figure 3



Source: NAO Survey of NHS Acute Trusts

1.6 A survey carried out in 1994 found that 62 different prostheses made by 19 companies⁵, were sold in the UK and new designs are continuing to be introduced. Choice of prosthesis will depend on factors such as age and lifestyle of the patient and clinical indication for surgery, but will also reflect surgeons' choices between familiar and tested prostheses, and newer ones which a manufacturer may claim give better results. Most patients in England, however, receive one of a small number of established designs.

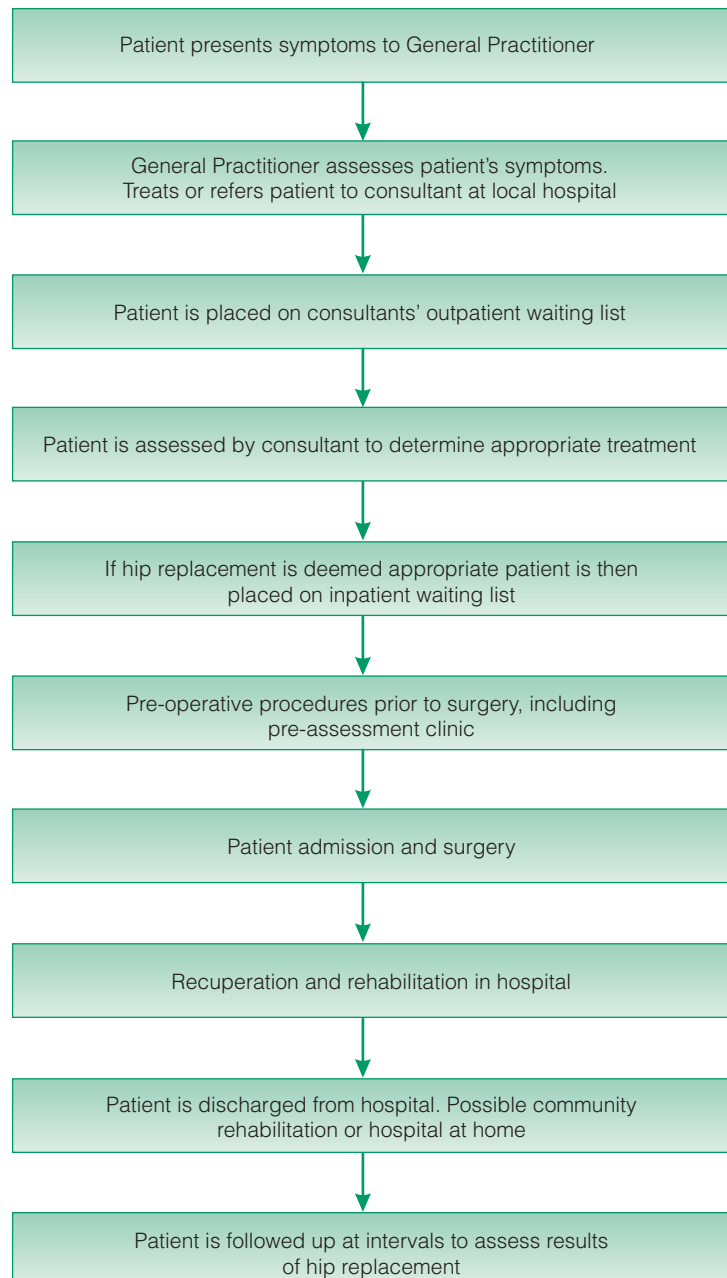
Revision surgery

1.7 Some five to ten per cent of hip replacement patients experience complications of varying degrees of severity, including infection and joint loosening (aseptic loosening). In such cases revision surgery may be necessary, replacing the original prosthesis with a new one. Revisions are more complex than primary hip replacements, due mainly to loss of bone around the joint, and the need to remove compacted cement from what may be a fragile femur. Higher failure rates are associated with revision surgery, which can be two to three times as expensive as primary hip replacement procedures.

⁵ *Primary Hip Replacement surgery: a systematic review of outcomes and modelling of cost effectiveness associated with different prostheses*. NHS Health Technology Assessment 1998, Vol 2, No 20

Treatment path for patients with hip pain

Figure 4



1.8 If the patient lives long enough, all hips will eventually fail; most commonly because of loosening of the prosthesis. Currently, most patients can expect their new hip to work effectively for some ten to fifteen years. Most hip replacement has been performed in older people, and the new hip prosthesis has survived for the lifetime of the patient. Hip replacements are now, however, more common in younger patients and will, at some stage, need to be replaced.

The roles of the Department of Health and the Medical Devices Agency

1.9 The organisational relationships, roles and accountabilities for hip replacement services are shown at Figure 5. The main role of the Department of Health in relation to hip replacement procedures is to develop appropriate policy, to react to situations as and when they arise, and to liaise with the Medical Devices Agency on the regulation of hip prostheses.

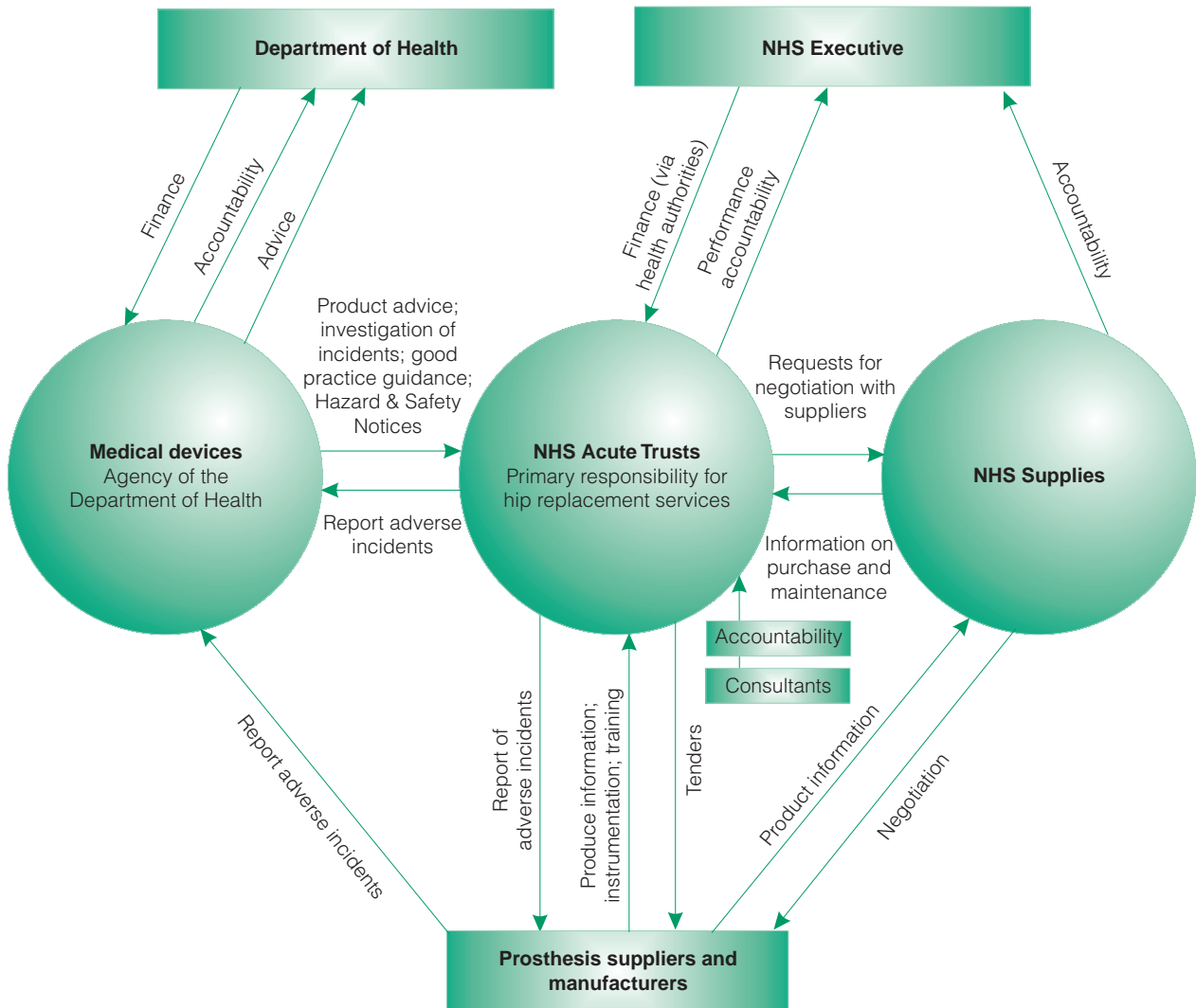
1.10 The Medical Devices Agency is an executive agency of the Department of Health. It is responsible for ensuring that all medical devices, including hip prostheses, are fit for the purpose for which they have been designed, and that they conform with UK legislation (Medical Devices Regulations) which are derived from the EC Medical Devices Directive. The Agency is also responsible for identifying problems in the use of hip prostheses through liaison with trusts and manufacturers.

Why the NAO examined total hip replacements

1.11 We examined total hip replacements in the NHS because:

- total hip replacement represents a substantial resource cost for the NHS. They cost some £140 million each year, and each acute trust on average spends some £257,000 on the purchase of hip prostheses;
- our preliminary work identified variations between trusts and between orthopaedic consultants in key aspects of total hip replacement, including alternative treatments offered, pre-admission procedures, and the extent to which patients are followed-up after surgery;

Figure 5 The organisational relationship, roles and accountabilities for hip replacement services



■ the large choice of hip prostheses, most – because of their newness - with little evidence of long-term effectiveness, places greater emphasis on the need to ensure new hip prostheses are evaluated properly and their use monitored. Our preliminary work identified possible shortcomings in these processes, which may impact directly on patients;

- there are wide variations in the cost of hip replacements. Factors may include length of stay in hospital, and prices paid for hip prostheses. This suggests that there may be scope for improved value for money, and financial savings which will facilitate the better use of resources;
- the study provided an opportunity to identify good practice in total hip replacement, to help trusts and the NHS Executive improve the management of total hip replacements.

Scope of our examination

1.12 Against this background we examined the procedures for introducing and monitoring hip prostheses, and looked at how trusts manage total hip replacements. In particular we examined:

- whether patients can expect good outcomes on the basis of the procedures that are in place to ensure the effectiveness of new hip prostheses;
- whether hip procedures are organised economically, efficiently and effectively; and
- whether the care pathway for hip replacements is designed to ensure the best outcomes for patients.

1.13 Our examination covers elective hip replacements only, and does not cover other joint replacements, which are becoming increasingly common. However we consider that they have a number of issues in common, and some of our conclusions and recommendations will therefore also apply more widely. We also excluded trauma hip surgery which, similarly, has issues in common with elective hip replacements but which has been examined by the Audit Commission.⁶

Methodology

1.14 Our report is based on a survey of all 207 acute NHS hospital trusts carrying out hip replacements in England, and 986 orthopaedic consultants undertaking hip replacements; and discussions with key stakeholders including the NHS Executive, the Medical Devices Agency and hip prosthesis manufacturers.

⁶ *United they stand: co-ordinating care for elderly patients with hip fracture.* Audit Commission, 1995

1.15 We visited a sample of trusts to discuss in detail some of the issues raised in the report, to validate survey responses, and to identify examples of good practice. In addition we visited the United States, where we held discussions with the Food and Drug Administration and with staff at three hospitals specialising in orthopaedics, to make relevant comparisons with practices in the UK. Further details of the methodology are at Appendix A.

1.16 Throughout the study we were assisted by a panel of experts who provided advice and assistance. Members of the panel included representatives from the British Orthopaedic Association and consumer groups, prominent orthopaedic consultants, and observers from the NHS Executive and the Medical Devices Agency. We are grateful for their valuable help and assistance. A full list of expert panel members is at Appendix B.

1.17 At Appendix C we provide a set of key questions which form the basis for information which clinicians may wish to discuss with patients about to undergo hip replacement.

