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Surgical data to 31st December 2010

National Joint Registry for England and Wales

8th Annual Report 2011

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Laurel Powers-Freeling

As the new Chairman of the National Joint Registry (NJR) Steering Committee, I am pleased to introduce our 8th Annual report and tell you a bit about the NJR's substantial progress and work during the past year.

But first, there are some very important contributors to acknowledge for their work in having made the year a success and helping the NJR continue to develop as one of the world's leading clinical audits and repositories of robust, quality data.

Firstly, I would like to thank Professor Paul Gregg, NJR Vice Chair, for undertaking the role of acting NJR Chair and maintaining the momentum of the NJR in its development. My thanks also go to the members of the NJR sub-committees, and in particular the Chairs of those committees: Paul, for his leadership of the Outlier Sub-Committee; Mr Keith Tucker, Chair of the NJR Implant Performance Sub-Committee; Mr Martyn Porter, who is Chair of the Editorial Board (and oversaw the preparation of this report); and Professor Alex MacGregor, who chairs the NJR Research Sub-Committee. I would also like to thank Mr Peter Howard for chairing the NJR Regional Clinical Co-ordinators Network and all of the surgeons who act as Regional Clinical Co-ordinators and underpin the success of the NJR with their support. Finally, my thanks go to the Healthcare Quality Improvement Partnership (HQIP) for providing sound management of the NJR everyday, and in particular I am grateful to Elaine Young for her tireless efforts on our behalf.

Everyone associated with the NJR was excited to celebrate one million procedures having been recorded with us, making the NJR the largest database of its kind in the world. We also recorded the largest ever number of submissions in a single year (179,450), the highest ever percent of records with patient consent (88.6%), and the highest ever percent of records submitted with both patient consent and patient NHS number, thus increasing the percentage of 'linkable' records for overall analysis to a new high of 83.4%.

The NJR saw a number of important developments that will allow us to continue to pursue our mission, which is to enable the continuous improvement of patient outcomes. Alongside our collection of hip and knee data, we have launched data collection for ankle joint replacements. We have also launched an NJR Supplier Feedback system to support the very necessary post-market surveillance of implants for quality and performance.

We have also increased the focus on implant performance through the establishment of an NJR Implant Performance Sub-Committee. Our outlier monitoring enabled the voluntary recall of a hip replacement system by its manufacturer, and the continued use of NJR data also supported the regulatory investigation into revisions due to apparent soft tissue reactions in patients receiving 'metal-on-metal' hip replacements.

In addition to monitoring and reporting, another core purpose for the NJR is to enable research. The past year saw the continued development of our research support process with the establishment of our NJR Research Sub-Committee, the appointment of a dedicated Research Officer, the engaging of two NJR Research Fellows, and the launch of an NJR Research web page on the NJR website. These actions will enhance our ability to support both wider research and facilitate specialist studies. Our new relationship with the University of Bristol will provide an improved platform of dedicated statistical support services using

data managed by our longstanding partner, Northgate Information Solutions.

But even with all this progress over the past twelve months, there is even more in store for the 2011/12 operating year:

- we have already started a large scale study to follow patients and report the outcomes of a hip and knee survey in England. This will extend the capture of PROMs work undertaken through the Department of Health National programme to include patient input at years one, three and five after joint replacement surgery.
- we will launch data collection for new joints, to include initial collections of shoulder and elbow joint data later this year.
- we will launch an NJR Management Feedback system, which will provide information directly to senior hospital management to support effective local clinical governance; this will build on further development of NJR outlier monitoring and improved reporting mechanisms to trusts.
- we will pursue a programme of greater international collaboration with worldwide registries to both share our work and benefit from the work of other registries, thus building on the success of recent NJR participation in European and international conferences.

However, one of the most significant changes that will take place in the coming year is the requirement of NJR reporting as a mandated dataset in the 2011/12 Standard Terms and Conditions for Acute Hospital Services. By making NJR reporting a requirement for NHS funding with significant penalties for non-compliance, we anticipate accelerated progress in closing the remaining gap in our data in the coming year. This will, in turn, make our reporting of outliers more robust and give senior hospital management even stronger and more precise tools to support the best possible patient outcomes.

The NJR has grown and matured substantially over the past nine years, but from my (very new) vantage point, I can see that it has even more potential to provide data and insights that will help our key stakeholders - surgeons, hospitals, implant manufacturers, regulators and government - in supporting the most important stakeholders of all, our patients. I look forward to working with the NJR to make this happen.

Laurel Powers-Freeling
Chairman, NJR Steering Committee

Vice Chairman's introduction

As Vice Chair of the National Joint Registry Steering Committee, I am pleased to add a brief introduction to the 8th Annual Report of the NJR.

First and foremost, I am very pleased to welcome our new Chairman, Laurel Powers-Freeling, and very much look forward to working with her in the future. Her previous experience will be of significant benefit to many aspects of the business of the NJR, as well as bringing a fresh insight to our work, ensuring continued progress in the future.

There is actually little for me to add to the Chair's comprehensive review of the work that has been undertaken over the last year, except to add my sincere thanks to all those mentioned in her introduction.

Particularly, I thank the Steering Committee members for their encouragement and support during the eighteen-month period I acted as Chair of the NJR Steering Committee. This ensured that the Registry continued to make further progress, particularly in relation to the development of our research capability, with the appointment of two NJR Research Fellows, and with continuing work to develop new arrangements for reporting surgeon performance to trusts.

Professor P J Gregg
Vice Chairman, NJR Steering Committee

Foreword from the Chairman of the Editorial Board

I would like to express my thanks to all members of the NJR Steering Committee and particularly the members of the Editorial Board for producing this report again on time. I would also like to welcome Laurel Powers-Freeling as our new Chairman of the NJR Steering Committee and express my gratitude to Paul Gregg as Vice Chair for all the hard work and support he has given this year.

The 8th Annual Report sees some important changes to Part 3 (survivorship analysis).

Previously this work has been carried out by the Clinical Effectiveness Unit (CEU) of the Royal College of Surgeons of England. Jan van der Meulen and Susan Charman have provided exceptional input, quality and innovation in producing Part 3 of the Annual Reports. This work has been greatly appreciated by the NJR. The contract for this work has now been awarded to the team at University of Bristol under a competitive tendering process. Professor Ashley Blom, Professor of Orthopaedics at University of Bristol is leading this team and I would like to thank Ashley and also Alison Smith, the statistician, for working so impressively taking up the reins and delivering this output in such a timely and professional manner.

The changes in Part 3 will be self-evident but I would like to emphasise some important points. First of all, the team at University of Bristol have taken a fresh look at the data which now contains over a million NJR records. Building on the work of the RCS CEU, they have analysed the NJR data and the linked NJR-HES/PEDW dataset which has been used previously to calculate survivorship analysis. The HES/PEDW dataset is the main NHS hospital dataset. In early reports we looked at survivorship in terms of revision and/or re-operation. An important change has therefore been to remove certain OPCS codes which could indicate a re-operation rather than a revision. This has had the effect of reducing the so-called revisions and, as such, readers will note a reduction in revision rates in the HES/PEDW data because of these exclusions, so the key message is that we have moved from revisions (and possible re-operations) to revisions alone. The University of Bristol team have also for the first time included an analysis of revisions recorded in the NJR database alone, i.e. a linked NJR to NJR survivorship analysis. This allows us to exclude revision for infection from the analysis so we are able to comment on revision for aseptic loosening which may be more pertinent in terms of assessing implants rather than other environmental and surgical factors. They have also included an analysis adjusting for risk factors such as age, gender and mortality risk.

As usual we will provide more detailed analysis in the in-depth studies. These will include a much more detailed analysis of the metal on metal bearing; the effect of head size; overall death risk; and prophylaxis for thrombo-embolic events.

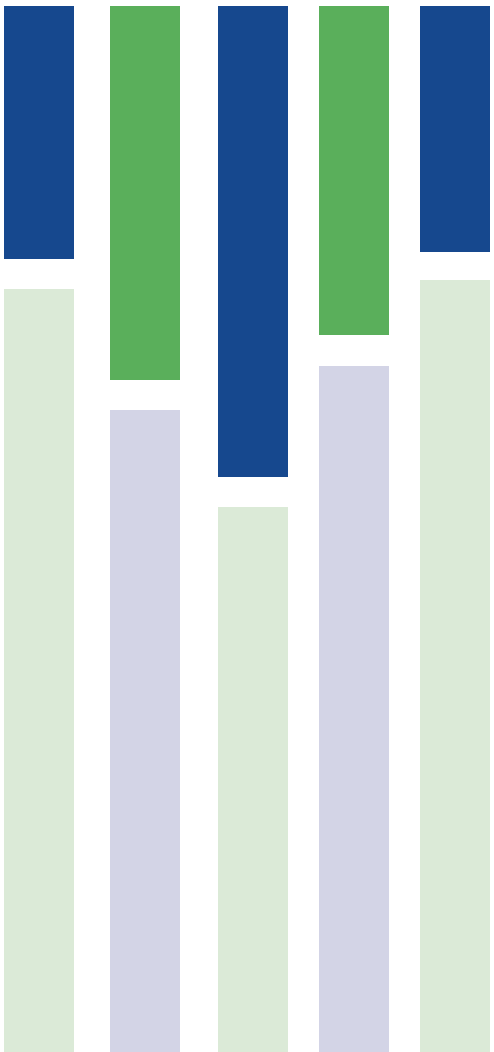
As I mentioned last year, I would particularly like to emphasise for the lay reader that all figures should be looked at carefully. When making comparisons of implants and fixation modalities, I would also strongly recommend looking at the confidence intervals which are displayed in brackets. It is also important to appreciate that although the NJR is the largest registry in the world, we are reporting mid-term results (between five to seven years) and the patterns that present mid-term may change at later time periods. The main findings reveal inferior performance of metal on metal joint replacement; but I would emphasise that certain implant brands within the metal on metal articulation can perform much better than others. In other words, there is quite extreme variation of implants within the metal-on-metal group. Also, we have not as yet fully risk assessed all brands within this material class and further work has yet to be carried out.

I would like also to emphasise that registry data describes a certain pattern and picture of what has happened in the past, the data is not foolproof. Different registries can report different observations mainly because the registries have unique attributes in terms of implants used, surgical techniques, data definitions, data validation and many other heterogeneous factors. It is important, therefore, to use other sources of information including clinical reports and indeed other registry data to get a better overall picture of what may actually be happening. Dealing with registry data is perhaps somewhat unique and differs substantially from reporting on either retrospective or prospective clinical trials where, in the main, the clinical trial methodology and data is much more controlled. It is important that registries regularly review the statistical and methodological processes that best describe the data within the registry.

Finally, I would like to thank all patients for consenting to have their data entered, also all surgeons and their data entry staff who have contributed to the NJR because without their co-operation, none of the NJR reports would have been possible.

Mr Martyn Porter
Chairman, NJR Editorial Board

Executive summary



Part 1: Annual progress

The 8th Annual Report of the National Joint Registry for England and Wales is the formal public report for the period 1st April 2010 to 31st March 2011 (Part 1). Also included are statistics on joint replacement activity for the period 1st January to 31st December 2010 (Part 2) and a survivorship analysis of hip and knee joint replacement surgery using data from 1st April 2003 to 31st December 2010 (Part 3).

The NJR aims to improve patient safety and clinical outcomes by providing information to all those involved in the management and delivery of joint replacement surgery, and to patients. This is achieved by collecting data in order to monitor the effectiveness of hip, knee and ankle replacement surgery and prosthetic implants.

The NJR began collecting data on hip and knee replacement operations on 1st April 2003. Data collection on ankle replacements began on 1st April 2010.

The work of the NJR is funded through a levy raised on the sale of hip, knee and ankle replacement implants.

Part 1 reports on the performance of the NJR during the financial year 2010/11, provides a summary of progress during the year and outlines key forthcoming developments.

The financial year 2010/11 saw:

- the total number of procedures recorded in the NJR exceeding one million for the first time. Between 1st April 2003 and 31st March 2011 1,082,932 procedures were submitted, of which:
  - 65.7% took place in NHS hospitals
  - 25.7% took place in independent hospitals
  - 4.3% took place in NHS treatment centres
  - 4.3% took place in independent sector treatment centres (ISTCs).
- the largest ever number of submissions in a single year, at 179,450. Overall compliance with the NJR from 1st April 2003 to 31st March 2011 was 85.2%.
- the highest annual rate of records submitted with patient consent, at 88.6%. This takes the overall consent rate for all NJR records to 81.2%.
- a greater proportion of records submitted with both patient consent and the patient's NHS number than in any previous year (94.7%), taking the overall percentage of linkable records for outcomes analysis to 83.4%.

Progress during 2010/11 included:

- the launch of the NJR Supplier Feedback system in support of post-market surveillance by implant suppliers.
- the voluntary recall of a hip replacement system by the manufacturer as a result of NJR implant performance data.
- the use of NJR data in a regulatory investigation into revisions due to apparent soft tissue reactions in patients receiving metal-on-metal (MoM) hip replacements, leading to a medical device alert for all MoM hip replacements.
- 178 hospitals notified by the NJR of more than 80,000 patients affected by Medical Device Alerts issued by the Medicines and Healthcare products Regulatory Agency (MHRA).
- the establishment of a research support process and infrastructure, and the appointment of two NJR Research Fellows.
- preparation for an NJR study to extend the follow-up of Patient Reported Outcome Measures (PROMs) to 12 months.

Forthcoming developments include:

- the launch of a service to provide performance information directly to the senior management of hospitals and trusts, supporting effective local clinical governance.
- commencement of data collection on elbow and shoulder replacements.

- further collaboration with international registries, including attendance at the International Consortium of Orthopaedic Registries (ICOR) Conference in Washington, USA and the International Society of Arthroplasty Registries (ISAR) Congress in Bergen, Norway.
- the completion of a data quality audit to assess the completeness of data on revision hip and knee replacement procedures stored in the NJR.

Part 2: Clinical activity 2010

Part 2 of the NJR 8th Annual Report summarises the data and findings for hip and knee procedures carried out in England and Wales between 1st January 2010 and 31st December 2010. For the first time the NJR Annual Report also shows the findings of ankle procedures which started being submitted on 1st April 2010. To be included in the report, all procedures must have been entered into the NJR by the 28th February 2011.

During 2010, 413 orthopaedic units were open, including NHS hospitals in England and Wales, independent hospitals, NHS treatment centres and ISTCs. Of these, 399 (97%) submitted at least one hip, knee or ankle procedure to the NJR. The compliance rate for the calendar year 2010 was 92.4%.

On average 196 hip replacements and 213 knee replacements were submitted per orthopaedic unit. These numbers are higher than the submissions in 2009. However, the number of procedures entered by units varied widely; the maximum number of hip submissions being 1,270 and the maximum number of knee submissions being 1,278.

Hip replacement procedures

In 2010, there were 76,759 hip replacement procedures recorded on the NJR, representing a 6% increase compared with the same reporting period last year[1]. Of these, 68,907 were primary procedures and 7,852 were revision surgeries, representing a revision 'burden' of 11.4%.

Of the 68,907 primary hip procedures undertaken in 2010, 36% were cemented total hip replacements (THRs), 43% were cementless THRs and 16% were hybrids[2] or reverse hybrid THRs. The remaining were large head metal-on-metal replacements[3], comprising 3% resurfacing and 2% large head metal-on-metal total hip replacements (LHMoM THRs).

In the 7th Annual Report (2009 data) it was noted that, despite the expected superior short-term results for cemented total hip replacements, there was an increasing trend away from fixation with cement towards cementless fixation, and 2009 was the first year that cementless fixation overtook cemented fixation as the preferred fixation modality. Although the percentage usage of cementless hip replacements has continued to increase in 2010, this has been accompanied by a sharp decline in the use of metal-on-metal resurfacing devices following the voluntary withdrawal from the market of the ASR device marketed by DePuy. The percentage usage of cemented devices has remained the same as in 2009.

Patient demographics in terms of age and gender distribution have not changed substantially since 2003. In 2010, 31% of patients were 75 years of age and above, 35% between the ages of 65 and 74, 23% between the ages of 55 and 64 and 12% below the age of 55.

This year, the ASA distribution is comparable to last year with 16% being regarded as fit and healthy prior to surgery (17% in 2009). However, there continues to be a decrease in the number of patients regarded as being fit and healthy prior to surgery (ASA grade 1)[4].

The average body mass index (BMI)[5] has increased to 28.5, compared with 27.3 in 2004.

It would appear that NHS hospitals are dealing with less fit patients, with 20% being ASA grade 3 or 4, compared with 7% in independent hospitals, 14% in

[1] 72,432 hip procedures were recorded in 2009. This number has now increased to 77,967 as a result of 2009 activity being registered in 2010. For the purposes of comparative analysis, 2009 figures reported in 7th Annual Report have been used.
[2] Of the hybrids, 86% were conventional hybrids (cemented stem and cementless socket) and 14% were reverse hybrids (cementless stem and cemented socket).
[3] Large head metal-on-metal replacements consist of a large diameter metal-on-metal head combined with a resurfacing cup.
[4] American Society of Anaesthesiology system for grading the overall physical condition of the patient as follows: P1 – fit and healthy; P2 – mild disease, not incapacitating; P3 – incapacitating systemic disease; P4 – life threatening disease; P5 – expected to die within 24 hrs with or without an operation.
[5] BMI: 20-24 normal; 25-29 overweight; 30-39 obese; 40+ morbidly obese.

NHS treatment centres and 6% in ISTCs. These data suggest that the average recipient of a hip prosthesis has become less fit and more overweight during the eight years that the NJR has been recording data.

Patients' age and gender significantly influenced the fixation type and type of replacement operation carried out. For example, in male patients under 55 years of age 22% of procedures were resurfacing and 11% cemented replacements, compared with male patients over 75 years of age where less than 1% were resurfacings and 48% were cemented. In female patients less than 55 years of age, 6% were resurfacing and 15% cemented replacements, compared with female patients over 75 years of age where less than 1% of procedures were resurfacings and 56% were cemented.

The indications for surgery were recorded as osteoarthritis (93%), avascular necrosis (2%), fractured neck of femur (2%), congenital dislocation (1%) and inflammatory arthropathy (1%).

In terms of surgical technique, the lateral position was used in 91% of cases and the posterior approach was used in 57%. Minimally invasive surgery was described as being used in 5% of cases and image-guided surgery in less than 1%. Antibiotic loaded bone cement was used in 93% of cases when cement was used.

The most frequently prescribed chemical method of thromboprophylaxis for total hip replacement was low molecular weight heparin (LMWH) (67% - a decrease of 4% on 2009) and the most used mechanical method was thrombo embolus deterrent (TED) stockings (65%).

In 2010, 146 different brands of femoral stem were used, 123 different brands of acetabular components and 13 different brands of resurfacing cups. This indicates a small decline for both femoral stems and acetabular components. It is difficult to ascertain the reason for this but it is thought that the CE (Conformité Européenne) reclassification of joint replacement products from class 2B to class 3 and the increased ODEP requirement for post-market surveillance data, may have slightly raised the barriers to entry for new products, and hastened the removal from the market of less successful brands.

The Orthopaedic Data Evaluation Panel (ODEP)[6] ratings for prostheses were again studied. The full 10A benchmark rating was achieved in 84% of cemented stems, 74% of cementless stems, 42% of cemented cups, 5% of cementless cups and 51% of resurfacing cups.

When cemented hip stems were used, the Exeter V40 remained the market leader with 63% of the market share. The Contemporary cup is the market leader with a market share of just under 35%.

With cementless brands, the Corail stem remains the market leader at 47% and the Pinnacle socket with a market share of approximately 34%.

Hip resurfacing has steadily declined from a peak of 6,484 reported procedures in 2006 to 5,707 in 2008, to 2,512 in 2010 amid ongoing concerns following the voluntary withdrawal from the market of the ASR device manufactured by DePuy. The Birmingham Hip Resurfacing (BHR) remains the market leader.

There is an increasing trend to use larger head devices in total hip replacements (excluding resurfacing). In 2010, 28% were 36mm or above, compared with 20% in 2008 and only 1% in 2003.

This represents a significant change in orthopaedic practice during the life of the NJR and will be the subject of a detailed analysis over the coming months.

A total of 7,852 hip revision procedures were reported in 2010, which is an increase of 649 compared with 2009. Of these, 86% were single stage revision procedures, 6% were stage one of a two stage procedure, 7% were stage two of a two stage procedure and 1% were excision arthroplasty procedures. This denotes a 3% increase in single stage revision procedures compared with 2009.

[6] Orthopaedic Data Evaluation Panel of NHS Supply Chain.

Indications for revision in single stage revision were aseptic loosening (50%), dislocation (17%) and infection (3%). When the indication was stage one of a two stage revision, aseptic loosening was recorded in 14% of cases and infection in 79%.

Both components were revised in 44% of single stage revisions, compared with 80% in stage one of a two stage revision.

During a single stage revision, 51% were cementless hip procedures, 28% were cemented and 19% were a hybrid reconstruction.

Knee replacement procedures

The number of knee replacement procedures recorded on the NJR during 2010 was 81,979, which represents an increase of 5.7% compared with 2009.

There were 5,109 revision procedures. The revision 'burden' for knee replacement procedures has increased from 5.9% in 2009 to 6.2% in 2010.

Unlike hip replacements, the type and fixation of knee replacements has remained largely unchanged over the lifespan of the NJR; though there has been a 2% increase in cemented total knee replacements (TKRs) since 2006. In 2010, 85% were cemented primary total knee replacements (TKRs), 5% were uncemented TKRs, and less than 1% were hybrid TKRs, 8% were unicondylar knee replacements and 1% were patello-femoral replacements.

For bicondylar primary knee replacements 73% were cruciate-retaining, 24% posterior-stabilised, 3% constrained condylar and less than 1% were hinged or linked knee replacements. Since 2005 there has been a 2% increase in cruciate-retaining and a decrease of 3% in posterior-stabilised designs. This trend towards less constrained knees has been despite the fact that patients would appear to have been becoming sicker and more obese since the inception of the NJR.

The ASA grades indicate that less fit patients were treated in NHS hospitals with approximately 19% being ASA grade 3 or 4, compared with 8% in independent hospitals, 13% in NHS treatment centres and 8% in ISTCs.

BMI has increased to 30.6 in 2010 from 29.3 in 2004. Patient BMI is higher in knee procedures compared with hip procedures. This indicates that the average recipient of a knee replacement would be classified as clinically obese.

Age and gender influence the choice of type of replacement. Male patients and younger patients (under 55 years of age) have a higher proportion of unicondylar and patello-femoral replacements, compared with elderly patients who have a higher proportion of bicondylar knees and of TKRs using cement.

In terms of surgical techniques, a medial parapatellar incision was used in 93% of cases. The patella was resurfaced in approximately one third of primary knee replacement procedures. Minimally invasive surgery was used in 7% of cases and image-guided surgery in 2%.

The most frequently prescribed chemical method of thromboprophylaxis for knee replacement was LMWH (65%). This is a decrease of 4% compared with last year and replicated the trend shown in hip procedures. TED stockings were the most commonly used mechanical method (69%).

The PFC Sigma Knee was the market leader for total condylar knee replacements, being used in approximately 36% of cases. The Oxford Knee was the market leader for unicondylar knee replacements, used in 69% of procedures. The Avon was the brand leader in patello-femoral joints, used in approximately 38% of cases, although its market share has fallen proportionally with an increase in the use of other brands.

Of the 5,082 knee revision procedures, 76% were single stage operations, 11% were stage one of a two stage procedure, and 12% were stage two of a two stage revision.

Ankle replacement procedures

The NJR started to collect total ankle replacement primary and revision procedures on 1st April 2010. In total 358 primary and 24 revision procedures were submitted during the nine months covered by this report. Due to the small number of procedures, the information supplied in the tables is given in a more abbreviated format than is provided for hips and knees.

For primary procedures, 56% of the patients were male. The average age of an ankle replacement patient was 66.8 years and had an average BMI of 29.9. The DePuy Mobility ankle was the most popular brand with 74% of the market share. All prosthesis on the UK market are uncemented but seven implants were reported as having been cemented in.

In terms of ankle revision procedures only 24 were recorded with 54% being single stage procedures and 33% conversions to arthrodesis. The average age of revision patients was 63.9 years and 46% of revisions were due to aseptic loosening and 25% for malalignment.

The introduction of ankle replacements to the NJR has been successful although this data only reflects nine of the initial 12 months and so it is important to be cautious with data interpretation. The numbers reported are lower than predicted and might reflect early teething problems with a new set of data entry forms and surgeons not used to a registry. As compliance increases and the number of ankle joint replacements reported increases, the NJR for ankle replacements is expected to have a major impact.

Part 3: Outcomes after joint replacement, 2003 to 2010

Part 3 of the 8th Annual Report describes the survivorship of hip and knee replacements in England and Wales up to almost eight years after primary surgery. This includes an analysis of revision rates and mortality after primary joint replacement. Differences according to implant characteristics (such as implant brand, and prosthesis, fixation, and bearing types) are explored and results for different patient groups are contrasted.

As in previous years, NHS data (HES and PEDW) has been matched to NJR data to identify revisions linked to a primary operation. From this, additional revisions are identified which increases revision rates above those calculated from NJR data alone. However, there is a concern that HES/PEDW data is over-counting revisions because of the inclusion of some re-operations as revisions (see Section 3.2). This approach is now under review and so for the first time, some analysis has been undertaken on the NJR data alone. Revision rates from the two data sources are compared in Sections 3.3.2 and 3.4.2.

The NJR-HES/PEDW data consists of 300,374 primary hip procedures linked to 6,971 first revisions (4,968 from NJR data with another 2,003 from HES/PEDW data) and 342,120 primary knee procedures linked to 8,017 first revisions (5,663 from NJR with another 2,354 from HES/PEDW data). The full NJR data consists of 384,760 primary hip procedures (linked to 5,794 first revisions) and 417,222 primary knee procedures (linked to 6,460 first revisions).

Hip replacement procedures

Overall revision rates were low: only 1.1% of primary hip replacements had been revised by one year after primary surgery rising to 2.3% by year three, 3.5% by year five, and 4.7% by year seven. However, there was substantial variation in revision rates according to prosthesis type. The lowest rates were associated with cemented prostheses (3% at seven years) although rates for the hybrid (3.8% at seven years) and uncemented (4.6% at seven years) groups were not exceptionally different. Much higher rates were associated with resurfacing procedures (11.8% at seven years) and stemmed metal-on-metal bearing surfaces (13.6% at seven years). There appears to be a sharp increase in the risk of revision at around six years after primary surgery for the metal-on-metal group although more data is needed to confirm this finding.

There was also variation in revision rates according to the characteristics of patients. Multi-variable analysis indicates that for patients aged under 60, there was little difference in revision rates between the cemented, uncemented and hybrid groups. However, for patients aged 70 or over, cemented prostheses were associated with the lowest revision rates. Adjusted revision rates for the resurfacing and stemmed metal-on-metal groups remained significantly above those of other groups indicating that the higher revision rates cannot simply be explained by the patients being younger on average and more typically male. Revision rates tended to be slightly lower for women than for men in the cemented, uncemented and hybrid groups but were significantly higher for women in the resurfacing and metal-on-metal groups.

Brand analysis was undertaken on NJR data only this year. Some variation in revision rates according to brand is apparent although differences are mainly small once 95% confidence intervals and fixation type are taken into account. In addition, analysis is unadjusted for other factors (such as different bearing surfaces and patient characteristics) that could influence revision rates. NJR revision rates for all cemented hips were 1.4% at five years while the lowest revision rate in this group was for the Exeter V40 stem with the Elite Plus Cemented Cup (0.7% at five years). NJR revision rates for uncemented hip prostheses were 3% at five years while the most

commonly used uncemented combination (the Corail stem with a Pinnacle cup) had a revision rate of 2.3% at five years. The NJR revision rate for resurfacing procedures was 4.9% at five years but here there was greater variation between brands. The market leader, the BHR, had the lowest revision rates in the group (3.4% at five years).

Around 20% of the linked first revisions considered here were due to infection. This is likely to be a higher proportion than among all revisions because infection is more likely to occur in the early period after primary surgery and the registry is still at a relatively early stage. Therefore, revision rates excluding infection have been produced and contrasted with all-cause revision rates.

The risk of death in the first 30 days (0.3%) and 90 days (0.6%) after surgery was similar to the overall risk of revision in these periods. Altogether, 16.8% of patients had died within seven years of their hip replacement (although death rates for these patients were lower than death rates among people in the general population of a comparable age and gender). Death can be considered a competing event to the risk of revision (as patients are no longer at risk of revision once they have died). Adjusting for the competing risk of death was found to be important as unadjusted analysis over-estimates revision rates (the seven-year overall revision rate falls from 4.7% to 4.3% once analysis is adjusted).

Knee replacement procedures

Overall, revision rates were low: only 0.7% of primary knee replacements had been revised by one year after primary surgery rising to 2.7% by year three, 3.9% by year five, and 4.9% by year seven. However, there was substantial variation in revision rates according to prosthesis type with the lowest rates associated with cemented prostheses (3.8% at seven years). There was no significant difference between the uncemented and hybrid groups and revision rates for these prostheses were only slightly higher than for cemented prostheses (4.8% at seven years). In contrast, revision rates for patello-femoral and unicondylar procedures were considerably higher at 20.4% and 16.6% respectively by seven years after primary surgery.

For total knee replacements, posterior cruciate-retaining implants had lower revision rates than posterior cruciate-stabilised implants (3.7% compared with 4.3% at seven years). These revision rates were lower again for posterior cruciate-retaining implants with fixed bearings compared with posterior cruciate-retaining implants with mobile bearings (3.4% versus 5.0% at seven years). Overall, the lowest revision rates for knee replacements were associated with a posterior cruciate-retaining, fixed bearing cemented prosthesis (3.4% at seven years).

In terms of patient characteristics, there were no significant differences between men and women in terms of the risk of revision. However, revision rates for those aged under 60 were much higher than for older age groups for all prosthesis types (for example, the seven-year revision rate for those aged under 60 with a cemented knee replacement was 7.5% compared with 2.6% of those aged 70 or over). Unicondylar revision rates remained much higher than for other prosthesis types regardless of age group with the highest revision rates for those aged under 60 (22.9% had been revised by seven years).

Brand analysis was undertaken on NJR data only. Some variation in revision rates according to brand was apparent although, as indicated by the overlapping 95% confidence intervals, not all results were statistically significant. In addition, this analysis is unadjusted for other factors (such as varying implant constraint, fixation method, and patient characteristics) that could influence revision rates. The most commonly used brands were not necessarily those with the lowest revision rates. Compared to an overall five-year revision rate of 2% for total knee replacements, the PFC Sigma, the market leader, had a five-year revision rate of 1.7% while a less commonly used brand, the MRK, had the lowest five-year revision rate of 1%. For unicondylar knee replacements, the MG Uni had the lowest revision rate (4.7% at five years compared with an overall group revision rate of 6.7%).

Around 26% of the linked first revisions considered here were due to infection. Therefore, as with hip replacements, revision rates excluding infection have been produced and contrasted with all-cause revision rates.

There was a small risk of death in the first 30 days (0.2%) and 90 days (0.4%) after primary surgery. Overall, 17.1% of patients had died within seven years of their knee replacement (although death rates for these patients are lower than death rates among people in the general population of a comparable age and gender). As with hip replacements, adjusting for the competing risk of death was found to be important as unadjusted analysis over-estimates revision rates (the seven-year overall revision rate falls from 4.9% to 4.5% once analysis is adjusted).

Part 1
Annual progress

1.1 Introduction

1.1.1 Annual Report

This is the 8th Annual Report of the National Joint Registry (NJR). The NJR provides information about hip and knee joint replacement surgery in England and Wales within both the NHS and the independent healthcare sector. Since April 2010, the NJR has also collected data on ankle replacement surgery. The information collected by the NJR may be used by a broad range of stakeholders in order to support improvements to patient safety and care quality. These stakeholders include surgeons, patients, regulators and manufacturers of hip, knee and ankle implants (artificial joints).

The report is divided into three main parts:

- **Part one** – a general outline of the work of the NJR for the financial year 1st April 2010 to 31st March 2011. It provides summary statistics of the data provided during the financial year, summarises major developments, and outlines proposed work for the financial year 2011/12.
- **Part two** – a description of joint replacement activity as reported to the NJR in the calendar year 1st January to 31st December 2010.
- **Part three** – provides an analysis of survivorship of hip and knee replacement surgery using data submitted to the NJR from 1st April 2003 to 31st December 2010. Data from the Hospital Episodes Statistics (HES) service and Patient Episode Database Wales (PEDW) are also included in the analysis.

1.1.2 The National Joint Registry

Following its establishment in October 2002, the NJR commenced collecting and analysing data on hip and knee replacement procedures in April 2003. The collection of data on ankle replacement surgery began in April 2010. The aim of the registry is to provide information regarding surgical and implant performance and clinical best practice to all those involved in the management and delivery of joint replacement surgery. This includes the regulatory authorities such as the Medicines and Healthcare products Regulatory Authority (MHRA) and the Care Quality Commission (CQC). Central to the provision of this information is the aim of improving clinical outcomes and patient safety.

In order to achieve its aims, the NJR requires a continuous supply of timely, accurate data with maximum coverage of operations undertaken. Only high quality data can enable long-term monitoring of the clinical effectiveness of hip, knee and ankle joint replacements. By 31st March 2011, the NJR held information on more than one million procedures.

1.1.3 Management and funding

The NJR is managed by the Healthcare Quality Improvement Partnership (HQIP) under contract with the Department of Health (DH). HQIP support the work of the NJR Steering Committee (NJRSC), an advisory non-departmental public body whose current list of members and their declarations are listed in Appendix 1. The NJRSC oversees the strategic direction and running of the registry.

The NJR Centre is responsible for the running and development of the NJR database for all data collection and analysis, and is managed by Northgate Information Solutions (UK) Ltd under contract with HQIP. HQIP has also contracted the University of Bristol from 1st April 2011 to undertake statistical analysis on the data held within the NJR. This includes all the statistical analysis in Part 3 of this report.

The NJR is funded through a levy raised on the sale of hip, knee and ankle implants. HQIP manages the levy payment collections and holds the NJR budget on behalf of the NJRSC.

Part 1

1.2 Data completeness and quality

1.2.1 Key indicators

Three key indicators are used to measure the completeness and quality of the data submitted to the NJR Centre:

- **Compliance:** this is the proportion of procedure records submitted to the NJR compared with the levy returns for the number of implants sold.
- **Consent:** the number of records submitted where the patient has agreed to their personal data being stored on the NJR database compared with the number of procedures recorded on the NJR[7].
- **Linkability:** the number of records submitted with the patient's NHS number compared with the number of procedures recorded on the NJR. The NHS number is required to link all primary and revision procedures relating to a single patient[8].

Performance against these indicators has continued to improve year on year, although the provision of continual support to orthopaedic units is required to maintain and improve performance levels. Detailed figures and trends are shown below.

1.2.2 Performance against key indicators

Progress against the three measures of compliance, consent and linkability for the financial year 2010/11 was as follows:

Compliance

From the 1st April 2011, the Standard NHS Contract for Acute Services was amended to include the requirement for NHS provider trusts to participate in audit, relevant to the services they provide, within the National Clinical Audit and Patient Outcome Programme (NCAPOP) which includes the NJR. All NHS trusts and NHS foundation trusts are therefore expected to record all hip, knee and ankle replacement operations on the NJR. For independent sector hospitals and independent sector treatment centres (ISTCs), the data collection is mandatory.

NJR compliance is measured by comparing the number of procedures submitted to the NJR against the number of levies raised through implant sales[9]. The compliance rate across all units for the past eight years compared to the number of levies is illustrated in Figure 1.1. Compliance rates have been averaged over three-year time bands in order to compensate for annual fluctuations in implant sales, and thus better illustrate the overall trend. The compliance rate has shown a steady upwards trend since 2003. The compliance rate for the three years 2008/09 to 2010/11 was 103.4% because more procedures were submitted to the NJR than implant levies raised over the period.

For NHS providers, compliance can also be measured by comparing NJR submissions with data submitted to the Hospital Episode Statistics (HES) database in England and the Patient Episode Database Wales (PEDW) service. The latest available NHS compliance rate (2010/11 Q2) is 72%. Compliance figures for individual NHS organisations are published on the NJR website.

As can be seen, there is a marked difference between the compliance calculated for all NJR (103%) and for NHS providers only (72%).There may be several reasons for this:

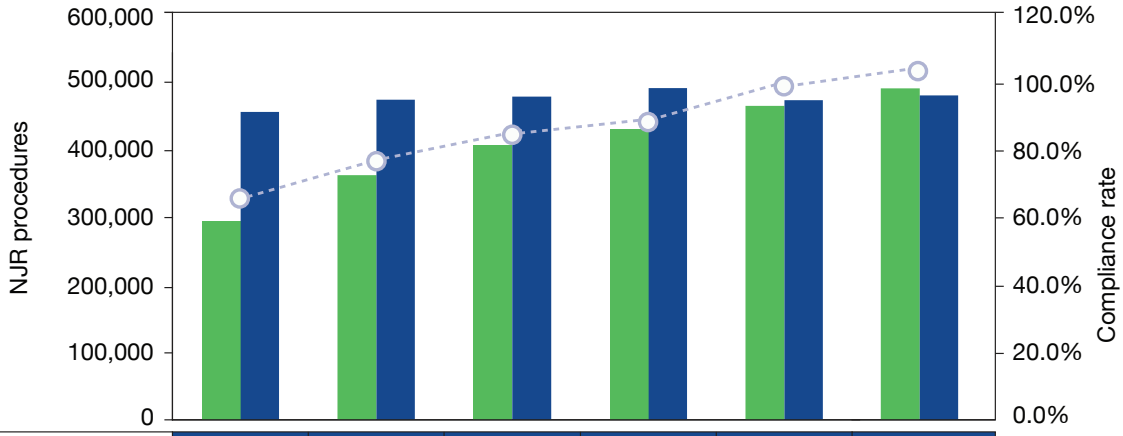
- delays in submission of levy returns from implant suppliers may lead to exaggerated compliance figures.
- submission to NJR is mandatory in the independent sector and therefore compliance is higher than in the NHS.

[7] Personal information includes NHS number, surname, date of birth and postcode.
[8] NJR data is submitted for NHS number tracing and the 'linkability' figure includes NHS numbers that were traced subsequent to the operation details being submitted to the NJR.
[9] For compliance analysis only, the number of procedures excludes the following procedures: re-operations other than revision; stage one of two stage revision; excision arthroplasty; amputation; and conversion to arthrodesis. These are excluded because they do not include the implantation of a component attracting the levy.

Figure 1.1

NJR compliance: 2003/04 to 2010/11, based on levies from implant sales.

Source: Procedures entered into the NJR 1st April 2003 to 31st March 2011 and levy submissions to NJR by implant suppliers and manufacturers[9].



Year	2003/04 - 2005/06	2004/05 - 2006/07	2005/06 - 2007/08	2006/07 - 2008/09	2007/08 - 2009/10	2008/09 - 2010/11
NJR procedures	297,746	364,393	408,120	435,893	468,839	497,625
Levy	459,797	478,207	480,531	492,504	473,052	481,279
Compliance rate (%)	64.8%	76.2%	84.9%	88.5%	99.1%	103.4%

The NJR publishes compliance rates for each NHS provider through the StatsOnline service on its website (www.njrcentre.org.uk). Patients, clinical staff, and management are able to view the contribution being made by their hospital to the NJR and, ultimately, to improving clinical effectiveness and patient safety.

The number of non-returning units has reduced from four in 2009/10 to one for the year in view. The Orthopaedics and Spine Specialist Hospital in Peterborough was the only hospital in England and Wales performing elective hip, knee or ankle replacement surgery which did not submit any data to the NJR during the year 1st April 2010 to 31st March 2011.

Consent

The NJR requires consent from patients to store their personal details, including their NHS number. It is not possible to determine the outcome of any procedure where the patient refuses consent. Therefore, without a high level of patient consent, the NJR would fail to meet its aims, because it would be unable to monitor the outcomes of joint replacement and identify, at an early stage, any problems with implants or surgery, so that appropriate action may be taken.

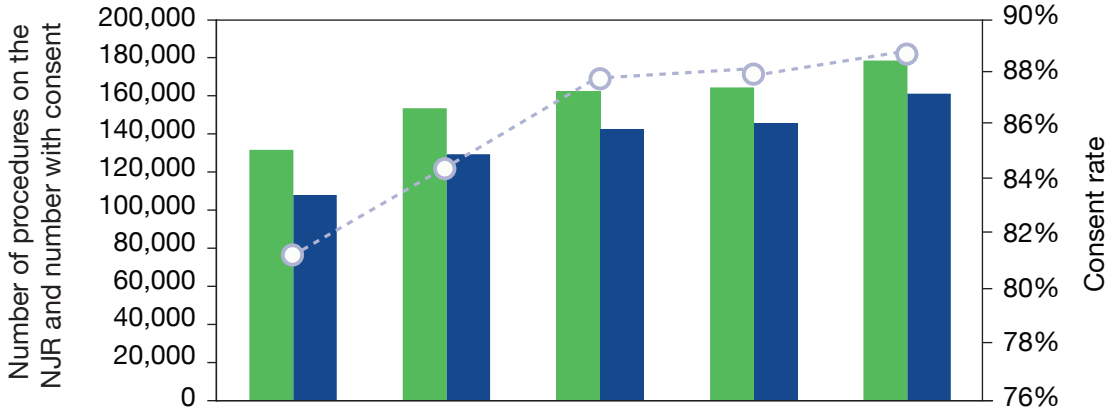
When a record is submitted to the NJR, the hospital or treatment centre is required to confirm whether the patient has consented to share their personal details. There are three options: 'Yes', 'No', and 'Not Recorded'. The NJR has been granted support under Section 251 of the NHS Act 2006, enabling patient details to be recorded where consent is 'Not Recorded'. This exemption is temporary and subject to annual review, and is granted on the understanding that efforts are made to ensure consent is recorded. It is thus vital that all units take action to ensure a robust consent process is in place. Patients, when asked, rarely decline to consent and the failure to record it usually results from the consent form not being available to the staff submitting the NJR record.

Figure 1.2 shows the rise in the consent rate over the past five years. The consent rate levelled off in 2009/10 due, in part, to previously non-compliant units commencing submission without a sound consent process in place. As part of their role in providing on-site support to hospitals, the NJR Regional Co-ordinators have worked with these units to improve consent rates. The consent rate began to increase once again in 2010/11, reaching 88.6%. The consent rate for all operations submitted to the NJR from 1st April 2003 to 31st March 2011 was 81.2%.

Figure 1.2

NJR consent: annual analysis of total records received and those received with patient consent, 2006/07 to 2010/11

Source: Procedures entered into the NJR 1st April 2006 to 31st March 2011.



Year	2006/07	2007/08	2008/09	2009/10	2010/11
Number of procedures	130,267	150,903	159,003	163,219	179,450
Number of procedures with consent	105,832	127,389	139,274	143,324	159,072
Consent rate (%)	81.2%	84.4%	87.6%	87.8%	88.6%

Linkability

The ability to link all operations relating to a single patient is vital in determining clinical outcomes. Operations are linked using the patient's NHS number. The linkability rate refers to the proportion of operations submitted with both patient consent and the NHS number recorded. Low rates of linkability adversely affect the ability of the NJR to monitor clinical and implant performance.

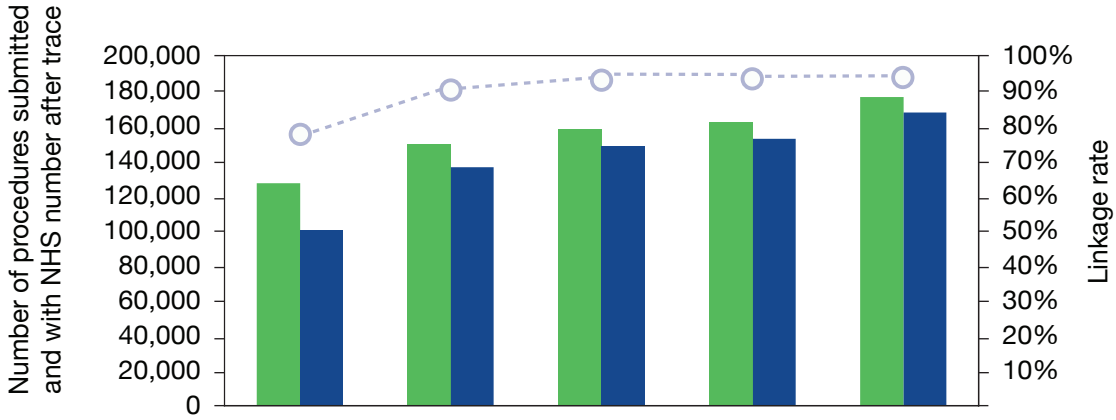
Where the NHS number is missing, tracing is attempted using the NHS Demographics Batch Service (DBS). This relies on the patient's name, date of birth and postcode being correctly entered.

The percentage of linkable records submitted to the NJR from 2006/07 to 2010/11 is shown in Figure 1.3. The linkability rate for 2010/11 was equal to the rate for 2009/10 (94.7%). The linkability rate for the whole NJR database is now 83.4%, the highest rate since the NJR began collecting data.

Figure 1.3

NJR linkability: analysis of total records received and those for which NHS numbers have been traced, 2006/07 to 2010/11.

Source: Procedures entered into the NJR 1st April 2006 to 31st March 2011.



Year	2006/07	2007/08	2008/09	2009/10	2010/11
Number of procedures	130,267	150,903	159,003	163,219	179,450
Number with NHS number traced	101,102	137,860	149,829	154,594	169,948
Linkage rate (%)	77.6%	91.4%	94.2%	94.7%	94.7%

Part 1

1.3 Key figures

1.3.1 Operation totals

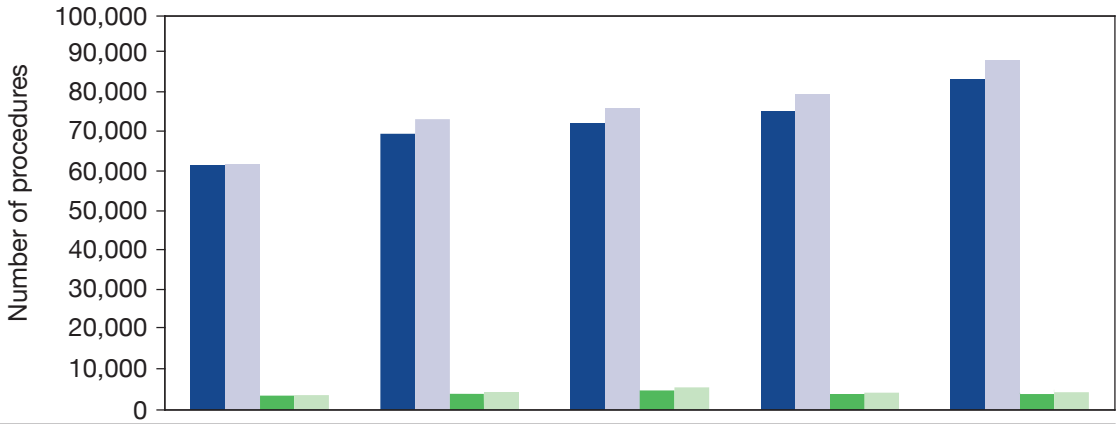
Between 1st April 2003 and 31st March 2011 1,082,932 hip, knee and ankle replacement procedures were reported to the NJR. The year in view saw 179,450 procedures submitted, a 9.9% increase on the previous year, and the largest number of submissions to date. A significant proportion of this increase can be accounted for by the clearance of backlogs by hospitals and treatment centres. It was announced during 2010/11 that the NJR would cease accepting submissions in the pre-2006 (MDSv2) format. This action was necessary in order to allow for the implementation of a new component management system to better accommodate new and future developments in the joint replacement implant industry. This provided an incentive for hospitals to update and submit incomplete records that they held. The NJR's Regional Co-ordinators supported local staff in clearing backlogs. 15.8% of submissions during 2010/11 related to operations that took place in previous years.

Figure 1.4 shows the total number of hip and knee procedures recorded on the NJR in England and Wales each year from 2006/07 to 2010/11. As for the previous four years, the number of knee replacement procedures (91,945) exceeded the number of hip replacement procedures (87,038) in 2010/11.

Figure 1.4

Total hip and knee joint replacement procedures entered into the NJR, 2006/07 to 2010/11, recorded by the country in which the procedure took place.

Source: Procedures entered into the NJR 1st April 2006 to 31st March 2011.



