

Report by the
Comptroller and Auditor General

NHS Executive

Hip replacements: Getting it right first time

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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 hospital³

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.