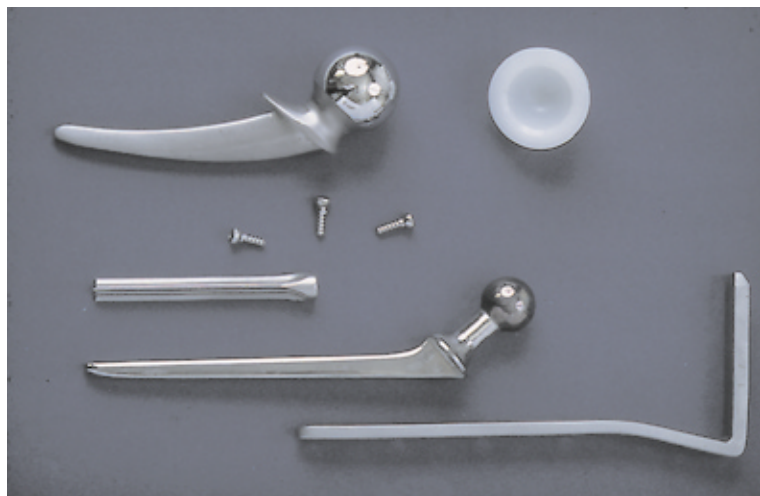
Part 2: The Hip Prosthesis

Introduction

2.1 Effectiveness of the hip prosthesis is a key element in ensuring a successful patient outcome from total hip replacement. Choice of prosthesis will take account of the age, lifestyle, general clinical condition and diagnosis of the patient. The prosthesis used will also reflect the views of individual consultants. Figure 6 shows the typical components of hip prostheses.

Photograph showing stems & cup parts of a hip prosthesis

Figure 6



Source: James Stevenson,
Science Photo Library

2.2 A survey carried out in 1994 found that 60 different hip prostheses made by 19 different companies were sold in the UK, costing from £300 to around £2,000, depending on function. Most patients in England, however, receive one of a small number of established designs. They range from established 'gold standard' prostheses, used successfully for many years, to experimental models featuring new materials or design. The Effective Health Care Bulletin commissioned by the Department of Health and published in October 1996⁷ noted that most of these prostheses had not been properly evaluated and that it was not possible to

determine how long they would last. The Bulletin, however, noted that there are difficulties in evaluating the evidence, for example because there are few high quality comparative studies.

2.3 This part of the report examines the controls and procedures for approving new prostheses for use in the UK, the choice of prosthesis by trusts and consultants, and the way trusts purchase prostheses.

Regulations govern the introduction of new prostheses

2.4 Prosthesis manufacturers are responsible for ensuring that hip prostheses are fit for the purpose for which they have been designed. The Medical Devices Agency is responsible for ensuring compliance with UK regulations, which are based upon European directives for medical devices. The Agency is also responsible for identifying problems in the use of hip prostheses through liaison with trusts, prosthesis manufacturers and other interested parties. Trusts and manufacturers are responsible for reporting medical device-related adverse incidents to the Agency, which records and investigates reports and takes action if appropriate.

2.5 The Medical Devices Regulations came into force on 1 January 1995, with a transitional period lasting until June 1998. They require that every medical device placed on the market after 14 June 1998 should bear a 'CE' marking demonstrating that it complies with essential requirements for safety. Prior to the Regulations, the UK operated a voluntary scheme through the Medical Devices Agency under which manufacturers documented and maintained quality assurance schemes in their design and manufacturing processes.

2.6 The Medical Devices Regulations contain a number of essential requirements that manufacturers must be able to demonstrate that their products meet. These cover general safety issues as well as, for example, issues of performance, design and construction. Independent Notified Bodies throughout the European Community, appointed in the United Kingdom by the Medical Devices Agency, assess conformity with the requirements, undertake an audit of the manufacturer and authorise the use of a 'CE' marking.

For most prostheses, evidence of long term effectiveness is unlikely to be required as part of ‘CE’ marking

2.7 It is for the Notified Body to determine the evidence and information required to support a manufacturer’s application for a ‘CE’ marking, which may cover a range of products. But for most hip prostheses it is unlikely that clinical evaluation data on long term effectiveness will be required unless new materials are involved in the manufacture, despite the fact that even small changes to existing prostheses can have a significant impact on performance and patient outcomes.

Post-market surveillance systems vary

2.8 A new control introduced by the Regulations is the requirement for manufacturers to establish a post-market surveillance system to ensure that any problems with hip prostheses are identified and rectified as soon as possible. It is the role of Notified Bodies to ensure that companies do this, and for the Medical Devices Agency to investigate reports of unacceptable performance. Some manufacturers rely on customer complaints to provide the input to their post market surveillance system; others are more proactive in seeking feedback on the performance of their prostheses. Given the importance of post-market surveillance, there is a need for clear guidance to be provided to manufacturers and Notified Bodies as to what constitutes an appropriate post-market surveillance system. The Medical Devices Agency has developed a draft guidance document on post-market surveillance, but this has yet to be formally promulgated.

2.9 The Medical Devices Regulations require prosthesis manufacturers to notify the Agency of certain adverse incidents under what is known as the “Vigilance System”. Its purpose is to protect patients and others by reducing the chance of the same types of adverse incident being repeated across the European Community.

Trusts are required to report problems with hip prostheses to the MDA but the reporting system may fail to pick up prostheses with poor results

2.10 In addition to the requirement for manufacturers to report adverse incidents to the Medical Devices Agency, Agency guidance sets out the circumstances in which trusts should also report on the performance of hip prostheses. These are:

- prosthetic failures;
- aseptic loosening;
- where the reason for revision surgery is unclear.

2.11 We asked trusts and consultants to identify the circumstances in which they would report prosthesis problems to the Medical Devices Agency. Five per cent of trusts said there are no circumstances in which they would report to the Agency, and a further five per cent did not know under what circumstances they would report. Some 79 per cent of consultants consider mechanical failure to be reportable, and only 52 per cent say they report aseptic loosening.

2.12 The Medical Devices Agency's monitoring system is one of the key processes by which the Agency identifies problems with hip prostheses. However it is clear from the responses to our surveys that trusts and consultants report a small proportion of reportable adverse incidents regarding hip prostheses.

The 3M Capital Hip prosthesis

2.13 The Capital hip prosthesis, manufactured by 3M Health Care and affixed a 'CE' marking in early 1995, was implanted between 1991 and 1997 in some 4,700 patients at 53 trusts. It was marketed by the company as a variant of the established 'gold standard' Charnley prosthesis, but at a lower cost.

2.14 After the launch of the Capital hip, the company received reports of early revisions and issued guidance on a revised surgical protocol in August 1995. The first indications of a possible design fault came in early 1995, and the company subsequently undertook an extensive survey of consultants. The results - a revision rate of 5 per cent as at January 1996 - were considered by 3M Health Care to be within industry standards. In July 1996 a television documentary alleged high failure rate of the Capital hip. As a result, the Medical Devices Agency made enquiries and subsequently learned of other consultants experiencing problems with the Capital hip.

2.15 In March 1997 3M Health Care stopped marketing the Capital hip for commercial reasons, and in August 1997 the Medical Devices Agency notified the company that its enquiries were complete, with no further action required. In January 1998 Agency staff at a conference learned of unconfirmed revision rates of the Capital hip as high as 20 per cent after two years at a small number of clinical

centres. This was later confirmed in relation to these centres, and the Agency issued a Hazard Notice in February 1998 advising that all patients implanted with the Capital hip should be recalled for clinical review.

2.16 Subsequently 3M Health Care undertook to finance the examination of patients who received a Capital hip, and to pay the costs of any necessary revision surgery and other necessary care. The company is also funding a clinical audit by the Royal College of Surgeons to identify the cause, or causes, of the reported poor performance of the Capital hip prosthesis. This is due to be published in Spring 2000.

2.17 Whilst the outcome of the clinical audit by the Royal College of Surgeons is not yet known, the events surrounding the Capital hip prosthesis may demonstrate that 'CE' marking is not a reliable predictor of the future clinical performance of a hip prosthesis. The events do, however, confirm our survey results which show that the system for reporting adverse incidents does not always operate effectively. Timely reports from all trusts experiencing problems with the Capital hip might have enabled the Medical Devices Agency to take action earlier.

Evidence of long-term effectiveness of hip prostheses is limited

2.18 Hip prosthesis technology is continually changing, with new designs and techniques being introduced. Some prosthetic designs have now been shown to have good long term outcomes; others, in the view of the NHS Health Technology Assessment⁸ fail "early and spectacularly", though the NHS Executive disputes this. There is a need to strike a balance between using prostheses with published long-term performance data, and the need to develop and improve hip prostheses through the introduction of new designs and materials.

2.19 Outcome information on the effectiveness of individual hip prostheses is important if patients, many of whom are elderly, are to have continued improvement to quality of life. In December 1998 the NHS Health Technology Assessment Programme published the results of research aimed at analysing the available evidence on whether hip prostheses differ in their medium to longer-term outcomes. The report drew on data between 1980 and 1995, including results from Sweden covering 92,000 patients and spanning 10 years. It concluded that "the poor quality of evidence overall does not provide a basis clearly and authoritatively to identify prostheses that could be - or should not be -

8 Effectiveness of hip prostheses in primary total hip replacement: a critical review of evidence and an economic model" Health Technology Assessment 1998, Vol 2, No 6

recommended for use in the NHS. However it is clear that the more expensive the prosthesis, the more difficult it is to provide justification for its selection on the basis of the current evidence.” Account does, however, need to be taken of case mix, and it may be that more expensive implants are being used for the more difficult clinical situations that are not adequately served by standard prostheses or operative techniques.

Some consultants use prostheses with a good track record

2.20 An NHS Health Technology Assessment Report in July 1998 (“Effectiveness of hip prostheses in primary total hip replacement: a critical review of evidence and an economic model”) stated that for cemented prostheses “models with good, published results (at 10 years or more) include the Stanmore, Howse, Lubinus, Exeter and Charnley.” Our survey showed that 51 per cent of consultants mainly used one of these prostheses for patients aged over 75, and 45 per cent used one of these prostheses for patients aged 50-75. However, care must be taken in drawing any conclusions from this finding since two of the prostheses would have been difficult to obtain in the UK; and, more importantly, since the Health Technology Assessment report was published, other hip prostheses commonly used in the UK have been shown to have favourable 10-year survivorship data.

Most consultants have published evidence of effectiveness for the prostheses they use, but 14 per cent do not

2.21 Whilst 81 per cent of consultants have published evidence for the effectiveness of the prosthesis they are using, 14 per cent – who in total performed over 3,400 hip replacements in 1998-99 - are using prostheses for which they have no evidence of effectiveness. Over half of consultants said there are prostheses currently available that they would avoid on the basis of poor outcome, and almost half said that they avoid certain prostheses due to lack of research evidence.

Most trusts have no policy for the introduction of prostheses

2.22 To determine the effectiveness of new or re-designed prostheses, consultants may formally monitor performance over time. Over half of trusts that responded to our survey were involved in such testing, with approval being given mainly by either the Clinical Director or individual consultants. Trusts told us that manufacturers offer a range of incentives to introduce new prostheses to a trust, mainly by providing instrumentation or research funding, which consultants

frequently accept. Four consultants told us they were offered commission by manufacturers to try out specific hip prostheses. Thirteen per cent of trusts said that these incentives were influential in introducing new prostheses.

2.23 Trusts need to exercise control over the introduction of prostheses into the trust for the first time, but we found that less than one third of trusts have a policy for doing so. Around 70 per cent of consultants always inform patients that they implant such a prosthesis, but some 27 per cent of consultants do not always do so.

There are questions over the effectiveness of control over new prostheses

2.24 The Medical Devices Regulations are an improvement on the previous voluntary system of control over the introduction of new prostheses to the UK market, and are intended to ensure the safety and performance of medical devices. However, the Medical Devices Agency told us that while the Regulations aim to ensure that a hip implant performs as its manufacturer intends during its useful life, there is a practical difficulty in using premarket measures to demonstrate long-term safety and performance after, say, 10 years of use, without causing unacceptable delays to the introduction of innovative new products which may bring benefits to patients.