Procedures by year and country	2006/07	2007/08	2008/09	2009/10	2010/11
England hip	61,287	69,381	72,184	75,108	83,014
England knee	61,425	73,042	76,244	79,565	87,424
Wales hip	3,661	4,180	4,918	3,928	4,024
Wales knee	3,894	4,300	5,657	4,618	4,521

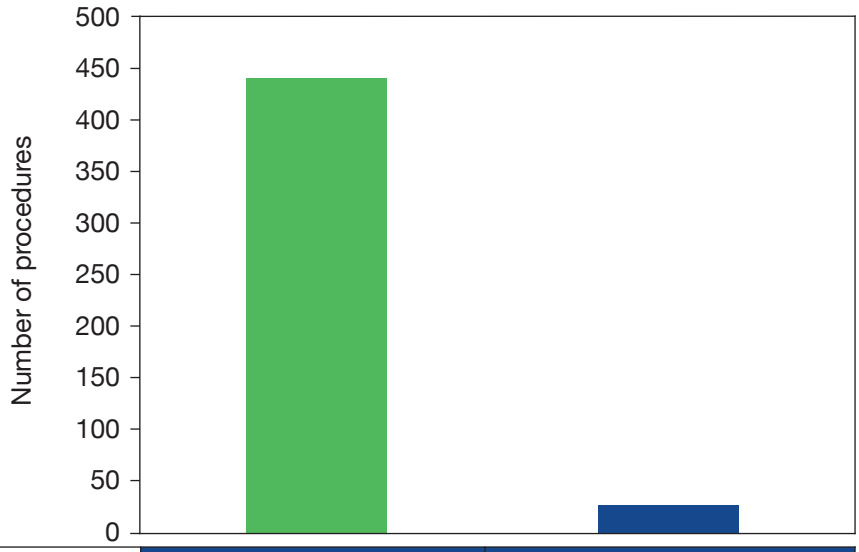
All of the growth in reported hip and knee replacement procedures took place in England (there was a 10.2% increase from 2009/10 to 2010/11), with no increase in the number of procedures being submitted in Wales.

Figure 1.5 shows the total number of ankle procedures recorded on the NJR in England and Wales in 2010/11. This was the first year of data collection for ankle joint replacement surgery. As the numbers of ankle procedures were small in comparison to hip and knee procedures, they are being displayed in a separate figure.

Figure 1.5

Total ankle joint replacement procedures entered into the NJR, 2010/11, recorded by the country in which the procedure took place.

Source: Procedures entered into the NJR 1st April 2010 to 31st March 2011.



Country	England	Wales
2010/11	442	25

1.3.2 Operation types

The following two types of hip, knee and ankle joint replacement procedures are recorded in the NJR:

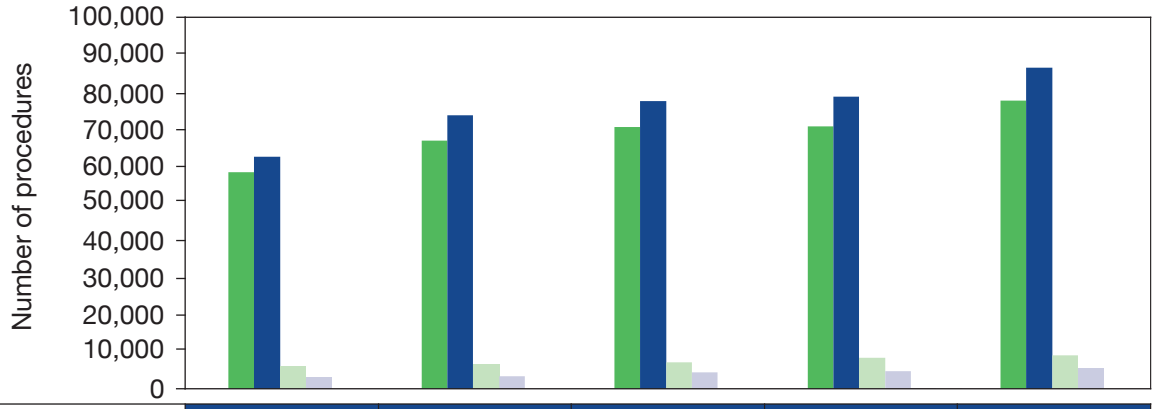
- **primary**: the first time a joint is replaced.
- **revision**: an operation that involves the removal and replacement of one or more components of a joint replacement.

Figure 1.6 shows the number of hip and knee procedures reported by type from 1st April 2006 to 31st March 2011. Primary operations continue to represent the most reported procedures (91.6%). There were more knee replacements than hip replacements but the gap has closed slightly (in 2010/11 there were 5.0% more knee primaries than hip primaries; the figure for 2009/10 was 5.5%).

Figure 1.6

Hip and knee joint replacement procedures entered into the NJR, 2006/07 to 2010/11, recorded by procedure type.

Source: Procedures entered into the NJR 1st April 2006 to 31st March 2011.



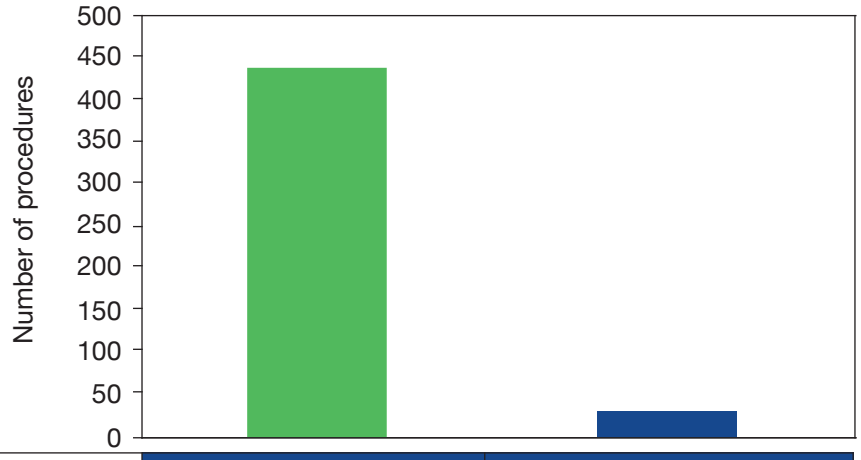
Procedures by year and joint/type	2006/07	2007/08	2008/09	2009/10	2010/11
Hip primary	58,445	66,556	69,681	70,669	77,800
Knee primary	61,648	73,204	77,295	78,938	86,067
Hip revision	6,198	6,725	7,345	8,285	9,200
Knee revision	3,298	3,699	4,518	5,169	5,829

A separate figure has been used to show ankle procedures due to the small number of procedures reported during 2010/11, the first year of data collection. Figure 1.7 shows the proportion of ankle joint replacement procedures by procedure type.

Figure 1.7

Ankle joint replacement procedures entered into the NJR, 2010/11, recorded by procedure type.

Source: Procedures entered into the NJR 1st April 2010 to 31st March 2011.



Procedure Type	Ankle primary	Ankle revision
2010/11	437	30

Where the operations took place

Of the 1,082,932 procedures submitted to the NJR since data collection began, 95.0% were submitted in England and 5.0% in Wales. In 2010/11, 170,768 (95.2%) procedures were submitted in England, compared to 8,570 (4.8%) in Wales.

There are four types of organisation in England carrying out hip, knee and ankle joint replacement surgery:

- NHS hospitals
- NHS treatment centres
- Independent sector hospitals
- Independent sector treatment centres (ISTCs).

There are no NHS treatment centres or ISTCs in Wales.

Since data collection began, 711,340 (65.7%) submitted procedures took place in NHS hospitals in England and Wales[10], 278,615 (25.7%) in independent sector hospitals, 46,247 (4.3%) in NHS treatment centres, and 46,730 (4.3%) in ISTCs. Figure 1.8 shows the proportion of procedures by type of provider.

Funding became a mandatory field from the third version of the NJR minimum dataset. The reduction in the proportion of procedures without funding selected reflects this change. By 2008/09, only a very small proportion of submissions did not include data on funding (a very small number of units are still using the second version of the minimum dataset). Since 2008/09, there has been an increase from 44.5% to 50.3% in the proportion of NHS-funded procedures in independent hospitals.

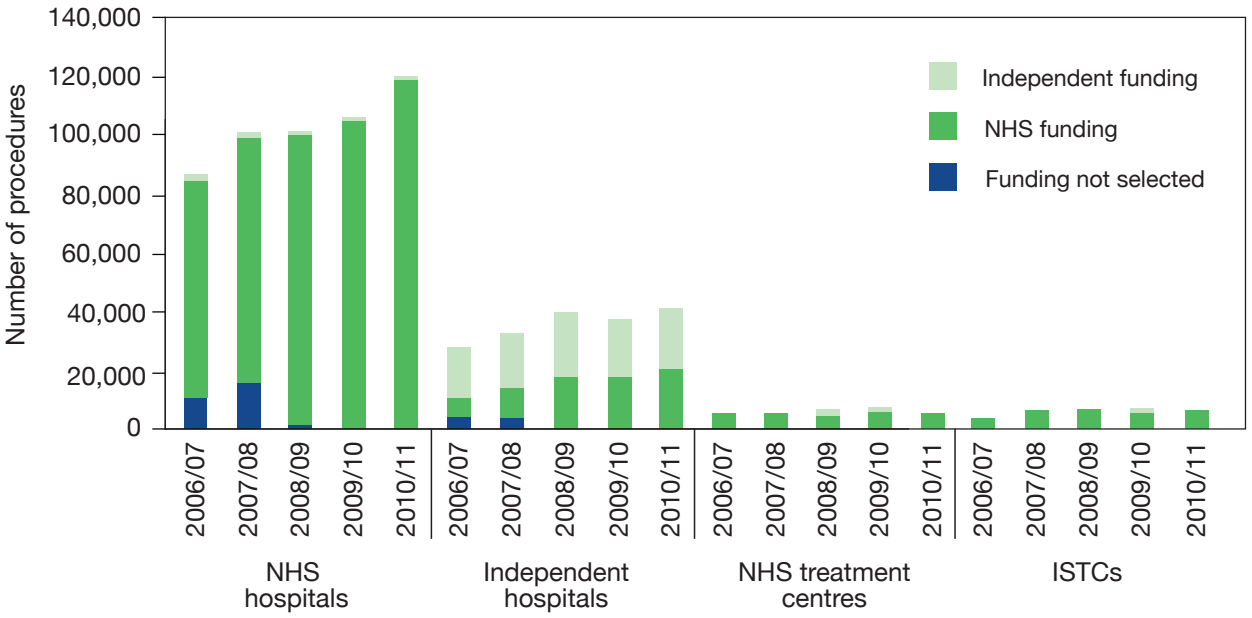
The proportion of hip replacement procedures reported to the NJR by type of provider is shown in Figure 1.9.

[10] These figures relate to the location of the hospital or treatment centre, not the residence of the patient. Note that it is not uncommon for patients to cross borders to receive treatment in another home nation.

Figure 1.8

Proportion of reported procedures by type of provider and funding, 2006/07 to 2010/11.

Source: Procedures entered into the NJR 1st April 2006 to 31st March 2011.

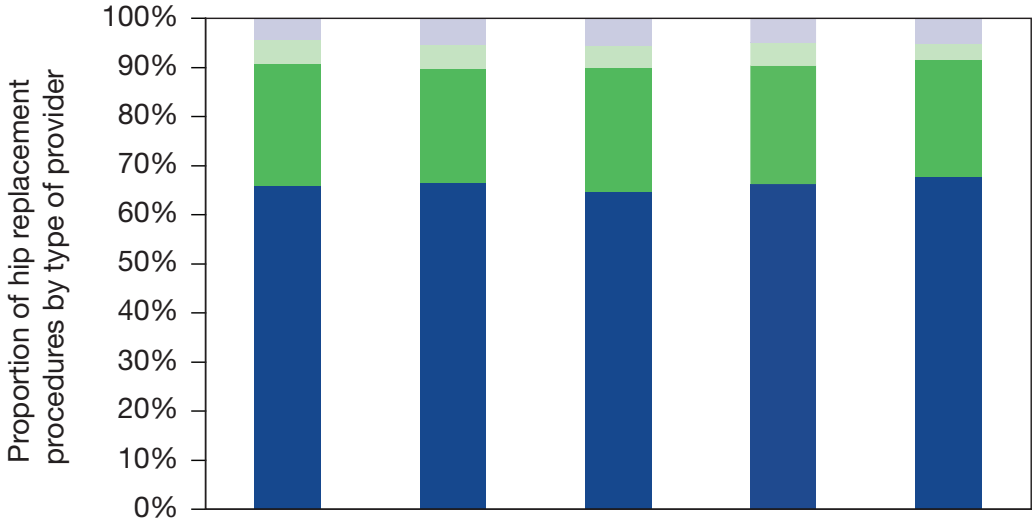


	NHS funding		Independent funding		Funding not selected		All NJR
NHS hospitals							
2006/07	72,303	82.7%	1,619	1.9%	13,465	15.4%	87,387
2007/08	83,157	82.2%	1,301	1.3%	16,646	16.5%	101,104
2008/09	98,300	95.9%	1,213	1.2%	2,946	2.9%	102,459
2009/10	106,404	98.3%	1,327	1.2%	531	0.5%	108,262
2010/11	119,731	98.8%	1,303	1.1%	211	0.2%	121,245
Independent hospitals							
2006/07	6,500	21.5%	17,750	58.7%	6,001	19.8%	30,251
2007/08	10,130	29.7%	18,096	53.1%	5,857	17.2%	34,083
2008/09	17,883	44.5%	21,463	53.4%	854	2.1%	40,200
2009/10	18,449	48.0%	20,011	52.0%	14	0.0%	38,474
2010/11	21,401	50.3%	21,133	49.6%	48	0.1%	42,582
NHS treatment centres							
2006/07	5,774	87.1%	27	0.4%	831	12.5%	6,632
2007/08	5,891	85.5%	21	0.3%	975	14.2%	6,887
2008/09	7,230	99.2%	11	0.2%	48	0.7%	7,289
2009/10	7,971	99.4%	29	0.4%	20	0.2%	8,020
2010/11	6,795	99.8%	11	0.2%	3	0.0%	6,809
ISTCs							
2006/07	5,430	90.5%	1	0.0%	566	9.4%	5,997
2007/08	6,988	79.1%	121	1.4%	1,720	19.5%	8,829
2008/09	8,512	94.0%	533	5.9%	10	0.1%	9,055
2009/10	8,060	95.2%	399	4.7%	4	0.0%	8,463
2010/11	8,799	99.8%	14	0.2%	1	0.0%	8,814

Figure 1.9

Proportion of hip replacement procedures by type of provider, 2006/07 to 2010/11.

Source: Procedures entered into the NJR 1st April 2006 to 31st March 2011.



Year	2006/07	2007/08	2008/09	2009/10	2010/11
NHS hospitals	**65.9%** 42,794	**66.4%** 48,834	**64.4%** 49,644	**66.3%** 52,362	**67.5%** 58,759
Independent hospitals	**25.2%** 16,384	**24.0%** 17,682	**26.3%** 20,253	**24.5%** 19,397	**24.3%** 21,183
NHS treatment centres	**4.7%** 3,032	**4.3%** 3,198	**4.2%** 3,220	**4.5%** 3,569	**3.6%** 3,104
ISTCs	**4.2%** 2,738	**5.2%** 3,847	**5.2%** 3,985	**4.7%** 3,708	**4.6%** 3,992
All NJR	64,948	73,561	77,102	79,036	87,038

There have been no major changes in the proportion of hip replacements performed by each type of provider within the past five years. Annual fluctuations between types of provider have been small, and the proportion for each type of provider in 2010/11 is within two percentage points of the figure for 2006/07.

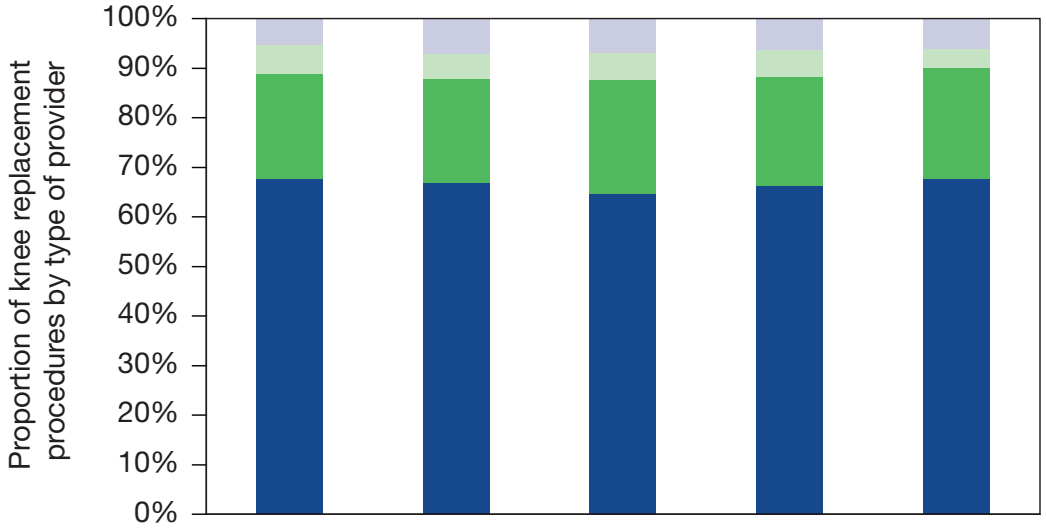
The proportion of procedures performed in treatment centres remains small. In contrast to other types of provider, NHS treatment centres saw a reduction in the number of hip replacement procedures submitted in 2010/11, with 13.0% fewer procedures submitted than in 2009/10.

Figure 1.10 shows the proportion of knee replacement procedures reported to the NJR by type of provider.

Figure 1.10

Proportion of knee replacement procedures by type of provider, 2006/07 to 2010/11.

Source: Procedures entered into the NJR 1st April 2006 to 31st March 2011.



Year	2006/07	2007/08	2008/09	2009/10	2010/11
NHS hospitals	**68.3%** 44,593	**67.6%** 52,270	**64.5%** 52,815	**66.4%** 55,900	**67.6%** 62,121
Independent hospitals	**21.2%** 13,867	**21.2%** 16,401	**24.4%** 19,947	**22.7%** 19,077	**23.2%** 21,320
NHS treatment centres	**5.5%** 3,600	**4.8%** 3,689	**5.0%** 4,069	**5.3%** 4,451	**4.0%** 3,703
ISTCs	**5.0%** 3,259	**6.4%** 4,982	**6.2%** 5,070	**5.6%** 4,755	**5.2%** 4,801
All NJR	65,319	77,342	81,901	84,183	91,945

As seen with hip replacement procedures, there have been no major changes to the proportion of knee replacements performed by each type of provider in the past five years. Annual fluctuations have been no more than three percentage points, and the proportion for each type of provider in 2010/11 is within two percentage points of the figure for 2006/07.

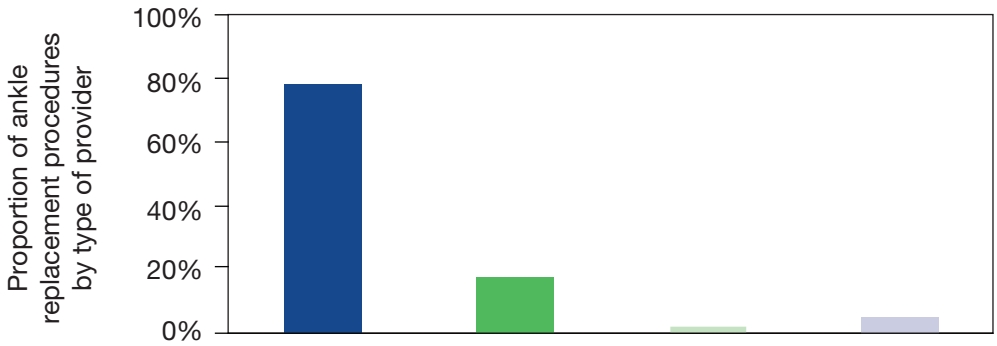
Like hip replacements, the number of knee replacements submitted in treatment centres has remained small compared with hospitals. NHS treatment centres saw a reduction in the number of knee replacement procedures performed in 2010/11, with 16.8% fewer procedures submitted than in 2009/10.

The proportion of ankle replacement procedures reported to the NJR by type of provider is shown in Figure 1.11.

Figure 1.11

Proportion of ankle replacement procedures by type of provider, 2010/11.

Source: Procedures entered into the NJR 1st April 2010 to 31st March 2011.



Type of provider	NHS hospitals	Independent hospitals	NHS treatment centres	ISTCs
2010/11	**78.2%** 365	**16.9%** 79	**0.4%** 2	**4.5%** 21

In this, the first year of data collection for ankle joint replacement surgery, a significant majority (78.2%) of the procedures were performed in NHS hospitals.

Part 1

1.4 Progress and plans

1.4.1 Strategic Plan

Significant work has been ongoing throughout the year to continue implementing the objectives of the NJR Strategic Plan 2009/11. Details of the key achievements are listed below. In 2011, work continues to assess priorities and develop the NJR Strategic Plan for the next two-year period 2011/13.

1.4.2 Investigating outlier data – implant performance

In 2010, the Implant Performance Committee was set up as a separate group within the Outlier Sub-Committee. It comprises a general committee, to discuss strategy and development of the methodology, and a scrutiny group which analyses the data about each implant that has been highlighted as needing evaluation. The representatives of industry do not attend the scrutiny group meetings.

The renewed focus on implant performance is enabled by the relative maturity of the NJR database, leading to a high degree of confidence in the results. The statistical methodology for outlier analysis is under review by the committee and any changes will be announced in due course. Over the past year a large number of devices have been evaluated, of which nine have been reported to the MHRA, with whom the NJR works closely.

1.4.3 Investigating outlier data – surgeon performance

The NJR has continued to actively monitor potential outlier performance for surgeons. Outlier reporting is undertaken on a bi-annual basis and the process now ensures that surgeons displaying outlying data are initially requested to verify the details which the NJR have recorded on their practice before further NJR analysis and review is undertaken. Recently, a new process has been agreed with the Department of Health whereby mortality and surgeon revision rates will be reported to trust managers on an annual basis.

The NJR has continued to work on the methodology and analytical approach for identifying all outliers and this will be further developed in collaboration with our contractors, the University of Bristol.

1.4.4 NJR Clinician Feedback

The use of the NJR Clinician Feedback system continues to increase, both in terms of the number of times it is accessed and the number of surgeons signing up to the service. The service gives surgeons access to a number of reports, including revision rates at one and three years and a funnel plot showing the actual revision rate against the expected revision rate per 100 patient years. Because the NJR can link a revision procedure to a primary procedure, even where the revising surgeon may be different to the surgeon carrying out the primary procedure, NJR Clinician Feedback provides surgeons with a more accurate assessment of their own revision rates.

This year, work will be undertaken to determine the requirements for the further development of the service. Improvements are likely to include more frequent updates of the data, extending the revision rate report to five years, and, subject to agreement with the NHS Information Centre and NHS Wales Informatics Service, to use HES and PEDW data to develop additional reports such as: length of stay, readmission rates, dislocation rates, and mortality rates. As with the other reports, these will enable surgeons to compare their outcomes with those of their colleagues at a local and national level.

1.4.5 NJR Supplier Feedback

Following the success of NJR Clinician Feedback, a new online service was launched in February 2011 to provide feedback directly to implant manufacturers and distributors. NJR Supplier Feedback provides industry stakeholders with key performance data relating to their own implant products. The data set links NJR primary procedures performed using the specified implant brand to any subsequent first revision procedure for the joint reported to the NJR. This data is updated on a monthly basis and supports post-market surveillance of implants, which is vital to improving patient safety. No patient-identifiable or surgeon-identifiable data are provided to suppliers via this service.

The NJR is currently the only national joint registry in the world to make this detailed data available to implant manufacturers and distributors on a monthly

basis as downloadable files. The dataset provides all the information necessary to allow the supplier to evaluate the performance of its products including the data needed to calculate revision rates using Kaplan-Meier and patient-time incidence rate, to look at any specific implant combination or construct in their catalogue, including the reason for each revision and the components revised.

The launch of the NJR Supplier Feedback service has been very warmly received by industry stakeholders, who are enthusiastic for the service to develop further. To support effective monitoring of device performance in the orthopaedic implant industry, the MHRA has also been given access to the same performance data relating to all products via the NJR Supplier Feedback portal.

1.4.6 Hospital Management Feedback

A new service is under development to provide performance information directly to the senior management of hospitals and trusts. Every unit in England and Wales undertaking hip, knee or ankle replacement surgery will receive a report annually, detailing its performance against a set of key NJR indicators.

Performance data will be aggregated at unit and surgeon level, and will include NJR data quality indicators and analysis of comparative revision rates. The report will give management full visibility of their unit's performance, and feed in to effective local clinical governance.

1.4.7 Elbow and Shoulder replacements

The extension of the NJR to include elbow and shoulder replacement procedures was delayed by the suspension of the approvals process for NHS data collections. Following the change of Government, the Review of Central Returns (ROCR) process was placed on hold for an extended period, pending a baseline review of all existing data collections. The ROCR process resumed in spring 2011, and approval was given to the NJR elbows and shoulders project. Preparation for the launch of data collection of elbow and shoulder replacements has resumed. Units will be given reasonable notice once the go-live date has been determined.

1.4.8 NJR PROMs

The NJR has commenced a study to extend the follow-up of Patient Reported Outcome Measures (PROMs) undertaken through the national Department of Health (DH) programme. Approximately 35,000 NHS patients in England who undergo a hip or knee replacement procedure over a six-month period, and who have agreed to participate in both national PROMs and the NJR, will receive a questionnaire 12 months post-operatively in addition to the six-month questionnaire in the DH programme. These questionnaires will allow comparison between baseline and follow-up pain and function, assess the contribution to outcome of a range of potential risk factors, and provide insight into the effect of arthroplasty on healthcare utilisation and satisfaction.

It is the intention of the NJR Steering Committee to follow up the same very large cohort of patients at three and five years. The cohort study will enrich the NJR with valid epidemiological data that will inform surgical practice and contribute to patient choice.

1.4.9 Research

2010 saw the NJR launch its research strategy. The NJR promotes research through enabling access to data for the research community. Research funding is allocated to methodological development of the register after rigorous selection procedures based on agreed best practice standards in research funding. In the past year, several projects have been approved and two research fellowships have been supported.

We have launched an area dedicated to research on the NJR website. This online portal describes the objectives for NJR-based research thus: 'The NJR aims to provide a substrate for definitive research into the full range of biological, mechanical, clinical and social factors influencing the outcome of joint replacement and to establish the impact of joint replacement surgery on the well-being of patients and the population'.

This resource has made available NJR access protocols, and the availability of NJR data for research purposes has also been a key message given by NJR representatives at conferences, seminars and other relevant live events during 2010/11.

The NJR is engaged in a wide consultation to ensure that all research activity in the register aligns with the broader strategic needs of arthroplasty and orthopaedic practice identified by the Department of Health and patient and professional groups.

The research strategy began to bear fruit in 2011. In the period January to June 2011 there were 17 research requests of which three were approved (see below) and 10 were under review at time of writing (July 2011). Four were rejected in this period. Elsewhere, a total of four research publications and one industry white paper were published and five papers, abstracts and a thesis are currently under review.

Approved research requests (as at July 2011):

"Orthopaedic Intervention in Rheumatoid Arthritis: A retrospective analysis of cumulative incidence, prognostic markers, outcomes and cost effectiveness over a 20 year period" Dr Adam Young

"Current trends in primary hip arthroplasty: Influence of these trends and associated factors on survival and revision rates" John Timperley

"To analyse in detail the epidemiology of revision knee replacement in England and Wales. To establish who is undergoing revision knee surgery, why it is being done and where, and what surgery is being performed. To identify any differences in the epidemiology of revision of total knee replacement and unicondylar knee replacement" Paul Baker

Paul Baker is one of two Research Fellows appointed by the NJR in 2010 alongside Mr Simon Jameson, whose project is analysing anaesthetic procedures for joint patients to attempt to establish the most positive procedures in terms of both patient outcomes and NHS resource management. The 12-month tenures began in April 2011.

1.4.10 Revisions data quality audit

A data quality audit is in progress to assess the completeness of data on revision hip and knee replacements stored in the NJR. Linkage work to HES/PEDW for the 7th Annual Report identified approximately 3,600 revision procedures recorded in HES/PEDW which were absent from the NJR database. The purpose of the audit is to determine the extent to which this discrepancy is due to non-compliance with the NJR or incorrect procedure data in HES/PEDW, caused by hospital miscoding of related procedures as revisions. For each discrepancy identified, the NJR Centre is contacting the surgeon concerned in order to ascertain details of the actual procedure undertaken.

In order for the project to proceed, an extension of the NJR's support under Section 251 of the NHS Act 2006 was required to allow for use of the HES data linkage for this purpose. This was granted in November 2010. In addition, a further data request to the Information Centre was required in order to obtain surgeon details for the episodes identified in the linkage analysis undertaken for the 7th Annual Report. This request was granted in January 2011.

1.4.11 International collaboration

The following collaboration has taken place between the NJR and international registries and orthopaedic associations during 2010/11:

- **Combined Orthopaedic Associations,** September 2010, Glasgow, UK – the surgeon representatives of the NJR Steering Committee presented at a combined meeting of the American, Australian, South African, New Zealand, Canadian and British Orthopaedic Associations. The NJR participated in a session on joint replacement registries worldwide, and presented the findings of the 7th Annual Report to an international audience.

Further international liaison is planned during 2011/12, including attendance and presentation at the International Consortium of Orthopaedic Registries (ICOR) Conference in Washington, USA and the

International Society of Arthroplasty Registries (ISAR) Congress in Bergen, Norway.

1.4.12 7th Annual Report in-depth studies

A number of topics identified in the 7th Annual Report are the subject of continuing analysis and, once completed, will be submitted for peer-reviewed publication. These include an analysis of the revision rate according to the volume of hip and knee replacements carried out by a surgeon or a unit; the use of capture-recapture methodology to assess the efficiency of the NJR to identify revisions; the development of prognostic models for revision by prosthesis type; and a detailed analysis of the reasons for revision. Further details of these topics and progress with analysis and publications can be found on the NJR website.

1.4.13 8th Annual Report in-depth studies

Four studies on specific topics are planned for the coming year:

- **Metal-on-metal bearings** – in depth analysis of metal-on-metal bearings to include resurfacing, large head metal-on-metal total hip replacement (THR) and large head metal-on-metal THR with XL head and resurfacing socket. To include sub-analysis of different types of implants and fixation modalities.
- **Femoral head size** – a study of the trend to use increasing femoral head size and outcomes in terms of revision overall and revision for dislocation. Depending on the quality of coding in Hospital Episode Statistics (HES) this study may address incidence of dislocation requiring manipulation under anaesthetic.
- **Thromboprophylaxis** – a study of prophylactic agents to reduce the incidence of thrombo-embolic complications in knee replacement surgery including an assessment of adverse events including infection, minor and major bleeding complications, readmission, re-operation, revision and death.
- **Re-revisions** – a study of revision hip and knee replacement to study the effect of subsequent re-revision of the first-time revisions, with particular focus on outcome, the reason for the first-time revision and the reason for subsequent revision.

Part 1

1.5 Governance and support

1.5.1 Managing the NJR

The work of the NJR benefits a large number of diverse stakeholders. A comprehensive list of these stakeholders can be found on the NJR website.

Steering Committee

The Steering Committee met four times during 2010/11, and the minutes of those meetings are published on the NJR website. The Committee's current members were appointed by the Appointments Commission on behalf of the Secretary of State for Health following a formal recruitment process. For a current list of NJR Steering Committee members and their declarations of interest, please see Appendix 1.

Sub-groups of the Steering Committee

Sub-groups have been established to oversee specific areas of the NJR's work and each is chaired by an NJRSC member:

- The NJR Editorial Board is responsible for overseeing the production of the Annual Report. The Chair of the Editorial Board is Mr Martyn Porter.
- The Research Sub-Committee is responsible for consideration of research requests, and for the establishment of a Research Request Protocol. The Chair of the Research Sub-Committee is Professor Alex MacGregor.
- The Outlier Sub-Committee – Surgeon performance is responsible for the development and management of the NJR surgeon outlier process. The Chair of the Outlier Sub-Committee for surgeon performance is Professor Paul Gregg.
- The Outlier Sub-Committee – Implant Performance is responsible for the development of the NJR implant outlier process. The Outlier Implant Scrutiny Group feeds into this group and is responsible for managing the implants identified as potential outliers. The Chair of both these groups is Mr Keith Tucker.

Regional Clinical Co-ordinators' Network

The NJR Regional Clinical Co-ordinators' Network consists of 21 consultant orthopaedic surgeons, acting as local 'champions' for the service and supporting the work of the NJRSC and the Regional Co-ordinators. Further information about the RCC Network and its members can be found in Appendix 2 and on the NJR website. The Chair of the RCC Network is Mr Peter Howard.

Regional Co-ordinators

The NJR Centre has eight Regional Co-ordinators (RCs). The role of the RCs is to provide on-site support to hospitals. Their contact details, along with their areas of responsibility, are available on the NJR website.

Information and communication

The NJR has continued to communicate regularly with all stakeholders, and a review of the communications strategy is included in the NJR Strategic Plan for 2011/13. Whilst publications have included the 7th Annual Report, Joint Approach newsletters, patient information leaflets, and information published on the NJR website, it is recognised that more information needs to be provided to different audiences and to ensure that it is appropriate and easily understood. This strategy is being supported this year with the publication of the National Joint Registry for England and Wales annual report Public and Patient guide, written specifically for patients.

Representatives of the NJR Centre have attended various conferences and events, including the BOA Annual Congress and the Society of Orthopaedic and Trauma Nursing. NJR staff have also continued to hold regional workshops and undertake training visits in hospitals.

Part 1

1.6 Finance

1.6.1 Income and expenditure, 2010/11

The NJR is self financing, funded by a levy raised on the sale of hip, knee and ankle implants to NHS and independent healthcare providers in England and Wales. The rate of the levy is recommended by the NJR Steering Committee for approval by the Department of Health (DH), and is subject to a Memorandum of Understanding between the DH, Welsh Government, Independent Healthcare Advisory Services and the Association of British Healthcare Industries (ABHI) Orthopaedics Special Interest Section.

The levy was set at £20.00 per joint from 1st April 2010 to 31st March 2011.

Levy income in 2010/11 was £2,616,597 (2009/10: £2,499,110). Expenditure for the same period was £2,750,605 (2009/10: £2,390,921) The NJR also transferred a grant of £150,000 to the National Hip Fracture Database.

Spending on the implementation of the NJR's 2009/11 Strategic Plan was £795,572 (2009/10: £577,297), most of this increase being the costs of including ankle implants under the levy, and development work to include elbow and shoulder implants in the near future.

Members of the NJR Steering Committee and RCC Network are volunteers and do not receive payment for their work. However, they are reimbursed for travel and subsistence expenses incurred while attending meetings. The total expenditure for members' expenses during 2010/11 was £28,105 (2009/10: £30,326).

The NJR's financial results are included in the audited accounts of HQIP (Healthcare Quality Improvement Partnership) which manages the registry. The full audited accounts are available on HQIP's website from September 2011, and also from the Charity Commission and Companies House.

Part 1

1.7 Appendices

Appendix 1
NJR Steering Committee, 2010/11

A1.1 NJR Steering Committee – composition

As an advisory, non-departmental public body, the composition of the NJRSC is:

• Chairman	1
• Orthopaedic surgeons	3
• Patient representative groups	2
• Implant manufacturer/supplier industry	2
• Public health/epidemiology	1
• NHS organisation management	1
• Independent healthcare provider	1
• Practitioner with special interest in orthopaedic care who is a GP, nurse or allied health professional (physiotherapist or occupational therapist)	1

A1.2 Membership from 1st October 2010

Members are appointed as posts become vacant.

Ms Laurel Powers-Freeling	Chairman (from April 2011)
Professor Paul Gregg	Orthopaedic Surgeon (from October 2003) Vice Chairman Acting Chairman (from October 2009 to March 2011)
Mr Michael Borroff	Orthopaedic device industry (from October 2002)
Ms Mary Cowern	Patient Representative. Patient group – Arthritis Care (from October 2006)
Professor Alex MacGregor	Public health and epidemiology (from October 2002)
Ms Carolyn Naisby	Practitioner with special interest in orthopaedics (from July 2006)
Mr Martyn Porter	Orthopaedic Surgeon (from January 2003)
Mr Dean Sleigh	Orthopaedic device industry (from April 2008)
Mr Keith Tucker	Orthopaedic Surgeon (from May 2007)
Mr Andrew Woodhead	NHS trust management (from January 2007)
Vacancy	Independent healthcare sector
Vacancy	Patient Representative

A1.3 Observers

The following have regularly attended NJR Steering Committee meetings as observers:

Mr Peter Howard	Chair of the NJR Regional Clinical Co-ordinators' Network
Dr Crina Cacou	MHRA
Mr Andy Smallwood	NHS Supply Chain (formerly the NHS Purchasing and Supply Agency)
Ms Elaine Young	National Development Lead, HQIP
Mr Robin Burgess	Chief Executive, HQIP
Mr Robin Rice	Welsh Government

A1.4 Members' declarations of interest

MsL aurelP owers-Freeling	No interests to declare
Professor Paul Gregg	Consultant Orthopaedic Surgeon, South Tees Hospitals NHS Trust (orthopaedic unit receives research/audit funding from DePuy International Ltd, Stryker UK and Smith & Nephew plc) Orthopaedic Advisor for Ramsay Healthcare
Mr Michael Borroff	Chair, ABHI Orthopaedics Special Interest Section Employed by DePuy International Ltd, manufacturer of orthopaedic prostheses
Ms Mary Cowern	Development Manager for the UK charity, Arthritis Care
Professor Alex MacGregor	Professor of Genetic Epidemiology, University of East Anglia Consultant Rheumatologist, Norfolk and Norwich University Hospital NHS Trust
Ms Carolyn Naisby	Consultant Physiotherapist, City Hospitals Sunderland NHS Foundation Trust
Mr Martyn Porter	Consultant Orthopaedic Surgeon, Wrightington, Wigan and Leigh NHS Trust (orthopaedic unit has received financial support from DePuy International for clinical and RSA studies for Elite Plus femoral stem and C-Stem) Has acted as a consultant to DePuy International in relation to the development of a hip femoral stem (C-Stem AMT) and received royalties on this hip stem
Mr Dean Sleigh	National Business Development Manager, Biomet Healthcare UK Ltd ABHI Council Member, ABHI Orthopaedics Special Interest Section
Mr Keith Tucker	Consultant Orthopaedic Surgeon, Norfolk and Norwich University Hospital NHS Trust (various sources of financial support for research undertaken by orthopaedic department) Royalties received from Johnson & Johnson Orthopaedics more than five years ago for contribution to design of hip prostheses (royalties paid to orthopaedic charity)
Mr Andrew Woodhead	Head of Mergers and Acquisitions, NHS London

Appendix 2
NJR Regional Clinical Co-ordinators, 2010/11

Chair Mr Peter Howard **Vice Chair** Mr Colin Esler	**South East Coast Strategic Health Authority** Mr Hagen Jähnich/Mr Helmut Zahn (shared position) Vacancy
South West Strategic Health Authority Mr Evert Smith Mr Matthew Wilson	**East Midlands Strategic Health Authority** Mr Colin Esler, Vice Chair Mr Peter Howard, Chair
West Midlands Strategic Health Authority Mr David Dunlop Mr Ian D M dos Remédios	**London Strategic Health Authority** Mr Marcus Bankes Mr Gareth Scott
North West Strategic Health Authority Mr Glyn Thomas Vacancy	**Yorkshire and Humberside Strategic Health Authority** Mr Ian Stockley Mr Malcolm Binns
North East Strategic Health Authority Mr John Anderson Professor Andrew McCaskie	**North Wales NHS Health Region** Mr Glynne Andrew
East of England Strategic Health Authority Mr Matthew Porteous Vacancy	**South East Wales NHS Health Region** Mr Alun John
South Central Strategic Health Authority Mr John Britton Mr Jonathan Rees	**Mid and West Wales NHS Health Region** Mr David Woodnutt

NJR website

The following information will also available on the NJR website:

1. NJR 8th Annual Report – Parts 1, 2 and 3 (annual progress 2010/11, clinical activity 2010 and implant survivorship 2003 to 2010)
2. NJR 8th Annual Report – Part 1: Annual Progress 2010/11 - Welsh Language
3. NJR 8th Annual Report – NJR Steering Committee Terms of Reference
4. NJR 8th Annual Report – NJR Regional Clinical Co-ordinators Terms of Reference
5. NJR 8th Annual Report – Prostheses Data
6. NJR 8th Annual Report – Tables and Figures
7. NJR 8th Annual Report – Public and Patient Guide

NJR Centre contact details

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Email: health_servicedesk@northgate-is.com
Website: www.njrcentre.org.uk

Part 2 Clinical activity 2010

2.1 Introduction

This section summarises the number of hip, knee and ankle replacement procedures undertaken in England and Wales between 1st January and 31st December 2010 and entered into the NJR by 28th February 2011. The information is summarised according to the type of hospital or treatment centre, procedure type and patient characteristics.

2.1.1 Hospitals and treatment centres participating in the NJR

During 2010, 413 orthopaedic units were open and, of these, 399 (97%) submitted at least one hip, knee or ankle procedure to the NJR (Table 2.1). A compliance rate of 92.4% (calculated from comparing the number of procedures[11] submitted with the number of leviable components sold) was recorded for 2010.

On average, 196 hip replacements and 213 knee replacements were recorded per orthopaedic unit over the year, although the numbers varied from one to 1,278 procedures. Compared with previous years, there has been an increase in the number of units performing more than 200 hip procedures and also an increase in the number units performing more than 300 knee procedures. There is a decrease in the number of units performing less than 100 knee procedures. Most units performing ankle procedures performed less than five in the nine-month period included in this report. However, as data collection for ankles only began in April 2010, it is likely that not all units submitted all their ankle procedures from this date.

Table 2.1 Total number of hospitals and treatment centres in England and Wales able to participate in the NJR and the proportion actually participating in 2010.

	Total number of units	Number of units submitting	Proportion participating
Total	**413**	**399**	**97%**
NHS hospitals	**224**	**215**	**96%**
England	207	198	96%
Wales	17	17	100%
Independent hospitals	**164**	**161**	**98%**
England	158	155	98%
Wales	6	6	100%
ISTCs	**14**	**14**	**100%**
England	14	14	100%
Wales	0	0	-
NHS treatment centres	**11**	**9**	**82%**
England	11	9	82%
Wales	0	0	-

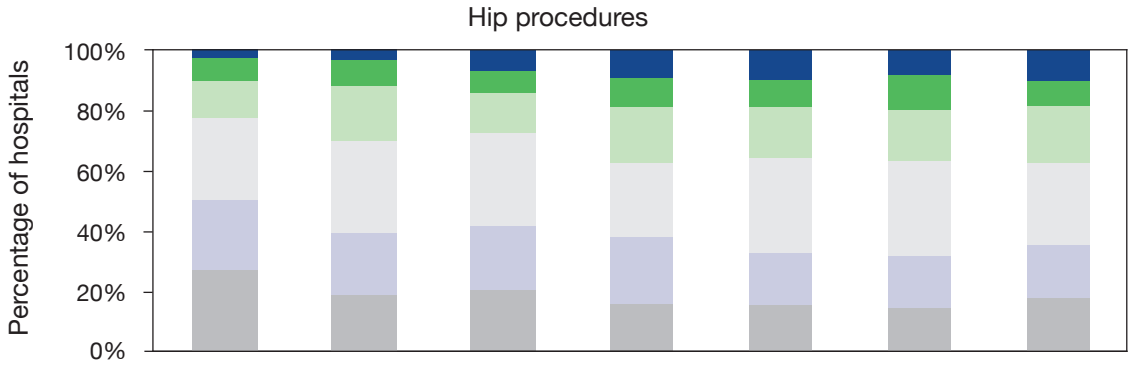
Table 2.2 Number of participating hospitals, according to number of procedures performed during 2010.

	Total number of hospitals	Number of procedures					
		<50	50 - 99	100 - 199	200 - 299	300 - 399	400+
Hip operations							
Hospitals entering replacements	398	70	73	108	74	35	38
Hospitals entering primary replacements	396	74	77	112	75	35	23
Knee operations							
Hospitals entering replacements	391	58	74	102	67	41	49
Hospitals entering primary replacements	390	59	79	103	66	39	44
Ankle operations	**Total number of hospitals**	**Number of procedures**					
		< 5	**5 - 9**	**10 - 14**	**15 - 19**	**20 - 24**	**25 +**
Hospitals entering replacements	91	75	6	5	2	1	2
Hospitals entering primary replacements	88	72	6	6	1	2	1

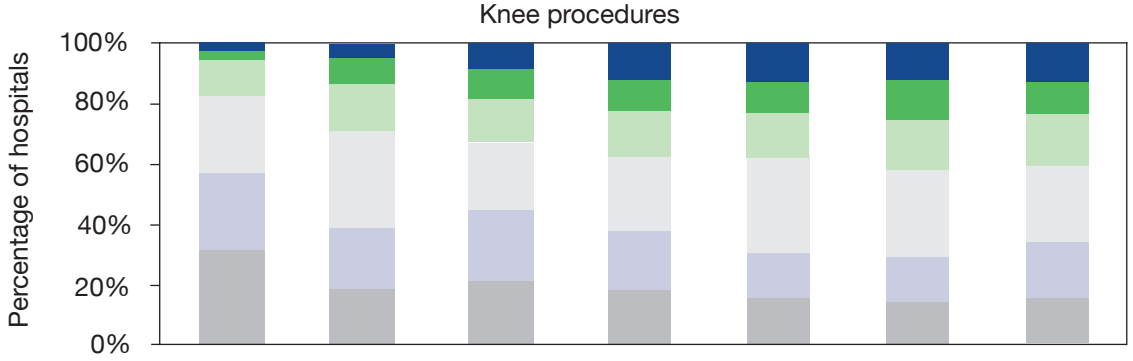
[11] Some procedure types are excluded from the compliance calculation as they do not use implants, i.e. Hip stage one of two stage revision, Hip excision arthroplasty, Knee stage one of two stage revision, Knee conversion to arthrodesis, Knee amputation, Ankle stage one of two stage revision, Ankle conversion to arthrodesis and Ankle amputation.

Figure 2.1

Percentage of participating hospitals by number of procedures per annum, 2004 to 2010.



Year	2004	2005	2006	2007	2008	2009	2010
400+	3%	4%	7%	9%	10%	8%	10%
300 - 399	7%	8%	7%	9%	9%	12%	9%
200 - 299	13%	18%	14%	18%	17%	17%	19%
100 - 199	27%	30%	30%	25%	31%	31%	27%
50-99	24%	22%	22%	23%	18%	19%	18%
<50	27%	19%	20%	16%	15%	14%	18%
Number of hospitals	392	393	397	391	394	395	398
Total hip procedures	53,268	63,832	66,404	74,051	77,372	77,784	76,759



Year	2004	2005	2006	2007	2008	2009	2010
400+	4%	5%	8%	12%	13%	12%	13%
300 - 399	4%	8%	9%	11%	10%	13%	10%
200 - 299	12%	14%	11%	14%	15%	17%	17%
100 - 199	25%	33%	24%	24%	31%	28%	26%
50-99	24%	20%	25%	20%	16%	15%	19%
<50	32%	19%	22%	19%	15%	15%	15%
Number of hospitals	391	391	397	389	389	393	391
Total knee procedures	48,916	63,969	65,995	77,584	81,867	82,984	81,979

Part 2

2.2 Hip replacement procedures, 2010

The total number of hip procedures entered into the NJR during 2010 was 76,759, an increase of 6% over 2009. Of these, 68,907 were primary and 7,852 were revision (and re-operation) procedures. The revision 'burden' has increased to 11% from 10% in the previous year.

Table 2.3 shows that 93% of patients at independent hospitals and ISTCs were graded as fit and healthy or with mild disease according to the ASA system, compared with 80% at NHS units.

Nearly all procedures (94%) undertaken at ISTCs were primary procedures. The percentage of primary hip resurfacings undertaken in independent hospitals (5%) is nearly double that of NHS hospitals (3%), as shown in Figure 2.2. At NHS treatment centres, 66% of primary procedure activity relates to cementless hip primary procedures – a greater proportion than at any other type of provider.

At NHS hospitals, revision procedures account for a higher percentage of total procedures (13%) than at any other type of provider (10% overall). NHS hospitals perform 84% of all hip revision procedures.

Table 2.3 Patient characteristics and procedure details, according to type of provider for hip procedures in 2010.

