Joint Approach

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THE NEWSLETTER OF THE
NATIONAL JOINT REGISTRY
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The NJR 1st Annual Report

The first steps to making it work

Development...
data collection and analysis...
looking to the future

National Joint Registry
www.njrcentre.org.uk

This Newsletter is also available in Welsh from the NJR Centre

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THIS ISSUE OF THE NEWSLETTER LARGELY FOCUSES ON SOME OF THE KEY FINDINGS OF THE NJR FIRST ANNUAL REPORT. READERS SHOULD REFER TO THE ANNUAL REPORT ITSELF FOR FURTHER DETAILS AND SUPPORTING INFORMATION. THE FULL REPORT AND A SUMMARY REPORT ARE AVAILABLE FROM THE NJR WEBSITE www.njrcentre.org.uk

Next newsletter publication: December 2004
If you would like to make a contribution to this Newsletter please contact the NJR Helpline, or by email to enquiries@njrcentre.org.uk. Let us know what you would find useful and would like to see in the next issue of the Newsletter.

All NJR information and documents are available on the NJR website **www.njrcentre.org.uk**

If you do not have access to the web, contact the NJR Helpline to receive a copy by email or by post.

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Events Diary

The NJR is at the following event:
BOA Annual Congress

15 - 17 September 2004 Manchester
The NJR 1st Annual Report will be launched on the first morning of the Congress.

The NJR 1st Annual Report - the essentials

On 15 September 2004 the NJR 1st Annual Report was launched at the BOA Annual Congress 2004. The report is a review of data collection and analyses from hip and knee replacements from 1 April to 31 December 2003. The full report and a summary report are available from the NJR website www.njrcentre.org.uk

The Annual Report is structured in three parts:

Part 1 provides a broad introduction to the NJR, an outline of the main issues encountered and how they have been addressed, and a look to the future.

Part 2 is an assessment of the data collected from total hip and knee replacement procedures between 1 April and 31 December 2003, with the quality of the data as the main focus.

Part 3 holds all the supporting appendices.

A summary of the key points are outlined in this newsletter but we recommend that readers refer to the Annual Report itself for supporting information and further details.

Your views

The NJR Centre is interested in your views on the 1st Annual Report and what you would ideally like to see in future reports. You can have your say by completing and returning the feedback questionnaire found in Appendix 8 of the Annual Report, or by completing the online version at www.njrcentre.org.uk. Your views will help inform the preparation of future Annual Reports.

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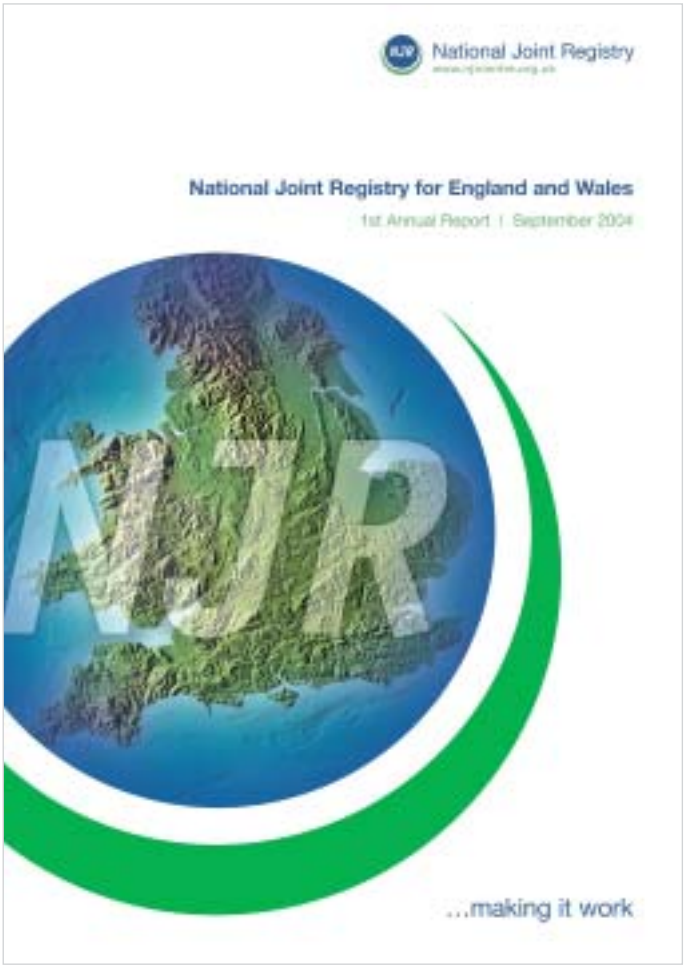
Part 1 - Introducing the NJR