2.25 To address these difficulties the Regulations allow manufacturers to show likely long term performance by a combination of in-vitro testing, clinical data on equivalent products and data from short term pre-market clinical investigations. These data may then be examined by an independent certification body prior to 'CE' marking. Additionally the Regulations require manufacturers to maintain an adequate post market surveillance system, so that devices which perform inadequately can be identified and appropriate action taken.

2.26 Poor performance by a hip prosthesis is a serious matter, particularly for the patients concerned. Around 30 per cent of consultants who responded to our survey saw risks in the current system. Whilst many patients will receive a replacement hip that will perform satisfactorily for many years, there has been a proliferation of design changes to prostheses whose long term effectiveness is unknown.

2.27 These issues are not unique to hip replacements. Across the whole of clinical care, there is a difficult balance to be struck between encouraging innovation, to develop new interventions which will improve patient care, and

ensuring that there is an adequate evidence base before innovations are accepted into routine use. The precise balance point is a matter of fine judgement and will differ from area to area.

2.28 The government has set up the National Institute for Clinical Excellence to appraise the evidence on clinical interventions, including new products and processes, and to give guidance on which can be recommended as clinically and cost effective. This guidance is not mandatory, but NHS bodies and clinicians will be expected to give it due weight in the decisions they take in individual circumstances, for instance in the purchasing decisions of individual trusts. Hip replacement was one of the first topics referred for appraisal by the National Institute for Clinical Excellence.

Trusts spend some £53 million on purchasing hip prostheses and many are taking initiatives to reduce purchasing costs

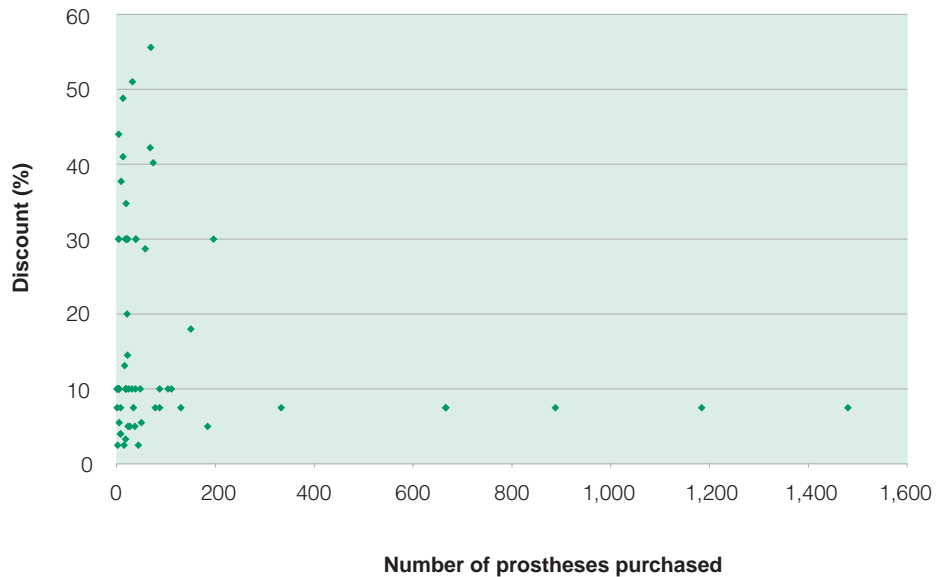
2.29 Each NHS trust spent on average £257,000 on hip prostheses in 1998-99; in total some £53 million a year. It is important, therefore, that trusts maximise the value for money of their purchasing procedures.

2.30 There is a range of initiatives trusts can take to ensure maximum value for money in their prosthesis purchasing, and our survey results indicate that many are doing so. For example, three quarters of trusts have negotiated a price discount for their prostheses, mainly based on the volume of purchases. However, the percentage discount obtained by trusts varies substantially from 2.5 per cent to 55.6 per cent (Figure 7) even though many trusts are purchasing similar volumes. Nearly two-thirds of trusts have tendered for the supply of prostheses, and around one-third have reduced the number of suppliers, with 16 per cent moving to a single supplier. Fifteen per cent of trusts have set a standard price for the prostheses they purchase and sixteen per cent of trusts have realised discounts by purchasing prostheses through NHS Supplies.

2.31 We attempted to compare the prices paid by trusts for individual hip prosthesis components to determine whether there was any variation. We were unable to make full comparisons, however, partly because of factors such as variations in suppliers and levels of un-discounted price and the volume purchased; and partly because 53 per cent of trusts were unable to provide accurate information. Our survey results showed that 35 trusts made an average saving of £42,000 following a review of purchasing practice and that seven of those trusts have saved over £100,000. This, and the wide variation in discount irrespective of volume highlighted in Figure 7, indicates that trusts should

Discounts received by trusts in purchasing modular hip joints

Figure 7



Source: Survey of NHS Acute Trusts

examine their purchasing procedures to ensure they are getting the best value for money from their prosthesis purchasing. We estimate that if all other NHS acute trusts achieved comparable savings the NHS could save a further £7.2 million per year. Although the NHS Executive accepts that further savings are probably possible, it does not accept the accuracy of the £7 million estimate as the variations of the many factors affecting prices across trusts could significantly affect the potential for savings at individual trusts.

2.32 In addition to discount negotiation, putting the contract for supply out to tender, and reducing the number of suppliers are the initiatives where trusts have so far demonstrated the most scope to achieve savings (see Case Studies 2-5). Trusts reported additional benefits from such initiatives, with two-fifths of trusts who have taken action reporting an improvement in the service provided by suppliers, and nearly one quarter reporting reductions in delivery time.

Case Studies 2-5: Examples of trusts which have reduced the cost of hip prostheses

- ✓ **Lincoln and Louth NHS Trust** generated £45,000 in annual savings through putting their supply contract out to tender, reducing the number of suppliers and negotiating a discount. This reduced their annual expenditure by some 20%.
- ✓ **Dudley Group of Hospitals NHS Trust** put their prostheses purchasing contract out to tender, reduced the number of prosthesis suppliers and introduced a standardisation policy. These measures resulted in annual savings of some £22,000.
- ✓ **Kettering General Hospital NHS Trust** estimate to have saved £42,000 over the last two years through tendering and negotiating a discount on the supply on hip prostheses. The current contract ceases in July 2000 and will then be re-negotiated.
- ✓ **Heatherwood and Wexham Park Hospitals NHS Trust** saved £35,000 through introducing a standardisation policy, negotiating a discount with their suppliers and implementing a computerised stock control system.

2.33 The NHS Executive, in June 1999, set out actions which NHS trusts and NHS Supplies should take to improve trusts' procurement performance. NHS Supplies are to identify and develop a national procurement strategy for key products and services; and a new agency of the Department of Health will be established to develop the national purchasing function, including exploring the scope for mandatory national contracts.

Getting a better deal for the patient and the NHS

2.34 Effectiveness of the prosthesis is a key element in ensuring a successful total hip replacement for the patient. Consultants have a wide choice of prostheses, most of which have limited or no published long-term data on effectiveness though many consultants do choose on the basis of track record. In examining monitoring, purchasing and introduction of prostheses we recommend that:

- Whilst we recognise that the Medical Devices Agency complies with European legislation, the Agency and the NHS Executive should take further action to protect the public from prostheses that may subsequently prove to perform poorly. In particular we recommend that consideration be given to requiring that hip prostheses are subject to appropriate trials before they enter into general use in the NHS;
- the Medical Devices Agency should issue guidance on systems of post-market surveillance to ensure consistent coverage;

- Trusts should consider restricting the prostheses available to consultants to those with long term evidence of effectiveness, in line with recommendations by the National Institute for Clinical Excellence, and make appropriate arrangements for controlling the exceptional use of other prostheses; The National Institute for Clinical Excellence should issue guidance to trusts on this issue;
- the Medical Devices Agency and the NHS Executive should review its procedures for adverse incident reporting. The NHS Executive should encourage trusts to comply with reporting guidance issued by the Medical Devices Agency. Trusts should develop a formal policy covering the introduction of hip prostheses into the trust for the first time, and should tell patients in every case before they receive a new prosthesis;
- In the light of best practice we observed, trusts should review the scope for improving their prosthesis purchasing procedures to save costs while maintaining quality standards.

Part 3: Getting it right first time: the hip operation

Introduction

3.1 Total hip replacement surgery has been widely practised in the UK for over 30 years, and some 31,296 primary operations and 5,503 revision operations were performed in 1998-9. This part of the report examines action taken by NHS trusts and orthopaedic consultants to have in place effective procedures to ensure that patients with hip pain have successful outcomes, and cost effective treatment.

There are no standard criteria used by General Practitioners to refer patients to a consultant

3.2 An NHS Health Technology Assessment report published in July 1998⁹ noted that "variations in the rates of total hip replacement across the regions in England raise questions about the consistency of decision-making in General Practitioner referrals". We asked consultants if they considered that patients had been appropriately referred by General Practitioners.

3.3 Three-quarters of consultants told us that 90 per cent or more of their referrals from General Practitioners were appropriate. Fourteen per cent of consultants said that they had no inappropriate referrals, and six per cent considered that 25 per cent or more of referrals were inappropriate. The NHS Executive does not believe that this pattern necessarily indicates a significant problem since one purpose of referral to a specialist is to gain reassurance in cases where surgery is not necessary. Inappropriate referrals may be reduced by drawing up agreed referral criteria between General Practitioners and consultants. Although less than 10 per cent of consultants have done this, they believe it would ensure a consistent referral approach by General Practitioners, and result in faster referral for suitable patients. The National Institute for Clinical Excellence has announced that it is to produce referral guidance on osteoarthritis for hips and knees.

9 Effectiveness of hip prostheses in primary total hip replacement: a critical review of evidence and an economic model (NHS Health Technology Assessment Report, July 1998)

The range of alternative treatments offered by consultants varies

3.4 For patients with hip disorders, total hip replacement may not be the appropriate treatment. We asked consultants about the extent to which they consider alternative treatments, and select patients for surgery. We found variations in the range of alternative treatments that consultants considered; and that while many offer a wide range of alternatives, including anti-inflammatory, analgesic and other pain relief drugs, and referring back to General Practitioners, some consultants only considered a much more narrow range of alternatives for patients in similar circumstances, such as referring patients for physiotherapy. This variation may be justified by case mix and clinical considerations, but there may be scope for a more standardised approach, for example through the use of referral guidelines produced by the National Institute for Clinical Excellence.

Surgery is not always offered on an equitable basis

3.5 Equity is a key principle of the NHS, and consultants should not discriminate unfairly on non-medical grounds against patients on grounds of age, weight or other factors. Surgery on the very old or the grossly overweight is more difficult and may not be in the patient's best interests. Thirty three per cent of consultants do not offer surgery to patients considered overweight, and 8 per cent may refuse surgery on grounds of age, in patients for whom surgery would otherwise be appropriate. However, whilst those consultants who might refuse surgery on grounds of age generally agree that 90 or 95 is an appropriate upper age limit, there is considerable variation in the weight above which consultants might refuse surgery - from 14 stone to 20 stone, and from 15 per cent to 50 per cent above ideal weight. This calls into question the equity with which patients are considered for surgery, and implies that in some cases, whether or not a patient is offered surgery depends on which consultant he or she sees.

Integrated care pathways are becoming increasingly common, but there is a difficulty in obtaining information on good models

3.6 The NHS White Paper (The new NHS) published in December 1997 describes the establishment of "programmes of care" for patients flowing across organisational boundaries. One tool suggested for this is the integrated care pathway, which sets out a comprehensive route of care, including the anticipated course of treatment and actions to be taken by each member of the medical team, for a particular condition. Developed initially in the United States, integrated care

pathways are becoming increasingly common in trusts, particularly in orthopaedics. The principal benefits of integrated care pathways are reduced costs, reduced length of stay, and improved quality of clinical care for the patient.