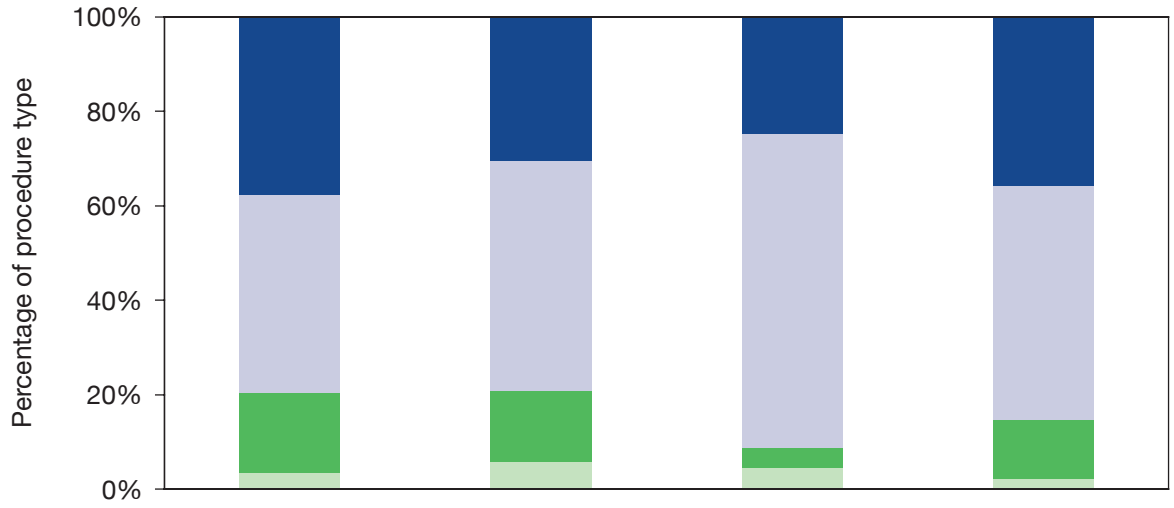
	NHS hospitals		Independent hospitals		NHS treatment centres		ISTCs		Total	
	No.	%	No.	%	No.	%	No.	%	No.	%
Total	**51,071**	**67%**	**19,669**	**26%**	**2,221**	**3%**	**3,798**	**5%**	**76,759**	
Patient physical status										
P1 - fit and healthy	6,454	13%	4,484	23%	435	20%	453	12%	11,826	15%
P2 - mild disease not incapacitating	34,197	67%	13,739	70%	1,469	66%	3,102	82%	52,507	68%
P3 - incapacitating systemic disease	9,962	20%	1,429	7%	314	14%	240	6%	11,945	16%
P4 - life threatening disease	446	<1%	16	<1%	3	<1%	3	<1%	468	<1%
P5 - expected to die within 24 hrs with or without an operation	12	<1%	1	<1%	0	0%	0	0%	13	<1%
Procedure type										
Primary procedures	**44,504**	**65%**	**18,656**	**27%**	**2,075**	**3%**	**3,672**	**5%**	**68,907**	**90%**
Primary total prosthetic replacement using cement	16,979	38%	5,784	31%	525	25%	1,316	36%	24,604	36%
Primary total prosthetic replacement not using cement	18,621	42%	9,012	48%	1,373	66%	1,821	50%	30,827	45%
Primary total prosthetic replacement not classified elsewhere (e.g. hybrid)	7,540	17%	2,866	15%	92	4%	466	13%	10,964	16%
Primary resurfacing arthroplasty of joint	1,364	3%	994	5%	85	4%	69	2%	2,512	4%
Revision procedures	**6,567**	**84%**	**1,013**	**13%**	**146**	**2%**	**126**	**2%**	**7,852**	**10%**
Hip single stage revision	5,542	84%	931	92%	132	90%	112	89%	6,717	86%
Hip stage one of two stage revision	441	7%	33	3%	5	3%	7	6%	486	6%
Hip stage two of two stage revision	511	8%	43	4%	9	6%	7	6%	570	7%
Hip excision arthroplasty	54	<1%	6	<1%	0	0%	0	0%	60	<1%
Hip re-operation other than revision[12]	19	<1%	0	0%	0	0%	0	0%	19	<1%
Bilateral or unilateral[13]										
Bilateral	216	<1%	148	<1%	22	<1%	40	<1%	426	<1%
Unilateral	50,855	100%	19,521	100%	2,199	100%	3,758	100%	76,333	100%
Funding										
Independent	760	1%	9,996	51%	2	<1%	17	<1%	10,775	14%
NHS	50,310	99%	9,673	49%	2,219	100%	3,781	100%	65,983	86%
Not selected	1	<1%	0	0%	0	0%	0	0%	1	<1%

[12] Hip re-operations other than revision are recorded because some units continue to use MDSv2 where these procedures were included. MDSv3 no longer records re-operations. Therefore, the re-operation procedure totals will not reflect the actual number performed.

[13] Bilaterals will only be counted as a bilateral if they are entered under the same operation during data entry. If the two procedures are recorded under two different operations they will be counted as two unilateral procedures. Therefore, the count of bilaterals is likely to be an underestimate.

Figure 2.2

Primary hip procedures by type of provider, 2010.



Type of provider	NHS hospitals	Independent hospitals	NHS treatment centres	ISTCs
Cemented	38%	31%	25%	36%
Cementless	42%	48%	66%	50%
Hybrid	17%	15%	4%	13%
Resurfacing	3%	5%	4%	2%
Number of procedures	44,504	18,656	2,075	3,672

2.2.1 Primary hip replacement procedures, 2010

Of the 68,907 primary hip replacement procedures undertaken in 2010, 36% were cemented THRs, 43% were cementless, 3% were hip resurfacing procedures and 2% were LHMoM THRs (Figure 2.3). Figure 2.3 shows an apparent decrease in the volume of hip procedures between 2009 and 2010. However, not all procedures performed in 2010 were entered into the database before the 28th February 2011 deadline and will be entered after this date whereas volumes for other years have also had until 28th February 2011 to be submitted.

Compared with the previous year, there has been a 4% increase in cementless procedures and a reduction in the number of resurfacing procedures.

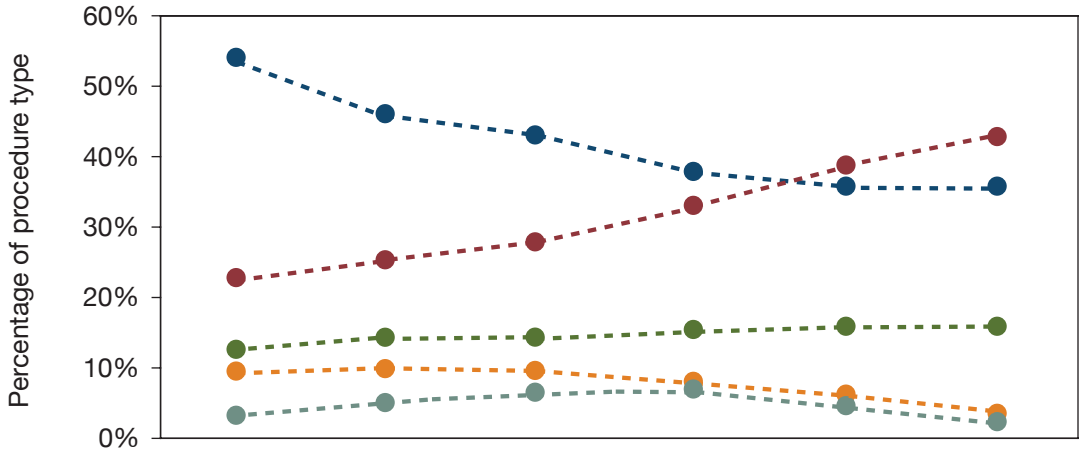
The percentage of cemented procedures did not change between 2009 and 2010 after being in steady decline since 2005.

Over the last year there has also been a significant decrease in the percentage of resurfacing procedures and in procedures where a large head is used with a resurfacing cup. This decline is thought to have resulted from the well-publicised voluntary withdrawal from the market of one brand of resurfacing device (ASR – DePuy), following the identification by the NJR of higher than expected revision rates for this product.

In 2010, 14% of hybrid procedures were reverse hybrid (cementless stem, cemented socket) and 86% were standard hybrid (cemented stem, cementless socket).

Figure 2.3

Type of primary hip replacement procedures undertaken between 2005 and 2010.



Year	2005	2006	2007	2008	2009	2010
Cemented	54%	46%	43%	38%	36%	36%
Cementless	22%	25%	28%	33%	39%	43%
Hybrid	12%	14%	14%	15%	16%	16%
Resurfacing	9%	10%	9%	8%	6%	3%
Large head with resurfacing cup	3%	5%	6%	7%	4%	2%
Number of procedures	56,350	59,715	66,615	69,839	69,936	68,907

2.2.1.1 Patient characteristics

Age and gender were included for those patients who gave consent for their personal identifiers to be entered into the NJR and where consent was 'Not recorded' (a total of 94% which is the same as reported in 2009). The average age was 67.2 years, 0.5 years older than last year. Approximately 59% of the patients were female (Table 2.4) which is 3% higher than 2009. On average, female patients were older than male patients at the time of their primary hip replacement (68.8 years and 66.3 years respectively, Table 2.5). Patients undergoing a resurfacing procedure were the youngest, at an average age of 54.8 years (Table 2.4). Four times as many males have a resurfacing procedure compared with females. These reported figures show good adherence by the orthopaedic community to guidelines issued by the British Orthopaedic Association during 2009/10, on patient selection criteria for metal-on-metal resurfacing prostheses.

According to the ASA system, 16% of patients undergoing a primary hip replacement in 2010 were graded as fit and healthy prior to surgery, compared with 37% in 2003. Figure 2.5 shows the changes in ASA grade over eight years. Patient BMI[14] has increased over the past eight years from 27.4 to 28.5, as shown in Figure 2.6(a). Females undergoing THR have a consistently lower mean BMI than males; the converse is the case for TKR (Figure 2.18(a)). Figure 2.6(b) shows that there has been an increase in the number of patients with a BMI of between 30 and 39 and a decrease in the number of patients with BMI between 18.5 and 24. The single largest indication recorded for surgery was osteoarthritis, recorded in 93% of procedures (Table 2.4). Figure 2.4(b) shows that the percentage of patients within the age group bands has not changed significantly since 2003, suggesting that the increase in BMI and reduction in fitness of patients is not due to an ageing patient cohort.

[14] BMI: 20-24 normal, 25-29 overweight, 30-39 obese, 40+ morbidly obese.

Table 2.4 Patient characteristics for primary hip replacement procedures in 2010, according to procedure type.

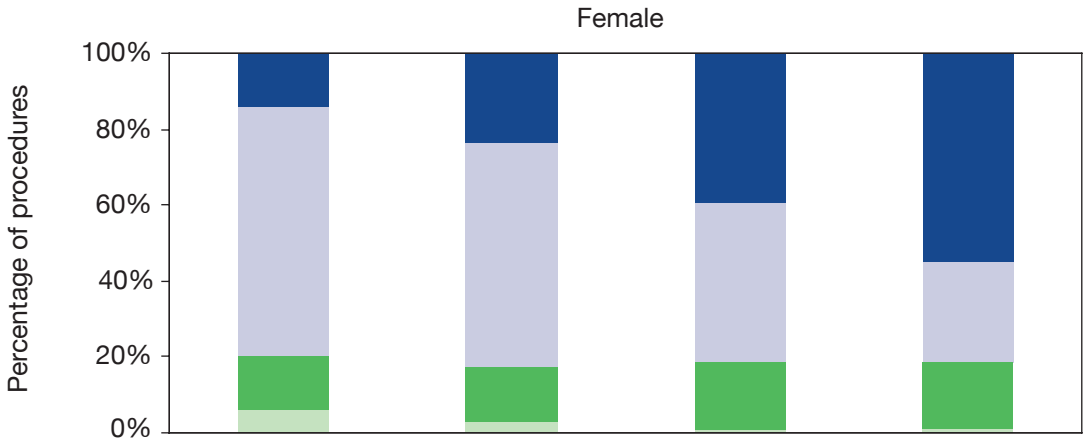
	Primary total prosthetic replacement using cement		Primary total prosthetic replacement not using cement		Primary total prosthetic replacement not classified elsewhere (e.g. hybrid)		Primary resurfacing arthroplasty of joint		Total	
	No.	%	No.	%	No.	%	No.	%	No.	%
Total hip primaries	**24,604**	**36%**	**30,827**	**45%**	**10,964**	**16%**	**2,512**	**4%**	**68,907**	
Total hip primaries with patient data	**23,418**	**95%**	**29,082**	**94%**	**10,320**	**94%**	**2,293**	**91%**	**65,113**	**94%**
Average age	73.00		65.57		69.81		54.84		67.2	
SD	9.55		11.23		10.82		9.53		13.27	
Interquartile range	67.4 - 79.7		59.0 - 73.5		63.7 - 77.3		48.9 - 61.2		62.0 - 76.6	
Gender										
Female	15,395	66%	16,399	56%	6,512	63%	424	18%	38,730	59%
Male	8,023	34%	12,683	44%	3,808	37%	1,869	82%	26,383	41%
Patient physical status										
P1 – fit and healthy	2,635	11%	5,831	19%	1,462	13%	1,129	45%	11,057	16%
P2 – mild disease not incapacitating	17,274	70%	21,359	69%	7,621	70%	1,316	52%	47,570	69%
P3 – incapacitating systemic disease	4,522	18%	3,518	11%	1,805	16%	67	3%	9,912	14%
P4 – life threatening disease	167	<1%	115	<1%	74	<1%	0	0%	356	<1%
P5 – expected to die within 24 hours with or without an operation	6	<1%	4	<1%	2	<1%	0	0%	12	<1%
BMI										
Number with BMI data	15,426	63%	18,218	59%	6,610	60%	1,507	60%	41,761	61%
Average	28.21		28.82		28.42		28.32		28.51	
SD	5.1		5.3		5.2		4.4		5.2	
Indications for surgery										
Osteoarthritis	22,956	93%	28,822	93%	9,874	90%	2,377	95%	64,029	93%
Avascular necrosis	447	2%	810	3%	328	3%	50	2%	1,635	2%
Fractured neck of femur	549	2%	438	1%	377	3%	4	<1%	1,368	2%
Congenital dislocation	132	<1%	603	2%	219	2%	68	3%	1,022	1%
Inflammatory arthropathy	347	1%	399	1%	225	2%	20	<1%	991	1%
Failed hemiarthroplasty	91	<1%	60	<1%	49	<1%	1	<1%	201	<1%
Trauma – chronic	280	1%	297	<1%	186	2%	18	<1%	781	1%
Previous surgery, non-trauma related	24	<1%	113	<1%	47	<1%	9	<1%	193	<1%
Previous arthrodesis	13	<1%	12	<1%	5	<1%	0	0%	30	<1%
Previous infection	25	<1%	19	<1%	23	<1%	0	0%	67	<1%
Other	396	2%	443	1%	205	2%	75	3%	1,119	2%
Side										
Bilateral	65	<1%	283	<1%	61	<1%	12	<1%	421	<1%
Left, unilateral	10,900	44%	13,880	45%	4,915	45%	1,226	49%	30,921	45%
Right, unilateral	13,639	55%	16,664	54%	5,988	55%	1,274	51%	37,565	55%

Table 2.5 Age and gender for primary hip replacement patients in 2010.

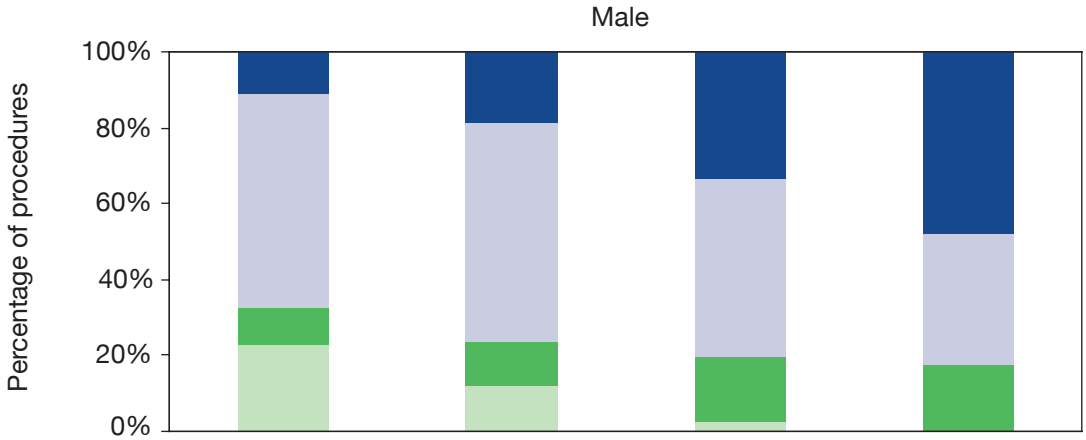
	Primary total prosthetic replacement using cement		Primary total prosthetic replacement not using cement		Primary total prosthetic replacement not classified elsewhere (e.g. hybrid)		Primary resurfacing arthroplasty of joint		Total	
	No.	%	No.	%	No.	%	No.	%	No.	%
Average age by gender										
Female	**15,395**	**40%**	**16,399**	**42%**	**6,512**	**17%**	**424**	**1%**	**38,730**	**59%**
Average	73.63		66.10		70.31		54.20		68.85	
SD	9.37		11.19		10.74		10.29		12.35	
Interquartile range	68.0 - 80.3		59.5 - 73.9		64.1 - 77.9		47.9 - 61.4		63.1 - 77.6	
Male	**8,023**	**30%**	**12,683**	**48%**	**3,808**	**14%**	**1,869**	**7%**	**26,383**	**41%**
Average	71.77		64.87		68.95		54.98		66.32	
SD	9.76		11.24		10.89		9.35		12.44	
Interquartile range	66.3 - 78.5		58.5 - 72.8		63.1 - 76.2		49.1 - 61.6		60.2 - 75.1	
Age group by gender										
Female										
<45 years	116	<1%	639	4%	135	2%	70	17%	960	2%
45 - 54 years	457	3%	1,875	11%	420	6%	144	34%	2,896	7%
55 - 64 years	2,021	13%	4,675	29%	1,228	19%	157	37%	8,081	21%
65 - 74 years	5,468	36%	5,689	35%	2,389	37%	47	11%	13,593	35%
75 - 84 years	5,886	38%	2,995	18%	1,966	30%	5	1%	10,852	28%
>85 years	1,447	9%	526	3%	374	6%	1	<1%	2,348	6%
Male										
<45 years	127	2%	650	5%	126	3%	272	15%	1,175	4%
45 - 54 years	319	4%	1,584	12%	267	7%	613	33%	2,783	11%
55 - 64 years	1,276	16%	3,856	30%	789	21%	756	40%	6,677	25%
65 - 74 years	3,064	38%	4,270	34%	1,498	39%	210	11%	9,042	34%
75 - 84 years	2,774	35%	2,108	17%	960	25%	17	<1%	5,859	22%
>85 years	463	6%	215	2%	168	4%	1	<1%	847	3%

Figure 2.4(a)

Age and gender for primary hip replacement patients in 2010.



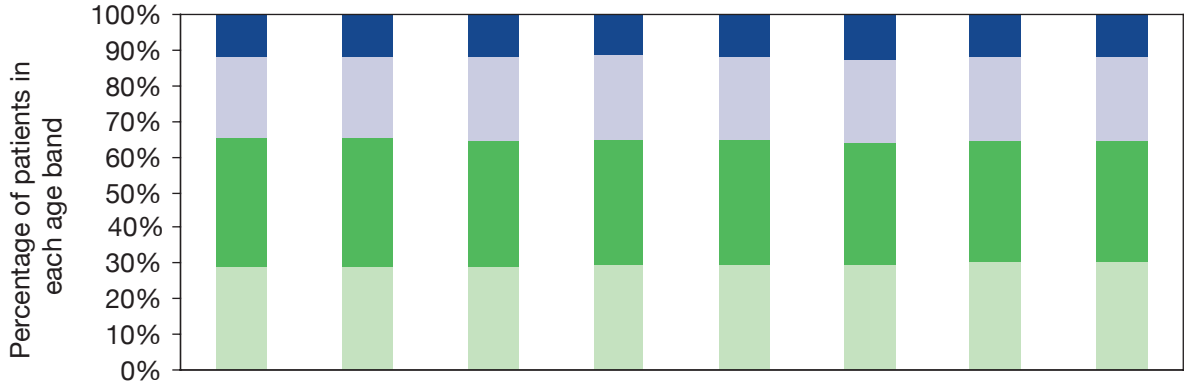
Age group	<55	55 - 64	65 -74	75+
Cemented	15%	25%	40%	56%
Cementless	65%	58%	42%	27%
Hybrid	14%	15%	18%	18%
Resurfacing	6%	2%	<1%	<1%
Number of patients	3,856	8,081	13,593	13,200



Age group	<55	55 - 64	65 -74	75+
Cemented	11%	19%	34%	48%
Cementless	56%	58%	47%	35%
Hybrid	10%	12%	17%	17%
Resurfacing	22%	11%	2%	<1%
Number of patients	3,958	6,677	9,042	6,706

Figure 2.4(b)

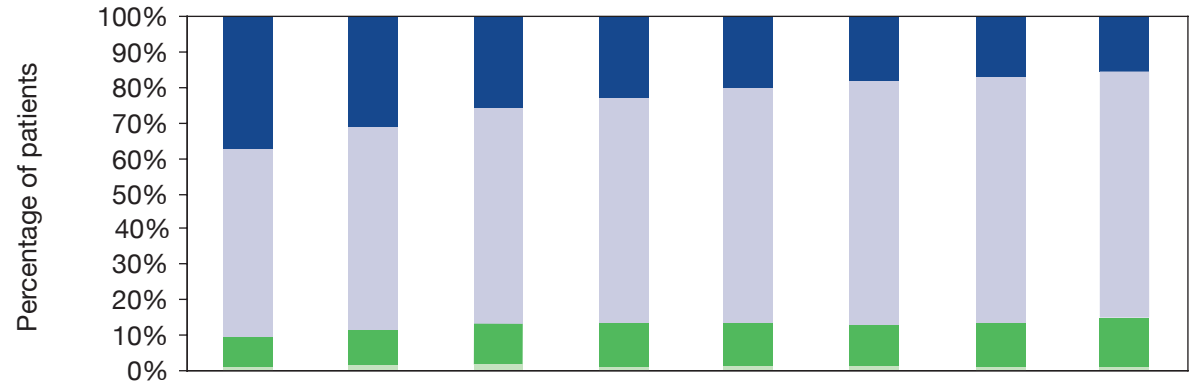
Age for primary hip replacement patients between 2003 and 2010.



Year	2003	2004	2005	2006	2007	2008	2009	2010
<55	12%	12%	12%	12%	12%	13%	12%	12%
55-64	23%	23%	23%	24%	24%	24%	23%	23%
65-74	36%	37%	36%	35%	35%	34%	35%	35%
75+	29%	29%	29%	29%	30%	30%	30%	31%
Number of patients	14,420	27,941	39,950	47,176	59,634	65,827	66,377	65,113

Figure 2.5

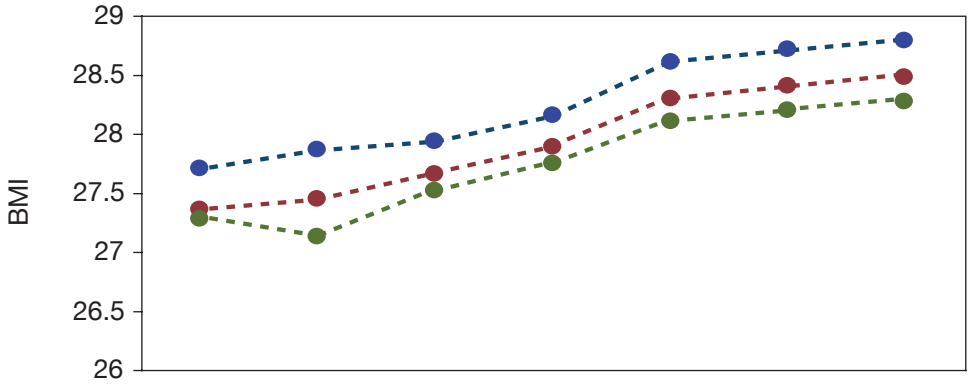
ASA grades for primary hip replacement patients between 2003 and 2010.



Year	2003	2004	2005	2006	2007	2008	2009	2010
P1	37%	31%	26%	23%	20%	18%	17%	16%
P2	53%	57%	60%	63%	66%	69%	69%	69%
P3	9%	11%	13%	13%	13%	13%	14%	14%
P4 and P5	<1%	1%	1%	1%	1%	1%	<1%	1%
Number of patients	26,432	48,030	57,490	59,715	66,616	69,839	69,936	68,907

Figure 2.6(a)

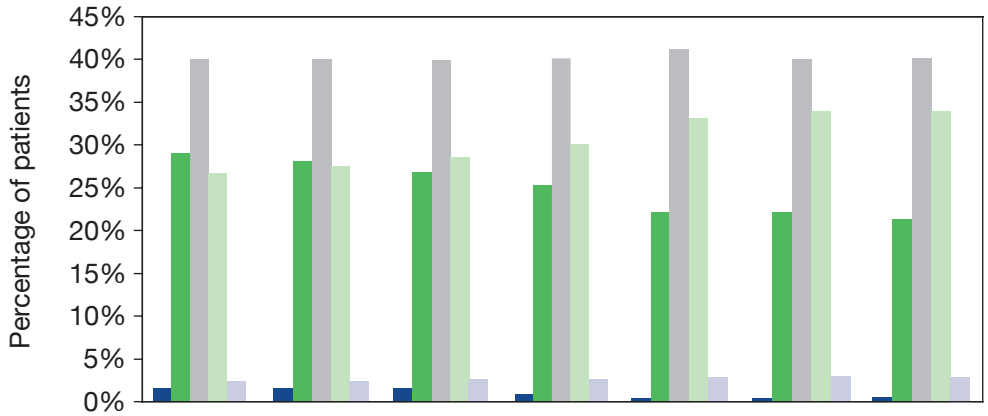
BMI for primary hip replacement patients between 2004 and 2010.



Year	2004	2005	2006	2007	2008	2009	2010
All	27.35	27.46	27.67	27.90	28.31	28.42	28.51
Female	27.28	27.15	27.53	27.76	28.12	28.21	28.30
Male	27.71	27.86	27.94	28.16	28.61	28.72	28.82
Number of patients with BMI data	5,906	8,984	10,443	14,134	33,655	39,002	41,761
Number of patients with BMI data (females)	2,471	4,410	5,465	8,093	19,565	22,524	24,306
Number of patients with BMI data (males)	1,753	2,947	3,715	5,412	13,353	15,646	16,781
Number of patients with BMI data (unknown gender)	1,682	1,627	1,263	629	737	832	674

Figure 2.6(b)

BMI groups for primary hip replacement patients between 2004 and 2010.



Year	2004	2005	2006	2007	2008	2009	2010
BMI <18.5	2%	2%	2%	1%	<1%	<1%	<1%
BMI 18.5 - 24	29%	28%	27%	25%	22%	22%	21%
BMI 25 - 29	40%	40%	40%	40%	41%	40%	40%
BMI 30 - 39	27%	28%	29%	30%	33%	34%	34%
BMI 40+	2%	2%	3%	3%	3%	3%	3%
Number of patients	5,906	8,984	10,443	14,134	33,655	39,002	41,761

2.2.1.2 Surgical techniques

The surgical techniques used in procedures undertaken in 2010 are summarised in Table 2.6. Patients were mainly positioned laterally. The lateral position was used more frequently in hybrid and resurfacing procedures than in cemented and cementless procedures. As would be expected, the most frequently used incision approach was posterior for all procedure types, though for cemented procedure types there were nearly as many procedures performed where a lateral (including Hardinge) approach was used.

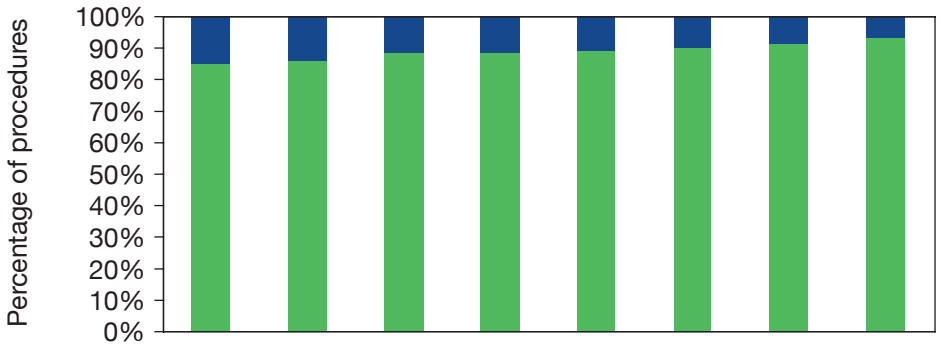
The reduction in the use of cemented stems from 77% in 2004 to 50% in 2010 and also in the use of cemented cups, from 56% to 34%, is consistent with the reduction seen in the overall number of cemented procedures (Figure 2.3). The relative usage of different types of bone cement is shown in Figure 2.7 and shows that the use of antibiotic cement has increased from 85% in 2003 to 93% in 2010. Use of minimally invasive surgery was greatest in cementless procedures; even though it was used in less than 5% of all procedures (Table 2.6), this is a 3% increase on 2009. It should, of course, be remembered that the definition of minimally invasive in this instance is purely based upon the understanding of an individual surgeon rather than on pre-set criteria.

Table 2.6 Characteristics of surgical practice for primary hip replacement procedures in 2010, according to procedure type.

	Primary total prosthetic replacement using cement		Primary total prosthetic replacement not using cement		Primary total prosthetic replacement not classified elsewhere (e.g. hybrid)		Primary resurfacing arthroplasty of joint		Total	
	No.	%	No.	%	No.	%	No.	%	No.	%
Total	**24,604**	**36%**	**30,827**	**45%**	**10,964**	**16%**	**2,512**	**4%**	**68,907**	
Patient position										
Lateral	21,519	87%	28,363	92%	10,420	95%	2,464	98%	62,766	91%
Supine	3,085	13%	2,464	8%	544	5%	48	2%	6,141	9%
Incision										
Antero/antero-lateral	68	<1%	30	<1%	75	<1%	9	<1%	182	<1%
Lateral (inc. Hardinge)	10,905	44%	10,834	35%	3,306	30%	443	18%	25,488	37%
Posterior	11,884	48%	18,316	59%	7,158	65%	1,989	79%	39,347	57%
Trochanteric osteotomy	423	2%	36	<1%	11	<1%	19	<1%	489	<1%
Other	1,324	5%	1,611	5%	414	4%	52	2%	3,401	5%
Minimally invasive surgery										
Yes	565	2%	2,410	8%	193	2%	44	2%	3,212	5%
No	24,038	98%	28,392	92%	10,727	98%	2,468	98%	65,625	95%
Not selected	1	<1%	25	<1%	44	<1%	0	0%	70	<1%
Image-guided surgery										
Yes	28	<1%	107	<1%	7	<1%	47	2%	189	<1%
No	24,575	100%	30,695	100%	10,913	100%	2,465	98%	68,648	100%
Not selected	1	<1%	25	<1%	44	<1%	0	0%	70	<1%
Bone graft used - femur										
Yes	143	<1%	253	<1%	38	<1%	19	<1%	453	<1%
No	24,461	99%	30,574	99%	10,926	100%	2,493	99%	68,454	99%
Bone graft used - acetabular										
Yes	791	3%	1,270	4%	745	7%	96	4%	2,902	4%
No	23,813	97%	29,557	96%	10,219	93%	2,416	96%	66,005	96%

Figure 2.7

Bone cement types for primary hip replacement procedures undertaken between 2003 and 2010.



Year	2003	2004	2005	2006	2007	2008	2009	2010
Non-antibiotic bone cement	15%	14%	12%	11%	11%	10%	8%	7%
Antibiotic loaded bone cement	85%	86%	88%	89%	89%	90%	92%	93%
Number of procedures using cement	18,888	33,203	39,223	38,945	42,307	41,314	39,443	37,251

2.2.1.3 Thromboprophylaxis

As shown in Table 2.7 the most frequently prescribed chemical method of thromboprophylaxis for hip replacement patients was LMWH, at 67%, and the most used mechanical method was TED stockings (65%). There has been a marked decrease over the past year in the use of aspirin (20% in 2009 to 12% in 2010) and LMWH (71% in 2009 to 67% in 2010). Direct thrombin inhibitor is now used in 7% of hip primary procedures and the use of what the NJR categorises as other chemicals has gone up from 7% in 2009 to 13% in 2010. This change is also seen in knee primary procedures. The number of procedures for which both chemical and mechanical methods were prescribed rose from 63% in 2007 to 87% in 2010.

Table 2.7 Thromboprophylaxis regime for primary hip replacement patients, prescribed at time of operation.

	Primary total prosthetic replacement using cement		Primary total prosthetic replacement not using cement		Primary total prosthetic replacement not classified elsewhere (e.g. hybrid)		Primary resurfacing arthroplasty of joint		Total	
	No.	%	No.	%	No.	%	No.	%	No.	%
Total	**24,604**	**36%**	**30,827**	**45%**	**10,964**	**16%**	**2,512**	**4%**	**68,907**	
Aspirin	3,329	14%	2,910	9%	1,715	16%	543	22%	8,497	12%
LMWH	17,269	70%	20,412	66%	6,974	64%	1,399	56%	46,054	67%
Pentasaccharide	321	1%	546	2%	363	3%	48	2%	1,278	2%
Warfarin	286	1%	280	<1%	137	1%	28	1%	731	1%
Direct thrombin inhibitor	1,804	7%	2,359	8%	777	7%	140	6%	5,080	7%
Other chemical (all)	2,286	9%	4,892	16%	1,071	10%	379	15%	8,628	13%
No chemical	1,678	7%	1,560	5%	924	8%	193	8%	4,355	6%
Foot pump	6,939	28%	7,883	26%	3,138	29%	596	24%	18,556	27%
Intermittent calf compression	8,231	33%	12,433	40%	3,850	35%	1,052	42%	25,566	37%
TED stockings	15,272	62%	20,991	68%	6,726	61%	1,672	67%	44,661	65%
Other mechanical	1,072	4%	581	2%	515	5%	80	3%	2,248	3%
No mechanical	1,970	8%	1,817	6%	779	7%	236	9%	4,802	7%
Both mechanical and chemical	20,944	85%	27,472	89%	9,249	84%	2,099	84%	59,764	87%
Neither mechanical nor chemical	21	<1%	28	<1%	19	<1%	16	<1%	84	<1%

2.2.1.4 Untoward intra-operative events

Untoward intra-operative events were reported in just under 1% of procedures (Table 2.8). Of the 837 untoward events reported, a decrease of 67 events compared with 2009, 30% were attributed to calcar crack. As would be expected, this occurred more often in cementless than in cemented hips. Furthermore, 16% were trochanteric fractures. More than one event could be recorded for a single procedure.

Table 2.8 Reported untoward intra-operative events for primary hip replacement patients in 2010, according to procedure type.

	Primary total prosthetic replacement using cement	Primary total prosthetic replacement not using cement	Primary total prosthetic replacement not classified elsewhere (e.g. hybrid)	Primary resurfacing arthroplasty of joint	Total
	No.	No.	No.	No.	No.
Total	**24,604**	**30,827**	**10,964**	**2,512**	**68,907**
Not specified	24,372	30,350	10,841	2,507	68,070
Event specified	**232**	**477**	**123**	**5**	**837**
Calcar crack	34	190	31	0	255
Pelvic penetration	38	45	17	1	101
Shaft fracture	13	15	4	0	32
Shaft penetration	2	12	1	0	15
Trochanteric fracture	52	51	32	0	135
Other	93	169	40	4	306

2.2.1.5 Hip primary components

This section outlines in more detail the trends in brand usage for hips. For a full listing of brands used in 2010, please visit the NJR website at www.njrcentre.org.uk. This section includes an analysis of usage according to National Institute for Health and Clinical Excellence (NICE) guidelines, as interpreted by ODEP.

2.2.1.5.1 Compliance with ODEP and NICE guidelines

In 2010, 123 brands of acetabular cups, 13 brands of resurfacing cups and 146 brands of femoral stems were used in primary and revision procedures and recorded on the NJR. There was a small decrease in acetabular cups and stems compared with 2009.

The 2nd NJR Annual Report in 2004[15] gave a full description of the NICE guidance on the selection of prostheses for primary THRs and metal-on-metal hip resurfacing arthroplasty. It also described the establishment of the Orthopaedic Data Evaluation Panel (ODEP). Its remit is to provide an independent assessment of clinical evidence, submitted by suppliers, on the compliance of their implants for THR and hip resurfacing against NICE benchmarks for safety and effectiveness. ODEP produced detailed criteria for this assessment and in 2010 there was an ongoing review of this guidance by all stakeholders.

The ODEP committee have reviewed suppliers' clinical data submissions and ODEP ratings have been given to 54 brands of femoral stems (38% of those available) and 48 brands of acetabular cups (41% of those available) used in primary procedures. However, there are 49 brands of acetabular cup (42%) and 67 brands of femoral stem (47%) currently being used in England and Wales for which no data have yet been submitted to ODEP. For information, the analysis in this report is based on the ODEP ratings as at March 2011. The latest listings for brands currently being used in England and Wales can be seen on the ODEP website:

http://www.supplychain.nhs.uk/odep/

[15] See pages 86 to 92 of the 2nd NJR Annual Report, available on the NJR website www.njrcentre.org.uk

Analysis of the summary data for primary procedures shows that the usage of products meeting the full 10 year (10A) benchmark, as recommended by NICE, is as follows:

- cemented stems 84% (using 15 brands out of 70 recorded on the NJR)
- cementless stems 74% (12 brands out of 72)
- cemented cups 42% (10 brands out of 42)
- cementless cups 5% (7 brands out of 73)
- resurfacing cups 51% (1 brand out of 10).

These percentages are based on the current ODEP ratings from clinical outcomes data already submitted to the ODEP committee. Manufacturers are expected to submit additional data to progress through the ratings and this will result in these percentages changing in the future.

Comparison with the 2009 figures shows that usage of cemented stems fully compliant with NICE guidelines has not changed significantly (83% in 2009 to 84% in 2010). However, the usage of fully compliant ODEP cementless stems has changed significantly from 62% in 2009 to 74% in 2010. Of some concern is the fact that only 5% of cementless cups currently implanted have a good ten year clinical history. This reflects the regularity with which manufacturers seem to launch new brands of acetabular cups aimed at improving clinical outcomes.

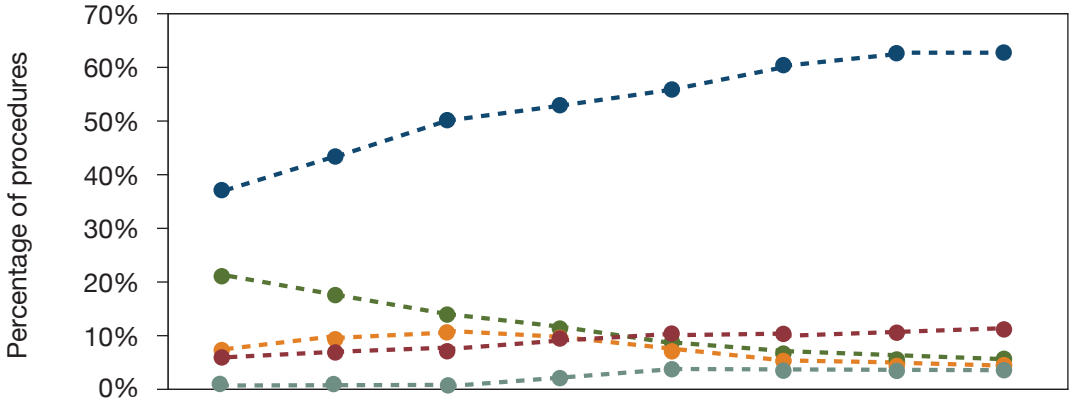
2.2.1.5.2 Hip brand usage in primary procedures

Figures 2.8 to 2.12 show historical trends in usage of the most popular brands of cemented stems, cemented cups, cementless stems, cementless cups and hip resurfacing cups.

Figure 2.8 shows that the market is dominated by polished collarless tapered stems, with the Exeter V40 having a market share of more than 63% and the CPT stem consolidating its position in second place. There has been a corresponding decrease in the usage of Charnley-type low friction arthroplasty implants; this segment in total now represents only approximately 8% of the overall market for cemented primary stems.

Figure 2.8

Top five cemented hip stem brands, usage trends 2003 to 2010.



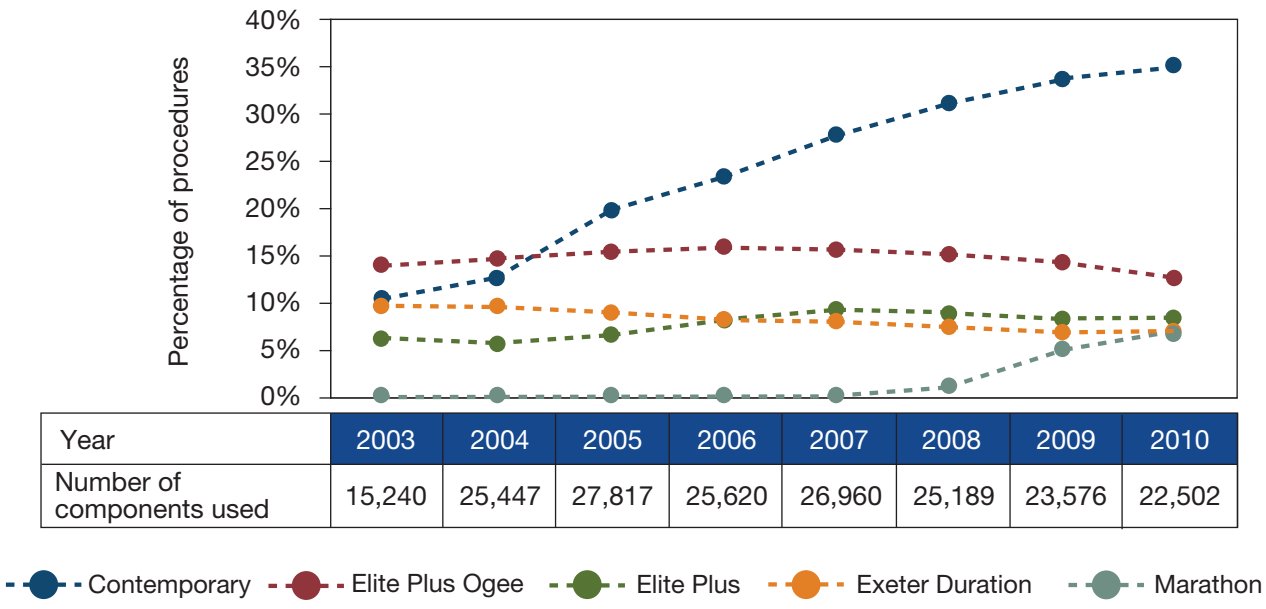
Year	2003	2004	2005	2006	2007	2008	2009	2010
Number of components used	19,095	32,298	35,960	34,291	35,909	34,043	32,900	32,237

Exeter V40 CPT Charnley C-Stem C-Stem AMT

The trend for cemented cups (Figure 2.9) continues to show that sales of different brands are in line with the popularity of the stem manufacturer. Therefore, the market share of the Contemporary cup from Stryker has grown, as sales of Exeter stems have increased during the last few years. The Marathon is now the fourth largest cemented cup after 2 years of being on the market.

Figure 2.9

Top five cemented hip cup brands, usage trends 2003 to 2010.

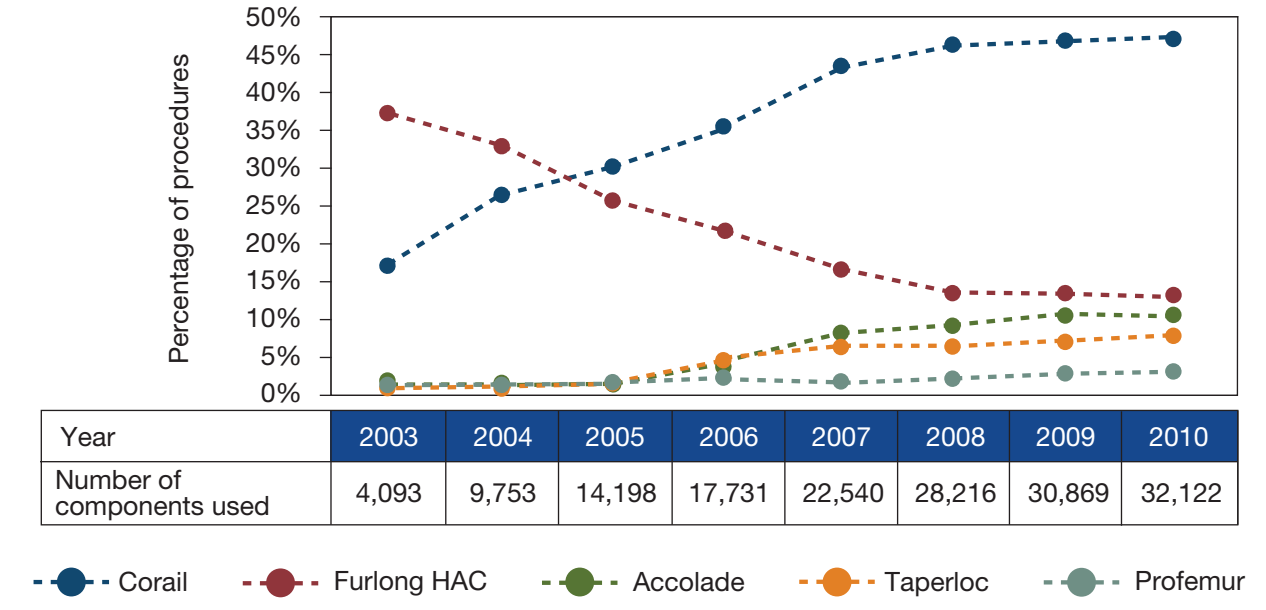


Year	2003	2004	2005	2006	2007	2008	2009	2010
Number of components used	15,240	25,447	27,817	25,620	26,960	25,189	23,576	22,502

The relative sales of cementless stem brands (Figure 2.10) are very similar to the previous year, with pressfit HA coated stems continuing to dominate the market.

Figure 2.10

Top five cementless hip stem brands, usage trends 2003 to 2010.

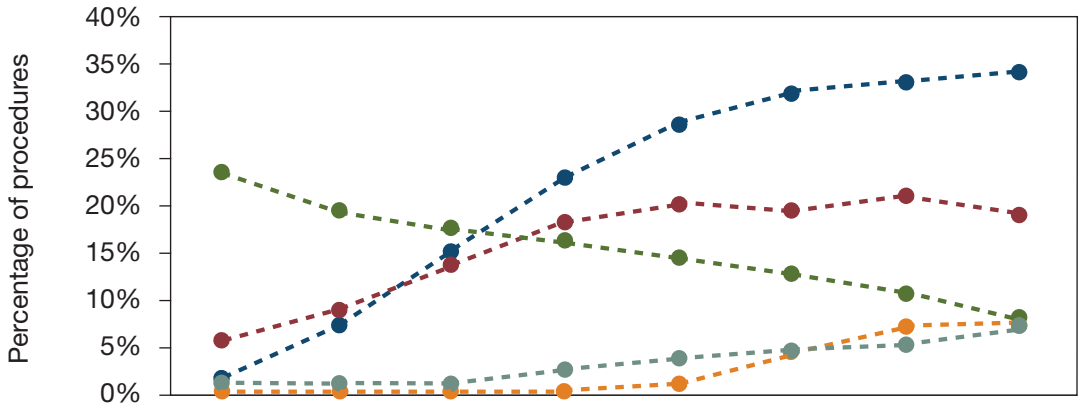


Year	2003	2004	2005	2006	2007	2008	2009	2010
Number of components used	4,093	9,753	14,198	17,731	22,540	28,216	30,869	32,122

The cementless stem market share has again been reflected in the sales of the corresponding cementless cups from the same manufacturers, which means that the Pinnacle cup from DePuy has further consolidated its position as the market leader (Figure 2.11). Another product enjoying high sales in this segment is the Trident cup from Stryker, partly due to its usage with the Exeter stem in hybrid procedures. It is especially interesting to note the relatively short clinical history of the two leading brands of cementless cups.

Figure 2.11

Top five cementless hip cup brands, usage trends 2003 to 2010.

