

Scottish Arthroplasty Project

Annual Report 2004

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1. Key Points

- There was a steady increase in the total number of primary and revision hip replacements performed from 1992 – 1999. Since 1999, the number of primary hip replacements performed has remained static and there has been a welcome downward trend in the number of revision of hip replacements.
- There has been a steady increase in the total number of primary and revision knee procedures from 1992 to 2003.
- There has been a slight reduction in the percentage of surgeons performing a low number of hip and knee procedures.
- Following publication of the 2003 report, consultants and NHS boards who had higher than average complication rates were asked to investigate and explain this anomaly. All 15 consultants have provided satisfactory responses. So far, only 2 out of 4 boards have responded.
- A large part of the project's work in the coming year will be the development of a Scottish National Joint Registry (see section 7.1).
- The project remains anonymous with no individual patient or surgeon identifiable information available to any member of the Project Management Group or the Steering Committee.
- Scottish Arthroplasty Project would like to welcome The Scottish Society of Anaesthetists, who have agreed to join SAP in exploring the outcomes following arthroplasty.

2. Summary

This 2004 Scottish Arthroplasty Project report follows the format of previous reports, outlining the processes involved and the results from the project with a commentary where appropriate. However, in an effort to reduce unnecessary duplication and paper waste, this year the full report will be available to all on the web (those specifically requiring a paper copy should contact the Scottish Arthroplasty Project, Information and Statistics Division). This summary will highlight and summarise the many important areas from the report. In addition to this summary, consultants who have data in the report will receive a detailed copy of their own results. A copy of the full report index will also be sent to consultants so that they are made aware of the information available by accessing the website.

Throughout the year a number of major projects and changes have been commenced and in some cases completed.

Confidentiality

The project remains anonymous with no individual patient or surgeon identifiable information available to anyone except the ISD analytical staff. The other members of the Project Management Group and Steering Committee have never had, nor can have, access to any individual's information (see under confidentiality and consent in the full report). Considerable efforts have been made to ensure that this anonymity is maintained throughout the audit process. This anonymity places considerable responsibility on the Steering Committee and orthopaedic community to ensure that there is a robust review and reporting structure to initiate enquiry and if necessary, action, on those results which appear to be at significant variance from the national average.

Governance

Following the publication and dissemination of last years report; which included the use of Shewhart control charts to highlight areas of practice (or data recording) which were at significant variance from the Scottish average; a system of reporting and validation was introduced, the outline structure is included in section 6.2 of the full report.

The 15 participants whose results were found to be at variance were asked to review the data and if necessary their practice. Participants were also asked to discuss the results and their response with a local colleague to ensure that the information and any action necessary could be viewed in a local context. A formal reply to the Arthroplasty Project Steering Committee was requested (countersigned by the colleague with whom the information was reviewed).

A full response was obtained from all surgeons whose results appeared at variance. A subgroup of the Steering Committee reviewed these responses (after anonymisation). The responses were thought to be appropriate and measured, only two replies required further clarification. In a number of cases there were problems with data quality or case mix. In some, questions were raised which we will attempt to answer through further analysis of the dataset. In a minority, the respondents confirmed the data and either outlined a plan for change or confirmed that they were ceasing to perform arthroplasty procedures.

A similar process was instituted for outlying NHS board based figures; at present there are a number of units which have not responded and this will be highlighted to the chief executive of NHSScotland.

This year's report again includes Shewhart control charts. Because individual reports include 5 years of data, many surgeons who were identified as at variance last year have again been highlighted. Where this has happened, and an appropriate response has been obtained, the result is circled and a full review will not be requested. However, a detailed list of the results will be forwarded to these individuals to ensure they remain well informed. It is hoped that over the next year, more specific and sensitive monitoring processes will be introduced. However, because of constraints on resource this will initially be limited to those results found to be at variance. Those surgeons whose processes appear to have moved into variance (or appear to have become worse) will be contacted separately to repeat the governance process. Because a statistical process is being applied it is important to remember that a similar proportion of results will always be outlying.

New analysis

This year survival curves for primary hip and knee replacement have been presented. Because arthroplasty has a much longer, successful outcome than many other treatments, surgeons view these curves as an important long-term outcome indicator of success and indeed, their generation is an important feature of the project. They show graphically the likelihood of a procedure lasting

over ten years. An initial glance may indicate that the results are disappointing when compared to other examples available online (particularly those selected figures used in advertising literature). Other projects select out and report specific causes for revision (usually aseptic loosening) and exclude other causes which occur early (infection, dislocation or fracture) from the data. However, the view has been taken that patients would wish to see revision for any cause as an endpoint, as any second procedure involves all the risks of surgery and anaesthesia.

Comparative data can be found in the Scandinavian registers with which the Scottish data are equitable:

- Norwegian arthroplasty register http://www.haukeland.no/nrl/
- Swedish national hip arthroplasty register <u>http://www.jru.orthop.gu.se/</u>

Website

www.show.scot.nhs.uk/arthro

This year has seen the set up of a comprehensive website which contains full copies of this and previous reports, copies of further ad hoc reports and useful links to other websites concerning arthroplasty. The website is aimed at both healthcare professionals and members of the public. It is proposed to place all information for open access on the web. Where information is used from the website, we would ask that the project be acknowledged.

Data completeness

This year we have again tried to bring forward the reporting process. However, the routine return of information from hospitals is tardy with considerable data delay, often over many months, which may give cause for concern about the completeness of the dataset.

Data trends

There was a steady increase in volumes of procedures performed from 1992 – 1999. Since this time, the volume of hip procedures have remained static, but the number of knee operations has increased. Primary knee replacements have increased by 11% since 1999 (3104 to 3430) and the number of revision of knee replacements has increased from 211 in 1999 to 297 in 2003 – an increase of 41%. It is good to see a continuing downward trend in the revision of hip replacements.

Because of the statistical nature of the control charts a similar proportion of surgeons have been identified as outliers as were identified last year.

There has been a slight reduction in the percentage of surgeons performing a low number of procedures; we must wait to see if this trend continues.

Case mix analysis

In previous reports, a crude case mix adjustment was made by selecting patients aged over 60 with a diagnosis of osteoarthritis when analysing complication rates for the NHS board areas. This methodology has been used again in this report. However, further work on the influence of age, sex and diagnosis has been carried out and a more detailed and sophisticated case mix analysis performed. This technique ensures that those patients with more challenging problems are not disadvantaged because of their increased risk of complication. In addition, NHS boards and consultants with lower volumes will receive a better idea of their results because all patients, suitably weighted, will be included in the analysis. This year the analysis is based on the unstandardised control charts for consistency with the approach used in 2003. The standardised charts will hopefully be introduced in future reports.

Conclusion

The work of SAP has grown considerably over the past year, and the project has expanded to include undertaking various pieces of developmental work.

A large part of the project's resources in the coming year will be devoted to the development of a Scottish National Joint Registry (see section 7.1). Aside from this project, SAP will continue to develop the clinical governance work in monitoring and following up those consultants and NHS boards whose complication rates are above control limits.

We have been heartened by the decision of the Scottish Society of Anaesthetists to join us in this project exploring the outcomes following arthroplasty and look forward to developing this section in future reports.

The website will continue to be developed so that it provides comprehensive information about the project to both consultants and patients alike.