3.7 We found that only 29 per cent of trusts use integrated care pathways for all their primary hip replacement patients. These trusts noted significant patient benefits including reduced length of stay (see Case Studies 6-9), an improved multi-disciplinary approach to quality of care, and a standardised approach to care. Most trusts that we visited which had developed, or were in the process of developing, integrated care pathways had found it difficult to obtain information on best practice. Many had used material available on the internet, and there was a strong feeling amongst trust staff that there was much wasted effort across the country in developing pathways for which good models may already exist elsewhere.

Case Studies 6-9: Examples of trusts using critical pathways to reduce length of stay

- ✓ **The Mid-Sussex NHS Trust** uses an Integrated Care Pathway for their hip replacement patients. This acts as a checklist for the multidisciplinary team and reduces documentation. It also facilitates early discharge planning in conjunction/agreement with the patient. If the patient is discharged early with the Trust's Intensive Home Nursing Service, the Integrated Care Pathway document goes with them and is therefore accessible to the Primary Care Team. This helps to ensure a smooth transition from the acute sector to the community.
- ✓ **Thanet Healthcare NHS Trust** introduced their critical pathway as a multidisciplinary document to improve communication of each patient's care and post-op recovery. This has resulted in the trust reducing its average length of stay for primary hip replacement patients from 13 days in 1997-98 to 11 days in 1998-99. This work is being developed further by the East Kent Hospitals NHS Trust of which Thanet is now a part.
- ✓ **Nottingham City Hospital NHS Trust** has reduced its average length of stay for primary hip replacement patients from 17 days in 1994-95 to 10 in 1998-99, through measures including the use of a critical pathway. The critical pathway provides a consistent approach for all hip replacement patients in the trust.
- ✓ **Southport and Formby NHS Trust** reduced its average length of stay for primary hip replacement patients from 15 ½ days in 1997-98 to 13 days in 1998-99 as a result of implementing its critical care pathway.

The scope of care pathways varies considerably

3.8 We reviewed a sample of integrated care pathways for hip replacement and found they varied considerably in both scope and detail. They ranged from 4 to 118 pages, and varied as to whether they covered physiotherapy, operating theatre procedures, discharge, and pre-assessment clinics. None of them were

cross-boundary in scope covering, for example, the relationship between trusts and General Practitioners; and very few included clinical or quality of care standards.

Delays and cancellations result in a loss of theatre time and lost operations but around one third of trusts have action plans to minimise delays in starting hip operations

3.9 It is important for trusts to take reasonable measures to minimise the number of delays and cancellations of hip replacement operations. Such events can have significant resource consequences, and can be upsetting for the patient. We found that across the country there is around a 10 per cent difference between the number of operations planned and completed, mainly because operations are cancelled or rescheduled. Trusts told us that one hour of theatre time each week on average is lost because of delays (some unavoidable) in starting hip operations. Some 25 per cent of trusts told us that this was mainly because the patient was not ready or was medically unfit; around 30 per cent of trusts told us that the main reason was related to whether trusts were using their resources effectively, such as facilities or staff not being available when required. Across the country this amounts to some 200 hours of theatre time lost each week - in total a significant resource. If theatre time could be used more effectively, for example by holding back-to-back theatre sessions, it would enable some of this time to be used to undertake additional hip replacements (see Case Study 10).

Case Study 10: Good practice in use of theatre time

- ✓ **The Glenfield Hospital NHS Trust** operates an all-day theatre list rather than two half-day lists. The all-day list runs from 8.30am to 4.30pm with no break for lunch, achieved by having overlapping nursing staff shifts. This has enabled the Trust to maximise available operating time and minimise wasted theatre time.

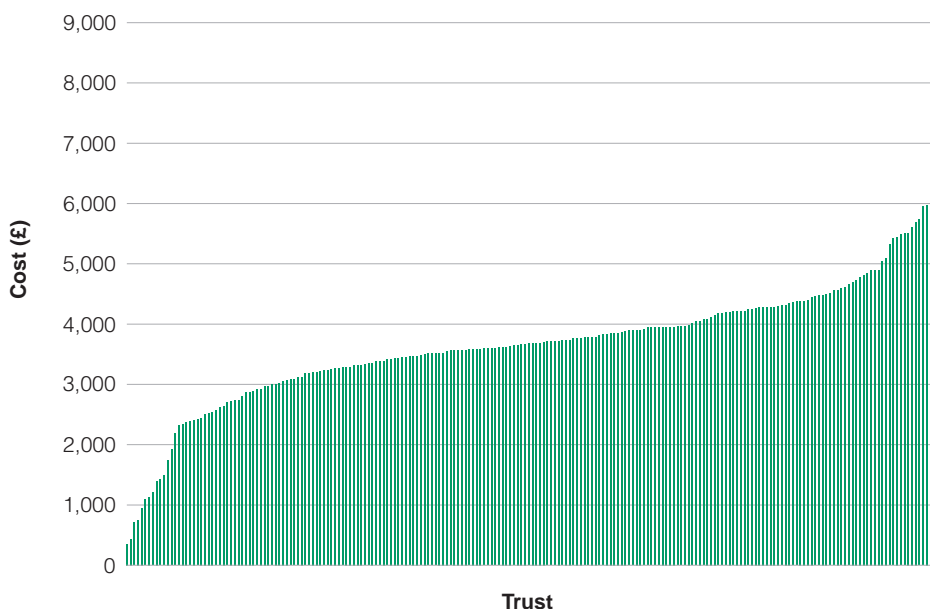
3.10 Some 34 per cent of trusts have a plan of action to reduce delays in starting hip operations. The main actions taken to reduce the impact of these delays on theatre utilisation include extra or extended daily theatre lists for hip replacement (37 per cent of trusts), extra weekend theatre lists (25 per cent) and extra or extended evening theatre lists (19 per cent).

Cost of total hip replacement varies between trusts and around one third of trusts have taken measures to reduce costs

3.11 The Department of Health National Schedule of Reference Costs published in November 1999 shows that the cost of carrying out primary hip replacements varies generally from £384 to £7,784 (Figure 8). Our survey results show that on average direct costs of the hip replacement procedure account for 57 per cent of the total cost of the procedure, a further 27 per cent is accounted for by indirect costs and 16 per cent by overheads. However these figures hide wide variations with, for example, direct costs varying between 16 per cent and 88 per cent of the total. Around one third of trusts had difficulty in providing accurate information on costs, and the survey results on cost therefore need to be treated with caution. Variations may be explained by factors such as differences in casemix, length of stay, volume of operations performed and the cost of the hip prosthesis, but the data provided by trusts was insufficient for useful analyses to be made.

Cost of primary hip replacement in 1998-99

Figure 8



Source: National Schedule of Reference Costs 1998-99

3.12 One of the benefits of the National Cost Reference Database is that trusts can compare their costs with similar trusts, and review their services where appropriate. We found that 29 per cent of trusts had taken action as a result of the publication of the Database (and not solely in relation to hip procedures), including introducing a new costing system or reviewing their costs (39 per cent of those taking action), making comparisons with similar trusts (36 per cent) and

establishing a steering group to discuss trust performance (16 per cent). Other initiatives taken include setting up projects to examine specific issues and establishing a local benchmarking group. These initiatives by trusts are encouraging, and are likely to result in benefits in terms of value for money improvements.

Few consultants measure outcomes on a continuous basis

3.13 Measuring the outcome of hip replacement is important to determine the success or otherwise of the hip replacement. Where outcomes are measured, trusts have used the results to introduce significant changes (see Case Study 11), including the introduction of pre-operative assessments, integrated care pathways, and changes in the rehabilitation programme. In our survey we sought to identify whether and how outcomes of hip replacement are measured.

Case Study 11: Example of outcome measurement

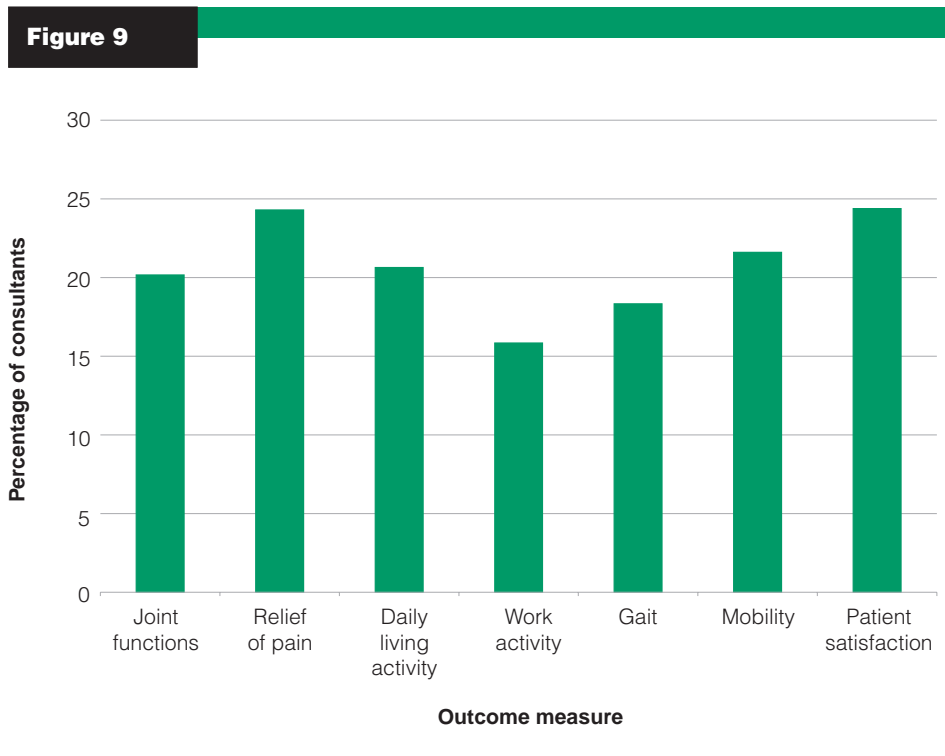
- ✓ **The Royal National Orthopaedic Hospital NHS Trust** continuously audit their outcomes in terms of joint function, relief of pain and daily living activity. As a result of this continuous audit, the Trust has changed the prostheses they use and introduced pre-operative assessments for hip replacement patients.

3.14 Outcomes of hip replacement can be measured in various ways. These include the rate of revision surgery, the percentage of patients free of pain, incidence of infection, rates of re-operations and re-admission, and rating against a recognised scoring system measuring a combination of pain, walking ability, function and mobility. Outcomes may be measured during follow up examinations of hip replacement patients (see paragraphs 4.27 to 4.29), through routine monitoring or through one-off clinical audits.

3.15 A numbers of factors affect the outcome of total hip replacement surgery, including the age, physical condition and co-morbidity of the patient. Choice of hip prosthesis can have a substantial impact on the outcome of surgery, as can the experience and skill of the orthopaedic consultant. Other factors include infection control procedures, and the extent to which patients follow the recommended post-operative regime.

3.16 The results of our survey show that fewer than half of consultants measure patient outcomes of hip replacement surgery, and of those that do, fewer than half do so on a continuing basis (Figure 9). Only 50 per cent of consultants monitor prosthetic failures and most of those that do were unable to tell us what their failure rates were at 3 and 5 years after the operation.

Percentage of consultants using continuous clinical audit to evaluate outcomes of hip replacement surgery



Source: Survey of NHS Acute Trusts

3.17 We also asked consultants who carried out primary hip replacements how many re-operations, re-admissions and dislocations they had had in relation to their hip replacements for operations carried out in 1997-98. Over half of consultants were unable to provide us with accurate data.

3.18 We consider that the lack of comprehensive outcome information on hip replacements is a matter of concern. In Part 2 of this report we have commented on weaknesses in the system for introducing new hip prostheses into the UK. Once they have been introduced, orthopaedic consultants can implant them, and with no comprehensive record of outcomes, problems with prostheses may not be identified sufficiently early to take appropriate action.

