National Joint Registry
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National Joint Registry for England and Wales

1st Annual Report | September 2004

...making it work

National Joint Registry for England and Wales

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Foreword

I am delighted to present the 1st Annual Report of the National Joint Registry (NJR) for England and Wales. The report specifically covers the collection and analysis of data related to hip and knee replacement procedures that took place between 1 April and 31 December 2003. However, I believe it is important to set those figures in their context and to reflect upon the enormous amount of work that has taken place in the two years since developmental work started in mid-September 2002.

The NJR launched the collection of data via Minimum Dataset version 1 (MDS v1) within just over six months of the contract being awarded. That required huge effort and dedication from everyone involved and it is to their credit that the launch was successful. Equally, it is appropriate to look at progress since January 2004 to give patients, professionals and the public a realistic look at the tremendous progress that has been achieved to the present.

During April and May 2003 there was an average weekly submission of 460 completed records. By December 2003, this weekly figure had risen to 1192. At the time of writing, the submission rate has now risen to 2474 operations per week[1]. On 11 August 2004, the NJR received its 100,000th completed electronic record.

There are currently 406 hospitals listed within the NJR system (NHS hospitals, independent sector hospitals, and Treatment Centres - both NHS-funded and privately funded). Of these, 384 have returned data, i.e. 94%. These statistics demonstrate great commitment from hospitals to ensure the success of the NJR in fulfilling its purpose of monitoring the performance of implants more effectively and enabling identification and dissemination of good surgical practice.

In June this year, MDS v2 was launched, prompted by the lessons learned using MDS v1. Two working groups composed of BHS and BASK members of the Regional Clinical Co-ordinator network advised the NJR Steering Committee on what modifications would be beneficial and should be incorporated into the data collection system. We now need a period of stability to allow use of MDS v2 to become fully established, related IT developments to be completed, and analyses incorporating data collected via MDS v1 and MDS v2 to be carried out for inclusion in the 2nd Annual Report.

As Chair of the NJR Steering Committee I would like to thank all of those who have been involved in this ambitious project. I would particularly like to thank the members of the Steering Committee and my Vice Chair, Professor Paul Gregg. The success of the NJR owes a great deal to the work of the Regional Clinical Co-ordinators who have given of their time unstintingly to ensure compliance and advise on progress. I would also like to acknowledge the support and co-operation that the Steering Committee has received from surgeons throughout England and Wales. May I also pay tribute to the professionalism and dedication of the staff of AEA Technology plc. Their contribution has been enormous.

We look forward to our next Annual Report with confidence and enthusiasm. The NJR is quickly becoming one of the largest databases of its kind in the world and I am confident that it will make a significant impact in improving orthopaedic care through clinical audit and good practice.

Bill Darling
Chair, NJR Steering Committee

16 August 2004

[1] The weekly submission rate is the average rate over the previous four weeks

It gives me great pleasure to join Bill Darling in presenting the 1st Annual Report of the NJR.

It has been a long time since Sir John Charnley first suggested the establishment of such a registry, a view later endorsed by Sir Rodney Sweetnam, Past President of the Royal College of Surgeons of England. The subsequent development of, and publications from, the Trent Arthroplasty Register, and later the North West Arthroplasty Register, kept the impetus going. Following on from these, strong recommendations for the establishment of a National Joint Registry came from the National Audit Office and NICE, with the Royal College of Surgeons' report on the investigation into the failure of the 3M Capital Hip finally leading to the establishment of the NJR.

I would like to add my sincere thanks to those of Bill Darling for all the hard work and support of the many people who have been involved in this very ambitious project. In particular, I would like to thank Bill, in his role of Chair of the NJR Steering Committee, for his support and the very fair and transparent way in which he has conducted the functioning of the Committee. Also, the way in which surgeon involvement outwith the main Steering Committee has been facilitated has brought positive results.

I firmly believe that the NJR will be good for patients and we must recognise the surgeon's responsibility to be accountable to them. They have every right to expect openness with regard to professional performance and I hope that participation in the NJR will send a clear signal of the orthopaedic surgical profession's commitment to this.

Paul Gregg
Vice Chair, NJR Steering Committee

2 September 2004

Sally Chaplin (nee Couzens)
RGN, National Association of Theatre Nurses (NATN)

Sally was a valued member of the NJR Steering Committee, bringing lively contribution to discussions. Her point of view provided significant input to NJR considerations, making sure that the care of patients was always kept in mind.

Sally died during the preparation of this report, having been party to the NJR since before its launch. She would have been pleased to have seen the results of the NJR's first nine months of achievement, and no doubt would have looked forward to building on the knowledge gained from the hard work of all involved.

Your valued input will be missed. Thank you, Sally, for having helped get the NJR underway so that its benefits can be realised.

Executive Summary

Introduction

This is the 1st Annual Report of the National Joint Registry (NJR) for England and Wales. The NJR has been set up to collect information on total hip and knee replacements carried out in both the NHS and independent healthcare sectors. It will quickly become the largest database of its kind in the world and will be used to optimise clinical outcomes of total hip and knee replacement.

Report structure

The report is structured in three parts for ease of use:

- Part 1 introduces the NJR, describing its background and development, what issues have been encountered and how they have been addressed, the current state of development, and then looks to the future
- Part 2 focuses on data analyses and interpretation, and looks specifically at data quality and completeness. It also provides some indications of the types of possible future analyses
- Part 3 of the report provides appendices to support Part 1 text. The web version of the report also includes additional appendices to support Part 2

Highlights of the development phase

A Steering Committee, with an independent chair, oversees the NJR's activities. To ensure that all stakeholders are represented, its members include patient groups, the surgical professions (25% of places), theatre nurses, implant suppliers, NHS Trust management and independent healthcare providers, the NHS Purchasing and Supply Agency, the Medicines and Healthcare products Regulatory Agency, the Department of Health and the Welsh Assembly Government, with the Scottish Executive having observer status. *Part 1, s4.1*

The contract to develop and run the NJR was awarded to AEA Technology plc in September 2002, in parallel with an announcement that electronic data collection would start on 1 April 2003. Thus began a six-month period of intense activity, the highlights of which included:

- Setting up the NJR Centre to manage the development and implementation phases of the database, as well as to manage dissemination of information. *Part 1, s4.2*
- Establishing a network of Regional Clinical Co-ordinators (RCCs) to help promote the Registry throughout England and Wales. RCCs are practising orthopaedic surgeons who act at a strategic level to facilitate feedback to surgeons and their teams, so enabling them to submit NJR data and optimise their clinical practice. Currently, there are 34 RCCs in place. *Part 1, s4.3*
- Developing a data entry tool that would work in the majority of hospitals with their existing IT systems; which was confirmed by carrying out an IT hardware 'health check' survey. *Part 1, s5.1.1*

- Orthopaedic suppliers, supported by the Association of British Health-Care Industries (ABHI), and the NJR Centre working together to develop and populate the NJR database with the relevant implant components. This incorporated coding components into product families to help make analysis simpler and faster, whilst also facilitating the analysis of new technologies as they become available. *Part 1, s7.3*
- The NJR Centre running a series of training roadshows in central locations across England and Wales in the weeks leading up to the launch. Involvement of RCCs in events helped to attract attendance from well over 1,000 participants. The feedback from attendees helped to fine-tune both the system and reference manual ahead of launch. *Part 1, s10.1*

Meeting the target launch date proved challenging, not least because the systems specification was constantly changing to reflect a still-evolving Minimum Dataset (MDS). However, hard work and determination ensured that NJR data collection started, as planned, on 1 April 2003.

Data quality, analysis and interpretation

Part 2 includes data analysis for hip and knee replacement procedures carried out between 1 April and 31 December 2003 inclusive (and which were entered into the NJR by 31 March 2004). Analyses and assessment of data quality were carried out by the Royal College of Surgeons Clinical Effectiveness Unit.

For hip procedures, data were collected for total primary hip replacement (with/without cement), hybrid procedures, resurfacing arthroplasty, and revision of all these procedures. For knee procedures, data were collected for primary total condylar knee, unicondylar knee, patello-femoral replacements, and revision of all these procedures.

The table below summarises the data analysed in the report.

	Hips		Knees		Total	
	Number	(%)	Number	(%)	Number	(%)
Country						
England	24,317	(97.3)	21,165	(97.1)	45,482	(97.2)
Wales	680	(2.7)	636	(2.9)	1,316	(2.8)
Type of procedure						
Primary	22,672	(90.7)	20,854	(95.7)	43,526	(93.0)
Revision	2,325	(9.3)	947	(4.3)	3,272	(7.0)
NHS hospitals	16,010	(64.0)	14,971	(68.7)	30,981	(66.2)
Independent hospitals	8,987	(36.0)	6,830	(31.3)	15,817	(33.8)
Total	**24,997**		**21,801**		**46,798**	

Key findings include:

- About 50% of relevant NHS hip and knee replacements were entered into the NJR. Consent to enter patient personal details (forename, surname, date of birth, home postcode and new NHS number) was obtained for 62.8% of procedures entered. NHS numbers were available for 65.1% of patients who gave consent. *Part 2, s4.2 and s5*
  - High levels of completeness can be achieved - 36 NHS Trusts had entered 80% or more of their expected joint replacements into the NJR
  - High levels of consent are achievable - more than half of all participating hospitals demonstrated consent rates of 80% or more
  - It is possible to record high levels of NHS numbers - 23 hospitals had 100% of NHS numbers for their consenting patients
- Primary hip replacement
  - Mean age of patients was 68 years. *Part 2, s6.1*
  - Overall, more consenting patients were female than male (59.5%)
  - The most common indication for surgery was osteoarthritis, present in 93.6% of patients
  - Most procedures used cement (82.3% used femoral cement, 61.9% used acetabular cement). *Part 2, s6.2.3*
  - 72 different brands of acetabular cups and 81 different brands of femoral stems, manufactured or distributed by 23 different companies, were recorded. The total number of different combinations of these cups and stems entered so far is 369, of which 98 were entered just once. *Part 2, s6.3.1 and s6.4.4*
- Primary knee replacement
  - Mean age of patients was 70.6 years. *Part 2, s7.1*
  - Overall, more consenting patients were female than male (56.3%)
  - The most common indication for surgery was osteoarthritis, present in 96.2% of patients
  - 37 brands of total condylar knee prostheses, 11 brands of unicondylar knee prostheses and 2 brands of patello-femoral prostheses were recorded. *Part 2, s7.3.1*
  - Fixed bearing menisci are used in 88% of primary total condylar knees. *Part 2, s7.3.2*
  - The patella was resurfaced in 38.8% of primary total condylar knee replacements. *Part 2, s7.3.3*
- Revisions
  - For hip revisions, the mean age of patients was 70.4 years. Overall, more consenting patients were female than male (53.4%). The most common indication for a hip revision was aseptic loosening, present in 62.2% of hip revision patients. *Part 2, s8.1*
  - For knee revisions, the mean age of patients was 70.6 years. Overall, more consenting patients were male than female (51.4%). The most common indication for a knee revision was aseptic loosening, present in 41.4% of patients. *Part 2, s8.1*
  - At this early stage of the NJR, 23 hip replacement patients and 4 knee replacement patients had both primary and revision procedures entered in the NJR that could be linked by their NHS numbers. *Part 2, s8.3*

Listening to users

It was known that at some point MDS version 1 would require modification to add re-operations. The Steering Committee decided to take advantage of this by endorsing a review of the first six months' use of MDS v1. Key elements of the review included obtaining feedback from hospitals of their experiences as well as obtaining expert consensus from two RCC working groups, one focusing on hips and the other on knees. It was important to consider the usability of the resultant MDS (MDS v2) in all hospital settings and guard against it becoming a tool for expert users only. *Part 1, s5.2*

User experience and suggestions are currently being reflected in the on-going development of:

- A bulk data upload facility (to export data from local hospital database systems directly into the NJR). *Part 1, s5.1.2*
- A bar code reader facility to scan component labels and thereby enter component details directly into the NJR in place of manual keying-in. *Part 1, s5.1.3*

Where are we now?

By mid-August 2004, the average weekly submission of completed records had reached 2,474 operations, with the NJR receiving its 100,000th record on 11 August. There are currently 406 hospitals listed on the NJR and, of these, 384 (94%) have returned data.

Although these statistics are very encouraging, there is still much to do. Areas that are receiving considerable attention include:

- Improving levels of completeness, particularly in relation to provision of an NHS number where patient consent is given (or postcode where an NHS number is not readily available). *Part 1, s4.4 and Part 2, s5*
- Ensuring that the NJR consent process is fully embedded in hospitals
- Working closely with the few hospitals that are experiencing difficulties in becoming NJR-compliant
- Working with stakeholders to confirm and develop the range of NJR reporting requirements. *Part 1, s12.2*

Looking to the future

A strategy for development of the NJR programme over the short to medium term (1 to 3 years) and longer term (5 to 10 years) is being compiled. Strategy objectives will be agreed, to be implemented by stakeholders working with the NJR Centre.

The Steering Committee's terms of reference include: 'facilitating, where appropriate, the use of the National Joint Registry data for research purposes'. In response, the NJR Research Sub Committee has been set up, having held its first meeting in July 2004 at which its proposed terms of reference were formulated. *Part 1, s13.2*

Identification and sharing of good practice is a continuing and growing element of the NJR programme. Examples of good practice are being developed and will be distributed via the NJR website, newsletter and the RCC and RAC (Regional Audit Co-ordinator) networks. *Part 1, s13.4*

Highlighting the NJR's aims, benefits and findings, with existing and future joint replacement patients, is high on the NJR communications agenda. Currently, the NJR newsletter and website provide information for patients and the public and all open reports will be made available on the website for their reference. *Part 1, s13.5*

We want to hear your views

We want to hear your views on the content and format of the current report, and also what you would like to see in future reports. Feedback received by the end of December 2004 will help to inform the planning process for the 2nd Annual Report. Readers are invited to complete the feedback form in Part 3, Appendix 8, and return it to the NJR Centre by fax or post. Alternatively, you can complete the online version on the NJR website (www.njrcentre.org.uk).

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The 20 cementless stem and cementless cup combinations entered most frequently into the NJR for hip primary procedures

Appendix 9F3

The 20 hybrid combinations entered most frequently into the NJR for hip primary procedures

Appendix 9G

The 20 stems and 20 cups entered most frequently into the NJR for hip primary procedures

Appendix 9H

Characteristics of surgical practice in primary knee procedures, according to patient procedure

Appendix 9I

Knee brands and manufacturers

Part 1

Introducing the NJR

1 Introduction

This is the first Annual Report of the National Joint Registry (NJR) for England and Wales. Work on the set-up and development of the NJR started in mid-September 2002, with the NJR data collection system being launched on 1 April 2003.

There are a large number of stakeholders involved in the NJR, including patients and the public, the orthopaedic profession, data entry staff, orthopaedic implant suppliers, regulatory bodies and hospital management. The Registry covers the independent healthcare sector as well as the NHS. Bearing in mind the range of users of the NJR, we have strived to produce a first Annual Report that:

- Is available free to everyone
  - downloadable from the NJR website
- Is suited to the orthopaedic specialist as well as being of interest to patients
  - the full report available on the website includes appendices for Part 2, Analyses and Interpretation that are not included in the printed version of the report
  - a summary report has been prepared
- Has a straightforward, logical structure that is easy to read
  - Part 1 of the report introduces the NJR, including: its background, why it has been developed, what issues have been encountered, how they have been addressed, the current state of development, and looking to the future
  - Part 2 of the report focuses on analyses of data collected and interpretation of the results, as well as describing data quality and completeness at this early stage of the NJR. It also provides some indications of the types of analyses that should be feasible in the coming years
  - Part 3 of the report provides Appendices 1 to 8 to support Part 1 text, including details of the NJR Steering Committee membership, copies of Minimum Dataset version 1 (MDS v1) proformas and the patient consent form. Appendices 9A to 9I, which provide support for Part 2 text, are included in the version of the Annual Report available on the NJR website, at www.njrcentre.org.uk

The authors and the Editorial Board are keen to know whether this report has met its objectives. Readers are invited to complete the feedback form in Part 3, Appendix 8 (also available on the NJR website to complete and submit online). We want to hear your views on the content and format of the current report, and also what you would like to see in future reports. This will help to inform the planning process for the 2nd Annual Report.

Part 2 of the 1st Annual Report includes data analysis for hip and knee replacement procedures that took place during the nine month period immediately following launch of NJR data collection - i.e. procedures carried out between 1 April and 31 December 2003 inclusive (and entered into the NJR by 31 March 2004).

It was considered important for Part 1 of the report to go beyond describing the broad range of activities carried out from mid-September 2002 to the end of 2003 and the issues that had been addressed. Developments up to the present time (mid-August 2004) are described, as well as looking to the future. This should provide the reader with a fuller appreciation of the progress made in establishing the NJR as a force for driving forward hip and knee surgery in England and Wales.

2 Background to the NJR

2.1 Why was the NJR set up?

Although calls for a national surveillance scheme for artificial joints were first made by Sir John Charnley in 1972 and echoed by Sweetnam in 1981[1], the establishment of the NJR for England and Wales was made in response to the Royal College of Surgeons' report[2] on the 3M Capital hip. The report suggested that the relatively poor performance of the 3M Capital hip would have been more readily apparent had data on implantation and revision been systematically collected and analysed, and had it been easier to efficiently recall patients for clinical review.

It is widely recognised that the orthopaedic community and its stakeholders have been working together for several years to turn the NJR from a concept into a reality. Reports by the British Orthopaedic Association[3], the National Audit Office (NAO)[4] and the National Institute for Clinical Excellence (NICE)[5] also identified a need to collect data to measure the long-term effectiveness of hip implants for all implant types in use.

In April 2002, the NAO report highlighted the potential benefits of a hip registry. The report noted that the Department of Health was to consider the case for a hip registry, and recommended that this be done quickly. The Committee of Public Accounts subsequently endorsed the establishment of a national hip registry and the Department, in its Treasury Minute of March 2001, confirmed that there had been extensive consultation with all potential stakeholders on the concept of a registry between October 2000 and January 2001. This showed widespread support for it, and the Department was then to consider whether and, if so, how the project should proceed[6].

The British Orthopaedic Association strongly supported a national hip registry, and in July 2001 the Royal College of Surgeons added its support. In the same month, the (then) Health Minister, Lord Hunt, announced that the Department would set up a National Joint Registry for hip and knee replacements, covering England and Wales.

In February 2002, the Department advertised for expressions of interest from companies wishing to run the Registry, with the intention that it would start collecting data on 1 April 2003.

Hip and knee joints comprise by far the largest number of joint replacements used in the UK and both are subject to a high proliferation of different implant brands and types that commonly lack data on their long-term effectiveness. Hence, the recommendation for a national hip registry was extended to include knee replacements. Both the NHS and the independent health care sector are included in the registry to ensure complete recording of national activity in England and Wales.

2.2 Awarding the work

Seven companies were invited to tender for the development and on-going running of the NJR. The contract was awarded to AEA Technology plc, with the national co-ordinating centre - the NJR Centre - being based at its Harwell site in southern Oxfordshire.

1 Sweetnam DR. *A surveillance scheme with 'recommended list' of artificial joints.* Health Trends. 1981; 13:43-4

2 Royal College of Surgeons (2001) *3M Capital Hip System, the lessons learned from the investigation*

3 British Orthopaedic Association (1999) *Total Hip Replacement: A Guide to Best Practice*

4 National Audit Office (2000) *Report HC417 Session 1999-2000*

5 National Institute for Clinical Excellence (2000) *Guidance on the selection of prostheses for primary total hip replacement*

6 National Audit Office (2003) *Report HC956 Session 2002-2003 Hip replacements: an update*

2.3 Is compliance mandatory?

Department of Health guidance[7] states that:

"From 1 April 2003 the NHS is expected to participate in the National Joint Registry by:

- *Putting in place systems to help with the implementation and working of the NJR, for example, appointing an NJR contact person*
- *Ensuring that data on total hip and knee replacements are entered on the database in every trust*
- *Contributing to the funding of the NJR by payment of the levy of £25 which is placed on the sales of hip and knee implants* (see Section 6)
- *Getting patient consent for the collection of patient identifiable information* (see Section 5.3)

Trusts that are not ready to participate should work towards joining the NJR as soon as they are ready. However, the levy is calculated from 100% participation and will be collected from all trusts from 1 April 2003."

In the independent sector, acute hospitals are mandated to participate in the NJR through the National Minimum Standards for Independent Healthcare, set down by the Department of Health and overseen by the National Care Standards Commission (the Health Commission (CHAI) took over this function on 1 April 2004).

For independently funded Treatment Centres, the Department of Health's National Implementation Team has stipulated within the provider contracts that compliance with the NJR is mandatory.

2.4 Is patient consent mandatory?

In accordance with the principles of data protection, explicit consent from joint replacement patients is required for their hospital to release their personal details to the NJR. In cases where patient consent is not obtained, the NJR will be sent only anonymous details of the operation and implants used. See Section 5.3 for details.

3 Aims of the Registry

The NJR is a keystone to delivering the commitment of both the Department of Health and the Welsh Assembly Government to improve the health and well-being of the population.

The stated aims of the NJR are to:

- Highlight in real time any brand of prosthesis showing high failure rates and allow prompt removal from the market, if necessary
- Ensure patients obtain the best clinical care during and following their joint replacement operation
- Improve evidence-based purchasing of joint replacement implants for orthopaedic units/hospitals
- Provide patients, clinicians, healthcare purchasers/commissioners, regulators and implant suppliers with evidence of which are the best performing implants
- Improve surgical practice through the identification of best practice in orthopaedic units/hospitals
- Ensure NHS and other healthcare resources are best used

[7] National Joint Registry: Department of Health Guidance (March 2003), Gateway Approval Number 1269

4 Structure of the NJR programme

4.1 Steering Committee

The NJR Steering Committee, which has an independent chair, oversees the NJR's activities. It currently comprises 20 members, representing the following stakeholder groups:

- Independent chair (1)
- The surgical professions (5)
- Patient groups (2)
- Industry (orthopaedic implant suppliers) (2)
- Public health and epidemiology (1)
- Theatre nurses (1)
- NHS Trust management (1)
- Independent healthcare providers (1)
- NHS Purchasing and Supply Agency (1)
- The Medicines and Healthcare products Regulatory Agency (1)
- Department of Health (1)
- Welsh Assembly Government (1)
- AEA Technology (contractor) (1)
- Scottish Executive (observer status) (1)

Part 3, Appendix 2 provides full details of the membership of the Steering Committee.

The terms of reference of the Steering Committee, as agreed in November 2002, are:

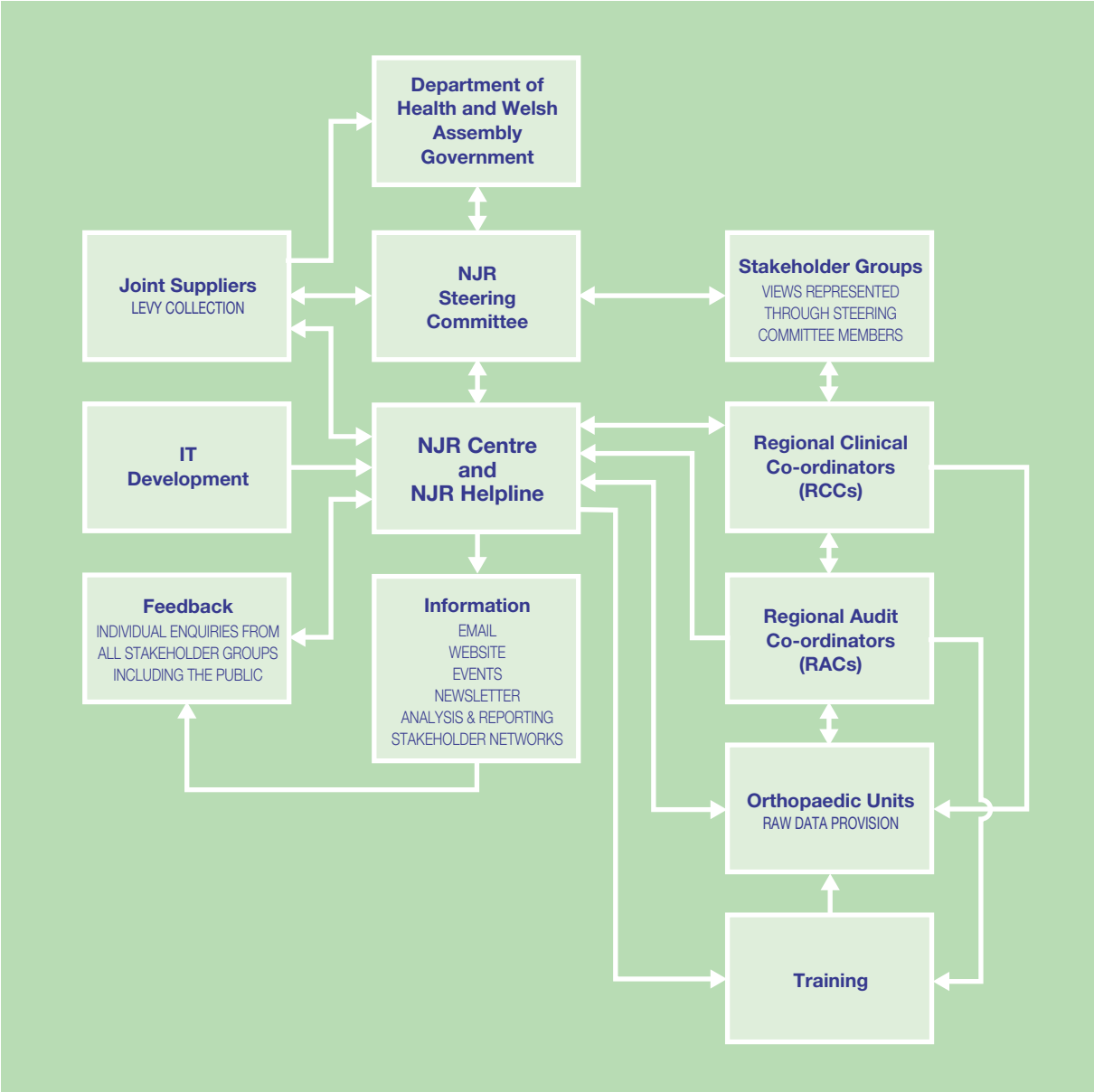
- To provide advice on the establishment and development of the NJR
- To set the work programme for the NJR
- To monitor that the NJR is keeping to its programme of work
- To set the cost of the levy based on the contractual costs of running the Registry and the work programme agreed
- To advise Ministers on what data should be made publicly available
- To provide advice to Ministers, orthopaedic hospitals or suppliers where the information shows concerns about the performance of certain prostheses
- To provide an annual report to Ministers on the performance of the NJR and, following Ministerial agreement, to make publicly available
- To establish and monitor the codes of conduct for the contractor dealing with orthopaedic units within NHS Trusts and independent healthcare providers, and with the orthopaedic implant industry
- To facilitate, where appropriate, the use of the NJR data for research purposes

4.2 NJR Centre

At the heart of the NJR is a database of information collected from all elective total hip replacement (THR) and elective total knee replacement (TKR) procedures in England and Wales. The NJR Centre was set up to manage the development and implementation phases of the database for all data collection and analyses, as well as to manage the dissemination of information. The NJR programme team brings expertise from the broad range of disciplines required to both set up and manage a successful National Joint Registry. This includes expertise in programme management, orthopaedics, Information Technology (IT) systems development, data security, subcontractor management, data analysis and reporting, stakeholder networking, event organisation, and communications (including newsletter production and running helplines, as well as website design and maintenance).

Figure 1 overleaf provides a simple representation of how the NJR operates and its key functions.

Figure 1 – *The NJR - how it operates*



4.3 Regional Clinical Co-ordinator network

A Regional Clinical Co-ordinator (RCC) network was established in late 2002, to promote the Registry and drive this initiative forward throughout England and Wales. RCCs are practising orthopaedic surgeons who act at a strategic level within trusts and hospitals, facilitating feedback to surgeons and their teams and so enabling them to submit NJR data and optimise their clinical practice. RCCs were appointed in close alignment with the 28 Strategic Health Authority (SHA) areas in England and the three NHS regions in Wales.

The RCC role comprises the following elements:

- Providing support to the initial set-up of the NJR
- Facilitating feedback to orthopaedic surgeons
- Communicating between the regionally based hospitals/orthopaedic units, the NJR Centre and the NJR Steering Committee
- Providing representation on organising committees for NJR-related events
- Hosting training roadshows and regional seminars

- Providing input to determining appropriate reporting, analysis and interpretation of NJR data

The RCCs played key roles in a series of regionally based NJR training events in March 2003 (see Section 10.1). Since early 2004, the RCCs have worked closely with the newly-formed team of Regional Audit Co-ordinators (see Section 4.4 below). Membership of the RCC network can be found in Part 3, Appendix 3.

4.4 Regional Audit Co-ordinator team

The Regional Audit Co-ordinator (RAC) team has been set up to provide field-based links between hospitals and the NJR Centre. The RACs are:

- Promoting the NJR to all orthopaedic units in England and Wales
- Facilitating the collection of accurate NJR data through practical application at individual hospitals
- Promoting good practice in relation to obtaining patient consent, data entry and local management
- Working closely with the RCCs and the NJR Centre to resolve issues and disseminate information to individual hospitals
- Providing a first point of contact, and a personal face, for hospitals and building good working relationships with them

The first RACs were in place in February 2004, with five RACs now providing complete coverage across England and Wales in the RAC regions 'South West', 'North East', 'North West', 'Central' and 'South East'.

The initial focus of the RACs has been to encourage and obtain the compliance of those hospitals that were not submitting data to the NJR, by helping to resolve any issues the hospitals had. The RACs have built good relationships and communication routes with these hospitals and encouraged the development and application of practical protocols for the collection and input of NJR data.

Immediately prior to the RAC team starting work, 71% of eligible hospitals had submitted data and the weekly submission rate for records was 1,130. Four months later this had increased to 88% of hospitals submitting data and 1,720 records submitted weekly[8].

The introduction of Minimum Dataset version 2 (MDS v2) (see Section 5.2) saw a change in priority for the RACs. They had a key role in working closely with hospitals to help facilitate the smooth transfer from MDS v1 submission to MDS v2 submission.

The extensive communications between hospitals and the RACs have aided identification of any problems that users have experienced with the NJR system. Not surprisingly, hospital users have provided good practical suggestions for minor changes to input functionality. This has contributed to continuous improvement of the application.

Following completion of the smooth transition to MDS v2, improving the quality and completeness of data submission will become a main focus. A key element of this is determining why patient consent levels are lower in certain hospitals and establishing strategies to address this (see Section 5.3 for details on the NJR patient consent process, the importance of obtaining consent, and measures being taken to increase consent rates).

The RACs - often in partnership with the relevant RCCs - have become the first point of contact for any issues or problems that hospitals face. The increasing knowledge of the systems and processes in place in individual hospitals is enabling the RACs to help hospitals establish good working protocols for quality data submission.

The ultimate goal of the RACs is for all eligible hospitals in England and Wales to be submitting complete and high-quality datasets of all relevant procedures. Work will continue to ensure this is achieved and maintained.

[8] The weekly submission rate is the average rate over the previous four weeks

4.5 Hospital interaction

In the set-up phase of the NJR and the early months of the NJR collecting data, interaction with individual hospitals was largely via staff at the NJR Centre, predominantly administrative staff, Helpline staff and IT system developers where queries were IT-related. As time has passed, and the RAC and RCC networks have evolved, much of the day-to-day interaction with hospitals is provided by the RACs working closely with the relevant RCCs, with central support being available as required. However, the Helpline retains a significant role.

4.6 Supplier interaction

Throughout the preparation and implementation phases of designing the NJR systems, the NJR Centre and the Steering Committee engaged in wide consultation with individual suppliers and the Association of British Health-Care Industries (ABHI), which is the representative trade body for the UK medical device industry. A Memorandum of Understanding was put in place between the ABHI, the Department of Health, the Welsh Assembly Government, and the Independent Healthcare Association (now the Independent Healthcare Forum), which includes specifying which components attract levy payments and how the levy is calculated and collected (see Section 6 for further details on the NJR levy).

In March 2003, the NJR Centre held a suppliers' information and training seminar to enable suppliers of implants to understand how to upload their implant details into the NJR system and confirm full details of how the levy collection process would operate.

Since this time, the NJR Centre has embarked on a wide-ranging process of communication and dialogue with suppliers. This includes: attendance at ABHI meetings, monthly dialogue to collect and acknowledge levy returns from individual suppliers, visits to suppliers' premises to engage and train data entry staff to keep catalogue entries up-to-date, teleconference calls and one-to-one correspondence.

More recently, suppliers have been involved in preparatory work relating to development of a bar code reader facility (see Section 5.1.3).

Box 1: Suppliers of component information to the NJR Centre

Amplitude SA
Apatech Ltd
Avatar
B Braun/Aesculap
Biomet Merck Ltd
Centerpulse (UK) Ltd (part of Zimmer)
Corin Group plc
DePuy International Ltd
Endo Plus (UK) Ltd
Finsbury Instruments Ltd
Forth Medical Ltd
Implants International Ltd / Mathys Orthopaedics Ltd
Intavent Orthofix Ltd
International Orthopaedics Ltd
Joint Replacement Instrumentation Ltd
Midland Medical Technologies Ltd (part of Smith & Nephew Healthcare Ltd)
New Splint Ltd (distributor of Waldemar Link)
Ortho ID Ltd
Orthodynamics Ltd (part of Summit Medical Ltd)
Plato Health Systems Ltd
Schering-Plough Ltd
Smith & Nephew Healthcare Ltd
Sovereign Medical Ltd
Stanmore Implants Worldwide Ltd
Stryker Howmedica Osteonics UK Ltd
Summit Medical Ltd
Surgicraft Ltd
Tornier SA
Wright Cremascoli Ortho Ltd
Zimmer
Zynergy Orthopaedics Ltd

5 Registry development

This section introduces some of the key issues that had to be considered when developing and launching the NJR. There has been a range of issues to address; the main ones are introduced here, with further details provided in later sections.

5.1 Electronic data input

5.1.1 IT hardware 'health check'

The main issue to be addressed when developing the data entry tool was that it should work in the majority of hospitals - English and Welsh, NHS and independent sectors - on their existing IT systems. This meant that it had to be a basic specification as IT systems in the health sector, especially the NHS, vary widely.

Consequently, the first action during the IT implementation phase was to conduct an IT hardware 'health check'. This involved carrying out a survey of all relevant hospitals to ask them a short series of questions that would establish whether they would be able to use the IT solution originally proposed by the NJR Centre.

The survey established that the proposed solution would be viable in the vast majority of hospitals. Where this was not the case, it was usually due to the hospital using an old web browser; a simple, free upgrade was all that was required to deal with this.

5.1.2 Bulk data upload

Many hospitals collect data on their local database systems and some requested a method of exporting that data directly into the NJR - a bulk data upload facility. The NJR Steering Committee approved the design and provision of such a facility. This will allow hospitals to collect the NJR dataset within their own internal hospital systems and upload the data at regular intervals to the NJR database. As bulk data upload avoids duplicate data entry, it also has the benefit of preserving data quality.

The bulk data upload facility is currently being developed, with the NJR Centre working closely with those hospitals that would like to use it. It was originally planned that this facility would be implemented during the first 12 months following the launch of the NJR. However, when it was known that the original NJR MDS v1 would be developed further to allow launch of MDS v2 in mid-2004, the decision was made to delay the introduction of bulk data upload until after the rollout of MDS v2. This was because any bulk upload facility requires hospitals to make adjustments to their internal IT systems to ensure compatibility. The time and cost implications for hospitals needing to make changes to their systems twice within a short timeframe - to adapt to bulk uploading of MDS v1, and then of MDS v2 - were considered unacceptable.