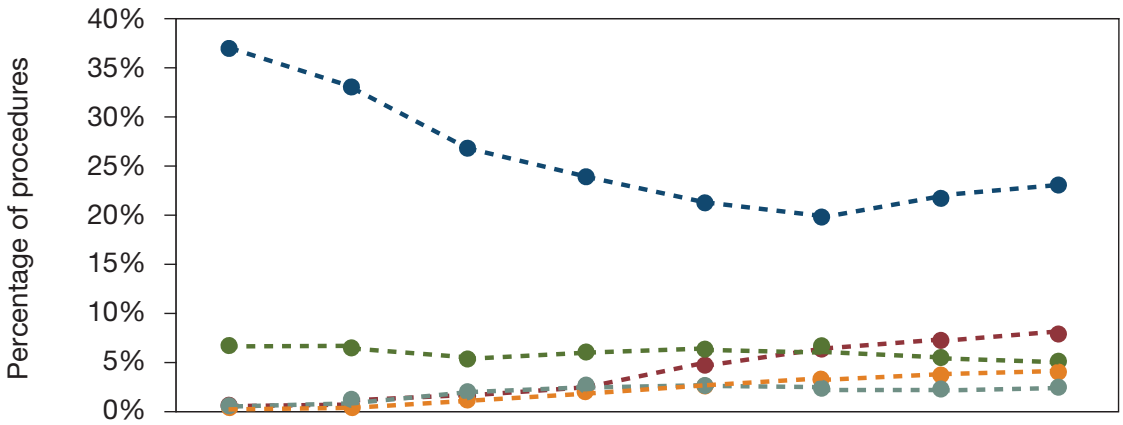


Year	2003	2004	2005	2006	2007	2008	2009	2010
Number of components used	7,859	16,362	21,133	24,017	28,420	33,874	38,919	42,260

Figure 2.12 shows the sales evolution of brands of hip resurfacing prostheses in the English and Welsh markets. It is evident that the previous trend towards a decline in the usage of the original brands has been reversed. The market share of the BHR and Adept brands, which are showing the best survivorship figures at five years, increased significantly during the course of 2010, at the expense of the ASR resurfacing prosthesis from DePuy which has now been withdrawn from the market due to poor outcome results.

Figure 2.12

Top five resurfacing head brands, usage trends 2003 to 2010.



Year	2003	2004	2005	2006	2007	2008	2009	2010
Number of components used	2,637	4,981	6,198	6,484	6,662	5,750	4,327	2,577

BHR Adept Cormet 2000 Recap Conserve

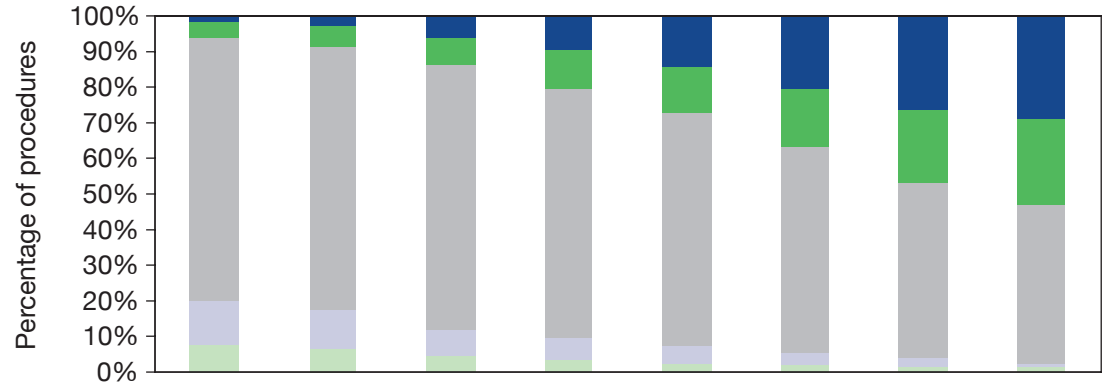
2.2.1.5.3 Trends in head size usage

Figure 2.13 shows the relative usage of different femoral head sizes each year since the inception of the NJR. It is immediately clear that there has been a gradual increase in the use of larger head sizes of 36mm diameter and above. This reflects an increase in LHMoM and ceramic-on-ceramic articulations used by surgeons in an attempt to reduce the incidence of dislocation, to reduce the number of revisions for recurrent dislocation and to reduce component wear.

This is perhaps the most profound change in clinical practice since the inception of the NJR and a detailed analysis of the practice will be undertaken by NJR research staff in the coming months.

Figure 2.13

Femoral head size trends, 2003 to 2010.



Year	2003	2004	2005	2006	2007	2008	2009	2010
36+mm	1%	3%	5%	10%	14%	20%	26%	28%
32mm	5%	6%	8%	11%	13%	16%	21%	24%
28mm	74%	74%	74%	70%	66%	58%	49%	44%
26mm	12%	11%	8%	6%	5%	4%	3%	2%
22mm	8%	6%	5%	4%	2%	2%	2%	1%
Number of components used	18,687	35,606	43,396	45,295	51,805	56,446	60,077	62,728

2.2.2 Hip revision procedures, 2010

A total of 7,852 hip revision procedures were reported in 2010, an increase of 649 compared with 2009. Table 2.9 shows that of these, 6,717 (86%) were single stage revision procedures, 486 (6%) were stage one of a two stage revision, 570 (7%) procedures were stage two of a two stage revision and 60 (<1%) were excision arthroplasty procedures. The 19 hip re-operations submitted are excluded from any counts in this section. Previous years have shown a relative increase in stage two of two stage revisions compared with single stage revisions but in 2010 this changed with a higher percentage of single stage revisions up from 83% in 2009 to 86% last year. It is not immediately apparent why this should be the case as infection as an indication for revision is unchanged at about 8% of the total. Adverse soft tissue reaction was added to the list of reasons for revision in July 2009 and was reported in 5% of all revisions.

Table 2.9 Patient characteristics for hip revision procedures in 2010, according to procedure type.

	Hip single stage revision		Hip stage one of two stage revision		Hip stage two of two stage revision		Hip excision arthroplasty		Total	
	No.	%	No.	%	No.	%	No.	%	No.	%
Total	**6,717**	**86%**	**486**	**6%**	**570**	**7%**	**60**	**<1%**	**7,833**	
Number with patient data	**6,326**	**94%**	**456**	**94%**	**540**	**95%**	**55**	**92%**	**7,377**	**94%**
Average age	70.6		69.08		67.7		70.04		69.83	
SD	12.1		10.9		12.3		14.6		12.61	
Interquartile range	63.2-79.2		62.7-76.9		61.9-76.5		63.6-80.0		63.1-78.9	
Gender										
Female	3,788	60%	207	45%	253	47%	33	60%	4,281	58%
Male	2,538	40%	249	55%	287	53%	22	40%	3,096	42%
Patient physical status										
P1 - fit and healthy	695	10%	30	6%	42	7%	1	2%	768	10%
P2 - mild disease not Incapacitating	4,241	63%	296	61%	355	62%	29	48%	4,921	63%
P3 - incapacitating systemic disease	1,682	25%	153	31%	170	30%	26	43%	2,031	26%
P4 - life threatening disease	99	1%	6	1%	3	<1%	4	7%	112	1%
P5 - expected to die within 24 hours with or without an operation	0	0%	1	<1%	0	0%	0	0%	1	<1%
Indications for surgery										
Aseptic loosening	3,387	50%	70	14%	62	11%	12	20%	3,531	45%
Lysis	1,019	15%	48	10%	32	6%	4	7%	1,103	14%
Pain	1,828	27%	102	21%	76	13%	11	18%	2,017	26%
Dislocation/subluxation	1,123	17%	15	3%	18	3%	13	22%	1,169	15%
Periprosthetic fracture	685	10%	21	4%	16	3%	9	15%	731	9%
Infection	213	3%	384	79%	423	74%	35	58%	1,055	13%
Malalignment	417	6%	9	2%	4	1%	3	5%	433	6%
Fractured acetabulum	100	1%	0	0%	2	<1%	0	0%	102	1%
Fractured stem	116	2%	2	<1%	5	1%	1	2%	124	2%
Fractured femoral head	25	<1%	0	0%	1	<1%	0	0%	26	<1%
Incorrect sizing head/socket	47	<1%	1	<1%	1	<1%	0	0%	49	<1%
Wear of acetabular component	935	14%	15	3%	12	2%	5	8%	967	12%
Dissociation of liner	93	1%	12	2%	3	<1%	3	5%	111	1%
Adverse soft tissue reaction	381	6%	6	1%	10	2%	1	2%	398	5%
Other	528	8%	20	4%	45	8%	4	7%	597	8%
Side										
Bilateral	0	0%	0	0%	0	0%	0	0%	0	0%
Left, unilateral	3,059	46%	233	48%	273	48%	25	42%	3,590	46%
Right, unilateral	3,658	54%	253	52%	297	52%	35	58%	4,243	54%

2.2.2.1 Patient characteristics

Table 2.9 summarises patient characteristics for the 7,833 hip revision procedures undertaken in 2010. Compared with 2009, the patient demographics have largely remained unchanged. However, the percentage of patients who were graded as being fit and healthy prior to surgery has decreased from 26% in 2003 to 10% in 2010.

Adverse soft tissue reaction was noted for 5% of all revision procedures (Table 2.9). Aseptic loosening and pain have decreased as reasons for revision compared with 2009 for all revision procedure types (Table 2.10).

Table 2.10 Indication for surgery for hip revision procedures, 2006 to 2010.

	2006		2007		2008		2009		2010		Total	
	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%
Indications for single stage revision	**5,441**		**6,100**		**6,340**		**6,474**		**6,717**		**31,072**	
Aseptic loosening	3,439	63%	3,698	61%	3,758	59%	3,585	55%	3,387	50%	17,867	58%
Lysis	1,156	21%	1,103	18%	1,099	17%	978	15%	1,019	15%	5,355	17%
Pain	1,074	20%	1,231	20%	1,731	27%	1,999	31%	1,828	27%	7,863	25%
Adverse soft tissue reaction	-	-	-	-	-	-	-	-	381	6%	381	1%
Infection	104	2%	102	2%	171	3%	187	3%	213	3%	777	3%
Indications for stage one of a two stage revision	**376**		**399**		**453**		**546**		**486**		**2,260**	
Aseptic loosening	79	21%	73	18%	88	19%	83	15%	70	14%	393	17%
Lysis	57	15%	46	12%	58	13%	49	9%	48	10%	258	11%
Pain	64	17%	57	14%	87	19%	102	19%	102	21%	412	18%
Infection	302	80%	303	76%	363	80%	433	79%	384	79%	1,785	79%

2.2.2.2 Components removed and components used

Both the acetabular and femoral components were removed in half of all revision procedures (Table 2.11). However, comparison of the different types of revision procedures indicates that both components were more likely to be removed during a two stage revision process than during a single stage revision. This is expected since the majority of two stage revisions are carried out for reasons of infection, where all components are routinely removed. The components used during revision procedures are shown in Table 2.12.

Table 2.11 Components removed during hip revision procedures in 2010.

	Hip single stage revision		Hip stage one of a two stage revision		Hip excision arthroplasty		Total	
	No.	%	No.	%	No.	%	No.	%
Total	**6,717**		**486**		**60**		**7,263**	
Both cup and stem	3,121	46%	389	80%	44	73%	3,554	49%
Acetabular cup only	1,861	28%	23	5%	1	2%	1,885	26%
Femoral stem only	1,145	17%	32	7%	8	13%	1,185	16%
Neither cup nor stem	590	9%	42	9%	7	12%	639	9%

Table 2.12 Components used during single stage hip revision procedures in 2010.

	Hip single stage revision	
	No. of procedures	%
Total	**6,717**	
Femoral prosthesis		
Cemented	3,205	48%
Cementless	1,085	16%
Not revised	2,427	36%
Acetabular prosthesis		
Cemented	1,242	18%
Cementless	4,123	61%
Not revised	1,352	20%

Part 2

2.3 Knee replacement procedures, 2010

The total number of knee replacement procedures entered into the NJR during 2010 was 81,979, an increase of 5.7% compared with 2009. Of the 81,979 procedures submitted, 76,870 were primary procedures and 5,109 were revision procedures. Table 2.13 summarises the patient characteristics and details of knee replacement procedures according to type of provider.

As a percentage of their activity, independent hospitals performed more unicondylar knee replacement procedures (Figure 2.14) than any other type of provider and ISTC's performed more cemented bicondylar knee procedures than any other provider. The revision procedures undertaken at NHS hospitals comprised 83% of all revision procedures performed.

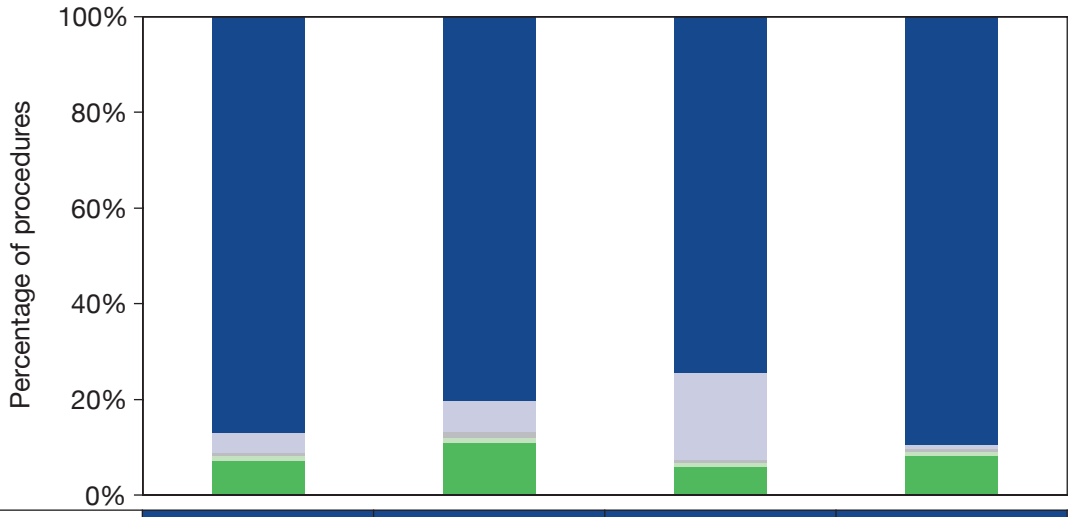
Table 2.13 Patient characteristics and procedure details, according to type of provider for knee procedures in 2010.

	NHS hospitals		Independent hospitals		NHS treatment centres		ISTCs		Total	
	No.	%	No.	%	No.	%	No.	%	No.	%
Total	**54,776**	**67%**	**20,015**	**24%**	**2,556**	**3%**	**4,632**	**6%**	**81,979**	
Patient physical status										
P1 - fit and healthy	5,174	9%	3,657	18%	376	15%	381	8%	9,588	12%
P2 - mild disease not incapacitating	39,017	71%	14,753	74%	1,826	71%	3,894	84%	59,490	73%
P3 - incapacitating systemic disease	10,321	19%	1,585	8%	343	13%	357	8%	12,606	15%
P4 - life threatening disease	258	<1%	16	<1%	11	<1%	0	0%	285	<1%
P5 - expected to die within 24 hours with or without an operation	6	<1%	4	<1%	0	0%	0	0%	10	<1%
Procedure type										
Primary procedures	**50,522**	**66%**	**19,383**	**25%**	**2,456**	**3%**	**4,509**	**6%**	**76,870**	**94%**
Total prosthetic replacement using cement	43,763	87%	15,582	80%	1,820	74%	4,039	90%	65,204	85%
Total prosthetic replacement not using cement	2,108	4%	1,199	6%	482	20%	40	<1%	3,829	5%
Hybrid total knee	394	1%	199	1%	8	<1%	15	<1%	616	1%
Patello-femoral replacement	747	1%	283	1%	11	<1%	61	1%	1,102	1%
Unicondylar knee replacement	3,510	7%	2,120	11%	135	5%	354	8%	6,119	8%
Revision procedures	**4,254**	**83%**	**632**	**12%**	**100**	**2%**	**123**	**2%**	**5,109**	**6%**
Knee single stage revision	3,168	74%	540	85%	72	72%	99	80%	3,879	76%
Knee stage one of two stage revision	493	12%	41	6%	15	15%	13	11%	562	11%
Knee stage two of two stage revision	555	13%	49	8%	13	13%	11	9%	628	12%
Knee conversion to arthrodesis	7	<1%	2	<1%	0	0%	0	0%	9	<1%
Amputation	4	<1%	0	0%	0	0%	0	0%	4	<1%
Knee re-operation other than revision	27	1%	0	0%	0	0%	0	0%	27	1%
Bilateral or unilateral[16]										
Bilateral	456	<1%	374	2%	82	3%	76	2%	988	1%
Unilateral	54,320	99%	19,641	98%	2,474	97%	4,556	98%	80,991	99%
Funding										
Independent	436	<1%	9,156	46%	4	<1%	18	<1%	9,614	12%
NHS	54,340	99%	10,859	54%	2,552	100%	4,614	100%	72,365	88%

[16] Bilaterals will only be counted as a bilateral if they are entered under the same single operation during data entry. If the two procedures are recorded under two different operations they will be counted as two unilateral procedures. Therefore, the count of bilaterals is likely to be an underestimate.

Figure 2.14

Primary knee procedures by type of provider, 2010.



Type of provider	NHS hospitals	Independent hospitals	NHS treatment centres	ISTCs
Cemented	87%	80%	74%	90%
Cementless	4%	6%	20%	<1%
Hybrid	<1%	1%	<1%	<1%
Patello-femoral	1%	1%	<1%	1%
Unicondylar	7%	11%	5%	8%
Number of procedures	50,522	19,383	2,456	4,509

2.3.1 Primary knee replacement procedures, 2010

Of the 76,870 primary knee replacements undertaken in 2010, 69,649 (91%) were total condylar procedures, 6,119 (8%) were unicondylar knee replacements and 1,102 (1%) were patello-femoral replacements (Table 2.14). Compared with previous years, these proportions have largely remained the same (Figure 2.15(a)) though there has been a slight increase in cemented TKR at the expense of cementless TKR over the past 2 years. Figure 2.15(a) shows an apparent decrease in the volume of knee procedures between 2009 and 2010. However, not all procedures performed in 2010 were entered into the database before the 28th February 2011 deadline and will be entered after this date. Figure 2.15(b) is based on total condylar knee replacements where the meniscal implant has been specified.

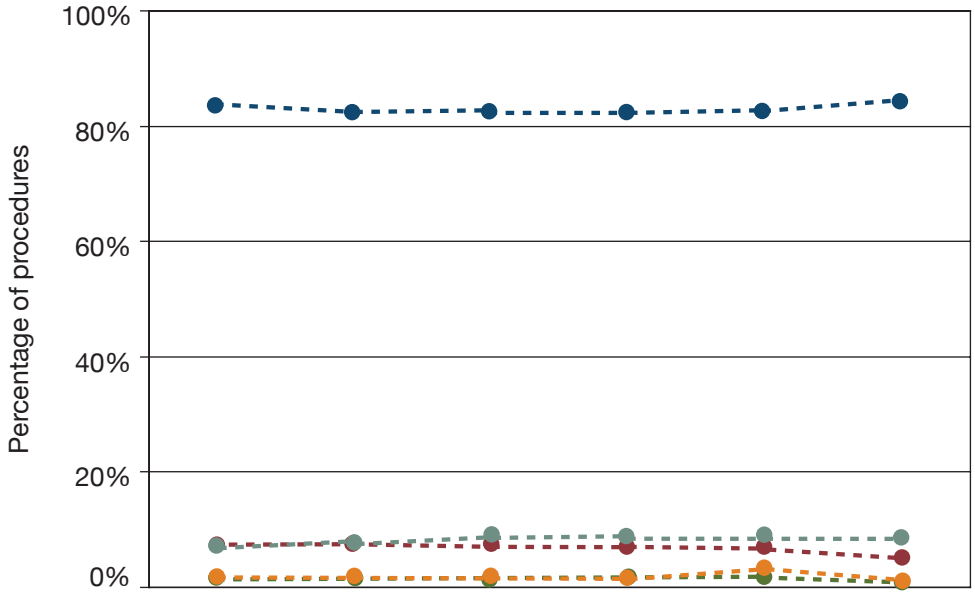
The single largest indication recorded for surgery was osteoarthritis, recorded in 97% of all primary procedures (Table 2.14).

Table 2.14 Patient characteristics for primary knee replacement procedures in 2010, according to procedure type.

	Primary total prosthetic replacement using cement		Primary total prosthetic replacement not using cement		Primary total prosthetic replacement not classified elsewhere (e.g. hybrid)		Patello-femoral replacement		Unicondylar knee replacement		Total	
	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%
Total knee primaries	**65,204**	**85%**	**3,829**	**5%**	**616**	**<1%**	**1,102**	**1%**	**6,119**	**8%**	**76,870**	
Total knee primaries with patient data	**62,091**	**85%**	**3,627**	**95%**	**598**	**97%**	**1,028**	**93%**	**5,702**	**93%**	**73,046**	**95%**
Average age	70.18		68.87		69.02		60.95		64.03		67.48	
SD	9.35		9.58		9.33		11.52		9.79		11.99	
Interquartile range	63.8-77.1		62.6-75.8		63.3-75.5		52.4-69.8		57.3-70.7		63.1-76.6	
Gender												
Female	35,755	58%	1,913	53%	329	55%	745	72%	2,675	47%	41,417	57%
Male	26,335	42%	1,714	47%	269	45%	283	28%	3,027	53%	31,628	43%
Patient physical status												
P1 - fit and healthy	6,834	10%	551	14%	70	11%	277	25%	1,421	23%	9,153	12%
P2 - mild disease not incapacitating	47,891	73%	2,800	73%	467	76%	734	67%	4,221	69%	56,113	73%
P3 - incapacitating systemic disease	10,246	16%	471	12%	78	13%	91	8%	474	8%	11,360	15%
P4 - life threatening disease	224	<1%	6	<1%	1	<1%	0	0%	3	<1%	234	<1%
P5 - expected to die within 24 hours with or without an operation	9	<1%	1	<1%	0	0%	0	0%	0	0%	10	<1%
BMI												
Number with BMI data	40,646	62%	2,058	54%	330	54%	651	59%	4,070	67%	47,755	62%
Average	30.74		30.55		31.24		29.66		30.01		30.66	
SD	5.52		5.38		5.6		5.27		5.07		5.48	
Indications for surgery												
Osteoarthritis	63,314	97%	3,754	98%	600	97%	1,061	96%	6,048	99%	74,777	97%
Avascular necrosis	226	<1%	11	<1%	3	<1%	0	0%	34	<1%	274	<1%
Inflammatory arthropathy	396	<1%	13	<1%	0	0%	1	<1%	4	<1%	414	<1%
Previous infection	42	<1%	0	0%	1	<1%	0	0%	0	0%	43	<1%
Rheumatoid arthritis	1,126	2%	59	2%	7	1%	8	<1%	7	<1%	1,207	2%
Previous trauma	240	<1%	17	<1%	5	<1%	3	<1%	23	<1%	288	<1%
Other	526	<1%	16	<1%	13	2%	38	3%	44	<1%	637	<1%
Side												
Bilateral	594	<1%	36	<1%	4	<1%	71	6%	269	4%	974	1%
Left, unilateral	30,613	47%	1,802	47%	276	45%	474	43%	2,932	48%	36,097	47%
Right, unilateral	33,997	52%	1,991	52%	336	55%	557	51%	2,918	48%	39,799	52%

Figure 2.15(a)

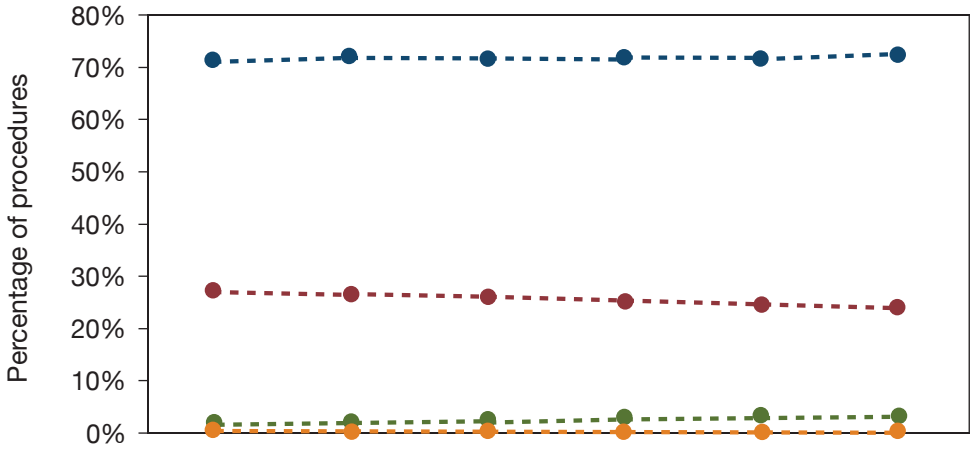
Type of primary knee replacement procedure undertaken between 2005 and 2010.



Year	2005	2006	2007	2008	2009	2010
TKR using cement	84%	83%	83%	83%	84%	85%
TKR not using cement	7%	7%	6%	6%	6%	5%
TKR hybrid	1%	1%	1%	1%	1%	<1%
Patello-femoral	1%	1%	1%	1%	2%	1%
Unicondylar	7%	8%	8%	8%	8%	8%
Number of procedures	59,388	62,240	73,297	77,208	78,021	76,870

Figure 2.15(b)

Implant constraint for bicondylar primary knee replacement procedures undertaken between 2005 and 2010.



Year	2005	2006	2007	2008	2009	2010
Cruciate-retaining	71%	72%	72%	71%	72%	73%
Posterior-stabilised	27%	26%	26%	25%	25%	24%
Constrained condylar	2%	2%	2%	3%	3%	3%
Hinged/Linked	<1%	<1%	<1%	<1%	<1%	<1%
Number of procedures	46,309	46,943	54,610	58,385	59,610	58,901

2.3.1.1 Patient characteristics

The average age of patients was 67.5 years and 57% were female. Patients undergoing a patello-femoral replacement were the youngest, at an average age of 60.9 years and 72% of these were female (Table 2.14). On average, female patients were of a similar age to male patients at the time of their primary knee replacement (68.3 years and 68.1 years respectively), see Table 2.15 and Figure 2.16. However, female patients were, on average, older than male patients for cementless, cemented and hybrid procedures but younger for patello-femoral and unicondylar procedures.

According to the ASA grade system, 12% of patients undergoing a primary knee replacement procedure were graded as fit and healthy (Table 2.14). Figure 2.17 shows the trend in ASA grade over the past eight years. Since 2003, there has been a 61% reduction in the number of patients assessed as being fit and healthy at the time of operation. Figure 2.18(a) shows the increase in BMI[17] over the past eight years for patients having primary knee procedures. This figure has increased from 29.2 to 30.6 over the past six years. Figure 2.18(b) shows that there has been a steady increase in the number of patients within the BMI range 30 to 39 and a decrease within the ranges 25 to 29 and 18.5 to 24. The average knee replacement patient in 2010, by BMI measurement, was clinically obese. It is interesting to note that the profile of Figure 2.18(b) is significantly different to the equivalent chart for hips, Figure 2.6(b).

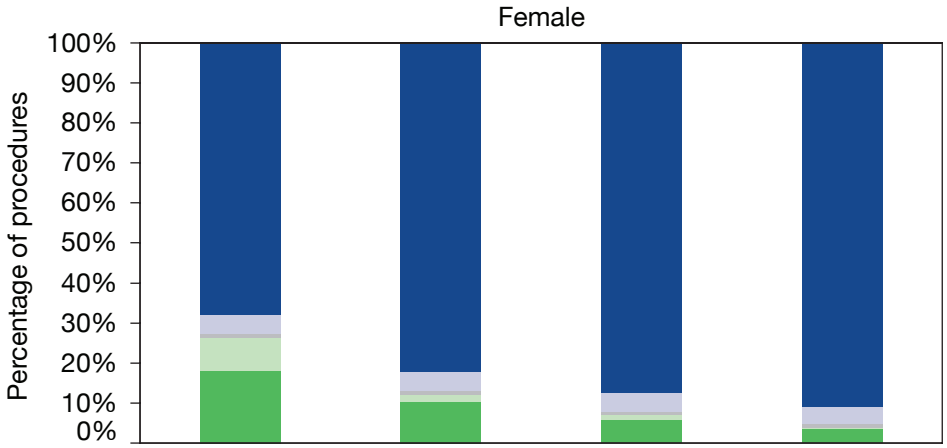
[17] BMI: 20-24 normal, 25-29 overweight, 30-39 obese, 40+ morbidly obese.

Table 2.15 Age and gender for primary knee replacement patients in 2010.

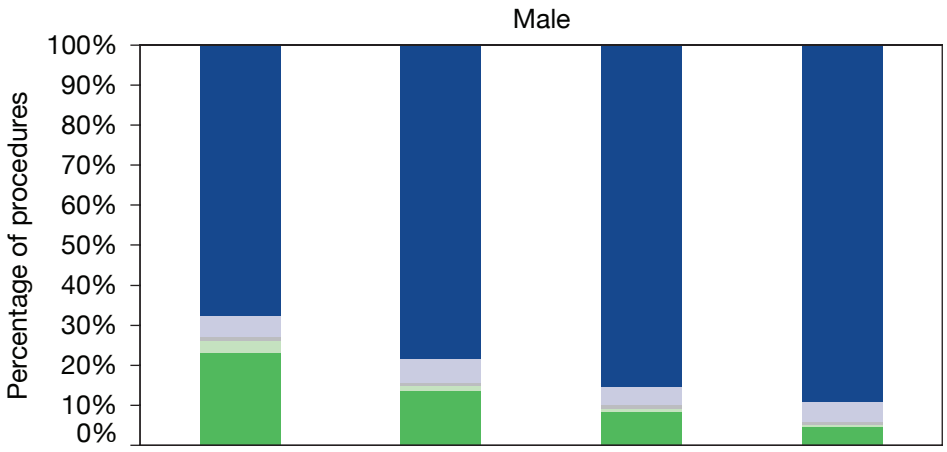
	Primary total prosthetic replacement using cement		Primary total prosthetic replacement not using cement		Primary total prosthetic replacement not classified elsewhere (e.g. hybrid)		Patello-femoral replacement		Unicondylar knee replacement		Total	
	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%
Average age by gender												
Female	**35,755**	**86%**	**1,913**	**5%**	**329**	**1%**	**745**	**2%**	**2,675**	**6%**	**41,417**	**57%**
Average	70.44		69.29		69.28		60.51		63.82		68.26	
SD	9.51		9.66		9.88		11.51		10.05		11.63	
Interquartile range	63.9-77.5		62.9-76.5		63.0-76.9		51.9-69.1		56.6-70.7		63.2-77.1	
Male	**26,335**	**83%**	**1,714**	**5%**	**269**	**<1%**	**283**	**<1%**	**3,027**	**10%**	**31,628**	**43%**
Average	69.82		68.4		68.7		62.14		64.22		68.15	
SD	9.12		9.47		8.61		11.5		9.56		10.88	
Interquartile range	63.7-76.4		62.4-75.2		63.4 -74.0		54.0-71.1		57.9-70.7		63.0-75.9	
Age group by gender												
Female												
<45 years	250	<1%	11	<1%	3	<1%	61	8%	67	3%	392	<1%
45 - 54 years	1,867	5%	147	8%	21	6%	197	26%	486	18%	2,718	7%
55 - 64 years	8,088	23%	466	24%	80	24%	223	30%	940	35%	9,797	24%
65 - 74 years	13,347	37%	722	38%	125	38%	168	23%	809	30%	15,171	37%
75 - 84 years	10,486	29%	488	26%	86	26%	91	12%	316	12%	11,467	28%
>85 years	1,717	5%	79	4%	14	4%	5	<1%	57	2%	1,872	5%
Male												
<45 years	181	<1%	16	<1%	2	<1%	20	7%	60	2%	279	<1%
45 - 54 years	1,356	5%	121	7%	14	5%	59	21%	459	15%	2,009	6%
55 - 64 years	6,446	24%	481	28%	70	26%	87	31%	1,111	37%	8,195	26%
65 - 74 years	10,407	40%	653	38%	116	43%	67	24%	991	33%	12,234	39%
75 - 84 years	6,989	27%	386	23%	63	23%	48	17%	363	12%	7,849	25%
>85 years	956	4%	57	3%	4	1%	2	<1%	43	1%	1,062	3%

Figure 2.16

Age and gender for primary knee replacement patients in 2010.



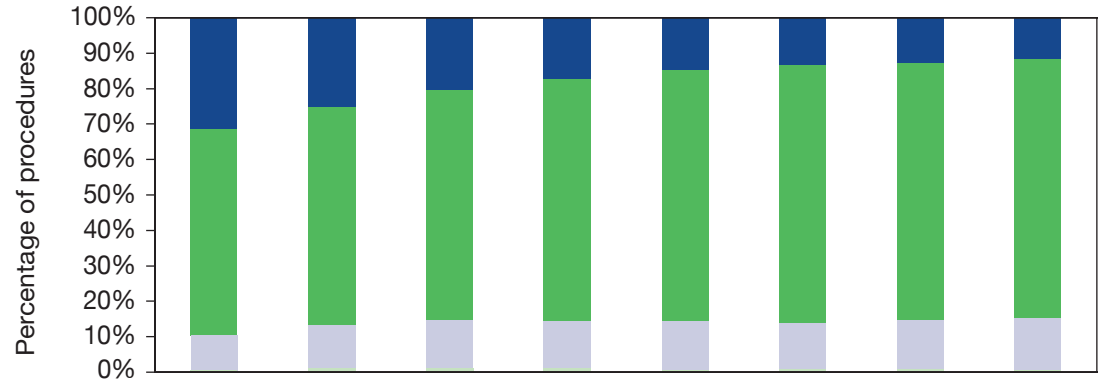
Age group	<55	55-64	65-74	75+
TKR using cement	68%	83%	88%	91%
TKR not using cement	5%	5%	5%	4%
TKR hybrid	1%	1%	1%	1%
Patello-femoral	8%	2%	1%	1%
Unicondylar knee	18%	10%	5%	3%
Number of patients	3,110	9,797	15,171	13,339



Age group	<55	55-64	65-74	75+
TKR using cement	67%	79%	85%	89%
TKR not using cement	6%	6%	5%	5%
TKR hybrid	1%	1%	1%	1%
Patello-femoral	3%	1%	1%	1%
Unicondylar knee	23%	14%	8%	5%
Number of patients	2,288	8,195	12,234	8,911

Figure 2.17

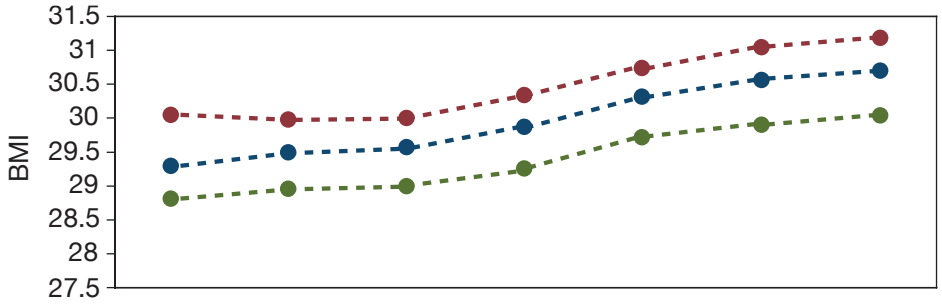
ASA grades for primary knee replacement patients between 2003 and 2010.



Year	2003	2004	2005	2006	2007	2008	2009	2010
P1	31%	25%	20%	17%	15%	13%	13%	12%
P2	58%	62%	65%	68%	71%	73%	72%	73%
P3	10%	13%	14%	14%	14%	13%	15%	15%
P4 and P5	<1%	1%	1%	1%	<1%	<1%	<1%	<1%
Number of procedures	24,662	46,577	60,704	62,240	73,297	77,208	78,021	76,870

Figure 2.18(a)

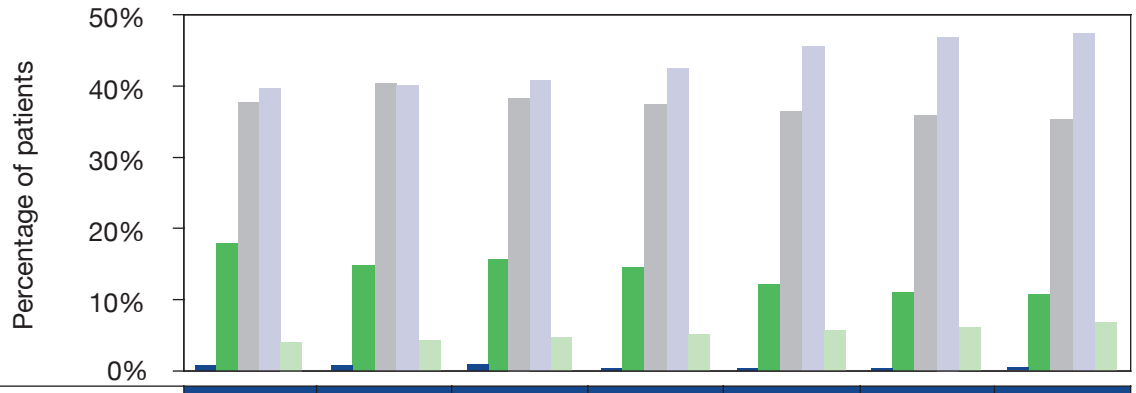
BMI for primary knee replacement patients between 2004 and 2010.



Year	2004	2005	2006	2007	2008	2009	2010
All	29.25	29.45	29.53	29.84	30.27	30.53	30.66
Female	30.02	29.96	29.97	30.31	30.72	31.03	31.15
Male	28.78	28.92	28.97	29.24	29.69	29.88	30.03
Number of procedures with BMI data	5,489	9,101	10,571	16,060	38,072	44,755	47,755
Number of procedures with BMI data (females)	2,193	4,113	5,376	8,742	21,076	24,701	26,440
Number of procedures with BMI data (males)	1,647	3,278	3,942	6,561	16,106	19,124	20,531
Number of procedures with BMI data (unknown gender)	1,649	1,710	1,253	757	890	930	784

Figure 2.18(b)

BMI groups for primary knee replacement patients between 2004 and 2010.



Year	2004	2005	2006	2007	2008	2009	2010
BMI <18.5	1%	1%	1%	<1%	<1%	<1%	<1%
BMI 18.5 - 24	18%	15%	16%	15%	12%	11%	11%
BMI 25 - 29	38%	40%	38%	37%	36%	36%	35%
BMI 30 - 39	40%	40%	41%	43%	46%	47%	47%
BMI 40+	4%	4%	5%	5%	6%	6%	7%
Number of procedures	5,489	9,101	10,571	16,060	38,072	44,755	47,755

2.3.1.2 Surgical techniques

The most common surgical approach was the medial parapatellar, used in 93% of procedures (Table 2.16). Minimally invasive surgery (MIS) was used in 51% of unicondylar knee replacement procedures, reflecting the popularity of the Oxford Partial Knee, but was used in only 3% of all other types of knee replacement intervention. For cemented knee procedures, 35% had the patella replaced at the time of the primary procedure whereas 9% of patellas were replaced during primary cementless knee procedures.

Compared with previous years, the surgical techniques used in primary knee replacements have largely remained unchanged. However, there has been an increase in the use of MIS in unicondylar knee replacements, from 37% in 2004 to 51% in 2010.

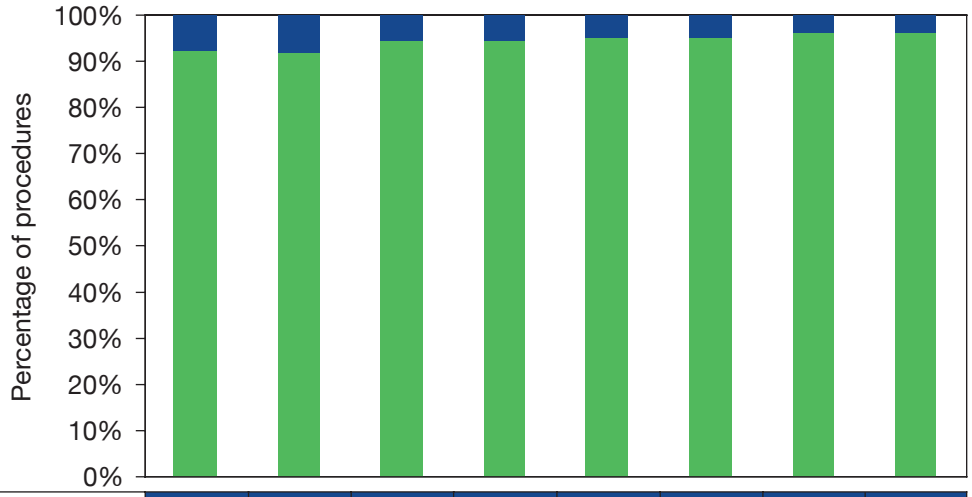
The use of bone cement in primary knee procedures is summarised in Figure 2.19.

Table 2.16 Characteristics of surgical practice for primary knee replacement procedures in 2010, according to procedure type.

	Primary total prosthetic replacement using cement		Primary total prosthetic replacement not using cement		Primary total prosthetic replacement not classified elsewhere (e.g. hybrid)		Patello-femoral replacement		Unicondylar knee replacement		Total	
	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%
Total	**65,204**	**85%**	**3,829**	**5%**	**616**	**<1%**	**1,102**	**1%**	**6,119**	**8%**	**76,870**	
Surgical approach												
Lateral parapatellar	509	<1%	44	1%	4	<1%	20	2%	228	4%	805	1%
Medial parapatellar	60,880	93%	3,607	94%	555	90%	997	90%	5,346	87%	71,385	93%
Mid-Vastus	1,757	3%	59	2%	44	7%	39	4%	172	3%	2,071	3%
Sub-Vastus	813	1%	32	<1%	4	<1%	28	3%	127	2%	1,004	1%
Other	1,245	2%	87	2%	9	1%	18	2%	246	4%	1,605	2%
Patella												
Patella implanted	22,686	35%	326	9%	298	48%	939	85%	85	1%	24,334	32%
Patella not implanted	42,518	65%	3,503	91%	318	52%	163	15%	6,034	99%	52,536	68%
Minimally invasive surgery												
Yes	2,112	3%	79	2%	14	2%	148	13%	3,139	51%	5,492	7%
No	63,092	97%	3,750	98%	602	98%	951	86%	2,980	49%	71,375	93%
Not Selected	0	0%	0	0%	0	0%	3	<1%	0	0%	3	<1%
Image-guided surgery												
Yes	1,612	2%	177	5%	11	2%	3	<1%	83	1%	1,886	2%
No	63,592	98%	3,652	95%	605	98%	1,096	99%	6,036	99%	74,981	98%
Not Selected	0	0%	0	0%	0	0%	3	<1%	0	0%	3	<1%
Bone graft used - femur												
Yes	482	<1%	50	1%	2	<1%	3	<1%	15	<1%	552	<1%
No	64,722	99%	3,779	99%	614	100%	1,099	100%	6,104	100%	76,318	99%
Bone graft used - tibia												
Yes	275	<1%	29	<1%	3	<1%	2	<1%	9	<1%	318	<1%
No	64,929	100%	3,800	99%	613	100%	1,100	100%	6,110	100%	76,552	100%

Figure 2.19

Bone cement types for primary knee replacement procedures undertaken between 2003 and 2010.



Year	2003	2004	2005	2006	2007	2008	2009	2010
Non-antibiotic bone cement	8%	8%	5%	6%	5%	5%	4%	3%
Antibiotic loaded bone cement	92%	92%	95%	94%	95%	95%	96%	97%
Number of procedures using cement	18,379	36,410	49,955	52,451	64,127	69,178	71,031	71,471

2.3.1.3 Thromboprophylaxis

Table 2.17 shows that the most frequently prescribed chemical method of thromboprophylaxis for knee replacement patients was LMWH (65%), while TED stockings were the most used mechanical method (69%). Compared with previous years, there has been an increase in the prescription of a combined chemical and mechanical regime, from 49% in 2004 to 86% in 2010. There has been a marked decrease over the past year in the use of aspirin, (a decrease from 20% in 2009 to 12% in 2010) and LMWH (down from 69% in 2009 to 65% in 2010). Direct thrombin inhibitor is now used in 7% of knee primary procedures and the use of what the NJR categorises as other chemicals has gone up from 7% in 2009 to 12% in 2010. This change was also seen in hip primary procedures. Less than 1% of patients had neither mechanical nor chemical-prescribed thromboprophylaxis.

Table 2.17 Thromboprophylaxis regime for primary knee replacement patients, prescribed at time of operation.

	Primary total prosthetic replacement using cement		Primary total prosthetic replacement not using cement		Primary total prosthetic replacement not classified elsewhere (e.g. hybrid)		Patello-femoral replacement		Unicondylar knee replacement		Total	
	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%
Total	**65,204**	**85%**	**3,829**	**5%**	**616**	**<1%**	**1,102**	**1%**	**6,119**	**8%**	**76,870**	
Aspirin	7,750	12%	381	10%	25	4%	135	12%	1,023	17%	9,314	12%
LMWH	43,186	66%	2,513	66%	439	71%	659	60%	3,479	57%	50,276	65%
Pentasaccharide	1,097	2%	22	<1%	1	<1%	29	3%	178	3%	1,327	2%
Warfarin	527	<1%	62	2%	9	1%	6	<1%	43	<1%	647	<1%
Direct thrombin inhibitor	4,378	7%	275	7%	26	4%	91	8%	498	8%	5,268	7%
Other chemical (all)	7,898	12%	664	17%	115	19%	126	11%	729	12%	9,532	12%
No chemical	5,088	8%	152	4%	25	4%	107	10%	600	10%	5,972	8%
Foot pump	17,490	27%	1,125	29%	207	34%	332	30%	1,733	28%	20,887	27%
Intermittent calf compression	23,586	36%	1,409	37%	184	30%	343	31%	2,115	35%	27,637	36%
TED stockings	44,478	68%	2,927	76%	411	67%	712	65%	4,214	69%	52,742	69%
Other	1,069	2%	17	<1%	6	<1%	45	4%	114	2%	1,251	2%
No mechanical	4,587	7%	156	4%	54	9%	67	6%	319	5%	5,183	7%
Both mechanical and chemical	55,615	85%	3,524	92%	538	87%	935	85%	5,212	85%	65,824	86%
Neither mechanical nor chemical	119	<1%	3	<1%	1	<1%	7	<1%	15	<1%	145	<1%

2.3.1.4 Untoward intra-operative events

Table 2.18 shows that untoward intra-operative events were rare, reported in less than 1% of knee procedures, however there were an additional 23 incidences compared with 2009.

Table 2.18 Reported untoward intra-operative events for primary knee replacement patients in 2010, according to procedure type.

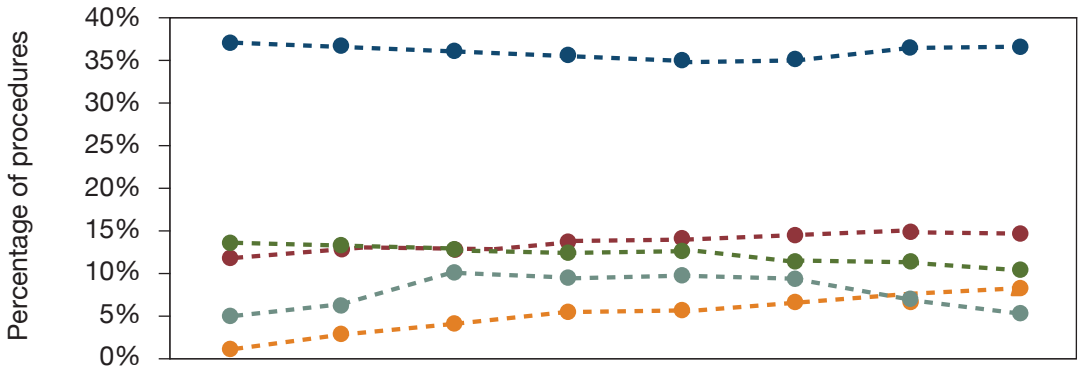
	Primary total prosthetic replacement using cement	Primary total prosthetic replacement not using cement	Primary total prosthetic replacement not classified elsewhere (e.g. hybrid)	Patello-femoral replacement	Unicondylar knee replacement	Total
	No.	No.	No.	No.	No.	No.
Total	**65,204**	**3,829**	**616**	**1,102**	**6,119**	**76,870**
Not selected	3	0	0	0	0	3
None	64,743	3,813	614	1,099	6,095	76,364
Total specified	**458**	**16**	**2**	**3**	**24**	**503**
Fracture	117	8	1	2	10	138
Patella tendon avulsion	29	3	0	1	1	34
Ligament injury	42	0	0	0	4	46
Other	270	5	1	0	9	285

2.3.1.5 Knee primary components

Figure 2.20 shows the leading brands of total condylar knees in England and Wales. The PFC Sigma knee, marketed by DePuy, continues to dominate the market. The Genesis 2 knee, marketed by Smith & Nephew, appears to be increasing in popularity.

Figure 2.20

Top five total condylar knee brands, usage trends 2003 to 2010.