Non-consultant grades undertake hip replacements without supervision

3.19 Research published in 1996 ("Effective Healthcare Bulletin: Hip Replacement", October 1996) indicates that total hip replacements performed by trainees were over 11 times more likely to need a revision than those carried out by a consultant. More recent research has shown that there is no difference in the outcome of surgery performed by non-consultant grades, but commonsense indicates that a certain degree of skill and experience, or appropriate supervision,

is necessary to ensure satisfactory outcomes. Ninety-six per cent of orthopaedic consultants consider that surgeon skill is very important or important in achieving a successful outcome to primary hip replacement.

3.20 Seventy-three per cent of trusts told us that some hip replacement operations are carried out by non-consultant grades of staff with varying degrees of skill and experience and unsupervised by a consultant, mainly to cover for leave and to reduce consultant workload. These staff grades include, however, highly trained and competent doctors and we have no evidence to suggest that insufficiently trained surgeons are undertaking hip operations unsupervised. While relatively inexperienced clinicians rightly undertake hip replacement surgery under supervision in order to gain the necessary experience, the higher complication rates that some studies show can arise suggest that trusts need to continue to manage carefully the risks involved.

Some surgeons may not operate on sufficient patients to ensure good outcomes

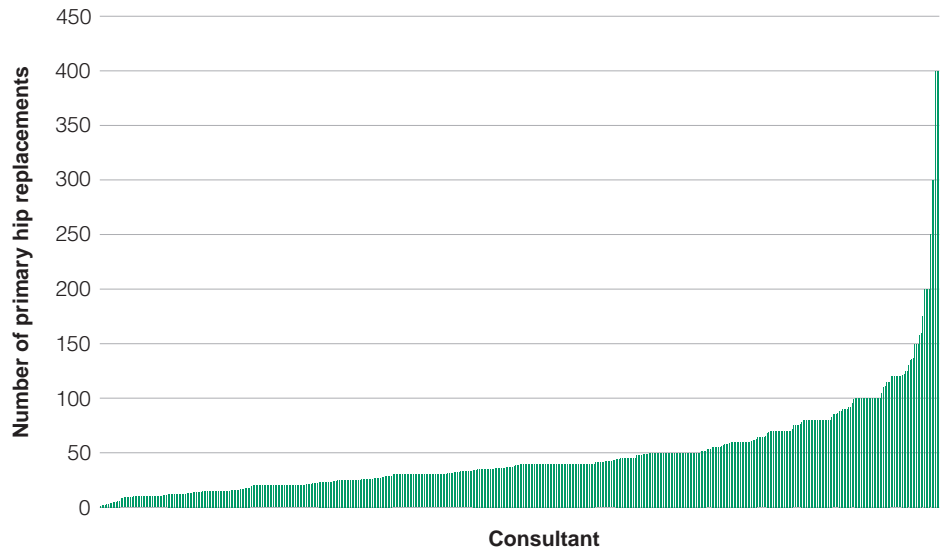
3.21 On average, consultants perform around 50 primary and 12 revision total hip replacements a year. This statistic, however, disguises some significant variations, with 65 per cent of consultants performing fewer than 50 primary hip replacements in 1998-99, and 8 per cent performing between 1 and 10 (Figure 10).

3.22 On revision surgery, 96 per cent of consultants who provided data performed less than 50 operations in 1998-99. Some 71 per cent of consultants performed between 1 and 10 revisions, and around half of these undertook fewer than five (Figure 11). Experts we consulted considered there should be further development of centres of excellence to undertake the majority of revision hip replacements.

3.23 Low numbers of procedures performed are not a reflection of the workload of consultants. Many perform a wide range of other surgical procedures, including trauma work and other joint work. However, consultants who perform a small number of hip replacements each year may not build up sufficient expertise to maximise successful outcomes, particularly in the more complex revision cases and younger age group. Many of the consultants who responded to our survey commented that the numbers being performed are, in many cases, insufficient to ensure that skill and experience levels are such as to maximise the chances of a successful outcome for the patient.

Total number of primary hip replacements by consultant carried out in 1998-99

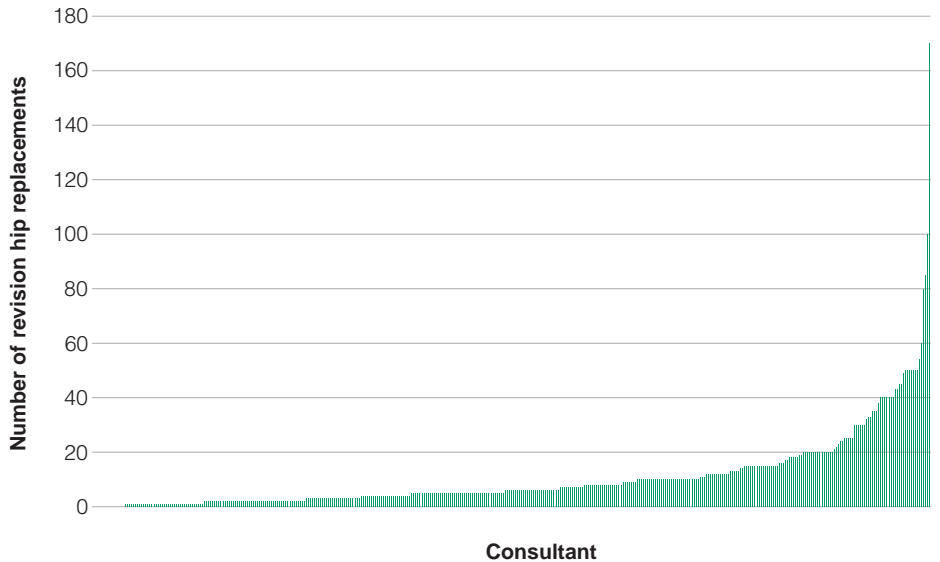
Figure 10



Source: Survey of NHS Acute Trusts

Total number of revision hip replacements by consultant carried out in 1998-99

Figure 11



Source: Survey of NHS Acute Trusts

Hip Registries are a useful tool for recording outcomes

3.24 A Hip Registry is a record of hip replacements. Content varies, but would usually include data on the patient, the prosthesis and the operation; additional data might include, for example, complications after surgery, and patient satisfaction. The purpose of a Registry also varies, but is generally used to identify

early prosthesis failures, provide information on surgeon outcomes, provide a benchmarking tool for consultants and trusts, and enable the speedy identification of relevant patients if a particular prosthesis gives cause for concern (see Figure 12).

3.25 In Sweden the use of a Hip Registry has resulted in a reduction in the range of different prostheses in use from 240 to five principal models, a lower revision rate, and improvements in surgical technique. In Norway a Hip Registry maintained since 1987 has been successful in highlighting various problems in hip replacement surgery resulting in changes in practice.

3.26 There have been a number of initiatives to create local or regional Hip Registries in the UK. The Trent Regional Arthroplasty Register, established in 1990, is the principal UK hip register. It records primary hip replacements in the Trent Health Region with the data recorded on a computer database in Leicester. It includes information from a patient questionnaire, and the data is verified to ensure accuracy and completeness. Extensive data from the register is shortly to be published.

One third of trusts use a Hip Registry

3.27 Over one third of trusts record total hip replacement activity on a Hip Registry. For those trusts that do so, most use a trust-based Registry, but a third record their activity on a regionally based Registry. A further 26 per cent of trusts plan to record hip replacement activity on a database in the future, and a significant number of trusts see benefits in doing so.

3.28 Most consultants consider that a national Hip Registry should be maintained. However there are potentially significant costs attached to the creation of a national Hip Registry, and this will need to be taken into account in determining whether such a Registry would be cost effective. The Department of Health's research and development Division has commissioned an independent options appraisal to review the desirability and feasibility of establishing a national Hip Registry, taking account of its costs. We consider this to be a useful step forward.

The main benefits of a Hip Registry

Figure 12

It provides:

- a record of all prostheses implanted so patients who have implants that subsequently perform poorly can be identified;
- a monitor of the performance of all prostheses implanted. This enables a long term track record to be established for each prosthesis;
- a history of each patient who has received a hip prosthesis;
- a list of all trusts which carry out hip replacements;
- a database of the numbers of hip replacements carried out by trust and by individual surgeon.

Achieving further improvements in patient outcomes

3.29 Many trusts have put in place procedures to ensure that patients have successful outcomes and receive cost-effective treatment. There is, however, more that trusts can do. In particular:

- the NHS Executive should assess the extent to which there is inequity in offering patients hip replacement surgery;
- trusts should use integrated care pathways for hip replacement patients. The NHS Executive should arrange the production of guidelines to enable trusts to institute care pathways cost-effectively
- trusts should review the extent to which there are avoidable delays and cancellations of surgery that result in lost theatre time. Where appropriate, and taking account of any impact on safety, they should prepare and implement an improvement action plan;
- trusts should ensure their financial information systems enable them to identify the costs of procedures including hip replacements. Trusts should benchmark their performance against the National Schedule of Reference Costs, and take action where costs are high in relation to others;
- trusts should measure the outcomes of hip replacements regularly. The Department of Health should complete its consideration of the case for a national Hip Registry as quickly as possible;

- trusts should check their arrangements to ensure that where operations are carried out by non-consultant grades without consultant supervision, there are effective risk management assessments and procedures in place;

- the NHS Executive, in consultation with the National Institute of Clinical Excellence and the British Orthopaedic Association, should explore whether a consultant should perform a minimum number of primary and revision hip replacements to maintain their expertise, and consider issuing guidance. They should also consider the merits of further development of centres of excellence to undertake, in particular, revision hip replacements.

Part 4: Quality of care provided to the patient

Introduction

4.1 For most patients a hip replacement brings immediate relief from pain, increased mobility, and improved quality of life. This part of the report examines the quality of care provided to patients prior to their admission to hospital, during their hospital stay and after discharge.

4.2 This part of the report also examines action taken by NHS trusts to minimise the waiting time for surgery, and maximise the opportunities for full recovery following a total hip replacement.

More information is needed to determine whether patients need a hip replacement

4.3 At an outpatient consultation the consultant examines the patient, reviews information on their condition, determines the appropriate treatment and, if necessary, assesses the patient's suitability and fitness for surgery. The consultant should explain the total hip replacement procedure, may discuss the choice of prosthesis and will, if appropriate, suggest alternatives to surgery. It is a crucial event for patients since it will determine whether or not they should have a hip replacement.

4.4 To assess fully the patient's condition, consultants told us they drew on information including a General Practitioner referral letter, x-rays, the patient's medical records, and data on the severity of the condition by means of a standard hip pain scoring system. This information is used to help prioritise patients for treatment, plan treatment and further appointments. It also improves throughput through the outpatient clinic and reduces waiting time.

4.5 In our survey, we asked what information consultants had available to them at the outpatient appointment. We found that all consultants had a General Practitioner referral letter, but that in many cases this was all that they had. Around half routinely had access to x-rays, and 60 per cent had access to the patient's medical records, needed to make informed clinical judgements. Very few

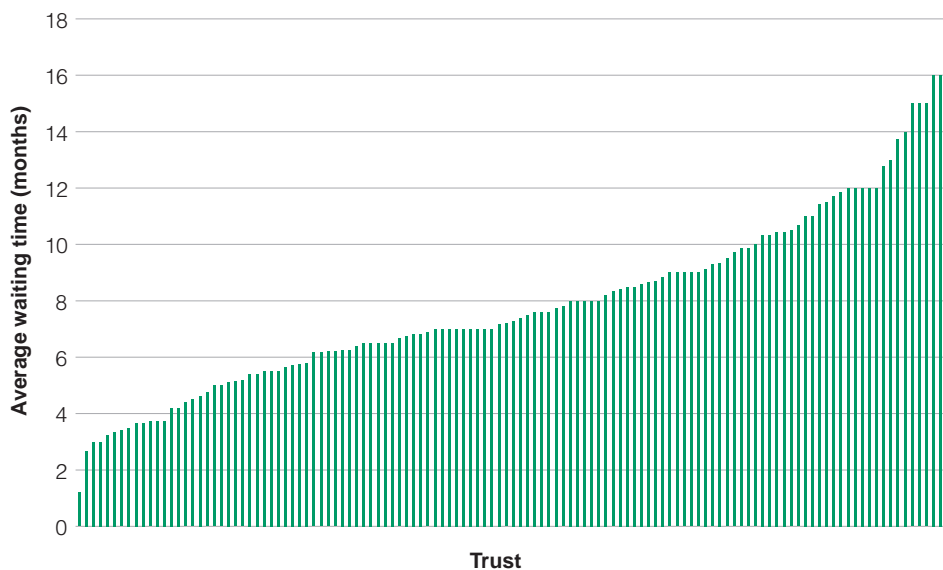
consultants (2 per cent) used a formal hip pain score to assess the severity of the patient's condition. Such information is very useful in making decisions about what care should be provided for the patient.