Part 1 provides the background to the NJR, from its early days of development through to the present situation. It introduces the structure of the NJR and provides some details on its main constituent parts. Part 1 also looks at the issues that were met along the way and how they have been or are currently being addressed.



Striking a balance

Obtaining and maintaining the commitment of all stakeholders is critical to the success of the NJR. At all stages of its development the needs of each stakeholder group are considered. For example, the NJR Steering Committee has always strived to find an optimum balance between:

- trying to collect all data relevant for current and future analyses, and
- limiting the administrative burden on busy hospital staff.

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Integral to this consideration were the initial development and the subsequent review of the NJR Minimum Dataset (MDS). The review resulted in the release of MDS version 2 (MDS v2). Stakeholder views and user experiences of collecting MDS v1 were incorporated to improve the overall robustness of MDS v2. To allow the use of the revised dataset to become fully established within hospitals and help bring about a period of stability, no major changes to the MDS are anticipated in the next year or two.

Helping data entry

To ease NJR data entry, two new facilities are being developed - bulk data upload and a barcode reader system.

Bulk data upload facility - Many hospitals collect data in their local database systems and some have requested a method of exporting that data directly into the NJR - a bulk data upload facility. This will allow hospitals to collect NJR data in their own IT system and then transfer them to the NJR database at regular intervals. Bulk data upload avoids duplicate data entry and hence helps to preserve data quality.

The bulk data upload facility is currently being developed, and the NJR Centre is working closely with those hospitals that have requested its availability. Originally planned for implementation during the first year of the NJR, this facility has been delayed until after the establishment of MDS v2. This decision was taken to minimise the changes that hospitals would need to make to their IT systems to ensure compatibility.

Barcode reader system - The current data entry process involves the manual keying-in of the product codes of the orthopaedic components used in an operation. A number of hospitals requested the provision of a barcode reader system so that the components' labels could be scanned. Following the results of a scoping study, the Steering Committee has agreed to its development.

Development of a system that can cope with all barcode formats used by component manufacturers and suppliers has its challenges. For example, it will need to be able to identify and then be able to read all the individual barcode formats used by the component manufacturers.

Barcode readers will help some hospitals reduce the time taken to input data. Whilst such a system will aid data entry for many users, not all suppliers currently provide barcodes on implant labels and so it will not always be possible to enter component details in this way.

The implementation of the barcode reader system will follow the introduction of the bulk data upload facility. Every hospital participating in the NJR will be issued with a barcode reader programmed for use in NJR-related data entry (at no cost to the hospital).

Part 2 - Analyses and interpretation

The data examined were for hip and knee replacement procedures performed between 1 April and 31 December 2003 inclusive (and which were submitted by 31 March 2004). The main areas of data analyses are summarised in pages 4 to 7 of this newsletter, please refer to the main Annual Report for further details and supporting information.

HOSPITAL PARTICIPATION AND THE LEVEL OF DATA SUBMISSION

The number of hip and knee replacement procedures entered by participating hospitals is shown in Table 1. The number of hip and knee replacements estimated to have taken place during this period is about 100,000 (estimated from the number of prostheses sold).

The dataset does not contain all hip and knee procedures expected to have taken place, since some hospitals have not entered data for all their procedures. This is largely due to the NJR being a new venture, with hospitals starting to provide data at various points throughout the data entry period. Some hospitals, however, have not entered any data at all.