5.1.3 Bar code reader facility

The current data collection process involves the manual keying-in of all the product codes and lot numbers of the components used during an orthopaedic procedure. In the early months of the NJR's release, a number of hospitals requested provision of a bar code reader system to facilitate the input of these details. Following the results of a scoping study, the Steering Committee agreed to development of an appropriate system.

The implementation of bar code readers to scan the components' labels will reduce the time required for data input. Development of a system that can cope with all bar code systems being used by component manufacturers and suppliers has its challenges. For example, since there is no single standard for the bar code format, the developed system will need to identify which specific bar code format each component manufacturer is using prior to it being able to read the bar code.

Whilst such a system will aid data entry for many users, not all suppliers currently provide bar codes on implant labels and so it will not always be possible to enter a component's details in this way.

The implementation of bar code readers will follow the introduction of the bulk upload facility.

Every hospital participating in the NJR will be issued with a bar code reader programmed for use in NJR-related data entry.

5.2 Minimum Dataset - versions 1 and 2

5.2.1 Initial development - MDS v1

The initial development and set-up phase for the NJR was short; work commenced in mid-September 2002, with a commitment for the NJR data collection to be launched on 1 April 2003. It was soon realised that this restricted timeframe could have adverse implications for the robustness of the NJR Minimum Dataset. As a result, it was decided that the dataset (MDS v1) would cover primary and revision procedures for hips and knees, but would not include data collection for 're-operation other than revision', i.e. procedures following a primary replacement that do not require component removal or replacement. This would be included at a later date.

5.2.2 Review of the MDS

MDS v1 was considered largely fit for purpose, with its design and content being informed by other existing regional and national Minimum Datasets, and the views of the NJR Steering Committee. However, knowing that it would require modification to add re-operations, led the Committee to develop a process for review of the scope and use of the NJR MDS. This was to ensure that the MDS fitted fully with the aims of the NJR and was optimised. Following the first six months' experience of using MDS v1, a review was initiated with the following key elements:

- Obtaining feedback from hospitals of their experiences of using MDS v1 and the paper proformas (see Section 8.1 for details of proformas)
- Interrogation of the NJR system to determine where potential problems lie (e.g. fields that are rarely completed or tend to be completed inaccurately)
- Collecting views and experiences of all stakeholder groups represented on the Steering Committee
- Obtaining expert consensus of two Regional Clinical Co-ordinator working groups, one focusing on hips and the other on knees

Some issues considered as part of the review process were:

- Whether there were any obvious omissions in MDS v1 that needed to be addressed to take epidemiological case mix into consideration in subsequent reporting
- Incorporation of 're-operation other than revision'
- The usability (including length) of the MDS in an average district general hospital, and guarding against the MDS becoming a tool for expert users only

5.2.3 Finding a balance

During the review process it was appreciated that a balance needed to be found between appropriate and sufficient data collection and surgeon/administrative staff workload. Effort was focused on ensuring that MDS v2 did not increase the administrative burden, especially as this was one prerequisite to obtaining Department of Health approval of the revised dataset.

This balance was achieved in a number of ways. Firstly, the paper proformas and NJR data entry screens were reformatted to follow the chronology of operations more closely, making a more intuitive workflow. The new proformas require fewer but more targeted data fields to be completed. Redundant data fields have been removed and new data fields made easier to complete. Drop-down menus and radio buttons have been incorporated into the data entry system, allowing details to be entered with a simple mouse-click.

The overall effect of these changes has been to increase the adequacy of the NJR's Minimum Dataset without increasing the burden placed on hospital staff.

5.2.4 Introduction of MDS v2

MDS v2 was introduced on 1 April 2004, initially as an optional route for data entry. Following approval by the Register of Central Returns, the NHS Information Board and the Department of Health, MDS v2 replaced MDS v1 as the NJR dataset on 1 June 2004. The ability to enter new records into MDS v1 was withdrawn from general use on 15 August 2004[9].

Further details on the development of MDS v2, its contents, and analyses of MDS v2 data will be included in the 2nd NJR Annual Report.

5.3 Patient consent

Patient personal details may only be submitted to the NJR where explicit informed patient consent has been given. If a patient does not give consent, only the anonymous operation and implant data may be submitted to the NJR. This practice conforms to the requirement of the Data Protection Act (1998).

Patient personal details requested by the NJR are:

- Surname
- Forename
- Date of birth
- Home address postcode
- New NHS number[10]

The NJR provides a form for collecting this information, which can be downloaded from the NJR website. It is available in English and Welsh and in standard and large text.

Patient details are encrypted once they are entered into the NJR, which means they are not stored in the database in an identifiable format.

Recording a patient's personal details enables the NJR to link a patient to the implant(s) they receive during joint implant surgery. This means that the NJR would be able to identify patients who had received a particular implant if there were early indications that there may be problems and urgent clinical review was needed.

Importantly, a patient's primary and any subsequent revision operations (including re-operations) are linked via their NHS number. Without this link, the survival of the implant (i.e. the revision end point) cannot be determined. Similarly, the date-of-birth (DOB) field enables the age of the patient to be determined, which allows age-related data analyses to be carried out. (A patient's NHS number and date of birth are classed as 'strong patient identifiers' and hence require the patient to give their consent to allow the NJR to record them.)

In the future, recording a patient's personal details will also enable the NJR to distribute patient feedback questionnaires. These questionnaires will be used to capture patient satisfaction and health-related quality of life information about their joint replacement surgery, which may provide early indications of implant failure. The patient feedback process is currently under development.

Obtaining high rates of patient consent is critical to being able to carry out robust evaluation of outcomes after joint replacement (see Part 2, Section 4.2). At the same time, patients must not be coerced into giving their NJR consent - or even (wrongly) perceive that they are under any pressure to do so. One consequence of this is that the NJR consent process must be kept entirely separate from the 'consent to operation' process. For example, use of a single form to obtain both NJR and operation consent is not allowed.

It is the responsibility of hospitals to define a process to ensure that seeking informed consent is incorporated into the patient care pathway. For example, a hospital may choose to collect patient consent at a patient's pre-operative assessment. One of the key tasks of the RAC team is to assist hospitals in identifying

[9] Following 15 August 2004, any hospitals that hold details for operations carried out between 1 April 2003 and 31 May 2004 inclusive, recorded only on MDS v1 proformas, and that wish to submit the data to the NJR are required to apply for permission via the NJR Helpline

[10] The allocation of new NHS numbers was introduced in 1996, replacing the previous NHS numbers that were unsuitable for use within computerised information systems

how the NJR consent process can be best embedded in their existing processes and systems. Where examples of good practice are identified, these are shared with other hospitals.

As with other aspects of the NJR, much has been learned from the early months of seeking NJR patient consent. The original NJR patient consent form has been updated to reflect hospital feedback, and now incorporates separate sections to record where consent has been given and where it has been withheld. The revised NJR patient consent form can be downloaded from the NJR website. (A copy of the original patient consent form - as used during the nine-month data collection period - can be found in Part 3, Appendix 4.)

The NJR Centre and RAC team continue to promote the importance of obtaining voluntary patient consent via a wide range of routes, including when liaising with hospitals, speaking at events, via information on the NJR website, and in articles in the NJR newsletter. As well as the consent forms, other related information that can be downloaded from the NJR website includes:

- Guidance on how to use the consent form, including a checklist to help hospitals consider how they will use the form. (The checklist should be adapted to fit with local procedures and appropriate staff made aware of how it will work in practice)
- A colour poster to use in patient areas, introducing the NJR and why patients are being asked for their consent to collect their data
- A colour Patient Safety Leaflet that outlines how the NJR can benefit patient safety. It covers the NJR's role in clinical governance, the importance of patient consent, and aspects of patient data security and confidentiality

5.4 Surgeon consent

The NJR database allows surgeons to access their individual data online. This functionality provides surgeons with the ability to perform tailored analyses and monitor their own performance over time. If a surgeon gives prior consent, the database also allows the surgeon's NJR hospital data manager to view their data.

Surgeon consent is recorded on the database under 'surgeon profile' and is registered by a tick mark in the allotted consent box. A surgeon's individual profile is confidential and can only be accessed by the surgeon. It contains: their default techniques for primary and revision hip and knee procedures (if they have entered the details), a list of hospitals that they are associated with (i.e. at which they perform operations), the facility to change their NJR password, and the consent box.

5.5 NJR stakeholder commitment

NJR stakeholders include all healthcare-related providers and agencies involved with maintaining and improving the quality of care for total hip and knee replacement patients. The NJR's main stakeholders are:

- Orthopaedic units (NHS and the independent healthcare sector)
- Patients and the public
- Orthopaedic implant suppliers
- Associated trade, professional and governmental bodies

The composition of the NJR Steering Committee (see Section 4.1) reflects the breadth of NJR stakeholders. The needs of each stakeholder are diverse and require a tailored and personal approach. The NJR website and newsletter provide information and address key issues relevant to each stakeholder group.

Obtaining and maintaining the commitment and buy-in of all stakeholder groups is critical to the success of the Registry. At all stages of development, the varying needs of the different groups have to be considered. Considerable effort is devoted centrally to ensuring that systems find the optimum balance between, for example:

- Trying to collect all data considered relevant for current and future analyses

- Not imposing unrealistic workloads on busy hospital staff (which would often result in incomplete, or even no records being submitted)

An important consideration woven throughout the NJR programme is being able to answer: *"What's in it for us?"*, whether asked by a single individual or on behalf of an entire stakeholder group. Section 12 examines current and proposed future reporting, which goes a long way to answering this question.

Quotes relating to benefits of the NJR are found throughout Part 1 of this report. They are from current and past members of the NJR Steering Committee, and were made in the early months of developing the NJR systems, before the NJR began collecting data on 1 April 2003. They capture the expectations and desires of different stakeholders and are constantly borne in mind.

NJR BENEFITS
the surgical profession

The Registry will have the benefit of providing a major research database and allow comparative audit of hospitals and prostheses. The Registry will also allow monitoring of 'new' joint replacement prostheses and identify patients requiring urgent clinical review. Overall, I expect that it will have the effect of improving clinical standards.

The Royal College of Surgeons of England and the British Orthopaedic Association have also welcomed this development and will work closely with the Steering Committee to ensure its success.

Professor Paul Gregg Vice Chair, NJR Steering Committee and former President of the British Orthopaedic Association

6 Registry funding

6.1 NJR funding

6.1.1 Costs for set-up and on-going operation and development

The initial set-up costs (for the period September 2002 to March 2003) were met by the Department of Health, but from 1 April 2003 the NJR has been self-financing. The costs associated with on-going operation and development of the NJR are funded through a levy placed on the sale of total hip and total knee prostheses. These arrangements apply to NHS trusts and independent healthcare hospitals in England and Wales, as well as NHS and independently funded Treatment Centres.

The levy was set by the Steering Committee for the first year of NJR operation (i.e. 1 April 2003 to 31 March 2004) at £25.00 per joint (inclusive of VAT). It will be reviewed annually by the Steering Committee. For year two of operation, the levy has remained unchanged.

The levy includes an administration fee to cover the costs of the orthopaedic suppliers collecting and processing the levy. This administration fee is included in the calculation of the levy.

The administration fee has been set by the Steering Committee for the first two years of NJR operation at £2.50 per joint and £1.70 in year three. The mechanism for levy collection by the suppliers is to be reviewed by the Steering Committee after two years of operation.

6.1.2 Principles of levy collection

The agreed principle of funding is that the supplier of a joint prosthesis collects a levy payment (the NJR levy) from the purchasing NHS Trust or independent healthcare provider for each applicable prosthesis sold (see Box 2 for definitions of applicable prostheses).

Within 10 working days of the end of each calendar month, implant suppliers inform the NJR Centre of the number of applicable prostheses sold during that month. The NJR Centre uses this

information to provide a statement of account to the Department of Health.

The Department invoices suppliers for the amount of the NJR element of the levy minus the NJR administration fee. The invoice includes VAT on the NJR element only. Suppliers make payment to the Department of Health within 30 days of the date of the invoice.

6.1.3 Definition of prostheses for NJR levy payment

Proposals for the definition of prostheses for NJR levy payment were agreed to minimise the administrative burden on collecting the levy for different components that may comprise a total joint prosthesis.

Box 2: Prostheses for NJR levy payment

The purchase of a one-piece (monobloc) acetabular cup or a modular acetabular cup shell component attracts an NJR levy payment for a total hip prosthesis.

The purchase of any knee femoral component (including the femoral component of a unicompartmental knee or patello-femoral joint prosthesis) or one-piece knee prosthesis attracts an NJR levy payment for a knee prosthesis.

Patient-specific custom implants are excluded from levy collection.

Where NHS Trusts or independent healthcare hospitals wish to purchase joint prostheses from UK or overseas suppliers that are not currently registered as suppliers of component information to the NJR Centre, they are required to inform the MHRA and NJR Centre of their intentions. This is to ensure that appropriate arrangements may be made to secure payment of the NJR levy and that the correct prosthesis details and product codes are made available within the NJR database.

The annual number of implants sold by suppliers is to be reconciled against the number of levies collected, the number of implants reported by suppliers to the NJR Centre, and the number of levyable implants recorded on the NJR data entry system.

6.2 What does the funding cover?

As indicated in Section 6.1.1, the purpose of the levy is to cover the costs associated with on-going operation and development of the NJR.

The main part of the levy funds the work programme, carried out and managed by the NJR Centre, with some elements being subcontracted. The levy is agreed in advance of the financial year to which it applies. This requires not only the envisaged activity for the year to be determined and costed, but also potential additional requirements to be predicted. In year 1, additional activities that were authorised included:

- Establishing the Regional Clinical Co-ordinator network
- Development of MDS v2
- Initial scoping of development of the bulk upload facility
- Initial scoping for developing the bar code reader facility
- Provision of bar code readers to hospitals
- Setting up the Regional Audit Co-ordinator team
- Contracting with the Clinical Effectiveness Unit at the Royal College of Surgeons to undertake required analyses for the annual report

Discussion is on-going on determining priorities for apportioning levy funds in the future. Key areas under consideration are:

- Funding NJR-related research
- Improving data collection (e.g. providing close support to hospitals where lack of resources is adversely affecting compliance with the NJR)
- Further development of the NJR system output (e.g. implementing a Public Key Interface (PKI) security system to allow the NJR to be used by surgeons as an online tool and resource library)
- Customisable data collection (allowing collection of local outcome data so that hospitals can put local systems in place to track, for example, cases of deep vein thrombosis and pulmonary embolism)
- Expanding the RAC team

- Providing more for patients by taking over development, implementation and management of the Owner's Manual - Hip from the NHS Information Authority (and if this proved a successful addition to the NJR remit, to consider development of an Owner's Manual - Knee)
- Development, validation and application of an NJR Patient Feedback Questionnaire
- Extension of the NJR to other joints, once it is fully established for hips and knees

If the level of levy funds collected in one year is found to be higher than needed (for example, if the number of levyable components sold in the period was higher than predicted) then the levy may be reduced in the following year. Conversely, if the levies collected are insufficient to cover authorised costs in one year then this would be taken into account in calculating the levy for the following year.

NJR BENEFITS
patients

I am delighted to be involved with the NJR, which I firmly believe, with a commonsense use of modern technology, can overcome many of the problems which currently bedevil the Health Service.

A hip or knee joint replacement can make a dramatic improvement to an individual's quality of life. The downside is the fact that too many people have to undergo unnecessary pain and restricted movement because of long waiting lists.

Certainly, any initiative which improves medical standards has to be welcomed as does confidence from the patient's point of view that their treatment will be first class, irrespective of where they live.

Colin Thomson All Wales Community Health Councils

7 Developing the IT solution

7.1 Data entry systems

Data are entered by hospitals and stored in a central database - the NJR. Having undertaken the IT hardware 'health check' - as described in Section 5.1.1 - the proposed data entry solutions were agreed and fixed. Two operating systems (i.e. user interfaces with the NJR) were built, both based on the Microsoft .NET solution. This technology was selected as it would significantly reduce the time taken to build both systems since much of the coding could be used in both solutions. A web browser-based ASP.NET client and a Windows-based (i.e. PC-based) VB.NET client were selected. The web-based system has a user interface that works with standard web browser technology, whilst the Windows-based system is a software application that is installed on the user's PC. The advantages of these two systems are:

- The web-based system
  - it is easy to ensure that all hospitals are using the same version of the system as changes are made centrally
  - can be used on any PC that meets the minimum technical requirements
  - is easily accessible to the widest possible audience as there is no need for the user to install any software
- The Windows-based system
  - allows connection to other hospital databases to avoid double entry of patient data
  - is a low bandwidth solution as only the data have to go down the wire because the application is installed locally
  - is faster than the web system

Each system has a set of minimum requirements that hospitals have to meet. To operate either system, hospitals must have a minimum specification of PC as follows:

- PC with a Pentium 2 style chip and 64MB of RAM
- Connection to the Internet/NHS Net (connection speed of 56 kilobits per second or greater)
- Internet/NHS Net connection (and any hospital firewalls) must allow both the HTTP (port 80) and HTTPS (port 443) transport protocols

NJR BENEFITS orthopaedic service users (patients)

When the idea of a new Registry to monitor joint replacement interventions was first mooted, my own organisation, Arthritis Care, responded enthusiastically. In our response to the Department of Health we made it clear that, as the leading UK organisation representing people with all forms of arthritis, we knew first hand that a great deal could be done to improve services around knee and hip replacements. A good proportion of our 60,000 or so members and supporters have regularly raised issues such as not knowing what to do if their new joint appeared to be failing them, or anxiety that they might never know if a fault was subsequently found with certain types of replacement. It is hugely encouraging to see issues such as these being captured by the Registry.

We also urged the Department of Health to ensure that there was adequate service user (or 'patient') representation on the Steering Committee from day one, and were delighted to see this suggestion picked up. As one of the two representatives in that capacity on the committee, I believe I can draw on both my personal experience of (juvenile) arthritis, as well as my professional role as a public policy specialist, to help the project bring maximum benefits to the people who matter most in all of this - the users of the service.

Neil Betteridge Head of Public Policy and Campaigning, Arthritis Care

In addition, the web-based system has the following minimum software requirements:

- Internet Explorer 5.5 or later or Netscape Navigator 6.2 or later
- The authorisation to allow scripting within the browser window

and for the Windows-based system, the following requirements apply:

- Hospitals must allow the installation of third party software including the Microsoft .NET framework

User feedback has helped to improve the NJR data entry system and ensure that it continues to evolve as an efficient and user-friendly data collection tool.

Feedback indicated that very few hospitals chose to use the Windows-based data entry option and this facility was withdrawn for new users in late 2003. The MDS v2 data entry system is available currently as a web-based system, with a bulk upload facility under development (see Section 5.1.2).

7.2 Data development phase

Once the IT delivery mechanisms were agreed and fixed, the IT development phase started. A launch date of 1 April 2003 was specified at the outset. Meeting this target date proved challenging, not least because during the development period the requirements specification was constantly changing to reflect a still-evolving Minimum Dataset.

Prior to the 1 April launch there were two critical phases. The first of these was a pilot phase, which had two distinct periods. Initially, a small number of hospitals were asked to check that the IT systems and paper proformas (see Section 8.1) functioned as expected. After this initial stage, the pilot was opened up to a larger number of hospitals covering a cross-section of types, including large and small orthopaedic centres and IT infrastructures that ranged from 'excellent', through 'fair', to 'poor'.

As expected, the pilot revealed a number of minor issues but confirmed that the solution was well built and contained no major flaws. Crucially, the pilot also confirmed that even hospitals with poor IT infrastructure would be able to submit data to the NJR.

Once the solution was developed, the last major phase before launch was to train users. This was achieved via a series of 14 training events in central locations across England and Wales, described in Section 10.

7.3 Categorising components

While developing the NJR database, it was known that there would be requirements in the future to use the data generated by the NJR for various research purposes. It was anticipated that, as well as examining the relative performance of individual implant brands, there would be a requirement to compare the performance of different materials and other surgical considerations - for example, arthroplasty with or without the use of bone cement.

To facilitate such analyses in the future, each implant component on the database has been allocated a four-digit numeric code that identifies the product family the component belongs to. Two examples of such groupings are:

- 0108 - 28mm alumina femoral heads
- 0701 - cemented bicondylar knee femoral components

In total there are over 100 codes to cover all product families within total hip and total knee replacement components.

Setting up the component element of the database in this way from the outset will make future analysis simpler and faster to carry out. It will also facilitate the analysis of new technologies as they become available.

8 Data collection methods

8.1 Paper proformas

Electronic data entry is defined as a prerequisite of the NJR system, but the NJR Centre developed two paper proformas (one for hip procedures and one for knee procedures) to facilitate the data entry process. Hospitals can submit data directly online, and those with web access in theatre often choose to do so. However, the provision of paper proformas allows data to be captured at the time of the operation and then submitted electronically at a convenient time.

The proformas were designed to allow non-surgical staff to complete the data entry process on behalf of the lead surgeon. They allow for recording of whether a patient has consented to their personal details being stored on the NJR database. The proformas also enable the lead surgeon to state if they have used their default technique for the procedure, which considerably reduces data collection and input time.

It is for each hospital to determine how it wishes to embed the NJR data collection within its existing systems and processes. But the basic steps in using the paper proforma are:

1. Well in advance of the operation day the appropriate paper-based THR or TKR proforma should be downloaded from the NJR website and stored in the patient notes
2. The proforma is completed immediately after the procedure
3. Stickers from any prostheses used during the procedure are adhered to the proforma
4. Nominated staff submit data electronically to the NJR

See Part 3, Appendix 5 for copies of the paper proformas used to collect MDS v1 data[11].

[11] A revised set of proformas has been developed for collection of MDS v2 data. They can be downloaded from the NJR website

NJR BENEFITS public health and epidemiology

The NJR is an important UK public health venture: for the first time we will be able to measure accurately the number of hip and knee replacement operations carried out across England and Wales and assess the variation in surgical techniques and practice. This also presents tremendous opportunities for research into the factors that influence patients' progress and outcome after surgery. Over the coming years the NJR will be an academic resource that will be of worldwide significance.

Alex MacGregor Consultant rheumatologist and epidemiologist. Professor of Chronic Disease Epidemiology at the University of East Anglia

8.2 Data entry system

8.2.1 The application

There are two methods of entering data into the NJR database, both based on the .NET solution:

- Standard web browser (using ASP.NET)
- Standalone Visual Basic programme (using VB.NET)

The application is based around the relatively new .NET technology, which is an XML web services platform. It allows developers to build visually rich interfaces with common controls found in Windows applications, including click buttons, drop down lists to select from, and text boxes. Such a solution was ideal for the NJR as it allows for quick and accurate submission of clinical data and is compliant with e-Government standards, including the standardisation on XML.

The data are transmitted using the secure sockets layer (SSL) protocol. All users of the system are also provided with a user name, memorable data and password. (Further details of security and confidentiality features of the NJR system and processes can be found in Section 9.)

As mentioned in Section 7.1, very few hospitals chose to use the Windows-based data entry option and this facility was withdrawn for new users in late 2003.

8.2.2 Data validation

Data validation is performed at the users' PC/server side, meaning that the client need not communicate with the NJR central server to check that the data input meets pre-defined criteria. This improves the responsiveness of the client for the user as client/server interaction is kept to a minimum.

The majority of data are selected from drop down lists rather than input manually. This reduces the need for validation checking because only valid options are presented to the user.

The component data element of the data entry system has been developed with expert orthopaedic advice. This includes setting up rules so that if a user tries to enter an unusual, non-standard component combination, a query flag asks them to confirm whether selection of this combination is correct. Only if the user confirms that the combination was used, are they allowed to override the warning and enter the data.

Patient identifying data are encrypted within the application and can only be retrieved via the use of an online encryption key. This follows current NHS Information Authority guidelines. Further details can be found in Section 9.

8.2.3 Online data retrieval

The NJR allows online CSV (comma separated values) text file downloads to the following user groups:

- Surgeons
  - can download details of all operations where they are the lead surgeon
- Hospital Data Manager
  - can download details of all operations carried out within their orthopaedic unit for all surgeons who have given their consent

for hospital access to their data (this consent is given online within the application)

- Suppliers
  - can download details of all their components

The data downloads do not contain any strong patient identifiers, i.e. forename, surname, date of birth, NHS number and postcode of home address are excluded from the reports generated.

8.3 Further development of the data collection system

A key feature of the NJR programme is that feedback is actively sought from system users, whether they be surgeons, other theatre staff, data entry personnel, hospital management etc. This feeds into a continuous improvement process of 'fine tuning' the system. As a consequence of listening to the feedback received and investigating the underlying reasons, some major developments are initiated. These include development of a bulk data upload facility and a bar code reader facility (see Sections 5.1.2 and 5.1.3 respectively). All developments are centred around improving one or more of the following:

- User compliance
  - by making compliance as easy, quick and error-free as possible
  - by ensuring that all users will be able to obtain useful output from the NJR
- Data validation, quality, completeness and verification

8.4 Embedding the data collection process within hospitals

To embed the NJR data collection process within a hospital, it is recommended that each hospital appoints an NJR co-ordinator, who may be a relevant responsible manager or orthopaedic unit manager. This member of staff is key to ensuring that all relevant staff are kept abreast of NJR developments and requirements, and provides a vital link between the various hospital departments that need to be involved in the data collection process.

To oversee the data entry, an NJR hospital data manager is often, but not necessarily, the same member of staff.

NJR BENEFITS the NHS Purchasing and Supply Agency

"The NJR will provide the NHS with invaluable survivorship data of prostheses used by the NHS. The data provided by the NJR will allow the NHS Purchasing and Supply Agency to help trusts ensure that they are fully aware of the status of prostheses in relation to the NICE guidance. In providing post-market surveillance figures, the NJR will enable the industry to demonstrate compliance with the NICE benchmarks. This will, in its turn, allow the production of a listing of NICE-compliant hips for the NHS."

Andy Smallwood Senior Buyer, NHS Purchasing and Supply Agency

Reference

National Institute for Clinical Excellence (2000) *Guidance on the selection of prostheses for primary total hip replacement*

9 Security and confidentiality of data

This section outlines how the NJR Centre handles data to ensure that its security and confidentiality are maintained.

9.1 Confidentiality of personal data

The collection, handling and use of personal data are treated as confidential at all times.

All electronic data are stored securely to guard against unauthorised access, disclosure, accidental loss or destruction or damage to personal data. This is a direct requirement of the Data Protection Act 1998.

No information that would lead to the identification of an individual patient, clinician or hospital staff member will be included in any NJR publication, without the prior agreement in writing of the individual concerned.

9.2 Collection, transfer and storage of data

The benefits of an electronic system for collection, transfer and storage of data are described in Part 3, Appendix 6.2.

9.3 Recording patient consent

The NJR provides a form for collecting patient consent, so that it is compliant with the Data Protection Act 1998.

The NJR data entry system prompts the person entering data to confirm whether or not patient consent has been given. It is important, therefore, that the person entering data is informed whether or not patient consent has been given. If consent has been given, the data entry person will be directed to the 'Patient Details' input screen. If consent has not been given, the 'Patient Details' input screen is bypassed, and only the details of the operation are recorded. This means that only anonymised operation data are collected when consent has been withheld (which is in accordance with the Data Protection Act 1998).

As part of future NJR audit, random checks will be undertaken to see that patient consent is being obtained for those records where patient personal details have been submitted. NJR data audits will be arranged with participating hospitals.

9.4 Encryption of patient data

Patient details are encrypted once they are submitted to the NJR database, i.e. they are not stored in the database in an identifiable format. They can only be decrypted via the use of an online encryption key.

9.4.1 Decryption of patient personal details

'Decrypted data' means that patient personal details are restored to an identifiable format and linked directly with their operation details. This would take place only in the special circumstances that are outlined below, and requires prior agreement of the NJR Steering Committee.

Once decrypted data had served their purpose, they would be destroyed to preserve data confidentiality in accordance with NHS Information Authority guidelines.

(a) Urgent clinical review

The NJR Centre would respond to a formal request from the Medicines and Healthcare products Regulatory Agency (MHRA) where, for example, there is a need to recall a specific implant component. The NJR database would be used to search for, and identify, which patients had received the specific implant component. The data for identified patients in this circumstance would be made available - via the MHRA - to the NHS to facilitate traceability and patient recall.

(b) Patient Feedback Questionnaires

Patient data will also be decrypted to allow distribution of Patient Feedback Questionnaires. The detail of this mechanism has yet to be finalised - the Patient Feedback process is currently under development in conjunction with the NJR Steering Committee and a specially formed Patient Feedback Advisory Group, and will be subject to appropriate approvals. The NJR patient consent form notifies the patient that they may be sent a Patient Feedback Questionnaire in the future.

(c) NHS Strategic Tracing Service (NSTS)

As part of the management of the NJR database, regular checks need to take place to determine when patients recorded on the NJR have died. It is important to know when a patient has died so that their data can be correctly accounted for in component survivability calculations (since the length of time the components would have lasted before needing revision cannot be determined). It is also important to ensure that a deceased individual's family is not contacted, either in the case of patient recall in an urgent clinical review, or during the patient feedback process (i.e. sent a questionnaire).

Decrypted NJR patient data are submitted to the NSTS to cross-check the patient NHS number they hold and the NHS number recorded on the NJR database. Patient personal data need to be decrypted for the data to be matched.

The NSTS is also used to source missing NHS numbers where other personal identifiers are known.

(d) Data analysis

Patient data will need to be decrypted for some statistical analyses that will form the basis of NJR reports, e.g. to deduce the average age of implant recipients. However, only anonymised data would be published.

9.5 Access to data

Individual data and data reports will be made accessible according to user type. This is discussed in Part 3, Appendix 6.5.

9.6 NJR IT system

The NJR data entry system is the user interface that allows data to be submitted to the central NJR database. Details of the system specifications for data transfer, how users can access the data entry system, and security of networking and IT interfacing are described in Part 3, Appendix 6.6.

NJR BENEFITS the orthopaedic industry (implant suppliers)

Working in collaboration with UK orthopaedic surgeons and NHS Trust hospitals, manufacturers already sponsor many detailed clinical and radiographic studies on their joint replacement products as part of their obligations to carry out post-marketing surveillance. These studies also often collect patient outcomes data. The survival and performance data provided by the NJR will supplement this research and provide useful additional evidence on the clinical effectiveness of the joint replacement service in the UK.

This will allow better monitoring of all joint prostheses and their routine use by orthopaedic units in both the NHS and independent sectors, and will hopefully identify any factors that could be changed to further improve outcomes for patients, thereby minimising early interventions for component loosening, should such occur.

The NJR also has the potential to help determine the benefits of new, cutting edge technologies, such as the use of computer-aided navigation during surgery that has the potential to improve surgical accuracy and the precision of component positioning, which may offer improved outcomes for patients.

Mick Borroff Chairman -
The Association of British Health-Care Industries,
Orthopaedics Special Interest Section

9.7 NJR contact database

The NJR contact database is used to store the contact details of individuals (primarily hospital staff and NJR data entry system users) who have been in communication with the NJR Centre. This database is secure and is used to facilitate communications between the NJR and the individuals concerned. This information is not shared with any third parties.

10 Training

Training continues to be an important element of the NJR Centre's role and that of the Regional Audit Co-ordinator team.

NJR BENEFITS NHS Trusts

I am delighted to be the NHS Trust management representative on the NJR Steering Committee. In terms of my contribution, I see this as providing some reality to the issues around the implementation of the Registry, and for providing information within the management arena that will affect its local implementation.

In my former years as a pharmacist, I was concerned about drug efficacy and the safety and national reporting mechanisms for ensuring that adverse events were picked up quickly and lessons learnt. Likewise, I have been concerned that a mechanism was not in place for monitoring prosthesis use. The NJR will provide such a mechanism, and will enable us to quickly identify any adverse events for the benefit of patients.

Within the orthopaedic community, views differ on whether revision rates will increase in the future; the NJR will help us to determine this. It will also be a useful tool for research and audit, which is vital for the future.

As with all new tools, there will be practical problems in the Registry's local implementation. It is vital that these problems are shared with the NJR team. I particularly believe that the regional clinician links are extremely important to ensure full implementation locally and I would like to thank those who have volunteered to do this vital role.

Do spend time implementing the Registry locally as it will provide huge benefits to patients, which is why we work for the NHS.

Christine Miles Chief Executive,
The Royal Orthopaedic Hospital NHS Trust

10.1 Pre-launch training roadshows - March 2003

In the weeks prior to the launch of the NJR, the NJR Centre ran a series of 14 training roadshows in central locations across England and Wales. The venues used were primarily hospital premises in locations that were easy for staff from other hospitals to reach.

One roadshow was arranged specifically for orthopaedic suppliers to attend and be briefed on those parts of the NJR system of most relevance to them - including component data entry and the process for electronic uploading of component data from their catalogues.

The main purpose of the remaining roadshows was to provide orthopaedic unit and hospital staff with the opportunity to learn about the aims and objectives of the NJR and to receive data entry training. Material distributed included reference manuals, and patient consent forms and associated guidance and posters to display in clinics. The roadshows proved extremely popular, attracting attendance from well over 1,000 participants.

Feedback received from attendees was used to fine-tune both the system and reference manual ahead of launch.

10.2 Developing tools to continue training of NJR system users

The NJR Centre continues to provide training to orthopaedic unit and hospital staff in the form of data entry workshop sessions. These are co-ordinated by the NJR Centre and supported by the Regional Clinical Co-ordinator network and the Regional Audit Co-ordinators. The workshop sessions are held locally in hospital settings and can accommodate up to 20 participants. The upper limit on numbers is to ensure that all participants have sufficient time allowed for practising data entry and receive one-to-one attention. The flexible workshop format aims to:

- Provide an overview of the NJR project

- Demonstrate the data entry system and offer participants the opportunity to enter data onto a duplicate version of the system
- Offer an opportunity for hospital staff to ask questions and talk through local issues
- Enable the NJR Centre to spread 'good practice' and give participants an insight into how other hospitals are successfully implementing the NJR within their orthopaedic units
- Provide valuable feedback to the NJR Centre from the end-users' perspective

In support of the provision of workshop sessions, the NJR Centre has developed a range of training tools to help orthopaedic unit and hospital staff successfully implement the NJR within their own units. These include:

- The **NJR website**, which hosts a wealth of training information, and offers a link to access the live database and an online training registration form - see Section 11.1 for details
- A **Helpline** that is available to register end-users to the system, solve data entry problems and provide general help and advice - see Section 11.4 for details
- The **Reference manual**, designed to guide end-users through the complete data entry process and offer practical advice for solving data entry problems
- **Joint Approach**, the quarterly NJR newsletter, which focuses on spreading 'good practice' and is used as a vehicle to expand end-users' knowledge of the data entry system - see Section 11.2 for details

10.3 Training in the future

In future, by drawing on feedback from end-users, the NJR Centre will re-examine users' varied training needs and compare these to the existing training tools to ensure that they are still meeting requirements.

Already, the NJR Centre is developing specific training packages, designed to meet a range of different needs by amalgamating aspects of existing training tools and developing new tools where gaps have been identified. In this way, it is possible to ensure that training remains effective and in line with end-users' requirements.

Locally held data entry workshop sessions will continue to be organised to support those hospitals, orthopaedic units and Treatment Centres that are not yet NJR compliant.

NJR BENEFITS the independent healthcare sector

IHA (now IHF) members are delighted to participate in the NJR in order to ensure that the Registry can adequately benchmark across the whole of healthcare and not just the NHS. It is now part of the overall clinical governance frameworks within independent hospitals in order to strive to improve patient care.

Sally Taber Head of Operational Policy, Independent Healthcare Forum

After some initial teething problems, BUPA Hospitals' experience of implementation and on-going management of the NJR has been excellent.

Chris Dark Director of Clinical Services, BUPA Hospitals

11 Dissemination

Since the launch of the NJR, several channels have been used to communicate with its stakeholders, maximise awareness and encourage hospital participation.