On average, patients wait just over 8 months for a hip replacement

4.6 In April 1995, the Department of Health introduced a requirement that no patient should wait for more than 18 months for an operation. All trusts met this target in respect of hip replacements. Our survey showed that the average waiting time was around 8 months, though at around 8 per cent of trusts, the waiting time was over 12 months (Figure 13).

Waiting time for a hip replacement

Figure 13



Source: Survey of NHS Acute Trusts

Some trusts have introduced initiatives to reduce waiting lists

4.7 There are many different factors that affect the size of the waiting list for individual consultants and at individual trusts. These include the number of orthopaedic consultants and the extent to which they undertake other orthopaedic work, the local demand for hip replacements, the extent to which a consultant or trust specialises in difficult cases, and the volume of hip replacements carried out.

4.8 Long waiting times can have an adverse impact on patients. For many, pain and reduced mobility affect ability to work and overall quality of life. While patients are on the waiting list their condition can deteriorate, causing further discomfort and making eventual surgery more difficult.

4.9 A number of trusts have introduced measures to reduce the waiting lists for total hip replacement, including the introduction of a weekend list for hip replacements at forty-two per cent of trusts. In addition, we found that around a quarter of trusts sent patients to a private hospital for their hip replacement in order to reduce waiting time. There is scope for more trusts to consider similar initiatives, so long as they are cost effective, to reduce the size of their hip replacement waiting lists.

Not all patients are prioritised on the basis of clinical need

4.10 Most consultants (78 per cent) prioritise patients on the hip replacement waiting list according to clinical priority, though some twenty per cent prioritise on a “first come first served” basis. Most consultants will re-prioritise patients on the waiting list in appropriate cases. Around 90 per cent of consultants said that patients could be re-prioritised on the basis of General Practitioner representation or on the basis of clinical need, and nearly half said patients could also be re-prioritised on the basis of a complaint from the patient, not related to clinical need. This latter practice is inadvisable since it may allow those patients who shout loudest to receive the speediest treatment. A number of trusts have introduced initiatives to improve the prioritisation of patients on the waiting list (see Case Study 12).

Case Study 12: Trusts have introduced initiatives to improve the prioritisation of patients on the waiting list

- ✓ **The Royal Bournemouth and Christchurch NHS Trust** are piloting a booked admissions system in their orthopaedic department. The patient attends the outpatient clinic to enable the consultant to assess whether the patient needs a hip replacement and subsequently to determine how urgently the operation should be carried out. The patient is provided with a card that indicates whether the patient is in urgent clinical need for the operation or whether the operation is less urgent. The receptionist uses this card to book a date for the patient's admission of their operation. The trust have found that patients are highly satisfied with the system as it enables them to prepare for their operation in advance.

Grades other than consultant can put patients on the list

4.11 Determining whether patients require hip replacement surgery and placing them on the in-patient waiting list requires careful consideration. Orthopaedic consultants need to be fully involved or appropriate protocols should be in place to facilitate decisions by non-consultant grades. If decisions are delegated to less experienced grades without prior involvement of consultants or

without protocols in place there is a potential risk that patients will be listed for surgery unnecessarily, although we have not identified this as a significant, widespread problem.

4.12 Over half of consultants told us that at their trust other grades including specialist registrars, staff grade doctors and associate specialists put patients on the waiting list. In most cases decisions taken by these staff will be under a protocol arrangement or discussed fully with the consultant before the patient is listed. However, to secure the best interests of patients, we consider that all trusts should ensure that the orthopaedic consultant is involved in this decision process or that protocol arrangements are in place.

Pre-assessment clinics are held by most trusts

4.13 Patients attend pre-assessment clinics to ensure they are fit to undergo surgery, to receive information and education on hospital admission and the hip replacement procedure and, in some cases, to enable the hospital to start planning for their ultimate discharge from hospital. Benefits for the hospital include a reduction in the number of patients subsequently cancelling their surgery, and the ability to determine the need for any post-operative patient support. For the patient there can be significant benefits including, reassurance and less confusion about the procedures, a shorter stay in hospital, assurance that appropriate discharge procedures have been put in place, and an improved quality of patient care overall (see Case Study 13).

4.14 We found that most trusts hold a pre-assessment clinic and that they have achieved significant benefits, including helping patients to cope after surgery, reducing cancellations and improving the throughput of patients. At one trust, the use of a pre-assessment clinic cost £6,500 a year, but had reduced patient length of stay by 1.5 days, improving patient satisfaction and reducing cost by around £300 per patient.¹⁰ York Health Services NHS Trust carried out an evaluation of the effects of their pre-operative assessment clinic on patient recovery after joint replacement surgery. The study looked at benefits to patients of pre-assessment clinics, and found considerable advantages. Those who had been pre-assessed were less anxious, experienced less pain and recovered quicker. And they were in hospital on average for 11 days compared to 13 days for those who had not been

¹⁰ See also the National Audit Office report on *Inpatient Admissions and Bed Management in NHS acute hospitals*, HC 254, Session 1999-2000, February 2000.

pre-assessed. There were no cancellations for those patients who had been pre-assessed compared to 8 cancellations for those who had not been pre-assessed.

Case Study 13: Pre-admission clinics reduce cancelled admissions

At **Harrogate District Hospital NHS Trust** a pre-admission clinic opened in December 1997 to perform a full medical, nursing and social assessment, to ensure all patients are prepared mentally and physically for their operation. Patients are seen one week before their operation and all information recorded in an integrated care pathway used by all healthcare professionals involved during the patient's stay in hospital. Benefits have included an increase in patients admitted on the day of surgery, and a dramatic reduction in cancellations by the patient or because the patient was unfit on admission.

Most trusts provide patient information, though the quality and content varies

4.15 Patients need information to re-assure them about the procedures, and to educate them as to what is expected of them, both before and after the surgery (see Case Study 14). Some 92 per cent of trusts provide information to patients about their hip replacement operation and the best approach to aid recovery after surgery.

Case Study 14: Education has important benefits for patients

✓ The Hospital for Special Surgery (HSS) in New York has a formal education process for patients. The main element is a 1.5 hour class held one week before admission, which takes the patient through the whole process. Patients are also given a videotape to watch at home. HSS has found that ensuring patients are educated about the process has benefits in terms of significantly increasing patient satisfaction, dramatically decreasing the amount of time spent answering patient queries prior to admission, and reducing average length of stay by about 1.5 days.

4.16 The content and quality of the information provided varied substantially from trust to trust. Over eighty per cent of trusts surveyed said that they covered rehabilitation, post-operative procedures, and activity modification pre and post-surgery. However, only 61 percent said that the information covered the pre-admission process, and 50 per cent covered facilities available on site. Two thirds of trusts did, however, provide further information to patients whilst in hospital, focusing mainly on exercise, permitted activities, activity modification and rehabilitation.

4.17 We reviewed patient information supplied by trusts and found that nearly one third did not include information or advice on exercises. Nearly a quarter of trusts did not include information on climbing stairs or bathing - both important

issues for hip replacement patients. A recent review of patient information by the King's Fund¹¹ also concluded that there is cause for concern about the quality of patient information currently available. The King's Fund has recommended that the NHS Executive fund the development of high quality patient information materials covering common clinical problems.

Effective discharge planning is important for patients

4.18 Planning discharge from hospital is important for patients. It is aimed at ensuring they do not remain in hospital longer than necessary, and that any post-operative support is in place when they return home. It is good practice that discharge planning should begin prior to patient admission, but at more than one-third of trusts, plans are not prepared until after admission.

4.19 Discharge planning may require a home visit prior to admission to assess the patient's needs after discharge for aids to assist in normal activities. Where pre-operative home visits are carried out, trusts identified significant patient benefits including improved quality of care and reduced length of stay. There may, in some cases, be practical difficulties in carrying out home visits - for example in rural locations - but in view of the considerable advantages to patients, the National Audit Office were surprised that at 50 per cent of trusts pre-admission home visits are not carried out.¹²

Length of stay for patients varies and could be reduced

4.20 Most patients prefer to spend as little time as possible in hospital. Short length of stay not only improves patient satisfaction, but also lowers the risk of hospital acquired infection, reduces hospital costs, and enables more effective use of hospital beds. Recent research has shown that shorter length of stay makes little impact on the success of hip replacement surgery.

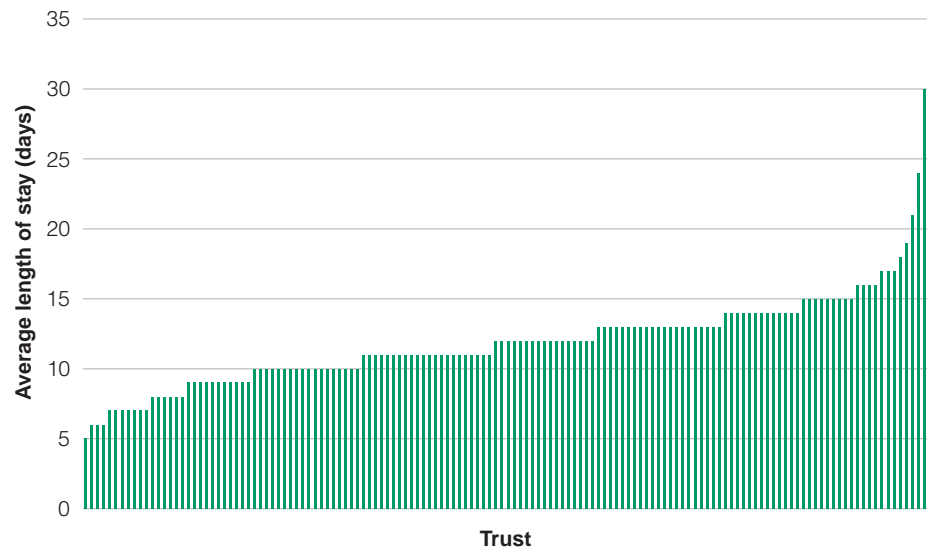
4.21 Average length of hospital stay for hip replacement surgery varies considerably across England - from 5 days to 30 days for primary hip replacement (Figure 14). Currently the average length of stay for primary hip surgery is 11 days, and 16 days for revision surgery. Factors affecting length of stay include case-mix,

11 Informing patients: An assessment of the quality of patient information materials. King's Fund, 1998

12 See also the National Audit Office report on *Inpatient Admissions and Bed Management in NHS acute hospitals*, HC 254, Session 1999-2000, February 2000

Average length of stay for primary hip replacement in 1998-99

Figure 14



Source: Survey of NHS Acute Trusts

complications, admission timing, the practice of individual consultants, hospital discharge policies, bed supply, and the availability of rehabilitation facilities after surgery.

4.22 Many trusts have taken steps to reduce length of stay, and most have seen a fall over the last five years, mainly through the use of pre-assessment clinics, improved discharge planning, early mobilisation of the patient, integrated care pathways, and improved patient education (see Case Studies 15-17). This mirrors similar falls in length of stay in the US (see Case Study 18) where, for example, one hospital in New York has reduced its average length of stay from 15 days to just under 6 days over three years through the introduction of a care pathway. Two thirds of consultants told us that length of stay at NHS trusts could be further reduced, most by between two and eight days, though most trusts have no specific plans to do so. We estimate that a reduction of between 2 and 6 days could lead to a cost saving for NHS trusts on in-patient care of between £15.5 and £46.5 million each year, releasing beds and other resources for other patients. This estimate does not, however, accurately represent the overall saving to the health system as earlier discharge from hospital could be dependent on hospital outpatient, community health and social care that could incur additional costs.