The level of participation in the NJR by NHS trusts, independent hospitals and Treatment Centres is shown in Table 2. Within the first three months, 223 hospitals had submitted procedures and by 31 December 2003 this had risen to 301. (Note: 331 hospitals contributed data by 31 March 2004.)

Of the participating hospitals, approximately 50% entered fewer than 50 hip or knee replacement procedures. The mean number of procedures entered per hospital is 77 hip procedures and 66 knee procedures. 36 trusts entered 80% or more of their procedures into the NJR, demonstrating that high levels of completeness can be achieved.

Table 1 - Number of procedures submitted to the NJR database

	Hips (%)	Knees (%)	Total (%)
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

Table 2 - Number of NHS trusts, independent hospitals and Treatment Centres participating in the NJR in England and Wales up to 31 December 2004

	Number expected to participate	Number actually participating[1] (%)
NHS hospitals	168	142 (84.5)
Independent hospitals	166	152 (91.6)
Treatment Centres	12	9 (75.0)

[1] A participating hospital is defined as having submitted at least one hip or knee procedure to the NJR database

Table 3 - Number of joint replacement procedures from 135 NHS trusts

	Number expected to have taken place[2]	Number submitted to the NJR (%)
NHS trusts	59,446	30,498 (51.3)

[2] HES and PEDW data are only available for 135 of the 142 NJR participating NHS trusts due to hospital closures, mergers and new trusts being formed. Also, some trusts had changed their name since HES/PEDW statistics were compiled.

LOOKING AT DATA QUALITY

Procedures entered into the NJR

Hospital Episode Statistics (HES) and Patient Episode Database, Wales (PEDW) data were used to compare the number of procedures entered into the NJR by participating NHS trusts in England in Wales respectively (there is no equivalent data for the independent sector, hence no comparisons can be made for independent hospitals). Based on these data, approximately half (51.3%) of the expected number of procedures from NHS trusts were entered into the NJR. The last three months' data (Oct - Dec 2003) showed that data submission had begun to improve (55.7%).

Only 0.2% of all the procedures recorded had mandatory data fields missing. Most of these missing data were for components, the majority being for knee revision operations that did not require components to be added anyway. Implausible or inconsistent values occurred very rarely and so do not give cause for concern.

Patient consent and NHS numbers

Of the 46,497 patients who received a joint replacement during the nine-month data period, 62.8% are recorded in the NJR as having given their consent. Patient consent allows personal data to be recorded (forename, surname, date of birth, postcode and NHS number).

Personal data are required to enable patients to be traced if they have received a prosthesis that is later found to be faulty. Patient details are also required if a patient is to be eligible for participation in any subsequent patient feedback process. Where patient consent is not given, personal data are not recorded and only the 'anonymous' operation data are entered.

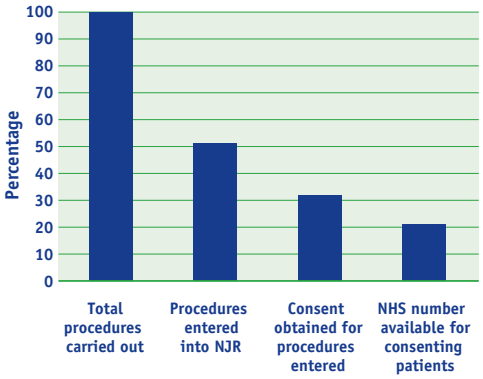
Importantly, the NHS number links the patient's primary joint replacement procedure with any subsequent revision procedures. This linkage is an essential element of the NJR to determine the survivability of implants and enable patient outcomes after joint replacement to be evaluated.

Encouragingly, more than half of the hospitals participating in the NJR achieved patient consent levels of greater than 80%.

However, 27 hospitals returned 0%. This contrasts with 68 hospitals that returned all their procedures with consent.

NHS numbers for some consenting patients were not entered into the NJR. In these instances the NHS Strategic Tracing Service (NSTS) used the patient's postcode, date of birth, forename and surname to find as many of the missing NHS numbers as possible. However, it has not been possible to locate all missing NHS numbers in this way, hence the importance of them being entered at the outset. Where NHS numbers are not known, more effort needs to be made to ensure the patient's postcode is entered correctly at source thereby enabling the NSTS to locate more NHS numbers.