3. Introduction

3.1. About the Scottish Arthroplasty Project

The Scottish Arthroplasty Project (SAP) was established in 1999 when orthopaedic surgeons in Scotland agreed to support a national arthroplasty audit. This audit would run under the guidance of the Scottish Committee for Orthopaedics and Trauma (SCOT). The aim of SAP is to encourage continual improvement in the quality of care provided to joint replacement surgery (arthroplasty) patients. This is done in two ways;

- by improving the quality of nationally collected data through feedback to consultants; and
- by providing analysis of national trends and patient outcomes in joint replacement surgery to both orthopaedic consultants and the public.

3.2. Elective Joint Replacement in Scotland

The Scottish Arthroplasty Project studies planned (elective) hip and knee joint replacements performed in Scotland. These operations can also be carried out as emergencies. However, these operations are excluded from the SAP, as they represent a slightly different group of patients.

There are 15 Health Boards in Scotland and 13 of these provide an elective joint replacement service. Within these 13 Health Boards, elective joint replacement is carried out at 29 hospitals. Details of the distribution of consultants within Scotland can be seen in appendix 2.

4. Data

4.1. The dataset

The data used by the Scottish Arthroplasty Project are derived from SMR01 records (Scottish Morbidity Record). All NHS Acute Hospitals in Scotland create an SMR01 record for every inpatient or daycase patient episode. An episode is defined as the time a patient is in an acute setting under the care of a particular consultant. If a patient is transferred to the care of a different consultant or a different hospital, a new SMR01 record is started. For example, if a patient is admitted under the care of consultant 'Bloggs', has an operation and then is transferred to the care of consultant 'Adams' and is discharged home, two SMR01 episodes will be created for that patient. All SMR01 records are sent to ISD, where they are held on a central database. These data are held under the strict confidentiality guidelines which were laid down in the Data Protection Act of 1998, which came into force in 2000.

SMR01 records contain information about a patient's episode of care, including;

- date of admission;
- diagnosis;
- the date and type of any procedures performed;
- the consultant who was responsible for the patient's care; and
- date of discharge.

The SMR01 records of all those patients who have undergone an arthroplasty procedure are selected from this national database for the Scottish Arthroplasty Project.

At ISD, all of these SMR01 episodes can be linked together and to the General Register Office for Scotland (GROS) death records. This means that a 'patient history' can be produced, i.e.;

- when a patient was admitted to hospital;
- why they were admitted;
- what treatment was carried out
- when they were discharged;
- whether or not they were readmitted at a later date; and
- if a patient dies, the date and the cause of death.

An example of a patient history is shown in Figure 1.

This information allows SAP to determine which patients had an unexpected event happen to them following surgery (known as a complication). As the consultant responsible for each patient is known, the proportion of patients having a complication can be worked out for each consultant and for each health board. This is called a complication rate, and is used as an indication of the quality of care patients receive.

Figure 1

stay in hospital	Location	Date of Admission	Specialty	Type of Admission	Diagnosis	Arthroplasty	Laterality
1	hospital A	02-Oct-1996	Orthopaedics	Elective	Coxarthrosis	Primary Hip	Left
2	hospital A	21-Jul-1997	Orthopaedics	Elective	Infected Prosthesis	Revision Hip	Left
3	hospital A	26-Jul-1999	Orthopaedics	Elective	Coxarthrosis	Primary Hip	Right
3	hospital A	31-Jul-1999	General Medicine	Transfer	Postprocedural Ren Failure		
4	hospital A	28-Dec-1999	General Medicine	Emergency	Chest Pain		
5	hospital A	22-May-2000	Orthopaedics	Emergency	Dislocation		
6	hospital A	01-Nov-2000	Orthopaedics	Emergency	Dislocation		
7	hospital A	17-Jan-2001	Orthopaedics	Elective	Recurrent Dislocation	Revision Hip	Right
8	hospital B	31-Aug-2001	Renal Medicine	Emergency	Acute Renal Failure		

Although ISD holds the SMR01 information, any mistakes in the data are corrected by the hospital and re-sent to ISD who then update the national database.

4.2. Data Completeness

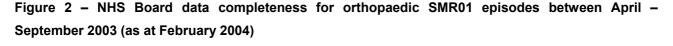
4.2.1. Data from NHS Scotland

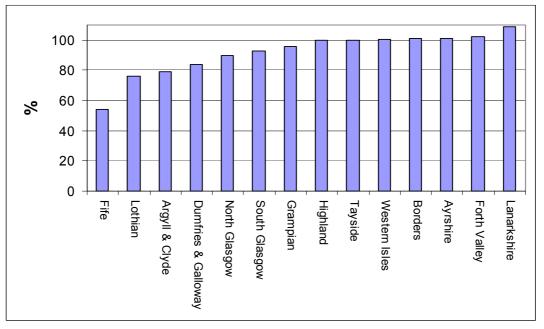
Hospitals send SMR01 records to ISD retrospectively. The national standard is for the records to be sent to ISD within 3 months of a patient's discharge from hospital. In practice, the majority of SMR01 records are submitted within 6 – 9 months of a patient's discharge.

To assess what proportion of a health board's SMR01 data have been sent to ISD for any given month, the SMR01 dataset can be compared with another dataset collected by ISD known as ISD(s)1. ISD(s)1 contains summary information about resources and activity in hospitals in Scotland. The ISD(s)1 data are much less detailed than SMR01. For example, if hospital X has treated 1000 patients in January, they will have at least 1000 SMR01 records. Correspondingly, this will generate one ISD(s)1 record which will show that the hospital treated 1000 patients.

To assess data completeness/timeliness, the number of SMR01 records received at ISD are compared to the number of patients treated (as recorded on ISD(s)1). The latest data in this report are for operations carried out between 1st April 2002 and 31st March 2003, and these data were extracted from the SMR01 database in February 2004.

The data up to March 2003 are practically complete (99% complete for orthopaedics), whilst data from April 2003 onwards are still incomplete (in February 2004, no records were available for October 2003 onwards), thus illustrating why it is not possible to use more up to date data in the report. The data completeness for each area for April – September 2003 is presented in Figure 2 below. Missing data will affect the total number of hip and knee joint replacements recorded and the resulting complication data.





Note: data completeness of >100% indicates that the number of SMR01 returns is > than the ISD(s)1 total: this sometimes happens, as ISD(s)1 is not always totally accurate, although it is regarded as the best data source with which to measure SMR01 data completeness.

4.2.2. Data from private hospitals

A growing number of people have their hip or knee joint replacement carried out at a private hospital. This happens for two reasons; either the patient has made a decision to be treated privately, or they are being treated under the waiting list initiative. The latter means that a patient's treatment is contracted to the private sector by the NHS so that the patient does not have to wait too long on a waiting list for their operation. Private hospitals do not currently submit SMR01 records for patients that they treat privately, however, they are moving towards doing this.

The SMR01 records for those patients treated as an NHS patient at a private hospital are the responsibility of the NHS Trust which contracts out the operation, although it is unclear as to whether all these SMR01 records are being submitted to ISD. Consequently, there is a proportion of the national data missing, i.e. the majority of patients treated at a private facility, either as a private or NHS patient. The proportion of procedures carried out privately could not be estimated as summary data concerning the number of hip and knee replacements carried out were only supplied by four out of the seven private hospitals in Scotland.