Case Studies 15-17: Examples of good practice in NHS Trusts taking steps to reduce length of stay

- ✓ The **Royal Bournemouth and Christchurch Hospitals NHS Trust** introduced pre-admission clinics and earlier access to rehabilitation and physiotherapy through provision of a seven-day physiotherapy service. They also improved their patient education and discharge planning. This resulted in their average length of stay for primary hip replacement patients falling from 15 to 12 days.
- ✓ **Trafford Healthcare NHS Trust** have reduced their average length of stay for primary hip replacement patients from 15.6 to 12 days and it is continuing to fall. This has been achieved through the use of an integrated care pathway, improved patient education, earlier mobilisation of the patient and improved discharge planning.
- ✓ **North East Lincolnshire NHS Trust** audited the effects of 7-day physiotherapy on in-patient length of stay, comparing average length of stay for patients admitted in early 1997 with that for patients admitted during the same period of 1998, after 7-day physiotherapy had been introduced. The results showed that the average length of stay fell from 14 days in 1997 to 12 days in 1998, with the number of patients staying in hospital for 10 days or more falling from 27 to 15.

Case Study 18: The US Experience

In the United States, the average length of stay decreased from 17 days to 6.3 days from 1983 to 1995, with some hospitals achieving a length of stay of just three days. Hospitals in the US have found that reductions in length of stay have come about mainly through the introduction of integrated care pathways and through admitting patients on the day of surgery - something that happens in the England for around only eleven per cent of patients.

Infection rates are frequently not monitored

4.23 Many of the patients requiring hip replacements are frail elderly, and are therefore more susceptible to hospital acquired infection. Deep infection following hip replacement can have serious consequences for patients including significantly increased length of stay in hospital, and the possibility of revision surgery, which is costly and often complicated (see Case Study 19). Trusts should have effective infection control procedures in place and monitor infection rates to ensure these procedures are minimising infection. A number of trusts have introduced measures to reduce infection rates (see Figure 15).¹³

13 See also the National Audit Office report on *The Management and Control of Hospital Acquired Infection in Acute NHS Trusts in England*, HC 230, Session 1999-2000, February 2000.

4.24 In our survey we asked trusts about their infection control procedures and monitoring. Over 90 per cent of trusts who responded monitor rates of infection in hip replacement operations. Around half of these trusts said that they always monitored rates of infection, though a further 33 per cent did so on a one-off basis. Nine per cent of trusts told us that they never monitor infection rates.

Case Study 19

In 1990 a patient suffered hip pain. Despite an arthroscopy and repair work on the hip in 1995 severe pain continued. In May 1996 the patient was put on the waiting list for a hip replacement.

The right hip was replaced in March 1997. It was part of a clinical trial of a new type of prosthesis. The patient recovered well, but subsequently had pain and was referred back to a consultant with septicaemia. Normally the hip joint is replaced after treatment of the infection. In this case, in September 1997, the consultant removed the hip, removed unhealthy tissue, washed the hip and re-inserted it.

After more pain the old hip was removed in December 1997, and a new hip inserted in March 1998. However the patient was still in severe pain from infection, and the replacement hip was removed in December 1998. The patient is currently without a right hip.

It was subsequently determined that the operating theatre airflow changes at the NHS Trust at the time of the operations were well below the British Orthopaedic Association guidelines, such that senior staff considered whether the trust should perform joint replacements until the operating theatres were upgraded.

The average infection rate is low, but varies between trusts

4.25 The British Orthopaedic Association noted in its 1998 guidelines that trusts should be aiming for infection rates of 1 or 2 per cent. Less than half of consultants maintain accurate data on infection rates for primary hip replacement operations. For those consultants that monitor infection, the average rate is 0.06%, varying between 0 per cent and 8 per cent.

4.26 In the absence of complete information on infection rates it is difficult to determine the impact on patients. However, 29 per cent of trusts told us that at least one hip replacement operation carried out by them in 1998-99 required a further operation as a result of infection.

Examples of good practice where NHS Trusts have taken a number of measures to reduce infection rates

Figure 15

Other measures that trusts have in place to reduce infection include:

- ✓ the use of dedicated orthopaedic theatres;
- ✓ the use of a patient's own blood during the operation, donated prior to hospital admission. We found that 14 per cent of consultants use this approach, of whom nearly a third noted that it had reduced their infection rates and 19 per cent that it had reduced the costs of surgery;
- ✓ antibiotic prophylaxis;
- ✓ laminar air flow theatres. In one trust the installation of a clean air theatre reduced the infection rate from 3.8 per cent to 1.7 per cent;
- ✓ the use of non- permeable gowns during surgery; and
- ✓ antibiotic cement.

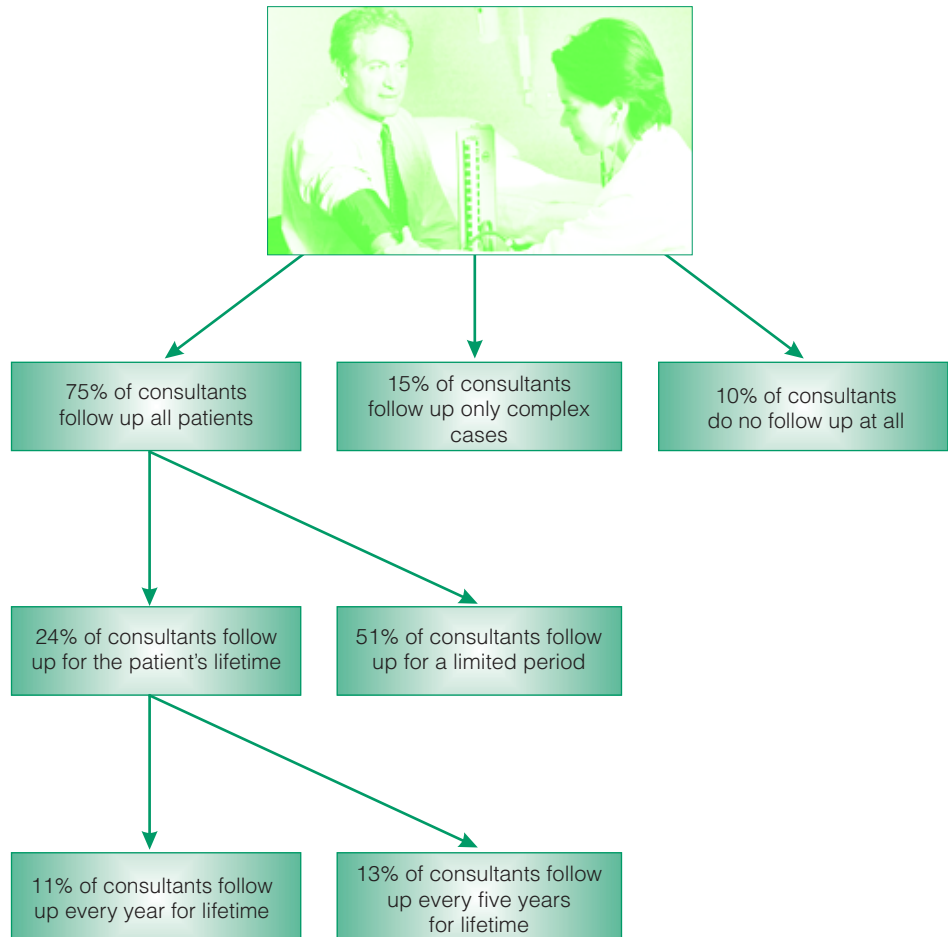
Most consultants follow up patients after surgery, but the frequency and duration of follow up varies substantially

4.27 The follow up of patients after hip surgery enables the consultant to identify the need for revision surgery at an early stage, while the patient may be experiencing no symptoms and before there is bone loss or other problems which may make surgery more difficult. It also helps to ensure that there are no post-operative complications and that the patient is progressing satisfactorily. A further benefit is to enable consultants to monitor the outcomes of their own work. There are, however, no guidelines on how often and for how long consultants should follow-up hip replacement patients.

4.28 Our survey found that three quarters of consultants follow up all their hip replacements. Fifteen per cent follow up complex cases only, and 10 per cent do not follow up at all (Figure 16). Most consultants who follow-up patients do so two or three times in the first year after surgery. Only 23 per cent follow up for the lifetime of the patient, though 60 per cent of consultants would like to do so. Thirty-four per cent of consultants do not follow-up patients after the first year.

Extent of follow up of hip replacement patients

Figure 16



Source: Survey of NHS Acute Trusts

4.29 Pressure of work and lack of funds are the main reasons consultants gave for not following up as frequently or for as long as they would like. There is also pressure from health authorities to limit the number of follow up patients that consultants see. However consultants that we spoke to at NHS trusts and on our Expert Panel told us that long term follow up is essential, and that it had led to improved design of hip prostheses and the use of better materials. A number of trusts have taken initiatives to undertake follow up effectively (see Case Study 20).

Case Study 20: Trusts have taken initiatives to undertake follow up effectively

- ✓ **The Norfolk and Norwich Healthcare Trust** follows up patients by reviewing a questionnaire completed by all patients on a regular basis. X-rays are also taken at 1, 2, 5, 7 and 10 years after operation and examined by a trained nurse. Any patient with an increase in symptoms as shown by the questionnaire and any x-rays which show signs that the prosthesis might be loosening or that there may be other related problems with the hip joint are referred to a Consultant Orthopaedic Surgeon for review.

Nearly three-quarters of trusts have carried out a patient satisfaction survey

4.30 Many trusts now place considerable focus on the experience of the patient. Surveys of patient satisfaction are one way in which trusts can capture the view of patients, and use the results to improve the services provided to patients.

4.31 We asked trusts whether they carried out patient satisfaction surveys. Some 33 per cent of trusts reported that they carry out patient satisfaction surveys at least annually, and a further 38 per cent carry them out less frequently. Twenty per cent have never carried them out. Where they have been undertaken, they have been used to improve patient information, make environmental improvements, and introduce changes in practice that have improved patient quality of care (see Case Studies 21-23).

4.32 Not surprisingly, the content of patient satisfaction surveys we reviewed varied. They ranged in length from 9 to 83 questions, and coverage was variable, with most including sections on catering and accommodation, but few covering medical care, explanation of treatment and pain management. Some surveys are undertaken annually, the results compared to targets and fed back to colleagues to improve the service to patients. Others are less frequent and gather little useful information, often because of poor response rates which may be due to pressure on NHS staff.

4.33 The National Survey of NHS Patients is part of the Government's commitment to listening to patients and consists of a rolling programme of questionnaire surveys examining patients' experiences. The first part of the survey was on General Practitioner services, and other surveys are being developed or are planned. In addition, consideration is being given to providing trusts with training which would enhance their ability to undertake their own surveys. These developments could usefully be applied to hip replacement work.

Case Studies 21-23: Examples of good practice in NHS trusts carrying out satisfaction surveys

- ✓ **Derbyshire Royal Infirmary NHS Trust** has developed a set of three patient questionnaires covering hospital ward stay and outpatient services. The questionnaires are well-designed, easy to complete and cover a wide range of issues. The hospital ward questionnaire includes sections on first impressions, communications, nurses and health care assistants, doctors, other team members, general services, the environment, toilet and washing facilities, catering, special needs, going home and ambulance transport.
- ✓ **Friarage Hospital, Northallerton NHS Trust** has undertaken regular small sample qualitative Patient Satisfaction Surveys since 1995. The results are fed back to colleagues by the Quality Facilitator to update them on what patients are thinking about various aspects of the service provided. The surveys are seen as a lever to improve quality of service, and the results are intended to be used to improve care where appropriate.
- ✓ **Northern General Hospital NHS Trust** undertook a patient satisfaction survey in 1995 and again in 1998. A problem with low response rates in the most recent survey was solved by direct interviewing of patients in those areas where the response was poor. A report comparing results of the two surveys was prepared by the Clinical Audit Department and sent to staff.