Both indirect and direct communication methods have been used, ranging from one-to-one meetings, seminars and attendance at national conferences to electronic media, typified by the NJR website.

11.1 NJR website

The NJR website - at www.njrcentre.org.uk - complements the data entry system since both use the internet. The NJR website is the main source of information and communication, and has dedicated sections that cater specifically for healthcare providers (including independent hospitals and implant suppliers), patients and the public. There is also an area for Welsh language users.

The website details the information necessary for healthcare providers to implement processes at a local level to submit data to the NJR. For example, relevant guidance documentation, such as the NJR training manual, patient consent forms and minimum dataset proformas, is included. The website also provides direct access to the data entry system, enabling operation details to be submitted remotely from hospitals.

The patients and the wider public area of the website contains background detail on the Registry's aims and benefits. The importance of consent to the individual patient and the project as a whole are explained in layman's terms.

11.2 NJR newsletter

The NJR produces a quarterly newsletter - Joint Approach - which is made available on the NJR website. It is also disseminated via direct email to the NJR co-ordinators within hospitals, and hard copies are distributed at conferences and events.

The newsletter provides supporting information to orthopaedic staff and implant suppliers involved in collecting and submitting data, keeping them abreast of developments and any changes to the NJR. The back page provides material of direct interest to patients. It usually provides an interview with someone who has undergone hip or knee replacement. Patient representatives have indicated that they find these articles of interest.

11.3 Regional networks

The Regional Clinical Co-ordinator and Regional Audit Co-ordinator networks provide an important feedback mechanism to the NJR Centre, enabling the delivery of support materials to match the future requirements of all NJR users.

11.4 NJR Helpline

The NJR Helpline - Tel: 0845 345 9991 - provides on-going support during normal working hours (9.00 to 17.00), five days a week (Monday to Friday). It responds to a range of queries relating to the Registry, either directly or by forwarding the enquiry to be addressed by an appropriate member of the NJR Centre team.

11.5 Events

In March 2003, a series of regional NJR training roadshows were held. These roadshows were one of the key routes for sharing the aims and objectives of the NJR whilst providing orthopaedic staff with hands-on experience of the NJR data entry system. On-going training is now provided on request (see Section 10.2).

The NJR has had a presence at strategically important conferences, such as the British Orthopaedic Association (BOA) Annual Congress 2003 and the National Patient Safety Agency Safety Event 2004. Throughout the set-up phase and its first years of operation, the NJR has been invited to a number of orthopaedic meetings, including the annual meetings of the British Hip Society (BHS) and British Association for Surgery of the Knee (BASK). The NJR has also been invited to meetings of the implant suppliers. The Steering Committee is keen to continue using these routes to encourage and provide widespread understanding of the NJR and its developments. They provide a forum for two-way communication with stakeholders and highlight the benefit of the NJR as an audit/patient safety tool.

The launch of the NJR 1st Annual Report has been timed to coincide with the BOA Annual Congress 2004 to maximise its impact with the surgical profession.

11.6 Articles

To promote an understanding of the NJR and to further promote awareness of the Registry, the NJR Centre provides articles of particular interest to journals and sector-specific publications, e.g. the British Orthopaedic Association's newsletter, Orthopaedic Product News and the BMJ.

12 Reporting

This section is split into three parts to briefly review existing reporting to individuals and groups, the future reporting regime, and the annual reporting process.

12.1 Existing reporting to individuals and groups

Different forms of reporting are required to cover the wide range of NJR users and their varied needs.

12.1.1 Input to patients' records

At the individual patient level - but only before data are submitted to the NJR Centre - the data entry person in a hospital can print off a record of the operation for storing with the patient's records.

12.1.2 Reporting to the Steering Committee

The NJR Steering Committee receives standard format reports on a quarterly basis to coincide with its regular meetings. The contents of these reports have evolved over time. They currently include:

- An Executive Summary
- Summary headline statistics
- Completed operations by week (since 1 April 2003)
- Cumulative completed operations by week (since 1 April 2003)
- Completed operations with Hospital Episode Statistics (HES) comparison data, by NHS trust, England
- Completed operations with Patient Episode Database, Wales (PEDW) comparison data, by NHS trust, Wales
- Completed operations, independent groups
- Completed operations, Treatment Centres (NHS and independent combined)
- Summary of number of registrations (surgeons, HDMs, HDEs), by trust/independent group

NJR BENEFITS the perioperative care of orthopaedic patients

At the side of every patient undergoing implant surgery is a nurse and/or operating department practitioner (ODP) as part of the multiprofessional team dedicated to providing optimal care of the highest standard.

In any winning team, all members respect one another and value the contribution of everyone. The NJR will prove to be a 'tool' of the team, a resource to help continually improve and update daily practice.

Assessing, planning and implementing care to meet patients' needs occurs intensely during the surgical episode and is individualised to meet specific needs. Monitoring and improving how care is delivered to patients is at the heart of nurses' and ODPs' practice.

The NJR offers the opportunity for valuable evaluative information to become a much larger part of the 'Process of caring' for patients during surgery.

Sally Couzens RGN,
National Association of Theatre Nurses

- Details of nil returning hospitals/Treatment Centres
- % of completed operations with patient consent, % of operations in edit stack (i.e. not entered into the NJR system as a completed operation), by trust/independent group

12.1.3 Reporting to the Regional Clinical Co-ordinator network

RCC network meetings are also held on an approximately quarterly schedule. Each RCC receives a report in advance of the meeting that provides:

- Total number of completed operations submitted to the NJR, and split by hip and knee
- For their own Strategic Health Authority or Welsh NHS region, for each hospital:
  - total cumulative completed operations (since 1 April 2003)
  - totals by hip and knee
  - % consent
  - % in edit stack
  - number of records in MDS v1 edit stack
  - number of surgeons registered
  - any key developments reported by the relevant RAC

As RCCs and RACs work closely together, there is considerable additional reporting on the situation at specific hospitals on an ad hoc basis.

12.1.4 Internal reporting

Data entry activity is regularly monitored by the NJR Centre to determine how data submission is progressing and establish the state of play. Database statistics are collated in two ways for complete examination. Cumulative statistics (collated from 1 April 2003 to present) are used to measure data entry progression from the NJR inception, whereas weekly statistics detail data entry for the latest calendar week. The statistics itemise, for example, the number of completed records and the number of records in edit mode by the type of procedure - hip or knee. Examining the data at this high level provides the NJR Centre with an overall picture of submission activity.

These weekly statistics, in conjunction with a suite of Microsoft Office products (Microsoft Query, Access and Excel), are used to produce an OLAP (Online Analytical Processing) NJR cube file. The NJR cube presents the weekly results graphically and allows the NJR Centre and the Regional Audit Co-ordinators to see how data entry is progressing at individual Strategic Health Authority, trust and hospital levels.

The NJR cube displays the individual hospital submission histories and allows easy tracking of any emerging trends. For example, the number of

records entered and the level of patient consent can be viewed at a glance. This tool is particularly useful for identifying low submission rates and periods of high activity. Since April 2004, the NJR cube has also been used to monitor hospitals' progress in switching from using MDS v1 to MDS v2, as well as to monitor the number of MDS v1 records hospitals have in edit mode.

Of particular value to the RACs is the ability to track individual hospital progress in real time. This knowledge enables them to prioritise their efforts with hospitals to maintain high-quality NJR data submissions.

12.1.5 Reporting to surgeons

A crucial aspect of developing the NJR was to try to provide, as early as possible, information back to surgeons and hospitals. A fundamental basis of the NJR is that all surgeons can see their data and only they can give permission for others to access it. If they wish to view their data, surgeons log on and download the data as a CSV file (a type of data file that puts each data item for an operation on one line, separated by commas). The data file can then be imported into a standard package such as Microsoft Excel or Access for further formatting and interrogation.

12.1.6 Reporting to hospitals

As for surgeons, individual hospitals can also download data in CSV format. However, they are only able to access data for surgeons within their hospital who have consented for their data to be viewed by the Hospital Data Manager (HDM).

Following agreement from the NJR Steering Committee, a letter was sent to the Chief Executive and Clinical Director of each NHS Trust, independent hospital and Treatment Centre (NHS and independent) in England and Wales. The letter provided them with a record of data that had been submitted to the NJR by their hospitals between 1 April 2003 and 31 May 2004 inclusive. The data fields provided were:

- Hospital name(s)
- Complete records submitted
- Complete records for hips
- Complete records for knees
- Records in edit mode
- Surgeons registered
- Records submitted with patient consent (%)

Each letter was sent from the relevant Regional Clinical Co-ordinator, with full contact details for the RCC, the name and contact details for the related Regional Audit Co-ordinator, and also the contact details for the NJR Centre.

This mailing has had a positive effect in that, for those trusts/hospitals already complying with the NJR, many are checking that the details on their internal systems agree with those held centrally by the NJR. Where there are discrepancies, these are being investigated. The mailing has also led to a number of trusts/hospitals requesting and obtaining additional assistance to help them become compliant.

12.1.7 Reporting to suppliers

Suppliers can download details of their component lists held on the NJR system as CSV files to confirm that details such as NJR categorisation code, description and supplier catalogue (reference) number are correct.

Suppliers have two major areas of interest:

- Sales analysis and market information/trends
- Product performance
  - on-going, for optimisation of design and materials etc
  - monitored on almost a daily basis for failures, to meet regulatory requirements and to help ensure patient safety

In addition to receiving information via the NJR Annual Report, suppliers will wish to be able to access certain information on a live basis.

Suppliers would like to know which products (item number/lot number) have been used in a certain time period and at which hospitals.

Once notified to a supplier by a hospital, certain revisions of a prosthesis must be reported to the MHRA by the supplier as part of the adverse incident reporting procedures[12]. Currently, there is no systematic procedure in place whereby all hospitals routinely inform a supplier when one of its implants has failed, and hence this requirement has never been fully met. The NJR could greatly improve the situation. For example, in every instance where the original primary joint replacement was entered into the NJR, each supplier could be given regular reports outlining revision cases involving its implants. For each incident this information could include:

- Hospital name
- Component catalogue number
- Component lot number
- Component description
- Time since primary operation
- Indication for revision (loosening, component failure, infection etc)

In theory, a similar report covering all suppliers could be provided to the MHRA to supplement the existing adverse incident reporting system.

Confirmation of consensus reporting requirements for suppliers - that do not conflict with security and confidentiality criteria - will be obtained as part of a review of reporting requirements (see Section 12.2).

12.2 Future reporting

Following completion of work on the NJR 1st Annual Report, attention will turn to reviewing the full range of NJR reporting requirements. The key elements of this review are:

- To confirm the full range of stakeholder groups
- To conduct a representative survey of each group to determine their views on: (a) their fundamental reporting requirements; (b) additional desired reporting. As well as determining the raw data and analyses required, stakeholders would be questioned on the format, delivery mechanism and frequency of reporting they wish to receive
- To confirm restrictions on data/analyses that can be provided to each stakeholder group - including confidentiality and security restrictions, and adherence to the agreed aims of the NJR
- To determine which data/analyses should be included in standard reporting, the costs of which are covered by the levy
- To determine which data/analyses could be made available as non-standard reporting, the costs of which would have to be met by the requester
- To develop the necessary protocols to ensure that data/analyses released are accurate and are provided only to authorised recipients

Both the RCC network and the NJR Centre's involvement in the BOA Annual Congress in September 2004 are expected to be instrumental in determining surgeon expectations in terms of reporting.

The overall aim of the NJR is to improve patient outcomes and this obviously requires relevant data and analyses to not only be made available, but to be used.

Whilst it is essential that, for example, confidential data are not released into the public domain, it is also important that appropriate data and analyses are released in a timely manner to the relevant individuals and groups who can use them in working towards the aims and overall goal of the NJR.

Section 12.1.7 outlined how suppliers may wish to make use of NJR data. Provision of downloaded data in CSV format has proved successful for surgeons who are experienced in viewing and analysing their own data. However, some surgeons have already requested a simpler reporting mechanism within the data

[12] Medicines and Healthcare products Regulatory Agency (1998) *Guidance on the medical devices vigilance system for CE marked joint replacement implants*

entry application that provides summary data of the operations they have performed to date.

It is expected that the survey of hospitals will identify a standard set of reports required, enabling each hospital to be able to view its own data in identifiable form (subject to surgeon consent being given) and benchmark its performance against that of other hospitals in anonymised form.

Subject to meeting stakeholders' requirements and all security and confidentiality restrictions being adhered to, the NJR Centre would wish to make as much use as possible of the NJR website to deliver data, analyses and reports to end-users.

12.3 Annual report

12.3.1 The reporting year

To allow alignment with a number of other UK health-related registries and databases, the NJR reporting year has been set as 1 January to 31 December.

This first report is different in that it covers the developmental phase - from mid-September 2002 to 31 March 2003 - and data collection for operations that took place from 1 April to 31 December 2003 inclusive, meaning that data analysis relates to hip and knee replacement procedures that took place in a nine-month period and not a full year.

However, the 2nd Annual Report will include analysis of data collected for procedures that took place from 1 April 2003 to 31 December 2004.

12.3.2 Linking data and analyses to their sources

In this 1st Annual Report, no analyses reveal the identity of specific SHAs or Welsh health regions, specific trusts or independent groups, or individual hospitals or Treatment Centres. Hospitals and Treatment Centres are only identified in Part 3, Appendix 1 according to whether they contributed data used in analyses, whether they have subsequently become NJR-compliant, or if - as at 20 August 2004 - they remained non-compliant.

NJR BENEFITS the Medicines and Healthcare products Regulatory Agency (MHRA)

"The Department of Health and MHRA recognise that we need to learn as much as possible from the past in order to improve patient care in the future. The NJR will be a key part of this process for joint replacements. It will prove invaluable in establishing the base-line for the performance of hip and knee implants so that we will have a clear idea of what we can reasonably expect from these products.

The NJR will benefit MHRA by giving early warning of poorly performing joint replacements. Based upon this information, MHRA will be able to:

- Take prompt action to ensure that unsatisfactory implants are withdrawn from use
- Provide timely advice to doctors and hospitals on the follow-up and treatment of patients who have received these implants

The NJR will also assist in identifying patients who have received poorly performing joint replacements.

Andy Crosbie Unit Manager, Biosciences and Implants, MHRA

In the longer term, it is envisaged that data and analyses will be linked to SHAs, Welsh NHS regions, trusts, independent groups, individual hospitals and Treatment Centres. The NJR Steering Committee will determine whether this linkage should be introduced in the 2nd Annual Report.

12.3.3 Obtaining reader feedback

Necessarily, the range of analyses that could be carried out in this first report has been limited and care has been taken not to over-interpret the results. As the dataset builds up - and completeness, quality and accuracy improve -

the range of analyses that can be performed will be greater and of more immediate interest to the reader, and the robustness of resulting interpretations will improve.

Part 2 gives some indication of analyses that could be carried out in the future. However, the NJR Steering Committee would welcome readers' views on:

- The 1st Annual Report
  - Which sections were of most interest to them, and why?
  - Which were of least interest, and why?
- The 2nd Annual Report
  - What would they like to see included, and why?
- Future Annual Reports
  - What would they like to see included, and why?

There is a genuine desire to match the report's format and contents to users' needs, although the range of users involved will require some compromises to be made.

A detachable feedback form is included in Part 3, Appendix 8. The feedback form is also available on the NJR website and can be completed and submitted online.

12.3.4 Summary report

As a first step to meeting readers' needs, a summary version of this report has been produced. This can be downloaded from the NJR website.

Related articles are also included in Issue No.7 of the NJR newsletter, Joint Approach.

The full report - including the appendices for Part 2, Analyses and Interpretation - is also available on the NJR website.

13 Looking to the future

Development of the NJR is a continuous process on many fronts. This section highlights some of the developments being taken forward.

13.1 The NJR strategy and 'road map'

A strategy for development of the NJR programme over the short to medium term (1 to 3 years) and longer term (5 to 10 years) is being compiled. The purpose of this strategy is to:

- Provide a clear statement of intent to focus the combined efforts of all stakeholders to achieve a common goal
- Facilitate budgeting and finance decisions
- Provide clarity for communications and avoid misunderstandings
- Drive forward realistic expectations
- Enable strategic and operational plans to be compiled on a longer, more sustainable timeframe
- Ensure that development of the NJR is implemented efficiently

This strategy is founded on the aims of the NJR programme and has been developed by:

- Considering the key drivers for the various stakeholders
- Identifying strategy objectives that address the drivers through development of:
  - data input compliance and quality
  - interpretation and dissemination of data

The strategy continues to evolve through discussions between members of the Steering Committee, the Research Sub Committee and the RCC network. Strategy objectives are being agreed, which will be implemented by stakeholders working with the NJR Centre. The actions required will be detailed in a 'road map'.

13.2 Research Sub Committee

The Steering Committee's terms of reference include: 'facilitating, where appropriate, the use of the National Joint Registry data for research purposes'. As a result, an NJR Research Sub Committee (RSC) has been set up, with its first meeting being held in late July 2004.

Stakeholder groups represented on the Sub Committee are:

- The surgical professions and orthopaedic research
  - the Royal College of Surgeons, Clinical Effectiveness Unit
  - the British Orthopaedic Association
  - the British Hip Society
  - the British Association for Surgery of the Knee
  - the Association of Professors of Orthopaedic Surgery
- Public health and epidemiology
- Orthopaedic implant suppliers
- The Patient Liaison Group of the British Orthopaedic Association

The RSC's Terms of Reference will require Steering Committee approval, but are expected to include the following activities:

- Stimulating use of the NJR data for research
- Prioritising specific areas of research
- Advising the NJR Steering Committee on the merits of potential research projects
- Commissioning research
- Acting as 'gatekeepers' of NJR data, ensuring that access is restricted to appropriate personnel for defined research purposes, with prior approval of the Steering Committee
- Providing peer review of any research carried out using NJR data

Various potential routes for funding research using NJR data are under consideration.

13.3 European Arthroplasty Register

The NJR has been kept informed of development of the European Arthroplasty Register (EAR) by its Co-ordinator, Dr Gerold Labek MD. This has included Dr Labek giving a presentation to the NJR Steering Committee.

At present, the majority view of the NJR Steering Committee is that the NJR should remain firmly focused on maximising hospital compliance with the NJR, and increasing data quality, completeness and accuracy. Therefore, at present, the NJR is not joining the EAR. However, strong and regular contact will be maintained and the situation reviewed on a regular basis.

Development of the NJR, its Minimum Dataset, its systems and evolving reporting have all made considerable use of the experiences of other Registries. This has included a visit to the long-established Swedish National Hip Arthroplasty Register as well as contact with more recently established Registries in Australia, New Zealand and Canada. Contributions from other Registries have been featured in the NJR newsletter.

13.4 Sharing of good practice

Identification and sharing of good practice is a continuing and growing element of the NJR programme. To facilitate this process, examples of good practice are being developed for distribution. The good practice examples aim to show how the NJR data collection process can integrate well within existing hospital infrastructures. The examples are not prescriptive but rather they demonstrate how different types of hospital can use the NJR in conjunction with their own internal processes.

Good practice examples will be disseminated via the NJR website, newsletter and individual case studies that can be distributed by the RCC and RAC networks.

13.5 Increasing patient involvement

The overall goal of the NJR is that patients should receive the best joint replacements and clinical care; for this reason, they are the ultimate beneficiaries of the findings of the Registry.

Currently, the NJR newsletter and website provide information for patients and the public, and all open reports will be made available on the NJR website for their reference.

It will be several years before the NJR will produce results to show which implants have the best performance so that patients can make an informed choice on which implants they would like to receive. However, the NJR offers a major benefit to patients who have consented to their personal details being recorded by the NJR - it will help to identify and trace those patients who have received a particular implant in the event of urgent clinical review.

The NJR Centre is fortunate in being able to access the views and suggestions of past and current patients and the public via:

- Patient representatives on the NJR Steering Committee
- Patient representation on the Patient Feedback Advisory Group and the Research Sub Committee
- Pro-actively establishing contact with groups that are expected to be interested in the NJR
- Phone, email and letter contact from patients seeking advice
- Contact from patient groups, e.g. the Total Hip Users Group
- Feedback on contents of the NJR website and newsletter

This contact is of particular help in informing the NJR Centre of what is of interest to patients in the early years of the NJR's existence, prior to comprehensive information on individual implant performance being available.

For example, patient representatives advise that they have a different viewpoint to the medical and surgical professions regarding the quality of care they require. On being informed that they require a hip or knee replacement, they will quickly seek further advice. Soundings will be taken from immediate family, friends and, often, total strangers. What is important is that these are people who have undergone a similar operation and know what the after-effects can be. This view is supported by the interest shown in the patient experience articles included in the NJR newsletter.

Interestingly, rather than being averse to their data being held centrally by the NJR, patients are reassured by knowing that (if they have given their consent) they should be traceable in years to come if there are issues with an implanted component. Past experience of medical records going astray seems to be one reason behind this.

Raising awareness of the NJR, by highlighting its aims, benefits and findings, with existing and future joint replacement patients is high on the NJR communications agenda. Patient-focused dissemination routes, such as magazines, events and websites, will be explored and patient groups approached to see how the NJR can get key messages included in patient organisation literature.

By creating awareness amongst patients so that they understand the benefits of the NJR, they may in time create a demand for the NJR and question hospitals that do not offer them the opportunity to participate in the NJR.

Part 2

Analyses and Interpretation

1 Introduction

Sections 2 to 5 of Part 2 of this report examine data entered into the NJR, the level of participation in the NJR by NHS Trusts, independent hospitals and Treatment Centres, the number of hip and knee replacement procedures entered by participating hospitals, consent levels achieved, and the quality of data entered.

Sections 6 and 7 follow, focusing on the data collected for primary hip and knee replacement procedures. These sections cover patient and surgeon characteristics, information regarding the types and brands of prostheses, and surgical practices used in these operations (as well as whether laminar flow theatres were used, and types of anaesthesia used). Section 8 covers the few revisions that were entered into the NJR database for the data collection period[1].

Given that this is the first annual report published by the NJR, and that data for a nine-month period are included, there are few conclusions that can be drawn regarding performance of prostheses or surgical techniques. At this stage, therefore, data quality is a key point of focus. Hip and knee replacements generally last for many years[2], so there are little data as yet that could be used to examine implant-related surgical outcomes.

2 Number of primary and revision joint replacement procedures (hip and knee) in the NJR

Table 1 contains information on all joint replacement procedures entered into the NJR for the data collection period. Data consist of relevant joint replacements that were performed in England and Wales between 1 April 2003 (when the NJR was launched) and 31 December 2003 inclusive, and entered into the database by 31 March 2004. (Part 3, Appendix 5 provides details of which types of procedure are expected to be entered into the NJR and which types are excluded.) The dataset does not contain all relevant hip and knee replacements carried out

Table 1 – *Hip and knee replacement procedures carried out in England and Wales from 1 April 2003 to 31 December 2003 inclusive and entered into the NJR, according to country, type of procedure, sector and funding*

	Hips		Knees		Total	
	Number	(%)	Number	(%)	Number	(%)
Country						
England	24,317	(97.3)	21,165	(97.1)	45,482	(97.2)
Wales	680	(2.7)	636	(2.9)	1,316	(2.8)
Type of procedure						
Primary	22,672	(90.7)	20,854	(95.7)	43,526	(93.0)
Revision	2,325	(9.3)	947	(4.3)	3,272	(7.0)
Bilateral[3]	119	(1.0)	182	(1.7)	301	(1.3)
Unilateral	24,759	(99.0)	21,437	(98.3)	46,196	(98.7)
NHS hospitals						
NHS hospital, NHS funding	14,381	(57.5)	13,664	(62.7)	28,045	(59.9)
NHS hospital, independent funding	736	(2.9)	404	(1.9)	1,140	(2.4)
NHS hospital, unknown funding[4]	893	(3.6)	903	(4.1)	1,796	(3.9)
Total	**16,010**	**(64.0)**	**14,971**	**(68.7)**	**30,981**	**(66.2)**
Independent hospitals						
Independent hospital, NHS funding	1,829	(7.3)	2,269	(10.4)	4,098	(8.8)
Independent hospital, independent funding	6,709	(26.9)	4,236	(19.4)	10,945	(23.4)
Independent hospital, unknown funding[4]	449	(1.8)	325	(1.5)	774	(1.6)
Total	**8,987**	**(36.0)**	**6,830**	**(31.3)**	**15,817**	**(33.8)**
Total	**24,997**		**21,801**		**46,798**	

in England and Wales. Orthopaedic units in some NHS Trusts and some independent hospitals have not been entering data for all of their joint replacement procedures, while a few others have not been entering any data at all (see Table 2). From levies collected by the NJR, the total number of specific hip and knee replacement prostheses sold (which is a proxy for operations performed) in England and Wales during the data collection period is estimated at about 100,000.

3 Description of orthopaedic units in England and Wales

Table 2 compares the total number of NHS Trusts, independent hospitals and Treatment Centres that perform hip or knee replacement surgery with those participating in the NJR[5]. This gives an indication of how complete the results of the NJR data analysis will be, and how much can be inferred from these results. A participating hospital is defined as having entered at least one hip or knee procedure into the NJR[1]. A participating trust is any NHS Trust that includes at least one participating hospital (some trusts may contain more than one hospital performing joint replacement). This table suggests that the majority of NHS Trusts and independent hospitals performing orthopaedic surgery are participating in the NJR. Treatment Centres do not yet have as good participation rates.

Of the participating hospitals, approximately 50% have entered fewer than 50 hip or knee replacement procedures for the nine-month data collection period (see Table 3 overleaf). Table 4 (overleaf) shows the mean number of hip and knee procedures entered into the NJR by hospitals. Treatment Centres are not included in the following tables due to the low level of data.

Table 2 – *Total number of NHS Trusts, independent hospitals and Treatment Centres in England and Wales according to country and sector, and those that participate in the NJR*

	Total in England and Wales	Participating in NJR (%)
NHS Trusts	**168**	**142 (84.5)**
England NHS Trusts	156	131 (84.0)
Wales NHS Trusts	12	11 (91.7)
Independent hospitals[6]	**166**	**152 (91.6)**
England	160	149 (93.1)
Wales	6	3 (50.0)
Treatment Centres	**12**	**9 (75.0)**

1 Data analysed were for hip and knee replacement procedures that took place between 1 April 2003 and 31 December 2003 inclusive and were entered into the NJR by 31 March 2004

2 NICE guidelines suggest that 90% of hip replacements should last at least 10 years. Many authors have recorded 10-year knee replacement survival rates in excess of 95%. See Patient demographics as a predictor of the 10-year survival rate in primary total knee replacement - Vazquez-Vela Johnson G. Worland RL. Keenan J. Norambuena N. *Journal of Bone & Joint Surgery - British Volume. January 2003 (85: 397-409)*

3 Bilateral operations are considered as two procedures in the NJR database. Therefore, while 301 bilateral operations were performed overall, this is counted as 602 procedures in the other areas of this table

4 The method of funding for the procedure (NHS/independent) was an optional question. Where funding was classed as unknown this question was not answered

5 Care should be taken when comparing the totals shown in Table 2 with the totals of hospitals and Treatment Centres listed in Part 3, Appendix 1, as those listings are subdivided to show which hospitals and Treatment Centres contributed data used in analyses in the current report, which became NJR-compliant more recently, and which have yet to become compliant

6 The independent sector is described here at the level of individual hospitals rather than owning organisation

Table 3 – *Number of participating hospitals according to number of procedures entered*

	Number of procedures entered into NJR				
	< 50	50 – 99	100 – 199	200 – 300	> 300
Hospitals entering hip replacements (%) (n=331[7])	157 (47.3)	90 (27.1)	57 (17.2)	13 (3.9)	15 (4.5)
Hospitals entering knee replacements (%) (n=331[8])	179 (53.9)	85 (25.6)	50 (15.1)	8 (2.4)	10 (3.0)

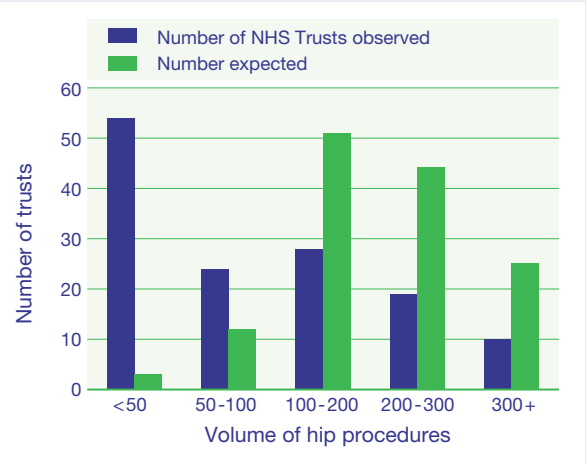
Table 4 – *Mean number of hip and knee replacements entered into the NJR (per hospital), according to country and sector*

	Hips	Knees
Country		
England	78	67
Wales	52	32
Sector		
NHS hospitals	91	83
Independent hospitals	60	46
Overall	**77**	**66**

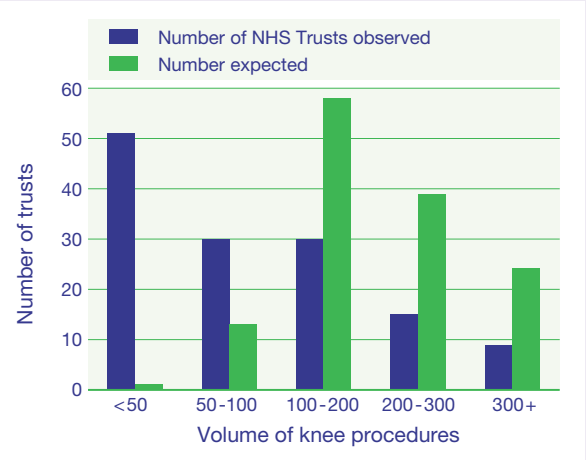
The distribution of the number of procedures entered by participating NHS Trusts in England and Wales was compared with the number expected from Hospital Episode Statistics (HES[9]) and Patient Episode Database, Wales (PEDW[10]) data respectively. This comparison was done at trust level rather than at hospital level. It can be made only for NHS Trusts since there is no equivalent for HES data in the independent sector. HES/PEDW data were available for 135[11] trusts (125 English and 10 Welsh). As the data in the NJR were collected for a nine-month period, while the HES and PEDW comparison data were collected for a year, the HES and PEDW data have been adjusted accordingly[12].

Graphs 1 and 2 show, for both hips and knees, that the number of hospitals entering fewer than 100 procedures is higher than expected, and the number of hospitals entering more than 200 procedures is lower than expected when compared to HES/PEDW. For the most part, this may be explained by the NJR being a new venture, with hospitals starting to provide data at various points of the nine-month data collection period.

Graph 1 – *Number of trusts according to volume of hip replacement procedures entered into the NJR, and volume expected from HES/PEDW*



Graph 2 – *Number of trusts according to volume of knee replacement procedures entered into the NJR, and volume expected from HES/PEDW*



[7] 6 of these hospitals did not enter any hip replacement procedures into the NJR for the period 1 April 2003 to 31 December 2003. At the time of preparing this report it remained to be confirmed whether or not they ever perform relevant hip surgery

[8] 6 of these hospitals did not enter any knee replacement procedures into the NJR for the period 1 April 2003 to 31 December 2003. At the time of preparing this report it remained to be confirmed whether or not they ever perform relevant knee surgery

[9] HES data used in this report are for 2002 - 2003

[10] PEDW data used in this report are for 2000 - 2001

[11] HES/PEDW data were not available for all 142 participating NHS Trusts due to some closures, mergers, new trusts being created and changes of trust names since HES/PEDW statistics were compiled

[12] The adjusted figure used for each trust was 75% of the HES/PEDW annual figure for that NHS Trust

4 Data quality

4.1 Procedures entered into the NJR

The overall completeness of joint replacement procedures is defined as the total number of procedures entered into the NJR by NHS Trusts expressed as a percentage of those expected from HES/PEDW data for those NHS Trusts[13]. Table 5 includes the number of procedures performed by the 135[11] NHS Trusts for which HES/PEDW data are available for comparison. The most recent three months were examined separately with the expectation that once trusts had a few months' experience of the process, they would enter a larger proportion of their joint replacements into the NJR (there may be issues of seasonality that have not been accounted for).

As time passes, there is an increasing awareness of the NJR, its requirements, and the various forms of support available to help trusts become compliant; hence trusts that were previously not participating are better able to make the necessary changes to their systems and processes to enable data collection and entry. Within the first three months of the data collection period, 223 hospitals had submitted completed records. This number rose to 285 for six months, and then to 331 for the nine-month data collection period.

On the basis of HES and PEDW data, 59,446 procedures were expected to have been performed in the 135 participating NHS Trusts during the nine-month data collection period[14]. Approximately half of this number (51.3%) were entered into the NJR. Referring back to Section 3, it can be seen that this is predominantly due to participating trusts not entering all of their joint replacement procedures into the NJR (see Graphs 1 and 2).

In the last three months of the data collection period, the percentages of procedures entered into the NJR are somewhat higher than they were for the whole nine-month period, which would suggest an improvement in procedure completeness, even if the improvement is relatively small (see Table 5).

4.2 Consent

Of 46,497 patients[15] who had a joint replacement within the data collection period, 29,188 (62.8%) are recorded in the NJR system as having given consent for their personal data (forename, surname, NHS number, date of birth and postcode) to be collected. The consent rates were 62.6% for the participating English hospitals, 53.9% for the Welsh hospitals, 60.2% for the NHS hospitals, and 66.6% for the independent hospitals. 15,704 of these consenting patients underwent a hip replacement and 13,484 had a knee replacement.

Table 5 – *Number of joint replacements expected from HES/PEDW data compared with number entered into the NJR (for 135 NHS trusts where HES/PEDW data were available)*

	Data for procedures performed between 1 April 2003 and 31 December 2003		Data for procedures performed between 1 October 2003 and 31 December 2003	
	Expected number of procedures	Number entered in NJR (%)	Expected number of procedures	Number entered in NJR (%)
Country				
England NHS Trusts (n=125)	56,951	29,831 (52.4)	18,984	10,750 (56.6)
Wales NHS Trusts (n=10)	2,495	667 (26.7)	832	290 (34.9)
Total NHS trusts (n=135)	**59,446**	**30,498 (51.3)**	**19,815**	**11,040 (55.7)**

[13] This comparison cannot be made for the independent sector due to the lack of HES equivalent data

[14] Data were for procedures performed between 1 April 2003 and 31 December 2003 inclusive, and entered into the NJR by 31 March 2004

[15] The number of patients can be identified from Table 1 by adding together the number of unilateral and bilateral procedures

Table 6 – *Number of hospitals according to consent rates*

	Consent rate					
	0	1 – 19%	20 – 39%	40 – 59%	60 – 79%	≥ 80%
Number of hospitals (%) (n=331)	27 (8.1)	34 (10.3)	30 (9.0)	25 (7.5)	45 (13.6)	170 (51.5)

If the NJR does not record that the patient has given consent then personal data cannot be collected. Personal data are required so that, should a patient require a revision, their primary joint replacement procedure can be linked with the revision procedure, the link being via the NHS number. This linkage is an essential element of the NJR to enable outcomes after joint replacement to be evaluated. Patient data are also required to enable tracing of patients who may have been implanted with a prosthesis that is later found to be faulty. Patient consent is also necessary if a patient is to be eligible for participation in any subsequent feedback process or other research project. Anonymous data regarding the joint replacement operation technique were collected, stored and analysed regardless of whether patient consent was obtained, as this data processing does not require patient consent.

Table 6 shows consent rates of all 331 participating hospitals. Over half of the hospitals are achieving consent rates greater than 80%. However, over a quarter are obtaining consent rates of less than 40%, and there were 27 (8.1%) participating hospitals that returned a zero consent rate. 68 hospitals obtained consent rates of 100%.