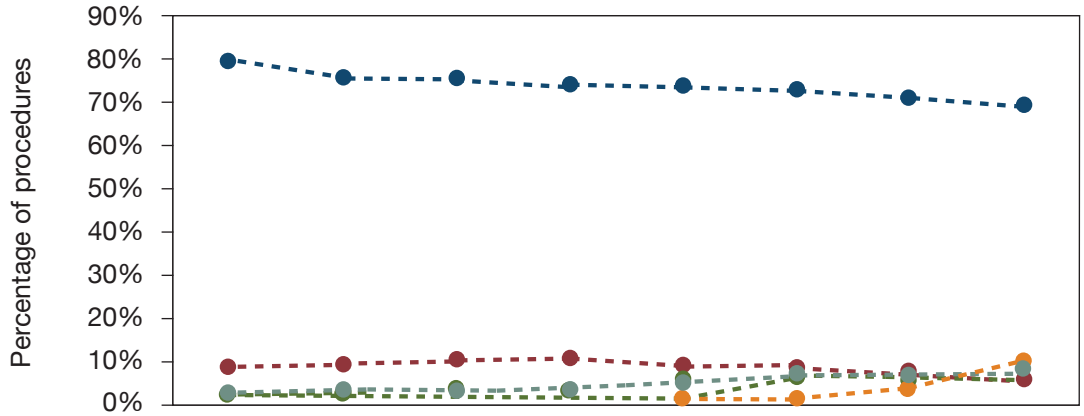
Year	2003	2004	2005	2006	2007	2008	2009	2010
Number of components used	21,810	41,145	53,706	54,839	64,499	67,888	68,606	67,620

PFC Sigma Nexgen AGC Genesis 2 Scorpio

Likewise, the market for unicondylar knees is dominated by one product, the Oxford Partial Knee (Figure 2.21). The market share of the Oxford Partial has decreased gradually since 2003 and the Sigma HP which is relatively new to the market is now the second most used brand of unicondylar knee system.

Figure 2.21

Top five unicondylar knee brands, usage trends 2003 to 2010.



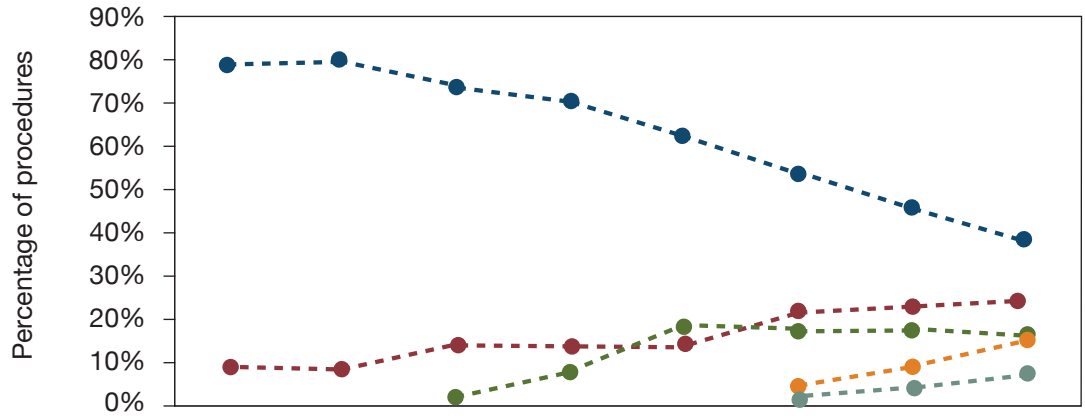
Year	2003	2004	2005	2006	2007	2008	2009	2010
Number of components used	2,226	4,256	5,430	5,737	6,614	7,016	7,027	6,955

Oxford partial knee — MG Uni — Zimmer Uni — Sigma HP — AMC/Uniglide

The brand usage for patello-femoral prostheses are shown in Figure 2.22 and the equivalent graph for highly constrained and hinged revision knees is shown in Figure 2.23.

Figure 2.22

Top five patello-femoral knee brands, usage trends 2003 to 2010.

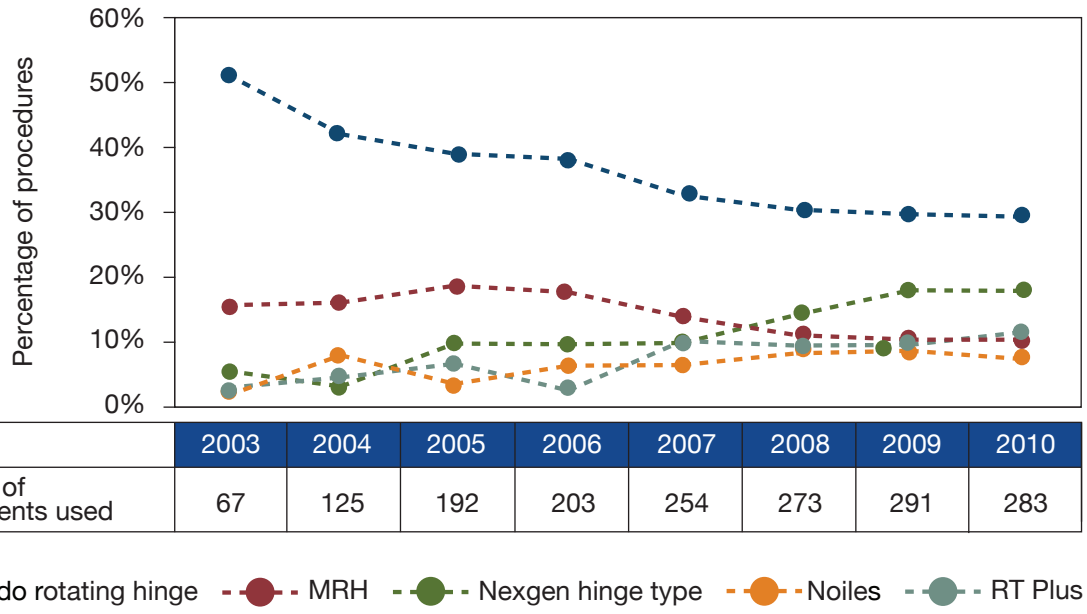


Year	2003	2004	2005	2006	2007	2008	2009	2010
Number of components used	267	503	671	726	999	1,126	1,138	1,056

AVON — FPV — Journey Competitor — Zimmer PFJ — Gender PF

Figure 2.23

Top five fixed hinged knee brands, usage trends 2003 to 2010.



Year	2003	2004	2005	2006	2007	2008	2009	2010
Number of components used	67	125	192	203	254	273	291	283

2.3.2 Knee revision procedures, 2010

A total of 5,082 knee revision procedures were reported, an increase of 11% on 2009. Of these, 3,879 (76%) were single stage revision procedures, 562 (11%) were stage one of a two stage revision and 628 (12%) were stage two of a two stage revision (Table 2.19). A further 13 procedures were recorded, comprising nine conversions of previous knee replacements to arthrodesis and four knee amputations. Compared with previous years, there has been no change in the types of revision procedures carried out. MDSv2 re-operations, other than revision, are not included in any of the tables below.

Table 2.19 Patient characteristics for knee revision procedures in 2010, according to procedure type.

	Knee single stage revision		Knee stage one of two stage revision		Knee stage two of two stage revision		Knee conversion to arthrodesis		Amputation		Total	
	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%
Total	**3,879**	**76%**	**562**	**11%**	**628**	**12%**	**9**	**<1%**	**4**	**<1%**	**5,082**	
Number with patient data	**3,683**	**95%**	**525**	**93%**	**597**	**95%**	**9**	**100%**	**3**	**75%**	**4,817**	**95%**
Average age	68.84		70.29		69.97		62.84		79.37		69.04	
SD	10.57		9.57		9.87		13.88		9.32		10.65	
Interquartile range	61.8 - 76.8		64.3 -76.9		63.9 -77.1		53.1 -71.0		75.0 - 84.3		62.3 - 76.9	
Gender												
Female	1,999	54%	220	42%	263	44%	4	44%	0	0%	2,486	52%
Male	1,684	46%	305	58%	334	56%	5	56%	3	100%	2,331	48%
Patient physical status												
P1 - fit and healthy	356	9%	37	7%	36	6%	2	22%	0	0%	431	8%
P2 - mild disease not incapacitating	2,616	67%	337	60%	399	64%	3	33%	3	75%	3,358	66%
P3 - incapacitating systemic disease	874	23%	178	32%	185	29%	4	44%	1	25%	1,242	24%
P4 - life threatening disease	33	<1%	10	2%	8	1%	0	0%	0	0%	51	1%
P5 - expected to die within 24 hrs with or without an operation	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
Indications for surgery												
Aseptic loosening	1,556	40%	46	8%	86	14%	0	0%	1	25%	1,689	33%
Infection	200	5%	468	83%	480	76%	5	56%	4	100%	1,157	23%
Pain	810	21%	31	6%	23	4%	2	22%	0	0%	866	17%
Instability	686	18%	28	5%	17	3%	1	11%	0	0%	732	14%
Wear of polyethylene component	532	14%	17	3%	15	2%	0	0%	0	0%	564	11%
Lysis	409	11%	57	10%	39	6%	1	11%	0	0%	506	10%
Malalignment	328	8%	9	2%	12	2%	0	0%	0	0%	349	7%
Stiffness	266	7%	9	2%	18	3%	3	33%	0	0%	296	6%
Progressive arthritis remaining	241	7%	4	<1%	4	<1%	0	0%	0	0%	249	5%
Dislocation/subluxation	167	4%	6	1%	7	1%	1	11%	0	0%	181	4%
Periprosthetic fracture	151	4%	4	<1%	6	<1%	0	0%	0	0%	161	3%
Component dissociation	87	2%	7	1%	2	<1%	1	11%	0	0%	97	2%
Implant fracture	38	<1%	2	<1%	1	<1%	0	0%	0	0%	41	<1%
Other	437	11%	25	4%	35	6%	1	11%	0	0%	498	10%
Side												
Bilateral	14	<1%	0	0%	0	0%	0	0%	0	0%	14	<1%
Left, unilateral	1,858	48%	278	49%	306	49%	6	67%	1	25%	2,449	48%
Right, unilateral	2,007	52%	284	51%	322	51%	3	33%	3	75%	2,619	52%

2.3.2.1 Patient characteristics

The mean age of knee revision patients was 69.0 years (Table 2.19). The average has increased by 0.1 years compared with 2009. There were more female (52%) than male patients (48%), although the gap is closing compared with 2004 when 56% of patients were female and 44% male. Aseptic loosening was the most common indication for single stage revision (40%) and infection was the most common indication for two stage revision, conversion to arthrodesis and amputation.

Compared with previous years, the patient characteristics described above have largely remained the same. However, there was a decrease in patients who are fit and healthy (ASA grade 1) and a corresponding increase in patients with incapacitating systemic disease (ASA grade 3) compared with 2009.

Part 2

2.4 Ankle replacement procedures, 2010

The NJR started recording primary and revision total ankle replacements on 1st April 2010.

358 ankle replacements, comprising 334 primary and 24 revision procedures carried out between 1st April and 31st December 2010, were submitted to the NJR by 28th February 2011. Due to the small number collected so far the procedures tables and graphs in this section are displayed at a summary level only, in comparison to the data provided for hips and knees. Of all the ankle procedures carried out 88% were funded by the NHS. 85% of patients were classified as P1 - fit and healthy (15%) or P2 - had mild disease not incapacitating (70%).

2.4.1 Primary ankle replacement procedures, 2010

Of the 334 primary procedures, 265 (79%) were performed in the NHS sector, 53 (16%) in the independent sector and 16 (5%) in ISTCs. Almost all of the primary procedures performed were uncemented but a cemented technique was reported in seven cases; however, only two cases listed cement in the component list. As all implants on the market at present are uncemented implants, we have concluded that in most cases reported as cemented, cement may not have been used and an error in data entry occurred. It is, however, possible that in these cases the implants might have been used in a manner that was not described in the manufacturer's instructions for use.

2.4.1.1 Patient Characteristics

The average age of patients having a primary procedure was 66.8 years and 56% of patients undergoing an ankle replacement were male. The BMI average was 29.9. No bilateral procedures were submitted to the NJR and 53% of procedures were performed on the right ankle. 79% of patients had their procedure performed due to osteoarthritis (Table 2.20). The average age for female patients (65.3 years) was less than for male patients (68.2 years) (Table 2.21).

Table 2.20 Patient characteristics for primary ankle replacement procedures in 2010.

	Primary procedures	
	No.	%
Total ankle primaries	**334**	
Patient physical status		
P1 - fit and healthy	49	15%
P2 - mild disease not incapacitating	237	71%
P3 - incapacitating systemic disease	47	14%
P4 - life threatening disease	1	<1%
P5 - expected to die within 24hrs with or without an operation	0	0%
Indications for surgery		
Osteoarthritis	265	79%
Rheumatoid arthritis	47	14%
Other inflammatory arthropathy	9	3%
Other	18	5%
Tibia-Hindfoot alignment		
Physiological Neutral	134	40%
5-15° Varus	68	20%
16-30° Varus	15	4%
>30° Varus	1	<1%
5-15° Valgus	54	16%
16-30° Valgus	7	2%
>30° Valgus	2	1%
Not Available	53	16%
Pre-operative range of movement Ankle Dorsiflexion		
5-20°	133	40%
Neutral	130	39%
Fixed Equinus	29	9%
Not Available	42	13%
Pre-operative range of movement Ankle Plantarflexion		
5-15°	171	51%
16-45°	111	33%
Not Available	52	16%

Table 2.21 Age and gender for primary ankle replacement patients in 2010.

	Primary procedures	
	No.	%
Total ankle primaries	**334**	
Total ankle primaries with patient data	**314**	
Female age	**139**	**44%**
Average	65.29	
SD	12.07	
Interquartile range	58.9 – 72.3	
Male age	**175**	**56%**
Average	68.18	
SD	9.5	
Interquartile range	63.4 – 75.1	
Female age groups		
<45 years	9	6%
45 - 54 years	19	14%
55 - 64 years	28	20%
65 - 74 years	58	42%
75 - 84 years	23	17%
>85 years	2	1%
Male age groups		
<45 years	5	3%
45 - 54 years	10	6%
55 - 64 years	44	25%
65 - 74 years	71	41%
75 - 84 years	44	25%
>85 years	1	1%

2.4.1.2 Surgical techniques

Table 2.22 details the surgical technique used during ankle primary procedures. During a primary ankle replacement other ankle related procedures may be performed, for example 10% of all TAR procedures also had Achilles tendon lengthening performed and 6% had a subtalar joint fusion. Bone graft was used in 11% of procedures. There were five primary procedures using a DePuy Mobility ankle replacement where a lateral (transfibular) approach was selected. The surgical technique for this implant is to insert the implant using an anterior approach. This data might reflect a data entry issue or that the prostheses were implanted in a manner that deviates from the manufacturer's instructions for use.

Table 2.22 Characteristics of surgical practice for primary ankle replacement procedures in 2010.

	Primary procedures	
	No.	%
Total	**334**	
Incision		
Anterior	309	93%
Anterolateral	13	4%
Lateral (transfibular)	5	1%
Other	7	2%
Associated procedures at time of surgery		
Subtalar Joint Fusion	21	6%
Talonavicular Fusion	6	2%
Calcaneal Displacement Osteotomy	8	2%
Achilles Tendon Lengthening	34	10%
Fusion Distal Tibiofibular Joint	0	0%
Fibula Osteotomy	1	<1%
Medial Malleolar Osteotomy	2	1%
Lateral Ligament Reconstruction	2	1%
Medial Ligament Reconstruction	0	0%
Other	55	16%
None	218	65%
Image-guided surgery		
Yes	4	1%
No	330	99%
Bone graft used		
Yes	38	11%
No	296	89%

2.4.1.3 Thromboprophylaxis

Table 2.23 shows that 65% of primary ankle replacement procedures used both chemical and mechanical thromboprophylaxis regimes and 4% used no regime. Low molecular weight heparin was the most popular chemical thromboprophylaxis regime used in 67% of TAR procedures.

Table 2.23 Thromboprophylaxis regime for primary ankle replacement patients, prescribed at time of operation.

	Primary procedures	
	No.	%
Total	**334**	
Aspirin	42	13%
LMWH	224	67%
Pentasaccharide	1	<1%
Warfarin	6	2%
Direct Thrombin Inhibitor	11	3%
Other Chemical (all)	26	8%
No Chemical	46	14%
Foot Pump	54	16%
Intermittent Calf Compression	87	26%
TED Stockings	161	48%
Other Mechanical	4	1%
No Mechanical	83	25%
Both Mechanical and Chemical	218	65%
Neither Mechanical nor Chemical	13	4%

2.4.1.4 Untoward intra-operative events

In 96% of procedures, no untoward intra-operative events were reported. Of those reported the most common was 'Fracture medial malleolus' which occurred in 3% of all procedures.

2.4.1.5 Ankle primary components

Total ankle replacement procedures predominantly use the DePuy Mobility brand which was used in 74% of primary procedures. For full details of all brands used in 2010, please visit the NJR website at www.njrcentre.org.uk.

2.4.2 Ankle revision procedures, 2010

Of the 24 revision procedures, 21 were performed in the NHS sector. 54% were single stage revisions, and 33% were conversions to arthrodesis. Of these 24 revision procedures only one links to an ankle primary procedure on the NJR database.

2.4.2.1 Patient characteristics

The average age for a patient having a revision procedure was 63.7 years, which was 3.1 years less than the average age reported for patients having a primary procedure. 17% of patients were fit and healthy and 52% of patients were male. Right-sided revisions accounted for 71% of the recorded revisions. Table 2.24 describes the indications for surgery and shows that 46% of revisions were due to aseptic loosening and 25% were due to malalignment.

Table 2.24 Patient characteristics for ankle revision procedures in 2010.

	Revision procedures	
	No.	%
Total	**24**	
Patient physical status		
P1 - fit and healthy	4	17%
P2 - mild disease not incapacitating	14	58%
P3 - incapacitating systemic disease	5	21%
P4 - life threatening disease	1	4%
P5 - expected to die within 24hrs with or without an operation	0	0%
Indications for surgery		
Infection high suspicion	2	8%
Infection low suspicion	6	25%
Aseptic loosening - Tibial	7	29%
Aseptic loosening - Talar	4	17%
Lysis - Tibia	6	25%
Lysis - Talus	4	17%
Malalignment	6	25%
Implant fracture - Tibia	0	0%
Implant fracture - Talar	0	0%
Implant fracture - Meniscal	3	13%
Wear of polyethylene component	0	0%
Meniscal insert dislocation	1	4%
Component migration/dissociation	1	4%
Pain (undiagnosed)	4	17%
Stiffness	1	4%
Soft tissue impingement	3	13%
Other	2	8%

Part 3 Outcomes after joint replacement, 2003 to 2010

3.1 Introduction

Part 3 of the 8th Annual Report considers the survivorship of hip and knee replacements in England and Wales in the period of almost eight years after primary surgery (1st April 2003 to 31st December 2010). This includes an analysis of revision rates and mortality after primary joint replacement. Part 3 has been prepared by Alison Smith and Ashley Blom with contributions from other members of the University of Bristol team (Kelly Vernon, Paul Dieppe, Emma Clark, and Jon Tobias). The structure of Part 3 is:

- Section 3.1 introduces Part 3 and contains an overall summary of key findings.
- Section 3.2 details the data sources used for this analysis, including the use of NHS data to supplement NJR data in terms of identifying revisions linked to a primary operation.
- Section 3.3 describes the outcomes after primary hip replacement.
- Section 3.4 explores outcomes after primary knee replacement.

3.1.1 Summary of key findings

3.1.1.1 Hip replacements

Revision rates

Overall revision rates were low: only 1.1% of primary hip replacements had been revised by one year after primary surgery rising to 2.3% by year three, 3.5% by year five, and 4.7% by year seven (Table 3.9). However, there was substantial variation in revision rates according to prosthesis type with the lowest rates associated with cemented prostheses (3% at seven years) and the highest rates associated with resurfacing (11.8% at seven years) and stemmed metal-on-metal bearing surfaces (13.6% at seven years) (Table 3.12). There appears to be a sharp increase in the risk of revision at around six years after primary surgery for the metal-on-metal group although more data is needed to confirm this finding (Figure 3.2).

There was also variation in revision rates according to the characteristics of patients. Multi-variable analysis indicates that for patients aged under 60, there was little difference in revision rates between the cemented, uncemented and hybrid groups (Table 3.16). However, for patients aged 70 or over, cemented prostheses were associated with the lowest revision rates (Table 3.18). Adjusted revision rates for the resurfacing and stemmed metal-on-metal groups remained significantly above those of other groups indicating that the higher revision rates cannot simply be explained by the patients being younger on average and more typically male (Section 3.3.1.7). Revision rates tended to be slightly lower for women than for men in the cemented, uncemented and hybrid groups but were significantly higher for women in the resurfacing and metal-on-metal groups (Section 3.3.1.7).

Mortality

The risk of death in the first 30 days (0.3%) and 90 days (0.6%) after surgery was similar to the overall risk of revision in these periods (Table 3.15). Overall, 16.8% of patients had died within seven years of their hip replacement (although death rates for these patients are lower than death rates among people in the general population of a comparable age and gender). The highest death rates were among the cemented group and the lowest were among the resurfacing group, reflecting the age distribution of these groups. For all patients except those in the resurfacing group, the risk of death over a particular year was higher than the risk of revision in that year.

3.1.1.2 Knee replacements

Revision rates

Overall, revision rates were low: only 0.7% of primary knee replacements had been revised by one year after the primary surgery rising to 2.7% by year three, 3.9% by year five, and 4.9% by year seven (Table 3.25). However, there was substantial variation in revision rates according to prosthesis type with the lowest rates associated with cemented prostheses (3.8% at seven years) (Table 3.25). There was no significant difference between the uncemented and hybrid groups and revision rates for these prostheses were only slightly higher than for cemented prostheses (4.8% at seven years). In contrast, revision rates for patello-femoral and unicondylar procedures were considerably higher at 20.4% and 16.6% respectively by seven years after primary surgery.

Posterior cruciate-retaining implants had lower revision rates than posterior cruciate-stabilised implants (3.7% compared with 4.3% at seven years) (Table 3.27). These revision rates were lower again for posterior cruciate-retaining implants with fixed bearings compared with posterior cruciate-retaining implants with mobile bearings (3.4% versus 5.0% at seven years) (Table 3.28). Overall, the lowest revision rates for knee replacements were associated with a posterior cruciate-retaining, fixed bearing cemented prosthesis (3.4% at seven years) (Table 3.29).

In terms of patient characteristics, there were no significant differences between men and women in terms of the risk of revision. However, revision rates for those aged under 60 were much higher than for older age groups for all prosthesis types (for example, the seven-year revision rate for those aged under 60 with a cemented knee was 7.5% compared with 2.6% of those aged 70 or over) (Table 3.31). Unicondylar revision rates remained much higher than for other prosthesis types regardless of age group with the highest revision rates for those aged under 60 (22.9% had been revised by seven years) (Table 3.31).

Mortality

There was a small risk of death in the first 30 days (0.2%) and 90 days (0.4%) after surgery (Table 3.32). Overall, 17.1% of patients had died within seven years of their knee replacement (although death rates for these patients are lower than death rates among people in the general population of a comparable age and gender). The highest death rates were among the cemented group and the lowest were among the patello-femoral group, reflecting the age distribution of these groups. For all total knee replacement patients, the risk of death over a particular year was higher than the risk of revision in that year.

Part 3

3.2 Data sources

This section describes the data sources used for the outcome analysis presented in Sections 3.3 and 3.4. The two sets of data analysed are briefly summarised in Table 3.1.

Table 3.1 Summary description of datasets used for survivorship analysis.

	NJR-HES/PEDW data	NJR data
Summary of data	NJR person-level data that can be linked to HES/PEDW data	All NJR procedure-level data restructured to person-level
Time period	1st April 2003 to 31st December 2010	1st April 2003 to 31st December 2010
Data exclusions	– Excludes data where patient-level identifier is not present – Excludes patients where no primary operation is recorded in NJR – Excludes any revisions after the first revision – Excludes data where no linkage to HES/PEDW is possible (operations with independent funding and those where linkage variables are not present)	– Excludes data where patient-level identifier is not present – Excludes patients where no primary operation is recorded in NJR – Excludes any revisions after the first revision
Number of primary operations	300,374 hips 342,120 knees	384,760 hips 417,222 knees
Number of revisions linked to a primary operation	NJR identified primary-linked first revisions: 4,968 hips 5,663 knees Extra HES/PEDW identified first revisions: 2,003 hips 2,354 knees	NJR identified primary-linked first revisions: 5,794 hips 6,460 knees

The rest of this section gives further details on these two data sources and the methodology used. In particular, there is discussion of the use of NHS data (Hospital Episode Statistics (HES) and Patient Episode Database for Wales (PEDW)) to supplement NJR data for survivorship analysis and the reasons why this approach is now under review (Section 3.2.1.1). There are also some reflections on the representativeness of NJR data more generally. The key findings are summarised here for those who do not require further detail:

- it is unclear whether NJR is accurately recording revisions relative to primary operations. There has previously been a view that it is under-recording revisions and so under-estimating the true revision rate.
- HES/PEDW data has been used to supplement NJR data in terms of identifying revisions. However, there is some evidence that the HES/PEDW data is over-estimating revision rates due to some re-operations being counted as revisions. A HES/PEDW audit is planned for 2011 to collect more evidence on this.
- this year for the first time, analysis is presented on both the NJR-HES/PEDW linked data and the NJR data.
- procedure-level data has to be restructured to person level so that revisions can be matched to primary operations for the same individual. Overall, 16.9% of NJR data is excluded because of a lack of a suitable person-level identifier.
- there are difficulties matching NJR to HES/PEDW. Overall, 80.1% of primary procedures in NJR could be linked to HES/PEDW and 69.7% of procedures in HES/PEDW could be linked to NJR. However, only around 39% of the revisions used for the survivorship analysis match exactly in NJR and HES/PEDW. As well as extra revisions in HES/PEDW that are not recorded in NJR, there are revisions in NJR that do not exist in HES/PEDW.
- because of lower levels of compliance, data from the early years of the registry may be less representative than that from more recent years. This should be taken into account when interpreting the five- and seven-year revision rates for both datasets.
- analysis based on the NJR-HES/PEDW linked data is not representative of all patients undergoing total joint replacement because it excludes independently-funded operations.

3.2.1 Accurately measuring the revision rate

As submission to NJR has not been mandatory and compliance in the early years of the registry was relatively low, there is a risk that NJR does not fully represent the situation in England and Wales. In particular, an under- or over-reporting of revisions relative to the reporting of primary operations could skew the survivorship analysis discussed later in this report. It is not straightforward to ascertain whether revisions are over- or under-reported to NJR. There are three possibilities:

1. Primary and revision operations have been reported to the same extent. This means that the survivorship analysis will not be affected and the results will be as representative as is NJR data more generally (given the lower levels of compliance in the early years).
2. Revisions are under-reported relative to primary operations (for example, if surgeons fail to report revisions). This means that NJR data would underestimate the true revision rate.
3. Revisions are more likely to be reported to NJR than primary operations. Revision surgery is more likely to be carried out by experienced surgeons and in specialist centres (for example, 8.9% of primary operations recorded in NJR in 2010 were carried out by surgeons who performed less than 50 primary operations a year compared with just 2.8% of revisions). As these surgeons will be more used to submitting NJR data, it is possible that the reporting of revision details to NJR would be more likely than the reporting of primaries by small-volume surgeons or centres. This means that NJR data would over-estimate the true revision rate.

3.2.1.1 Using HES/PEDW data to supplement NJR data

Since the 4th NJR Annual Report in 2007, HES and, where available, PEDW data have been used to supplement NJR data for survivorship analysis. In the early days of the registry, this was because of low levels of compliance. This approach has been continued, despite rising compliance levels, because of a concern that NJR was under-recording revisions (Section 3.2.2.1, NJR 7th Annual Report).

This process of using HES/PEDW data involves identifying extra revisions within the HES/PEDW data that are not recorded in NJR and then adding them to the NJR identified revisions. Analysis is then performed on just the NJR-HES/PEDW linked data (which excludes around 20% of the total NJR data including operations with independent funding). However, recent case audits undertaken as part of the NJR implant performance review process have demonstrated that HES/PEDW data is also not without its problems. Specifically, some of the HES/PEDW defined extra revisions were found not to be revisions (involving the removal and replacement of one or more components of a total joint prosthesis) but re-operations (such as wound exploration, debridement for infection, evacuation of a haematoma, or open reduction of dislocation).

Defining revisions in HES/PEDW

To understand why this might be the case, it is necessary to look at how revisions are defined in the HES/PEDW data. Unlike NJR, definitions of primary and revision operations in HES/PEDW are based on OPCS-4 codes (Office of Population, Censuses and Surveys classification of interventions and procedures, 4th revision). There are many thousands of these codes and so reliably identifying any particular operation is not straightforward. Some OPCS-4 codes used to define primary and revision hip and knee surgery do so quite precisely (such as “W378: Total prosthetic replacement of hip joint using cement”). However, combinations of more ambiguous codes are also used (such as “W394: Attention to total prosthetic replacement of hip joint” combined with “Y037: Removal of prosthesis from organ”, or “W523: Prosthetic replacement of articulation of other bone using cement”, used in combination with Z843 or Z761 or Z756 to identify hip). This process of deciding which OPCS-4 codes should be used to identify primary and revision operations has evolved over the years and now involves a total of 110 different OPCS-4 codes. The numbers of OPCS-4 codes used for each surgery type are summarised in Table 3.2. Full details of the individual codes and the code combinations are available from the NJR website.

Table 3.2 Numbers of OPCS-4 codes used to define primary and revision surgery in the HES/PEDW data.

	Primary hips	Primary knees	Revision hips	Revision knees
Single OPCS-4 code	18	12	22	14
Combination of multiple codes	6 combinations of 9 codes	6 combinations of 12 codes	19 combinations of 24 codes	24 combinations of 33 codes

Of particular concern is the extent to which the more ambiguous multiple code combinations are used to identify revisions. For primary operations, 4.1% of hips and 5.2% of knees were defined in HES/PEDW by a combination of the more ambiguous codes. For revisions, 18.4% of hips and 20.6% of knees were defined by the more ambiguous multiple codes (Table 3.3). It would be useful to understand more about why a combination of codes might be used by a hospital to code a revision instead of the more straightforward single revision codes.

Table 3.3 Type of revision identified in HES/PEDW.

Revision definition	Hip revisions	Knee revisions
Use of single OPCS-4 code		
1) Revision defined by single "Revision of…" OPCS-4 code	44,042 (59.7%)	25,488 (65.3%)
2) Revision defined by single "Conversion to…" OPCS-4 code	16,229 (22.0%)	5,509 (14.1%)
Use of multiple OPCS-4 codes		
3) Revision defined by "Attention to…" OPCS-4 code with other qualifying code relating to removal or renewal of prosthesis	9,058 (12.3%)	6,757 (17.3%)
4) Revision defined by other combination of multiple OPCS-4 codes	4,506 (6.1%)	1,288 (3.3%)
Base: all HES/PEDW data 2003-2010	73,835	39,042

Is HES/PEDW over-counting revisions?

There is a concern that the use of the more ambiguous multiple codes could overestimate revisions within the HES/PEDW data because these may cover various procedures other than revision. In addition, given the complexity and quantity of codes within OPCS-4, coding errors are possible. HES/PEDW coding is undertaken by NHS coding staff (rather than the surgical team carrying out the procedure) and so it may be difficult to distinguish between a re-operation or revision procedure from the information available.

One area that can shed some light on this issue is to examine how the small numbers of re-operations recorded in NJR match to HES/PEDW. These are not counted as revisions for the survivorship analysis but are recorded separately as re-operations in NJR. However, the same operation often appears as a revision in HES/PEDW. Analysis indicates that for NJR hip re-operations linked to an NJR primary, 99 out of 259 (38.2%) were defined as a revision in HES/PEDW. For NJR knee re-operations linked to an NJR primary, 94 out of 490 (19.2%) were defined as a revision in HES/PEDW. These false HES/PEDW-defined revisions were drawn from both the single and multiple OPCS-4 codes described in Table 3.3 but they were more likely than other revisions to be drawn from the multiple code combinations. In particular, the false knee revisions were disproportionately drawn from the fourth category of OPCS-4 codes in Table 3.3 while false hip revisions were disproportionately drawn from the third and fourth categories.

This analysis is based on relatively small numbers but, if representative, it confirms the findings of the smaller case audits that the HES/PEDW data is over-counting revisions because of the inclusion of some re-operations. However, without knowing about the volume of re-operations relative to the volume of revisions, it is difficult to estimate what impact this may have on revision rates calculated using HES/PEDW data.

Given these issues, the use of HES/PEDW data for the survivorship analysis is under review. A comprehensive HES/PEDW audit is planned for 2011 which we hope will inform decisions about how analysis should be undertaken for future annual reports. This year, we have chosen to continue the NJR linkage to HES/PEDW but to restrict the definition of HES/PEDW extra revisions to exclude some of the more ambiguous multiple OPCS-4 code combinations and those that we know from NJR are re-operations. The effect of this is discussed further in Section 3.2.2 along with an assessment of the HES/PEDW data and how it links to NJR. This year for the first time, we present the survivorship analysis using both the NJR-HES/PEDW linked data and the NJR data. Specifically, given that we are unsure of the validity of the HES/PEDW defined extra revisions, the brand analysis has been produced for the NJR data only.

3.2.2 Details of the linkage of NJR to HES/PEDW

Only operations that took place between 1st April 2003 and 31st December 2010 are considered in both the NJR and HES/PEDW data sources. Table 3.4 indicates the number of primary and revision joint replacement operations in NJR for each year 2003 to 2010. Until 2010, numbers have increased each year for all procedures which reflects an increase in this type of surgery as well as an increase in the extent of data reported to NJR (discussed further in Part one of this report). In 2010, numbers of primary procedures were slightly lower than in 2009 (a reduction of around 1.5%).

3.2.2.1 Linking at person level

For the survivorship analysis, revisions must be matched to primary operations and so the data has to be restructured from operation level to person level. This requires a person-level identifier to indicate how different operations are related to an individual person. Overall, 16.9% of NJR data is lost from the analysis because a suitable person-level identifier is not available (Table 3.4). Around half of this (47%) is due to the patient refusing consent for personal details to be held and the rest is attributable to tracing and linkage difficulties. Table 3.4 indicates that a person-level identifier was available for around 95% of operations from 2008 to 2010. However, for the early years of registry, the ability to link operations for individuals is much lower: for example, only 58% of operations in 2004 have a person-level identifier. When interpreting the survivorship analysis in later sections, it is important to remember that the patients on which five- and seven-year revision rates are based may be less representative than the sample of patients that form the basis of the one- and three-year revision rates.

Table 3.4 Summary of NJR data, April 2003 to December 2010.

Year of operation	Primary hip	Revision hip	Primary knee	Revision knee	All
Number of all NJR records					
2003 (April-Dec)	26,432	2,826	24,662	1,157	55,077
2004	48,032	5,238	46,577	2,339	102,186
2005	57,490	6,342	60,704	3,265	127,801
2006	59,715	6,689	62,240	3,755	132,399
2007	66,616	7,436	73,297	4,287	151,636
2008	69,839	7,533	77,208	4,659	159,239
2009	69,936	7,848	78,021	4,963	160,768
2010	68,907	7,852	76,870	5,109	158,738
All years	466,967	51,764	499,579	29,534	1,047,844
Number of NJR records with person-level identifier					
2003 (April-Dec)	14,473	1,422	13,469	636	30,000
2004	27,958	2,809	27,478	1,318	59,563
2005	39,979	4,082	41,478	2,190	87,729
2006	47,209	4,900	49,082	2,814	104,005
2007	59,684	6,506	65,844	3,839	135,873
2008	65,906	6,972	72,956	4,356	150,190
2009	66,450	7,416	74,096	4,706	152,668
2010	65,211	7,415	72,819	4,851	150,296
All years	386,870	41,522	417,222	24,710	870,324
Percentage of total with person-level identifier					
2003 (April-Dec)	54.8%	50.3%	54.6%	55.0%	54.5%
2004	58.2%	53.6%	59.0%	56.3%	58.3%
2005	69.5%	64.4%	68.3%	67.1%	68.6%
2006	79.1%	73.3%	78.9%	74.9%	78.6%
2007	89.6%	87.5%	89.8%	89.5%	89.6%
2008	94.4%	92.6%	94.5%	93.5%	94.3%
2009	95.0%	94.5%	95.0%	94.8%	95.0%
2010	94.6%	94.4%	94.7%	95.0%	94.7%
All years	82.8%	80.2%	83.5%	83.7%	83.1%

Table 3.5 presents the numbers of hip and knee primary and revision operations from April 2003 to December 2010 identified in the HES/PEDW data based on the OPCS-4 codes discussed earlier. This shows a trend of increasing numbers of operations from 2004 to 2009 but a drop in 2010 (2010 figures were around 12% lower than 2009 figures). These numbers will not be directly comparable with those in Table 3.4 because NJR data includes independently-funded patients. Data for 2010 (where funding information in NJR is complete) suggests that because of the inclusion of independently-funded patients, we would expect total NJR numbers to be higher than total HES/PEDW numbers in the region of 15% for primary hips, 12% for primary knees, 11% for revision hips and 10% for revision knees. A comparison of primary operations shows that this is broadly the case: total NJR primary hips for 2010 are around 16% higher than the total number of HES/PEDW primary hips and total NJR primary knees for 2010 are around 11.5% higher than total HES/PEDW primary knees. Numbers of revisions in NJR are lower than in HES/PEDW but this may be because of the definition issues discussed earlier.

Table 3.5 Summary of HES/PEDW data, April 2003 to December 2010.

Year of operation	Primary hip	Revision hip	Primary knee	Revision knee	Other	All
Number of HES/PEDW records						
2003 (Apr-Dec)	37,509	6,152	38,518	2,587	185	84,951
2004	53,570	8,743	57,743	3,798	238	124,092
2005	54,866	8,957	61,942	4,296	243	130,304
2006	56,676	9,145	62,696	4,681	284	133,482
2007	64,965	9,910	75,015	5,288	320	155,498
2008	69,080	10,219	79,774	6,055	323	165,451
2009	67,958	10,288	78,472	6,047	338	163,103
2010	59,405	9,018	68,954	5,504	327	143,208
All years	464,029	72,432	523,114	38,256	2,258	1,100,089
Number of HES/PEDW records with person-level linkage to NJR						
2003 (Apr-Dec)	14,239	2,011	15,568	1,002	68	32,888
2004	25,358	3,591	28,174	1,789	101	59,013
2005	32,417	4,561	37,330	2,448	137	76,893
2006	38,816	5,405	44,047	3,102	184	91,554
2007	49,803	6,737	59,059	4,037	231	119,867
2008	55,213	7,375	65,091	4,871	233	132,783
2009	56,130	7,882	65,831	5,057	269	135,169
2010	49,279	7,026	57,709	4,710	266	118,990
All years	321,255	44,588	372,809	27,016	1,489	767,157
Percentage of HES/PEDW records with person-level linkage to NJR						
2003 (Apr-Dec)	38.0%	32.7%	40.4%	38.7%	36.8%	38.7%
2004	47.3%	41.1%	48.8%	47.1%	42.4%	47.6%
2005	59.1%	50.9%	60.3%	57.0%	56.4%	59.0%
2006	68.5%	59.1%	70.3%	66.3%	64.8%	68.6%
2007	76.7%	68.0%	78.7%	76.3%	72.2%	77.1%
2008	79.9%	72.2%	81.6%	80.4%	72.1%	80.3%
2009	82.6%	76.6%	83.9%	83.6%	79.6%	82.9%
2010	83.0%	77.9%	83.7%	85.6%	81.3%	83.1%
All years	69.2%	61.6%	71.3%	70.6%	65.9%	69.7%

Note: Other category refers to HES/PEDW records where operation type cannot be clearly determined such as an operation that is coded as both a hip and a knee or both a primary and a revision. This can occur because up to 24 separate OPCS-4 codes are recorded in the HES/PEDW data for a single operation.

Table 3.5 also shows the number of HES/PEDW records that could possibly be linked with NJR at person level. Linkage can only be attempted for those NJR patients with a suitable person-level identifier (83.1% of the total, see Table 3.4). In addition, records can only be matched for those procedures with NHS funding as independently-funded operations will not be included in HES/PEDW. The linkage process attempts to match the HES and PEDW data to a procedure in NJR by using a hierarchical linkage algorithm based on combinations of NHS number, date of birth, gender, hospital identifier and local hospital number. Therefore, in cases where an NJR procedure was linked to more than one HES/PEDW record, the link most likely to be correct according to this hierarchy was chosen. The hierarchical linkage algorithm, in descending order of importance, is:

- linkage based on NHS number, year of birth and gender
- linkage based on local hospital, local hospital number, date of birth and gender
- linkage based on local hospital, local hospital number and date of birth

- linkage based on local hospital, date of birth and gender
- linkage based on NHS number, local hospital and local hospital number.

Overall, 69.7% of the procedures in HES/PEDW could be linked to NJR by a person-level linkage as shown above. Table 3.5 indicates that this linkage ability has risen from 38.7% in 2003 to 83.1% in 2010 which reflects the availability of a suitable person-level identifier shown in Table 3.4. Again, this trend should be taken into account when interpreting the five- and seven-year revision rates discussed in the survivorship analysis in later sections.

Altogether, 80.1% of primary procedures in NJR could be linked to HES/PEDW. As would be expected given the nature of the HES/PEDW data, linkage was more commonly successful for operations carried out in NHS hospitals and NHS treatment centres (Table 3.6). When interpreting the survivorship analysis, it should be remembered that the NJR-HES/PEDW linked data is not representative of all joint replacement patients in England and Wales because of the exclusion of independently-funded patients.

Table 3.6 NJR to HES/PEDW linkage by organisation type of primary operation.

Organisation type	Primary hip	Primary knee	All
Number of all NJR records with person-level identifier			
NHS hospital	252,726	282,172	534,898
Independent hospital	100,058	96,010	196,068
NHS treatment centre	14,177	16,626	30,803
Independent treatment centre	17,799	22,414	40,213
All	384,760	417,222	801,982
Number of linked NJR-HES/PEDW records			
NHS hospital	241,808	271,942	513,750
Independent hospital	29,788	35,142	64,930
NHS treatment centre	13,667	16,153	29,820
Independent treatment centre	15,111	18,883	33,994
All	300,374	342,120	642,494
Percentage of total that are HES/PEDW linked			
NHS hospital	95.7%	96.4%	96.0%
Independent hospital	29.8%	36.6%	33.1%
NHS treatment centre	96.4%	97.2%	96.8%
Independent treatment centre	84.9%	84.2%	84.5%
All	78.1%	82.0%	80.1%

3.2.2.2 Linking at operation level

Despite successful overall linking of NJR and HES/PEDW records at person-level, the operations for these individuals do not always match exactly. The matching of NJR and HES/PEDW revisions is done on a combination of factors including joint, side of body and date of operation. Where the side of body is not recorded for a revision in HES/PEDW, no linkage was attempted. This is because sensitivity analysis on NJR data indicated that if side of body was ignored when identifying linked revisions in NJR, the number of revisions identified would increase by 51% for hips and 36.2% for knees. Recording of side of body in HES/PEDW was incomplete for 4.8% of hip revisions and 4.9% of knee revisions.

Overall, 4,968 hip revisions that were linked to an observed primary operation were identified in NJR with an additional 2,003 identified from HES/PEDW. For knees, 5,663 were identified in NJR with another 2,354 identified from HES/PEDW. This means that the extra revisions identified from HES/PEDW data comprise 28.7% of the total linked hip revisions and 29.4% of the total linked knee revisions for the survivorship analyses (Table 3.7). Restricting the definitions of HES/PEDW defined revisions to exclude some revisions identified from the more ambiguous multiple OPCS-4 code combinations and those revisions defined as re-operations in NJR meant that a further 363 hip procedures and 341 knee procedures were not added as extra HES/PEDW defined revisions.

Table 3.7 summarises the linking of revision records and indicates that only around 39% of the revisions used for the survival analysis match exactly in the NJR and HES/PEDW data. It is not simply that some data is in HES/PEDW and not in NJR; there are also revision operations for linked individuals that are recorded in NJR but do not exist in HES/PEDW. This illustrates some of the difficulties in trying to match two very different data sources.

Table 3.7 Matching status of revisions identified for survivorship analysis.

	Hip revisions	Knee revisions
NJR identified revisions		
Exact match in NJR and HES/PEDW based on date, joint and side of body	38.8%	39.3%
In NJR and HES/PEDW – match on joint and side; date differs by less than one month	9.8%	7.5%
In NJR and HES/PEDW – match on joint and side but date differs by more than one month	8.3%	9.4%
In NJR and HES/PEDW – joint and date match but side mismatch	1.8%	1.1%
Recorded in NJR but not recorded in HES/PEDW	12.6%	13.3%
Extra HES/PEDW identified revisions		
Recorded in HES/PEDW but not in NJR	28.7%	29.4%
Total	6,971	8,017

The extra HES/PEDW identified revisions tended to be earlier revisions than the NJR identified revisions. For hips, 47.9% of the extra HES/PEDW revisions occurred within one year of primary surgery compared with 42.2% of the NJR revisions. For knees, 33% of the extra HES/PEDW revisions occurred within one year of primary surgery compared with 24.7% of the NJR revisions. This could potentially reflect an over-counting of revisions in the HES/PEDW data due to the inclusion of some re-operations (as re-operations will tend to happen earlier than revisions).

3.2.3 Person-level data for the survivorship analysis

The survivorship analysis requires the data to be restructured to person level so that a patient is observed from the time of their primary joint replacement until the time of revision, time of death, or 31st December 2010 (depending on which comes first). Therefore, this analysis is based on those people with at least one primary joint replacement between April 2003 and December 2010 recorded in NJR.

Some patients will have had primary joint replacements before NJR started recording data. For example, some individuals (5% of patients in the NJR person-level data) only had one or more revision operations observed between April 2003 and December 2010 and so are excluded from the analysis. In addition, some patients (1.6%) had a revision observed but not for the primary operation recorded in NJR (so a revision of the other side). Overall, just 21.6% of revisions recorded in NJR with a person-level identifier could be linked to a primary operation also recorded in NJR.

Some patients had hip replacements and knee replacements during the observation period and so will appear in both the hip and knee analysis datasets (2.9% of patients in the NJR dataset and 4.2% in the NJR-HES/PEDW linked dataset). In addition, many patients will have both hips or both knees replaced over their lifetime. In the observation period April 2003 to December 2010, around 11% of hip replacement patients and around 16% of knee replacement patients had both sides replaced (Table 3.8). These people appear in the analysis dataset twice so the survivorship of each primary operation can be analysed. There are sometimes statistical concerns about including the same person in any analysis twice, particularly if there is likely to be a correlation between the records in terms of the outcome or explanatory variables. This is unlikely to be a problem here as the survivorship of one joint is largely independent of the other one and patient characteristics like age are recorded at the time of primary surgery on each occasion and so will differ over time (except for the very small number of patients who had bilateral operations: 0.6% of hip patients and 1.4% of knee

patients). In addition, it is not possible to apply a condition of only considering the first primary joint replacement to everyone as many of the patients with only one primary joint replacement observed in this time period will also have had the other side replaced but before we started observing them. To check that the inclusion of these patients was not distorting the analysis, a multi-variable statistical model confirmed that patients who were recorded as having both sides replaced in the observation period were no more or less likely to experience revision than were other patients.

Table 3.8 Composition of person-level datasets for survivorship analysis.

	Hips		Knees	
	NJR-HES/PEDW	NJR	NJR-HES/PEDW	NJR
Number of people with one joint replacement	239,590	309,788	246,918	304,424
Number with two primary joint replacements (both sides)	30,392	37,486	47,601	56,399
Number with bilateral joint replacement (same operation date for both)	1,567	2,431	4,087	5,958
Total number of people	269,982	347,274	294,519	360,823
Total number of person-level records for analysis	300,374	384,760	342,120	417,222
Percentage of people with both sides replaced	11.3%	10.8%	16.2%	15.6%
Percentage of people with a bilateral operation	0.6%	0.7%	1.4%	1.7%

Part 3

3.3 Outcomes after primary hip replacement, 2003 to 2010

This section contains statistical analysis of the survivorship of hip replacements in the period up to almost eight years after primary surgery (1st April 2003 to 31st December 2010). This analysis examines the length of time between the primary hip replacement and the first revision of that hip replacement or the patient's death.

In Section 3.3.1, all-cause revision and mortality is considered. This analysis is based on the NJR-HES/PEDW linked data described in Section 3.2. This section starts by presenting descriptive analysis that is unadjusted for any wider influences on revision rates. It then moves on to using multi-variable analysis to adjust the revision rates for patient characteristics and the competing risk of death.

A comparison of the NJR-HES/PEDW and NJR revision rates is made in Section 3.3.2. As discussed in Section 3.2, each data source has its strengths and limitations and so this analysis is intended to inform the wider debate about data quality and methodological matters.

In Section 3.3.3, NJR data (discussed in Section 3.2) is used to examine revisions other than for infection. Analysis of revision rates for the most commonly used implant brands is shown in Section 3.3.4. This is also based on NJR data and shows all-cause revision rates as well as revision rates excluding those for infection.

Finally, Section 3.3.5 contains our conclusions and recommendations.