Improving patients' quality of care

4.34 Trusts have launched a range of initiatives to help ensure a consistent and high quality service to patients with hip pain and who may require a total hip replacement. We found, however, that there is scope for more trusts to introduce identified good practice. In particular we recommend that :

- trusts should draw on best practice to reduce, within available resources, the length of time that patients wait for hip replacement;
- consultants should discuss with Primary Care Groups what information should be available at the outpatient clinic. This could usefully be included in General Practitioner referral guidelines to be produced by the National Institute for Clinical Excellence
- trusts should ensure that the re-prioritisation of patients on waiting lists is undertaken solely on clinical grounds;
- better quality patient information should be developed. Trust should consider designating a senior member of staff responsible for ensuring that patient information materials meet high quality standards.

- as for other planned admissions, trusts should ensure that discharge planning is agreed or underway prior to hospital admission. Health and Social Services professionals should also consider home visits to patients prior to admission where it is cost-effective to do so;
- consistent with maintaining standards of care, and in line with guidance in “The New NHS 1999 Reference Costs”, trusts should take steps to prevent unnecessary length of stay in hospital for hip replacement patients;
- trusts should accurately monitor infection rates and take cost-effective action to reduce them;
- the NHS Executive, in consultation with the British Orthopaedic Association, should ask the National Institute of Clinical Excellence to issue guidance on the frequency and duration of follow up of hip replacement patients. Trusts should consider options for providing cost-effective follow up;
- the NHS Executive should issue guidance to ensure consistent and well-designed patient satisfaction surveys. Trusts should undertake such surveys on a regular basis, using the results to improve patient services.

Appendix A

Audit methodology

1 The methodology for undertaking the study of total hip replacements comprised:

- a self-completion questionnaire issued to Directorate Managers of all 207 NHS trusts in England undertaking orthopaedic work;
- a self-completion questionnaire to all 986 orthopaedic consultants;
- appointing a consultant to obtain the views of hip prosthesis manufacturers;
- carrying out a literature search of relevant research articles;
- study of good practice at the Food and Drug Administration and three orthopaedic hospitals in the United States;
- analysis of relevant data from the Department of Health;
- forming an expert panel to advise on key stages of the study (see Appendix B);
- carrying out in-depth audit visits to:

Westmorland General Hospital, part of Morecambe Bay

Hospitals NHS Trust

Nuffield Orthopaedic Centre NHS Trust

Wrightington Hospital NHS Trust

Worcester Royal Infirmary NHS Trust

Gloucester Royal NHS Trust

Grantham and District Hospitals NHS Trust

Kidderminster Healthcare NHS Trust

Mid-Sussex NHS Trust

Northern General Hospital NHS Trust

Royal Bournemouth & Christchurch Hospital NHS Trust
Southampton University Hospital NHS Trust
Trafford Healthcare NHS Trust

- organising a benchmarking forum for 40 managers and consultants from NHS trusts.

Survey questionnaires¹⁴

2 We undertook a survey of all 207 NHS trusts in England that carry out orthopaedic work. The objective was to gain information on a range of issues that affect the provision of hip replacement services in trusts. We developed and piloted a self-completion questionnaire and this was issued to Orthopaedic Directorate Managers in April 1999. Harris Research were commissioned to assist with the design, administration and analysis of the questionnaire.

3 We also surveyed all orthopaedic consultants undertaking hip replacement work. The purpose was to obtain information on clinical aspects of hip replacement work and to obtain examples of good practice.

4 We analysed the information provided by trusts and consultants for a range of issues. However a number of analyses that we had hoped to carry out were not possible, partly because of a lack of complete information provided on the survey questionnaires. Analyses that we were unable to perform included a comparison of volume of hip replacements performed against cost, cost of hip replacement compared with length of stay, and a comparison of the prices paid by trusts for identical hip prostheses.

Obtaining the views of hip prosthesis manufacturers

5 We appointed a consultant to undertake a series of visits to hip prosthesis manufacturers, to ascertain their views particularly in relation to the control and monitoring of hip prostheses. The five major suppliers were visited - Zimmer Ltd, Stryker Howmedica Osteonics Ltd, Smith and Nephew Healthcare Limited, Depuy International Limited, and Joint Replacement Instrumentation - and meetings held with senior staff in accordance with an agreed audit programme. In addition,

14 A copy of the questionnaire is available from the National Audit Office on request

3M Health Care Limited, who no longer manufacture hip prostheses but who developed the Capital Hip prosthesis, provided written comments in response to questions from the NAO.

Study of good practice in the USA

6 Recent years have seen significant changes in hip replacement procedures in the United States, largely as a result of pressure from health insurers to reduce costs. This has been thought to have resulted in cost reductions without a loss of quality or impacting on patient care. To identify examples of good practice we visited three leading hospitals with a key interest and expertise in orthopaedics, initially identified by the Council of International Hospitals - Hospital for Special Surgery in New York, Hospital for Joint Diseases in New York and Hartford Hospital, Connecticut. In addition we visited the Food and Drug Administration to discuss issues surrounding the introduction of new prostheses. Documentary information was obtained from Sweden on the operation and benefits of the Swedish hip register.

Audit visits

7 Audit visits were undertaken at an early stage of the study to familiarise the study team with hip replacement procedures. The team visited major centres of orthopaedic expertise and held discussions with consultants, managers, theatre staff, procurement staff and patients. The team also observed hip replacement surgery with the patient's consent.

8 At later stages of the study the team visited trusts which were selected on the basis of information given in their self-completion questionnaire responses. The purpose of these visits was to follow up examples of good practice in more detail.

Benchmarking

9 We invited approximately 40 managers and consultants from NHS trusts to attend a benchmarking day at the NAO. The purpose was to share the results of our survey questionnaires with trusts, to enable them to benchmark themselves against the performance of similar trusts and to learn from examples of good practice identified by others. The NHS Executive attended as observers.

Calculation of savings

Savings in the purchase of prostheses

10 Thirty-five trusts in our survey made an average saving of £41,874 in 1998-99. Additional savings of £7,202,328 could be achieved if the remaining 172 NHS acute trusts that carry out hip replacements achieved similar savings. Although the NHS Executive accepts that further savings are probably possible, it does not accept the accuracy of the £7 million estimate as the variations of the many factors affecting prices across trusts could significantly affect the potential for savings at individual trusts.

Savings following a reduction in length of stay

11 The Department of Health's Expenditure Plans 1999-2000 indicate an average unit cost per acute case of £1,106, and that the average length of stay is five days, giving an average cost per acute day of £221. A reduction in average length of stay of two days for 35,000 hip replacements would result in potential savings for NHS trusts of £15,470,000, a reduction of six days would result in potential savings of £46,410,000. This estimate does not, however, accurately represent the overall saving to the health system as earlier discharge from hospital could be dependent on hospital outpatient, community health and social care that could incur additional costs.

Appendix B

Expert panel

1 The NAO invited a group of experts to form an expert panel for the study of hip replacements. The aim was to circulate them with draft documents, hold meetings of the panel at regular intervals and thus obtain their views and the benefit of their experience to feed into the study results. The panel comprised:

Mr David Browning - Associate Director, Audit Commission
Ms Caroline Gardner - Director, Accounts Commission (Scotland)
Professor Joe Harper - Professor of Orthopaedic Trauma Surgery,
Leicester Royal Infirmary
Mrs Frances Hunt - Assistant Director, Age Concern
Ms Barbara Meredith - Policy and Communication Manager, Age
Concern London
Mr Hugh Phillips - President, British Orthopaedic Association
Mr Kevin Newman - Orthopaedic Consultant, St Peter's Hospital
Mr David Swarbrick - General Manager (Orthopaedics), Nuffield
Orthopaedic Centre
Professor Mike Wroblewski - Consultant Surgeon, Wrightington
Hospital

The following attended meetings of the expert panel as observers:

Dr Val Chishti - Department of Health
Mr Andy Crosbie - Medical Devices Agency, and
Dr Jon Hopper, Medical Devices Agency

Appendix C

Key questions to ask your consultant about hip replacement

In the light of our work, we have identified key questions for hip replacement surgery. They form the basis for the sort of information that clinicians may wish to discuss with patients about to undergo hip replacement.

1. What alternative treatments are available?
2. What hip prosthesis will you use? Why?
3. Will you be using a cemented or cementless prosthesis? Why?
4. What are your results using that prosthesis?
5. What published evidence of long-term effectiveness is there for that prosthesis?
6. What possible complications might I expect?
7. Do you use general anaesthetic or spinal/epidural anaesthetic?
8. How long should I expect to stay in hospital?
9. Will you perform the operation yourself?
10. How many primary hip replacements do you perform each year?
11. What are your deep infection rates?
12. Can I pre-donate my own blood for use during the operation?
13. How long will I have to wait for the operation?
14. How will you manage my condition while I am on the waiting list?

- 15.** What happens if my condition worsens?
- 16.** Is there anything I can do in the meantime to better prepare myself for the operation?
- 17.** What facilities are there for rehabilitation?
- 18.** How often and for how long will you follow-up my condition after the operation?
- 19.** How long can I expect my new hip to last before it needs to be replaced again?

Glossary

Acetabulum	Socket of the hip bone or pelvis
Adverse incident reports	reports of problems notified to the Medical Devices Agency by NHS trusts and prosthesis manufacturers
Aseptic loosening	Non-septic (that is, not as a result of infection) loosening of the hip prosthesis, commonly as a result of normal wear and tear over a period of time
Cartilage	Low friction soft-tissue surface on bones
CE marking	An EC-wide stamp on a range of goods, demonstrating safety and quality control in manufacture. CE stands for 'Conformite Europeen'
Direct Cost	Cost related directly to a service e.g. salaries, drugs incurred in the provision of a service
Femur	The thigh bone that extends from the pelvis to the knee. It is the largest and longest bone in the body
Follow-up	Process by which patients who have had total hip replacement are reviewed at regular intervals, mainly to enable early identification of conditions that may require a revision operation
Hip register	A record of primary and revision total hip replacements, including data on the patient and prosthesis. It may be local, regional or national
Integrated care pathways	The anticipated course of treatment for a particular condition set out in a document which identifies the responsibilities of all clinical staff
Medical Devices Regulations	UK regulations based on a EU Directive on medical devices which require medical devices, including hip prostheses, to have a CE-marking providing assurance of safety
Notified Bodies	Independent companies appointed by the competent authorities (the Medical Devices Agency in the UK) to assess devices against the requirements for a CE marking
Outcomes	A measurement of the degree to which a total hip replacement has been successful
Orthopaedic consultant	A physician specialising in surgery of the skeletal system, especially joints

Overhead	Costs relating to more than one service, typically not involved in face-to-face patient contact, whose costs are apportioned on a "fair share" basis not related to an activity statistic e.g. building maintenance apportioned on the basis of building volumes
Post-market surveillance	Procedure by which new designs of hip prostheses are monitored after they have been introduced in the UK
Pre-assessment clinic	Clinic, usually held 2-4 weeks before hospital admission to ensure patients are fit to undergo surgery, inform and educate the patient and, in some cases, start planning discharge from hospital
Primary hip replacement	Replacement of the femoral head and acetabulum with an artificial hip prosthesis for the first time
Prosthesis	A device to augment or substitute for a part of the body that has become weak or has failed
Rehabilitation	The process by which normal function is restored after injury or illness. Typically, after hip replacement, it will involve physiotherapy and take place in hospital or at home
Revision hip replacement	Replacement of an already implanted artificial hip, due to loosening, deterioration, failure or other condition
Surgery - elective	Surgery chosen and planned by patient or physician for a condition that is not life-threatening
- trauma	Unplanned surgery, usually for a wound or injury. Most common trauma work in relation to hips is surgery following a hip fracture
Synovial fluid	A transparent fluid contained in joint cavities that acts as a lubricant
Total hip replacement	See 'Primary Hip Replacement'