NHS numbers were available for 65.1% of those patients who gave consent. Nearly a third (32.1%) of hospitals had recorded NHS numbers for 80% or more of consenting patients and 23 hospitals collected NHS numbers for all their patients, demonstrating that high levels of completeness can be achieved. Graph 1 illustrates the total hip and knee procedures, and how many were entered into the NJR with NHS numbers.



Graph 1 - Total hip and knee procedures, and how many were entered into the NJR with NHS numbers

As compliance with the NJR becomes embedded within hospital processes and systems, it is expected that data completeness will increase. Already 11 NHS trusts and 30 independent hospitals have shown both high patient consent levels and availability of NHS numbers.

Primary hip replacement procedures

Patient characteristics

The average age of primary hip replacement patients recorded in the NJR is 68 years. The average age of female patients tends to be 3 or 4 years older than the average age of male patients (depending on procedure). Of consenting patients, a greater proportion of females had hip replacements (59.5%), although more males had a resurfacing arthroplasty (65.6%). The most common indication for surgery was osteoarthritis (93.6%).

Surgeon characteristics

Consultants were the lead surgeons in 81.8% of all total replacement procedures recorded on the NJR. 4.5% of lead surgeons were locums.

For the nine-month data period the mean number of primary hip procedures entered per lead surgeon is 15. For individual surgeons the number of procedures entered against their name ranged from 1 to 262.

Surgical practice

Most patients had conventional surgery in a laminar flow theatre. The most common method of anaesthesia was spinal anaesthesia, followed by epidural. The most frequent patient position was lateral, and for most patients the approach was from the front or side (anterior, antero-lateral or lateral).

Most procedures used cement; the most common cementing techniques used are shown in Table 4 (please refer to the Annual Report itself for the complete table). Of all the procedures recorded, 0.9% used image-guided surgery and 3.9% were performed using minimally invasive incisions; both are relatively new techniques.

The two most frequently recommended post-operative regimes were TED stockings and low molecular weight heparin.

Brands of hip prostheses

There are numerous different brands of hip prostheses for sale in the UK and one of the NJR's main aims is to examine their relative long-term performance.

Table 4 - Cementing techniques used in cemented primary hip replacements

	Frequency	%
Femoral cement used	18,649	
Gun used	16,416	88.0
Pulsatile lavage	16,889	90.6
Cement pressuriser	13,161	70.6
Vacuum mixing	16,697	89.5
Open bowl and spatula	1,952	10.5
Acetabular cement used	14,044	
Gun used	5,158	36.7
Pulsatile lavage	12,600	89.7
Cement pressuriser	10,446	74.4
Vacuum mixing	12,471	88.8
Open bowl and spatula	1,573	11.2

In total, there were 72 different brands of acetabular cups and 81 different brands of femoral stems entered into the NJR, which were manufactured or distributed by 23 different companies. The number of different combinations of cups and stems reported was 369, of which 98 were entered just once.

The Exeter V40 and the Charnley stems were the most frequently used, making up nearly half of all stems recorded. The most frequently used cups recorded in the NJR were the OGEE and the Charnley, which make up nearly 30% of the cups used. The most frequent combinations of cups and stems are the Charnley cup implanted with a Charnley stem.

Fewer brands were evident for resurfacing prostheses, the most popular one being the BHR, used in 82.6% of resurfacing procedures in the NJR.

In the NJR, a modular femoral head size of 28mm was implanted in 71.6% of the primary hip replacements that utilised modular stems. The most popular femoral head material used was metal, which was used in 76.3% of primary hip replacements. Surgeons sometimes choose to use a femoral component (incorporating a metallic or ceramic modular head) from one manufacturer with an acetabular component (incorporating a polythene bearing surface) from another. This type of 'mixing and matching' occurred in 22.1% of all primary hip replacement procedures recorded in the NJR.

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 meet the NICE 10-year benchmark. However, the ODEP report[1] could only refer to brands that were introduced more than 10 years ago and a considerable number of brands have been introduced since.