Throughout the section, details relating to statistical issues have been summarised separately as methodological notes for readers who require more information.

Methodological note

Throughout this section, survival analysis is used to examine the length of time between a primary joint replacement and the first revision or the time between surgery and the patient's death. Survival analysis involves a shift from analysing people or operations to analysing time. It has the advantage of being able to handle the unequal lengths of time that people have been observed and so does not require those who have not been observed for a certain time period to be dropped from the analysis (as this can introduce bias). Aspects of this analysis (for example, the cumulative hazard or the cumulative incidence function) indicate the risk of an event happening over continuous time and so can be used to approximate incidence rates at certain time points.

Terminology note

The metal-on-metal group discussed in this section refers to patients with a stemmed prosthesis and metal bearing surfaces (a metal femoral head, a metal acetabular cup and, in some cases, a metal liner). Resurfacing procedures (where a surface replacement femoral prosthesis is combined with a metal acetabular cup) are treated as a separate category.

3.3.1 Outcomes: all-cause revision and mortality

This section considers the first revision after primary hip replacement (due to any cause) and, in addition, the risk of death following primary hip replacement. Analysis in this section is undertaken on the NJR-HES/PEDW linked data discussed in Section 3.2.

3.3.1.1 Prosthesis type

The risk of revision after primary hip replacement is shown in Figure 3.1 and summarised in Table 3.1 by the four main prosthesis types. Overall, revision rates were relatively low: only around 1.1% of primary hip replacements had been revised by one year after the primary surgery (Table 3.9). This rises to 2.3% at year three, 3.5% by year five, and 4.7% by year seven. In the first year following surgery, the risk of revision in the first 30 or 90 days was proportionally greater than in the remaining part of the year for all prosthesis

groups. However, overall this remained a small risk: the 30-day revision rate was 0.3% and the 90-day revision rate 0.6%.

However, there was substantial variation in revision rates according to prosthesis type with the lowest rates associated with cemented prostheses (3.1% at seven years) (Table 3.9). In contrast, revision rates for resurfacing procedures were almost four times higher (11.8% at seven years). The revision rate for uncemented prostheses was around twice that for cemented prostheses for the first five years whereas the revision rate for the hybrid group tended to lie between those of the cemented and uncemented groups (Figure 3.1).

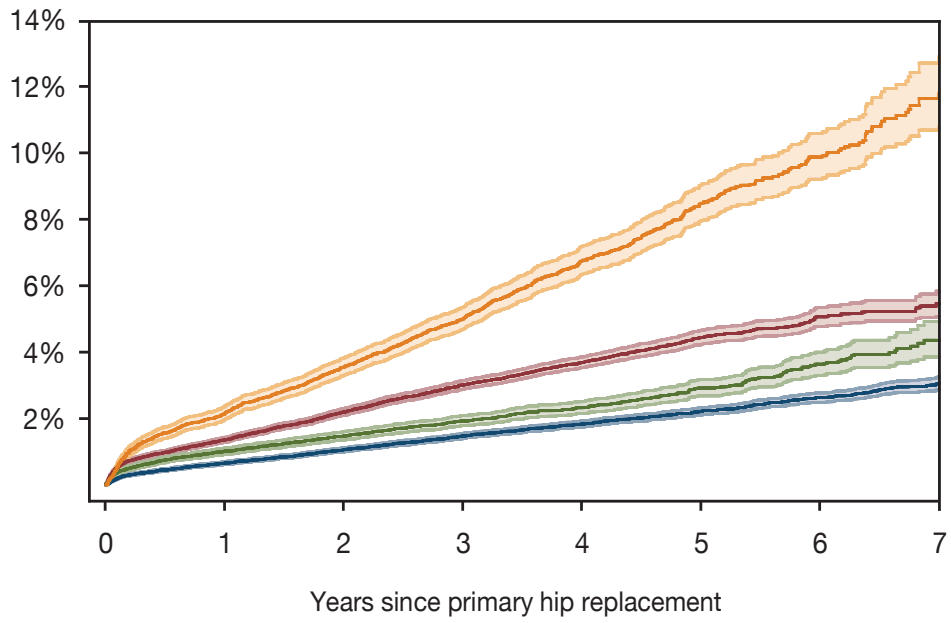


Figure 3.1

Risk of revision following primary hip replacement (cumulative hazard with 95% confidence intervals), by prosthesis type.

Table 3.9 Estimated revision rates following primary hip replacement, by prosthesis type (95% confidence intervals).

	Prosthesis type				All
	Cemented	Uncemented	Hybrid	Resurfacing	
30 days	0.18% (0.16%-0.21%)	0.50% (0.46%-0.55%)	0.36% (0.31%-0.42%)	0.45% (0.37%-0.55%)	0.34% (0.32%-0.36%)
90 days	0.34% (0.31%-0.38%)	0.78% (0.73%-0.84%)	0.56% (0.49%-0.63%)	1.13% (0.99%-1.28%)	0.58% (0.55%-0.61%)
Year 1	0.67% (0.62%-0.71%)	1.37% (1.30%-1.45%)	1.03% (0.93%-1.13%)	2.17% (1.98%-2.38%)	1.07% (1.03%-1.10%)
Year 2	1.07% (1.01%-1.13%)	2.20% (2.11%-2.31%)	1.48% (1.36%-1.61%)	3.55% (3.30%-3.83%)	1.69% (1.64%-1.74%)
Year 3	1.48% (1.41%-1.56%)	3.02% (2.89%-3.16%)	1.93% (1.79%-2.09%)	5.01% (4.69%-5.35%)	2.32% (2.25%-2.38%)
Year 4	1.84% (1.75%-1.93%)	3.70% (3.54%-3.86%)	2.34% (2.16%-2.53%)	6.74% (6.33%-7.18%)	2.89% (2.81%-2.97%)
Year 5	2.23% (2.12%-2.34%)	4.44% (4.24%-4.66%)	2.92% (2.69%-3.18%)	8.48% (7.95%-9.04%)	3.50% (3.40%-3.60%)
Year 6	2.64% (2.50%-2.78%)	5.07% (4.79%-5.35%)	3.64% (3.30%-4.01%)	9.88% (9.22%-10.59%)	4.07% (3.95%-4.20%)
Year 7	3.08% (2.89%-3.28%)	5.46% (5.09%-5.85%)	4.36% (3.86%-4.93%)	11.81% (10.80%-12.90%)	4.65% (4.48%-4.83%)
Base	132,511 (44.1%)	102,688 (34.2%)	43,933 (14.6%)	21,242 (7.1%)	300,374 (100%)

3.3.1.2 Bearing surfaces

The risk of revision by bearing surface is shown in Figure 3.2. There was little substantive difference between the ceramic-on-ceramic, ceramic-on-polyethylene and metal-on-polyethylene groups. However, the risk of revision for metal-on-metal and resurfacing prostheses was considerably higher than for other bearing surfaces. Metal-on-metal was close to the revision rate for resurfacing (also metal-on-metal) up to six years after surgery but then appears to overtake the resurfacing revision rate. This is because of a sharp increase in the risk of revision at around six years for the metal-on-metal group. As the width of the 95% confidence intervals indicate, these results should be interpreted cautiously at this stage as more data is needed to confirm this finding. The details are summarised in Table 3.10.

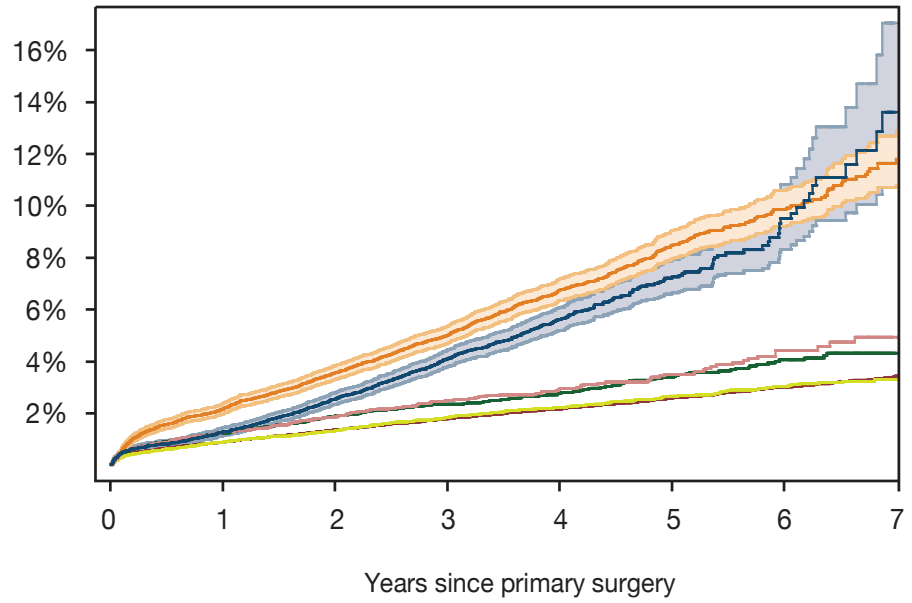


Figure 3.2

Risk of revision following primary hip replacement (cumulative hazard with 95% confidence intervals), by bearing surface.

- Resurfacing
- Metal-on-metal
- Metal-on-polyethylene
- Ceramic-on-polyethylene
- Ceramic-on-ceramic
- Other/unknown

Note: 95% confidence intervals are not shown for all groups due to overlap obscuring plot.

Table 3.10 Estimated revision rates following primary hip replacement, by bearing surface (95% confidence intervals).

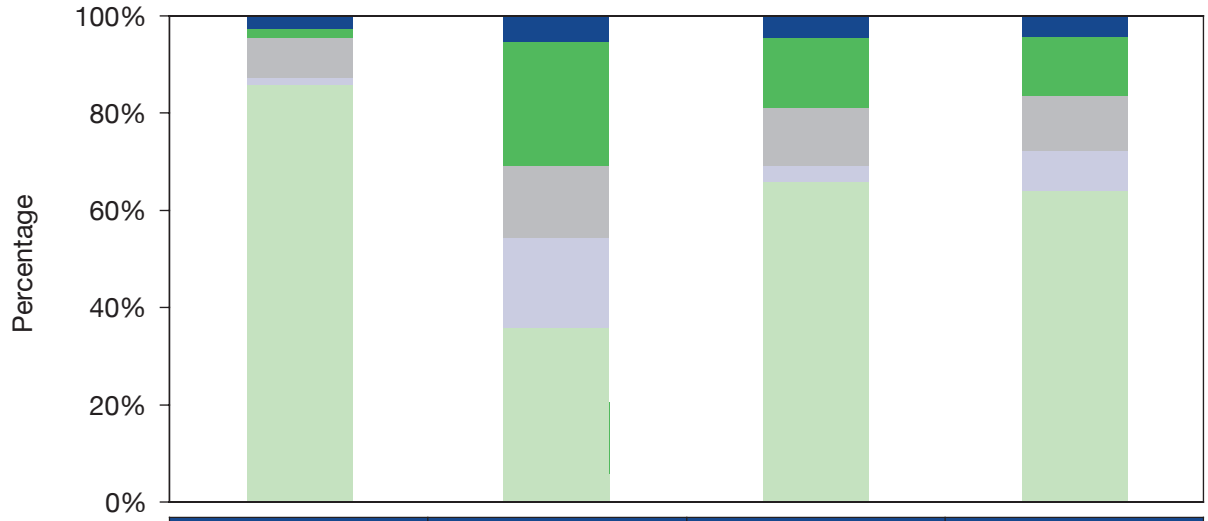
	Bearing surface					
	Resurfacing	Metal-on-metal	Metal-on-polyethylene	Ceramic-on-polyethylene	Ceramic-on-ceramic	Other/ unknown
30 days	0.45% (0.37%-0.55%)	0.43% (0.35%-0.53%)	0.30% (0.28%-0.33%)	0.27% (0.22%-0.34%)	0.39% (0.33%-0.46%)	0.51% (0.39%-0.66%)
90 days	1.13% (0.99%-1.28%)	0.67% (0.57%-0.78%)	0.50% (0.47%-0.53%)	0.45% (0.38%-0.53%)	0.68% (0.60%-0.78%)	0.68% (0.54%-0.85%)
Year 1	2.17% (1.98%-2.38%)	1.29% (1.15%-1.45%)	0.89% (0.85%-0.94%)	0.88% (0.78%-1.00%)	1.22% (1.10%-1.34%)	1.28% (1.08%-1.52%)
Year 2	3.55% (3.30%-3.83%)	2.55% (2.33%-2.79%)	1.35% (1.30%-1.41%)	1.33% (1.20%-1.48%)	1.89% (1.74%-2.06%)	1.85% (1.59%-2.14%)
Year 3	5.01% (4.69%-5.35%)	4.10% (3.79%-4.44%)	1.79% (1.72%-1.86%)	1.84% (1.67%-2.03%)	2.35% (2.16%-2.56%)	2.50% (2.18%-2.87%)
Year 4	6.74% (6.33%-7.18%)	5.62% (5.19%-6.08%)	2.17% (2.08%-2.25%)	2.22% (2.02%-2.44%)	2.78% (2.55%-3.03%)	2.95% (2.57%-3.39%)
Year 5	8.48% (7.95%-9.04%)	7.26% (6.64%-7.94%)	2.59% (2.49%-2.70%)	2.66% (2.42%-2.94%)	3.37% (3.06%-3.71%)	3.49% (3.02%-4.03%)
Year 6	9.88% (9.22%-10.59%)	9.50% (8.34%-10.83%)	3.02% (2.89%-3.15%)	3.03% (2.73%-3.37%)	4.06% (3.61%-4.56%)	4.42% (3.74%-5.22%)
Year 7	11.81% (10.80%-12.90%)	13.61% (10.86%-17.05%)	3.44% (3.26%-3.63%)	3.31% (2.94%-3.73%)	4.33% (3.80%-4.93%)	4.94% (4.08%-5.99%)
Base	21,242 (7.1%)	21,917 (7.3%)	179,838 (59.9%)	30,795 (10.2%)	35,296 (11.7%)	11,286 (3.8%)

Note: figures for all are those shown in Table 3.9.

There tended to be a relationship between prosthesis type and bearing surface (Figure 3.3). For example, 86.1% of cemented hips were recorded as metal-on-polyethylene compared with 35.6% of uncemented hips and 66.5% of hips with a hybrid fixation. Ceramic use was most commonly associated with uncemented (39.8%) or hybrid (26.8%) fixation.

Figure 3.3

Bearing surface of primary hip replacements by prosthesis type.



	Cemented (n=132,511)	Uncemented (n=102,688)	Hybrid (n=43,933)	All (n=279,132)
Other/ unknown	2.9%	5.7%	3.8%	4.0%
Ceramic-on -ceramic	1.8%	25.6%	15.1%	12.6%
Ceramic-on -polyethylene	8.4%	14.2%	11.7%	11.0%
Metal-on -metal	0.9%	18.9%	3.0%	7.9%
Metal-on -polyethylene	86.1%	35.6%	66.5%	64.4%

Metal-on-metal stemmed implants

Patients with metal-on-metal bearing surfaces comprise a relatively small group of the total hip replacements considered here (7.3%, with resurfacing accounting for another 7.1%). However, some studies have raised concerns about metal-on-metal implants in terms of higher revision rates and poorer patient outcomes (related to pain and function) compared with other bearing surfaces. In particular, there are concerns about the possibility of metal debris damage to soft tissue surrounding the joint (metallosis) and the uncertain effects of any release of cobalt and chromium ions into the patient's blood. Attention has tended to focus on whether these problems could be associated with the use of large diameter head sizes and on particular designs such as the ASR implants (the ASR XL Acetabular Hip System and ASR Hip Resurfacing System) which were voluntarily recalled by the manufacturer DePuy in August 2010.

The majority of metal-on-metal patients considered here had an uncemented fixation (88.7%) and most had a head size of at least 36mm (89.7%). Analysis in Table 3.11 breaks down the metal-on-metal group into four categories to compare small head metal-on-metal with large heads (36mm or above) split by whether a conventional modular cup or a resurfacing type cup was used. Results for the ASR cup are also shown separately. Clearly, the ASR results are

noticeably worse than other groups by two years post surgery but because these cases comprise less than 10% of the total, these results do not markedly distort the overall figures for the metal-on-metal group. This can be seen by comparing the non-ASR groups in Table 3.11 with the overall metal-on-metal figures. Revision rates for the small head metal-on-metal group and the large head conventional modular cup group were slightly lower than revision rates for those with a large head resurfacing cup. However, these rates remain higher than those of other bearing surfaces shown in Table 3.10. In addition, the sharp increase in the slope of the graph around year six for the overall metal-on-metal group observed in Figure 3.2 cannot simply be explained by the inclusion of ASR prostheses as there is still a marked increase in the slope of the graph at this time even when the ASR cases are excluded (Figure 3.4).

Table 3.11 Estimated revision rates following primary hip replacement for metal-on-metal prostheses (95% confidence intervals).

	Metal-on-metal type				
	Small head with conventional modular cup	Large head with conventional modular cup	Large head with resurfacing cup (excl. ASR)	Large head with ASR cup	All metal-on-metal stemmed prostheses
Year 1	1.23% (0.84%-1.79%)	1.38% (1.17%-1.63%)	1.18% (0.95%-1.48%)	1.24% (0.85%-1.82%)	1.29% (1.15%-1.45%)
Year 2	1.92% (1.41%-2.62%)	2.32% (2.03%-2.66%)	2.53% (2.15%-2.97%)	4.03% (3.23%-5.01%)	2.55% (2.33%-2.79%)
Year 3	2.92% (2.24%-3.82%)	3.47% (3.06%-3.93%)	4.10% (3.56%-4.71%)	7.50% (6.30%-8.92%)	4.10% (3.79%-4.44%)
Year 4	3.72% (2.87%-4.82%)	4.49% (3.94%-5.12%)	5.85% (5.08%-6.73%)	10.79% (9.16%-12.72%)	5.62% (5.19%-6.08%)
Year 5	4.74% (3.66%-6.15%)	5.17% (4.47%-5.96%)	7.48% (6.35%-8.81%)	17.16% (14.03%-21.00%)	7.26% (6.64%-7.94%)
Year 6	6.91% (5.20%-9.18%)	6.86% (5.25%-8.95%)	8.63% (6.78%-10.99%)	28.96% (17.80%-47.14%)	9.50% (8.34%-10.83%)
Base	2,250 (10.3%)	10,857 (49.5%)	6,694 (30.5%)	2,116 (9.7%)	21,917 (100%)

Note: numbers in the smaller sub-groups are too small to reliably estimate Year 7 revision rates. Small head refers to head diameter of less than 36mm. Large head refers to head diameter of 36mm or more.

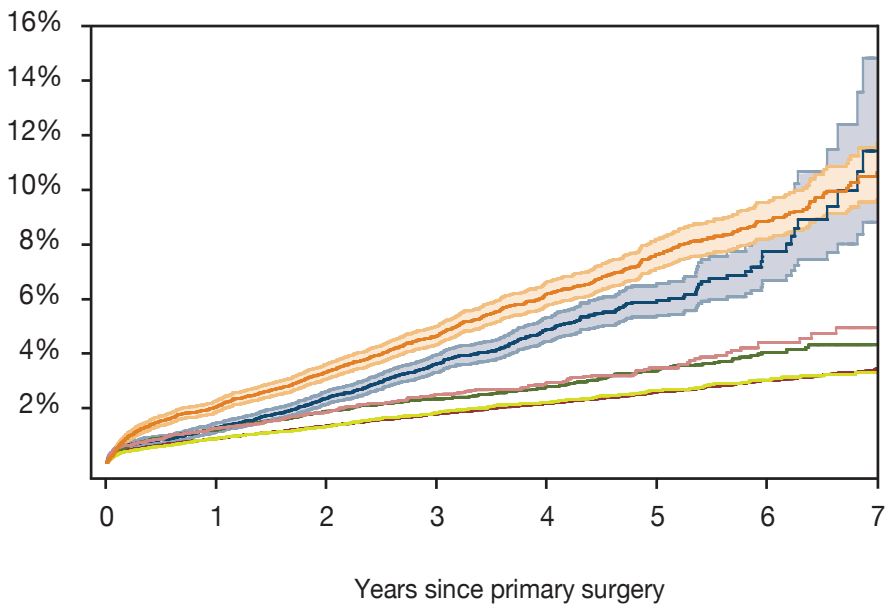


Figure 3.4

Risk of revision following primary hip replacement (cumulative hazard with 95% confidence intervals), by bearing surface excluding ASR brands.

3.3.1.3 A new classification for hip prostheses?

Given the much higher revision rates for the metal-on-metal group and the relationship between fixation method and the use of metal-on-metal, Table 3.12 and Figure 3.5 show an alternative classification for prosthesis type that separates metal-on-metal out of the cemented, uncemented, and hybrid groups. This reduces the revision rates for the uncemented (reduced from 5.5% to 4.6% at seven years) and hybrid groups (reduced from 4.4% to 3.8% at seven years) and so narrows the differences in revision rates observed in Table 3.9 between these groups and the cemented group.

Table 3.12 Estimated revision rates following primary hip replacement, by prosthesis type (95% confidence intervals).

	Prosthesis type				
	Cemented	Uncemented	Hybrid	Metal-on-metal stemmed prostheses	Resurfacing
90 days	0.34% (0.31%-0.37%)	0.80% (0.74%-0.86%)	0.57% (0.50%-0.64%)	0.67% (0.57%-0.78%)	1.13% (0.99%-1.28%)
Year 1	0.66% (0.62%-0.71%)	1.37% (1.29%-1.46%)	1.03% (0.94%-1.14%)	1.29% (1.15%-1.45%)	2.17% (1.98%-2.38%)
Year 2	1.06% (1.00%-1.12%)	2.07% (1.97%-2.18%)	1.48% (1.36%-1.61%)	2.55% (2.33%-2.79%)	3.55% (3.30%-3.83%)
Year 3	1.46% (1.39%-1.53%)	2.69% (2.56%-2.83%)	1.87% (1.72%-2.03%)	4.10% (3.79%-4.44%)	5.01% (4.69%-5.35%)
Year 4	1.81% (1.73%-1.91%)	3.17% (3.01%-3.34%)	2.20% (2.03%-2.39%)	5.62% (5.19%-6.08%)	6.74% (6.33%-7.18%)
Year 5	2.20% (2.09%-2.31%)	3.73% (3.53%-3.94%)	2.76% (2.53%-3.02%)	7.26% (6.64%-7.94%)	8.48% (7.95%-9.04%)
Year 6	2.60% (2.47%-2.75%)	4.23% (3.97%-4.50%)	3.38% (3.05%-3.74%)	9.50% (8.34%-10.83%)	9.88% (9.22%-10.59%)
Year 7	3.02% (2.84%-3.22%)	4.59% (4.23%-4.97%)	3.77% (3.35%-4.24%)	13.61% (10.86%-17.05%)	11.81% (10.80%-12.90%)
Base	131,345 (43.7%)	83,254 (27.7%)	42,616 (14.2%)	21,917 (7.3%)	21,242 (7.1%)

Note: figures for all can be found in Table 3.9.

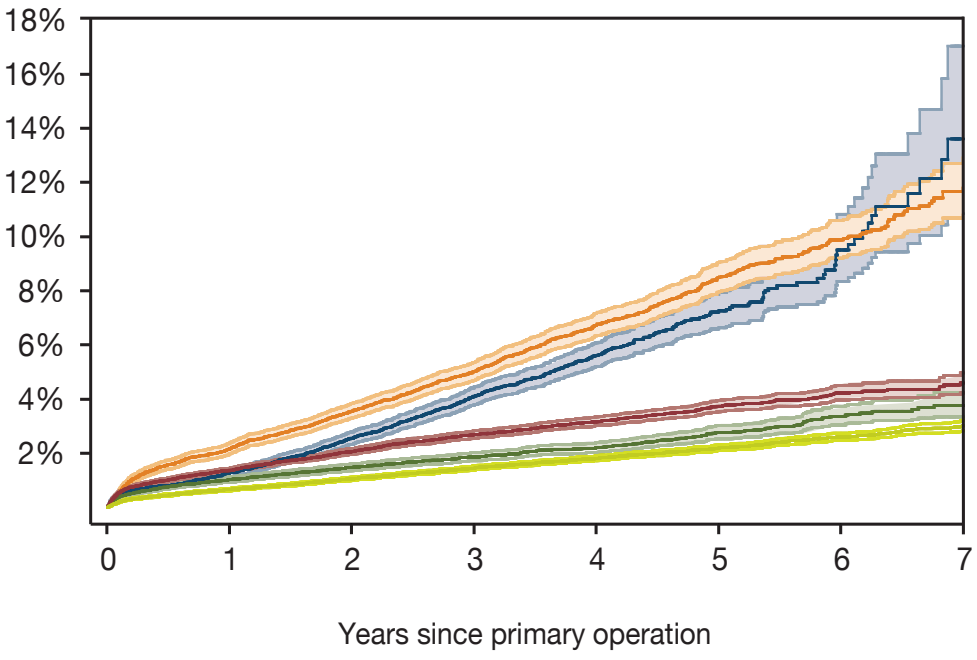


Figure 3.5

Risk of revision following primary hip replacement (cumulative hazard with 95% confidence intervals), by new prosthesis type grouping.

Another way of comparing the prosthesis groups is to look at the patient-time incidence rates (Table 3.13). This indicates that for the cohort we have been observing (those who had a primary hip replacement since 1st April 2003), the highest incidence of revision was for metal-on-metal hips with 1.73 revisions per 100 observed years. This is another way of saying that there has been approximately one revision per 58 years of use for metal-on-metal hips. This compares with one revision per 70 years for resurfacing hips, one revision per 106 years for uncemented hips, one per 152 years for hybrid hips and one every 204 years for cemented hips. Of course, these incidence rates are likely to change as the risk of revision increases over time.

Methodological note

The patient-time incidence rate divides the number of revisions by the total length of time the patients have been observed to be at risk of revision (that is the time between the date of primary surgery and the date of revision, date of death, or 31st December 2010). It is shown in the format of the number of revisions per hundred observed years. This is a standardised format that enables straightforward comparisons to be made between the prosthesis groups and it avoids the need to choose time-points at which to estimate incidence rates. However, it does not give any information about how the risk of revision might change over time and it, therefore, may be an inappropriate indicator of survivorship if the risk of revision is not constant and does vary substantially over time.

Table 3.13 Patient-time incidence rate of revision per 100 observed years following primary hip replacement, by new prosthesis grouping.

Prosthesis group	Total time observed (years)	Number of revisions	Patient-time incidence rate per 100 observed years	95% confidence interval
Cemented	426,559.9	2,095	0.49	(0.47 - 0.51)
Uncemented	208,616.9	1,964	0.94	(0.90 - 0.98)
Hybrid	119,510.9	790	0.66	(0.62 - 0.71)
Metal-on-metal	72,588.1	1,255	1.73	(1.64 - 1.83)
Resurfacing	61,170.1	867	1.42	(1.33 - 1.51)
All	888,445.9	6,971	0.78	(0.77 - 0.80)

3.3.1.4 Adjusting for other factors

It would be dangerous to make a simple comparison of the prosthesis types or bearing surfaces based on this descriptive analysis alone as it does not control for substantial differences between the groups in terms of patient characteristics. These are summarised in Table 3.14 and indicate that patients with a cemented prosthesis were more likely to be older, female, and in poorer health than were those in the other groups. Patients in the resurfacing group were notably younger and more commonly male than those in other groups. The use of ceramic-on-ceramic and metal-on-metal bearing surfaces was also associated with younger patients.

Table 3.14 Summary of patient characteristics by hip prosthesis type and bearing surface.

	Percentage of all	Mean age (years)	Percentage female	Percentage with osteoarthritis	Mean ASA score
Prosthesis type					
Cemented	44.1%	72.3	65.6%	93.9%	2.1
Uncemented	34.2%	64.8	57.1%	93.0%	1.9
Hybrid	14.6%	68.5	62.9%	91.0%	2.0
Resurfacing	7.1%	54.0	34.3%	93.7%	1.6
Bearing surface					
Metal-on-metal	7.3%	63.0	49.5%	92.0%	1.9
Metal-on-polyethylene	59.9%	72.5	64.9%	94.0%	2.1
Ceramic-on-polyethylene	11.8%	64.9	60.6%	92.7%	1.9
Ceramic-on-ceramic	10.2%	58.8	56.7%	90.7%	1.8
Other/unknown	3.8%	66.6	60.9%	91.0%	1.9
All (n=300,374)	100.0%	67.9	60.1%	93.2%	2.0

Note: bases for the prosthesis and bearing surface groups can be found in Tables 3.9 and 3.10. Bearing surface categorisation here excludes resurfacing to avoid duplication with the prosthesis type categorisation.

3.3.1.5 Risk of death

Previous NJR Annual Reports have shown patient characteristics to be related to the risk of revision so differences between the groups could distort any comparison of revision rates. In addition, these characteristics are also important because they affect the risk of another event happening instead of revision: the risk of death. This can also be estimated over time from survival analysis (Figure 3.6). Given the age of these patients, the risk of death in the years following a primary hip replacement is not trivial. In fact, for all patients except those in the resurfacing group, the risk of death over a particular year was higher than the risk of revision in that year (for all years between the date of surgery and seven years later). Overall, almost one in five (16.8%) of patients had died within seven years of their hip replacement (Table 3.15). The highest death rates were among the cemented group and the lowest were among the resurfacing group, reflecting the age distribution of these groups.

The overall risk of death in the first 30 days (0.3%) and 90 days (0.6%) after surgery was similar to the overall risk of revision in these periods.

Methodological note

Analysis in this section does not attempt to investigate whether hip replacement surgery is in itself associated with an increased risk of death. It is complex to disentangle the risk of death associated specifically with undergoing surgery from the risk of death more generally. The risk of death will vary for individual patients as it is known to strongly increase with age and is generally higher for males than females. Of course, the presence of illness and disease will also strongly influence the risk of death. Therefore, death in the years following hip replacement surgery would not be unexpected for some of the patients considered here. An analysis of all-cause mortality rates for England and Wales suggests a likely overall death rate by one year after surgery of around 3.2% (based on the age and gender distribution of these patients). Therefore, the observed overall death rate of 1.64% (Table 3.15) is lower than the expected death rate for these patients based on their age and gender alone. This is likely to reflect what has been observed in other research studies that patients undergoing joint replacement may be generally healthier than others of a comparable age and gender.

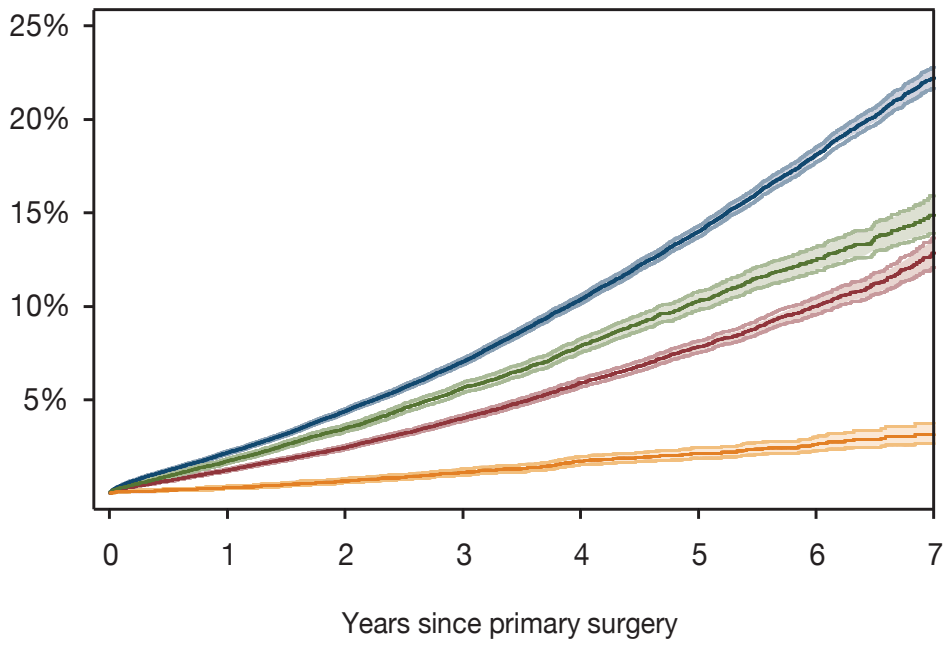


Figure 3.6

Risk of death following primary hip replacement (cumulative hazard with 95% confidence intervals), by prosthesis type.

Table 3.15 Estimated mortality rates following primary hip replacement, by prosthesis type (95% confidence intervals).

	Prosthesis type				All
	Cemented	Uncemented	Hybrid	Resurfacing	
30 days	0.36% (0.33%-0.39%)	0.20% (0.17%-0.23%)	0.27% (0.23%-0.32%)	0.07% (0.04%-0.11%)	0.27% (0.25%-0.29%)
90 days	0.75% (0.70%-0.80%)	0.40% (0.37%-0.44%)	0.52% (0.46%-0.60%)	0.10% (0.07%-0.16%)	0.55% (0.53%-0.58%)
Year 1	2.16% (2.08%-2.24%)	1.21% (1.14%-1.29%)	1.70% (1.58%-1.83%)	0.30% (0.23%-0.38%)	1.64% (1.59%-1.68%)
Year 2	4.35% (4.23%-4.47%)	2.39% (2.29%-2.51%)	3.41% (3.22%-3.61%)	0.65% (0.55%-0.78%)	3.29% (3.22%-3.36%)
Year 3	6.94% (6.78%-7.11%)	3.90% (3.75%-4.06%)	5.53% (5.27%-5.81%)	1.04% (0.90%-1.21%)	5.31% (5.21%-5.41%)
Year 4	10.21% (9.99%-10.44%)	5.72% (5.50%-5.94%)	7.71% (7.35%-8.08%)	1.62% (1.42%-1.85%)	7.80% (7.67%-7.94%)
Year 5	13.75% (13.46%-14.05%)	7.55% (7.25%-7.86%)	10.05% (9.58%-10.54%)	2.02% (1.77%-2.31%)	10.49% (10.31%-10.68%)
Year 6	17.77% (17.38%-18.17%)	9.59% (9.16%-10.04%)	12.13% (11.51%-12.78%)	2.46% (2.13%-2.84%)	13.55% (13.30%-13.81%)
Year 7	21.75% (21.20%-22.31%)	12.31% (11.57%-13.11%)	14.47% (13.55%-15.46%)	2.87% (2.44%-3.38%)	16.81% (16.43%-17.19%)
Base	132,511 (44.1%)	102,688 (34.2%)	43,933 (14.6%)	21,242 (7.1%)	300,374 (100%)

In terms of looking at the risk of revision, the possibility of death can be considered a competing risk in this context. Clearly, a patient cannot have a revision of their hip replacement if they are no longer alive.

Therefore, if we want to make valid comparisons between the prosthesis types, we need the analysis to control for differences in patient characteristics and to take account of the risk of death.

Methodological note

Standard survival analysis (based on Kaplan-Meier estimation) treats those who have died as censored. This means that the patient no longer contributes to the analysis once they have died; only the time observed between primary surgery and death (when they were at risk of revision) is counted in the analysis. Censoring is the correct approach for patients who have not been revised yet and where we have simply stopped observing them for now (such as the cut-off date of 31st December 2010 for this analysis). These patients are still at risk of revision in the future. In contrast, death is a permanent condition that prevents future revision from occurring altogether and so is a competing event to revision. Because competing events are different from standard censoring, standard survival analysis tends to overestimate the risk of the main event occurring. This inaccuracy gets cumulatively worse over time. Therefore, a new methodology – a competing-risks analysis – is required.

Therefore, analysis to control for differences in patient characteristics and to take account of the risk of death is a multi-variable competing risks flexible parametric proportional hazards model where risk of revision is the main risk and risk of death is treated as a competing risk. Patient characteristics of age, gender, ASA and diagnosis at time of primary operation are treated as covariates in the model that can independently affect the risk of revision and the risk of death. Prosthesis type and bearing surface have been treated as possible predictors for the risk of revision but not for the risk of death. This analysis produces an adjusted cumulative incidence function that can be used to estimate revision rates in the face of a competing risk of death. In order to illustrate differences between the prosthesis types, the values of other covariates in the model need to be held constant.

Based on the findings so far, prosthesis type and bearing surface has been based on the new grouping in Table 3.12 which treats metal-on-metal implants as a distinct category. Age has been grouped into three groups: less than 60 years, 60-69 years, and 70 or over. These groups were chosen to give large enough numbers in each prosthesis group to allow meaningful comparisons.

3.3.1.6 Adjusting for the competing risk of death

The effect of the competing risk of death on revision rates is illustrated in Figure 3.7. This effect can be clearly seen by around three years following primary surgery as the lines start to diverge. This discrepancy increases over time as the lines move further apart which means that unadjusted analysis will overestimate revision rates for later time points. For example, the seven-year overall revision rate of 4.65% in Table 3.9 is adjusted to 4.26% when the competing risk of death is taken into account (a reduction of around 8%). This type of effect was seen across all the prosthesis groups. In summary, while this is unlikely to be substantially affecting the revision rates discussed earlier, adjusting for the competing risk of death is likely to become more important over the life of the registry.

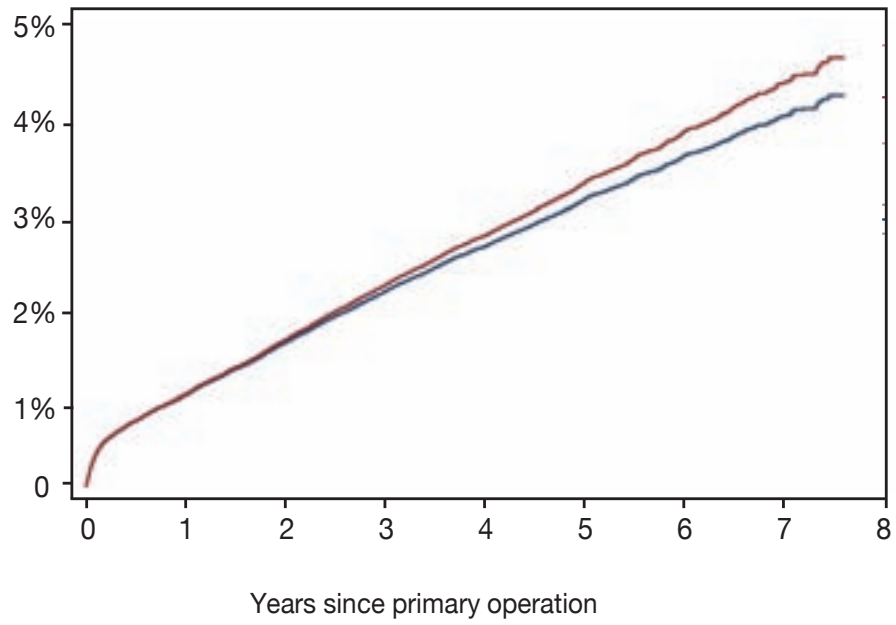


Figure 3.7

Cumulative incidence of revision following primary hip replacement adjusted for the competing risk of death.

3.3.1.7 Adjusted revision rates

Estimated revision rates, adjusted for patient characteristics and the competing risk of death, are shown in Tables 3.16, 3.17 and 3.18 for a typical patient (a person with osteoarthritis and an ASA score of one or two) and split by age group and gender. The results are summarised for each age group below.

For patients aged under 60 (Table 3.16):

- revision rates for the cemented and hybrid groups were the lowest and were very similar to each other. This suggests that hybrid fixation is as successful as cemented fixation for patients aged under 60 and that either of these techniques results in the lowest revision rates in the first five years after surgery. Uncemented revision rates were slightly higher but the difference was very small (smaller than that observed in the unadjusted analysis earlier).
- revision rates for the resurfacing and metal-on-metal groups were significantly higher than for other groups indicating that the differences in revision rates observed earlier cannot simply be explained by the different characteristics of the patients.
- revision rates tended to be slightly lower for women than for men in the cemented, uncemented and hybrid groups.
- in contrast, revision rates for women in the resurfacing and metal-on-metal groups were significantly higher than those for men in those groups. With a five-year revision rate of around 10%, resurfacing can hardly be considered a successful technique for women aged under 60.
- revision rates for metal-on-metal at five years were around twice that of the cemented and hybrid groups for men and over three times as high for women.

Table 3.16 Estimated revision rates by hip prosthesis type (based on adjusted multivariable competing risks model for a patient aged under 60 with ASA<3 and osteoarthritis) (95% confidence intervals).

	Prosthesis type				
	Cemented	Uncemented	Hybrid	Resurfacing	Metal-on-metal stemmed prostheses
Male aged under 60					
Year 1	1.05% (0.91%-1.22%)	1.37% (1.23%-1.54%)	1.06% (0.87%-1.31%)	1.68% (1.50%-1.88%)	1.28% (1.10%-1.50%)
Year 3	2.12% (1.84%-2.44%)	2.67% (2.40%-2.96%)	1.89% (1.55%-2.29%)	3.74% (3.41%-4.10%)	3.73% (3.27%-4.26%)
Year 5	3.25% (2.83%-3.73%)	3.64% (3.28%-4.04%)	2.79% (2.30%-3.37%)	6.05% (5.55%-6.60%)	6.70% (5.88%-7.62%)
Base	3,076	7,171	1,943	8,765	3,223
Female aged under 60					
Year 1	0.83% (0.72%-0.96%)	1.23% (1.11%-1.37%)	0.83% (0.68%-1.01%)	2.91% (2.61%-3.25%)	1.72% (1.48%-2.01%)
Year 3	1.67% (1.45%-1.92%)	2.40% (2.17%-2.65%)	1.48% (1.22%-1.79%)	6.43% (5.88%-7.03%)	4.99% (4.40%-5.65%)
Year 5	2.57% (2.24%-2.95%)	3.27% (2.96%-3.62%)	2.19% (1.82%-2.64%)	10.33% (9.50%-11.22%)	8.92% (7.90%-10.06%)
Base	4,742	10,342	3,315	4,880	2,854

For patients aged 60-69 years (Table 3.17):

- revision rates were lowest for the cemented group. However, revision rates for the hybrid group were only slightly higher and where there are overlapping 95% confidence intervals, these differences may not be statistically significant. Uncemented revision rates were slightly higher again but again observed differences were smaller than those in the unadjusted analysis.
- revision rates for the resurfacing and metal-on-metal groups were significantly higher than for other groups. Again, the higher revision rates shown earlier cannot simply be explained away by the variation in patient characteristics.
- revision rates for women were significantly higher than those for men in the resurfacing and metal-on-metal groups. Around one in eight women aged 60-69 years with a resurfacing had been revised within five years.
- as seen with the under 60 year olds, revision rates for metal-on-metal at five years were around twice that of the cemented and hybrid groups for men and over three times as high for women.
- as before, revision rates tended to be slightly lower for women than for men in the cemented, uncemented and hybrid groups.

Table 3.17 Estimated revision rates by hip prosthesis type (based on adjusted multivariable competing risks model for a patient aged 60-69 years with ASA<3 and osteoarthritis) (95% confidence intervals).

	Prosthesis type				
	Cemented	Uncemented	Hybrid	Resurfacing	Metal-on-metal stemmed prostheses
Male aged 60-69 years					
Year 1	0.83% (0.75%-0.92%)	1.35% (1.22%-1.48%)	1.14% (0.97%-1.33%)	1.98% (1.73%-2.26%)	1.06% (0.90%-1.24%)
Year 3	1.67% (1.52%-1.83%)	2.60% (2.38%-2.84%)	2.02% (1.74%-2.33%)	4.38% (3.89%-4.93%)	3.06% (2.67%-3.51%)
Year 5	2.55% (2.33%-2.80%)	3.53% (3.26%-3.86%)	2.96% (2.57%-3.41%)	7.06% (6.30%-7.90%)	5.48% (4.78%-6.27%)
Base	10,532	11,124	4,331	3,513	3,530
Female aged 60-69 years					
Year 1	0.65% (0.59%-0.72%)	1.21% (1.10%-1.32%)	0.89% (0.77%-1.03%)	3.42% (2.97%-3.94%)	1.42% (1.22%-1.65%)
Year 3	1.32% (1.21%-1.44%)	2.34% (2.15%-2.54%)	1.58% (1.38%-1.81%)	7.52% (6.64%-8.51%)	4.11% (3.62%-4.66%)
Year 5	2.02% (1.86%-2.20%)	3.19% (2.93%-3.47%)	2.33% (2.04%-2.67%)	12.01% (10.67%-13.48%)	7.34% (6.47%-8.32%)
Base	17,591	15,390	7,014	1,340	3,315

For patients aged 70 or over (Table 3.18):

- differences in revision rates between the cemented group (with the lowest rates) and the hybrid and uncemented groups are now more apparent, suggesting that cemented fixation is the most successful (in terms of revision rates by five years) for older patients.
- as seen before, revision rates for women in the cemented, uncemented and hybrid groups tended to be lower than for men in these groups.
- resurfacing remained the least successful operation in terms of five-year revision rates, although numbers receiving this type of surgery were small in this age group.
- as seen with the other age groups, revision rates for metal-on-metal at five years were around twice that of the cemented and hybrid groups for men and over three times as high for women.

Table 3.18 Estimated revision rates by hip prosthesis type (based on adjusted multivariable competing risks model for a patient aged 70+ years with ASA<3 and osteoarthritis) (95% confidence intervals).

	Prosthesis type				
	Cemented	Uncemented	Hybrid	Resurfacing	Metal-on-metal stemmed prostheses
Male aged 70+ years					
Year 1	0.71% (0.65%-0.78%)	1.37% (1.24%-1.53%)	1.15% (0.99%-1.35%)	1.38% (0.95%-2.01%)	1.01% (0.84%-1.23%)
Year 3	1.41% (1.29%-1.54%)	2.63% (2.38%-2.90%)	2.02% (1.75%-2.33%)	3.05% (2.12%-4.37%)	2.89% (2.42%-3.43%)
Year 5	2.11% (1.94%-2.30%)	3.53% (3.20%-3.89%)	2.91% (2.53%-3.36%)	4.87% (3.42%-6.90%)	5.05% (4.25%-6.86%)
Base	21,172	9,547	5,543	379	2,091
Female aged 70+ years					
Year 1	0.56% (0.52%-0.61%)	1.23% (1.12%-1.37%)	0.90% (0.78%-1.04%)	3.05% (2.12%-4.37%)	1.36% (1.14%-1.63%)
Year 3	1.12% (1.04%-1.21%)	2.37% (1.27%-2.60%)	1.59% (1.39%-1.81%)	5.28% (3.69%-7.52%)	3.90% (3.32%-4.58%)
Year 5	1.69% (1.58%-1.82%)	3.21% (2.92%-3.51%)	2.31% (2.03%-2.63%)	8.40% (5.93%-11.80%)	6.86% (5.85%-8.03%)
Base	44,576	14,456	10,380	211	2,569

3.3.2 Comparison of NJR and NJR-HES/PEDW revision rates

This section compares the NJR-HES/PEDW revision rates discussed in Section 3.3.1 with those calculated from NJR data alone. To make a valid comparison, analysis is undertaken on the same set of patients (where we have both NJR and HES/PEDW data) and includes revisions for all causes. Section 3.2 discusses these two data sources in more detail. To briefly summarise, it is possible that NJR underestimates revisions to some undetermined extent. However, the HES/PEDW data is likely to overestimate revisions to some degree because of the inclusion of some re-operations as revisions. It is likely then that the "real" revision rate lies somewhere between the two rates presented in Table 3.19.

Revision rates identified with NJR data alone were generally lower than those calculated with additional HES/PEDW data across all time periods and prosthesis groups (Table 3.19). NJR revision rates ranged from between 65% and 78% of the value of the NJR-HES/PEDW revision rate for the same time period and prosthesis group. Generally, the three-, five- and seven-year revision rates across the two data sources were more similar. This is probably because the extra revisions being identified from HES/PEDW are disproportionately early revisions (see Section 3.2.2.2). However, despite the divergences, it is reassuring that both data sources show the same general trends in revision rates over time and between prosthesis groups.

Table 3.19 Comparison of NJR-HES/PEDW and NJR all-cause revision rates, by hip prosthesis type (95% confidence intervals).