4.3 Missing values

Data items are categorised as 'Identifiers', 'Compulsory', and 'Others'. Identifiers can only be recorded with consent from the patient. A patient's NHS number is the key data item used for linking their primary and revision procedures. For some consenting patients, their NHS number was not entered into the NJR. In these instances, the NHS Strategic Tracing Service (NSTS) used patient postcode, date of birth, forename and surname collected by the NJR to trace these patients' NHS numbers. If the NSTS was unable to find an NHS number for these patients, the postcode, date of birth, forename or surname may not have been entered into the NJR, or may have been entered incorrectly.

Table 7 shows how many of the consenting patients have their NHS number stored in the NJR database after the NSTS has traced as many as possible. Of all patients who consented to give their personal information, 65.1% could be linked.

Table 7 – *Consenting patients in the NJR, and number with NHS number available*

	Consenting patients	NHS number available (%)
Country		
England	28,479	18,622 (65.4)
Wales	709	369 (52.0)
NHS/independent sector		
NHS hospitals	18,649	12,558 (67.3)
Independent hospitals	10,539	6,433 (61.0)
Total	**29,188**	**18,991 (65.1)**

The percentage of NHS numbers available for each hospital is summarised in Table 8. Over a quarter of hospitals had NHS numbers for 80% or more of their consenting patients, and 23 of these had an NHS number for all patients.

Compulsory data items were those considered by orthopaedic surgeons and researchers on the NJR Steering Committee to be the most valuable, and where the relevant data needed to be collected in all cases. Only 113 out of 46,798 (0.2%) records had any of these compulsory data items missing. 111 of these missing values were for components, the vast majority being for knee revision operations that did not require components to be added. The remaining two missing compulsory data items were hospital name; the NJR data entry system has been adjusted so that it is no longer possible to omit this information.

Table 8 – *Number of hospitals according to percentage of NHS numbers available for consenting patients*

	Percentage of NHS numbers available for consenting patients					
	0	1 – 19%	20 – 39%	40 – 59%	60 – 79%	≥ 80%
Number of hospitals (%) (n=304[16])	16 (5.2)	25 (8.2)	34 (11.2)	47 (15.4)	85 (27.9)	97 (32.1)

Any data item not categorised as compulsory or an identifier fell into the 'Others' category. As these data items are not mandatory, a large number of missing values or 'not selected' responses were found. A full list of data items, their categories, and any missing values is available in Appendix 9A of the web version of this report. (See NJR website at www.njrcentre.org.uk.)

4.4 Implausible values and inconsistencies

Implausible or inconsistent values occurred very rarely and so do not give cause for concern. These values included 35 patients who were entered with a date of birth that would make their age at surgery outside our acceptable range[17], 116 hip patients who were reported as lying on their back and having a posterior incision, and 141 hip procedures and 167 knee procedures that had cement components entered, but stated that cement had not been used.

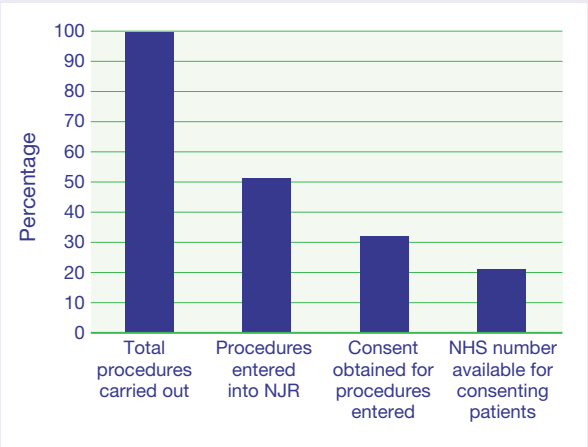
5 Summary

The three main issues identified in this section are:

1. About 50% of relevant NHS hip and knee replacement procedures were entered into the NJR[18]
2. Consent was obtained for only 62.8% of procedures that were entered
3. NHS numbers were available for only 65.1% of those patients who gave consent

To obtain an end result of how many linkable procedures the NJR has data for, these three percentages need to be multiplied (50%* 62.8%* 65.1%* ≈ 20%). This is illustrated in Graph 3 and shows an overall result that, of all relevant hip and knee replacements carried out in England and Wales during the data collection period, about 20% have been entered into the NJR with an NHS number, and so can have primary and any subsequent revision procedures linked. The remaining 80% either were not entered by hospitals or were entered without linkable data and so cannot be used to investigate outcomes of joint replacement surgery. However, data can still be used to look at the range of surgical techniques currently practised and comparisons of these can be made. Initiatives are being introduced to improve both overall compliance and consent rate figures (see Part 1, Sections 4.4 and 5.3).

Graph 3 – *Total hip and knee procedures, and how many were entered into the NJR with NHS numbers*



The majority of orthopaedic units are NJR participants (see Table 2), but Graphs 1 and 2 showed that a large number did not enter all of their relevant joint replacements into the database during the data collection period. However, high levels of completeness[19] can be achieved; 36 NHS Trusts had entered 80% or more of their expected joint replacements into the NJR.

[16] The 27 hospitals that had consent rates of zero are not included in Table 8

[17] Ages over 100 years old or less than 10 years old were unlikely. This range was suggested by orthopaedic professionals

[18] This value cannot be obtained for the independent sector due to lack of HES equivalent data. It is assumed that the percentage is roughly the same for the independent sector

[19] Completeness is defined as the number of procedures entered expressed as a percentage of those expected from HES/PEDW data

For patients for whom consent was not obtained, this can be due to patients withholding their consent, not being asked to consider giving their consent, or the data entry person not having proof available that consent was obtained. High levels of consent are achievable; more than half of all participating hospitals demonstrated consent rates of 80% or more (see Table 6).

To improve the frequency of NHS numbers being available for linking it is suggested that, in the future, if the NHS number is unknown when data are entered, more effort be made to ensure the patient's postcode is entered[20]. This will enable the NSTS to identify more of the unknown NHS numbers. It is possible to achieve high levels of NHS numbers being available; 23 hospitals had 100% of NHS numbers for their consenting patients.

For the first nine months of operation, the NJR has received an encouraging amount of data. As the NJR becomes increasingly recognised and compliance becomes embedded within hospital processes and systems, it is expected that data completeness will increase. 11 NHS Trusts have already shown high levels in each of the three areas mentioned (compliance, consent rates and availability of NHS numbers) and 30 independent hospitals have shown high consent rates and availability of NHS numbers. Therefore, it can be seen that the NJR has provided a facility for excellent levels of data collection in the short time the NJR has been in existence. With more hospitals being trained in using the NJR and understanding the importance of each of the above concerns, linkable data available in the NJR can only increase, so making the NJR more valuable.

6 Primary hip replacement procedures

This section summarises the data and analysis of all primary total hip replacements performed between 1 April and 31 December 2003 inclusive in England and Wales, and that were entered into the NJR database by 31 March 2004.

6.1 Description of patient characteristics

Table 9 shows that the mean age of primary hip replacement patients in the NJR is 68 years. 50% of the patients were aged between 61.1 and 76.1. Patients receiving a conventional total hip replacement (THR) using cement were generally older, with a mean age of 71.7, and patients who underwent a resurfacing arthroplasty procedure were the youngest group, with a mean age of 54. Overall, the proportion of female patients is greater: 59.5% of consenting hip replacement patients were female. Resurfacing arthroplasty is the only procedure where the opposite is true, since 65.6% of consenting resurfacing patients were male. The majority of THR patients had a physical status of 'mild disease', as classified by the American Society of Anaesthesiology scoring system (ASA grade), while most resurfacing patients were 'fit and healthy' according to the same system. The most common indication for surgery was osteoarthritis, which was present in 93.6% of patients.

6.2 Description of primary hip replacement procedures

Table 10 shows that 0.5% of primary hip replacements were bilateral operations, and that more right hips were operated on than left hips.

[20] Date of birth, forename and surname are already mandatory data items

[21] A hybrid is a procedure where the femoral prosthesis is cemented and the acetabular prosthesis is not cemented. A reverse hybrid procedure has the acetabular prosthesis cemented and the femoral prosthesis not cemented. There were 83 reverse hybrid procedures entered into the NJR database

[22] Patient physical status according to the ASA scoring system

[23] More than one indication may be selected per procedure, so these values add up to more than the total number of procedures

[24] Bilateral operations are classed as two procedures. Therefore, where 25 bilateral resurfacing operations were entered, these count as 50 resurfacing procedures in other areas of Table 10. From Table 1, there are 119 bilateral operations; the 114 bilateral primary procedures recorded here and 5 revisions

[25] Fellow was the most common "Other" grade, accounting for 405 of the procedures recorded

Table 9 – *Patient characteristics for primary hip replacement patients, according to type of procedure*

	Patient procedure				
	Total replacement using cement	Total replacement not using cement	Total replacement not classified (e.g. hybrid[21])	Resurfacing arthroplasty	Total
Age (consenting patients only)					
Mean age (Std Dev)	71.7 (9.3)	64.6 (11.1)	65.9 (11.0)	54.0 (9.3)	**68.0 (11.3)**
Inter-quartile range 25%	66.2	58.4	59.2	48.7	**61.1**
75%	78.2	71.9	73.5	60.1	**76.1**
Gender (consenting patients) (%)					
Male	3,208 (35.3)	1,006 (43.1)	588 (41.3)	1,040 (65.6)	**5842 (40.5)**
Female	5,869 (64.7)	1,328 (56.9)	836 (58.7)	546 (34.4)	**8579 (59.5)**
Physical status[22] (%)					
Fit and healthy	4,270 (29.9)	1,533 (42.7)	907 (36.8)	1,654 (70.7)	**8364 (36.9)**
Mild disease, not incapacitating	8,343 (58.4)	1,773 (49.4)	1,316 (53.4)	635 (27.2)	**12067 (53.2)**
Incapacitating systemic disease or life-threatening disease	1,667 (11.7)	284 (7.9)	241 (9.8)	49 (2.1)	**2145 (9.9)**
Indications for surgery[23] (%)					
Osteoarthritis	13,438 (94.1)	3,330 (92.8)	2,256 (91.6)	2,206 (94.4)	**21,230 (93.6)**
Rheumatoid arthritis	247 (1.7)	43 (1.2)	30 (1.2)	16 (0.7)	**336 (1.5)**
Avascular necrosis	488 (3.4)	176 (4.9)	98 (4.0)	75 (3.2)	**837 (3.7)**
Congenital dislocation	113 (0.8)	105 (2.9)	70 (2.8)	95 (4.1)	**383 (1.7)**
Fractured neck of femur	192 (1.3)	40 (1.1)	31 (1.3)	0	**263 (1.2)**
Failed internal fixation	94 (0.7)	32 (0.9)	22 (0.9)	1 (0)	**149 (0.7)**
Hip trauma	87 (0.6)	37 (1.0)	28 (1.1)	16 (0.7)	**168 (0.7)**
Previous arthrodesis	6 (0)	3 (0.1)	7 (0.3)	0	**16 (0.1)**
Other	49 (0.3)	65 (1.8)	47 (1.9)	173 (7.4)	**334 (1.5)**
Total number of procedures	**14,280**	**3,590**	**2,464**	**2,338**	**22,672**

Table 10 – *Characteristics of the primary hip replacement procedures, according to side, lead surgeon grade and locum*

	Patient procedure				
	Total replacement using cement	Total replacement not using cement	Total replacement not classified (e.g. hybrid[21])	Resurfacing arthroplasty	Total
Side (%)					
Left, unilateral	6,245 (43.9)	1,607 (45.0)	1,108 (45.3)	1,083 (46.8)	**10,043 (44.5)**
Right, unilateral	7,927 (55.7)	1,953 (54.6)	1,316 (53.9)	1,205 (52.1)	**12,401 (55.0)**
Bilateral[24]	54 (0.4)	15 (0.4)	20 (0.8)	25 (1.1)	**114 (0.5)**
Lead surgeon grade (%)					
Consultant	11,324 (79.3)	3,041 (84.7)	1,957 (79.5)	2,231 (95.4)	**18,556 (81.8)**
Associate Specialist/Staff Grade/ Clinical Assistant	1382 (9.7)	397 (11.1)	106 (4.3)	46 (2.0)	**1,932 (8.6)**
With consultant assistance	189 (1.3)	32 (0.9)	10 (0.4)	12 (0.5)	**243 (1.1)**
Without consultant assistance	1,193 (8.4)	365 (10.2)	96 (3.9)	34 (1.5)	**1,689 (7.5)**
Specialist Registrar (SPR)/ Senior House Officer (SHO)/ House Officer/Other[25]	1,441 (10.1)	132 (3.7)	386 (15.6)	61 (2.6)	**2,020 (8.9)**
With consultant assistance	630 (4.4)	80 (2.2)	118 (4.8)	30 (1.3)	**858 (3.8)**
Without consultant assistance	811 (5.7)	52 (1.5)	268 (10.8)	31 (1.3)	**1,162 (5.1)**
Part of visiting surgical team from overseas	133 (0.9)	20 (0.5)	15 (0.6)	0	**168 (0.7)**
Lead surgeon is locum (%)					
Yes	770 (5.4)	133 (3.7)	89 (3.6)	29 (1.2)	**1,021 (4.5)**
No	13,510 (94.6)	3,457 (96.3)	2,375 (96.4)	2,309 (98.8)	**21,651 (95.5)**
Total	**14,280**	**3,590**	**2,464**	**2,338**	**22,672**

6.2.1 Description of surgeons

Table 10 also shows that consultants were the lead surgeons in 81.8% of all total hip replacements entered into the NJR. Resurfacing arthroplasty has the highest percentage of consultants leading on a procedure at 95.4%, while THR with cement has the lowest percentage at 79.3%.

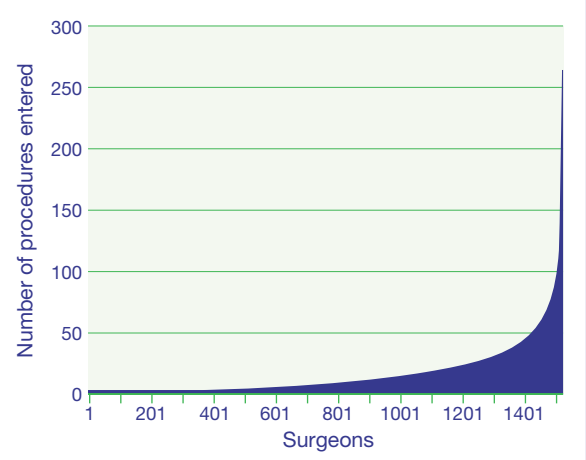
The surgeon grades other than consultant have been looked at according to whether or not a consultant was assisting with the operation (see Table 10). Consultants assisted more frequently in operations performed by specialist registrars and house officers compared with operations performed by associate specialists and staff grades. 4.5% of lead surgeons were locums.

The consultant in charge of a case often, but not always, performs the operation. For 18,104 primary hip replacements (79.9%), the consultant in charge of the case was also the lead surgeon for the operation.

6.2.2 Number of primary hip replacements per surgeon

The number of primary hip replacement procedures performed per surgeon was calculated by counting each time a particular surgeon was declared as being the lead surgeon for a primary procedure. For the data available in the NJR, the mean number of primary hip procedures entered per surgeon is 15 for the nine-month data entry period, ranging from 1 to 262. Further information on the distribution of the number of procedures performed is shown in Graph 4 and Table 11. 387 surgeons (25.3%) have entered just one or two procedures into the NJR. This does not mean that they only performed one or two procedures during the nine-month data collection period, but that only these procedures were entered into the NJR, possibly to demonstrate a minimum level of compliance.

Graph 4 – *Number of primary hip replacement procedures per surgeon entered into the NJR for nine-month period*



6.2.3 Description of surgical practice in primary hip replacements

Table 12 shows variation in surgical practice. A detailed version of this table, showing surgical practice according to type of hip replacement procedure, is given in Appendix 9B of the web version of this report. (See NJR website at www.njrcentre.org.uk.) Most patients had conventional surgery (i.e. not minimally invasive surgery) in a laminar flow theatre. The most common method of anaesthesia was spinal anaesthesia, followed by epidural. General anaesthesia was used in only 16.7% of cases. The most frequent patient position was lateral, and for most patients the approach to the hip was from the front or the side (Anterior, Antero-lateral or Lateral). Trochanteric osteotomy was used in 5.9% of procedures and bone grafts were not commonly used as would be expected in primary procedures. Most procedures used cement and only 0.9% of procedures used the new technique of image guided surgery. However, 3.9% of procedures were already being performed using minimally invasive incisions. This is also a relatively new technique.

Table 11 – *Number of surgeons according to number of primary hip replacement procedures entered in the NJR*

	Number of hip replacements entered into NJR per surgeon				
	< 25	25 – 49	50 – 99	100 – 199	> 200
Number of surgeons (%) (n=1,532)	1,259 (82.2)	179 (11.7)	77 (5.0)	15 (1.0)	2 (0.1)

Table 12 – *Characteristics of surgical practice*

All primary hip replacement procedures (%)	
Laminar flow theatre	
Yes	21,138 (93.2)
No	1,216 (5.4)
Unknown	218 (1.4)
Type of anaesthesia used[26]	
General	3,787 (16.7)
Epidural	6,990 (30.8)
Nerve block	1,909 (8.4)
Spinal	9,576 (42.2)
Unknown	410 (1.9)
Patient position	
Lateral	18,179 (80.2)
Supine	4,493 (19.8)
Incision	
Anterior/Antero-lateral/Lateral	14,686 (64.8)
Posterior	7,986 (35.2)
Trochanteric osteotomy	
With trochanteric osteotomy	1,347 (5.9)
Without trochanteric osteotomy	21,325 (94.1)
Femoral bonegraft used	
Yes	671 (3.0)
No	22,001 (97.0)
Acetabular bonegraft used	
Yes	1,780 (7.9)
No	20,892 (92.1)
Femoral cement used	
Yes	18,649 (82.3)
No	4,023 (17.7)
Acetabular cement used	
Yes	14,044 (61.9)
No	8,628 (38.1)
Minimally invasive surgery used	
Yes	893 (3.9)
No	21,779 (96.1)
Image guided surgery used	
Yes	213 (0.9)
No	22,459 (99.1)
Total number of procedures	**22,672**

Table 13 shows the post-operative regime recommended at the time of operation. The two most frequently recommended methods were TED stockings and low molecular weight heparin (LMWH), while aspirin, foot pumps and intermittent calf compression were also common choices. Patients could be given more than one type of thrombo-prophylaxis. The most frequent combination was LMWH with TED stockings, which was recommended for 3,199 hip replacement patients (14.1%).

[26] More than one anaesthetic may be used

[27] Patients may receive more than one thrombo-prophylaxis treatment

Table 13 – *Thrombo-prophylaxis regime for primary hip replacement patients, recommended at time of operation*

Thrombo-prophylaxis regime[27]	Frequency of use (%)
Aspirin	4,777 (21.1)
Chloroquine	11 (0)
Low dose heparin	1,009 (4.5)
Low molecular weight heparin	10,572 (46.6)
Pentasaccharide	121 (0.5)
Warfarin	984 (4.3)
Foot pump	4,600 (20.3)
Intermittent calf compression	4,956 (21.9)
TED stockings	11,709 (51.7)
Other	574 (2.5)
None selected	1,880 (8.3)
Number of procedures	**22,672**

Table 14 shows that a cement gun was used in 88% of cases where femoral cement was used, but only 36.7% of cases where acetabular cement was used. Pulsatile lavage and cement pressurisers were used in most of the cemented procedures, and vacuum mixing was used in nearly 90% of the cemented procedures. Just over 10% of cemented total hips are still being performed using the traditional method of mixing with bowl and spatula followed by finger packing of the cement. A more detailed version of this table is given according to type of hip replacement in Appendix 9C of the web version of this report. (See NJR website at www.njrcentre.org.uk.)

Table 14 – *Cementing techniques used in cemented primary hip replacements*

Femoral cement used	18,649
Gun used	16,416 (88.0)
Gun not used	22,33 (12.0)
Pulsatile lavage used	16,889 (90.6)
Pulsatile lavage not used	1,760 (9.4)
Cement pressuriser used	13,161 (70.6)
Cement pressuriser not used	5,488 (29.4)
Mixing for femoral cement	
Open bowl and spatula	1,952 (10.5)
Vacuum mixing	16,697 (89.5)
Acetabular cement used	**14,044**
Gun used	5,158 (36.7)
Gun not used	8,886 (63.3)
Pulsatile lavage used	12,600 (89.7)
Pulsatile lavage not used	1,444 (10.3)
Cement pressuriser used	10,446 (74.4)
Cement pressuriser not used	3,598 (25.6)
Mixing for acetabular cement	
Open bowl and spatula	1,573 (11.2)
Vacuum mixing	12,471 (88.8)

6.3 Description of prostheses in primary hip replacements

There are numerous different brands[28] of hip prostheses available for sale on the UK market, and one of the major goals of the NJR is to examine the relative long-term performance of different types and brands of prostheses.

6.3.1 Brands of prostheses entered most frequently into the NJR

This section includes only hip replacements for which both a stem and a cup were entered into the NJR. In total, there were 72 different brands of acetabular cups and 81 different brands of femoral stems entered into the NJR[29]. These were manufactured or distributed by 23 different companies. Table 15 shows that the Exeter V40 and the Charnley stem were used most frequently in the NJR, making up nearly half of all stems. In Appendices 9D1 and 9D2 of the web version of this report, numbers are presented separately for cemented and cementless stems. Appendix 9E details the manufacturers of each hip prosthesis brand entered into the NJR. (See NJR website at www.njrcentre.org.uk.)

Table 15 – *The 20 stem brands entered most frequently into the NJR for hip primary procedures*

Brand	Number used (%)	Cemented stem
Exeter V40	5,863 (30.6)	✔
Charnley	3,455 (18.1)	✔
Furlong HAC	1,261 (6.6)	
C-Stem	1,152 (6.0)	✔
Exeter	894 (4.7)	✔
CPT	734 (3.8)	✔
Elite Plus	705 (3.7)	✔
Corail	592 (3.1)	
Stanmore Modular	580 (3.0)	✔
ABG 2	435 (2.3)	
Furlong Cemented	335 (1.8)	✔
Ultima	314 (1.6)	✔
Versys	238 (1.2)	✔
SP11	225 (1.2)	✔
MS-30	178 (0.9)	✔
SL-PLUS	169 (0.9)	
SS Muller	139 (0.7)	✔
Anca-fit	135 (0.7)	
Centrament	117 (0.6)	✔
Omnifit	100 (0.5)	
Others[30]	1,501 (8.0)	
Total	**19,122**	

Table 16 shows that the most frequently used cups in the NJR were the OGEE cup and the Charnley cup. These make up nearly 30% of the cups. Numbers are presented separately for cemented and cementless cups in Appendices 9D3 and 9D4 of the web version of this report. (See NJR website at www.njrcentre.org.uk.)

Table 16 – *The 20 cup brands entered most frequently into the NJR for hip primary procedures*

Brand	Number used (%)	Cemented cup
OGEE Cup	3,805 (19.9)	✔
Charnley	1,888 (9.9)	✔
Duration	1,424 (7.4)	✔
Trilogy	1,351 (7.1)	
Exeter	1,287 (6.7)	✔
CSF	1,177 (6.2)	
Elite Plus	733 (3.8)	✔
Duraloc	664 (3.5)	
ARCOM	605 (3.2)	✔
ABG 2	490 (2.6)	
Ultima	445 (2.3)	Both[31]
JRI Cup	383 (2.0)	✔
Opera	364 (1.9)	✔
Muller	341 (1.8)	✔
ZCA	338 (1.8)	✔
Trident	335 (1.8)	
Wroblewski Golf Ball	310 (1.6)	✔
Reflection	242 (1.3)	
Duraloc Option	237 (1.2)	
ODC	225 (1.2)	✔
Others[32]	2,478 (12.8)	
Total	**19,122**	

Table 17 shows the 20 most frequent combinations of cups and stems used, and shows that the Charnley cup implanted with a Charnley stem has the highest frequency of usage in the NJR. Due to the numerous different combinations, there are many grouped as 'Others' (35.7%). This information is expanded and shown separately for cemented combinations, cementless combinations, and hybrid[33] combinations in Appendices 9F1, 9F2 and 9F3 of the web version of this report. (See NJR website at www.njrcentre.org.uk.)

Table 18 shows that there were fewer brands of resurfacing prostheses entered into the NJR, the most popular one being the BHR which was used in 82.6% of the resurfacing procedures in the NJR.

Table 17 – *The 20 stem and cup combinations entered most frequently into the NJR for hip primary procedures*

Stem	Cemented	Cup	Cemented	Number	Mixed and matched[34]
Charnley	✔	Charnley	✔	1,588	
Charnley	✔	OGEE	✔	1,503	
Exeter V40	✔	Duration	✔	1,375	
Exeter V40	✔	OGEE	✔	1,129	✔
Furlong HAC		CSF		1,067	
Exeter V40	✔	Exeter	✔	1,046	
Exeter V40	✔	Trilogy		501	✔
Stanmore Modular	✔	ARCOM	✔	500	
Exeter V40	✔	Elite Plus	✔	398	✔
C-Stem	✔	OGEE	✔	382	
Elite Plus	✔	OGEE	✔	381	
Corail		Duraloc		349	
Furlong Cemented	✔	JRI Cup	✔	325	
CPT	✔	ZCA	✔	306	
Ultima	✔	Ultima	Both	253	
Exeter	✔	OGEE	✔	252	✔
Exeter V40	✔	ABG 2		245	
CPT	✔	Trilogy		235	
Exeter		Exeter		235	
Versys		Trilogy		233	
Others[35]				6,819	
Total				**19,122**	

Table 18 – *Resurfacing prostheses entered most frequently into the NJR for primary resurfacing procedures*

Brand	Number used (%)
BHR	1,881 (82.6)
Cormet 2000	350 (15.4)
Conserve	22 (1.0)
Centerpulse	11 (0.5)
ASR	10 (0.4)
Biomet	3 (0.1)
Total	**2,277**

6.3.2 Femoral head sizes

Due to usage of monobloc stems, not all primary hip procedures entered a modular femoral head into the NJR. However, Table 19 shows that, where a modular femoral head was used, the most popular head size in the NJR is 28mm. This was used in 71.6% of primary hip replacements that utilised modular stems.

Table 19 – *Frequency of modular femoral head sizes implanted in primary hip procedures that were entered into the NJR*

Head size	Number used (%)
22.225mm	1,238 (7.7)
26mm	2,275 (14.1)
28mm	11,525 (71.6)
32mm	645 (4.0)
Other size	407 (2.6)
Total	**16,090[36]**

6.3.3 Femoral head material used

Table 20 shows that the most popular femoral head material was metal, which was implanted in 76.3% of primary hip replacements.

Table 20 – *Frequency of material chosen for femoral head implants*

Material	Number used (%)
Metal	12,277 (76.3)
Ceramic	3,813 (23.7)
Total	**16,090**

[28] 'Brand' refers to a manufacturer's product description, e.g. Charnley Elite. 'Type' refers to the generic description of an implant, e.g. modular cemented stem

[29] This total includes cemented and cementless prostheses, and those used in a primary or a revision procedure

[30] 'Others' consists of 56 brands made by 14 different manufacturers

[31] Ultima cups can be cemented or cementless

[32] 'Others' consists of 49 brands made by 14 different manufacturers

[33] A hybrid is a procedure where the femoral prosthesis is cemented and the acetabular prosthesis is not cemented. A reverse hybrid procedure has the acetabular prosthesis cemented and the femoral prosthesis not cemented. There were 83 reverse hybrid procedures entered into the NJR database. Of the 20 combinations most frequently entered into the NJR for primary procedures, none were reverse hybrids

[34] See Section 6.3.4 for details on mixing and matching of prostheses

[35] 349 'Other' combinations

[36] Due to usage of monobloc stems, not all procedures entered a modular femoral head into the NJR

6.3.4 Mixing and matching of prostheses

When performing hip replacement operations, surgeons sometimes choose to implant a femoral component (incorporating a metallic or ceramic modular head) from one manufacturer with an acetabular component (incorporating a polyethylene bearing surface) from another. This is known as 'mixing and matching' or 'cross-breeding'. In the NJR data, 22.1% of all primary hip replacement procedures entered had mixed and matched components. No evidence was found of mixing of other types of component from different manufacturers.

Table 21 shows the extent of mixing and matching in primary procedures in the NJR. Of the 20 most frequently used stem/head combinations, the percentage implanted with a cup made by the same manufacturer was greater than 90% for half (i.e. 10) of the stems. The lowest percentage was 35.5% for the Exeter stem. Table 21 also shows the most commonly used cup made by a different manufacturer. In many cases, the favourite cup from an alternative manufacturer is the OGEE cup. For example, the NJR shows 734 CPT brand stems implanted in primary hip procedures. Of these, 541 (i.e. 73.7%) were used with a cup made by the same manufacturer. Of the remaining 193 stems, 82 were implanted with an OGEE cup made by a different manufacturer (11.2% of the total CPT stems implanted in primary hip procedures). Appendix 9G in the web version of this report shows the 20 most frequently used cups and stems and how often they were used together. (See NJR website at www.njrcentre.org.uk.)

6.4 Discussion

6.4.1 Comparison of NJR results

The results from the NJR in England and Wales were compared with results from national joint registries in Sweden, Australia and Canada. Sweden has a registry that has been collecting data on hip replacement surgery since 1979, Australia since 1999, and Canada since 2001. Sweden, Australia and Canada have so far published results on data collected up to the end of 2002, whereas data in the NJR for England

Table 21 – *Frequency of cups made by same manufacturer as stem, and most commonly used cup made by different manufacturer from stem in primary procedures (20 stem brands most frequently entered into the NJR)*

Stem brand	Number of stems implanted	Number of stems used with a cup made by same manufacturer	%	Most commonly used cup made by a different manufacturer	Number of cups implanted	%
Exeter V40	5,863	2,816	48.0%	OGEE	1,129	19.3%
Charnley	3,455	3,321	96.1%	Opera	108	3.1%
Furlong HAC	1,261	1,204	95.5%	Trilogy	32	2.5%
C-Stem	1,152	949	82.4%	Opera	110	9.5%
Exeter	894	299	35.5%	OGEE	252	28.2%
CPT	734	541	73.7%	OGEE	82	11.2%
Elite Plus	705	648	91.9%	Flange Cup	18	2.6%
Corail	592	514	86.8%	Trilogy	72	12.2%
Stanmore Modular	580	505	87.1%	Elite Plus	23	4.0%
ABG 2	435	294	67.6%	All cups made by different manufacturers		
Furlong Cemented	335	332	99.1%	All cups made by different manufacturers		
Ultima	314	288	91.7%	EPF – Plus	16	5.1%
Versys	238	237	99.6%	OGEE	1	0.4%
SP11	225	152	67.6%	ARCOM	27	12.0%
MS-30	178	152	85.4%	Trilogy	15	8.4%
SL-PLUS	169	167	98.8%	Flange Cup	2	1.2%
SS Muller	139	137	98.6%	All cups made by different manufacturers		
Anca-fit	135	72	53.3%	CSF	60	44.4%
Centrament	117	117	100.0%			
Omnifit	100	99	99.0%	Mallory Head	1	1.0%

and Wales that are analysed in this report were collected for operations that took place between 1 April and 31 December 2003 inclusive.

6.4.2 Patient characteristics

In England and Wales, the average age of primary hip replacement patients was 68. The average age for female primary hip replacement patients tends to be three to four years older than the average age for male primary hip replacement patients (depending on procedure), with these results being similar throughout the four registries.

In each of the registries, roughly 60% of the hip replacement patients are female. In England and Wales, there was a markedly higher proportion of men than women having resurfacing arthroplasty. Other registries have not commented on gender proportions in resurfacing.

Each of the four registries shows osteoarthritis to be the most common indication for primary hip replacement, present in over 80% of all patients (80.5% in Sweden, 87.9% in Australia, 81% in Canada and 93.6% in England and Wales). In Sweden and Australia, only one indication for surgery is given, whereas in Canada and England and Wales, one or more indications may be selected.

6.4.3 Type of procedure

The proportion of procedures using cement varies between the four registries examined (see Table 22). Sweden has a higher proportion of fully cemented procedures compared with Australia and England and Wales. Hybrid procedures[37] are also less common in Sweden and far more common in Australia. Canada does not state the percentage of operations in terms of cemented, cementless and hybrids, but states that 44% of femoral prostheses and 7% of acetabular prostheses were cemented. This represents a lower usage of cement fixation than in Australia and England and Wales. The Swedish registry does not state percentages for cemented/cementless cups and stems separately. There is obviously a large difference in the incidence of bone cement usage for both cup and stem between these different countries. This cannot be explained by differences in patient characteristics and is probably the result of several economic and historical factors.

The information collected on different surgical techniques (see Table 12) will become increasingly important in the future when trying to assess what impact these surgical methods have on outcomes, and whether surgical practices change over time. Currently, Sweden and Canada have remarked on these factors in their annual reports whereas Australia has not.

A recent report from the Committee of Public Accounts[39] asked that information from the NJR be used to research the number of procedures performed per surgeon. The Swedish, Australian and Canadian registries have not discussed this matter and with only half of all hip replacements being entered into the NJR for England and Wales, little can be drawn from the data currently available. However, the topic has been examined

Table 22 – *Use of cement in total hip replacements, according to Joint Registry*

National joint registry	Cemented	Cementless	Hybrid[37]	Unknown
Sweden	90.3%	3.0%	6.0%	0.7%
Australia	18.2%	41.0%	34.0%	6.7%
England and Wales	63.0%	15.8%	10.9%	10.3%[38]
National joint registry	**Cemented cups**	**Cementless cups**	**Cemented stems**	**Cementless stems**
Australia	18.5%	81.5%	58.4%	41.6%
Canada	7%	90%	44%	55%
England and Wales	69.3%	30.7%	80.7%	19.3%

[37] A hybrid is a procedure where the femoral prosthesis is cemented and the acetabular prosthesis is not cemented. A reverse hybrid procedure has the acetabular prosthesis cemented and the femoral prosthesis not cemented

[38] These were resurfacing procedures for which cementing methods were unknown

[39] House of Commons Committee of Public Accounts. *Hip replacements: an update*. Seventeenth Report of Session 2003 - 04 http://www.publications.parliament.uk/pa/cm200304/cmselect/cmpubacc/40/40.pdf

in several reports for the USA, Canada and the UK[40] with evidence suggesting outcomes after joint replacement are usually better if the replacement is performed by surgeons who carry out many of these procedures per year.

6.4.4 Brands of prosthesis

In total, 81 different brands of femoral stems and 72 different brands of acetabular cups have been entered into the NJR for England and Wales during the nine-month data collection period. These products were manufactured or distributed by 23 different companies. The total number of different combinations of these 81 stems and 72 cups so far entered into the NJR is 369, of which 98 were entered just once. Sweden reports that 163 stem brands and 158 cup brands have been entered into its registry throughout the 23 years of data collection. Australia reports that 128 stem brands and 105 cup brands have been entered into its registry for the three years it has been collecting data. Canada has not mentioned prosthesis brands in its 2004 annual report. Mixing and matching (according to the definition given in Section 6.3.4) has not been discussed in the annual reports of the Swedish, Australian or Canadian registries. In England and Wales, this practice was found to occur in 22.1% of hip replacement procedures entered into the NJR.

The most frequently used brands of prosthesis vary across the four different registries. Some of the more frequently used prostheses in Sweden have not been entered at all in the NJR for England and Wales, although many of these were entered in Sweden several years ago and so it is possible they are no longer manufactured. The femoral stems most frequently entered into the registries are:

- Charnley in Sweden
- Exeter in Australia
- Exeter V40 in England and Wales

All of these are cemented stems. The acetabular cups most frequently entered into the registries are:

- Flange Cup (Lubinus) in Sweden
- Trident in Australia
- OGEE in England and Wales

The Flange and OGEE cups are cemented, and Trident cups are cementless. Canada does not state which brands of stems and cups are used most in hip replacements. In summary, there is obviously considerable variation in brand usage in different countries.