Comparison of NJR results

The results from the NJR were compared with those from other national joint registries in Sweden, Australia and Canada. Patient characteristics were similar throughout all four registries 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. The type of hip replacement a patient receives, in terms of operation and prosthesis, depends on which country they have the operation in.

Future analyses

There are many examples of analyses of differences in clinical outcome that could be carried out in the future. Just a few are:

- cemented versus cementless stems in similar-aged patient groups
- 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, four of the five cemented stems most frequently entered into the NJR were collarless, polished, tapered stems, although they were manufactured by three different companies.

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

Primary knee replacement procedures

The data examined were for primary total-condylar knee, unicondylar knee and patello-femoral replacements performed in the nine-months between 1 April and 31 December 2003 inclusive.

Patient characteristics

The average age of primary knee replacement patients recorded 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.

More females than males had primary knee procedures, although more male patients had unicondylar knee replacements. The most common indication for surgery was osteoarthritis (96.2%).

Surgeon characteristics

A consultant was the lead surgeon for 78.2% of all primary knee procedures entered into the NJR. There were more consultants leading patello-femoral replacements (89.6%) than non-classified total knee replacements, such as hybrids (71.1%). In 76.3% of cases the consultant in charge performed the operation. 5.2% of lead surgeons were locums.

The mean number of knee replacements entered for a lead surgeon for the nine-month data period was 13. For individual surgeons the number of procedures undertaken during this period ranged from 1 to 230. For 353 surgeons (22.8%), only one or two procedures were entered for an individual. This does not necessarily mean that these surgeons have only performed one or two procedures, since not all procedures for the reporting period have been entered into the NJR.

Surgical practice

Most operations were carried out in a laminar flow theatre and conventional surgery was used rather than minimally invasive incisions. The most common method of anaesthesia was spinal anaesthesia, followed by general. The most common surgical approach was medial parapatellar, and the most frequent skin incision was midline. 1.3% of procedures used image-guided surgery.

The two most frequent methods of thrombo-prophylaxis recommended at the time of operation were TED stockings and low molecular weight heparin, while aspirin, foot

pumps and intermittent calf compression were also popular choices.

Brands of knee prostheses

In total, 37 brands of total condylar, 11 brands of unicondylar and two brands of patello-femoral knee prostheses were recorded by the NJR. These were manufactured or distributed by 16 different companies.

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.

The Oxford unicondylar knee was the most common unicondylar prosthesis in the NJR, used in 78.2% of unicondylar knee replacements.

The two brands of patello-femoral knee prostheses entered into the NJR were the Avon, which was used in the majority of patello-femoral replacements (89%), and the Lubinus (11%).

Fixed bearing menisci were more frequently used (88%) than mobile bearing menisci (12%).

The patella was resurfaced in 38.8% of primary total condylar knee replacements.

Comparison of NJR results

The results from the NJR were compared with those from other national joint registries in Sweden, Australia and Canada. On average, female patients tend to be 6 to 18 months older than male patients in all four registries (depending on procedure) and 55 - 60% of knee replacement patients are female. In all four countries, most knee replacement patients are likely to have a cemented knee replacement procedure, although in Australia cementless and hybrid operations are fairly common.

There is no brand of knee prosthesis that is most frequently used throughout the four registries compared, hence it appears that the type of knee replacement prosthesis a patient receives varies according to the country in which the operation took place.

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 (as shown in data for 2002).

Future analyses

Possible areas of interest that could be explored in future include:

- comparison of mobile bearing menisci versus fixed bearing menisci outcomes
- 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 group of patients.

Revision procedures

There were 2,325 hip revision procedures captured by the NJR and 947 knee revisions. Many of the analyses carried out for primary replacements could not be performed for revision operation data since the number of revisions recorded in the NJR in the first nine-month data period is relatively low. As numbers increase in future years, more analyses will be performed.

Patient characteristics

The average age of revision hip replacement patients recorded in the NJR is 70.4 years. There were more female hip revision patients (53.4%) than males. The most common indication for a hip revision was aseptic loosening (62.2%).