	90 days	Year 1	Year 3	Year 5	Year 7
Cemented					
NJR-HES/PEDW	0.34% (0.31%-0.38%)	0.67% (0.62%-0.71%)	1.48% (1.41%-1.56%)	2.23% (2.12%-2.34%)	3.08% (2.89%-3.28%)
NJR	0.22% (0.19%-0.25%)	0.44% (0.40%-0.48%)	1.04% (0.98%-1.11%)	1.60% (1.51%-1.70%)	2.22% (2.06%-2.39%)
Uncemented					
NJR-HES/PEDW	0.78% (0.73%-0.84%)	1.37% (1.30%-1.45%)	3.02% (2.89%-3.16%)	4.44% (4.24%-4.66%)	5.46% (5.09%-5.85%)
NJR	0.52% (0.48%-0.57%)	0.96% (0.90%-1.02%)	2.21% (2.10%-2.33%)	3.27% (3.09%-3.46%)	4.07% (3.74%-4.43%)
Hybrid					
NJR-HES/PEDW	0.56% (0.49%-0.63%)	1.03% (0.93%-1.13%)	1.93% (1.79%-2.09%)	2.92% (2.69%-3.18%)	4.36% (3.86%-4.93%)
NJR	0.38% (0.33%-0.45%)	0.70% (0.63%-0.79%)	1.42% (1.30%-1.56%)	2.27% (2.06%-2.51%)	3.41% (2.96%-3.93%)
Resurfacing					
NJR-HES/PEDW	1.13% (0.99%-1.28%)	2.17% (1.98%-2.38%)	5.01% (4.69%-5.35%)	8.48% (7.95%-9.04%)	11.81% (10.80%-12.90%)
NJR	0.79% (0.68%-0.92%)	1.53% (1.37%-1.71%)	3.76% (3.48%-4.06%)	6.40% (5.95%-6.89%)	8.99% (8.12%-9.95%)
All					
NJR-HES/PEDW	0.58% (0.55%-0.61%)	1.07% (1.03%-1.10%)	2.32% (2.25%-2.38%)	3.50% (3.40%-3.60%)	4.65% (4.48%-4.83%)
NJR	0.39% (0.37%-0.41%)	0.73% (0.70%-0.76%)	1.69% (1.63%-1.74%)	2.59% (2.51%-2.68%)	3.47% (3.32%-3.62%)

Note: bases are those in Table 3.9.

3.3.3 NJR revision rates excluding those for infection

This section briefly considers revisions other than for infection. Analysis is based on NJR data only and excludes revisions undertaken for infection (these patients are treated as no longer observed at the point they have a revision for infection). It should be remembered that unlike the NJR-HES/PEDW data used earlier, the NJR data includes independently-funded patients and others that could not be matched to HES/PEDW so it is a larger and more representative dataset.

Infection was the reason for revision for 20.3% of the patients considered here (those with a linked primary and first revision in NJR). Other reasons for revision included aseptic loosening (26.7%), dislocation/subluxation (22.1%), pain (20.8%), periprosthetic fracture (12.6%), malalignment (10.6%), lysis (4.3%), and failure of the implant or liner (6.6%). More than one reason for revision could be chosen. These results will not be representative of reasons for all revisions. For example, infection is more likely to occur in the early years after primary surgery whereas aseptic loosening often occurs later. Therefore, at this relatively early stage of the registry, an analysis of all

revisions could be affected by the disproportionate number that was revised for infection. A major advantage of NJR is that, unlike HES/PEDW, it is possible to identify revisions for infection.

The proportion of revisions that were due to infection varied by prosthesis group. For example, 30.7% of revisions for cemented implants were revised for infection compared with 17.1% of the uncemented group and 23.2% of the hybrid group. The equivalent figure for the resurfacing group was 10.5%. This result should not be interpreted as suggesting that the use of cement increases the risk of infection as it may simply reflect that other methods of failure were less common among cemented implants. The type of cement used for these hip replacements was mainly antibiotic loaded (92.6%).

Revision rates other than for infection are summarised in Table 3.20 and compared with NJR revision rates for all causes. Overall, revision rates other than for infection were lower than all-cause revision rates at all time periods although the extent varied across prosthesis groups. Excluding revisions for infection reduced the revision rates proportionately more for cemented hips than for other groups.

Table 3.20 Estimated incidence rates for all-cause revision and revision other than for infection, by hip prosthesis type (95% confidence intervals).

	90 days	Year 1	Year 3	Year 5	Year 7
Cemented (n=163,981)					
All revisions	0.21% (0.19%-0.23%)	0.42% (0.39%-0.45%)	0.95% (0.90%-1.00%)	1.41% (1.33%-1.49%)	1.94% (1.81%-2.08%)
Excluding infection	0.17% (0.15%-0.19%)	0.29% (0.27%-0.32%)	0.62% (0.58%-0.67%)	0.97% (0.91%-1.04%)	1.44% (1.32%-1.57%)
Uncemented (n=130,920)					
All revisions	0.51% (0.47%-0.55%)	0.93% (0.88%-0.98%)	2.04% (1.95%-2.14%)	2.95% (2.80%-3.10%)	3.74% (3.45%-4.04%)
Excluding infection	0.45% (0.42%-0.49%)	0.78% (0.73%-0.83%)	1.67% (1.58%-1.76%)	2.44% (2.30%-2.57%)	3.15% (2.88%-3.43%)
Hybrid (n=55,551)					
All revisions	0.34% (0.29%-0.39%)	0.62% (0.55%-0.69%)	1.26% (1.16%-1.38%)	1.96% (1.79%-2.15%)	2.86% (2.52%-3.24%)
Excluding infection	0.26% (0.22%-0.31%)	0.47% (0.41%-0.53%)	0.95% (0.86%-1.05%)	1.53% (1.38%-1.70%)	2.25% (1.94%-2.60%)
Resurfacing (n=34,308)					
All revisions	0.64% (0.56%-0.73%)	1.26% (1.14%-1.38%)	2.95% (2.76%-3.16%)	4.87% (4.57%-5.19%)	6.62% (6.09%-7.19%)
Excluding infection	0.58% (0.50%-0.67%)	1.14% (1.03%-1.26%)	2.60% (2.42%-2.80%)	4.35% (4.07%-4.66%)	5.98% (5.48%-6.54%)
All (n=384,760)					
All revisions	0.37% (0.35%-0.39%)	0.69% (0.67%-0.72%)	1.54% (1.49%-1.58%)	2.30% (2.24%-2.37%)	3.07% (2.95%-3.19%)
Excluding infection	0.32% (0.30%-0.34%)	0.56% (0.54%-0.58%)	1.20% (1.16%-1.24%)	1.84% (1.78%-1.90%)	2.52% (2.40%-2.64%)

3.3.4 Revision rates for main implant brands

Analysis in this section is based on NJR data only.

This is a different approach from previous NJR Annual Reports and the reasons for this are discussed in Section 3.2. Revision rates are shown both for revisions excluding those for infection and for all-cause revisions.

Methodological note

In this section, revision rates are shown excluding revisions undertaken for infection. This is not to suggest that choice of brand is completely unrelated to the risk of infection, but the early time period after primary surgery considered here means that there is an over-representation of revisions for infection that could skew the results. However, because of a greater proportion of revisions being done for infection, excluding revisions for infection disproportionately reduces revision rates for cemented implants. In addition, for revisions of metal-on-metal implants, it is believed that a number of metallosis cases (where fluid was present) were initially incorrectly diagnosed and recorded as infected (as it is difficult to accurately diagnose infection until microbiology results are received in the weeks following revision surgery). Therefore, the infection-excluded analysis could inadvertently be more favourable to metal-on-metal and cemented prostheses. For this reason, the all-cause revision rates are also shown in this section.

As any part of a hip replacement could cause the need for revision, analysis here considers stem and cup combinations rather than looking at stems and cups in isolation. Revision rates at one, three and five years are presented. Although NJR contains data to seven years after primary surgery, when the data is split into relatively small sub-groups like brands, there is not enough data to reliably estimate seven-year revision rates. Analysis is only shown for brands with at least 2,500 patients. This cut-off point was chosen because analysis based on fewer patients results in more uncertain estimations (demonstrated by wide confidence intervals) which make any comparisons problematic. Because of a smaller initial group size for resurfacing patients, this cut-off point has been reduced to 1,000 patients for the analysis of resurfacing brands but this does result in some very wide confidence intervals and so comparisons should be made cautiously.

In addition, the analysis here is unadjusted in that it does not control for patient characteristics or any other factors that could influence revision rates. It should be noted that there may be variations in revision rates within a particular brand grouping such as with modular uncemented cups, where products may differ in the relative proportions of different bearing types. Overlapping 95% confidence intervals mean that differences are not statistically significant and so could simply reflect random variation.

Stem and cup combinations

There were 935 different combinations of stems and cups used for these primary total hip replacements. Only results for those with at least 2,500 patients are shown here. These have been grouped into five main types according to design and fixation. Comparison of brands within these groupings shows little substantive difference between the brands, particularly when the 95% confidence intervals are taken into account (Table 3.21 and Table 3.22). For example, all-cause revision rates for cemented hips were 1.41% at five years (Table 3.20) whereas the lowest revision rate in this group was the Exeter V40 stem with the Elite Plus Cemented Cup (0.70% at five years, Table 3.22). All-cause revision rates for uncemented hip prostheses were 2.95% at five years (Table 3.20) while the most commonly used uncemented combination (the Corail stem with a Pinnacle cup) had a revision rate of 2.29% at five years (Table 3.22).

As reported earlier, cemented stems and cups tended to have lower revision rates than did hybrid and uncemented combinations. However, as seen in Table 3.20, excluding revisions for infection tended to reduce revision rates proportionately more for cemented combinations than for uncemented and hybrid combinations.

Table 3.21 Revision rates (excluding for infection) for main hip stem and cup combinations (95% confidence intervals).

Combination: stem, cup	Number of patients	Revision rate at 1 year	Revision rate at 3 years	Revision rate at 5 years
Cemented composite beam stems and cemented cups				
Charnley Cemented Stem, Charnley Cemented Cup	9,209	0.16% (0.09%-0.26%)	0.44% (0.31%-0.61%)	0.89% (0.68%-1.15%)
Charnley Cemented Stem, Charnley Ogee	7,958	0.16% (0.09%-0.27%)	0.58% (0.42%-0.79%)	0.95% (0.72%-1.25%)
Stanmore Modular, Stanmore-Arcom	2,718	0.26% (0.13%-0.55%)	0.57% (0.33%-1.00%)	0.69% (0.39%-1.21%)
Cemented taper slip stems and cemented cups				
C-Stem Cemented Stem, Elite Plus Ogee	3,036	0.31% (0.16%-0.59%)	0.66% (0.42%-1.06%)	0.90% (0.57%-1.44%)
CPT, ZCA	5,798	0.49% (0.33%-0.71%)	0.83% (0.60%-1.14%)	1.39% (1.02%-1.90%)
Exeter V40, Contemporary	37,995	0.27% (0.22%-0.33%)	0.60% (0.52%-0.70%)	0.92% (0.78%-1.08%)
Exeter V40, Elite Plus Cemented Cup	4,155	0.18% (0.09%-0.39%)	0.42% (0.24%-0.73%)	0.42% (0.24%-0.73%)
Exeter V40, Elite Plus Ogee	13,246	0.16% (0.10%-0.25%)	0.35% (0.25%-0.49%)	0.58% (0.42%-0.79%)
Exeter V40, Exeter Duration	11,267	0.43% (0.32%-0.57%)	0.71% (0.56%-0.90%)	1.25% (1.01%-1.56%)
Cemented taper slip stems and uncemented cups				
CPT, Trilogy	5,602	0.61% (0.44%-0.86%)	0.89% (0.66%-1.20%)	1.46% (1.05%-2.02%)
Exeter V40, Trident	18,358	0.39% (0.31%-0.49%)	0.73% (0.60%-0.89%)	1.26% (0.99%-1.59%)
Exeter V40, Trilogy	7,791	0.36% (0.25%-0.53%)	0.71% (0.53%-0.96%)	1.09% (0.81%-1.47%)
Uncemented stems and uncemented cups				
Accolade, Trident	10,021	0.82% (0.65%-1.03%)	1.60% (1.30%-1.95%)	2.12% (1.61%-2.79%)
Corail, Duraloc Cementless Cup	4,333	0.58% (0.42%-0.79%)	1.31% (0.99%-1.74%)	1.91% (1.46%-2.48%)
Corail, Pinnacle	40,879	0.63% (0.56%-0.72%)	1.42% (1.28%-1.58%)	1.85% (1.63%-2.10%)
Furlong HAC, CSF	13,330	0.78% (0.64%-0.95%)	1.40% (1.20%-1.63%)	1.81% (1.56%-2.09%)
Furlong HAC, CSF Plus	6,357	0.98% (0.75%-1.29%)	1.87% (1.41%-2.49%)	-
SL-Plus Cementless Stem, EPF-Plus	3,583	0.90% (0.64%-1.29%)	2.15% (1.67%-2.78%)	3.60% (2.72%-4.76%)
Taperloc Cementless Stem, Exceed	4,959	0.66% (0.46%-0.94%)	1.30% (0.92%-1.84%)	1.47% (1.01%-2.16%)
Uncemented stems and resurfacing cup				
Corail, ASR Resurfacing Cup	2,540	0.74% (0.47%-1.17%)	3.76% (3.02%-4.68%)	9.13% (7.18%-11.60%)
Other				
Other combination	97,307	0.53% (0.49%-0.58%)	1.13% (1.05%-1.21%)	1.65% (1.54%-1.76%)
Unknown combination	38,926	0.62% (0.54%-0.71%)	1.17% (1.05%-1.31%)	1.78% (1.60%-1.99%)
All	349,368	0.50% (0.48%-0.53%)	1.04% (1.00%-1.08%)	1.54% (1.48%-1.60%)

Note: for newer brands it is not always possible to estimate five-year revision rates.

Table 3.22 Revision rates (all causes) for main hip stem and cup combinations (95% confidence intervals).

Combination: stem, cup	Number of patients	Revision rate at 1 year	Revision rate at 3 years	Revision rate at 5 years
Cemented composite beam stems and cemented cups				
Charnley Cemented Stem, Charnley Cemented Cup	9,209	0.29% (0.20%-0.43%)	0.80% (0.63%-1.02%)	1.38% (1.12%-1.69%)
Charnley Cemented Stem, Charnley Ogee	7,958	0.33% (0.22%-0.48%)	1.12% (0.89%-1.40%)	1.71% (1.40%-2.10%)
Stanmore Modular, Stanmore-Arcom	2,718	0.26% (0.13%-0.55%)	0.83% (0.52%-1.34%)	1.10% (0.67%-1.80%)
Cemented taper slip stems and cemented cups				
C-Stem Cemented Stem, Elite Plus Ogee	3,036	0.48% (0.28%-0.80%)	0.92% (0.62%-1.36%)	1.22% (0.82%-1.80%)
CPT, ZCA	5,798	0.63% (0.45%-0.88%)	1.04% (0.79%-1.38%)	1.68% (1.27%-2.22%)
Exeter V40, Contemporary	37,995	0.38% (0.32%-0.45%)	0.86% (0.76%-0.98%)	1.26% (1.10%-1.44%)
Exeter V40, Elite Plus Cemented Cup	4,155	0.29% (0.16%-0.53%)	0.64% (0.41%-1.00%)	0.70% (0.45%-1.09%)
Exeter V40, Elite Plus Ogee	13,246	0.26% (0.18%-0.36%)	0.67% (0.53%-0.86%)	0.98% (0.78%-1.23%)
Exeter V40, Exeter Duration	11,267	0.54% (0.42%-0.70%)	1.04% (0.85%-1.27%)	1.64% (1.36%-1.98%)
Cemented taper slip stems and uncemented cups				
CPT, Trilogy	5,602	0.78% (0.58%-1.06%)	1.13% (0.58%-1.06%)	1.83% (1.37%-2.45%)
Exeter V40, Trident	18,358	0.52% (0.42%-0.64%)	1.01% (0.85%-1.20%)	1.69% (1.39%-2.07%)
Exeter V40, Trilogy	7,791	0.50% (0.36%-0.69%)	0.96% (0.75%-1.20%)	1.35% (1.04%-1.75%)
Uncemented stems and uncemented cups				
Accolade, Trident	10,021	0.96% (0.77%-1.18%)	1.83% (1.52%-2.21%)	2.35% (1.83%-3.02%)
Corail, Duraloc Cementless Cup	4,333	0.75% (0.53%-1.07%)	1.77% (1.38%-2.26%)	2.56% (2.04%-3.22%)
Corail, Pinnacle	40,879	0.75% (0.67%-0.85%)	1.73% (1.57%-1.91%)	2.29% (2.04%-2.57%)
Furlong HAC, CSF	13,330	0.89% (0.74%-1.07%)	1.58% (1.37%-1.83%)	2.03% (1.77%-2.33%)
Furlong HAC, CSF Plus	6,357	1.21% (0.95%-1.54%)	2.10% (1.61%-2.73%)	-
SL-Plus Cementless Stem, EPF-Plus	3,583	1.16% (0.85%-1.58%)	2.82% (2.26%-3.52%)	4.52% (3.54%-5.77%)
Taperloc Cementless Stem, Exceed	4,959	0.80% (0.57%-1.11%)	1.44% (1.04%-1.99%)	1.61% (1.13%-2.30%)
Uncemented stems and resurfacing cup				
Corail, ASR Resurfacing Cup	2,540	0.94% (0.63%-1.40%)	4.84% (3.99%-5.87%)	11.34% (9.06%-14.18%)
Other				
Other combination	97,307	0.67% (0.62%-0.72%)	1.51% (1.42%-1.60%)	2.16% (2.04%-2.29%)
Unknown combination	38,926	0.77% (0.69%-0.87%)	1.52% (1.38%-1.68%)	2.26% (2.06%-2.49%)
All	349,368	0.64% (0.61%-0.66%)	1.38% (1.33%-1.42%)	2.00% (1.93%-2.06%)

Note: for newer brands it is not always possible to estimate five-year revision rates.

Resurfacing brands

Tables 3.23 and 3.24 show revision rates for the main resurfacing brands (those with at least 1,000 patients). Revision rates were lowest for the Birmingham Hip Resurfacing (BHR) system with a five-year all-cause revision rate of 3.44%, although this is still higher than all the cemented and hybrid combinations in Table 3.22. The ASR Resurfacing, now withdrawn, has the highest all-cause revision rate (9.63% at five years). There remains considerable variation between the highest and lowest rates for resurfacing cups for other brands.

Table 3.23 Revision rates (excluding for infection) for main hip resurfacing brands (95% confidence intervals).

Resurfacing brand	Number of patients	Revision rate at 1 year	Revision rate at 3 years	Revision rate at 5 years
Adept Resurfacing	3,355	1.19% (0.87%-1.64%)	2.36% (1.82%-3.05%)	3.93% (2.93%-5.27%)
ASR Resurfacing	3,153	1.46% (1.10%-1.96%)	4.34% (3.63%-5.18%)	8.84% (7.56%-10.34%)
BHR Resurfacing	17,366	0.96% (0.82%-1.12%)	2.01% (1.80%-2.25%)	3.00% (2.70%-3.33%)
Conserve Plus	1,247	1.91% (1.27%-2.87%)	4.29% (3.21%-5.75%)	7.99% (5.91%-10.83%)
Cormet 2000	3,844	1.16% (0.87%-1.56%)	2.94% (2.41%-3.59%)	5.64% (4.70%-6.77%)
Durom Resurfacing	1,726	1.23% (0.80%-1.89%)	3.15% (2.37%-4.19%)	5.78% (4.36%-7.66%)
Recap Resurfacing	1,563	1.85% (1.28%-2.68%)	3.09% (2.25%-4.26%)	5.98% (3.79%-9.45%)
Other resurfacing	1,925	0.89% (0.54%-1.45%)	2.59% (1.86%-3.60%)	3.35% (2.42%-4.65%)
All resurfacing	34,179	1.14% (1.03%-1.26%)	2.60% (2.42%-2.80%)	4.36% (4.07%-4.66%)

Table 3.24 Revision rates (all causes) for main hip resurfacing brands (95% confidence intervals).

Resurfacing brand	Number of patients	Revision rate at 1 year	Revision rate at 3 years	Revision rate at 5 years
Adept Resurfacing	3,355	1.22% (0.89%-1.67%)	2.54% (1.98%-3.25%)	4.42% (3.34%-5.84%)
ASR Resurfacing	3,153	1.56% (1.18%-2.06%)	4.85% (4.10%-5.74%)	9.63% (8.28%-11.19%)
BHR Resurfacing	17,366	1.08% (0.93%-1.24%)	2.32% (2.09%-2.58%)	3.44% (3.12%-3.79%)
Conserve Plus	1,247	1.91% (1.27%-2.87%)	4.65% (3.50%-6.18%)	8.35% (6.21%-11.22%)
Cormet 2000	3,844	1.35% (1.02%-1.77%)	3.40% (2.82%-4.09%)	6.30% (5.31%-7.47%)
Durom Resurfacing	1,726	1.35% (0.90%-2.03%)	3.35% (2.54%-4.42%)	6.35% (4.86%-8.30%)
Recap Resurfacing	1,563	1.98% (1.38%-2.83%)	3.48% (2.55%-4.73%)	6.37% (4.12%-9.83%)
Other resurfacing	1,925	1.16% (0.76%-1.78%)	3.06% (2.27%-4.13%)	3.94% (2.93%-5.30%)
All resurfacing	34,179	1.53% (1.37%-1.71%)	3.76% (3.48%-4.06%)	6.40% (5.95%-6.89%)

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3.3.5 Conclusions and recommendations

It has been the policy in previous reports not to draw conclusions or make recommendations derived from the data reported, but rather to allow the reader to draw their own conclusions. However, the data shows some very strong trends that merit discussion and recommendations. We hope that this will provoke debate and encourage surgeons and manufacturers to re-evaluate their practice in light of the evidence provided. We accept that the data is open to other interpretations and we welcome this. We must stress very strongly that the NJR provides only part of the picture, that of survivorship, and only survivorship of a short- to medium-term duration. We do not know whether these trends will continue in the longer term. Indeed, one of the lessons that we have learnt is that survivorship is not linear. Survivorship also gives little indication of satisfaction, relief of pain, improvement in function and greater participation in society. In many instances, these are more important to patients than survivorship. Moreover, the data is imperfect and we are reliant on surgeons completing the data accurately and recording every procedure without exception.

The data shows that implanting metal-on-metal bearings of 36mm or greater leads to much higher revision rates regardless of whether in a resurfacing or when implanted with a stemmed prosthesis. The data indicates a potentially marked increase in failure at around the sixth year in stemmed implants with metal-on-metal bearing surfaces. However, as the width of the confidence intervals demonstrate, more data is needed to confirm this finding. Further analysis to be undertaken over the upcoming year will shed light on whether this increase is true for all metal-on-metal stemmed implants or if it varies for certain sub-groups. Likewise, it is difficult to draw firm conclusions on metal-on-metal bearings of less than 36mm as relatively few have been recorded in the NJR.

Resurfacing has a higher revision rate than stemmed total hip replacement regardless of brand. Even the resurfacing brand with the best survivorship (the BHR) has worse survivorship than almost all of the common stem/cup combinations up to five years using unadjusted data. It remains to be seen if this holds true with adjusted data at brand level.

Resurfacing and stemmed metal-on-metal do particularly badly in women of all ages. Likewise, the survivorship in men is far poorer than conventional stemmed hip replacement with alternative bearings. This is true, even in men under the age of 60.

In men and women over the age of 70 all cemented hip replacements have the best survivorship. These are also quite often the cheapest available option. We thus recommend that these should be the preferred option unless good clinical reasons, such as the need for constrained prostheses, indicate otherwise.

In patients under the age of 70 the data is less clear cut with overlapping confidence intervals between cemented and hybrid and between hybrid and uncemented hips. The revision rates appear to differ by about one percentage point between these options. We do not thus feel that we can offer guidance as to which option the surgeon should take based on the survivorship data that we currently have. However, longer follow-up may give us a clearer picture.

With regard to advice on brands, which is a thorny topic, the data shows that many different stem cup combinations (indeed most) give survivorship of the entire construct of greater than 97% at five years. In sharp contradistinction, no resurfacing achieves this level of survivorship.

The data highlights a few areas that require further research. We need an in-depth analysis of bearing surfaces controlling for factors such as fixation, patient demographics and head size. The metal-on-metal data that we present here does not break down larger head sizes, but simply considers all sizes above 32mm as a single group. Planned changes in the way NJR data is recorded will enable us to do this in the future.

There needs to be an in-depth analysis of resurfacing compared with total hip replacement to see if resurfacing confers a benefit with regard to both survivorship and patient-based outcome measures in any sub-group of patients. As the current situation is still unclear, there is a need for randomised controlled trials to establish the best treatment options in patients under the age of 70 years using survivorship, patient-based outcome measures, and health economic indicators as end-points.

Part 3

3.4 Outcomes after primary knee replacement, 2003 to 2010

This section contains statistical analysis of the survivorship of knee replacements in the period up to almost eight years after primary surgery (1st April 2003 to 31st December 2010). This analysis examines the length of time between the primary knee replacement and the first revision of that knee replacement or the patient's death.

In Section 3.4.1, all-cause revision and mortality is considered. This analysis is based on the NJR-HES/PEDW linked data described in Section 3.2.

A comparison of the NJR-HES/PEDW and the NJR revision rates is shown in Section 3.4.2. As discussed in Section 3.2, each data source has its strengths and limitations and so this analysis is intended to inform the wider debate about data quality and methodological matters.

In Section 3.4.3, the NJR data (discussed in Section 3.2) is used to examine revisions other than for infection. Analysis of revision rates for the most commonly used implant brands is shown in Section 3.4.4. This is also based on NJR data and shows all-cause revision rates as well as revision rates excluding those for infection.

Finally, Section 3.4.5 contains our conclusions and recommendations.

Throughout the section, details relating to statistical issues have been summarised separately as methodological notes for readers who require more information.

Methodological note

Throughout this section, survival analysis is used to examine the length of time between a primary joint replacement and the first revision or the time between surgery and the patient's death. Survival analysis involves a shift from analysing people or operations to analysing time. It has the advantage of being able to handle the unequal lengths of time that people have been observed and so does not require those who have not been observed for a certain time period to be dropped from the analysis (as this can introduce bias). Aspects of this analysis (for example, the cumulative hazard or the cumulative incidence function) indicate the risk of an event happening over continuous time and so can be used to approximate incidence rates at certain time points.

Terminology note

Both total and partial knee replacement procedures are discussed in this section. At present, the NJR does not differentiate between medial and lateral unicondylar knee replacements. Changes to data collection methods will enable this in the future. There are also other knee designs, such as combinations of unicondylar and patello-femoral joint replacements, but these are not considered here as numbers are too small to comment.

3.4.1 Outcomes: all-cause revision and mortality

This section considers the first revision after primary knee replacement (due to any cause) and, in addition, the risk of death following primary knee replacement. Analysis in this section is undertaken on the NJR-HES/PEDW linked data discussed in Section 3.2.

3.4.1.1 Prosthesis type

The risk of revision after primary knee replacement is shown in Figure 3.8 and summarised in Table 3.25 by the five main prosthesis types.

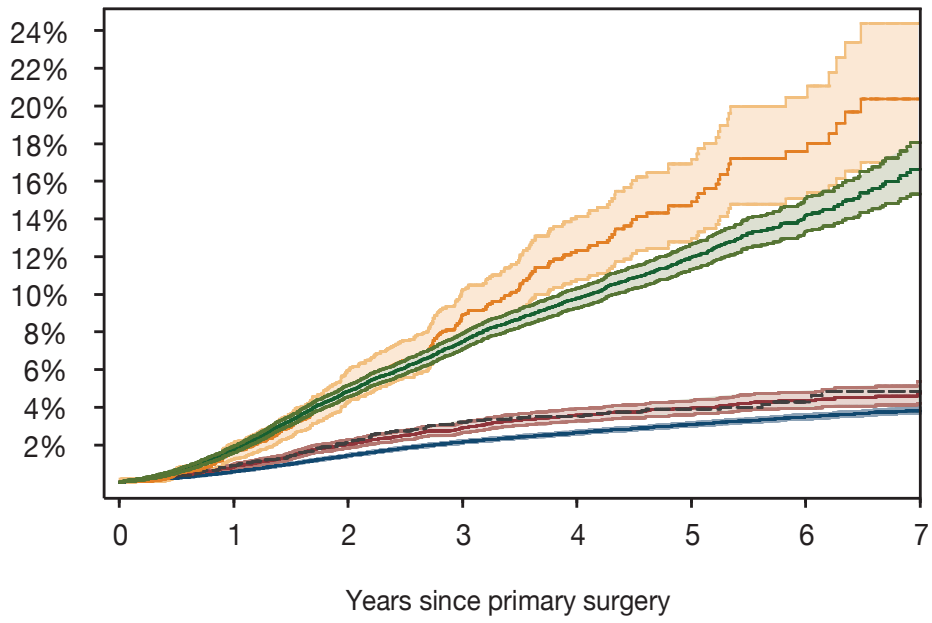

Figure 3.8

Risk of revision following primary knee replacement (cumulative hazard with 95% confidence intervals), by prosthesis type.

Note: 95% confidence intervals not shown for hybrid group because of overlap obscuring plot.

Table 3.25 Estimated revision rates following primary knee replacement, by prosthesis type (95% confidence intervals).

	Prosthesis type					All
	Cemented	Uncemented	Hybrid	Patello-femoral	Unicondylar	
30 days	0.06% (0.05%-0.07%)	0.09% (0.06%-0.14%)	0.13% (0.05%-0.32%)	0.05% (0.01%-0.21%)	0.08% (0.05%-0.13%)	0.06% (0.06%-0.07%)
90 days	0.13% (0.12%-0.15%)	0.18% (0.13%-0.24%)	0.24% (0.12%-0.46%)	0.08% (0.03%-0.24%)	0.22% (0.17%-0.29%)	0.14% (0.13%-0.16%)
Year 1	0.58% (0.55%-0.61%)	0.85% (0.72%-0.99%)	0.93% (0.66%-1.31%)	1.60% (1.23%-2.09%)	1.76% (1.59%-1.94%)	0.70% (0.67%-0.73%)
Year 2	1.43% (1.38%-1.48%)	2.04% (1.84%-2.27%)	2.12% (1.67%-2.69%)	5.04% (4.27%-5.95%)	4.85% (4.55%-5.17%)	1.77% (1.72%-1.82%)
Year 3	2.16% (2.09%-2.22%)	2.91% (2.64%-3.19%)	3.22% (2.63%-3.94%)	8.85% (7.69%-10.19%)	7.49% (7.09%-7.92%)	2.68% (2.61%-2.74%)
Year 4	2.66% (2.58%-2.74%)	3.58% (3.27%-3.92%)	3.53% (2.90%-4.31%)	12.34% (10.77%-14.13%)	9.79% (9.28%-10.33%)	3.34% (3.26%-3.42%)
Year 5	3.08% (2.99%-3.17%)	3.95% (3.60%-4.34%)	3.90% (3.20%-4.76%)	14.70% (12.77%-16.91%)	11.96% (11.31%-12.65%)	3.89% (3.80%-3.99%)
Year 6	3.48% (3.37%-3.60%)	4.33% (3.92%-4.78%)	4.28% (3.48%-5.26%)	17.57% (15.08%-20.47%)	14.19% (13.33%-15.11%)	4.43% (4.31%-4.55%)
Year 7	3.81% (3.67%-3.96%)	4.75% (4.20%-5.37%)	4.83% (3.86%-6.04%)	20.37% (17.02%-24.37%)	16.64% (15.33%-18.06%)	4.92% (4.76%-5.08%)
Base	288,729 (84.4%)	20,542 (6.0%)	3,798 (1.1%)	3,837 (1.1%)	25,214 (7.4%)	342,120 (100%)

Overall, revision rates were relatively low: only around 0.7% of primary knee replacements had been revised by one year after the primary surgery (Table 3.25). This rises to 2.7% at year three, 3.9% by year five, and 4.9% by year seven. The risk of revision in the first few months after surgery was very low at only 0.14% by 90 days.

However, there was substantial variation in revision rates according to prosthesis type with the lowest rates associated with cemented prostheses (3.8% at seven years) (Table 3.25). There was no statistically significant difference between the uncemented and hybrid groups and revision rates for these prostheses were only slightly higher than for cemented prostheses. In contrast, revision rates for patello-femoral procedures were around five times higher (20.4%) than for cemented procedures at seven years. Revision rates for unicondylar knees were also relatively high at 16.6% by seven years. Results were similar for patello-femoral and unicondylar knees for the first two or three years after primary surgery and then the patello-femoral revision rates overtook the unicondylar revision rates (Figure 3.8).

Another way of comparing the prosthesis groups is to look at patient-time incidence rates (Table 3.26). This indicates that for the cohort we have been observing (those who had a primary knee replacement since 1st April 2003), the highest incidence of revision was for patello-femoral replacements with 2.73 revisions per 100 observed years. This is another way of saying that there has been approximately one revision for every 37 years of use for patello-femoral knees. This compares with one revision per 42 years for unicondylar knees, one revision per 118 years for uncemented and hybrid knees, and one every 156 years for cemented knees. Of course, these incidence rates are likely to change as the risk of revision increases over time.

Methodological note

The patient-time incidence rate divides the number of revisions by the total length of time the patients have been observed to be at risk of revision (that is the time between the date of primary surgery and the date of revision, date of death, or 31st December 2010). It is shown in the format of the number of revisions per hundred observed years. This is a standardised format that enables straightforward comparisons to be made between the prosthesis groups and it avoids the need to choose time-points at which to estimate incidence rates. However, it does not give any information about how the risk of revision might change over time and it, therefore, may be an inappropriate indicator of survivorship if the risk of revision is not constant and does vary substantially over time.

Table 3.26 Patient-time incidence rate of revision per 100 observed years following primary knee replacement, by prosthesis type.

Prosthesis group	Total time observed (years)	Number of revisions	Patient-time incidence rate per 100 observed years	95% confidence interval
Cemented	839,970.5	5,381	0.64	(0.62 - 0.66)
Uncemented	63,959.7	542	0.85	(0.78 - 0.92)
Hybrid	13,193.9	112	0.85	(0.71 - 1.02)
Patello-femoral	10,201.7	279	2.73	(2.43 - 3.08)
Unicondylar	72,055.3	1,703	2.36	(2.25 - 2.48)
All	999,381.1	8,017	0.80	(0.78 - 0.82)

3.4.1.2 Implant constraint and bearing types

Overall, 91.5% of knee replacements were bicondylar procedures (the remainder being patello-femoral and unicondylar knee replacements). The majority of these (60.6%) were a posterior cruciate-retaining implant (sometimes called an unconstrained implant). Another 20.9% were posterior cruciate-stabilised and 2.3% were a constrained condylar. There were small numbers of other types including 0.4% that were hinged or linked implants, 0.4% that were custom implants while another 14% had a monobloc tibia implant. These were mainly of the metal backed monobloc tibia form (93.8%). Revision rates based on implant constraint for bicondylar knees are shown in Table 3.27. This indicates that posterior cruciate-retaining implants had the lowest revision rates although these were very similar to those of the monobloc tibia group. Use of a posterior cruciate-stabilised implant was associated with higher revisions rates (for example, 4.3% at seven years compared with 3.7% for posterior cruciate-retaining implants).

Table 3.27 Estimated revision rates for bicondylar knees, by implant constraint type (95% confidence intervals).

	Implant constraint			Other		
	Posterior cruciate-retaining	Posterior cruciate-stabilised	Constrained condylar	Monobloc tibia	Other/ unknown	All bicondylar
90 days	0.13% (0.12%-0.15%)	0.15% (0.12%-0.18%)	0.30% (0.19%-0.46%)	0.08% (0.06%-0.11%)	0.36% (0.24%-0.53%)	0.14% (0.13%-0.15%)
Year 1	0.57% (0.54%-0.61%)	0.71% (0.65%-0.78%)	1.05% (0.83%-1.34%)	0.46% (0.40%-0.53%)	0.91% (0.71%-1.16%)	0.61% (0.58%-0.63%)
Year 2	1.39% (1.33%-1.45%)	1.68% (1.57%-1.80%)	2.04% (1.68%-2.46%)	1.37% (1.25%-1.50%)	2.23% (1.88%-2.64%)	1.48% (1.44%-1.53%)
Year 3	2.07% (1.99%-2.15%)	2.52% (2.38%-2.67%)	2.77% (2.31%-3.31%)	2.15% (1.98%-2.32%)	3.30% (2.84%-3.83%)	2.22% (2.16%-2.29%)
Year 4	2.55% (2.45%-2.64%)	3.12% (2.94%-3.30%)	3.19% (2.64%-3.85%)	2.65% (2.46%-2.86%)	3.91% (3.38%-4.52%)	2.73% (2.66%-2.81%)
Year 5	2.95% (2.84%-3.07%)	3.59% (3.39%-3.81%)	3.68% (2.98%-4.54%)	2.96% (2.74%-3.20%)	4.70% (4.04%-5.45%)	3.15% (3.06%-3.24%)
Year 6	3.29% (3.15%-3.43%)	4.05% (3.80%-4.31%)	4.06% (3.41%-5.00%)	3.43% (3.15%-3.74%)	5.79% (4.88%-6.86%)	3.55% (3.44%-3.66%)
Year 7	3.67% (3.49%-3.86%)	4.33% (4.03%-4.65%)	4.06% (3.41%-5.00%)	3.72% (3.36%-4.12%)	6.10% (5.04%-7.39%)	3.89% (3.75%-4.04%)
Base	189,601 (60.%)	65,355 (20.9%)	7,075 (2.3%)	43,708 (14.0%)	7,330 (2.3%)	313,069 (100%)

Note: Monobloc tibia refers to tibial components which are entirely composed of polyethylene or components which comprise a pre-assembled construct of a metal tibial tray and polyethylene meniscal component. The other/unknown category mainly refers to fixed or rotating hinged knees and custom devices. In both types it is not always possible for NJR to ascertain what degree of constraint is designed into these components.

Table 3.28 shows revision rates by fixed or mobile bearing surfaces for bicondylar posterior cruciate-retaining and posterior cruciate-stabilised implants. Revision rates for posterior cruciate-retaining implants were lower for fixed bearings than for mobile bearings (3.4% versus 5.0% at seven years) (Figure 3.9). There was a similar pattern of results for posterior cruciate-stabilised implants but differences between fixed and mobile bearings were smaller and, as indicated by the overlapping confidence intervals, not always significant. Analysis is not shown for unicondylar knees as there were no statistically significant differences in revision rates between fixed bearings, mobile bearings and monobloc tibia implants.

Table 3.28 Estimated revision rates by implant constraint and bearing type for bicondylar knees (95% confidence intervals).

	Implant constraint and bearing type			
	Posterior cruciate-retaining		Posterior cruciate-stabilised	
	Fixed bearing	Mobile bearing	Fixed bearing	Mobile bearing
90 days	0.12% (0.11%-0.14%)	0.20% (0.15%-0.26%)	0.14% (0.11%-0.17%)	0.19% (0.11%-0.33%)
Year 1	0.54% (0.50%-0.58%)	0.76% (0.66%-0.88%)	0.70% (0.63%-0.77%)	0.85% (0.64%-1.11%)
Year 2	1.31% (1.25%-1.38%)	1.85% (1.68%-2.04%)	1.64% (1.53%-1.76%)	2.05% (1.70%-2.47%)
Year 3	1.94% (1.86%-2.02%)	2.81% (2.58%-3.06%)	2.45% (2.30%-2.60%)	3.17% (2.70%-3.71%)
Year 4	2.38% (2.28%-2.48%)	3.53% (3.25%-3.84%)	3.02% (2.84%-3.21%)	3.91% (3.34%-4.57%)
Year 5	2.77% (2.66%-2.89%)	4.02% (3.69%-4.38%)	3.50% (3.28%-3.72%)	4.39% (3.72%-5.19%)
Year 6	3.10% (2.96%-3.25%)	4.37% (3.99%-4.78%)	3.95% (3.70%-4.23%)	4.87% (4.03%-5.90%)
Year 7	3.44% (3.26%-3.64%)	5.04% (4.45%-5.72%)	4.25% (3.94%-4.58%)	4.87% (4.03%-5.90%)
Base	162,700 (63.8%)	26,901 (10.6%)	58,938 (23.1%)	6,417 (2.5%)

Note: analysis is based on the posterior cruciate-retaining and posterior-stabilised groups shown in Table 3.27.

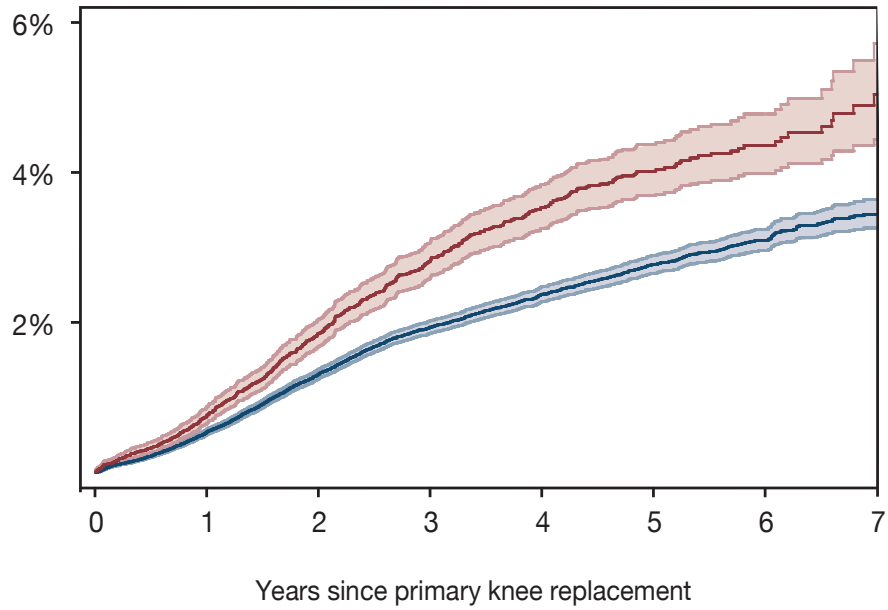

Figure 3.9

Risk of revision (cumulative hazard with 95% confidence intervals), by bearing type for posterior cruciate-retaining bicondylar knee replacements.

Therefore, the lowest revision rates were associated with a posterior cruciate-retaining, fixed bearing prosthesis. There tended to be a relationship between method of fixation and implant constraint and bearing surface. Cemented total knee replacements more commonly involved a posterior cruciate-retaining fixed bearing prosthesis (53.7%) than did total knee replacements with an uncemented or hybrid fixation (31.3%). Table 3.29 briefly explores the combined effect of fixation, constraint and bearing type. This shows that the lowest revision rates were for a cemented total knee with a posterior cruciate-retaining, fixed bearing prosthesis although rates for an uncemented/hybrid fixation with a posterior cruciate-retaining, fixed bearing prosthesis were only slightly higher.

Table 3.29 Estimated revision rates by fixation, implant constraint and bearing type for bicondylar knees (95% confidence intervals).

	Fixation, constraint and bearing type			
	Cemented		Uncemented/hybrid	
	Posterior cruciate-retaining fixed bearing	Other constraint and bearing type	Posterior cruciate-retaining fixed bearing	Other constraint and bearing type
Year 1	0.53% (0.49%-0.57%)	0.65% (0.60%-0.69%)	0.80% (0.61%-1.04%)	0.89% (0.75%-1.05%)
Year 2	1.29% (1.22%-1.35%)	1.60% (1.53%-1.68%)	1.79% (1.48%-2.15%)	2.17% (1.94%-2.43%)
Year 3	1.90% (1.82%-1.99%)	2.44% (2.34%-2.55%)	2.60% (2.21%-3.06%)	3.12% (2.82%-3.45%)
Year 4	2.34% (2.24%-2.45%)	3.02% (2.90%-3.14%)	3.06% (2.61%-3.58%)	3.80% (3.45%-4.19%)
Year 5	2.74% (2.62%-2.87%)	3.46% (3.32%-3.61%)	3.36% (2.87%-3.94%)	4.21% (3.81%-4.65%)
Year 6	3.09% (2.94%-3.24%)	3.93% (3.75%-4.12%)	3.51% (2.98%-4.13%)	4.73% (4.25%-5.27%)
Year 7	3.41% (3.22%-3.61%)	4.27% (4.05%-4.51%)	4.10% (3.39%-4.94%)	5.12% (4.47%-5.88%)
Base	155,087 (49.5%)	133,642 (42.7%)	7,613 (2.4%)	16,727 (5.3%)

Note: analysis is based on bicondylar knees. The uncemented and hybrid groups have been combined as their revision rates in Table 3.25 are very similar and this allows large enough numbers for robust analysis.

3.4.1.3 The effect of patient characteristics

While there was some variation in patient characteristics between the different prosthesis type and implant constraint groups, this was not as pronounced as among the hip replacement patients considered in Section 3.3. Overall, patello-femoral and unicondylar knee implants were typically used with younger patients (Table 3.30). Patello-femoral implants were more commonly used in women (76.9% were female). Generally, patients with mobile bearings had a younger average age than those with fixed bearings but the differences were not large.

Table 3.30 Summary of patient characteristics by knee prosthesis type and implant constraint.

	Percentage of all	Mean age (years)	Percentage female	Percentage with osteoarthritis	Mean ASA score
Prosthesis type					
Cemented	84.4%	70.0	57.9%	96.7%	2.0
Uncemented	6.0%	68.5	53.6%	97.6%	2.0
Hybrid	1.1%	68.6	55.0%	95.9%	2.0
Patello-femoral	1.1%	60.4	76.9%	96.0%	1.9
Unicondylar	7.4%	63.8	48.7%	98.9%	1.9
Implant constraint for bicondylar knees					
Posterior cruciate-retaining	55.4%	69.9	57.8%	97.1%	2.0
- Fixed bearing	47.6%	70.1	58.0%	97.0%	2.0
- Mobile bearing	7.9%	68.8	55.9%	97.7%	2.0
Posterior cruciate-stabilised	19.1%	69.8	58.0%	96.1%	2.0
- Fixed bearing	17.2%	70.2	58.4%	96.1%	2.1
- Mobile bearing	1.9%	66.5	54.8%	96.2%	2.0
Constrained condylar	2.1%	70.0	53.3%	96.2%	2.0
Monobloc tibia	12.8%	70.2	56.8%	97.3%	2.0
Other	0.7%	70.9	62.9%	86.9%	2.1
- Hinged/linked	0.3%	72.0	67.9%	76.7%	2.2
- Custom	0.4%	69.9	58.4%	96.0%	2.0
Not known	1.4%	68.4	57.6%	95.7%	2.0
All (n=342,120)	100.0%	69.4	57.3%	96.9%	2.0

Note: bases for the prosthesis and implant constraint groups can be found in Tables 3.23, 3.24 and 3.25.

These relatively minor variations in patient characteristics cannot explain the different revision rates among the prosthesis groups shown in Table 3.25. For example, this means that the higher revision rates for unicondylar knees are not simply due to the operation being undertaken on younger patients and performed more commonly on men.

Differences in revision rates between men and women were small for all prosthesis groups and, in the main, were not statistically significant and so are not shown here. Table 3.31 explores the effect of age in more detail. To summarise:

- revision rates for those aged under 60 were much higher than for older age groups for all prosthesis groups. For example, the seven-year revision rate for those aged under 60 with a cemented knee was 7.5% compared with 2.6% of those aged 70 or over.
- for those aged under 60, there were no significant differences in revision rates between the cemented and the uncemented/hybrid groups and both groups had much lower revision rates than did the unicondylar knee group. For those aged over 60, a small but noticeable difference between the cemented and the uncemented/hybrid groups was apparent with cemented knees having the lowest revision rates.
- unicondylar revision rates remained much higher than for other groups regardless of age group. Revision rates were highest for those aged under 60: 22.9% had been revised by seven years (compared with 10.5% of those aged 70 or over).

Table 3.31 Estimated revision rates by age group and knee prosthesis type (95% confidence intervals).

	Age Group			All
	Aged under 60	Aged 60-69	Aged 70 or over	
Cemented				
Year 1	0.94% (0.84%-1.05%)	0.61% (0.56%-0.67%)	0.48% (0.45%-0.52%)	0.58% (0.55%-0.61%)
Year 3	3.99% (3.75%-4.25%)	2.46% (2.34%-2.59%)	1.55% (1.48%-1.62%)	2.16% (2.09%-2.22%)
Year 5	6.03% (5.66%-6.42%)	3.58% (3.40%-3.76%)	2.10% (2.00%-2.20%)	3.08% (2.99%-3.17%)
Year 7	7.50% (6.93%-8.12%)	4.46% (4.18%-4.75%)	2.57% (2.41%-2.74%)	3.81% (3.67%-3.96%)
Base	36,825	93,640	158,264	288,729
Uncemented/hybrid				
Year 1	0.98% (0.71%-1.35%)	0.92% (0.73%-1.16%)	0.77% (0.62%-0.95%)	0.86% (0.75%-0.99%)
Year 3	4.64% (3.93%-5.49%)	3.33% (2.90%-3.82%)	2.08% (1.80%-2.41%)	2.96% (2.71%-3.22%)
Year 5	6.70% (5.69%-7.89%)	4.56% (3.99%-5.22%)	2.51% (2.18%-2.90%)	3.94% (3.62%-4.28%)
Year 7	7.11% (5.96%-8.47%)	5.71% (4.88%-6.67%)	3.30% (2.61%-4.18%)	4.79% (4.29%-5.35%)
Base	4,164	8,431	11,745	24,340
Unicondylar				
Year 1	2.26% (1.94%-2.63%)	1.56% (1.32%-1.85%)	1.45% (1.18%-1.77%)	1.76% (1.59%-1.94%)
Year 3	10.65% (9.80% 11.57%)	6.68% (6.08%-7.35%)	5.11% (4.51%-5.78%)	7.49% (7.09%-7.92%)
Year 5	16.97% (15.61%-18.46%)	10.82% (9.84%-11.89%)	8.05% (7.13%-9.09%)	11.96% (11.31%-12.65%)
Year 7	22.88% (20.29%-25.81%)	16.17% (14.01%-18.67%)	10.49% (8.86%-12.43%)	16.64% (15.33%-18.06%)
Base	8,328	9,708	7,178	25,214

Note: the uncemented and hybrid groups have been combined as their revision rates in Table 3.25 are very similar and this allows large enough numbers for robust analysis. The patello-femoral group is excluded because total numbers are too small for this type of breakdown. Age has been grouped to allow large enough numbers in each prosthesis group for robust analysis.