According to the criteria laid down by the Orthopaedic Data Evaluation Panel (ODEP) of the NHS Purchasing and Supply Agency, 28% of the stems and 37% of the cups entered into the NJR for England and Wales meet the 10-year benchmark criteria set by NICE. However, the ODEP report[41] could only refer to brands that were introduced more than 10 years ago and a considerable number of brands have been introduced since. Therefore, some of the current major suppliers have not been included in the ODEP report. Also, it should be noted that many of the stems for which full NICE compliance is being claimed are now being used in a different modularity or with a different modular head size than the original design, for which the clinical evidence has been provided.

6.4.5 Types of prosthesis

Due to a coding system applied within the NJR database, the performance of implants of a similar type from a number of manufacturers can be compared directly with different types of prosthesis, e.g. cemented versus cementless stems.

[40] Early failures of total hip replacement: Effect of surgeon volume - Losina E, Barrett J, Mahomed NN, Baron JA, Katz JN. *Arthritis & Rheumatism, April 2004 (50: 1338-43)*

Are complication rates for elective primary total hip arthroplasty in Ontario related to surgeon and hospital volumes? A preliminary investigation - Kreder HJ, Williams JI, Jaglal S, Hu R, Axcell T, Stephen D. *Canadian Journal of Surgery, December 1998 (41: 431-7)*

Relationship between outcome and annual surgical experience for the Charnley total hip replacement. Results from a regional hip register - Fender D, van der Meulen JH, Gregg PJ. *Journal of Bone & Joint Surgery - British Volume, March 2003 (85: 187-90)*

[41] ODEP website: www.pasa.nhs.uk/medsurg/shared/orthopaedics

Although nine months is too short a time in which to be making such comparisons, there are many examples of analyses of differences in clinical outcome that could be undertaken in the future. These could include, but not be limited to, comparisons of:

- Cemented versus cementless stems in similar aged patient cohorts
- Conventional hip replacement versus hip resurfacing in patients, for example, under 60 years of age
- Different femoral head sizes
- Different material combinations in head/cup articulation
- Hydroxyapatite coating versus porous coating only, versus pressfit only, for stem or cup
- Surgical preference; for example, it was interesting to note that four of the five cemented stems most frequently entered into the NJR were collarless/polished/tapered stems, although manufactured by three different companies

6.4.6 Summary

Patients who have hip replacement surgery in Sweden, Australia, Canada and England and Wales have similar characteristics in terms of age, gender and indications for surgery. However, there appear to be many variations in the type of surgery performed and the prostheses implanted. Hip replacement patients in Sweden are more likely to receive a cemented hip than patients in Australia, for example, and patients in Australia are more likely to receive a hybrid hip than patients in England and Wales. The brand of hip likely to be implanted also shows wide variation according to country. The reasons for this are less likely to be clinical, but more due to economic, historical and marketing factors. Therefore, the type of hip replacement a patient receives, in terms of operation and prosthesis, depends on which country they have the operation in.

7 Primary knee replacement procedures

This section summarises the data and analysis of all primary total-condylar knee, unicondylar knee and patello-femoral replacements performed between 1 April and 31 December 2003 inclusive in England and Wales, and that were entered into the NJR database by 31 March 2004.

7.1 Description of patient characteristics

Table 23 (overleaf) shows that the mean age for primary knee replacement patients in the NJR is 70.6 years. Patients who underwent a total knee replacement were generally older than patients who had either a unicondylar or patello-femoral knee replacement. 56.3% of consenting knee patients were female, and only unicondylar knee replacements had a higher proportion of males than females. Nearly 90% of patients were 'fit and healthy' or had a 'mild, not incapacitating disease' according to the classification of the American Society of Anaesthesiology scoring system (ASA grade). The most common indication for surgery was osteoarthritis, which was present in 96.2% of patients.

7.2 Description of primary knee replacement procedures

Table 24 (overleaf) shows that 0.9% of knee procedures were bilateral operations, and that right knees were operated on more often than left knees.

7.2.1 Description of surgeons

Table 24 shows that a consultant was the lead surgeon for 78.2% of all primary knee procedures entered into the NJR. Patello-femoral replacements had the highest percentage of consultants leading on the procedure at 89.6%, while total knee replacements not classified (e.g. hybrid) had the lowest percentage of consultants leading on the procedure, at 71.1%.

Table 23 – *Patient characteristics for primary knee replacement patients, according to type of procedure*

	Patient procedure					
	Total replacement using cement	Total replacement not using cement	Total replacement not classified (e.g. hybrid[42])	Unicondylar knee replacement	Patello-femoral replacement	Total
Age (consenting patients only)						
Mean age (Std Dev)	71.2 (9.0)	70.2 (9.1)	69.2 (9.0)	65.8 (9.5)	64.1 (10.7)	**70.6 (9.2)**
Inter-quartile range 25%	65.3	64.5	62.6	59.3	56.2	**64.6**
75%	77.7	76.5	75.2	72.5	71.7	**77.3**
Gender (consenting patients) (%)						
Male	4,640 (43.0)	413 (44.0)	76 (46.6)	536 (53.8)	28 (22.1)	**5,963 (43.7)**
Female	6,155 (57.0)	526 (56.0)	87 (53.4)	460 (46.2)	98 (77.9)	**7,326 (56.3)**
Physical status[43] (%)						
Fit and healthy	5,054 (29.6)	522 (31.7)	75 (34.4)	796 (47.0)	93 (42.1)	**6,540 (31.4)**
Mild disease, not incapacitating	10,143 (59.4)	919 (55.9)	127 (58.3)	792 (46.7)	120 (54.3)	**12,101 (58.0)**
Incapacitating systemic disease or life-threatening disease	1,879 (11.0)	204 (12.4)	16 (7.3)	106 (6.3)	8 (3.6)	**2,213 (10.6)**
Indications for surgery[44] (%)						
Osteoarthritis	16,373 (95.9)	1,584 (96.3)	213 (97.7)	1,681 (99.2)	213 (96.4)	**20,064 (96.2)**
Rheumatoid arthritis	596 (3.5)	50 (3.0)	3 (1.4)	4 (0.2)	0	**653 (3.1)**
Avascular necrosis	69 (0.4)	4 (0.2)	0	10 (0.6)	0	**83 (0.4)**
Failed internal fixation	7 (0)	3 (0.2)	0	0	0	**10 (0)**
Knee trauma	131 (0.8)	9 (0.5)	4 (1.8)	8 (0.5)	2 (0.9)	**154 (0.7)**
Previous arthrodesis	4 (0)	0	0	0	0	**4 (0)**
Other	128 (0.7)	14 (0.9)	4 (1.8)	5 (0.3)	9 (4.1)	**160 (0.8)**
Total number of procedures	**17,076**	**1,645**	**218**	**1,694**	**221**	**20,854**

Table 24 – *Characteristics of the primary knee replacement procedures, according to side, lead surgeon grade and locum*

	Patient procedure					
	Total replacement using cement	Total replacement not using cement	Total replacement not classified (e.g. hybrid[42])	Unicondylar knee replacement	Patello-femoral replacement	Total
Side (%)						
Left, unilateral	7,916 (46.7)	791 (48.6)	92 (42.6)	776 (46.3)	95 (43.6)	**9,670 (46.8)**
Right, unilateral	8,884 (52.5)	818 (50.3)	122 (56.5)	884 (52.7)	120 (55.0)	**10,828 (52.4)**
Bilateral[45]	138 (0.8)	18 (1.1)	2 (0.9)	17 (1.0)	3 (1.4)	**178 (0.9)**
Lead surgeon grade (%)						
Consultant	13,192 (77.3)	1,249 (75.9)	155 (71.1)	1,506 (88.9)	198 (89.6)	**16,305 (78.2)**
Associate Specialist/Staff Grade/ Clinical Assistant	1,932 (11.3)	241 (14.7)	36 (16.5)	60 (3.6)	5 (2.3)	**2,275 (10.9)**
With consultant assistance	271 (1.6)	12 (0.8)	1 (0.4)	11 (0.7)	1 (0.5)	**299 (1.4)**
Without consultant assistance	1,661 (9.7)	229 (13.9)	35 (16.1)	49 (2.9)	4 (1.8)	**1,979 (9.5)**
Specialist Registrar (SPR)/ Senior House Officer (SHO)/ House Officer/Other[46]	1,870 (10.9)	139 (8.4)	13 (6.0)	128 (7.5)	18 (8.1)	**2,168 (10.4)**
With consultant assistance	851 (4.9)	86 (5.2)	8 (3.7)	48 (2.8)	15 (6.8)	**1,008 (4.8)**
Without consultant assistance	1,021 (6.0)	53 (3.2)	5 (2.3)	80 (4.7)	3 (1.3)	**1,162 (5.6)**
Part of visiting surgical team from overseas	82 (0.5)	16 (1.0)	14 (6.4)	0	0	**112 (0.5)**
Lead surgeon is locum (%)						
Yes	911 (5.3)	129 (7.8)	3 (1.4)	43 (2.5)	2 (0.9)	**1,088 (5.2)**
No	16,165 (94.7)	1,516 (92.2)	215 (98.6)	1,651 (97.5)	219 (99.1)	**19,766 (94.8)**
Total	**17,076**	**1,645**	**218**	**1,694**	**221**	**20,854**

Table 25 – *Number of surgeons according to number of primary knee replacement procedures entered in NJR*

	Number of knee replacements entered into NJR per surgeon				
	< 25	25 – 49	50 – 99	100 – 199	> 200
Number of surgeons (%) (n=1,547)	1,286 (83.1)	200 (12.9)	56 (3.6)	4 (0.3)	1 (0.1)

The surgeon grades other than consultant have been looked at according to whether or not a consultant was assisting with the operation (see Table 24). Consultants assisted more frequently in operations performed by specialist registrars and house officers compared with operations performed by associate specialists and staff grades. 5.2% of lead surgeons were locums.

The consultant in charge of a case often, but not always, performs the operation. For 15,919 primary knee replacements (76.3%), the consultant in charge of the case was also the lead surgeon for the operation.

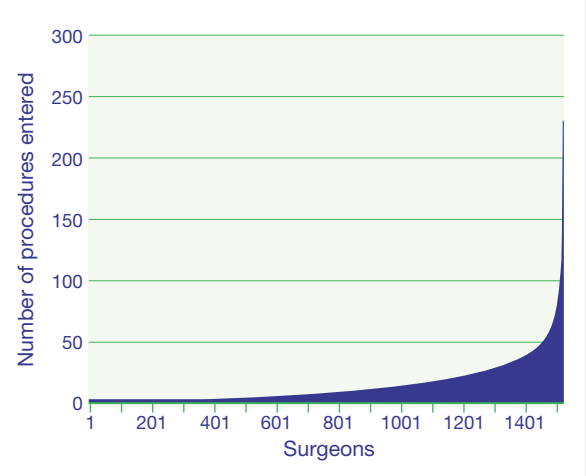
7.2.2 Number of primary knee replacements per surgeon

The number of knee replacement procedures performed per surgeon was calculated by counting each time a particular surgeon was declared as being the lead surgeon for a procedure. For the data recorded in the NJR, the mean number of knee replacement procedures entered by each surgeon is 13 for the nine-month data entry period, ranging from 1 to 230. 353 surgeons (22.8%) have entered just one or two procedures into the NJR. This does not mean that these surgeons have only performed one or two procedures, but that only these procedures were entered into the NJR, possibly to demonstrate a minimum level of compliance. Further information on the distribution of the number of procedures performed is given in Graph 5 and Table 25.

7.2.3 Description of surgical practice in primary knee replacements

Table 26 (overleaf) shows the variation in surgical practice observed in the NJR for primary knee replacement procedures. A detailed version of this table showing surgical practice according to type of knee replacement is given in Appendix 9H of the web version of this report. (See NJR website at www.njrcentre.org.uk.) Most operations were carried out in a laminar flow theatre and most procedures were carried out using conventional rather than minimally invasive incisions. The most common anaesthetic used was spinal anaesthetic, followed by general. Medial parapatellar was the most common surgical approach, and midline was the skin incision used most frequently. Tourniquets were used in most of the operations, and in the majority of cases at least one component was implanted with bone cement. Most patients had the fat pad partially removed. 1.3% of procedures used image guided surgery.

Graph 5 – *Number of primary knee replacement procedures per surgeon entered into the NJR for nine-month period*



[42] A hybrid operation is one where either the femoral or tibial side of the joint receives a cemented prosthetic component and the other receives a cementless component

[43] Patient physical status according to the ASA scoring system

[44] More than one indication may be selected per procedure, so these values add up to more than the total number of procedures

[45] Bilateral operations are classed as two procedures. Therefore, where 178 bilateral knee procedures were entered, these count as 356 procedures elsewhere in the table

[46] Fellow was the most common 'Other' grade, accounting for 363 of the procedures recorded

Table 26 – *Characteristics of surgical practice for knee replacement procedures*

All primary knee replacement procedures (%)	
Laminar flow theatre	
Yes	19,263 (92.4)
No	1,210 (5.8)
Unknown	381 (1.8)
Type of anaesthesia used[47]	
General	5,937 (28.5)
Epidural	3,204 (15.4)
Nerve block	3,304 (15.8)
Spinal	8,001 (38.4)
Unknown	408 (1.9)
Surgical approach	
Lateral parapatellar	548 (2.6)
Medial parapatellar	19,213 (92.1)
Sub-vastus	329 (1.6)
Other	764 (3.7)
Skin incision	
Lateral	150 (0.7)
Medial	2,861 (13.7)
Midline	17,843 (85.6)
Tourniquet used	
Yes	19,379 (92.9)
No	1,475 (7.1)
Fat pad removed	
Yes, fully	5,624 (27.0)
Yes, partially	12,222 (58.6)
No	3,008 (14.4)
Cement used	
Yes	19,089 (91.5)
No	1,765 (8.5)
Minimally invasive surgery used	
Yes	1,240 (5.9)
No	19,614 (94.1)
Image guided surgery used	
Yes	267 (1.3)
No	20,587 (98.7)
Total number of procedures	**20,854**

Table 27 shows the post-operative thrombo-prophylaxis regime recommended at the time of operation for primary knee replacements. Patients could be recommended more than one type of thrombo-prophylaxis. The two most frequent methods were TED stockings and low molecular weight heparin (LMWH), while aspirin, foot pumps and intermittent calf compression were also common choices. The most frequent combination was LMWH with TED stockings, which was recommended for 2,615 knee replacement patients.

Table 27 – *Thrombo-prophylaxis regime for primary knee replacement patients, recommended at time of operation*

Thrombo-prophylaxis regime[48]	Frequency of use (%)
Aspirin	4,443 (21.1)
Chloroquine	7 (0)
Low dose heparin	875 (4.2)
Low molecular weight heparin	9,002 (43.2)
Pentasaccharide	88 (0.4)
Warfarin	529 (2.5)
Foot pump	4,313 (20.7)
Intermittent calf compression	4,336 (20.8)
TED stockings	10,272 (49.3)
Other	551 (2.6)
None selected	1,977 (9.5)
Number of procedures	**20,854**

7.3 Description of prostheses in primary knee replacements

One of the major goals of the NJR is to examine the relative long-term performance of different types and brands[49] of knee prostheses.

7.3.1 Brands of prostheses entered most frequently into the NJR

In total, 37 brands of total condylar knee prostheses, 11 brands of unicondylar knee prostheses and two brands of patello-femoral prostheses were entered into the NJR. These were manufactured or distributed by 16 different companies. (The supplier of each brand of knee prosthesis entered into the NJR is given in Appendix 9I of the web version of this report. See NJR website at www.njrcentre.org.uk.) Table 28 shows the PFC Sigma and the AGC are the two most frequently used total condylar knee prostheses in the NJR. These two brands make up over 50% of all prostheses entered for total knee replacements.

Table 29 shows that the Oxford unicondylar knee was the most popular unicondylar prosthesis in the NJR, used in 78.2% of unicondylar knee replacements.

Table 30 shows that only two brands of patello-femoral joints were entered into the NJR, Avon being used in 89% of the patello-femoral replacements.

Table 28 – *The 20 total condylar knee brands entered most frequently into the NJR for primary procedures*

Brand	Number used (%)	Fixed bearing menisci	Mobile bearing menisci[50]
PFC Sigma	6,717 (36.3)	✔	✔
AGC	2,679 (14.5)	✔	
Nexgen	2,049 (11.1)	✔	✔
Kinemax Plus	1,514 (8.2)	✔	✔
LCS	1,246 (6.7)		✔
Scorpio	779 (4.2)	✔	✔
AMK	413 (2.2)	✔	
Profix	326 (1.8)	✔	
Rotaglide Plus	322 (1.7)		✔
Genesis	315 (1.7)	✔	✔
IB 2 (Wright)	260 (1.4)	✔	
Endo Plus	230 (1.2)	✔	✔
Advance	205 (1.1)	✔	
IB 2 (Zimmer)	188 (1.0)	✔	
Duracon	160 (0.9)	✔	
Genesis 2	149 (0.8)	✔	✔
NK2	140 (0.8)	✔	
Maxim	119 (0.6)	✔	
JRI	77 (0.4)	✔	
Alpina	74 (0.4)	✔	
Others[51]	553 (3.0)		
Total	**18,515**		

Table 29 – *The unicondylar knee brands entered most frequently into the NJR for primary procedures*

Brand	Number used (%)
Oxford	1,498 (78.2)
MG2	163 (8.5)
Preservation	159 (8.3)
Sled	38 (2.0)
ACM/Uniglide	31 (1.6)
Genesis	10 (0.5)
Euis	6 (0.3)
UC-PLUS	4 (0.2)
PFC Sigma	3 (0.2)
Allegretto	2 (0.1)
Total	**1,914**

Table 30 – *The patello-femoral joint knee brands entered most frequently into the NJR for primary procedures*

Brand	Number used (%)
Avon	195 (89.0)
Lubinus	24 (11.0)
Total	**219**

7.3.2 Incidence of usage of fixed versus mobile bearing menisci in primary total condylar knees

Table 31 shows that fixed bearing menisci are used more frequently than mobile bearing menisci. This was also demonstrated in Table 28.

Table 31 – *Incidence of usage of fixed versus mobile bearing menisci in primary total condylar knees*

Menisci type	Frequency	(%)
Fixed bearing	16,116	88.0%
Mobile bearing	2,194	12.0%
Total	**18,310**	

7.3.3 Patella resurfacing

The patella was resurfaced in 7,196 (38.8%) of primary total condylar knee replacements.

7.4 Discussion

7.4.1 Comparison of NJR results

The results from the NJR in England and Wales were compared with results from national joint registries in Sweden, Australia and Canada. Sweden has a registry that has been running since 1975, Australia since 1999, and Canada since 2001. Sweden, Australia and Canada have so far published results on data collected up to the end of 2002, whereas data in the NJR for England and Wales that are analysed for this report were collected between 1 April and 31 December 2003 inclusive.

7.4.2 Patient characteristics

In England and Wales, the average age of primary knee replacement patients was 70.6 years. The average age for female primary knee replacement patients was 6 to 18 months older than the average age for male patients (depending on procedure), and these results are similar throughout the four registries. In each of the registries, 55% to 60% of the knee replacement patients are female.

[47] More than one anaesthetic may be used

[48] Patients may be recommended more than one thrombo-prophylaxis treatment

[49] 'Brand' refers to a manufacturer's product description, e.g. Rotaglide Plus. 'Type' refers to the generic description of an implant, e.g. patello-femoral joint

[50] Other brands may also have mobile bearing menisci, but were not entered into the NJR system as such

[51] 'Others' consists of 16 brands made by 12 different manufacturers

Table 32 – *Use of cement in total knee replacements, according to Joint Registry*

National joint registry	Cemented	Cementless	Hybrid	Unknown
Sweden	98.2%	1.4%	0.2%	0.2%
Australia	48.8%	22.3%	28.1%	0.8%
Canada				100%
England and Wales	81.9%	7.9%	1.0%	9.2%[52]

Osteoarthritis was shown to be the most common indication for primary knee replacement. In England and Wales, it was present in 96.2% of patients, in Australia it was present in 96.3% of patients, and in Canada it was present in 93% of patients. Sweden did not directly refer to the percentage of knee patients who suffered from osteoarthritis.

7.4.3 Type of procedure

In each of the four registries, cemented operations are the most common type of total knee replacement procedure, although there is quite substantial variation between different registries (see Table 32). The Canadian registry states that 85% of femoral prostheses and 96% of tibial prostheses are cemented, and 14% of femoral knee prostheses and 2% of tibial prostheses are cementless. (Remaining percentages are given as unknown.)

The information collected on surgical procedures (see Table 26) will be useful in the future when looking at what impact these surgical methods have on outcomes, and whether surgical practices change over time. Currently, Canada has discussed these factors in its annual reports while Sweden and Australia have not.

The Swedish knee registry found a relationship between the number of operations performed in hospitals and the hospitals' revision rates. A group of units that performed fewer than 23 operations per year had substantially more revisions than those that performed more. Results from Canada also suggest that 'low-volume hospitals' have comparatively higher early revision rates[53].

7.4.4 Brands of prosthesis

In total, 37 brands of total condylar knee prostheses, 11 brands of unicondylar knee prostheses and two brands of patello-femoral prostheses were entered into the NJR for England and Wales during the nine-month data collection period. These products were manufactured or distributed by 16 different companies. It is unclear how many brands of knee prostheses have been entered into the Swedish and Canadian registries. Australia reports that 56 brands of total condylar knee prostheses, 14 brands of unicondylar knee prostheses and four brands of patello-femoral prostheses have been entered into its registry for the three years it has been collecting data.

The total condylar knee prostheses most frequently entered into the registries are:

- AGC in Sweden
- LCS in Australia
- PFC Sigma in England and Wales

All of these are cemented prostheses. The unicondylar prostheses most frequently entered into the registries are:

- Link-Endo in Sweden
- Oxford in Australia
- Oxford in England and Wales

These are also all cemented prostheses. Avon is the brand of patello-femoral prostheses most frequently entered into the Australian registry and the England and Wales registry. Sweden and Canada do not give details on prosthesis brands for patello-femoral joint replacement.

[52] These were unicondylar and patello-femoral procedures for which cementing methods were unknown

[53] Provider volume and other predictors of outcome after total knee arthroplasty: a population study in Ontario - Kreder HJ, Grosso P, Williams JI, Jaglal S, Axcell T, Wai EK, Stephen DJG. *Canadian Journal of Surgery, February 2003 (46: 15-22)*

7.4.5 Types of prosthesis

Already in this first report, it can be seen that the usage of mobile bearing menisci in total condylar replacement is much lower in Europe than in Australia, where a brand of mobile bearing knee was the most used product in 2002. It will be interesting to explore the long-term results of these two practices. Other areas of interest may include but not be limited to:

- Consideration of whether or not to resurface the patella during total condylar replacement
- Comparison of the long-term outcome of unicondylar versus total condylar replacement as the primary procedure
- Examining the results of patello-femoral replacement in a large patient cohort

7.4.6 Summary

The patient characteristics for knee replacement patients are similar throughout the four joint registries discussed. Most knee replacement patients are likely to have a cemented knee replacement procedure, although in Australia cementless and hybrid operations are fairly common. In addition, the usage of mobile bearing knees is higher in Australia than England and Wales. There is no brand of knee prosthesis that is most frequently used throughout the registries that have been compared. Therefore, it would seem that the type of knee replacement a patient receives varies according to the country in which they have the operation, and that brand choice is more likely due to historical, economic and market factors than clinical reasons.

8 Revision procedures of hip and knee procedures

This section summarises the data analysis of all revision hip and knee replacement procedures that were performed between 1 April and 31 December 2003 inclusive, and entered into the NJR by 31 March 2004. The total number of procedures includes revisions of conventional total hip prostheses, hip resurfacing devices, total condylar knees, unicondylar knees and patello-femoral joints. Revisions for primary procedures that were also entered in the NJR are mentioned in Section 8.3. Many of the analyses carried out in the previous sections could not be repeated for revision operations since the number of revisions recorded in the NJR at this early stage is relatively low. As numbers increase in future years, more analyses will be performed.

8.1 Description of patient characteristics

Table 33 (overleaf) shows that the revision hip replacement patients have a mean age of 70.4 years. More of the hip revision patients are female (53.4%). Most patients had a ‘mild, not incapacitating disease’ as classified under the American Society of Anaesthesiology scoring system (ASA grade). The most common indication for a hip revision is aseptic loosening which was present in 62.2% of hip revision patients.

The mean age for revision knee replacement patients is 70.6 years. There are slightly more males than females that were entered as having a revision knee operation (51.4% males). Most patients had a ‘mild, not incapacitating disease’ as classified by the ASA scoring system. Aseptic loosening was again the most common indication for revision, present in 41.4% of knee revision patients.

Table 33 – *Patient characteristics for revision hip and knee replacement patients*

	Hip patients (%)	Knee patients (%)
Age (consenting patients only)		
Mean age (Std Dev)	70.4 (11.4)	70.6 (9.9)
Inter-quartile range 25%	64.3	65.0
75%	78.4	77.6
Gender (consenting patients only)		
Male	637 (46.6)	296 (51.4)
Female	729 (53.4)	280 (48.6)
Patient physical status[54]		
Fit and healthy	608 (26.2)	227 (24.0)
Mild disease, not incapacitating	1,247 (53.6)	535 (56.5)
Incapacitating systemic disease or life-threatening disease	470 (20.2)	185 (19.5)
Most frequent indications for revision[55]		
Aseptic loosening	1,446 (62.2)	392 (41.4)
Dislocation/subluxation	319 (13.7)	52 (5.5)
Pain	308 (13.2)	218 (23.0)
Infection	215 (9.2)	174 (18.4)
Lysis	194 (8.3)	80 (8.4)
Instability	N/A	143 (15.1)
Wear of polyethylene component	170 (7.3)	94 (9.9)
Others[56]	451 (19.4)	277 (29.3)
Total number of procedures	**2,325**	**947**

8.2 Description of revision procedures

For both hip and knee revision procedures, few operations were bilateral and the right side was operated on more frequently than the left (see Table 34). Consultants performed the majority of revisions (89.1% of hips and 89.8% of knees), and assisted more often in operations undertaken by specialist registrars and house officers than in operations performed by associate specialists and staff grades. For hips and knees, locums performed 2.2% of revision procedures.

Table 34 – *Procedure characteristics for revision hip and knee replacement patients*

	Hip patients (%)	Knee patients (%)
Side		
Left, unilateral	1,092 (47.0)	463 (48.9)
Right, unilateral	1,221 (52.5)	478 (50.5)
Bilateral[57]	6 (0.5)	3 (0.6)
Lead surgeon grade		
Consultant	2,071 (89.1)	850 (89.8)
Associate Specialist/Staff Grade/Clinical Assistant	117 (5.0)	45 (4.7)
With consultant assistance	29 (1.2)	6 (0.6)
Without consultant assistance	88 (3.8)	39 (4.1)
Specialist Registrar (SPR)/Senior House Officer (SHO)/ House Officer/Other	130 (5.6)	52 (5.5)
With consultant assistance	66 (2.8)	35 (3.7)
Without consultant assistance	64 (2.8)	17 (1.8)
Part of visiting surgical team from overseas	7 (0.3)	0
Lead surgeon is locum		
Yes	51 (2.2)	21 (2.2)
No	2,274 (97.8)	926 (97.8)
Total number of procedures	**2,325**	**947**

8.3 Revisions linkable with NJR primary procedures

At this early stage of the NJR, 23 hip replacement patients and four knee replacement patients had both primary and revision procedures entered in the NJR that could be linked by their NHS numbers. These numbers are low, partly because of the low likelihood of a revision being required within the first nine months following primary surgery. In addition, for any patients who did have a revision so soon after their primary operations, it may be that either their primary or revision procedure was not entered into the NJR, or was entered without consent and, therefore, without patient-identifying variables. Given that there are so few procedures that can be linked at this early stage, it is not appropriate to look at these in further detail.

[54] Patient physical status according to ASA scoring system

[55] More than one indication may be selected per procedure, so these values add up to more than the total number of procedures

[56] 'Others' includes implant fractures, malalignment, peri-prosthetic fracture, incorrect sizing, patella maltracking and wear of tibia and patella

[57] Bilateral operations are classed as two procedures

Part 3

Appendices

APPENDIX 1A

All NHS hospitals that are submitting data to the NJR

Key:

S – Hospital submitted data by 31 March 2004 for operations performed between 1 April 2003 and 31 December 2003, and therefore its data have been included in analyses in Part 2 of the 1st Annual Report.

C – Hospital submitted data by 20 August 2004, but its data have not been included in analyses in Part 2 of the 1st Annual Report because they relate to operations that took place on or since 1 January 2004, and/or they relate to operations within the timeframe of interest but were submitted after the 31 March 2004 deadline for inclusion in analyses.

ENGLAND		
Trust	**Hospital**	**Submitting data**
Addenbrooke's NHS Trust	Addenbrooke's Hospital	S
Aintree Hospitals NHS Trust	University Hospital Aintree	S
Airedale NHS Trust	Airedale General Hospital	S
Barking, Havering and Redbridge Hospitals NHS Trust	King George Hospital	S
Barking, Havering and Redbridge Hospitals NHS Trust	Oldchurch Hospital	S
Barnet and Chase Farm Hospitals NHS Trust	Barnet General Hospital	S
Barnet and Chase Farm Hospitals NHS Trust	Chase Farm Hospital	C
Barnsley District General Hospital NHS Trust	Barnsley District General Hospital	S
Barts and the London NHS Trust	Barts and the London NHS Trust	S
Barts and the London NHS Trust	Royal London Hospital, The	S
Basildon and Thurrock University Hospitals NHS Trust	Basildon Hospital	S
Bedford Hospitals NHS Trust	Bedford Hospital South Wing	C
Birmingham Heartlands and Solihull (Teaching) NHS Trust	Solihull Hospital	S
Blackburn, Hyndburn and Ribble Valley Health Care NHS Trust	Blackburn Royal Infirmary	S
Blackpool, Fylde and Wyre Hospitals NHS Trust	Blackpool Victoria Hospital	S
Blackpool, Fylde and Wyre Hospitals NHS Trust	South Shore Hospital	S
Bolton Hospitals NHS Trust	Royal Bolton Hospital, The	S
Bradford Hospitals NHS Trust	Bradford Royal Infirmary	C
Brighton and Sussex University Hospitals NHS Trust	Princess Royal Hospital	S
Brighton and Sussex University Hospitals NHS Trust	Royal Sussex County Hospital	S
Buckinghamshire Hospitals NHS Trust	Stoke Mandeville Hospital	S
Burnley Health Care NHS Trust	Burnley General Hospital	S
Burton Hospitals NHS Trust	Queens Hospital	S
Calderdale and Huddersfield NHS Trust	Calderdale Royal Hospital	S
Calderdale and Huddersfield NHS Trust	Huddersfield Royal Infirmary	S
Central Manchester and Manchester Children's University Hospitals NHS Trust	Manchester Royal Infirmary	C
Chelsea and Westminster Healthcare NHS Trust	Chelsea & Westminster Hospital	S
Chesterfield and North Derbyshire Royal Hospital NHS Trust	Chesterfield & North Derbyshire Royal Hospital	S
City Hospitals Sunderland NHS Trust	Royal Sunderland Hospital	S
Countess of Chester Hospital NHS Trust	Countess of Chester Hospital	S
County Durham and Darlington Acute Hospitals NHS Trust	Darlington Memorial Hospital	C
County Durham and Darlington Acute Hospitals NHS Trust	University Hospital of North Durham	S
Dartford and Gravesham NHS Trust	Darent Valley Hospital	S
Doncaster and Bassetlaw Hospitals NHS Trust	Bassetlaw Hospital	S
Doncaster and Bassetlaw Hospitals NHS Trust	Doncaster Royal Infirmary	S
Dudley Group of Hospitals NHS Trust	Corbett Hospital	S
Dudley Group of Hospitals NHS Trust	Russells Hall Hospital	S
Ealing Hospital NHS Trust	Ealing Hospital	S
East and North Hertfordshire NHS Trust	Lister Hospital	C

ENGLAND (continued)		
Trust	**Hospital**	**Submitting data**
East and North Hertfordshire NHS Trust	Queen Elizabeth II Hospital	C
East Cheshire NHS Trust	Macclesfield District General Hospital	S
East Kent Hospitals NHS Trust	Queen Elizabeth The Queen Mother Hospital	S
East Kent Hospitals NHS Trust	William Harvey Hospital (Ashford)	S
East Somerset NHS Trust	Yeovil District Hospital	S
East Sussex Hospitals NHS Trust	Conquest Hospital	S
East Sussex Hospitals NHS Trust	Eastbourne District General Hospital	S
Epsom and St Helier NHS Trust	Epsom General Hospital	C
Epsom and St Helier NHS Trust	St Helier Hospital	S
Essex Rivers Healthcare NHS Trust	Colchester General Hospital	C
Frimley Park Hospital NHS Trust	Frimley Park Hospital	S
Gateshead Health NHS Trust	Queen Elizabeth Hospital	S
George Eliot Hospital NHS Trust	George Eliot Hospital - Acute Services	S
Gloucestershire Hospitals NHS Trust	Cheltenham General Hospital	S
Gloucestershire Hospitals NHS Trust	Gloucestershire Royal Hospital	C
Gloucestershire Hospitals NHS Trust	Standish Hospital	S
Good Hope Hospital NHS Trust	Good Hope Hospital	C
Guy's and St Thomas' NHS Trust	Guy's Hospital	S
Hammersmith Hospitals NHS Trust	Charing Cross Hospital	S
Hammersmith Hospitals NHS Trust	Ravenscourt Park Hospital	S
Harrogate Health Care NHS Trust	Harrogate District Hospital	S
Heatherwood and Wexham Park Hospitals NHS Trust	Heatherwood Hospital	S
Heatherwood and Wexham Park Hospitals NHS Trust	Wexham Park Hospital	S
Hereford Hospitals NHS Trust	Hereford County Hospital	S
Hinchingbrooke Health Care NHS Trust	Hinchingbrooke Hospital	S
Homerton University Hospital NHS Trust	Homerton University Hospital	S
Hospital Management Trust	Claremont Hospital	S
Hospital Management Trust	St Hugh's Hospital	S
Hull and East Yorkshire Hospitals NHS Trust	Castle Hill Hospital	S
Ipswich Hospital NHS Trust	Ipswich Hospital	S
Isle of Wight Healthcare NHS Trust	St Mary's Hospital	S
James Paget Healthcare NHS Trust	James Paget Hospital	S
Kettering General Hospital NHS Trust	Kettering General Hospital	S
King's College Hospital NHS Trust	King's College Hospital (Denmark Hill)	S
Kings Lynn and Wisbech Hospitals NHS Trust	Queen Elizabeth Hospital	S
Kingston Hospital NHS Trust	Kingston Hospital	S
Lancashire Teaching Hospitals NHS Trust	Chorley and South Ribble District General Hospital	S
Lancashire Teaching Hospitals NHS Trust	Royal Preston/Sharoe Green Hospitals	S
Leeds Teaching Hospitals NHS Trust	Chapel Allerton Hospital	C
Leeds Teaching Hospitals NHS Trust	Leeds General Infirmary	S
Leeds Teaching Hospitals NHS Trust	St James's University Hospital	S
Leeds Teaching Hospitals NHS Trust	Wharfedale Hospital	S
Lewisham Hospital NHS Trust, The	University Hospital Lewisham	S
Luton and Dunstable Hospital NHS Trust	Luton & Dunstable Hospital	S
Maidstone and Tunbridge Wells NHS Trust	Kent & Sussex Hospital	S
Maidstone and Tunbridge Wells NHS Trust	Maidstone District General Hospital	S
Mayday Healthcare NHS Trust	Mayday University Hospital	C
Medway NHS Trust	Medway Maritime Hospital	C
Mid Cheshire Hospitals NHS Trust, The	Leighton Hospital	S
Mid Essex Hospital Services NHS Trust	Broomfield Hospital	C
Mid Staffordshire General Hospitals NHS Trust	Cannock Chase Hospital	S
Mid Staffordshire General Hospitals NHS Trust	Staffordshire General Hospital	S
Mid Yorkshire Hospitals NHS Trust	Dewsbury Hospitals	S
Mid Yorkshire Hospitals NHS Trust	Pinderfields Hospitals	C
Mid Yorkshire Hospitals NHS Trust	Pontefract General Infirmary	C
Milton Keynes General Hospital NHS Trust	Milton Keynes General Hospital	S
Morecambe Bay Hospitals NHS Trust	Furness General Hospital	S