4.3. Data Quality

The SMR01 dataset is subject to quality assurance in several different ways. Firstly, the data have to pass ISD validation (a series of checks to ensure that the data is accurate) before they are added to the national dataset. This is either undertaken at the hospital or at ISD, depending on whether the hospital is accredited by ISD to validate its own data. This type of validation ensures that several basic rules are applied. For example;

- all data fields which are compulsory have been completed; and
- it would not be possible to submit a record where an operation date is earlier than the date the patient was admitted to hospital.

Although this validation goes a long way to ensuring the accuracy of the submitted data, it is still possible for mistakes to be made. These mistakes are identified by comparing the SMR01 record with the patient's notes. The data intelligence team within ISD carries out a rolling programme of data checking across Scotland, visiting hospitals and checking SMR01 records against patient notes. Further details about data checking and validation can be found on the Information and Statistics Division website www.isdscotland.org.

One of the aims of SAP is to improve the quality of data held within the national database. Every three months each orthopaedic consultant practising arthroplasty in Scotland is sent a list of patients that have undergone an arthroplasty procedure under their care. This list is generated from the SMR01 database held at ISD, and is produced for procedures occurring 9-12 months retrospectively. This delay is for reasons outlined in section 4.2. For example, in July 2003, Consultant Bloggs was sent a list of all the patients on whom he had performed an arthroplasty procedure between July 2002 and September 2002. Consultants are encouraged to inform their hospital coding department of any errors in the list, as SMR01 records can be corrected by the hospital and re-sent to ISD. In this way, the SMR01 data relating to arthroplasty patients can be quality assured by orthopaedic consultants.

In March 2003, an audit of arthroplasty data was carried out by staff from the Scottish Trauma Audit Group (STAG) for SAP. Orthopaedic consultants were sent (by recorded delivery) a list of all their patients recorded as having suffered a complication within a year of undergoing a hip or knee replacement. One hundred and nineteen consultants from 22 hospitals were surveyed. This comprises about 80% of the total number of consultants practising arthroplasty in Scotland at the time. STAG staff visited these consultants and asked them if they had received the list of complications, if they found it useful and if they had used it to check the quality of the nationally collected data. Of the 113 consultants who had been in post more than a year;

- 76 (67%) confirmed they had received the listing
- 21 (19%) said they had not received the listing (despite the report being sent via recorded delivery).
- 16 (14%) did not know whether or not they had received it.

Of the 76 consultants who had received the 5 year list, 63 (83%) had the list available and 32 (42%) had checked the list against the patient's notes.

Consultants were asked to gauge how accurate the list was in terms of operation and complication. Out of 32 consultants who had received the list and checked it, nine felt that it was about 90% accurate and complete. Six consultants felt that the list was less than 50% accurate.

With consultants' consent, STAG staff then went on to validate the accuracy of the data against patients' notes. To produce complication rates, both nationally and for each consultant, it is important that the index operation (i.e. the primary hip or knee arthroplasty) and the complication

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episode are correctly recorded by hospitals. The name of the consultant performing the index arthroplasty operation, the procedural code for that operation and the diagnostic code for the complication episode are the minimum details that need to be correct in order to produce accurate complication rates. From the audit, the overall 'accuracy' rate (those episodes with no coding errors at all) was 55%. However, there were clear patterns to the errors, most notably;

- attribution of surgeon and side of operation;
- the presence of infection or deep vein thrombosis (dvt); and
- complex cases with multiple admissions (and therefore opportunities for coding problems).

The governance process opportunities confirmed that there were problems with some data, but that overall the process was identifying patterns of care which were over or near the control limits set.

Incorrect data arises from a mistake in the entry of data onto the SMR01 record or from an error in the assignment of the 'code' to the diagnosis or operation performed. Whilst the apparent level of error seems high, these data are provided by many hospitals and there will be regional variation in the quality of the data. It is important to realise that the results require local investigation and interpretation rather than over interpretation, and provide a guide to areas where further investigation should be carried out.

Under the clinical governance process initiated as part of this project (see section 6), a number of consultants were contacted about their complication rates and asked to scrutinise them carefully. This process did reveal some coding errors, but in the majority of cases the results were accurate. In the cases where there were data errors, although correction brought the results closer to the average, all consultants still had more than the expected number of complications.

Following on from the STAG audit, several key coding issues were identified. These issues were:

- Patients undergoing a revision of their hip or knee replacement in two separate operations were being coded as having had their replacement revised twice, instead of having a two staged revision procedure. There had been no way of coding this situation previously, but specific codes have now been identified to allow this situation to be coded properly.
- A patient has been coded as having a DVT (deep vein thrombosis) or PE (pulmonary embolism) when in fact the patient never had the DVT or PE confirmed. This occurs as coders

are looking for certain language within medical notes to confirm the DVT/PE, and medical staff are probably unaware that this is the case.

Updated coding guidance has subsequently been produced for both orthopaedic surgeons and clinical coding staff, and a seminar for clinical coding staff was held in February 2004. The purpose of this seminar was not only to discuss the updated coding guidance, but to also inform coding staff of an area to which their work provides an important contribution.

5. Data Analysis

5.1. Results

5.1.1. National trends in numbers of operations

Figure 3 to 6 represent the numbers of joint replacement operations (both primary and revision for hip and knee) recorded as performed in NHS Scotland in each of the last 12 years (1992 to 2003).

There was a steady increase in volumes of primary and revision hip procedures performed from 1992 to 1999. Since this time, the volume of hip procedures have remained static, but the number of revision hip procedures has shown a slight fall.

The number of primary and revision knee procedures continues to rise year on year. Primary knee replacements have increased by 11% since 1999 (3104 to 3430) and the number of revision of knee replacements has increased from 211 in 1999 to 297 in 2003 – an increase of 41%.

It is good to see a continuing downward trend in the revision of hip replacements. The majority of arthroplasty revisions are carried out many years after the initial procedure, therefore the rise in knee revisions (and fall in hip revisions) reflects the number of primary procedures carried out several years ago.

Figure 3 -Primary hip replacements by year ending March

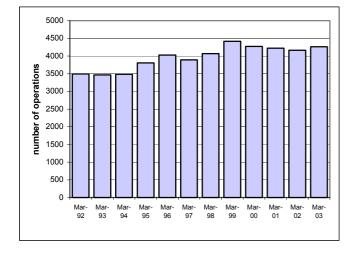


Figure 5 - Revision hip replacements by year ending March

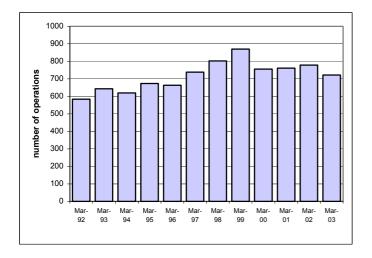


Figure 4 - Primary knee replacements by year ending March

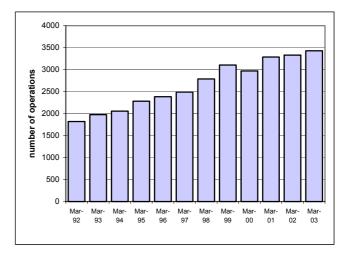
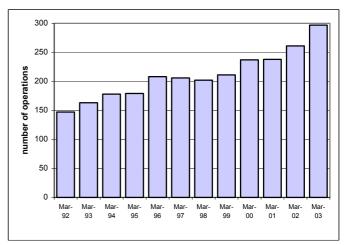


Figure 6 - Revision knee replacements by year ending March



5.1.2. Number of arthroplasty procedures performed per surgeon

Figures 7 to 10 illustrate the number of joint replacements (primary and revision for both hip and knee) recorded as performed by each consultant surgeon operating in NHSScotland. Each consultant and hospital has a unique work pattern and arthroplasty represents only a small part of that workload. These figures should therefore not be seen as total workload figures. It should also be noted that consultants commencing or retiring from their post during the year may well appear to be performing low volumes of procedures if they were not working for the whole year.