3.4.1.4 Risk of death

The patient characteristics discussed in the previous section are also important because they affect the risk of another event happening instead of revision: the risk of death. This can also be estimated over time from survival analysis (Figure 3.10). Given the age of these patients, the risk of death in the years following a primary knee replacement is not trivial. In fact, for all patients except those in the patello-femoral and unicondylar groups, the risk of death over a particular year was higher than the risk of revision in that year. Overall, almost one in five (17.1%) of patients had died within seven years of their knee replacement (Table 3.32), similar to the results for hip replacement patients. The highest death rates were among the cemented group and the lowest were among the patello-femoral group, reflecting the age distribution of these groups.

Methodological note

Analysis in this section does not attempt to investigate whether knee replacement surgery is in itself associated with an increased risk of death. It is complex to disentangle the risk of death associated specifically with undergoing surgery from the risk of death more generally. The risk of death will vary for individual patients as it is known to strongly increase with age and is generally higher for males than females. Of course, the presence of illness and disease will also strongly influence the risk of death. Therefore, death in the years following knee replacement surgery would not be unexpected for some of the patients considered here. An analysis of all-cause mortality rates for England and Wales suggests a likely overall death rate by one year after surgery of around 3.27% (based on the age and gender distribution of these patients). Therefore, the observed overall one-year death rate of 1.26% (Table 3.32) is lower than the expected death rate for these patients based on their age and gender alone. This is likely to reflect what has been observed in other research studies that patients undergoing joint replacement may be generally healthier than others of a comparable age and gender.

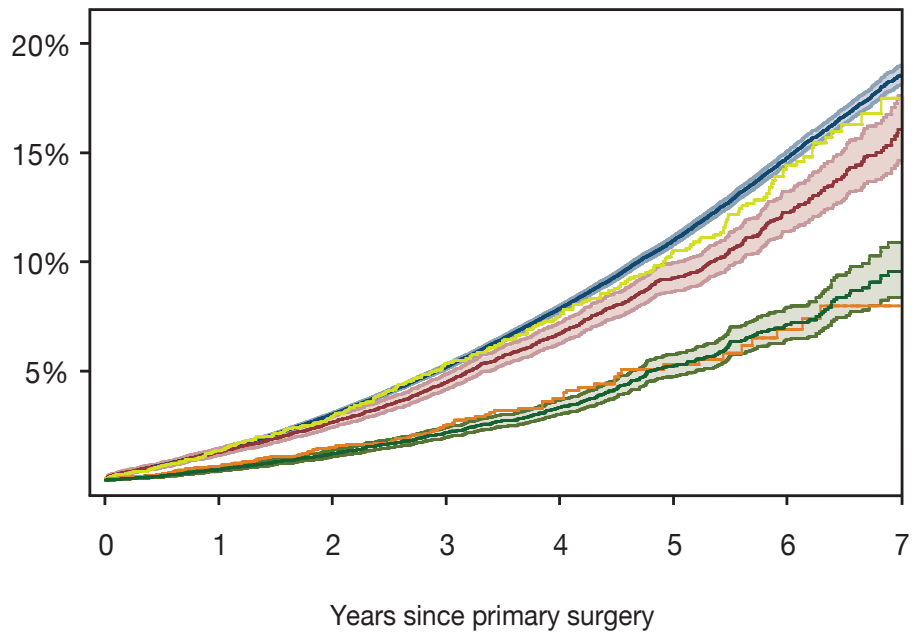

Figure 3.10

Risk of death following primary knee replacement (cumulative hazard with 95% confidence intervals), by prosthesis type.

Note: 95% confidence intervals are not shown for all groups where overlap obscures plot.

Table 3.32 Estimated mortality rates following primary knee replacement, by prosthesis type (95% confidence intervals).

	Prosthesis type					All
	Cemented	Uncemented	Hybrid	Patello-femoral	Unicondylar	
30 days	0.24% (0.22%-0.26%)	0.23% (0.18%-0.31%)	0.21% (0.11%-0.42%)	0.08% (0.03%-0.24%)	0.04% (0.02%-0.07%)	0.22% (0.21%-0.24%)
90 days	0.42% (0.40%-0.45%)	0.42% (0.34%-0.52%)	0.37% (0.22%-0.63%)	0.16% (0.07%-0.35%)	0.10% (0.07%-0.15%)	0.40% (0.37%-0.42%)
Year 1	1.33% (1.29%-1.38%)	1.28% (1.13%-1.45%)	1.34% (1.01%-1.78%)	0.62% (0.41%-0.94%)	0.47% (0.39%-0.57%)	1.26% (1.22%-1.30%)
Year 2	3.00% (2.93%-3.07%)	2.62% (2.38%-2.87%)	2.90% (2.37%-3.55%)	1.46% (1.09%-1.97%)	1.18% (1.04%-1.34%)	2.82% (2.76%-2.88%)
Year 3	5.12% (5.02%-5.23%)	4.41% (4.08%-4.77%)	5.25% (4.47%-6.17%)	2.39% (1.84%-3.10%)	2.08% (1.87%-2.31%)	4.82% (4.73%-4.91%)
Year 4	7.74% (7.60%-7.88%)	6.58% (6.13%-7.07%)	7.34% (6.34%-8.50%)	3.53% (2.76%-4.51%)	3.14% (2.85%-3.46%)	7.27% (7.14%-7.39%)
Year 5	10.77% (10.57%-10.96%)	9.03% (8.42%-9.68%)	10.27% (8.94%-11.80%)	4.88% (3.80%-6.25%)	4.82% (4.38%-5.29%)	10.14% (9.97%-10.31%)
Year 6	14.43% (14.15%-14.72%)	11.92% (11.06%-12.85%)	14.07% (12.22%-16.21%)	6.28% (4.76%-8.28%)	6.45% (5.83%-7.14%)	13.59% (13.34%-13.84%)
Year 7	18.10% (17.67%-18.53%)	15.58% (14.21%-17.08%)	17.04% (14.40%-20.17%)	7.20% (5.34%-9.71%)	8.46% (7.47%-9.59%)	17.11% (16.73%-17.50%)
Base	288,729 (84.4%)	20,542 (6.0%)	3,798 (1.1%)	3,837 (1.1%)	25,214 (7.4%)	342,120 (100%)

In terms of looking at the risk of revision, the possibility of death can be considered a competing risk in this context. Clearly, a patient cannot have a revision of their knee replacement if they are no longer alive. Therefore, as with hip replacement patients, the analysis can be adjusted to take account of the competing risk of death.

Methodological note

Standard survival analysis (based on Kaplan-Meier estimation) treats those who have died as censored. This means that the patient no longer contributes to the analysis once they have died; only the time observed between primary surgery and death (when they were at risk of revision) is counted in the analysis. Censoring is the correct approach for patients who have not been revised yet and where we have simply stopped observing them for now (such as the cut-off date of 31st December 2010 for this analysis). These patients are still at risk of revision in the future. In contrast, death is a permanent condition that prevents future revision from occurring altogether and so is a competing event to revision. Because competing events are different from standard censoring, standard survival analysis tends to overestimate the risk of the main event occurring. This inaccuracy gets cumulatively worse over time. Therefore, a new methodology is required. This is a competing risks flexible parametric proportional hazards model where risk of revision is the main risk and risk of death is treated as a competing risk.

3.4.1.5 Adjusting for the competing risk of death

The effect of the competing risk of death on revision rates is illustrated in Figure 3.11. This effect can be clearly seen by around three years following primary surgery as the lines start to diverge. This discrepancy increases over time as the lines move further apart which means that unadjusted analysis will overestimate revision rates for later time points. For example, the seven-year overall revision rate of 4.92% in Table 3.25 is adjusted to 4.53% when the competing risk of death is taken into account (a reduction of around 8%). In summary, while this is unlikely to be substantially affecting the revision rates discussed earlier, adjusting for the competing risk of death is likely to become more important over the life of the registry.

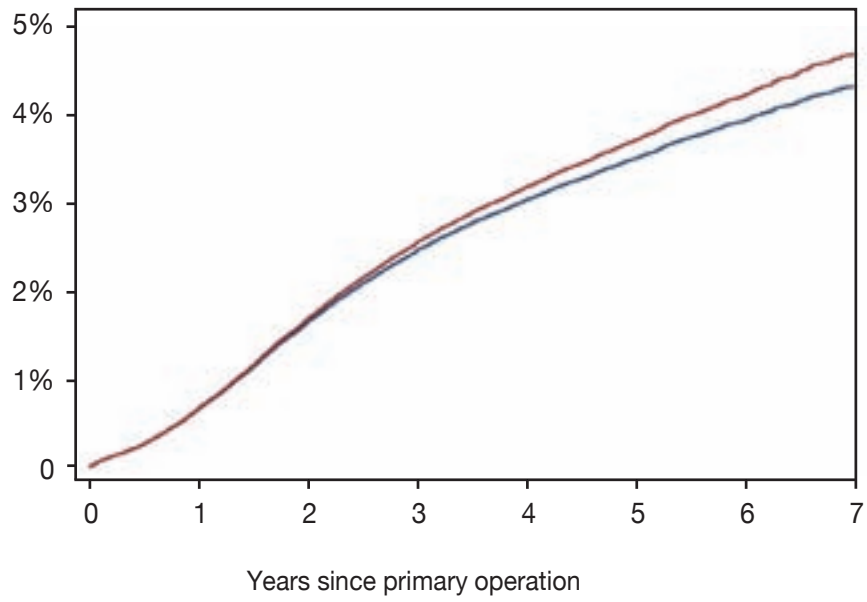

Figure 3.11

Cumulative incidence of revision following primary knee replacement adjusted for the competing risk of death.

Cumulative revision rate adjusted for competing risk of death

Unadjusted cumulative incidence of revision

3.4.2 Comparison of NJR and NJR-HES/PEDW revision rates

This section compares the NJR-HES/PEDW revision rates discussed in Section 3.4.1 with those calculated from NJR data alone. To make a valid comparison, analysis is undertaken on the same set of patients (where we have both NJR and HES/PEDW data) and includes revisions for all causes. Section 3.2 discusses these two data sources in more detail. To briefly summarise, it is possible that NJR data underestimates revisions to some undetermined extent. However, the HES/PEDW data is likely to overestimate revisions to some degree because of the inclusion of some re-operations as revisions. It is likely then that the "real" revision rate lies somewhere between the two rates presented in Table 3.33.

Revision rates identified with NJR data alone were generally lower than those calculated with additional HES/PEDW data across all time periods and prosthesis groups (Table 3.33). NJR revision rates ranged from between 38% and 77% of the value of the NJR-HES/PEDW revision rate for the same time period and prosthesis group. Generally, the three-, five- and seven-year revision rates across the two data sources were more similar. This is probably because the extra revisions being identified from HES/PEDW are disproportionately early revisions (see Section 3.2.2.2). However, despite the divergences, it is reassuring that both data sources show the same general trends in revision rates over time and between prosthesis groups.

Table 3.33 Comparison of NJR-HES/PEDW and NJR revision rates, by knee prosthesis type (95% confidence intervals).

Data source	90 days	Year 1	Year 3	Year 5	Year 7
Cemented					
NJR-HES/PEDW	0.13% (0.12%-0.15%)	0.58% (0.55%-0.61%)	2.16% (2.09%-2.22%)	3.08% (2.99%-3.17%)	3.81% (3.67%-3.96%)
NJR	0.06% (0.05%-0.07%)	0.36% (0.34%-0.38%)	1.47% (1.42%-1.53%)	2.16% (2.08%-2.24%)	2.69% (2.57%-2.82%)
Uncemented					
NJR-HES/PEDW	0.18% (0.13%-0.24%)	0.85% (0.72%-0.99%)	2.91% (2.64%-3.19%)	3.95% (3.60%-4.34%)	4.75% (4.20%-5.37%)
NJR	0.09% (0.06%-0.15%)	0.59% (0.49%-0.72%)	2.09% (1.87%-2.34%)	2.82% (2.53%-3.15%)	3.40% (2.99%-3.87%)
Hybrid					
NJR-HES/PEDW	0.24% (0.12%-0.46%)	0.93% (0.66%-1.31%)	3.22% (2.63%-3.94%)	3.90% (3.20%-4.76%)	4.83% (3.86%-6.04%)
NJR	0.13% (0.05%-0.32%)	0.57% (0.37%-0.88%)	2.25% (1.77%-2.88%)	2.77% (2.19%-3.52%)	3.69% (2.82%-4.84%)
Patello-femoral					
NJR-HES/PEDW	0.08% (0.03%-0.24%)	1.60% (1.23%-2.09%)	8.85% (7.69%-10.19%)	14.70% (12.77%-16.91%)	20.37% (17.02%-24.37%)
NJR	0.03% (0.00%-0.19%)	1.10% (0.80%-1.52%)	6.00% (5.07%-7.10%)	10.17% (8.54%-11.87%)	13.78% (11.10%-17.11%)
Unicondylar					
NJR-HES/PEDW	0.22% (0.17%-0.29%)	1.76% (1.59%-1.94%)	7.49% (7.09%-7.92%)	11.96% (11.31%-12.65%)	16.64% (15.33%-18.06%)
NJR	0.15% (0.11%-0.21%)	1.29% (1.15%-1.45%)	5.51% (5.17%-5.88%)	8.96% (8.40%-9.55%)	12.75% (11.59%-14.02%)
All					
NJR-HES/PEDW	0.14% (0.13%-0.16%)	0.70% (0.67%-0.73%)	2.68% (2.61%-2.74%)	3.89% (3.80%-3.99%)	4.92% (4.76%-5.08%)
NJR	0.06% (0.05%-0.07%)	0.45% (0.43%-0.48%)	1.87% (1.81%-1.92%)	2.78% (2.70%-2.86%)	3.56% (3.42%-3.70%)

Note: bases are those in Table 3.25.

3.4.3 Outcomes: revisions other than for infection

This section briefly considers revisions other than for infection. Analysis is based on NJR data only and excludes revisions undertaken for infection (these patients are treated as no longer observed at the point they have a revision for infection). It should be remembered that unlike the NJR-HES/PEDW data used earlier, the NJR data includes independently-funded patients and others that could not be matched to HES/PEDW so it is a larger and more representative dataset.

Infection was the reason for revision for 25.6% of the patients considered here (those with a linked primary and first revision in NJR). Other reasons for revision included aseptic loosening (26.5%), pain (23.2%), instability (13.1%), malalignment (8.2%), stiffness (6.9%), dislocation/subluxation (4.9%), lysis (4.8%), periprosthetic fracture (3.3%), and wear or failure of some part of the implant (5.3%). More than one reason for revision could be chosen. These results will not be representative of reasons for all revisions. For example, infection is more likely to occur in the early years after primary surgery whereas aseptic loosening often occurs

much later. Therefore, at this relatively early stage of the registry, an analysis of all revisions could be affected by the disproportionate number revised for infection. A major advantage of NJR is that, unlike HES/PEDW, it is possible to identify revisions for infection.

As seen with hip replacements, the proportion of revisions that were due to infection varied by prosthesis group. For example, 33% of revisions for cemented implants were revised for infection compared with 20% of the uncemented group and 22.9% of the hybrid group. The equivalent figures for the patello-femoral and unicondylar groups were 4.4% and 7.2% respectively. This result should not be interpreted as suggesting that the use of cement increases the risk of infection as it may simply reflect that other methods of failure were less common among cemented implants. The type of cement used for these knee replacements was mainly antibiotic loaded (95.9%).

Table 3.34 Estimated incidence rates for all-cause revision and revision other than for infection, by knee prosthesis type (95% confidence intervals).

	90 days	Year 1	Year 3	Year 5	Year 7
Cemented (n=343,589)					
All revisions	0.06% (0.05%-0.07%)	0.35% (0.33%-0.37%)	1.37% (1.33%-1.42%)	1.99% (1.92%-2.06%)	2.43% (2.33%-2.54%)
Excluding infection	0.03% (0.02%-0.03%)	0.19% (0.18%-0.21%)	0.89% (0.85%-0.93%)	1.35% (1.30%-1.41%)	1.69% (1.60%-1.79%)
Uncemented (n=25,365)					
All revisions	0.10% (0.07%-0.15%)	0.60% (0.51%-0.71%)	1.90% (1.71%-2.11%)	2.55% (2.30%-2.83%)	3.07% (2.71%-3.47%)
Excluding infection	0.06% (0.04%-0.10%)	0.45% (0.37%-0.55%)	1.51% (1.34%-1.69%)	2.06% (1.84%-2.32%)	2.53% (2.20%-2.92%)
Hybrid (n=5,000)					
All revisions	0.10% (0.04%-0.24%)	0.59% (0.40%-0.86%)	2.00% (1.60%-2.51%)	2.41% (1.93%-3.01%)	3.16% (2.45%-4.09%)
Excluding infection	0.06% (0.02%-0.19%)	0.41% (0.26%-0.65%)	1.48% (1.14%-1.92%)	1.82% (1.41%-2.36%)	2.57% (1.91%-3.47%)
Patello-femoral (n=5,842)					
All revisions	0.03% (0.01%-0.14%)	0.92% (0.69%-1.23%)	5.29% (4.58%-6.12%)	8.40% (7.30%-9.67%)	10.66% (8.90%-12.77%)
Excluding infection	0.03% (0.01%-0.14%)	0.86% (0.64%-1.16%)	5.08% (4.38%-5.89%)	7.98% (6.91%-9.22%)	10.24% (8.50%-12.34%)
Unicondylar (n=37,426)					
All revisions	0.16% (0.12%-0.20%)	1.23% (1.11%-1.35%)	4.62% (4.36%-4.89%)	7.24% (6.84%-7.66%)	9.84% (9.10%-10.65%)
Excluding infection	0.13% (0.09%-0.17%)	1.08% (0.98%-1.20%)	4.25% (4.01%-4.52%)	6.71% (6.32%-7.12%)	9.05% (8.35%-9.80%)
All (n=417,222)					
All revisions	0.07% (0.06%-0.08%)	0.46% (0.44%-0.48%)	1.76% (1.71%-1.81%)	2.58% (2.51%-2.65%)	3.24% (3.13%-3.36%)
Excluding infection	0.04% (0.03%-0.05%)	0.30% (0.28%-0.32%)	1.29% (1.25%-1.34%)	1.97% (1.90%-2.03%)	2.51% (2.41%-2.62%)

Revision rates other than for infection are summarised in Table 3.34 and compared with NJR revision rates for all causes. Overall, revision rates other than for infection were lower than all-cause revision rates. This was especially so in the early months after primary surgery (42.9% lower at 90 days) but revision was so rare in the first 90 days after knee replacement that these 90-day figures should be treated with caution. By year five, revision rates excluding infection were 23.6% lower than all-cause revision rates. Excluding revisions for infection reduced the revision rates proportionately more for cemented knees than for other groups.

3.4.4 Revision rates for main implant brands

Analysis in this section is based on NJR data only. This is a different approach from previous NJR Annual Reports and the reasons for this are discussed in Section 3.2. Revision rates are shown both for revisions excluding those for infection and for all-cause revisions.

Methodological note

In this section, revision rates are shown excluding revisions undertaken for infection. This is not to suggest that choice of brand is completely unrelated to the risk of infection, but the early time period after primary surgery considered here means that there is an over-representation of revisions for infection that could skew the results. However, because excluding revisions for infection disproportionately reduces revision rates for cemented implants, the all-cause revision rates are also shown in this section.

Revision rates at one, three and five years are presented. Although NJR contains data to seven years after primary surgery, when the data is split into relatively small sub-groups like brands, there is not enough data to reliably estimate seven-year revision rates. Analysis is only shown for brands with at least 2,500 patients. This cut-off point was chosen because analysis based on fewer patients results in more uncertain estimations (demonstrated by wide confidence intervals) which make any comparisons problematic. Because of smaller initial group sizes for unicondylar and patello-femoral replacements, this cut-off point has been reduced to 1,000 patients but this does result in some very wide confidence intervals and so comparisons should be made cautiously.

The analysis here is unadjusted in that it does not control for patient characteristics or any other factors that could influence revision rates. It should be noted that there may be variations in revision rates within a particular brand grouping because of different constraints (e.g. posterior cruciate-retaining/posterior cruciate-stabilised) and bearing types used. Overlapping 95% confidence intervals mean that differences are not statistically significant and so could simply reflect random variation.

Tables 3.35 and 3.36 show revision rates for the main implant brands for total knee replacements. The lowest five-year revision rates excluding infection were around 1% and these were associated with the market leader – the PFC Sigma Bicondylar Knee (accounting for 34.9% of patients) – and some newer brands such as the Triathlon, the Vanguard and the Finsbury MRK. For all-cause revision rates, the PFC Sigma had a five-year revision rate of 1.7% while the MRK had the lowest five-year revision rate of 1%.

Table 3.35 Revision rates (excluding for infection) by main implant brands for total knee replacement (95% confidence intervals).

Brand	Number of patients	Revision rate at 1 year	Revision rate at 3 years	Revision rate at 5 years
Advance Bicondylar Knee	4,335	0.15% (0.07%-0.34%)	1.21% (0.87%-1.68%)	1.57% (1.15%-2.15%)
AGC	41,895	0.13% (0.10%-0.17%)	0.80% (0.70%-0.91%)	1.12% (0.99%-1.28%)
Columbus	2,522	0.29% (0.13%-0.64%)	1.83% (1.21%-2.77%)	1.83% (1.21%-2.77%)
Endoplus Bicondylar Knee	12,682	0.35% (0.26%-0.47%)	1.15% (0.96%-1.39%)	1.57% (1.30%-1.89%)
Genesis 2	20,580	0.26% (0.19%-0.35%)	1.05% (0.88%-1.26%)	1.65% (1.36%-2.01%)
Insall-Burstein	2,537	0.08% (0.02%-0.32%)	1.06% (0.71%-1.58%)	2.04% (1.49%-2.81%)
Kinemax	10,733	0.14% (0.09%-0.23%)	1.25% (1.05%-1.50%)	2.01% (1.72%-2.34%)
LCS Complete	13,270	0.26% (0.18%-0.37%)	1.09% (0.88%-1.34%)	1.76% (1.41%-2.18%)
MRK	4,067	0.21% (0.10%-0.42%)	0.57% (0.35%-0.94%)	0.69% (0.41%-1.16%)
Nexgen	50,779	0.18% (0.14%-0.22%)	0.85% (0.75%-0.95%)	1.43% (1.28%-1.61%)
PFC Sigma Bicondylar Knee	130,358	0.19% (0.17%-0.22%)	0.74% (0.69%-0.80%)	1.08% (1.00%-1.16%)
Profix	4,632	0.39% (0.24%-0.63%)	1.38% (1.05%-1.80%)	1.55% (1.19%-2.02%)
Scorpio	28,657	0.20% (0.16%-0.27%)	1.06% (0.93%-1.21%)	1.69% (1.49%-1.92%)
Triathlon	13,442	0.20% (0.13%-0.31%)	0.91% (0.66%-1.26%)	0.99% (0.71%-1.39%)
Vanguard	6,326	0.15% (0.06%-0.32%)	0.77% (0.46%-1.30%)	0.98% (0.55%-1.74%)
Other brands	19,241	0.39% (0.31%-0.50%)	1.59% (1.40%-1.81%)	2.18% (1.94%-2.46%)
Unknown brand	7,898	0.39% (0.27%-0.56%)	1.31% (1.03%-1.66%)	1.93% (1.51%-2.48%)
All total knee	373,954	0.21% (0.20%-0.23%)	0.92% (0.90%-0.98%)	1.41% (1.36%-1.47%)

Table 3.36 Revision rates (all causes) by main implant brands for total knee replacement (95% confidence intervals).

Brand	Number of patients	Revision rate at 1 year	Revision rate at 3 years	Revision rate at 5 years
Advance Bicondylar Knee	4,335	0.26% (0.14%-0.48%)	1.64% (1.24%-2.17%)	2.10% (1.60%-2.77%)
AGC	41,895	0.26% (0.21%-0.32%)	1.28% (1.15%-1.41%)	1.76% (1.59%-1.95%)
Columbus	2,522	0.46% (0.25%-0.85%)	2.27% (1.58%-3.26%)	2.50% (1.72%-3.63%)
Endoplus Bicondylar Knee	12,682	0.65% (0.52%-0.81%)	1.78% (1.53%-2.06%)	2.38% (2.04%-2.78%)
Genesis 2	20,580	0.38% (0.30%-0.49%)	1.42% (1.22%-1.65%)	2.31% (1.95%-2.74%)
Insall-Burstein	2,537	0.28% (0.13%-0.59%)	1.48% (1.06%-2.08%)	2.66% (2.02%-3.51%)
Kinemax	10,733	0.24% (0.16%-0.35%)	1.72% (1.48%-2.00%)	2.63% (2.30%-2.99%)
LCS Complete	13,270	0.45% (0.34%-0.59%)	1.53% (1.29%-1.82%)	2.41% (2.01%-2.89%)
MRK	4,067	0.26% (0.14%-0.49%)	0.89% (0.59%-1.35%)	1.00% (0.65%-1.54%)
Nexgen	50,779	0.34% (0.29%-0.40%)	1.29% (1.17%-1.42%)	2.03% (1.84%-2.23%)
PFC Sigma Bicondylar Knee	130,358	0.35% (0.32%-0.39%)	1.20% (1.13%-1.28%)	1.67% (1.57%-1.77%)
Profix	4,632	0.46% (0.30%-0.71%)	1.58% (1.23%-2.03%)	1.93% (1.52%-2.46%)
Scorpio	28,657	0.39% (0.33%-0.48%)	1.65% (1.49%-1.83%)	2.36% (2.13%-2.62%)
Triathlon	13,442	0.29% (0.20%-0.42%)	1.25% (0.95%-1.64%)	1.56% (1.16%-2.10%)
Vanguard	6,326	0.36% (0.22%-0.58%)	1.56% (1.07%-2.27%)	1.76% (1.18%-2.63%)
Other brands	19,241	0.60% (0.50%-0.73%)	2.20% (1.98%-2.45%)	2.94% (2.66%-3.25%)
Unknown brand	7,898	0.60% (0.45%-0.80%)	1.95% (1.62%-2.36%)	2.70% (2.21%-3.30%)
All total knee	373,954	0.37% (0.35%-0.39%)	1.42% (1.37%-1.47%)	2.03% (1.97%-2.10%)

Tables 3.37 and 3.38 show revision rates for patello-femoral and unicondylar knees. For patello-femoral knees, the market leader (the Avon) had lower revision rates than other brands. In contrast, for unicondylar knees, the lowest revision rates were not associated with the market leader (the Oxford Partial Knee) but with the MG Uni. At the other end of the scale, the Preservation unicondylar knee (now withdrawn due predominantly to failure of the mobile-bearing variant) had a five-year revision rate excluding infection of almost 10%.

Table 3.37 Revision rates (excluding for infection) by main implant brands for patello-femoral and unicondylar knees (95% confidence intervals).

Brand	Number of patients	Revision rate at 1 year	Revision rate at 3 years	Revision rate at 5 years
Patello-femoral				
Avon	2,962	0.74% (0.47%-1.14%)	4.12% (3.33%-5.11%)	7.03% (5.77%-8.56%)
Other brands	2,195	1.20% (0.79%-1.82%)	7.25% (5.82%-9.03%)	10.71% (8.45%-13.58%)
All patello-femoral	5,842	0.86% (0.64%-1.16%)	5.08% (4.38%-5.89%)	7.98% (6.91%-9.22%)
Unicondylar				
AMC/Uniglide	1,637	2.84% (2.08%-3.87%)	7.42% (5.95%-9.25%)	10.38% (8.20%-13.13%)
MG Uni	2,752	0.66% (0.41%-1.07%)	3.21% (2.53%-4.08%)	4.74% (3.78%-5.94%)
Oxford Partial Knee	26,317	1.02% (0.90%-1.16%)	3.95% (3.67%-4.26%)	6.36% (5.92%-6.84%)
Preservation	1,492	1.66% (1.11%-2.47%)	6.57% (5.30%-8.13%)	9.76% (8.00%-11.91%)
Zimmer Uni	1,292	0.47% (0.19%-1.13%)	2.32% (1.23%-4.36%)	-
Other brands	2,998	1.21% (0.84%-1.73%)	6.49% (5.35%-7.87%)	10.45% (8.64%-12.65%)
All unicondylar	37,426	1.08% (0.98%-1.20%)	4.25% (4.01%-4.52%)	6.71% (6.32%-7.12%)

Note: data where brand was not recorded (685 patello-femoral cases and 938 unicondylar cases) have been excluded from the analysis. For newer brands, it is not always possible to estimate five-year revision rates.

Table 3.38 Revision rates (all causes) by main implant brands for patello-femoral and unicondylar knees (95% confidence intervals).

Brand	Number of patients	Revision rate at 1 year	Revision rate at 3 years	Revision rate at 5 years
Patello-femoral				
Avon	2,962	0.77% (0.50%-1.18%)	4.16% (3.36%-5.14%)	7.21% (5.94%-8.75%)
Other brands	2,195	1.30% (0.87%-1.95%)	7.64% (6.17%-9.45%)	11.55% (9.18%-14.51%)
All patello-femoral	5,842	1.10% (0.80%-1.52%)	6.00% (5.07%-7.10%)	10.17% (8.54%-11.87%)
Unicondylar				
AMC/Uniglide	1,637	2.97% (2.19%-4.02%)	7.72% (6.23%-9.58%)	10.68% (8.48%-13.44%)
MG Uni	2,752	0.82% (0.53%-1.25%)	3.49% (2.78%-4.39%)	5.22% (4.21%-6.47%)
Oxford Partial Knee	26,317	1.14% (1.02%-1.29%)	4.28% (3.99%-4.60%)	6.85% (6.39%-7.35%)
Preservation	1,492	2.14% (1.50%-3.04%)	7.45% (6.10%-9.10%)	10.75% (8.91%-12.97%)
Zimmer Uni	1,292	0.47% (0.19%-1.13%)	2.47% (1.35%-4.53%)	-
Other brands	2,998	1.39% (0.99%-1.94%)	7.02% (5.83%-8.45%)	11.45% (9.53%-13.75%)
All unicondylar	37,426	1.29% (1.15%-1.45%)	5.51% (5.17%-5.88%)	8.96% (8.40%-9.55%)

Note: data where brand was not recorded (685 patello-femoral cases and 938 unicondylar cases) have been excluded from the analysis. For newer brands, it is not always possible to estimate five-year revision rates.

3.4.5 Conclusions and recommendations

It has been the policy in previous reports not to draw conclusions or make recommendations derived from the data reported, but rather to allow the reader to draw their own conclusions. However, the data shows some strong trends that merit discussion and recommendations. We hope that this will provoke debate and encourage surgeons and manufacturers to re-evaluate their practice in light of the evidence provided. We accept that the data is open to other interpretations and we welcome this. We must stress very strongly that the NJR provides only part of the picture, that of survivorship, and only survivorship of a short to medium term duration. We do not know whether these trends will continue in the longer term. Indeed, one of the lessons that we have learnt is that survivorship is not linear. Survivorship also gives little indication of satisfaction, relief of pain, improvement in function and greater participation in society. In many instances, these are more important to patients than survivorship. Moreover, the data is imperfect and we are reliant on surgeons completing the data accurately and recording every procedure without exception.

The data shows that short- to medium-term survivorship is excellent after almost all common types of total knee replacements whether they are cemented, uncemented or have hybrid fixation. However, multiple studies have now demonstrated that some patients are dissatisfied with their pain and/or function after total knee replacement. We, therefore, advise that surgeons and patients consider patient-based outcome measures in addition to survivorship when choosing prostheses.

For bicondylar knee replacements, posterior cruciate-retaining implants had lower revision rates than posterior cruciate-stabilised implants while mobile bearing prostheses tended to have a higher failure rate than fixed bearing prostheses. Thus, the lowest revision rates were associated with a posterior cruciate-retaining, fixed bearing prosthesis.

Patello-femoral joint replacements have a very high failure rate. However, it should be remembered that patello-femoral joint replacements are undertaken for different reasons than total knee replacements and so a direct comparison of revision rates would be erroneous. Patello-femoral joint replacements may be revised to a total knee replacement because of problems with a different part of the knee and so the reason for revision may be unrelated to the original procedure. In addition, there may be reasons related to the aetiology of patello-femoral arthritis that could explain why replacing the joint, without significantly correcting the underlying biomechanical cause, may not always be a successful strategy. We recommend that further research be undertaken into the aetiology of patello-femoral arthritis, thereby leading to more effective strategies to treat this difficult condition.

Unicondylar knee replacements also have a higher failure rate than total knee replacements. Again, unicondylar knee replacements may be undertaken for different reasons than total knee replacements and they may be revised to a total knee replacement because of disease progression in a non-operated compartment which is unrelated to the original procedure. Therefore, comparing revision rates with total knee replacements is not straightforward. However, given the sizeable difference in failure rates, it would need to be established that unicondylar knee replacements give significantly better function and pain relief to justify using them over a total knee replacement. Further research needs to be undertaken in this field including qualitative research into the rationale of using unicondylar knee replacements and into the rationale of revision of both unicondylar and total knee replacements.

Glossary

A	
Acetabular component	The portion of a total hip replacement prosthesis that is inserted into the acetabulum – the socket part of a ball and socket joint.
Acetabular cup	See Acetabular component.
Acetabular prosthesis	See Acetabular component.
Arthrodesis	A procedure where a natural joint is fused together (stiffened).
Arthroplasty	A procedure where a natural joint is reconstructed with an artificial prosthesis.
ABHI	Association of British Healthcare Industries - the UK trade association of medical device suppliers.
ASA	American Society of Anaesthesiology scoring system for grading the overall physical condition of the patient, as follows: P1 – fit and healthy; P2 – mild disease, not incapacitating; P3 – incapacitating systemic disease; P4 – life threatening disease; P5 – expected to die within 24 hrs with or without an operation.
B	
Bearing type	The two surfaces that articulate together in a joint replacement. Options include metal-on-polyethylene, metal-on-metal, ceramic-on-polyethylene and ceramic-on-ceramic.
Bilateral operation	Operation performed on both sides, e.g. left and right knee procedures carried out during a single operation.
BMI	Body mass index. A statistical tool used to estimate a healthy body weight based on an individual's height. The BMI is calculated by dividing a person's weight (kg) by the square of their height (m^2).
BOA	British Orthopaedic Association - the professional body representing orthopaedic surgeons.
Brand (of prosthesis)	The brand of a prosthesis (or implant) is the manufacturer's product name, e.g. the Exeter V40 brand for hips, the PFC Sigma brand for knees, the Mobility brand for ankles.
C	
CQC	Care Quality Commission. Regulators of care provided by the NHS, local authorities, private companies and voluntary organisations.
Case ascertainment	Proportion of all relevant joint replacement procedures performed in England and Wales that are entered into the NJR.
Case mix	Term used to describe variation in surgical practice, relating to factors such as indications for surgery, patient age and sex.
Cement	The material used to fix cemented joint replacements to bone – polymethyl methacrylate (PMMA).
Cemented	Prostheses designed to be fixed into the bone using cement.
Cementless	Prostheses designed to be fixed into the bone by bony ingrowth or ongrowth, without using cement.
Compliance	The percentage of all total joint procedures that have been entered into the NJR within any given period compared with the number of levies returned.
Competing risks survival analysis	An alternative to standard survival analysis methods (such as Kaplan-Meier estimation or the Cox proportional hazards model) when there are competing risks. A competing risk can prevent the event of interest from occurring (in this case, death is a competing risk to the risk of revision as patients who die will never experience revision). A competing-risks survival analysis adjusts the results accordingly.

Confidence Interval (CI)	A confidence interval (CI) gives an estimated range of values which is likely to include the unknown population parameter (e.g. a revision rate) being estimated from the given sample. If independent samples are taken repeatedly from the same population, and a confidence interval calculated for each sample, then a certain percentage (confidence level: e.g. 95%) of the intervals will include the unknown population parameter.
Confounding	Systematic variation due to the presence of factors not on the causal pathway, which affect the outcome, which are unequally distributed amongst interventions being compared which leads to inaccurate inferences about the results.
Cox proportional hazards model	A semi-parametric survival analysis model commonly used to model time-to-event data as it does not require the underlying hazard function to take a particular shape. As it is a multi-variable model, it can be used to explore the effects of covariates on the outcome of interest and reduce the impact of confounding.
Cup	See Acetabular component.
D	
Data collection periods for annual report analysis	The NJR Annual Report Part 1 reports on data collected between 1st April 2010 and 31st March 2011 – the 2010/11 financial year. The NJR Annual Report Part 2 analyses data on hip and knee procedures undertaken between 1st January and 31st December 2010 inclusive – the 2010 calendar year. The NJR Annual Report Part 2 analyses data on ankle procedures undertaken between 1st April and 31st December 2010 inclusive. The NJR Annual Report Part 3 reports on hip and knee joint replacement revision rates for procedures that took place between 1st April 2003 and 31st December 2010.
DDH	Developmental Dysplasia of the Hip. A condition where the hip joint is malformed, usually with a shallow socket (acetabulum), which may cause instability.
DH	Department of Health.
DVT	Deep Vein Thrombosis. A blood clot that can form in the veins of the leg, and is recognised as a significant risk after joint replacement surgery.
E	
Excision arthroplasty	A procedure where the articular ends of the bones are simply excised, so that a gap is created between them or when a joint replacement is removed and not replaced by another prosthesis.
F	
Femoral component (hip)	Part of a total hip joint that is inserted into the femur (thigh bone) of the patient. It normally consists of a stem and head (ball).
Femoral component (knee)	Portion of a knee prosthesis that is used to replace the articulating surface of the femur (thigh bone).
Femoral head	Spherical portion of the femoral component of the artificial hip replacement.
Femoral prosthesis	Portion of a total joint replacement used to replace damaged parts of the femur (thigh bone).
Femoral stem	The part of a modular femoral component inserted into the femur (thigh bone). Has a femoral head mounted on it to form the complete femoral component.
Flexible parametric proportional hazards model	Developed by Royston and Parmar, this model extends the standard Cox proportional hazards approach by modelling the baseline distribution parametrically using a restricted cubic spline function. This allows more flexibility in modelling the shape of the baseline hazard function than using standard parametric distributions.
Funnel plot	A graphical representation of analyses that plots observed values against expected values. Control limits based on standard deviation are superimposed on the plot.

H	
Head	See Femoral head.
Healthcare provider	NHS or independent sector organisation that provides healthcare; in the case of the NJR, orthopaedic hip, knee or ankle replacement surgery.
HES	Hospital Episode Statistics. Data on case mix, procedures, length of stay and other hospital statistics collected routinely by NHS hospitals in England.
Hybrid procedure	Joint replacement procedure in which cement is used to fix one prosthetic component while the other is cementless. For hip procedures, the term hybrid covers both reverse hybrid (cementless stem, cemented socket) and hybrid (cemented stem, cementless socket).
HQIP	Health Quality Improvement Partnership. Manages the NJR on behalf of the Department of Health. Promotes quality in health services and works to increase the impact that clinical audit has in England and Wales.
I	
Image/computer-guided surgery	Surgery performed by the surgeon, using real time images to assist alignment and positioning of prosthetic components.
Independent hospital	A hospital managed by a commercial company that predominantly treats privately-funded patients but does also treat NHS-funded patients.
Index joint	The primary joint replacment that is the subject of an NJR entry.
Indication (for surgery)	The reason for surgery. The NJR system allows for more than one indication to be recorded.
ISTC	Independent sector treatment centre (see Treatment centre).
K	
Kaplan-Meier	A statistical method of carrying out a survivorship analysis that can take into account 'censored' data, i.e. patient losses from the sample before the final outcome is observed (for instance, if a patient dies). It is a form of univariable analysis and so does not adjust for any confounding factors.
L	
Levy	Additional payment placed on the sales of specific hip, knee and ankle implants to cover the costs associated with the ongoing operation and development of the NJR.
Linkable percentage	Linkable percentage is the percentage of all relevant procedures that have been entered into the NJR, which may be linked via NHS number to other procedures performed on the same patient.
Linkable procedures	Procedures entered into the NJR database that are linkable to a patient's previous or subsequent procedures by the patient's NHS number.
LHMoM	Large head metal-on-metal. Large metal femoral head placed on the end of a femoral stem. Normally used with a metal resurfacing cup.
LMWH	Low molecular weight heparin. A blood thinning drug used in the prevention and treatment of Deep Vein Thrombosis (DVT).
M	
MDS	Minimum dataset, the set of data fields collected by the NJR. Some of the data fields are mandatory (i.e. they must be filled in). Fields that relate to patients' personal details must only be completed where informed patient consent has been obtained.
MDS 1 (MDSv1)	Minimum dataset version one, used to collect data from 1st April 2003. MDS 1 closed to new data entry on 1st April 2005.
MDS 2 (MDSv2)	Minimum dataset version two, introduced on 1st April 2004. MDS 2 replaced MDS 1 as the official data set on 1st June 2004.

MDS 3 (MDSv3)	Minimum dataset version three, introduced on 1st November 2007 replacing MDS 2 as the new official data set.
MDS 4 (MDSv4)	Minimum dataset version four, introduced on 1st April 2010 replacing MDS 3 as the new official dataset. This dataset has the same hip and knee MDS 3 dataset, but includes the data collection for total ankle replacement procedures.
MHRA	Medicines and Healthcare products Regulatory Agency – the UK regulatory body for medical devices.
Minimally invasive surgery	Surgery performed using small incisions (usually less than 8cm). This may require the use of special instruments.
Mixing and matching	Also known as 'cross breeding'. Hip replacement procedure in which a surgeon chooses to implant a femoral component from one manufacturer with an acetabular component from another.
Modular	Component composed of more than one piece, e.g. a modular acetabular cup shell component with a modular cup liner, or femoral stem coupled with a femoral head.
Monobloc	Component composed of or supplied as one piece, e.g. a monobloc knee tibial component.
N	
NHS	National Health Service.
NICE	National Institute for Health and Clinical Excellence.
NICE benchmark	See ODEP ratings.
NJR	National Joint Registry for England and Wales. The NJR has collected and analysed data on hip and knee replacements from 1st April 2003 and on ankle replacements from 1st April 2010. It covers both the NHS and independent healthcare sectors to ensure complete recording of national activity in England and Wales.
NJR Centre	National co-ordinating centre for the NJR.
NJR StatsOnline	Web facility for viewing and downloading NJR statistics on www.njrcentre.org.uk
O	
ODEP	Orthopaedic Data Evaluation Panel of the NHS Supply Chain.
ODEP ratings	ODEP ratings are the criteria for product categorisation of prostheses for primary total hip replacement against NICE benchmarks. The categorisation is based on NICE benchmarks: pre-entry benchmark (products commercially available that are involved in post-market clinical follow up studies); entry benchmark (after three, five and seven years; level A – acceptable evidence, level B – weak evidence); full benchmark (10 years; level A – strong evidence, level B – reasonable evidence, level C – weak evidence). For each year, there is a level for unacceptable evidence, where products should only be used as part of a clinical trial.
OPCS-4	Office of Population, Censuses and Surveys: Classification of Surgical Operations and Procedures, 4th Revision – a list of surgical procedures and codes.
Outlier	Data for a surgeon, unit or implant brand that falls outside of the defined control limits.
P	
Pantalar (ankle)	Affecting the whole talus, i.e. the ankle (tibio talar) joint, the subtalar (talo calcaneal) joint and the talonavicular joint.
Patella resurfacing	Replacement of the surface of the patella (knee cap) with a prosthesis.
Patello-femoral knee	Procedure involving replacement of the trochlear and replacement resurfacing of the patella.
Patello-femoral prosthesis	Two-piece knee prosthesis that provides a prosthetic (knee) articulation surface between the patella and troclear.

Patient consent	Patient personal details may only be submitted to the NJR where explicit informed patient consent has been given or where patient consent has not been recorded. If a patient refuses to consent, only the anonymous operation and implant data may be submitted.
Patient physical status	See ASA.
Patient procedure	Type of procedure carried out on a patient, e.g. primary total prosthetic replacement using cement.
Patient time	The summation of time (in years) for a cohort of primary procedures where the time is measured from the primary date to either date of revision, date of patient's death or analysis date (last observation date).
PDS	The NHS Personal Demographics Service is the national electronic database of NHS patient demographic details. The NJR uses the PDS Demographic Batch Service (DBS) to source missing NHS numbers and to determine when patients recorded on the NJR have died.
PEDW	Patient Episode Database Wales. The Welsh equivalent to Hospital Episode Statistics (HES) in England.
Primary hip/knee/ankle replacement	The first time a total joint replacement operation is performed on any individual joint in a patient.
Prosthesis	Orthopaedic implant used in joint replacement procedures, e.g. a total hip, a unicondylar knee or a total ankle.
PROMs	Patient Reported Outcome Measures.
PTIR	Patient-Time Incidence Rate. This is the rate of occurrences of an incidence (i.e. revision) for a given patient time (usually reported as revisions per 100 observed component years).
R	
Resurfacing (hip)	Resurfacing of the femoral head with a surface replacement femoral prosthesis and insertion of a monobloc acetabular cup, with or without cement.
Revision hip/knee/ankle replacement	Operation performed to remove (and usually replace) one or more components of a total joint prosthesis for whatever reason.
S	
Single stage revision	A revision carried out in a single operation.
Standard Deviation (SD)	The standard deviation is a measure of the spread of the data about the average. The smaller the standard deviation, the less spread out the data.
Subtalar Joint (ankle)	The joint between the talus and the calcaneum.
Surgical approach	Method used by a surgeon to gain access to, and expose, the joint.
Survivorship analysis	A statistical method that is used to determine what fraction of a population, such as those who have had a particular hip implant, has survived unrevised past a certain time. See Kaplan-Meier.
T	
Talar Component	Portion of an ankle prosthesis that is used to replace the articulating surface of the talus at the ankle joint.
TAR	Total ankle replacement (total ankle arthroplasty). Replacement of both tibial and talar surfaces, with or without cement.
TED stockings	Thrombo embolus deterrent (TED) stockings. Elasticised stockings that can be worn by patients following surgery and which may help reduce the risk of deep vein thrombosis (DVT).
THR	Total hip replacement (total hip arthroplasty). Replacement of the femoral head with a stemmed femoral prosthesis and insertion of an acetabular cup, with or without cement.

Thromboprophylaxis	Drug or other post-operative regime prescribed to patients with the aim of preventing blood clot formation, usually deep vein thrombosis (DVT), in the post-operative period.
Tibial component (knee)	Portion of a knee prosthesis that is used to replace the articulating surface of the tibia (shin bone) and the knee joint. May be modular or monobloc (one piece).
Tibial component (ankle)	Portion of an ankle prosthesis that is used to replace the articulating surface of the tibia (shin bone) at the ankle joint.
TKR	Total knee replacement (total knee arthroplasty). Replacement of both tibial and femoral condyles (with or without resurfacing of the patella), with or without cement.
Total condylar knee	Type of knee prosthesis that replaces the complete contact area between the femur and the tibia of a patient's knee.
Treatment centre	Treatment centres are dedicated units that offer elective and short stay surgery and diagnostic procedures in specialities such as ophthalmology, orthopaedic and other conditions. These include hip, knee and ankle replacements. Treatment centres may be NHS (NHS treatment centre) or privately funded (independent sector treatment centre – ISTC).
Trochanter	Bony protuberance of the femur, found on its upper outer aspect.
Trochanteric osteotomy	Temporary incision of the trochanter, used to aid exposure of hip joint during some types of total hip replacement.
Two stage revision	A revision procedure carried out as two operations, often used in the treatment of deep infection.
Type (of prosthesis)	Type of prosthesis is the generic description of a prosthesis, e.g. modular cemented stem (hip), patello-femoral joint (knee), talar component (ankle).
U	
Uncemented	See cementless.
Unicondylar arthroplasty	Replacement of one tibial condyle and one femoral condyle in the knee, with or without resurfacing of the patella.
Unicondylar knee replacement	See Unicondylar arthroplasty.
Unilateral operation	Operation performed on one side only, e.g. left hip.

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