ENGLAND (continued)		
Trust	**Hospital**	**Submitting data**
Morecambe Bay Hospitals NHS Trust	Royal Lancaster Infirmary	S
Morecambe Bay Hospitals NHS Trust	Westmorland General Hospital	S
Newcastle Upon Tyne Hospitals NHS Trust, The	Freeman Hospital	S
Newham Healthcare NHS Trust	Newham General Hospital	S
Norfolk and Norwich University Hospital NHS Trust	Norfolk & Norwich Hospital	S
North Bristol NHS Trust	Southmead Hospital	S
North Cheshire Hospitals NHS Trust	Warrington Hospital	S
North Cumbria Acute Hospitals NHS Trust	Cumberland Infirmary	S
North Cumbria Acute Hospitals NHS Trust	West Cumberland Hospital	S
North Hampshire Hospitals NHS Trust	North Hampshire Hospital	S
North Middlesex University Hospital NHS Trust	North Middlesex Hospital	S
North Tees and Hartlepool NHS Trust	University Hospital of Hartlepool	S
North Tees and Hartlepool NHS Trust	University Hospital of North Tees	S
North West London Hospitals NHS Trust	Central Middlesex Hospital	S
Northamptonshire Healthcare NHS Trust	Northampton General Hospital	S
Northern Devon Healthcare NHS Trust	North Devon District Hospital	S
Northern Lincolnshire and Goole Hospitals NHS Trust	Diana Princess of Wales Hospital	C
Northern Lincolnshire and Goole Hospitals NHS Trust	Goole District Hospital (Acute)	C
Northern Lincolnshire and Goole Hospitals NHS Trust	Scunthorpe General Hospital	C
Northumbria Health Care NHS Trust	Hexham General Hospital	S
Northumbria Health Care NHS Trust	North Tyneside General Hospital	S
Northumbria Health Care NHS Trust	Wansbeck Hospital	S
Nottingham City Hospital NHS Trust	Nottingham City Hospital	S
Nuffield Orthopaedic NHS Trust	Nuffield Orthopaedic Centre	S
Pennine Acute Hospitals NHS Trust	North Manchester General Hospital	S
Pennine Acute Hospitals NHS Trust	Pennine Acute (Bury)	S
Pennine Acute Hospitals NHS Trust	Rochdale Infirmary	S
Pennine Acute Hospitals NHS Trust	Royal Oldham Hospital	S
Peterborough Hospitals NHS Trust	Edith Cavell Hospital	S
Plymouth Hospitals NHS Trust	Derriford Hospital	S
Princess Royal Hospital NHS Trust, The	Princess Royal Hospital	S
Queen Elizabeth Hospital NHS Trust	Queen Elizabeth Hospital	S
Queen Mary's Sidcup NHS Trust	Queen Mary's Hospital	S
Queen's Medical Centre, Nottingham University Hospital NHS Trust	Queens Medical Centre, Nottingham University Hospital	S
Robert Jones and Agnes Hunt Orthopaedic And District Hospital NHS Trust	Robert Jones and Agnes Hunt Orthopaedic Hospital	S
Rotherham General Hospitals NHS Trust	Rotherham District General Hospital	S
Royal Berkshire and Battle Hospitals NHS Trust	Royal Berkshire Hospital	C
Royal Bournemouth and Christchurch Hospitals NHS Trust	Royal Bournemouth General Hospital	S
Royal Cornwall Hospitals NHS Trust	Royal Cornwall Hospital (Treliske)	C
Royal Cornwall Hospitals NHS Trust	St Michael's Hospital	C
Royal Devon and Exeter Healthcare NHS Trust	Royal Devon & Exeter Hospital (Wonford)	S
Royal Free Hampstead NHS Trust	Royal Free Hospital	S
Royal Liverpool and Broadgreen University Hospitals NHS Trust	Broadgreen Hospital	S
Royal Liverpool and Broadgreen University Hospitals NHS Trust	Royal Liverpool University Hospital	S
Royal National Orthopaedic Hospital NHS Trust, The	Royal National Orthopaedic Hospital (Stanmore), The	S
Royal Orthopaedic Hospital NHS Trust	Royal Orthopaedic Hospital	S
Royal Surrey County Hospital NHS Trust	Royal Surrey County Hospital	S
Royal United Hospital Bath NHS Trust	Royal United Hospital	S
Royal West Sussex NHS Trust	St Richard's Hospital	S
Royal Wolverhampton Hospitals NHS Trust, The	New Cross Hospital	C
Salford Royal Hospitals NHS Trust	Hope Hospital	S
Salisbury Health Care NHS Trust	Salisbury District Hospital	S
Sandwell and West Birmingham Hospitals NHS Trust	City Hospital	S
Sandwell and West Birmingham Hospitals NHS Trust	Sandwell General Hospital	S
Scarborough and North East Yorkshire Health Care NHS Trust	Scarborough General Hospital	S

ENGLAND (continued)		
Trust	**Hospital**	**Submitting data**
Sheffield Teaching Hospitals NHS Trust	Northern General Hospital	S
Sherwood Forest Hospitals NHS Trust	Kings Mill Hospital	S
South Buckinghamshire NHS Trust	Wycombe General Hospital	S
South Manchester University Hospitals NHS Trust	Wythenshawe Hospital	S
South Tees Hospitals NHS Trust	Friarage Hospital	S
South Tees Hospitals NHS Trust	James Cook University Hospital, The	S
South Tees Hospitals NHS Trust	Middlesbrough General Hospital (closed for orthopaedics)	S
South Tyneside Health Care NHS Trust	South Tyneside District General Hospital	S
South Warwickshire General Hospitals NHS Trust	Warwick Hospital	C
Southampton University Hospitals NHS Trust	Southampton General Hospital	S
Southern Derbyshire Acute Hospitals NHS Trust	Derby Royal Infirmary	S
Southport and Ormskirk Hospital NHS Trust	Ormskirk & District General Hospital	S
Southport and Ormskirk Hospital NHS Trust	Southport Formby District General Hospital	S
St George's Healthcare NHS Trust	St George's Hospital	S
St Helens and Knowsley Hospitals NHS Trust	St Helens Hospital	S
St Helens and Knowsley Hospitals NHS Trust	Whiston Hospital	S
St Mary's NHS Trust	St Mary's Hospital	C
Stockport NHS Trust	Stepping Hill Hospital	S
Surrey and Sussex Healthcare NHS Trust	Crawley Hospital	C
Surrey and Sussex Healthcare NHS Trust	East Surrey Hospital	S
Swindon and Marlborough NHS Trust	Great Western Hospital, The	S
Tameside and Glossop Acute Services NHS Trust	Tameside General Hospital	S
Taunton and Somerset NHS Trust	Musgrove Park Hospital	S
Trafford Healthcare NHS Trust	Trafford General Hospital	S
United Bristol Healthcare NHS Trust	Bristol Royal Infirmary	S
United Lincolnshire Hospitals NHS Trust	Grantham & District General Hospital	S
United Lincolnshire Hospitals NHS Trust	Lincoln County Hospital	S
United Lincolnshire Hospitals NHS Trust	Louth County Hospital	S
United Lincolnshire Hospitals NHS Trust	Pilgrim Hospital	C
University College London Hospitals NHS Trust	Middlesex Hospital	S
University Hospitals Coventry and Warwickshire NHS Trust	Coventry & Warwickshire Hospital	S
University Hospitals Coventry and Warwickshire NHS Trust	Hospital of St Cross	S
University Hospitals of Leicester NHS Trust	Glenfield General Hospital	S
University Hospitals of Leicester NHS Trust	Leicester General Hospital	S
University of North Staffordshire NHS Trust	City General Hospital	S
Walsall Hospitals NHS Trust	Manor Hospital	C
West Dorset General Hospitals NHS Trust	Dorset County Hospital	S
West Hertfordshire Hospitals NHS Trust	Hemel Hempstead General Hospital	S
West Hertfordshire Hospitals NHS Trust	St Albans City Hospital	S
West Hertfordshire Hospitals NHS Trust	Watford General Hospital	S
West Suffolk Hospitals NHS Trust	West Suffolk Hospital	S
Weston Area Health NHS Trust	Weston General Hospital	S
Whipps Cross University Hospital NHS Trust	Whipps Cross University Hospital	S
Winchester and Eastleigh Healthcare NHS Trust	Royal Hampshire County Hospital	S
Wirral Hospital NHS Trust	Arrowe Park Hospital	S
Wirral Hospital NHS Trust	Clatterbridge Hospital	S
Worcestershire Acute Hospitals NHS Trust	Alexandra Hospital, The	S
Worcestershire Acute Hospitals NHS Trust	Worcestershire Royal Hospital	S
Worthing and Southlands Hospitals NHS Trust	Southlands Hospital	S
Worthing and Southlands Hospitals NHS Trust	Worthing Hospital	S
Wrightington, Wigan and Leigh NHS Trust	Royal Albert Edward Infirmary	C
Wrightington, Wigan and Leigh NHS Trust	Wrightington Hospital	S

WALES		
Trust	**Hospital**	**Submitting data**
Bro Morgannwg NHS Trust	Neath Port Talbot Hospital	S
Bro Morgannwg NHS Trust	Princess Of Wales Hospital	C
Carmarthenshire NHS Trust	Prince Philip Hospital	S
Carmarthenshire NHS Trust	West Wales General Hospital	C
Ceredigion and Mid Wales NHS Trust	Bronglais General Hospital	S
Conwy and Denbighshire NHS Trust	Abergele Hospital	S
Conwy and Denbighshire NHS Trust	Glan Clwyd General Hospital	C
Gwent Healthcare NHS Trust	Nevill Hall Hospital	S
North East Wales NHS Trust	Wrexham Maelor Hospital	S
North Glamorgan NHS Trust	Prince Charles Hospital	S
North West Wales NHS Trust	Ysbyty Gwynedd	S
Pembroke and Derwen NHS Trust	Withybush General Hospital	S
Pontypridd and Rhondda NHS Trust	Royal Glamorgan Hospital, The	S
Swansea NHS Trust	Morriston Hospital	S

APPENDIX 1B

All independent hospitals that are submitting data to the NJR

Key:

S – Hospital submitted data by 31 March 2004 for operations performed between 1 April 2003 and 31 December 2003, and therefore its data have been included in analyses in Part 2 of the 1st Annual Report.

C – Hospital submitted data by 20 August 2004, but its data have not been included in analyses in Part 2 of the 1st Annual Report because they relate to operations that took place on or since 1 January 2004, and/or they relate to operations within the timeframe of interest but were submitted after the 31 March 2004 deadline for inclusion in analyses.

ENGLAND		
Company	**Hospital**	**Submitting data**
Abbey Caldew Hospital	Abbey Caldew Hospital	S
Abbey Gisburne Hospital	Abbey Gisburne Hospital	S
Aspen Healthcare Limited	Holly House Hospital	S
Aspen Healthcare Limited	Parkside Hospital	S
Birkdale Clinic	Birkdale Clinic	C
BMI Healthcare	BMI Alexandra Hospital	S
BMI Healthcare	BMI Bath Clinic	S
BMI Healthcare	BMI Beardwood Private Hospital	S
BMI Healthcare	BMI Bishops Wood Hospital	S
BMI Healthcare	BMI Blackheath Hospital	S
BMI Healthcare	BMI Chatsworth Suite	S
BMI Healthcare	BMI Chaucer Hospital	S
BMI Healthcare	BMI Chelsfield Park Hospital	S
BMI Healthcare	BMI Clementine Churchill Hospital	S
BMI Healthcare	BMI Esperance	S
BMI Healthcare	BMI Fawkham Manor Hospital	S
BMI Healthcare	BMI Garden Hospital	S
BMI Healthcare	BMI Goring Hall Hospital	S
BMI Healthcare	BMI Hampshire Clinic	S
BMI Healthcare	BMI Highfield Hospital	S
BMI Healthcare	BMI Kings Oak Hospital	S
BMI Healthcare	BMI Manor Hospital	S
BMI Healthcare	BMI Nuneaton Private Hospital	S
BMI Healthcare	BMI Park Hospital, The	S

ENGLAND (continued)		
Company	**Hospital**	**Submitting data**
BMI Healthcare	BMI Princess Margaret	S
BMI Healthcare	BMI Priory Hospital	S
BMI Healthcare	BMI Ridgeway Hospital	S
BMI Healthcare	BMI Runnymede Hospital	S
BMI Healthcare	BMI Sandringham Hospital	S
BMI Healthcare	BMI Sarum Road Hospital	C
BMI Healthcare	BMI Saxon Clinic	C
BMI Healthcare	BMI Shelburne Hospital	S
BMI Healthcare	BMI Sloane Hospital	S
BMI Healthcare	BMI South Cheshire Hospital	S
BMI Healthcare	BMI The Alexandra Hospital Victoria Park	C
BMI Healthcare	BMI The Beaumont Hospital	S
BMI Healthcare	BMI The Chiltern	S
BMI Healthcare	BMI The Droitwich Spa Hospital	S
BMI Healthcare	BMI The Harbour Hospital	S
BMI Healthcare	BMI The Paddocks	S
BMI Healthcare	BMI The Somerfield Hospital	S
BMI Healthcare	BMI Thornbury Hospital	S
BMI Healthcare	BMI Three Shires Hospital	S
BMI Healthcare	BMI Winterbourne Hospital	S
BUPA	BUPA Alexandra Hospital	S
BUPA	BUPA Cambridge Lea Hospital	S
BUPA	BUPA Clare Park Hospital	S
BUPA	BUPA Dunedin Hospital	S
BUPA	BUPA Fylde Coast Hospital	S
BUPA	BUPA Gatwick Park Hospital	S
BUPA	BUPA Hartswood Hospital	S
BUPA	BUPA Hospital Bristol	S
BUPA	BUPA Hospital Bushey	S
BUPA	BUPA Hospital Elland	S
BUPA	BUPA Hospital Harpenden	C
BUPA	BUPA Hospital Hastings	S
BUPA	BUPA Hospital Hull, East Riding	S
BUPA	BUPA Hospital Leeds	S
BUPA	BUPA Hospital Leicester	S
BUPA	BUPA Hospital Little Aston	C
BUPA	BUPA Hospital Manchester	S
BUPA	BUPA Hospital Norwich	S
BUPA	BUPA Hospital Portsmouth	S
BUPA	BUPA Hospital Southampton	S
BUPA	BUPA Hospital Washington	S
BUPA	BUPA Methley Park Hospital	S
BUPA	BUPA Murrayfield Hospital - Wirral	S
BUPA	BUPA North Cheshire Hospital	S
BUPA	BUPA Parkway Hospital	S
BUPA	BUPA Regency Hospital	S
BUPA	BUPA Roding Hospital	S
BUPA	BUPA South Bank Hospital	S
BUPA	BUPA St Saviours Hospital	S
BUPA	BUPA Tunbridge Wells Hospital	S
BUPA	BUPA Wellesley Hospital	S
Capio Healthcare	Ashtead Hospital	S
Capio Healthcare	Berkshire Independent Hospital	S
Capio Healthcare	Capio Fulwood Hall Hospital	S
Capio Healthcare	Duchy Hospital, The	S
Capio Healthcare	Euxton Hall Hospital	S
Capio Healthcare	Fitzwilliam Hospital	S
Capio Healthcare	Mount Stuart House	C
Capio Healthcare	New Hall Hospital	S

ENGLAND (continued)		
Company	**Hospital**	**Submitting data**
Capio Healthcare	North Downs Hospital	S
Capio Healthcare	Oaklands Hospital	S
Capio Healthcare	Oaks Hospital	S
Capio Healthcare	Park Hill Hospital	S
Capio Healthcare	Pinehill Hospital	S
Capio Healthcare	Renacres Hall Hospital	S
Capio Healthcare	Rivers Hospital	S
Capio Healthcare	Rowley Hall Hospital	S
Capio Healthcare	Springfield Hospital	S
Capio Healthcare	West Midlands Hospital	S
Capio Healthcare	Winfield Hospital	S
Capio Healthcare	Woodland Hospital	S
Capio Healthcare	Yorkshire Clinic, The	S
Cromwell Clinic	Cromwell Clinic	S
Cromwell Hospital	Cromwell Hospital	C
Fairfield Independent Hospital	Fairfield Independent Hospital	S
Foscote Private Hospital	Foscote Private Hospital	S
HCA International Ltd	Lister Hospital, The	S
HCA International Ltd	London Bridge Hospital	S
HCA International Ltd	Princess Grace Hospital, The	S
HCA International Ltd	Wellington Hospital, The	S
Horder Centre for Arthritis, The	Horder Centre for Arthritis, The	S
Hospital Management Trust	Claremont Hospital	C
Hospital Management Trust	St Hugh's Hospital	C
Hospital of St John and St Elizabeth	Hospital of St John and St Elizabeth	S
King Edward VII Hospital, Midhurst	King Edward VII Hospital, Midhurst	S
King Edward VII Hospital Sister Agnes	King Edward VII Hospital Sister Agnes	S
London Clinic, The	London Clinic, The	S
London Independent	London Independent	S
Lourdes Hospital	Lourdes Hospital	S
Mount Alvernia Hospital	Mount Alvernia Hospital	S
New Victoria Hospital, The	New Victoria Hospital, The	S
Nuffield Hospitals	Birmingham Nuffield Hospital, The	S
Nuffield Hospitals	Bournemouth Nuffield Hospital, The	S
Nuffield Hospitals	Bristol Nuffield Hospital, The	S
Nuffield Hospitals	Bury St Edmunds Nuffield Hospital, The	S
Nuffield Hospitals	Cheltenham, Gloucester Nuffield Hospital, The	S
Nuffield Hospitals	Chichester Nuffield Hospital, The	S
Nuffield Hospitals	Cleveland Nuffield Hospital, The	S
Nuffield Hospitals	Essex Nuffield Hospital, The	S
Nuffield Hospitals	Exeter Nuffield Hospital, The	S
Nuffield Hospitals	Grosvenor Nuffield Hospital, The	S
Nuffield Hospitals	Guildford Nuffield Hospital, The	S
Nuffield Hospitals	HRH Princess Christian Nuffield Hospital, The	S
Nuffield Hospitals	Huddersfield Nuffield Hospital, The	S
Nuffield Hospitals	Hull Nuffield Hospital, The	S
Nuffield Hospitals	Lancaster, Lakeland Nuffield Hospital, The	S
Nuffield Hospitals	Leeds Nuffield Hospital, The	S
Nuffield Hospitals	Leicester Nuffield Hospital, The	S
Nuffield Hospitals	Lincoln Nuffield Hospital, The	S
Nuffield Hospitals	Newcastle Nuffield Hospital, The	S
Nuffield Hospitals	North London Nuffield Hospital, The	S
Nuffield Hospitals	North Staffordshire Nuffield Hospital, The	S
Nuffield Hospitals	Nottingham Nuffield Hospital, The	S
Nuffield Hospitals	Nuffield Hospital Cambridge	S
Nuffield Hospitals	Nuffield Hospital Derby	S
Nuffield Hospitals	Nuffield Hospital Harrogate	S
Nuffield Hospitals	Nuffield Hospital Haywards Heath	S
Nuffield Hospitals	Nuffield Hospital Ipswich	S

ENGLAND (continued)		
Company	**Hospital**	**Submitting data**
Nuffield Hospitals	Plymouth Nuffield Hospital, The	S
Nuffield Hospitals	Purey Cust Nuffield Hospital, The	S
Nuffield Hospitals	Shropshire Nuffield Hospital, The	S
Nuffield Hospitals	Somerset Nuffield Hospital, The	S
Nuffield Hospitals	Sussex Nuffield Hospital, The	S
Nuffield Hospitals	Thames Valley Nuffield Hospital, The	S
Nuffield Hospitals	Tunbridge Wells Nuffield Hospital, The	S
Nuffield Hospitals	Warwickshire Nuffield Hospital, The	S
Nuffield Hospitals	Wessex Nuffield Hospital, The	S
Nuffield Hospitals	Woking Nuffield Hospital, The	S
Nuffield Hospitals	Wolverhampton Nuffield Hospital, The	C
Nuffield Hospitals	Wye Valley Nuffield Hospital, The	S
Orchard Hospital, The	Orchard Hospital, The	S
St Anthonys	St Anthonys	S
Woodlands Hospital Darlington	Woodlands Hospital Darlington	S

WALES		
Company	**Hospital**	**Submitting data**
BMI Healthcare	BMI Werndale Hospital	S
BUPA	BUPA Hospital Cardiff	S
BUPA	BUPA Yale Hospital	C
Hospital Management Trust	Sancta Maria Hospital	C
St Josephs Hospital	St Josephs Hospital	C

APPENDIX 1C

All Treatment Centres that are submitting data to the NJR

Key:

Treatment Centres may be NHS-funded or privately funded.

S – Treatment Centre submitted data by 31 March 2004 for operations performed between 1 April 2003 and 31 December 2003, and therefore its data have been included in analyses in Part 2 of the 1st Annual Report.

C – Treatment Centre submitted data by 20 August 2004, but its data have not been included in analyses in Part 2 of the 1st Annual Report because they relate to operations that took place on or since 1 January 2004, and/or they relate to operations within the timeframe of interest but were submitted after the 31 March 2004 deadline for inclusion in analyses.

Organisation name	Submitting data
CUAH Bassetlaw Treatment Centre	C
CUAH Ilkeston Treatment Centre	C
Goole Hospital TC	C
Ravenscourt Park TC	C
Redwood Diagnosis and Treatment Centre	S
Royal Hospital at Haslar TC	C
Torbay TC	C
University College London Hospital TC	S
Weston TC	S

APPENDIX 1D

All NHS hospitals that are yet to comply with submitting data to the NJR as at 20 August 2004

ENGLAND	
Trust	**Hospital**
Ashford and St Peter's Hospitals NHS Trust	Ashford Hospital
Barking, Havering and Redbridge Hospitals NHS Trust	Harold Wood Hospital
County Durham and Darlington Acute Hospitals NHS Trust	Bishop Auckland General Hospital
Guy's and St Thomas' NHS Trust	St Thomas' Hospital
Hillingdon Hospital NHS Trust, The	Hillingdon Hospital
North West London Hospitals NHS Trust	Northwick Park Hospital
Oxford Radcliffe Hospital NHS Trust	Horton General Hospital
Portsmouth Hospitals NHS Trust	Queen Alexandra Hospital (1)
Princess Alexandra Hospital NHS Trust, The	Princess Alexandra Hospital
Sherwood Forest Hospitals NHS Trust	Newark Hospital
Southend Hospital NHS Trust	Southend Hospital
Whittington Hospital NHS Trust, The	Whittington Hospital, The
York Health Services NHS Trust	York District General Hospital

(1) Carry out only a small number of complex revisions per year. None undertaken since 1 April 2003.

WALES	
Trust	**Hospital**
Cardiff and Vale NHS Trust	Llandough Hospital
Gwent Healthcare NHS Trust	Royal Gwent Hospital

APPENDIX 1E

All independent hospitals that are yet to comply with submitting data to the NJR as at 20 August 2004

ENGLAND	
Company	**Hospital**
Abbey Sefton Hospital	Abbey Sefton Hospital
BMI Healthcare	BMI Shirley Oaks Hospital
Nuffield Hospitals	Acland Nuffield Hospital, The

WALES	
Company	**Hospital**
Bettercare Group Ltd	North Wales Medical Centre, The

APPENDIX 1F

All Treatment Centres that are yet to comply with submitting data to the NJR as at 20 August 2004

Note: Treatment Centres may be NHS-funded or privately funded.

Organisation name
Cannock TC
Kings College Hospital TC
South West London Elective Ortho Centre

APPENDIX 2

Membership of the NJR Steering Committee

Membership as at 20 August 2004	
Bill Darling	Chair
Paul Gregg	Vice Chair
Judy Murray	British Orthopaedic Association (representing the surgical profession)
Martyn Porter	British Hip Society
Timothy Wilton	British Association for Surgery of the Knee
Jan van der Meulen	Royal College of Surgeons (representing the surgical profession)
Alex MacGregor	School of Medicine, Health Policy and Practice University of East Anglia (representing public health and epidemiology)
	National Association of Theatre Nurses
Martin Jones	Arthritis Care (patient group representative)
Colin Thomson	All Wales Community Health Councils (patient group representative)
Kenneth Bateman	Smith & Nephew Healthcare Ltd, ABHI (representing the orthopaedic device industry)
Michael Borroff	DePuy International Ltd, ABHI (representing the orthopaedic device industry)
Christine Miles	Royal Orthopaedic Hospital (representing NHS Trust management)
Chris Dark	Director of Clinical Services, BUPA Hospitals (representing the IHA)
	Department of Health
Stephen Chamberlain	Welsh Assembly Government
Andrew Crosbie	Medicines and Healthcare products Regulatory Agency
Andrew Smallwood	NHS Purchasing and Supply Agency
Fiona Davies	AEA Technology (representing the contractor)
Colin Howie	Representing the Scottish Executive (observer status)

The following are thanked for their considerable contributions as past members of the Steering Committee. The Foreword pays tribute to Sally, who died during the preparation of this 1st Annual Report.

Hugh Phillips	British Orthopaedic Association (representing the surgical profession)
Sally Couzens	National Association of Theatre Nurses
Neil Betteridge & Elizabeth Nokes	Arthritis Care
Paul Woods	Department of Health
Shaun Chainey	Welsh Assembly Government

APPENDIX 3

Membership of the NJR Regional Clinical Co-ordinator network

Membership as at 20 August 2004	
Strategic Health Authority/Welsh NHS region	**Regional Clinical Co-ordinator**
ENGLAND	
Avon, Gloucestershire and Wiltshire Strategic Health Authority	Evert Smith (focusing on hips) John Newman (focusing on knees)
Bedfordshire and Hertfordshire Strategic Health Authority	Richard Rawlins
Birmingham and The Black Country Strategic Health Authority	David Dunlop
Cheshire and Merseyside Strategic Health Authority	Richard Parkinson
County Durham and Tees Valley Strategic Health Authority	John Anderson
Coventry, Warwickshire, Herefordshire and Worcestershire Strategic Health Authority	Kevin O'Dwyer
Cumbria and Lancashire Strategic Health Authority	Martyn Porter
Dorset and Somerset Strategic Health Authority	Nick Fiddian
Essex Strategic Health Authority	Godfrey Charnley
Greater Manchester Strategic Health Authority	David Sochart
Hampshire and Isle of Wight Strategic Health Authority	John Britton
Kent and Medway Strategic Health Authority	Philip Housden Hagen Jähnich
Leicestershire, Northamptonshire and Rutland Strategic Health Authority	Colin Esler
Norfolk, Suffolk and Cambridgeshire Strategic Health Authority	Keith Tucker
North and East Yorkshire and Northern Lincolnshire Strategic Health Authority	Mark Andrews Meng Khaw
North Central London Strategic Health Authority	John Skinner
North East London Strategic Health Authority	Gareth Scott
North West London Strategic Health Authority	John Hollingdale
Northumberland, Tyne and Wear Strategic Health Authority	Andrew McCaskie
Shropshire and Staffordshire Strategic Health Authority	Ian dos Remedios
South East London Strategic Health Authority	Patrick Li
South West London Strategic Health Authority	David Ward
South West Peninsula Strategic Health Authority	John Timperley
South Yorkshire Strategic Health Authority	Ian Stockley
Surrey and Sussex Strategic Health Authority	Kenneth Tuson
Thames Valley Strategic Health Authority	Riyaz Jinnah
Trent Strategic Health Authority	Peter Howard
West Yorkshire Strategic Health Authority	Mark Emerton
WALES	
Mid and West Wales	David Woodnutt
North Wales	Ian Smith
South East Wales	Alun John Robin Rice

The following are thanked for their considerable contributions as past members of the Regional Clinical Co-ordinators network.

Anthony Hui, Michael Fordyce, David Murray, Philip Radford

APPENDIX 4

Patient consent form

National Joint Registry
www.njrcentre.org.uk

This form is also available from the NJR Centre in Welsh

The National Joint Registry - What does it mean for you as a patient?

About the National Joint Registry (NJR)

Hip and knee joint replacements have become common and highly successful operations that bring many patients improved mobility and relief from pain. A number of people may at some time in the future need another operation on the same joint. This may occur for a variety of reasons, most commonly because the joint implant has worn out. There are many different types of hip and knee implants, many of which do not have data on their long-term effectiveness. To further improve the success of this surgery, the Department of Health and the Welsh Assembly Government have set up the National Joint Registry (also known as the NJR) to monitor the performance of joint implants.

The NJR is designed to record details of hip and knee replacement operations in England and Wales. Both the NHS and the independent healthcare sector are included and to be successful the NJR needs to gather information on as many people having these operations as possible.

The benefits the NJR will bring to you

The NJR data will be used to bring direct benefits to patients by:

- improving patient awareness of the outcomes of hip and knee joint replacement
- finding out how long the different joint replacements last
- helping to identify individual patients who have received an implant if there is a need for urgent clinical review

The NJR data will also be used to bring additional long-term benefits by:

- providing feedback to orthopaedic surgeons and teams to help maintain high clinical standards
- promoting open publication of performance of implants
- providing feedback on implant performance to regulatory authorities
- providing feedback to suppliers about the performance of their implants
- monitoring and comparing the performance of hospitals

Data collected via the NJR may be used for medical research, however these data will be anonymised so that it will not be possible to identify you. Research projects are subject to ethical review and will only be permitted if the outcomes are expected to provide significant benefits to the healthcare of patients.

How to find out more about the NJR

You can visit the NJR website at http://www.njrcentre.org.uk or contact the NJR Helpline.

NJR Helpline	Mon-Fri from 9am to 5pm (not including public holidays)
NJR Centre	
329, Harwell	Tel: 0845 345 9991
Didcot	Fax: 0845 345 9992
Oxon OX11 0QJ	E-mail: enquiries@njrcentre.org.uk

Patients should ensure that they return their signed consent form to their hospital and NOT the NJR Centre.

Personal information - what is required and why?

The information required for the NJR includes your personal details shown below and your operation details. It will link you to the implant(s) you received as well as linking any future joint implant surgery you may have. If the performance of any implant is identified as being a problem, having your personal details in the NJR will help us to make contact with you. We may also contact you in the future to ask you to complete a patient follow-up questionnaire.

Data collection - its security and confidentiality

The NJR will use an electronic system for data collection. The data will be securely coded for transfer to a central database. This avoids sending paper records through the post and ensures maximum data security.

Your personal information is confidential and cannot be used outside of the NJR. Procedures are in place to protect your information and keep it confidential, it will only be available to you and your surgeon. If you wish, you can obtain access to a copy of your own record in accordance with the Data Protection Act 1998.

Your participation is voluntary

This form asks for your consent for personal information to be recorded by the NJR. Your participation in the NJR is entirely voluntary. If you agree and then change your mind, you may revoke this permission at any time by contacting the NJR Centre. If you do not agree, data about your operation will be entered but without any personal details attached. This will ensure that individual operation details are not traceable back to you. If you have any questions, concerns or need further information on the NJR or your rights under the Data Protection Act 1998, please contact the NJR Centre.

Patient Details	***Hospital Details***
Surname	*Hospital* .....
Forename	*Address* .....
Date of Birth	.....
Home address postcode	.....
New NHS Number	.....

I consent to my personal details being recorded within the NJR. I understand that the NJR will not release my personalised data unless required by law or where there is a clear overriding public interest in disclosure. However, where possible, I will be told if any disclosure is to take place.

☐ Yes ☐ No Signature ..... Date .....

To be completed by Hospital (person accepting patient consent)

Name	*Signature* .....
Position	*Date* .....

NOTE: A signed copy of this form should be kept as part of the patient record, please DO NOT send this form to the NJR Centre.

APPENDIX 5A

National Joint Registry
www.njrcentre.org.uk

NJR Helpline
0845 345 9991

Minimum Dataset Version 1 **HIP OPERATION**

IMPORTANT: You **MUST** complete all sections marked ❊. Please circle relevant numbers. All component stickers should be affixed to the accompanying 'Minimum Dataset Form - Component Labels Sheet'. Please ensure that the two sheets are stapled together. Following electronic data entry into the National Joint Registry system, the completed Minimum Dataset Form and accompanying Component Labels Sheet must be retained on the patient's records.

HAS THE PATIENT CONSENTED FOR THEIR DATA TO BE STORED? IF 'NO', DO NOT COMPLETE SECTION 1.