A total of 150 consultant surgeons are recorded as having performed primary hip replacements in 2003 in the NHS. There were 15 consultant surgeons who performed less than 5 primary hip replacements and 66 out of 116 (57%) who performed less than 5 revisions of primary hip replacements. This was a decrease from 2002 when 75 out of 122 (61%) performed less than 5 revisions.

One hundred and forty three consultant surgeons performed primary knee replacements in 2003. Eleven of these consultant surgeons (8%) performed less than 5 primary knee replacements, which is slightly less than 12% in 2002. These 11 consultants performed 0.7% of the total number of primary knee replacements. Of the 89 consultant surgeons who performed revisions of primary knee replacements, 31 consultant surgeons performed only one. This is again a slight decrease to 34% when compared to 43% in 2002.

While the number of primary hip and knee replacements performed per consultant surgeon compares favourably with the USA (Katz et al, 2001) the numbers for revision of hip and knee replacements are disappointing, given that there are sufficient consultant surgeons performing more than 5 operations to cover each site in Scotland. Performing a low number of procedures has been shown to have some effect on patient outcomes in several different specialties. (Birkmeyer et al 2003, Carter 2003, Kizer 2003). Previous reports (Scottish Arthroplasty Project 2003) have highlighted that performing low volumes of procedures can result in higher rates of the complications deep vein thrombosis (dvt), infected prosthesis and dislocation of prosthesis, but not in higher rates of revision surgery.

Figure 7 - Primary hip replacements by year ending March 2003

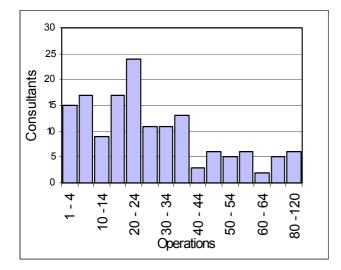


Figure 8 - Primary knee replacements by year ending March 2003

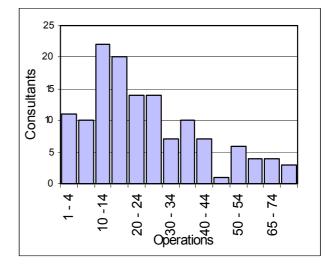


Figure 9 - Revision hip replacements by year ending March 2003

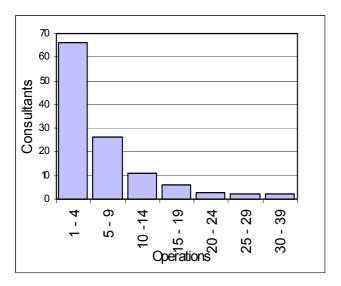
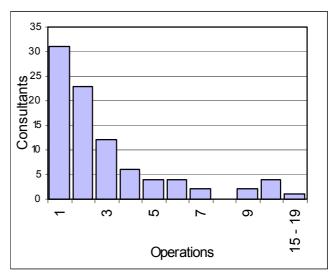


Figure 10 - Revision knee replacements by year ending March 2003



5.1.3. Analysis of complication rates

Last year, Shewhart control chart methodology (Adab P et al 2002) was used to present complication data for the first time and this approach has been used again this year. Control charts are a simple, graphical way to display data and outcomes. The main advantage of Shewhart control charts is their simplicity – they are relatively easy both to construct and to interpret, and have been designed to identify any unusual variation in a process (Young et al 2004). In a control chart, the outcomes for different units or individuals are plotted on a chart along with a mean line. Control limits are plotted at 3 standard deviations above and below the mean line to allow for 'normal' (common cause) statistical variation (Mohammed et al 2001). In the control chart, control limits are calculated around the Scottish rate and then the rates for areas and consultants are examined to see whether they fall between the 2 control limits or not. Consultants who have a 'normal' number of patients suffering from a complication should be in-between the control limits. It is important to realise that the results between the control limits are as likely to be as a result of random statistical variation as differences in clinical outcome.

As was the case last year, complication data are presented for a specific group of patients (patients aged 60 or over suffering from osteoarthritis section 5.1.4, 5.1.5) and also as overall complication rates for primary hip and knee replacement (sections 5.1.6, 5.1.7). The complication rates produced are based on elective primary hip and knee replacement procedures.

As a basic method of adjusting for case mix (the different clinical circumstances of each patient), patients aged 60 or over having a hip or knee replacement for the same clinical condition (osteoarthritis) were looked at. It would be expected that these patients would have similar rates of clinical complications. This group was chosen as it represents the most common, clinically similar group of patients who undergo primary hip or knee replacement. The results for this group of patients are presented by health board so that the number of patients is large enough to produce meaningful numbers of complications.

Five years of operations (April 1997 – March 2002) have been used to increase the number of operations per consultant surgeon and hence reduce the variability and increase the reliability of the results. Analysis for death and DVT (deep vien thrombosis) are presented for up to 90 days following surgery as these represent the period of increased morbidity identified from previous work by the Scottish Arthroplasty Project. For dislocation and revision rates, complications occurring up to one year after surgery are presented.

A degree of caution should be exercised when interpreting the following complication data. A recent audit of complication data by the Scottish Arthroplasty Project has indicated that the coding of complications and the linking of records to produce these figures are not entirely accurate (see section 4.3) However, preliminary results suggest that the significant data problems are in the identification of complications following revision of hip or knee replacement, and there are less inaccuracies regarding complication rates following primary hip or knee replacement.

5.1.4. Complications following elective primary hip replacement - osteoarthritis patients

Figures 11 to 14 represent the complication rates for elective primary hip replacements in patients aged over 60 yrs suffering from osteoarthritis. This particular group of patients has been chosen as it represents the most common, clinically similar group of patients who undergo primary hip replacement.

On the graphs, number of operations per NHS board are plotted against the number of patients who had complication within that board – each cross therefore represents an NHS board. Points lying within the control limits (the outer lines on each graph) can be said to be within control limits. Those lying outside the control limits (one area in figure 12 and one in figure 13) represent areas at which the complication rates are above the control limit and further investigation is advisable to determine the causes of these outlying rates.

All those areas identified in last year's report which had figures at significant variance within both the hip and knee control charts were contacted and asked to carry out a detailed local audit as part of the governance process. Where this has been performed the results will continue to be monitored to ensure they move towards the norm or that there has been an examination of local results. Outlying figures would not be expected to return to the average result over one year as the charts are all based on five years of data. Any area which lies above the upper control limit this year but did not last year will be contacted to explore the reasons for this change. Areas that were outlying both last year and this year have been marked with a circle.

<u>Complications following elective primary hip replacement (April 1997 – March 2002) by NHS</u> <u>Board - osteoarthritis patients 60 yrs old and over.</u>

NHS Boards who were outlying both last year and this year have been marked with a circle and will not be asked to repeat the governance process.