The average age of revision knee replacement patients is 70.6 years. There were slightly more males than females who had a knee revision operation (51.4% males). The most common indication for a knee revision was aseptic loosening (41.4%).

Surgery characteristics

There were few bilateral hip and knee revisions, and the right side was operated on more than the left (52.5% hips and 50.5% knees). Consultants performed the majority of revision procedures (89.1% hips and 89.8% knees). Locums performed 2.2% of revision procedures.

Linked procedures

The first nine months of NJR data show that 23 hip replacement patients and 4 knee replacement patients had both their primary and revision procedures entered in the NJR and could be linked by their NHS numbers.

These numbers are likely to be low for several reasons, such as:

- there is a low likelihood of patients requiring a revision operation in the first nine months following primary surgery
- it is possible for those patients who did need a revision so soon after their primary operation that either their primary or revision operation was not entered into the NJR
- even if both primary and revision operations were entered in the NJR, patient consent may not have been obtained for both, so patient personal details may not have been available in both NJR records.

Given that that there are so few linkable procedures recorded in the NJR at this early stage, it is not appropriate to look at these in further detail.

Preserving the security and confidentiality of NJR data

The NJR has several safety measures in place to protect the data it collects.

The collection, handling and use of personal data are treated as confidential at all times in accordance with the Data Protection Act 1998. Electronic data are securely stored to guard against unauthorised access.

Collection, storage and transfer of data

The NJR uses an electronic system for collection, storage and transfer of data, which provides the following benefits:

- Improves security - data are encrypted and transmitted over a secure Internet connection, avoiding distribution of hard copy records through the post
- 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
- Reduces administration - electronic data facilitate the analysis of large datasets.

Accessing the data entry system

All users are required to login to the data entry system. The login process establishes a secure connection with the NJR database server and verifies the user by ensuring that their username, password and 'memorable data' match the stored values.

Patient data

Patient personal details should only be recorded on the NJR where explicit informed patient consent has been obtained. 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.

Patient personal details requested by the NJR are:

- Surname
- Forename
- Date of birth
- Home address postcode
- New NHS number.

The NJR provides a form for collecting this information - version 1.4 (February 2004), which can be downloaded from the NJR website **www.njrcentre.org.uk.**

The NJR data entry system prompts the person entering data to confirm whether patient consent has been given. If consent has been obtained, the data entry person is directed to the 'Patient Details' input screen. If consent has been withheld then only the details of the operation should be recorded (collecting anonymised operation data is in accordance with the Data Protection Act 1998).

It is the responsibility of hospitals to define a process to ensure the consent requirement is incorporated into the patient care pathway, e.g. a hospital may choose to collect patient consent at the pre-operative assessment stage.

Data transfer

The NJR data entry system is an application that works with standard web browsers and technology. Data are securely transferred to the database from the data entry system using industry standard 128-bit secure sockets layer (SSL) protocol.

Once data have been registered on the database, strong patient identifiers (i.e. patient personal details) are encrypted using asymmetric key pair encryption.

Networking and IT interfacing

A secure and robust hosting solution that is suitable for handling patient sensitive data is in place. The hosting of the IT infrastructure is managed by INSL - a specialist network security company. INSL has implemented similar physical and virtual security solutions for high street banks and other financial organisations, police departments and Government agencies.

The NJR database and associated web servers are physically located at the INSL data centre in London. This centre has several layers of security providing 24/7 protection and has industry standard facilities such as dual power supply, dual Internet connections and a controlled physical environment. The virtual security of the database is ensured by a series of firewalls and intruder detectors similar to those used by online banks to secure customer data.

Why does the NJR need to record a patient's personal details?

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 revision operations are linked via their NHS number. Without this link, the survivability of the implant (i.e. the revision end point) cannot be determined. Similarly, the date-of-birth data field enables the age of the patient to be determined, which allows age-related data analyses to be carried out. (The patient's NHS number and date of birth are strong patient identifiers and hence patient consent is required to allow the NJR to record them.)

Recording a patient's personal details will also enable the NJR to distribute Patient Feedback Questionnaires. Patient Feedback Questionnaires will be used to capture patient satisfaction and 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.