1 PATIENT DETAILS

FORENAME: ❊	
SURNAME: ❊	
GENDER: ❊	**1** MALE **2** FEMALE **3** NOT KNOWN **4** NOT SPECIFIED
DATE OF BIRTH: ❊	
PATIENT POSTCODE:	
PATIENT'S PREFERRED LANGUAGE:	
OTHER PATIENT PREFERRED LANGUAGE:	**1** ENGLISH **2** ARABIC **3** BENGALI **4** CANTONESE **5** CREOLE **6** DUTCH **7** FARSI **8** FINNISH **9** FLEMISH **10** FRENCH **11** GAELIC **12** GERMAN **13** GREEK **14** GUJARATI **15** HAKKA **16** HAUSA **17** HINDI **18** IBO **19** ITALIAN **20** MANDARIN **21** NORWEGIAN **22** PATOIS **23** POLISH **24** PORTUGUESE **25** PUNJABI **26** PUSHTOO **27** SOMALI **28** SPANISH **29** SWAHILI **30** SWEDISH **31** SYLHETHI **32** TAMIL **33** TURKISH **34** URDU **35** VIETNAMESE **36** WELSH **37** YORUBA **38** OTHER (PLEASE SPECIFY)
NHS NUMBER:	
PATIENT HOSPITAL ID:	

2 OPERATION DETAILS

HOSPITAL: ❊	
OPERATION DATE: ❊	
ANAESTHETIC TYPES: *YOU MAY SELECT MORE THAN ONE OPTION*	**1** GENERAL **2** REGIONAL - EPIDURAL **3** REGIONAL - NERVE BLOCK **4** REGIONAL - SPINAL (INTRATHECAL)
PATIENT PHYSICAL STATUS: ❊	**1** P1 - FIT AND HEALTHY **2** P2 - MILD DISEASE NOT INCAPACITATING **3** P3 - NCAPACITATING SYSTEMIC DISEASE **4** P4 - LIFE THREATENING DISEASE
OPERATION FUNDING:	**1** NHS FUNDING **2** INDEPENDENT FUNDING
WAS THE OPERATION PERFORMED IN A LAMINAR FLOW THEATRE?	**1** NO **2** YES

3 SURGEON DETAILS

CONSULTANT IN CHARGE: ❊	
LEAD SURGEON: ❊	
LEAD SURGEON GRADE: ❊	**1** CONSULTANT **2** ASSOCIATE SPECIALIST **3** STAFF GRADE / CLINICAL ASSISTANT **4** SPECIALIST REGISTRAR (SPR) **5** SENIOR HOUSE OFFICER (SHO) **6** HOUSE OFFICER (HO) **7** PART OF VISITING SURGICAL TEAM FROM OVERSEAS **8** OTHER (PLEASE SPECIFY):
IS THE LEAD SURGEON A LOCUM? ❊	**1** NO **2** YES
FIRST ASSISTANT GRADE: ❊	**1** CONSULTANT **2** ASSOCIATE SPECIALIST **3** STAFF GRADE / CLINICAL ASSISTANT **4** SPECIALIST REGISTRAR (SPR) **5** SENIOR HOUSE OFFICER (SHO) **6** HOUSE OFFICER (HO) **7** SURGICAL ASSISTANT **8** PART OF VISITING SURGICAL TEAM FROM OVERSEAS **9** NON-MEDICALLY QUALIFIED PRACTITIONER **10** OTHER (PLEASE SPECIFY):
IS THE FIRST ASSISTANT A LOCUM? ❊	**1** NO **2** YES

4 HIP OPERATION DETAILS

PRIMARY OR REVISION?	**1** PRIMARY **2** REVISION
PRIMARY PROCEDURE DATE: (REVISION ONLY)	
REVISION NO: (REVISION ONLY)	
PRIMARY PROCEDURE HOSPITAL: (REVISION ONLY)	
INDICATION FOR REVISION: ❊ (REVISION ONLY) *YOU MAY SELECT MORE THAN ONE OPTION*	**1** ASEPTIC LOOSENING **2** DISLOCATION / SUBLUXATION **3** IMPLANT FRACTURE - ACETABULUM **4** IMPLANT FRACTURE - FEMORAL HEAD **5** IMPLANT FRACTURE - STEM **6** INCORRECT SIZING **7** INFECTION **8** LYSIS **9** MALALIGNMENT **10** PAIN **11** PERIPROSTHETIC FRACTURE **12** WEAR POLYETHYLENE COMPONENT **13** OTHER (PLEASE SPECIFY) REVISION
INDICATIONS FOR IMPLANTATION: ❊ *YOU MAY SELECT MORE THAN ONE OPTION* *(IF REVISION, SELECT INDICATIONS FOR ORIGINAL PRIMARY PROCEDURE IF KNOWN)*	**1** OSTEOARTHRITIS **2** AVASCULAR NECROSIS **3** CONGENITAL DISLOCATION/ DYSPLASIA OF THE HIP **4** FAILED INTERNAL FIXATION **5** FRACTURED NECK OF FEMUR **6** PREVIOUS ARTHRODESIS **7** PREVIOUS HIP TRAUMA NOT SPECIFIED **8** SERONEGATIVE RHEUMATOID ARTHRITIS **9** SEROPOSITIVE RHEUMATOID ARTHRITIS **10** TRAUMA **11** OTHER (PLEASE SPECIFY)
PATIENT PROCEDURE: ❊	**1** PRIMARY TOTAL PROSTHETIC REPLACEMENT USING CEMENT **2** PRIMARY TOTAL PROSTHETIC REPLACEMENT NOT USING CEMENT **3** PRIMARY RESURFACING ARTHROPLASTY OF JOINT **4** PRIMARY TOTAL PROSTHETIC REPLACEMENT NOT ELSEWHERE CLASSIFIED (eg HYBRID)
	1 REVISION OF TOTAL PROSTHETIC REPLACEMENT USING CEMENT **2** REVISION OF TOTAL PROSTHETIC REPLACEMENT NOT USING CEMENT **3** REVISON OF RESURFACING ARTHROPLASTY OF JOINT **4** REVISION OF TOTAL PROSTHETIC REPLACEMENT NOT ELSEWHERE CLASSIFIED (eg HYBRID) REVISION
SIDE: ❊	**1** LEFT **2** RIGHT
SURGEON'S NOTES:	

5 HIP TECHNIQUE

THROMBO-PROPHYLAXIS REGIME *(OTHER THAN THE TYPE OF ANAESTHETIC INDICATED EARLIER)* *YOU MAY SELECT MORE THAN ONE OPTION*	**1** CHEM - ASPIRIN **2** CHEM - CHLOROQUINE **3** CHEM - LOW DOSE HEPARIN (LDH) **4** CHEM - LOW MOLECULAR WEIGHT HEPARIN (LMWH) **5** CHEM - PENTASACCHARIDE **6** CHEM - WARFARIN **7** CHEM - OTHER (PLEASE SPECIFY) **8** MECH - FOOT PUMP **9** MECH - INTERMITTENT CALF COMPRESSION **10** MECH - TED STOCKINGS **11** MECH - OTHER (PLEASE SPECIFY)
HAS THE DEFAULT TECHNIQUE BEEN USED?	**1** YES *(NO NEED TO FILL IN REST OF SECTION 5)* **2** NO *(PLEASE COMPLETE REST OF SECTION 5)*
FEMORAL CEMENTING TECHNIQUE	
WAS THE FEMORAL PROSTHESIS CEMENTED? ❊	**1** NO **2** YES *(IF 'YES', PLEASE ANSWER THE FOLLOWING QUESTIONS)*
WAS A GUN USED?	**1** NO **2** YES
WAS PULSATILE LAVAGE USED?	**1** NO **2** YES
WERE CEMENT PRESSURISERS USED?	**1** NO **2** YES
WHICH CEMENT MIXING SYSTEM USED?	**A** OPEN BOWL AND SPATULA **B** VACUUM MIXING
ACETABULAR CEMENTING TECHNIQUE	
WAS THE ACETABULAR PROSTHESIS CEMENTED? ❊	**1** NO **2** YES *(IF 'YES', PLEASE ANSWER THE FOLLOWING QUESTIONS)*
WAS A GUN USED?	**1** NO **2** YES
WAS PULSATILE LAVAGE USED?	**1** NO **2** YES
WERE CEMENT PRESSURISERS USED?	**1** NO **2** YES
WHICH CEMENT MIXING SYSTEM USED?	**A** OPEN BOWL AND SPATULA **B** VACUUM MIXING
WAS A FEMORAL BONEGRAFT USED? ❊	**1** NO **2** YES
WAS AN ACETABULAR BONEGRAFT USED? ❊	**1** NO **2** YES
WAS IMAGE GUIDED SURGERY USED? ❊	**1** NO **2** YES
SURGICAL APPROACH: ❊ PATIENT POSITION	**1** LATERAL **2** SUPINE
INCISION	**1** ANTERIOR **2** ANTERO-LATERAL **3** LATERAL **4** POSTERIOR
TROCHANTER	**1** WITH TROCHANTERIC OSTEOTOMY **2** WITHOUT TROCHANTERIC OSTEOTOMY
MINIMALLY INVASIVE SURGERY USED? ❊	**1** NO **2** YES

APPENDIX 5B

National Joint Registry
www.njrcentre.org.uk

NJR Helpline
0845 345 9991

Minimum Dataset Version 1 **KNEE OPERATION**

IMPORTANT: You **MUST** complete all sections marked ❊. Please circle relevant numbers. All component stickers should be affixed to the accompanying 'Minimum Dataset Form - Component Labels Sheet'. Please ensure that the two sheets are stapled together. Following electronic data entry into the National Joint Registry system, the completed Minimum Dataset Form and accompanying Component Labels Sheet must be retained on the patient's records.

HAS THE PATIENT CONSENTED FOR THEIR DATA TO BE STORED? IF 'NO', DO NOT COMPLETE SECTION 1.

1 PATIENT DETAILS

FORENAME: ❊	
SURNAME: ❊	
GENDER: ❊	**1** MALE **2** FEMALE **3** NOT KNOWN **4** NOT SPECIFIED
DATE OF BIRTH: ❊	
PATIENT POSTCODE:	
PATIENT'S PREFERRED LANGUAGE:	
OTHER PATIENT PREFERRED LANGUAGE:	**1** ENGLISH **2** ARABIC **3** BENGALI **4** CANTONESE **5** CREOLE **6** DUTCH **7** FARSI **8** FINNISH **9** FLEMISH **10** FRENCH **11** GAELIC **12** GERMAN **13** GREEK **14** GUJARATI **15** HAKKA **16** HAUSA **17** HINDI **18** IBO **19** ITALIAN **20** MANDARIN **21** NORWEGIAN **22** PATOIS **23** POLISH **24** PORTUGUESE **25** PUNJABI **26** PUSHTOO **27** SOMALI **28** SPANISH **29** SWAHILI **30** SWEDISH **31** SYLHETHI **32** TAMIL **33** TURKISH **34** URDU **35** VIETNAMESE **36** WELSH **37** YORUBA **38** OTHER (PLEASE SPECIFY)
NHS NUMBER:	
PATIENT HOSPITAL ID:	

2 OPERATION DETAILS

HOSPITAL: ❊	
OPERATION DATE: ❊	
ANAESTHETIC TYPES: *YOU MAY SELECT MORE THAN ONE OPTION*	**1** GENERAL **2** REGIONAL - EPIDURAL **3** REGIONAL - NERVE BLOCK **4** REGIONAL - SPINAL (INTRATHECAL)
PATIENT PHYSICAL STATUS: ❊	**1** P1 - FIT AND HEALTHY **2** P2 - MILD DISEASE NOT INCAPACITATING **3** P3 - NCAPACITATING SYSTEMIC DISEASE **4** P4 - LIFE THREATENING DISEASE
OPERATION FUNDING:	**1** NHS FUNDING **2** INDEPENDENT FUNDING
WAS THE OPERATION PERFORMED IN A LAMINAR FLOW THEATRE?	**1** NO **2** YES

3 SURGEON DETAILS

CONSULTANT IN CHARGE: ❊	
LEAD SURGEON: ❊	
LEAD SURGEON GRADE: ❊	**1** CONSULTANT **2** ASSOCIATE SPECIALIST **3** STAFF GRADE / CLINICAL ASSISTANT **4** SPECIALIST REGISTRAR (SPR) **5** SENIOR HOUSE OFFICER (SHO) **6** HOUSE OFFICER (HO) **7** PART OF VISITING SURGICAL TEAM FROM OVERSEAS **8** OTHER (PLEASE SPECIFY):
IS THE LEAD SURGEON A LOCUM? ❊	**1** NO **2** YES
FIRST ASSISTANT GRADE: ❊	**1** CONSULTANT **2** ASSOCIATE SPECIALIST **3** STAFF GRADE / CLINICAL ASSISTANT **4** SPECIALIST REGISTRAR (SPR) **5** SENIOR HOUSE OFFICER (SHO) **6** HOUSE OFFICER (HO) **7** SURGICAL ASSISTANT **8** PART OF VISITING SURGICAL TEAM FROM OVERSEAS **9** NON-MEDICALLY QUALIFIED PRACTITIONER **10** OTHER (PLEASE SPECIFY):
IS THE FIRST ASSISTANT A LOCUM? ❊	**1** NO **2** YES

4 KNEE OPERATION DETAILS

PRIMARY OR REVISION?	**1** PRIMARY **2** REVISION
PRIMARY PROCEDURE DATE: (REVISION ONLY)	
REVISION NO: (REVISION ONLY)	
PRIMARY PROCEDURE HOSPITAL: (REVISION ONLY)	
INDICATION FOR REVISION: ❊ (REVISION ONLY) *YOU MAY SELECT MORE THAN ONE OPTION*	**1** ASEPTIC LOOSENING **2** DISLOCATION / SUBLUXATION **3** IMPLANT FRACTURE - FEMORAL **4** IMPLANT FRACTURE - PATELLA **5** IMPLANT FRACTURE - TIBIAL **6** INCORRECT SIZING **7** INFECTION **8** INSTABILITY **9** LYSIS **10** MALALIGNMENT **11** PAIN **12** PATELLA MALTRACKING **13** PERIPROSTHETIC FRACTURE **14** WEAR OF PATELLA **15** WEAR OF POLYETHYLENE COMPONENT **16** WEAR OF TIBIA **17** OTHER (PLEASE SPECIFY) REVISION
INDICATIONS FOR IMPLANTATION: ❊ *YOU MAY SELECT MORE THAN ONE OPTION* *(IF REVISION, SELECT INDICATIONS FOR ORIGINAL PROCEDURE IF KNOWN)*	**1** OSTEOARTHRITIS **2** AVASCULAR NECROSIS **3** FAILED INTERNAL FIXATION **4** PREVIOUS ARTHRODESIS **5** PREVIOUS KNEE TRAUMA NOT SPECIFIED **6** SERONEGATIVE RHEUMATOID ARTHRITIS **7** SEROPOSITIVE RHEUMATOID ARTHRITIS **8** TRAUMA **9** OTHER (PLEASE SPECIFY)
PATIENT PROCEDURE: ❊	**1** PRIMARY TOTAL PROSTHETIC REPLACEMENT USING CEMENT **2** PRIMARY TOTAL PROSTHETIC REPLACEMENT NOT USING CEMENT **3** UNICONDYLAR KNEE REPLACEMENT **4** PATELLO-FEMORAL REPLACEMENT **5** PRIMARY TOTAL PROSTHETIC REPLACEMENT NOT ELSEWHERE CLASSIFIED
	1 REVISION OF TOTAL PROSTHETIC REPLACEMENT USING CEMENT **2** REVISION OF TOTAL PROSTHETIC REPLACEMENT NOT USING CEMENT **3** REVISION OF TOTAL PROSTHETIC REPLACEMENT NOT ELSEWHERE CLASSIFIED REVISION
SIDE: ❊	**1** LEFT **2** RIGHT
SURGEON'S NOTES:	

5 KNEE TECHNIQUE SCREEN

THROMBO-PROPHYLAXIS REGIME *(OTHER THAN THE TYPE OF ANAESTHETIC INDICATED EARLIER)* *YOU MAY SELECT MORE THAN ONE OPTION*	**1** CHEM - ASPIRIN **2** CHEM - CHLOROQUINE **3** CHEM - LOW DOSE HEPARIN (LDH) **4** CHEM - LOW MOLECULAR WEIGHT HEPARIN (LMWH) **5** CHEM - PENTASACCHARIDE **6** CHEM - WARFARIN **7** CHEM - OTHER (PLEASE SPECIFY) **8** MECH - FOOT PUMP **9** MECH - INTERMITTENT CALF COMPRESSION **10** MECH - TED STOCKINGS **11** MECH - OTHER (PLEASE SPECIFY)
HAS THE DEFAULT TECHNIQUE BEEN USED?	**1** YES *(NO NEED TO FILL IN REST OF SECTION 5)* **2** NO *(PLEASE COMPLETE REST OF SECTION 5)*
KNEE TO SKIN INCISION: ❊	**1** MIDLINE **2** MEDIAL **3** LATERAL
SURGICAL APPROACH: ❊	**1** LATERAL PARAPATELLAR **2** MEDIAL PARAPATELLAR **3** SUB-VASTUS **4** OTHER (PLEASE SPECIFY)
MINIMALLY INVASIVE SURGERY USED? ❊	**1** NO **2** YES
IMAGE GUIDED SURGERY USED? ❊	**1** NO **2** YES
TOURNIQUET USED? ❊	**1** NO **2** YES
HAS THE FAT PAD BEEN REMOVED? ❊	**1** NO **2** YES - FULLY **3** YES - PARTIALLY
CEMENT USED? ❊	**1** NO **2** YES

National Joint Registry
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Minimum Dataset Form -
COMPONENT LABELS SHEET

Please affix any component labels to this sheet. Please ensure that the component labels sheet is attached to the main Minimum Dataset Form (either Hip Operation or Knee Operation).

APPENDIX 5C

Operations to be included in/excluded from the NJR database

Note: Reference list for use with Minimum Dataset version 1 (MDS v1)

HIPS	Operations to include in the NJR
Primary	Total joint replacement - i.e. replacement of the femoral head with a stemmed femoral prosthesis and the insertion of an acetabular cup With cement/Without cement
Primary	Hip resurfacing - Resurfacing of the femoral head with surface replacement femoral prosthesis and insertion of an acetabular cup
Revision	Revision of total joint replacement With cement/Without cement
Revision	Revision of hip resurfacing

HIPS	Operations to exclude from the NJR
	Hemiarthroplasty - i.e. replacement of only the femoral head following fracture of the femoral neck

KNEES	Operations to include in the NJR
Primary	Total knee arthroplasty - i.e. replacement of both tibial condyles and both femoral condyles with or without resurfacing of the patella With cement/Without cement
Primary	Unicondylar arthroplasty - i.e. replacement of one tibial condyl and one femoral condyl, with or without resurfacing of the patella
Primary	Patello-femoral replacement - i.e. where the femoral condyles are replaced and the patella is resurfaced
Revision	Revision of total knee arthroplasty With cement/Without cement
Revision	Revision of unicondylar arthroplasty
Revision	Revision of patello-femoral replacement

Note: 'Re-operations excluding revisions' - e.g. for dislocation, infection - are not specifically captured in MDS v1.

APPENDIX 6

A6 Security and confidentiality of data

This section outlines how the NJR Centre handles data to ensure that its security and confidentiality are maintained.

A6.1 Confidentiality of personal data

The collection, handling and use of personal data are treated as confidential at all times.

All electronic data are stored securely to guard against unauthorised access, disclosure, accidental loss or destruction or damage to personal data. This is a direct requirement of the Data Protection Act 1998.

No information that would lead to the identification of an individual patient, clinician or hospital staff member will be included in any NJR publication, without the prior agreement in writing of the individual concerned.

A6.2 Collection, transfer and storage of data

The NJR uses an electronic system for collection, transfer and storage of data.

The benefits of an electronic system:

- Improves security - by avoiding distribution of hard copy records through the post. Data are encrypted and transmitted over a secure Internet connection
- Reduces administration - electronic data facilitate the analysis of large datasets
- Provides online data validation - some data validation can begin at the time of data submission, which helps prevent invalid data being supplied from the outset, e.g. the selection of certain implant components for a particular procedure
- Provides confirmation of data submission - the person entering data receives an online message when data have been submitted successfully

The data fields (the NJR Minimum Dataset) are entered at source by each orthopaedic unit/hospital. Data from operations can be entered directly into the NJR database. Where this is not feasible, NJR paper proformas should be used but data must subsequently be submitted electronically.

A6.3 Recording patient consent

The NJR provides a form for collecting patient consent, so that it is compliant with the Data Protection Act 1998.

For a patient's personal details to be submitted to the NJR, their informed consent must first be obtained on an NJR consent form, which can be downloaded from the NJR website.

It is the responsibility of hospitals to define a procedure to ensure the process of seeking informed consent is incorporated into the patient pathway, e.g. a hospital may choose to collect patient consent at a patient's pre-operative assessment.

The NJR data entry system prompts the person entering data to confirm whether or not patient consent has been given. It is important, therefore, that the person entering data is informed whether or not patient consent has been given. If consent has been given, the data entry person will be directed to the 'Patient Details' input screen. If consent has not been given, the 'Patient Details' input screen is bypassed, and only the details of the operation are recorded. This means that only anonymised operation and implant data are collected when consent has been withheld (which is in accordance with the Data Protection Act 1998).

As part of future NJR audit, random checks will be undertaken to see that patient consent is being obtained for those records where patient personal details have been submitted. NJR data audits will be arranged with participating hospitals.

A6.4 Encryption of patient data

Patient details are encrypted once they are submitted to the NJR database, i.e. they are not stored in the database in an identifiable format.

They can only be decrypted via the use of an online encryption key.

A6.4.1 Decryption of patient personal details

'Decrypted data' means that patient personal details are restored to an identifiable format and linked directly with their operation details. This would take place only in the special circumstances that are outlined below, and requires prior agreement of the NJR Steering Committee.

Once decrypted data had served their purpose, they would be destroyed to preserve data confidentiality in accordance with NHS Information Authority guidelines.

(a) Urgent clinical review

The NJR Centre would respond to a formal request from the Medicines and Healthcare products Regulatory Agency (MHRA) where, for example, there is a need to recall a specific implant component. The NJR database would be used to search for, and identify, which patients had received the specific implant component. The data for identified patients in this circumstance would be made available - via the MHRA - to the NHS to facilitate traceability and patient recall.

(b) Patient Feedback Questionnaires

Patient data will also be decrypted to allow distribution of Patient Feedback Questionnaires. The detail of this mechanism has yet to be finalised - the Patient Feedback process is currently under development in conjunction with the NJR Steering Committee and a specially formed Patient Feedback Advisory Group, and will be subject to appropriate approvals. The NJR patient consent form notifies the patient that they may be sent a Patient Feedback Questionnaire in the future.

(c) NHS Strategic Tracing Service (NSTS)

As part of the management of the NJR database, regular checks need to take place to determine when patients recorded on the NJR have died. It is important to know when a patient has died so that their data can be correctly accounted for in component survivability calculations (since the length of time the components would have lasted before needing revision cannot be determined). It is also important to ensure that a deceased individual's family is not contacted, either in the case of patient recall in an urgent clinical review, or during the patient feedback process (i.e. sent a questionnaire).

Decrypted NJR patient data are submitted to the NSTS to cross-check the patient NHS number they hold and the NHS number recorded on the NJR database. Patient personal data need to be decrypted for the data to be matched.

The NSTS is also used to source missing NHS numbers where other personal identifiers are known.

(d) Data analysis

Patient data will need to be decrypted for some statistical analyses that will form the basis of NJR reports, e.g. to deduce the average age of implant recipients. However, only anonymised data would be published.

A6.5 Access to data

Individual data and data reports will be made accessible according to user type, as discussed below.

A6.5.1 Patients

In accordance with the Data Protection Act 1998, a patient can request a copy of their personal data held on the NJR database. Requests must be made in writing to the NJR Centre. The NJR Centre will make a patient's record available in paper form, subject to being satisfied that the person making the request is the relevant individual.

A6.5.2 Data entry system users

The NJR data entry system allows specific user types to access certain data online. Data reports are made available as CSV (comma separated values) files, which allow users to carry out

bespoke data analyses themselves, thereby providing maximum flexibility for data reports.

Patient personal details cannot be recalled by any user type - these details are encrypted on submission to the NJR. This means that all data recalled online by authorised users are anonymised.

The NJR does, however, provide a data field for recording a hospital patient ID number. Surgeons can identify their own patients on the NJR providing the hospital ID number has been entered.

A6.5.3 User categories

There are four NJR user categories that have a specified level of data access.

(a) NJR Hospital Data Entry (HDE)

This user type can enter data on the system but does not have access to any data reports.

(b) NJR Hospital Data Manager (HDM)

This user type has access to all NJR data for the hospital under which they have registered. However, the NJR HDM can only view data for the surgeons that have given their prior permission. (This permission can only be given online within the data entry system via the individual surgeon's user account.)

(c) Surgeon

A lead surgeon has access to their own data only.

A surgeon has access to all the data for which they have been recorded as the consultant-in-charge; this includes the lead surgeon's data.

A surgeon is able to access all their own data recorded for the operations they have performed in hospitals for which they are registered on the NJR.

(d) Implant supplier

Implant suppliers only have access to their own component data. The NJR data entry system allows individual suppliers to download their component list, i.e. NJR categorisation code, descriptor and supplier catalogue (reference) number, for checking purposes.

A6.5.4 User verification

The NJR Centre verifies the identity of each new NJR user as they register to use the data entry system. The NJR Centre must receive written authority from the hospital for HDE and HDM user accounts.

Written hospital authorisation must be:

- Written on headed hospital paper
- Signed by an accountable person, e.g. a unit manager, Clinical Director, lead surgeon etc
- Sent to the NJR Centre by post or by facsimile

Surgeons can verify and activate their account over the telephone if they provide their GMC number at the same time. If this is not possible, the person who registers the surgeon on their behalf will need to provide a letter of verification signed by the surgeon. Surgeons cannot register for a user account without a GMC code.

A6.5.5 NJR user accounts

At the time of registration a user will be issued with unique ID data, including:

- User name
- Memorable data
- Password

A user can specify their own password and memorable data (which is essentially a second password). Alternatively, the NJR Centre provides unique ID details on request.

A format for passwords and 'memorable data' has been devised to maintain NJR security. A password and memorable data must:

- Be between 8 and 16 characters
- Contain a mixture of upper and lower case letters (at least one of each)
- Contain at least one numeric
- Not contain spaces

The NJR Centre sets a default expiry period of 30 days for all new user passwords and 'memorable data'. The NJR data entry system allows users to change their passwords and 'memorable data' at any time. If a user forgets their password and/or 'memorable data' they have to contact the NJR Helpline. To maintain security, the NJR Centre does not keep a copy of user passwords or memorable data, therefore the NJR Helpline resets all forgotten passwords after the caller's identity has been verified. The NJR data entry system allows users to increase the password expiry period up to 90 days.

A6.5.6 Research applicants

Anonymised data may be made available for research purposes, with the data aggregated in such a way that it is not possible to identify an individual surgeon or patient. An NJR Research Sub Committee has been formed that will act as an advisory group to the NJR Steering Committee. The detailed mechanism for granting permission for using the NJR to collect data for research purposes has yet to be agreed.

A6.6 NJR IT system

The NJR data entry system is the user interface that allows data to be submitted to the central NJR database. Hospitals link to the NJR data entry system via a connection enabled by the Internet.

A6.6.1 System specifications for data transfer

The IT system conforms to all relevant Government standards.

The NJR data entry system is an application that works with standard web browsers and technology (it is built based on the Microsoft .NET platform using ASP.NET web forms). The data entry system communicates with a central web service that validates the data before they are passed to the central NJR database. The central NJR database has been built using Microsoft SQL Server 2000.

Data are securely transferred to the database from the data entry system using the industry standard 128-bit SSL protocol. Once data have been registered on the database, strong patient identifiers are encrypted using asymmetric key pair encryption. Encryption keys are generated by the RSA 1024 bit asymmetric algorithm. Unencrypted data can only be viewed off-line and are controlled by the NJR Centre.

The data are transmitted using the secure sockets layer (SSL) protocol.

Summary of SSL protocol used for NJR data transmission

- SSL is a widely used and accepted method of securely transmitting data over the Internet
- The NJR server presents a security certificate to the user - confirming the server's identity. The user connection automatically confirms independently that this certificate is valid. (Periodically the security certificate is updated, and the user must load the certificate locally onto their PC for the update to be automatically recognised)
- The data entry user and NJR server agree encryption keys to use to exchange data during the data transmission session
- The sending server automatically encrypts all data it sends and the receiving server automatically decrypts them using the agreed data transmission session keys
- SSL performs checks to identify if the data have been tampered with during transmission

A6.6.2 Accessing the data entry system

All users are required to login to the data entry system. The login process authenticates the user by ensuring that their username, password and 'memorable data' match the stored values on the central NJR database.

Passwords and 'memorable data' can be modified using an online facility. In practice, the user's server establishes a secure SSL connection with the central NJR database server and transmits the username, password and 'memorable data'. The central NJR database server validates these against its stored information. Users are allowed to access the system if their details are validated but access is denied if they do not match. The username, password and 'memorable data' cannot be intercepted on the Internet without decrypting the secure SSL communication between the servers.

A6.6.3 Networking and IT interfacing

Interfaces are web-based and secure communication is via the SSL port 443. A secure and robust hosting solution that is suitable for handling patient sensitive data is in place. The hosting solution is managed by a specialist Internet security organisation. It caters for the physical and virtual security of the central NJR database.

The central NJR database and associated web servers are physically located at a secure data centre. This provides full industry standard facilities such as dual power supply, dual Internet connections and a controlled environment. The virtual security is ensured by a series of firewalls and intruder detectors similar to those used by online banks to secure their customers' data.

A6.7 **NJR contact database**

The NJR contact database is used to store the contact details of individuals (primarily hospital staff and NJR data entry system users) who have been in communication with the NJR Centre. This database is secure and is used to facilitate communications between the NJR and the individuals concerned. This information is not shared with any third parties.

APPENDIX 7

GLOSSARY

A	
ABHI	Association of British Health-Care Industries, the representative trade body for the UK medical device industry
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 (hip)	See *Acetabular component*
Acetabular prosthesis	See *Acetabular component*
Arthroplasty	A procedure where a natural joint, or part of a natural joint, is replaced by an artificial prosthesis

B	
Bar code reader facility	To be introduced to allow electronic scanning of orthopaedic component labels and reduce the time required for entry of component data into the NJR database
BASK	British Association for Surgery of the Knee, a specialist society of the British Orthopaedic Association
BHS	British Hip Society, a specialist society of the British Orthopaedic Association
Bilateral operation	Operation performed on both sides, e.g. left and right knee procedures carried out during a single operation
BOA	British Orthopaedic Association
Brand	The brand of a prosthesis (or implant) is the manufacturer's product name, e.g. the Charnley brand for hips, the Rotaglide Plus brand for knees
Bulk data upload	A facility to be introduced that will allow hospitals to collect the NJR dataset within their own internal systems and upload data at regular intervals to the NJR database

C	
Cement gun	A pressurised container used to insert bone cement into bony cavities
Cement pressuriser	A device used to aid the surgeon in optimising the strength of adhesion between bone cement and bone
CHAI	Commission for Healthcare Audit and Inspection, commonly known as the Healthcare Commission
Completed operations	A completed operation is one where the details on the data record are complete and have been submitted, as compared to a record left in edit mode (see *Edit mode*)
Condyl	The two areas on the surface of the femur and tibia within the knee that articulate with each other
CSV files	Comma separated values files that, for the NJR, put each data item for an operation on one line, separated by commas. The data file can be imported into a standard package for further formatting and interrogation
Cup	See *Acetabular component*

D	
Default techniques	The surgical techniques used most often by an individual surgeon when performing joint replacement

E

EAR	European Arthroplasty Register
Edit mode	An incomplete set of data relating to an operation that is stored in a holding file (in the edit stack) within the NJR system, awaiting completion
Elective surgery	Surgical procedures which are planned and booked in advance and that do not occur as a result of unexpected events, such as a road traffic accident

F

Femoral component (hip)	The part of a total hip joint that is inserted into the femur (thigh bone) of the patient. It normally consists of a stem and a head (ball)
Femoral component (knee)	The portion of a knee prosthesis that is used to replace the articulating surface of the femur (thigh bone)
Femoral head	The ball-shaped portion of the femur that forms part of the ball and socket hip joint
Femoral prosthesis	The portion of a total joint replacement used to replace damaged parts of the femur (thigh bone)
Femoral stem	See *Femoral component (hip)*
Finger packing (of cement)	The technique of manually inserting bone cement into bony cavities immediately prior to the insertion of a prosthesis

H

HDE	Hospital Data Entry, a user registered with the NJR who has been appointed by a hospital to enter its data
HDM	Hospital Data Manager, a user registered with the NJR who has been appointed by a hospital to have access rights to download hospital data via the NJR system (where surgeons have given their prior consent to their data being accessed)
Head	See *Femoral head*
Hemiarthroplasty	Replacement of only one articulating surface within a damaged joint. Such procedures are not included within the NJR database
HES	The Hospital Episode Statistics (HES) system is a database containing details of all patients admitted to NHS hospitals in England. HES covers all medical specialities and includes private patients treated in NHS hospitals. The NJR uses certain HES data for comparison purposes, e.g. the annual totals of different types of procedure performed by each NHS unit in England
Hybrid procedure	A hip procedure where the femoral prosthesis is cemented and the acetabular prosthesis is not cemented. A reverse hybrid is where the acetabular prosthesis is cemented and the femoral prosthesis is not cemented. A knee procedure where either the femoral or tibial side of the joint receives a cemented prosthetic component and the other receives a cementless component

I

IHF	Independent Healthcare Forum (previously the Independent Healthcare Association). This organisation represents independent healthcare providers
Image-guided surgery	Surgery performed by the surgeon, using real time images (normally X-rays) to help with alignment and positioning of prosthetic components
Indication (for surgery)	Reason for surgery. The NJR system allows more than one indication to be recorded

L

Laminar flow (in theatres)	A system which ensures a continuous flow of 'clean' air around the patient during surgical procedures
Lead surgeon	Surgeon that directs and performs an operation, assisted by others. The lead surgeon may or may not also be the consultant in charge, i.e. the person who is ultimately responsible for the patient
Levy	Additional payment (currently £25.00 including VAT) placed on the sales of specific hip and knee implants to cover the costs associated with on-going operations and development of the NJR
Levyable implants	The purchase of a one-piece (monobloc) acetabular cup or a modular acetabular cup shell component attracts an NJR levy payment for a total hip prosthesis. The purchase of any knee femoral component (including the femoral component of a unicompartmental knee or patello-femoral joint prosthesis) or one-piece knee prosthesis attracts an NJR levy payment for a knee prosthesis
LMWH	Low molecular weight heparin

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 patient personal details must only be completed where informed patient consent has been obtained
MDS v1	Minimum Dataset version 1, that was used to collect data from 1 April 2003
MDS v2	Minimum Dataset version 2, that was introduced on 1 April 2004. MDS v2 replaced MDS v1 as the official NJR dataset on 1 June 2004
Menisci (mobile and fixed bearing types)	A mobile bearing knee is a design of knee prosthesis that has a tibial component combining a metal baseplate and a polyethylene articulating surface that allows relative movement between the two surfaces A fixed bearing knee is as described above but designed with a polyethylene articulating surface fixed to a metal baseplate that does not allow for any movement between the two surfaces
MHRA	Medicines and Healthcare products Regulatory Agency
Minimally invasive surgery	Surgery performed using special instruments that allow very small incisions to be made in the tissues of the patient
Mixing and matching	Also known as 'cross-breeding'. Hip replacement procedure where a surgeon chooses to implant a femoral component (incorporating a metallic or ceramic modular head) from one manufacturer with an acetabular component (incorporating a polyethylene bearing surface) from another
Modular	A component composed of more than one piece, e.g. a modular acetabular cup shell component
Monobloc	One piece, e.g. a monobloc femoral stem

N

NAO	National Audit Office
NICE	National Institute for Clinical Excellence
NICE 10-year benchmark	Any hip system that has shown a failure rate of 10% or less at 10 years using criteria established by the ODEP group (see opposite) meets the NICE 10-year benchmark
NJR	National Joint Registry for England and Wales. Since 1 April 2003, the NJR has collected and analysed data on hip and knee replacements. It covers both the NHS and independent healthcare sector to ensure complete recording of national activity in England and Wales
NJR Centre	National co-ordinating centre for the NJR, based at Harwell, southern Oxfordshire
NJR contact database	Used to store the contact details of individuals who have been in communication with the NJR Centre
NJR cube	Displays individual hospital submission histories (to the RAC team) and allows easy tracking of any emerging trends
NSTS	NHS Strategic Tracing Service. Used to source missing NHS numbers and also to determine when patients recorded on the NJR have died

O

ODEP	Orthopaedic Data Evaluation Panel of the NHS Purchasing and Supply Agency

P

PASA	NHS Purchasing and Supply Agency
Patella resurfacing	Replacement of the surface of the patella (kneecap) with a prosthesis
Patello-femoral knee replacement	Procedure involving replacement of the femoral condyles and resurfacing of the patella
Patello-femoral prosthesis (knee)	A two-piece knee prosthesis that provides a prosthetic articulation surface between the patella and femoral condyles
Patient consent	Patient personal details may only be submitted to the NJR where explicit informed patient consent has been given. If a patient does not give consent, only the anonymous operation and implant data may be submitted
Patient consent form	Whether a patient gives or withholds their consent should be recorded on an NJR patient consent form, signed and dated by the patient
Patient feedback questionnaire	A tool that will be used to capture patient satisfaction and health-related quality of life information
Patient hospital ID	The reference number a hospital assigns to a patient to identify them within their hospital system
Patient physical status	Describes the overall condition of the patient using the American Society of Anaesthesiology (ASA) scoring system grades of 'fit and healthy', 'mild disease, not incapacitating', 'incapacitating systemic disease', and 'life-threatening disease'
Patient procedure	Type of procedure carried out on a patient, e.g. primary total prosthetic replacement using cement
PEDW	Patient Episode Database, Wales, the Welsh equivalent of Hospital Episode Statistics in England *(see HES)*
PFAG	Patient Feedback Advisory Group, a subcommittee of the NJR Steering Committee formed to determine: the key aims of the process for obtaining future feedback from NJR patients; the sample size of patients required to meet these aims; the contents of the NJR Patient Feedback Questionnaire
PKI	Consideration is being given to implementing a Public Key Interface (PKI) security system to allow the NJR to be used by surgeons as an online tool and resource library
Primary hip/knee replacement	The first total joint replacement performed on any individual patient
Proforma	Data has to be submitted electronically to the NJR database. Where hospitals wish, they can capture data on paper proformas at the time of operation and submit electronically at a convenient time
Prosthesis	Orthopaedic implant used in joint replacement procedures, e.g. a total hip or a unicondylar knee
Pulsatile lavage	A pulsed jet of sterile water used to clean the bony surfaces prior to the implantation of a total joint replacement

R

RAC	Regional Audit Co-ordinator. RACs provide field-based links between hospitals and the NJR Centre. They work closely with the RCCs and the NJR Centre to identify and resolve issues, disseminate information to individual hospitals, and identify and facilitate sharing of good practice
RCC	Regional Clinical Co-ordinator. RCCs are practising orthopaedic surgeons who act at a strategic level within trusts and hospitals, facilitating feedback to surgeons and their teams and so enabling them to submit NJR data and optimise their clinical practice
RCS	Royal College of Surgeons
Resurfacing arthroplasty	See *Resurfacing (hip)*
Resurfacing (hip)	Resurfacing of the femoral head with a surface replacement femoral prosthesis and insertion of an acetabular cup, with or without cement
Re-operation other than revision	Procedure following a primary replacement that does not require component removal or replacement
Reverse hybrid procedure (hip)	A hip procedure where the acetabular prosthesis is cemented and the femoral prosthesis is not cemented
Revision hip/knee replacement	An operation performed to remove and replace one or more components of a total joint prosthesis, for whatever reason

S

SHA	Strategic Health Authority
Stem	See *Femoral component (hip)*
Surgical approach	The surgical technique used by a surgeon to expose the bone prior to joint replacement whilst minimising the damage to surrounding tissues

T

TED stockings	Pressurised stockings worn by patients following surgery. These help to prevent blood clots forming in the blood vessels of the legs
THR	Total hip replacement (total hip arthroplasty). Replacement of the femoral head with a stemmed femoral prosthesis and the insertion of an acetabular cup, with or without cement
Thrombo-prophylaxis	A drug or other post-operative regime prescribed to patients with the aim of preventing blood clot formation in the post-operative period
TKR	Total knee replacement (total knee arthroplasty). Replacement of both tibial condyles and both femoral condyles, with or without resurfacing of the patella, and with or without cement
Total condylar knee	A type of knee prosthesis that replaces the complete contact area between the femur and tibia of a patient
Trochanter	A bony protuberance of the femur found just below the femoral head
Trochanteric osteotomy	The temporary incision of the trochanter, used to aid exposure of the hip joint during some types of total hip replacement
Type	The type of a prosthesis is the generic description of a prosthesis, e.g modular cemented stem (hip), patello-femoral joint (knee)

U

Unicompartmental knee	Also known as unicondylar knee. Normally used to define the type of prosthesis used in unicondylar arthroplasty
Unicondylar arthroplasty	Replacement of one tibial condyl and one femoral condyl, with or without resurfacing of the patella
Unicondylar knee replacement	See *Unicondylar arthroplasty*
Unilateral operation	Operation performed on one side only, e.g. on left hip

APPENDIX 8

National Joint Registry
www.njrcentre.org.uk

National Joint Registry for England and Wales

1st Annual Report | September 2004

FEEDBACK FORM

The authors and Editorial Board are keen to know whether the 1st Annual Report has met its objectives. Readers are invited to complete this feedback form and return it to the NJR Centre via fax or post. **Alternatively, the form can be accessed on the NJR Annual Report pages of the NJR website (at www.njrcentre.org.uk) for completion and submission online.**

We want to hear your views on the content and format of the current report, and also what you would like to see in future reports. Feedback received by the end of December 2004 will help to inform the planning process for the 2nd Annual Report.