Figure 11 - Observed and expected deaths

within 90 days

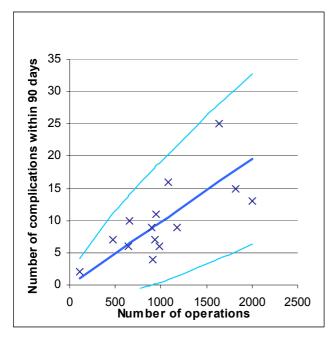


Figure 13 - Observed and expected joint infections within 365 days

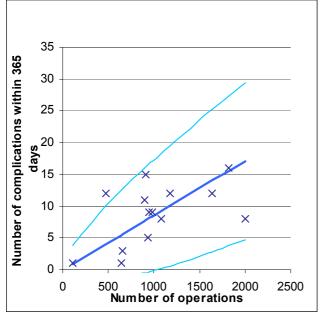
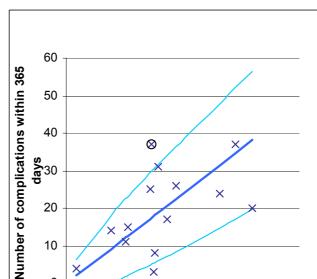


Figure 12 - Observed and expected hip



1000

Number of operations

2000

2500

1500

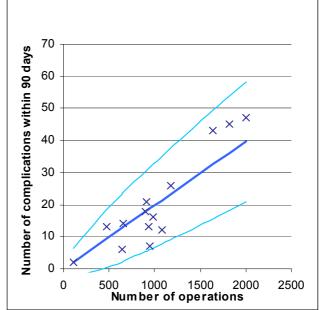
dislocations within 365 days

Figure 14 - Observed and expected DVT/PEs within 90 days

500

0

0



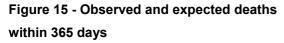
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5.1.5. Complications following elective primary knee replacement - osteoarthritis patients

Figures 15 to 18 represent the complication rates for elective primary knee replacements in patients aged over 60 yrs suffering from osteoarthritis. This particular group of patients has been chosen as it represents the most common, clinically similar group of patients who undergo primary knee replacement. Dislocation following an elective primary knee replacement is not included in this set of charts, as it is extremely rare and therefore the numbers would be too small to draw reliable conclusions. As in figures 11 - 14, the number of operations in each board area are plotted against the number of complications and boards who were outlying last year as well as this year have been marked with a circle.

<u>Complications following elective primary knee replacement (April 1997 – March 2002) by</u> <u>NHS Board - osteoarthritis patients 60 yrs old and over.</u>

NHS Boards who were outlying both last year and this year have been marked with a circle and will not be asked to repeat the governance process.



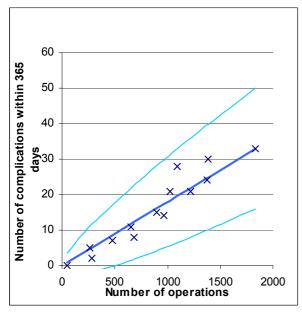


Figure 17 - Observed and expected joint infections within 365 days

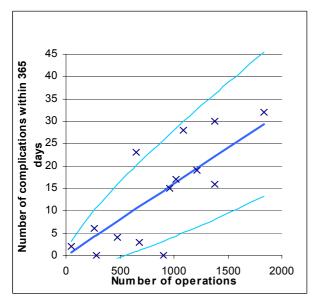


Figure 16 - Observed and expected revisions within 365 days

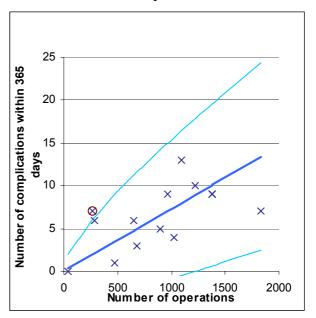
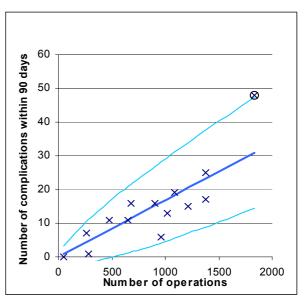


Figure 18 - Observed and expected DVT/PEs within 90 days



5.1.6. Consultant surgeon data for complications following elective primary hip replacement

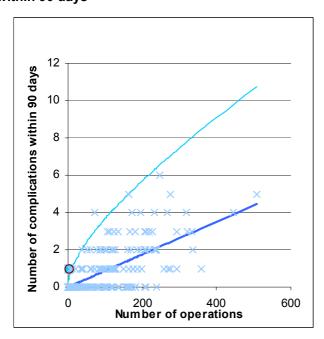
The following charts (Figure 19 to 22) represent complication rates for individual consultant surgeons for the time period April 1997 – March 2002. Each point on a chart represents the number of complications following elective primary hip replacement carried out by a particular consultant surgeon.

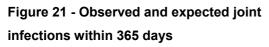
Following last year's report, all those consultants whose rates were outwith the control limits on either the hip or knee control charts were contacted and asked to carry out a detailed local audit as part of the governance process. Where this has been performed the results will continue to be monitored to ensure they move towards the norm or that there has been an examination of local results. Outlying figures would not be expected to return to the average result over one year as the charts are all based on five years of data. Any consultant whose data lies above the upper control limit this year but did not last year will be contacted to explore the reasons for this change. Consultants who were outlying both last year and this year have been marked with a circle. Within the 7 charts presented, 11 consultants who have outlying data are no longer practising arthroplasty in Scotland.

<u>Consultant Surgeon Data for Complications Following Elective Primary Hip Replacement</u> (April 1997 – March 2002)

Consultants who were outlying both last year and this year have been marked with a circle and will not be asked to repeat the governance process.

Figure 19 - Observed and expected deaths within 90 days





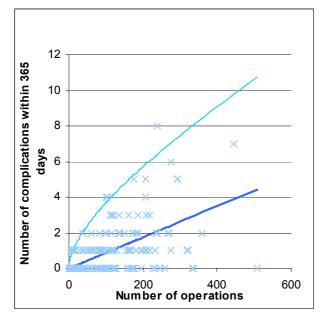


Figure 20 - Observed and expected hip dislocations within 365 days

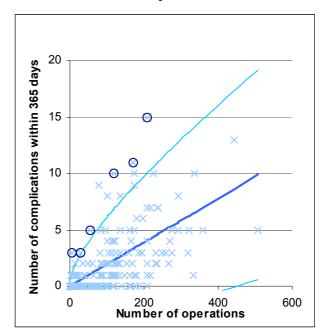
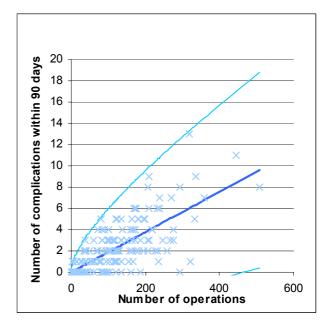


Figure 22 - Observed and expected DVT/PEs within 90 days



5.1.7. Consultant surgeon data for complications following elective primary knee replacement

Figures 23 to 25 represent individual consultant surgeon complication data. Each point on a chart represents the number of complications following elective primary knee replacement carried out by a particular consultant surgeon. Dislocation following an elective primary knee replacement is not included in this set of charts, as it is extremely rare and hence numbers are too small to be meaningful.

<u>Consultant Surgeon Data for Complications Following Elective Primary Knee Replacement</u> (April 1997 – March 2002)

Consultants who were outlying both last year and this year have been marked with a circle and will not be asked to repeat the governance process.