Name (optional)

Reader type (e.g. patient, surgeon, data entry clerk, Trust Chief Executive, implant supplier)

Q1. **What were your main reasons for reading the report?**

Q2. **Which sections of the report were of most interest to you, and why?**

Q3. **Which sections of the report were of less interest to you, and why?**

Please turn over

Q4. **What would you like to see included in the 2nd Annual Report, if possible?**

Q5. **As the NJR database builds up in future years, what types of questions would you like to see addressed, and why?**

Please use the space below for any further comments.

Thank you for taking the time to provide us with your valuable feedback.

Your completed form should be either:

Faxed to:
0845 345 9992 or

Posted to:
Fiona Davies
The NJR Centre
Building 329, Harwell
Didcot
Oxfordshire OX11 0QJ
England

Do you have any questions?

If you have **any questions** relating to this 1st Annual Report, please call the NJR Helpline (Tel: 0845 345 9991) or email enquiries@njrcentre.org.uk

APPENDIX 9A

Data Items

Data item	Hip		Knee	
	No. (%) missing	Total	No. (%) missing	Total
Identifiers				
Gender	2 (0)	15,789[1]	2 (0)	13,597[2]
Patient Postcode	3,632 (23.0)	15,789	2,949 (21.7)	13,597
NHS number	5,586 (35.4)	15,789	4,693 (34.5)	13,597
Date of birth	14 (0.1)	15,789	11 (0.1)	13,597
Forename	0	15,789	0	13,597
Surname	0	15,789	0	13,597
Operation date	0	24,997[3]	0	21,801[4]
Compulsory data items				
Revision	0	24,997	0	21,801
Patient physical status	0	24,997	0	21,801
Lead surgeon grade (and other)	0	24,997	0	21,801
Lead surgeon is locum	0	24,997	0	21,801
First assistant grade (and other)	0	24,997	0	21,801
First assistant is locum	0	24,997	0	21,801
Indication(s) for implantation (primary only)	0	22,672[5]	0	20,854[6]
Indication(s) for revision (revision only)	0	2,325[7]	0	947[8]
Patient procedure	0	24,997	0	21,801
Side	0	24,997	0	21,801
Minimally invasive surgery used	0	24,997	0	21,801
Image guided surgery used	0	24,997	0	21,801
Tourniquet used (knee only)			0	21,801
Fat pad removed (knee only)			0	21,801
Cement used (knee only)			0	21,801
Surgical approach (knee only)			0	21,801
Patient position (hip only)	0	24,997		
Trochanter (hip only)	0	24,997		
Cement used acetabular (hip only)	0	24,997		
Cement used femoral (hip only)	0	24,997		
Femoral bone graft (hip only)	0	24,997		
Acetabular bone graft (hip only)	0	24,997		
Incision	0	24,997	0	21,801
Hospital/Trust/Nationality	1 (0)	24,878[9]	1 (0)	21,619[10]
Prosthesis cat. Number	75 (0.3)	24,997	50 (0.2)	21,801
Implant batch number	291 (1.2)	24,997	323 (1.5)	21,801
Component manufacturer, implant category, component category and details	69 (0.3)	24,997	42 (0.2)	21,801

Missing component information usually relates to revision procedures where not all components have required replacement.

1 There were 15,789 consenting hip patients

2 There were 13,597 consenting knee patients

3 There were 24,997 hip replacement procedures entered into the NJR

4 There were 21,801 knee replacement procedures entered into the NJR

5 There were 22,672 primary hip replacement procedures entered into the NJR

6 There were 20,854 primary knee replacement procedures entered into the NJR

7 There were 2,325 hip revision procedures entered into the NJR

8 There were 947 knee revision procedures entered into the NJR

9 There were 24,878 hip patients in total (bilateral patients count as 1 patient, and two procedures)

10 There were 21,619 knee patients in total (bilateral patients count as 1 patient, and two procedures)

APPENDIX 9A (continued)

Data Items

Data item	Hip		Knee	
	No. (%) missing	Total	No. (%) missing	Total
Other data items				
Procedure number	0	24,997	0	21,801
Funding	1,342 (5.4)	24,997	1,228 (5.6)	21,801
Clean air theatre	350 (1.4)	24,997	394 (1.8)	21,801
Primary procedure date (revision only)	1,159 (49.8)	2,325	422 (44.6)	947
Gun used acetabular (hip, where cement was used)	0	15,194[11]		
Cement pressuriser acetabular (hip, where cement was used)	0	15,194		
Pulsatile lavage acetabular (hip, where cement was used)	0	15,194		
Cement mix technique acetabular (hip, where cement was used)	0	15,194		
Gun used femoral (hip, where cement was used)	0	19,759[12]		
Cement pressuriser femoral (hip, where cement was used)	0	19,759		
Pulsatile lavage femoral (hip, where cement was used)	0	19,759		
Cement mix technique femoral (hip, where cement was used)	0	19,759		
Patient hospital ID	1,523 (9.6)	15,789	1,457 (10.7)	13,597
Patient preferred language	0	15,789	0	13,597
Thrombo-prophylaxis information	2,171 (8.7)	24,997	2,094 (9.6)	21,801
Anaesthetic information	452 (1.8)	24,997	429 (2.0)	21,801

[11] There were 15,194 hip replacement procedures where cement was used for the acetabular prosthesis

[12] There were 19,759 hip replacement procedures where cement was used for the femoral prosthesis

APPENDIX 9B

Characteristics of surgical practice in primary hip procedures, according to patient procedure

	Patient procedure				
	Total replacement using cement	Total replacement not using cement	Total replacement not classified (e.g. hybrid[13])	Resurfacing arthroplasty	Total
Laminar flow theatre					
Yes	13,302 (93.2)	3,279 (91.3)	2,330 (94.5)	2,227 (95.2)	**21,138 (93.2)**
No	757 (5.3)	272 (7.6)	103 (4.2)	84 (3.6)	**1,216 (5.4)**
Unknown	221 (1.5)	39 (1.1)	31 (1.3)	27 (1.2)	**318 (1.4)**
Anaesthetic used					
General	2,298 (16.1)	548 (15.3)	635 (25.8)	306 (13.1)	**3,787 (16.7)**
Epidural	4,093 (28.7)	1,277 (35.6)	656 (26.6)	964 (41.2)	**6,990 (30.8)**
Nerve block	1,152 (8.1)	399 (11.1)	162 (6.6)	196 (8.4)	**1,909 (8.4)**
Spinal	6,461 (45.2)	1,299 (36.2)	971 (39.4)	845 (36.1)	**9,576 (42.2)**
Unknown	276 (1.9)	67 (1.8)	40 (1.6)	27 (1.2)	**410 (1.9)**
Patient position					
Lateral	10,719 (75.1)	2,970 (82.7)	2,234 (90.7)	2,256 (96.5)	**18,179 (80.2)**
Supine	3,561 (24.9)	620 (17.3)	230 (9.3)	82 (3.5)	**4,493 (19.8)**
Incision					
Anterior/Antero-lateral/ Lateral	10,238 (71.7)	2,418 (67.4)	1,473 (59.8)	557 (23.8)	**14,686 (64.8)**
Posterior	4,042 (28.3)	1,172 (32.6)	991 (40.2)	1,781 (76.2)	**7,986 (35.2)**
Trochanteric osteotomy					
With trochanteric osteotomy	1,056 (7.4)	106 (3.0)	70 (2.8)	115 (4.9)	**1,347 (5.9)**
Without trochanteric osteotomy	13,224 (92.6)	3,484 (97.0)	2,394 (97.2)	2,223 (95.1)	**21,325 (94.1)**
Femoral bonegraft used					
Yes	458 (3.2)	133 (3.7)	35 (1.4)	45 (1.9)	**671 (3.0)**
No	13,822 (96.8)	3,457 (96.3)	2,429 (98.6)	2,293 (98.1)	**22,001 (97.0)**
Acetabular bonegraft used					
Yes	950 (6.7)	362 (10.1)	314 (12.7)	154 (6.6)	**1,780 (7.9)**
No	13,330 (93.3)	3,228 (89.9)	2,150 (87.3)	2,184 (93.4)	**20,892 (92.1)**
Femoral cement used					
Yes	14,088 (98.7)	144 (4.0)	2,360 (93.6)	2,111 (90.3)	**18,649 (82.3)**
No	192 (1.3)	3,446 (96.0)	158 (6.4)	227 (9.7)	**4,023 (17.7)**
Acetabular cement used					
Yes	13,380 (93.7)	107 (3.0)	332 (13.5)	225 (9.6)	**14,044 (61.9)**
No	900 (6.3)	3,483 (97.0)	2,132 (86.5)	2,113 (90.4)	**8,628 (38.1)**
Minimally invasive surgery used					
Yes	514 (3.6)	257 (7.2)	62 (2.5)	60 (2.6)	**893 (3.9)**
No	13,766 (96.4)	3,333 (92.8)	2,402 (97.5)	2,278 (97.4)	**21,779 (96.1)**
Image guided surgery used					
Yes	171 (1.2)	17 (0.5)	9 (0.4)	16 (0.7)	**213 (0.9)**
No	14,109 (98.8)	3,573 (99.5)	2,455 (99.6)	2,322 (99.3)	**22,459 (99.1)**
Total number of procedures	**14,280**	**3,590**	**2,464**	**2,338**	**22,672**

[13] A hybrid is a procedure where the femoral prosthesis is cemented and the acetabular prosthesis is not cemented. A reverse hybrid procedure has the acetabular prosthesis cemented and the femoral prosthesis not cemented. There were 83 reverse hybrid procedures entered into the NJR database

APPENDIX 9C

Cementing technique for primary hip replacement patients, according to type of procedure[14]

	Patient procedure				
	Total replacement using cement	Total replacement not using cement[15]	Total replacement not classified (e.g. hybrid[16])	Resurfacing arthroplasty	Total
Femoral cement used	**14,088 (98.7)**	**144 (4.0)**	**2,306 (93.4)**	**2,111 (90.3)**	**18,649**
Gun used	13,498 (95.8)	128 (88.9)	2,278 (98.8)	512 (24.3)	16,416
Gun not used	590 (4.2)	16 (11.1)	28 (1.2)	1,599 (75.7)	22,33
Pulsatile lavage used	12,856 (91.3)	123 (85.4)	2,014 (87.3)	1,896 (89.8)	16,889
Pulsatile lavage not used	1.232 (8.7)	21 (14.6)	292 (12.7)	215 (10.2)	1,760
Cement pressuriser used	10,573 (75.1)	100 (69.4)	2,029 (88.0)	459 (21.7)	13,161
Cement pressuriser not used	3,515 (24.9)	44 (30.6)	277 (12.0)	1,652 (78.3)	5,488
Mixing for femoral cement					
Open bowl and spatula	975 (6.9)	15 (10.4)	216 (9.4)	746 (35.3)	1,952
Vacuum mixing	13,113 (93.1)	129 (89.6)	2,090 (90.6)	1,365 (64.7)	16,697
Acetabular cement used	**13,380 (93.7)**	**107 (3.0)**	**332 (13.5)**	**225 (9.6)**	**14,044**
Gun used	4,948 (37.0)	37 (34.6)	97 (29.2)	76 (33.8)	5,158
Gun not used	8,432 (73.0)	70 (65.4)	235 (70.8)	149 (66.2)	8,886
Pulsatile lavage used	12,001 (89.7)	88 (82.2)	300 (90.4)	211 (93.8)	12,600
Pulsatile lavage not used	1,379 (10.3)	19 (17.8)	32 (9.6)	14 (6.2)	1,444
Cement pressuriser used	9,919 (74.1)	82 (76.6)	278 (83.7)	167 (74.2)	10,446
Cement pressuriser not used	3,461 (25.9)	25 (23.4)	54 (16.3)	58 (25.8)	3,598
Mixing					
Open bowl and spatula	1,501 (11.2)	10 (9.3)	35 (10.5)	27 (12.0)	1,573
Vacuum mixing	11,879 (88.8)	97 (90.7)	297 (89.5)	198 (88.0)	12,471
Total number of procedures	**14,280**	**3,590**	**2,464**	**2,338**	**22,672**

[14] Observations were not included if option 'Not selected' was used

[15] The inconsistency of non-cement procedures using cement was mentioned in Part 2, Section 4.4

[16] A hybrid is a procedure where the femoral prosthesis is cemented and the acetabular prosthesis is not cemented. A reverse hybrid procedure has the acetabular prosthesis cemented and the femoral prosthesis not cemented. There were 83 reverse hybrid procedures entered into the NJR database

APPENDIX 9D1

The 20 cemented stem brands entered most frequently into the NJR for primary hip procedures

Brand	Number used (%)
Exeter V40	5,863 (38.0)
Charnley	3,455 (22.4)
C-Stem	1,152 (7.4)
Exeter	894 (5.8)
CPT	734 (4.7)
Elite Plus	705 (4.6)
Stanmore Modular	580 (3.7)
Furlong Cemented	335 (2.2)
Ultima	314 (2.0)
SP11	225 (1.5)
MS-30	178 (1.1)
SS Muller	139 (0.9)
Centrament	117 (0.8)
CMK	86 (0.6)
Versys	75 (0.5)
CPS-PLUS	65 (0.4)
Spec	63 (0.4)
Muller	62 (0.4)
Olympia	56 (0.4)
Bi-Metric	45 (0.3)
Others[17]	292 (1.9)
Total	**15,435**

[17] 27 other brands made by 11 manufacturers

APPENDIX 9D2

The 20 cementless stem brands entered most frequently into the NJR for primary hip procedures

Brand	Number used (%)
Furlong HAC	1,261 (34.2)
Corail	592 (16.1)
ABG 2	435 (11.8)
SL-PLUS	169 (4.6)
Versys	163 (4.4)
Anca-fit	135 (3.7)
Omnifit	100 (2.7)
CLS	66 (1.8)
Accolade	55 (1.5)
Bi-Metric Collarless	50 (1.4)
Aura 2	48 (1.3)
Synergy	46 (1.2)
Bicontact	39 (1.0)
Freeman	18 (0.5)
Taperloc	17 (0.4)
Panatomic	14 (0.4)
Mallory-Head	12 (0.3)
BI-MET	10 (0.3)
C-Fit	10 (0.3)
Summit	10 (0.3)
Others[18]	437 (11.8)
Total	**3,687**

[18] 16 other brands made by 8 different manufacturers

APPENDIX 9D3

The 20 cemented cup brands entered most frequently into the NJR for primary hip procedures

Brand	Number used (%)
OGEE Cup	3,805 (28.7)
Charnley	1,888 (14.2)
Duration	1,424 (10.7)
Exeter	1,287 (9.7)
Elite Plus	733 (5.5)
ARCOM	605 (4.6)
JRI Cup	383 (2.9)
Opera	364 (2.7)
Muller	341 (2.6)
ZCA	338 (2.5)
Ultima	335 (2.5)
Wroblewski Golf Ball	310 (2.3)
ODC	225 (1.7)
Cenator	218 (1.7)
Wroblewski Angle Bore	152 (1.2)
Flange Cup	128 (1.0)
Apollo	122 (0.9)
Chirulen	94 (0.7)
CMK	81 (0.6)
Interplanta	46 (0.4)
Others[19]	368 (2.8)
Total	**13,247**

[19] 16 other brands made by 11 manufacturers

APPENDIX 9D4

The 20 cementless cup brands entered most frequently into the NJR for primary hip procedures

Brand	Number used (%)
Trilogy	1,351 (23.0)
CSF	1,177 (20.0)
Duraloc	664 (11.3)
ABG 2	490 (8.3)
Trident	335 (5.7)
Duraloc Option	237 (4.0)
Reflection	235 (4.0)
Fitmore	220 (3.7)
Ultima	110 (1.9)
Secur-fit	101 (1.7)
Bicon-Plus	99 (1.7)
EP-Fit Plus	98 (1.7)
Threaded Cup	83 (1.4)
Anca-fit	79 (1.4)
Plasmacup	76 (1.3)
Exceed	63 (1.1)
Plasmacup SC	52 (0.9)
EPF-Plus	50 (0.9)
Allofit	43 (0.7)
Mallory-Head	43 (0.7)
Others[20]	269 (4.6)
Total	**5,875**

[20] 16 other brands made by 9 different manufacturers

APPENDIX 9E

Hip brands and manufacturers

Brand	Manufacturer
ABG 1	Stryker Howmedica Osteonics
ABG 2	Stryker Howmedica Osteonics
AML	DePuy
ARCOM	Biomet
ARDEN	Stryker Howmedica Osteonics
ASR	DePuy
Accolade	Stryker Howmedica Osteonics
Ace	Wright Cremascoli Ortho
Alfa	B Braun/Aesculap
Alize	Biomet
Alloclassic	Centerpulse
Allofit	Centerpulse
Anatomic	Zimmer
Anca-fit	Wright Cremascoli Ortho
Apollo	Biomet
Arpege	Biomet
Atlas	Surgicraft
Aura 2	Biomet
Avantage	Biomet
Avatar	Avatar
BHR	Midland Medical Technologies Ltd
BI-MET	Biomet
Bi-Metric	Biomet
Bi-Metric Collarless	Biomet
Bi-Metric Ctd	Biomet
Bi-Metric P/Coat	Biomet
Bicon-Plus	Endo Plus (UK) Limited
Bicontact	B Braun/Aesculap
Biomet	Biomet
Biomex	Biomet
C-Fit	Corin
C-Stem	DePuy
CF-30	Centerpulse
CLS	Centerpulse
CMK	Biomet
CPCS	Smith & Nephew
CPS-PLUS	Endo Plus (UK) Limited
CPT	Zimmer
CSF	Joint Replacement Instrumentation Ltd
Cannulok	Orthodynamics
Cenator	Corin
Centrament	B Braun/Aesculap
Centerpulse	Centerpulse
Charnley	DePuy
Charnley Evolution	DePuy
Chirulen	B Braun/Aesculap
Conelock	Biomet
Conserve	Wright Cremascoli Ortho
Corail	DePuy
Cormet 2000	Corin
Cti	Corin
DC Fit	Corin
Duraloc	DePuy
Duraloc Option	DePuy
Duration	Stryker Howmedica Osteonics
EP-Fit Plus	Endo Plus (UK) Limited
EPF-Plus	Endo Plus (UK) Limited
ESOP	Surgicraft
Echelon	Smith & Nephew
Elite Plus Cup	DePuy
Elite Plus Stem	DePuy
Epoch	Zimmer
Exceed	Biomet
Exeter	Stryker Howmedica Osteonics
Exeter V40	Stryker Howmedica Osteonics
FRF	Joint Replacement Instrumentation Ltd
Fitmore	Centerpulse
Flange Cup	Waldemar Link
Freeman	Finsbury
Freeman Revision Stem	Finsbury
Furlong Cemented	Joint Replacement Instrumentation Ltd
Furlong HAC	Joint Replacement Instrumentation Ltd
Hedrocel	Smith & Nephew
Hi-nek	Corin
Howse 2	DePuy
IPS	DePuy
Interloc	Biomet
Interplanta	Waldemar Link
JRI Cup	Joint Replacement Instrumentation Ltd
LFT	Avatar
LMT	Orthodynamics
Logic	Orthodynamics
M-H Solid Shell	Biomet
MM	B Braun/Aesculap
MS-30	Centerpulse
Mallory-Head	Biomet
Mayo	Zimmer
McMinn	Waldemar Link
Mem Monobloc	Centerpulse
Muller	Centerpulse
Muller Mainstream	Biomet
ODC	Stryker Howmedica Osteonics
OGEE Cup	DePuy
Olympia	Biomet
Omnifit	Stryker Howmedica Osteonics
Opera	Smith & Nephew
Orthodynamics	Orthodynamics
PE-PLUS	Endo Plus (UK) Limited
Panatomic	Corin
Pinnacle	DePuy
Plasmacup	B Braun/Aesculap
Plasmacup SC	B Braun/Aesculap
Profix	Smith & Nephew
Proxima	Corin
Reflection	Smith & Nephew

APPENDIX 9E (continued)

Hip brands and manufacturers

Brand	Manufacturer
Restoration	Stryker Howmedica Osteonics
S-ROM	DePuy
SL-PLUS	Endo Plus (UK) Limited
SLF	Corin
SP11	Waldemar Link
SPC	Centerpulse
SS Muller	Centerpulse
Secur-fit	Stryker Howmedica Osteonics
Snap Fit	Waldemar Link
Solution	DePuy
Sovereign	Zynergy Orthopaedics
Spec	Smith & Nephew
Spec Revision	Smith & Nephew
Stanmore	Biomet
Stanmore Modular	Biomet
Stanmore Monobloc	Biomet
Summit	DePuy
Synergy	Smith & Nephew
Taper-fit	Corin
Taperloc	Biomet
Threaded Cup	Joint Replacement Instrumentation Ltd
Transcend	Wright Cremascoli Ortho
Tri-fit	Corin
Trident	Stryker Howmedica Osteonics
Trilogy	Zimmer
Ultima	DePuy
Ultima Collared	DePuy
Universal 2	Biomet
Versys	Zimmer
Versys Monobloc	Zimmer
Wagner	Centerpulse
Weber	Centerpulse
Wroblewski Angle Bore	DePuy
Wroblewski Golf Ball	DePuy
ZCA	Zimmer

APPENDIX 9F1

The 20 cemented stem and cemented cup combinations entered most frequently into the NJR for primary hip procedures

Stem	Cup	Number	Mixed and matched
Charnley	Charnley	1,588	
Charnley	OGEE	1,503	
Exeter V40	Duration	1,375	
Exeter V40	OGEE	1,129	✓
Exeter V40	Exeter	1,046	
Stanmore Modular	ARCOM	500	
Exeter V40	Elite Plus	398	✓
C-Stem	OGEE	382	
Elite Plus	OGEE	381	
Furlong Cemented	JRI	325	
CPT	ZCA	306	
Exeter	OGEE	252	✓
Exeter	Exeter	235	
C-Stem	Wroblewski	222	
Charnley	Wroblewski	220	
Elite Plus	Elite Plus	163	
Exeter V40	Ultima	160	✓
Ultima	Ultima	143	
SS Muller	Muller	137	
Exeter V40	Charnley	113	✓
Others[21]		2,069	
Total		**12,647**	

[21] 127 other combinations used

APPENDIX 9F2

The cementless stem and cementless cup combinations entered most frequently into the NJR for primary hip procedures

Stem	Cup	Number	Mixed and matched
Furlong HAC	CSF	1,067	
Corail	Duraloc	349	
ABG 2	ABG 2	194	
Versys	Trilogy	161	
Corail	Duraloc Option	121	
SL-PLUS	Bicon-Plus	99	
ABG 2	Trident	99	
Furlong HAC	Threaded Cup	83	
Corail	Trilogy	72	✓
Anca-fit	CSF	60	✓
Omnifit	Secur-fit	59	
SL-PLUS	EP-Fit Plus	56	
Accolade	Trident	54	
Anca-fit	Anca-fit	52	
Synergy	Reflection	45	
CLS	Fitmore	33	
Bicontact	Plasmacup SC	32	
Furlong HAC	Trilogy	32	✓
Furlong HAC	FRF	27	
CLS	CLS	22	
Bi-Metric Collarless	Mallory-Head	22	
Others[22]		348	
Total		**3,087**	

[22] 64 other combinations

APPENDIX 9F3

The hybrid[23] combinations entered most frequently into the NJR for primary hip procedures

Stem	Cup	Number	Mixed and matched
Exeter V40	Trilogy	501	✓
Exeter V40	ABG 2	245	
CPT	Trilogy	235	
Exeter V40	Reflection	178	✓
Exeter V40	Trident	142	
Ultima	Ultima	110	
Exeter V40	Duraloc	108	✓
Exeter	Trilogy	100	✓
C-Stem	Duraloc Option	78	
Versys	Trilogy	72	
C-Stem	Trilogy	69	✓
C-Stem	Duraloc	67	
Exeter V40	Fitmore	60	✓
Muller	Fitmore	58	
Exeter	Fitmore	46	✓
Olympia	Duraloc	34	✓
Exeter V40	Plasmacup	30	✓
CPT	ABG 2	28	✓
Ultima	Duraloc	28	
CPS PLUS	EP-Fit Plus	28	
Exeter V40	Exceed	28	✓
Others[24]		1,143	
Total		**3,388**	

[23] A hybrid is a procedure where the femoral prosthesis is cemented and the acetabular prosthesis is not cemented. A reverse hybrid procedure has the acetabular prosthesis cemented and the femoral prosthesis not cemented. There were 83 reverse hybrid procedures entered into the NJR database. Of the top 20 combinations most frequently entered into the NJR for primary procedures, none were reverse hybrids

[24] 135 other combinations

APPENDIX 9G

The 20 stems and 20 cups entered most frequently into the NJR for primary hip procedures *(shading indicates mixing and matching)*

Stem	Cup									
	OGEE Cup	Charnley	Duration	Trilogy	Exeter	CSF	Elite Plus	Duraloc	ARCOM	ABG 2
Exeter V40	1,129	113	1,375	501	1,046	25	398	108	2	245
Charnley	1,503	1,588						10		
Furlong HAC	3			32	1	1,067	3	5		
C-Stem	382	90		69			101	67	2	
Exeter	252	1	48	100	235	10	32	10		18
CPT	82			235	1		3	2		28
Elite Plus	381	64		14			163	17		
Corail	27			72				349		
Stanmore Modular	3			20		2	23	17	500	
ABG 2			1	1		1			1	194
Furlong Cemented	1				1	6		1		
Ultima	3						4	28	3	
Versys	1			233						
SP11				5		6	4	1	27	
MS-30	11			15						
SL-PLUS										
SS Muller										
Anca-fit						60			1	
Centrament										
Omnifit					2					

	Wroblewski	Ultima	JRI Cup	Opera	Muller	ZCA	Trident	Reflection	Duraloc Option	ODC
Exeter V40		160	15	67	6	3	142	178		1
Charnley	220			108						
Furlong HAC			27						9	
C-Stem	222	7		110	7	2			78	
Exeter		4	14			1	13			1
CPT				33	1	306			20	
Elite Plus	20			6	1	11		5	3	
Corail							2	2	121	
Stanmore Modular		1				4	1		1	1
ABG 2						1	99			
Furlong Cemented			325							
Ultima		253						1		
Versys						4				
SP11										6
MS-30					93					
SL-PLUS										
SS Muller					137					
Anca-fit					1					
Centrament										
Omnifit							19			19

APPENDIX 9H

Characteristics of surgical practice for primary knee procedures, according to patient procedure

	Patient procedure					
	Total replacement using cement	Total replacement not using cement	Total replacement not classified (e.g. hybrid[25])	Unicondylar knee replacement	Patello-femoral replacement	Total
Laminar flow theatre						
Yes	15,829 (92.7)	1,445 (87.8)	201 (92.2)	1,576 (93.0)	212 (95.9)	**19,263 (92.4)**
No	926 (5.4)	167 (10.2)	14 (6.4)	97 (5.7)	6 (2.7)	**1,210 (5.8)**
Unknown	321 (1.9)	33 (2.0)	3 (1.4)	21 (1.3)	3 (1.4)	**381 (1.8)**
Anaesthetic used						
General	4,655 (27.2)	422 (25.7)	70 (32.1)	706 (47.1)	84 (38.0)	**5,937 (28.5)**
Epidural	2,729 (16.0)	211 (12.8)	38 (17.4)	199 (11.7)	27 (12.2)	**3,204 (15.4)**
Nerve block	2,676 (15.7)	258 (15.7)	19 (8.7)	309 (18.2)	42 (19.0)	**3,304 (15.8)**
Spinal	6,657 (39.0)	729 (44.3)	88 (40.4)	467 (27.6)	60 (27.2)	**8,001 (38.4)**
Unknown	359 (2.1)	25 (1.5)	3 (1.4)	13 (0.8)	8 (3.6)	**408 (1.9)**
Surgical approach						
Lateral parapatellar	432 (2.5)	50 (3.0)	2 (0.9)	61 (3.6)	3 (1.4)	**548 (2.6)**
Medial parapatellar	15,810 (92.6)	1,498 (91.1)	184 (84.4)	1,508 (89.0)	213 (96.4)	**19,213 (92.1)**
Sub-vastus	252 (1.5)	56 (3.4)	3 (1.4)	18 (1.1)	0	**329 (1.6)**
Other	582 (3.4)	41 (2.5)	29 (13.3)	107 (6.3)	5 (2.3)	**764 (3.7)**
Skin incision						
Lateral	100 (0.6)	18 (1.1)	0	29 (1.7)	3 (1.4)	**150 (0.7)**
Medial	1,589 (9.3)	214 (13.0)	51 (23.4)	964 (56.9)	43 (19.5)	**2,861 (13.7)**
Midline	15,387 (90.1)	1,413 (85.9)	167 (76.6)	701 (41.4)	175 (79.2)	**17,843 (85.6)**
Tourniquet used						
Yes	15,996 (93.7)	1,336 (81.2)	210 (96.3)	1,626 (96.0)	211 (95.5)	**19,379 (92.9)**
No	1,080 (6.3)	309 (18.8)	8 (3.7)	68 (4.0)	10 (4.5)	**1,475 (7.1)**
Fat pad removed						
Yes, fully	4,923 (28.8)	513 (31.2)	85 (39.0)	85 (5.0)	18 (8.1)	**5,624 (27.0)**
Yes, partially	10,187 (59.7)	939 (57.1)	96 (44.0)	905 (53.4)	95 (43.0)	**12,222 (58.6)**
No	1,966 (11.5)	193 (11.7)	37 (17.0)	704 (41.6)	108 (48.9)	**3,008 (14.4)**
Cement used						
Yes	16,892 (98.9)	108 (6.6)	213 (97.7)	1,655 (97.7)	221 (100)	**19,989 (91.9)**
No	184 (1.1)	1,537 (93.4)	5 (2.3)	39 (2.3)	0	**1,765 (8.1)**
Minimally invasive surgery used						
Yes	364 (2.1)	31 (1.9)	6 (2.8)	833 (49.2)	6 (2.7)	**1,240 (5.9)**
No	16,712 (97.9)	1,614 (98.1)	212 (97.2)	861 (50.8)	215 (97.3)	**19,612 (94.1)**
Image guided surgery used						
Yes	212 (1.2)	26 (1.6)	2 (0.9)	25 (1.5)	2 (0.9)	**267 (1.3)**
No	16,864 (98.8)	1,619 (98.4)	216 (99.1)	1,669 (98.5)	219 (99.1)	**20,587 (98.7)**
Total number of procedures	**17,076**	**1,645**	**218**	**1,694**	**221**	**20,854**

[25] A hybrid operation is one where either the femoral or tibial side of the joint receives a cemented prosthetic component and the other receives a cementless component

APPENDIX 9I

Knee brands and manufacturers

Brand	Manufacturer
ACM/Uniglide	Corin
AGC	Biomet
AMC	Corin
AMK	DePuy
Advance	Wright Cremascoli Ortho
Advantim	Wright Cremascoli Ortho
Allegretto	Centerpulse
Alpina	Biomet
Avon	Stryker Howmedica Osteonics
CCI	Soverign Medical
CKS	Biomet
Coordinate	DePuy
DBK	Finsbury
Duracon	Stryker Howmedica Osteonics
Endo Plus	Endo Plus (UK) Limited
Euis	Stryker Howmedica Osteonics
Evolution	B Braun/Aesculap
FS 1000	Finsbury
Freeman Samuelson	Centerpulse
Genesis	Smith & Nephew
Genesis 2	Smith & Nephew
IB 2	Wright Cremascoli Ortho
IB 2 (Zimmer)	Zimmer
JRI	Joint Replacement Instrumentation Ltd
Kinemax Plus	Stryker Howmedica Osteonics
LCS	DePuy
Lubinus	Waldemar Link
MBK	Zimmer
MG2	Zimmer
MRK	Finsbury
Maxim	Biomet
NK2	Centerpulse
Nexgen	Zimmer
Nuffield	Corin
Optetrak	Intavent - Orthofix
Oxford	Biomet
PFC Sigma	DePuy
Preservation	DePuy
Profix	Smith & Nephew
Rotaglide Plus	Corin
Scorpio	Stryker Howmedica Osteonics
Sled	Waldemar Link
St. Leger	Zynergy Orthopaedics
Tack	Waldemar Link
UC-PLUS	Endo Plus (UK) Limited

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