Figure 23 - Observed and expected deaths

within 90 days

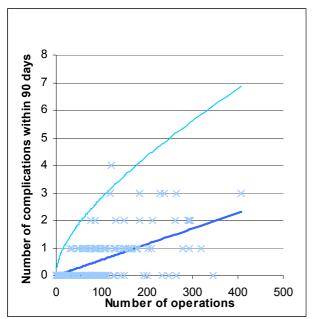


Figure 24 - Observed and expected joint infections within 365 days

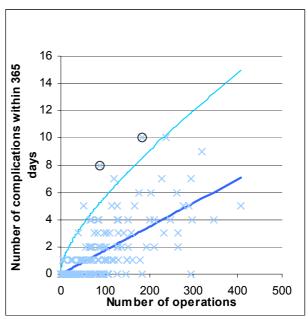
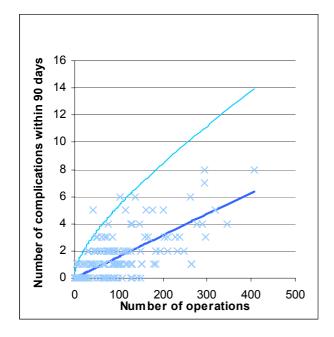


Figure 25 - Observed and expected DVT/PEs within 90 days



5.1.8. Survival of joint replacement by area

It is possible to use the SMR01 data to graphically illustrate the survival of both hip and knee joint replacements. The type of survival analysis used in this section is known as Kaplan-Meier survival analysis. The graphs are constructed by selecting a particular group of patients, following them over a set period of time and monitoring if and when they have their joint revised.

At day 0, no patients have had their joint revised and hence the survival is always 1. When a patient has a joint revised, the survival rate drops. In this case, a higher survival rate is better and so in Figure 26 for example, patients aged greater than 75 years who have had a hip replacement will on average find that there is a longer time before they need their joint revised than a patient aged less than 55 years.

A good explanation of this type of survival analysis can be found on the orthoteers website at http://www.orthoteers.co.uk/Nrujp~ij33lm/Orthstatssurvival.htm (correct link at time of writing).

For the national charts (Figures 26–39), patients who had their joint replaced between April 1992 – March 2003 were followed for up to 11 years after their operation and the number of replacements and revisions included are based on 11 years of SMR01 data (tables 1 and 2). However, for graphical presentation, we have truncated the survival curves at 10 years as the last year of data presented has less than 10% of the patients contributing to it and is hence the most variable. Similarly for data presented by NHS board (table 3), we have followed patients for 6 years (April 1997 to March 2003) but presented only 5 years of data in the survival curves (figures 32-40). For the NHS board analysis, we chose to present only 5 years of data as we wished the results to be as relevant as possible to the consultants currently in post and hence it was necessary to compromise between including many years of data in the analysis and having enough data to present meaningful results for all NHS boards. A full discussion of the results is in section 5.2.

For the national analyses, we used the Log-rank test to see if there was a difference in survival between the groups of patients (Bland et al 2004).

National Survival of Hip and Knee replacements

Table 1 – <u>National Survival of P</u>	imary Hip replacements	by patient age for	operations performed
<u>between April 1992 – March 2003</u>			

Grouping	Number of primary operations	Number of patients not revised	Number of revisions	p-value
age of patient				<0.0001
<55 years	4084	3844	240	
55 – 75 years	22321	21459	862	
>75 years	11064	10804	260	
volume of procedures performed by surgeons				0.1456
0-9	3853	3704	149	
10-19	6762	6489	273	
20+	26854	25914	940	
diagnosis				0.0002
Osteoarthritis	30763	29728	1035	
Rheumatoid arthritis	1324	1255	69	

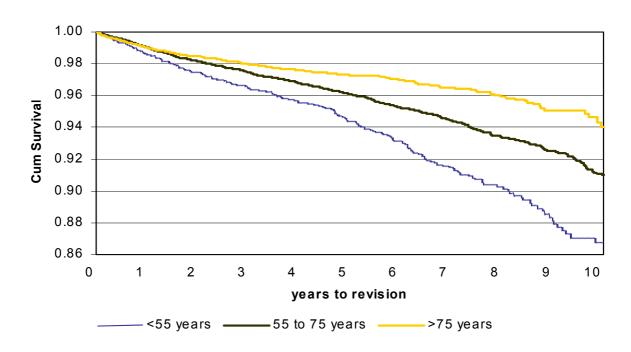
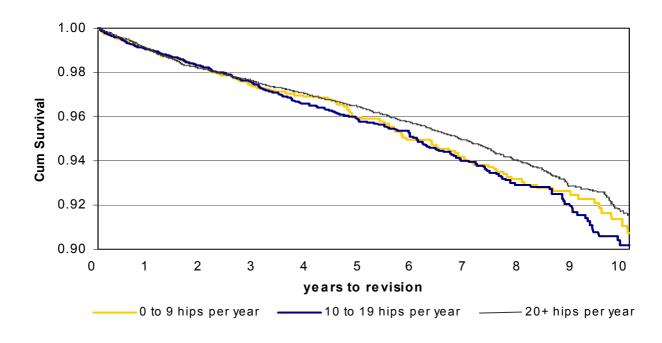
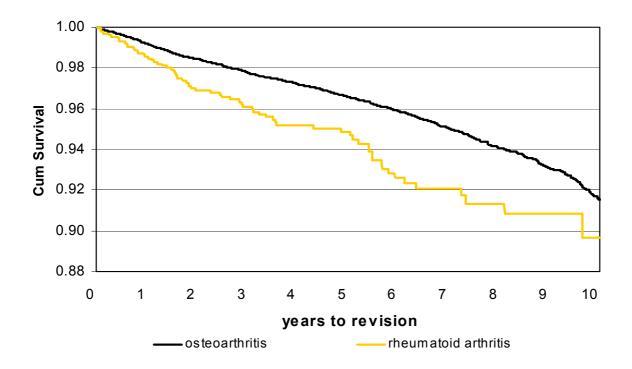


Figure 26 - <u>Survival of Primary Hip replacements by patient age for operations performed between</u> <u>April 1992 – March 2003</u>

Figure 27 – <u>Survival of Primary hip replacements by volume of procedures performed by surgeons</u> for operations performed between April 1992 – <u>March 2003</u>



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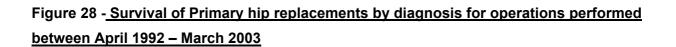
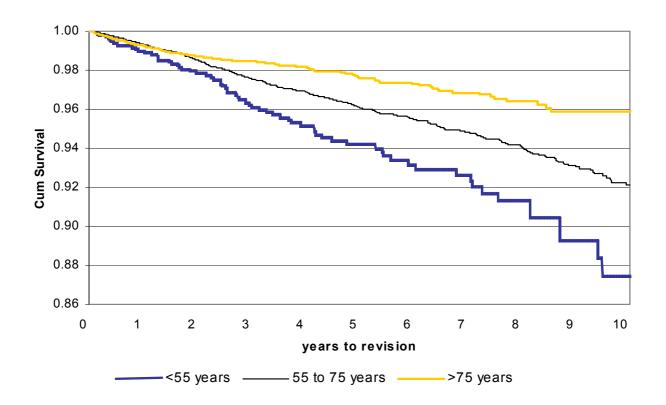
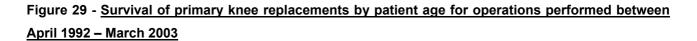
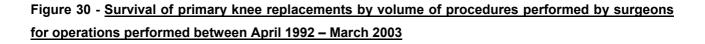


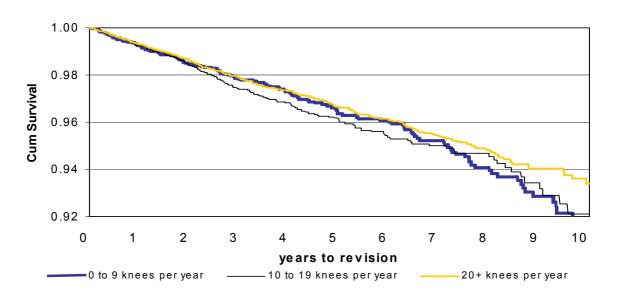
Table 2 - National Survival of Primary	<u>/ knee replacements by</u>	y patient age for	operations performed
<u>between April 1992 – March 2003</u>			

Grouping	Number of primary operations	Number of patients not revised	Number of revisions	p value
age				<0.0001
<55	1348	1277	71	
55-75	15292	14795	497	
>75	7281	7144	137	
volume of procedures performed by surgeons				0.2495
0-9	4262	4130	132	
10-19	6690	6486	204	
20+	12969	12600	369	
diagnosis				0.8999
osteoarthritis	20455	19777	678	
rheumatoid arthritis	1867	1795	72	

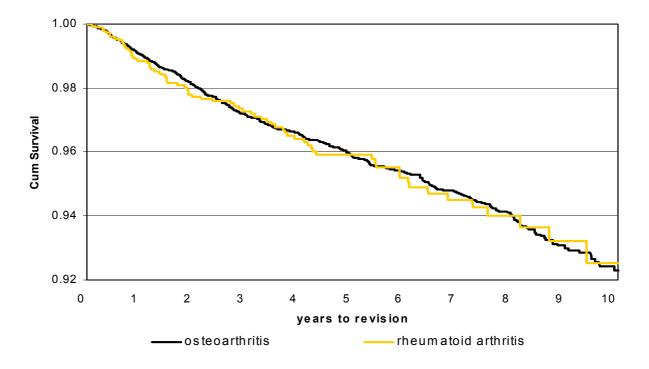


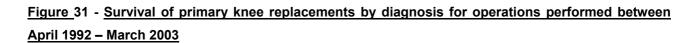












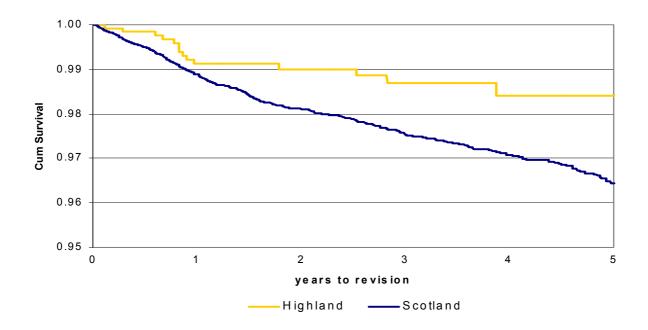
NHS Boards – Survival of hip replacements

For the analysis at NHS board level, we produced survival curves for all NHS boards who perform hip arthroplasty operations. However, for a number of boards, the number of primary hip operations performed was too small to give an accurate assessment of the revision rate and hence we have only included those boards who performed more than 1300 primary hip operations in the 6 year period analysed (April 1997 – March 2003).

Table 3 – NHS Boards: Survival of primary hip replacements for operations performed	<u>d between April</u>
1997 - March 2003	

NHS Board		Number of patients not revised	Number of revisions
Glasgow		3526	108
Lothian	3170	3092	78
Grampian	2921	2859	62
Tayside	2516	2442	74
Lanarkshire	1615	1592	23
Ayrshire and Arran	1520	1494	26
Fife	1513	1481	32
Argyll and Clyde	1350	1324	26
Highland	1336	1322	14
Forth Valley	978	963	15
Borders	918	900	18
Dumfries & Galloway	636	633	3
Western Isles	189	187	2
Scotland	22296	21815	481

Figure 32 – NHS Highland: Revision after Primary Hip Replacement ; April 1997 - March 2003



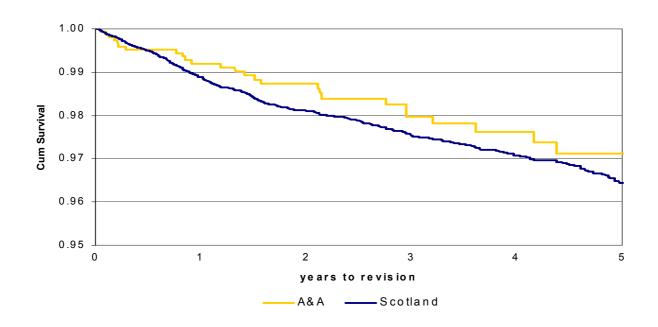
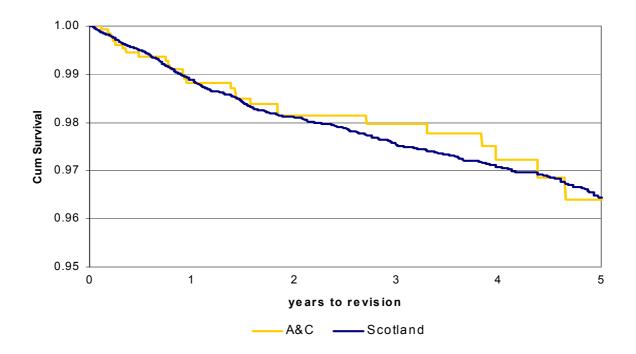
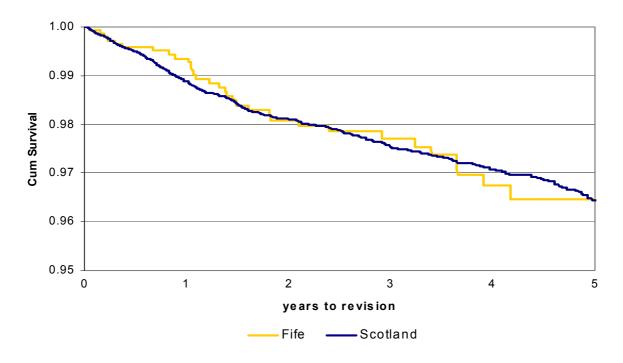


Figure 33 - NHS Ayrshire & Arran : Revision after Primary Hip Replacement ; April 1997 - March 2003

Figure 34 - NHS Argyll & Clyde : Revision after Primary Hip Replacement ; April 1997 - March 2003



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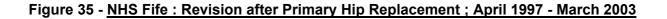
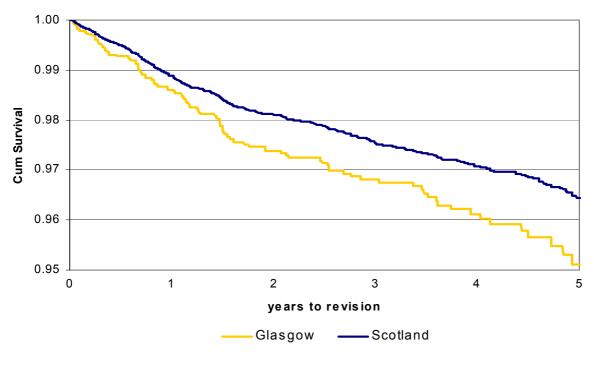
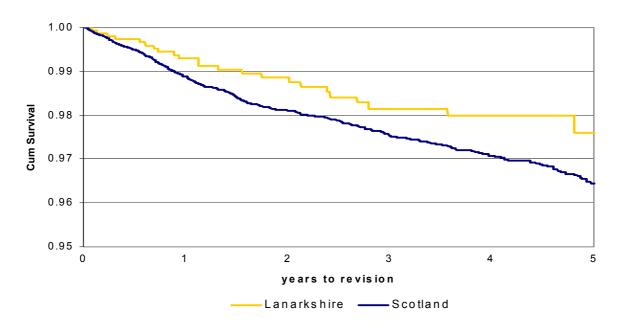


Figure 36 – <u>NHS Greater Glasgow: Revision after Primary Hip Replacement ; April 1997 -</u> <u>March 2003</u>







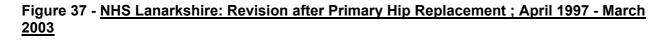
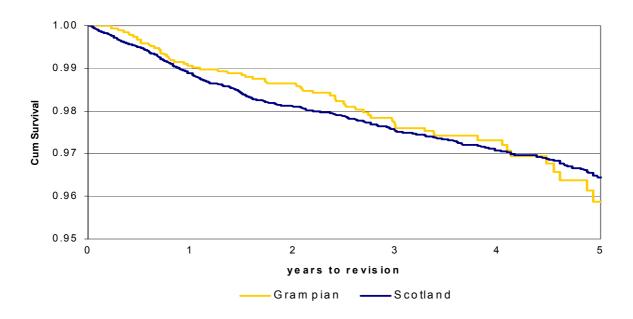


Figure 38 - <u>NHS Grampian: Revision after Primary Hip Replacement ; April 1997 - March</u> 2003



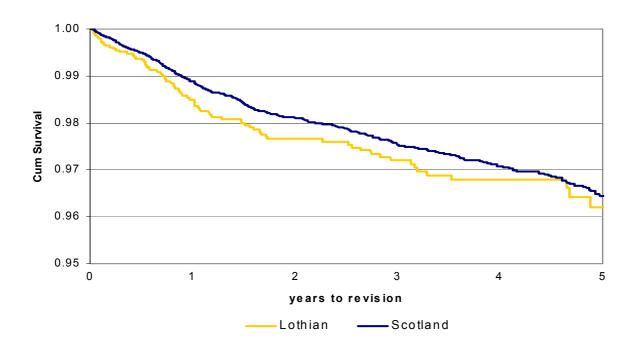
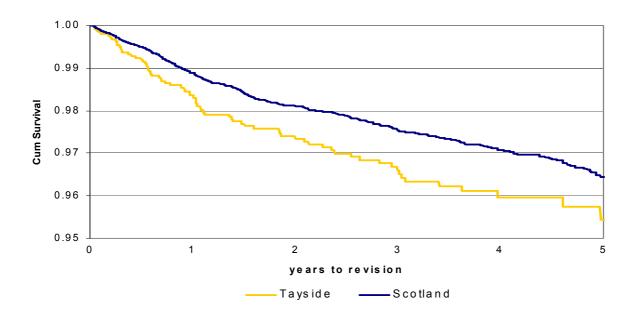




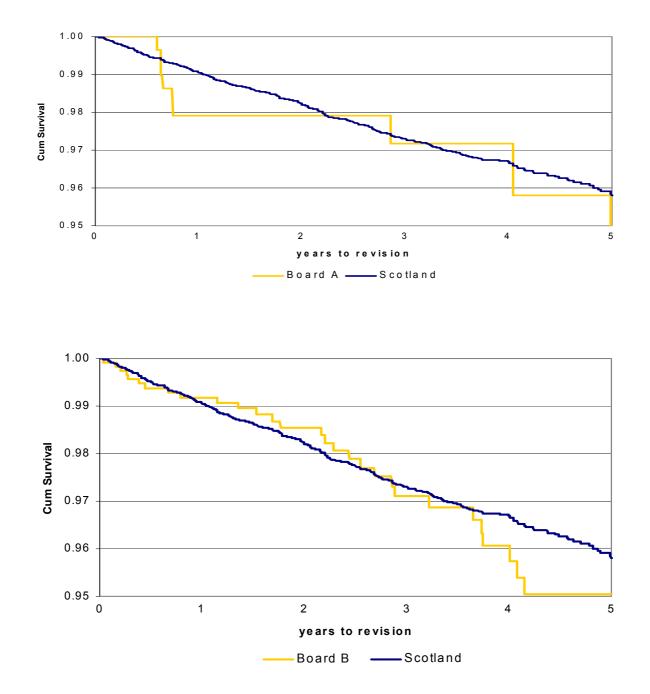
Figure 40 – NHS Tayside: Revision after Primary Hip Replacement ; April 1997 - March 2003

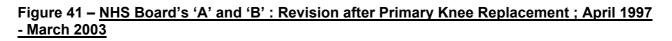


NHS Boards: Survival of Knee Replacements April 1997 – March 2003

For the analysis of primary knee operations at NHS board level, there were very few boards who performed sufficient primary operations to produce a meaningful and reliable analysis. We have therefore include some anonymised survival curves to illustrate the variability found (**Figure 41**).

NHS Board	Number of primary operations	Number of patients not revised	Number of revisions
Glasgow	3165	3078	87
Lothian	2381	2325	56
Grampian	1605	1576	29
Tayside	1678	1640	38
Lanarkshire	1211	1182	29
Ayrshire and Arran	1344	1323	21
Fife	1206	1181	25
Argyll and Clyde	801	782	19
Highland	657	641	16
Forth Valley	824	810	14
Borders	347	338	9
Dumfries & Galloway	306	297	9
Western Isles	62	62	0
Scotland	15587	15235	352





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5.2. Discussion

These results are for all joints replacements carried out in Scotland over 10 years (five years for NHS Board data). The endpoint (failure) is taken as revision for any reason. Unfortunately we cannot be sure as to the cause for revision nor the implant which was revised as we do not have access to those data at present.

When compared directly with equivalent figures from Scandinavia (http://www.jru.orthop.gu.se/) the Scottish results are similar (within statistical and methodological variation). Few countries produce data of this detail to allow comparison. We have included the Log rank statistic to allow significance to be assessed.

The evidence for surgeon volume related outcomes is not clear on the graphs, but patient age at the time of surgery and diagnosis both predict the survival of the implant. This is similar to work produced from the Scandinavian registers. Previous more detailed work on surgeon volumes and outcome reported in 2002's annual report focused on specific complications and surgeon volumes (and supported those figures of Katz et al 2001). The survival graphs presented here may not reflect these detailed issues because of the generally good outcomes following arthroplasty (i.e. the large number of good outcomes heavily outweigh the small number of complications).

Generally quoted scientific papers on implant survival use as their endpoint aseptic loosening and exclude revisions for other reasons, (dislocation, fracture or infection) and therefore the commonly quoted higher survival figures for the implant (used in the advertising literature) are misleading in this context.

Individual consultant results are not available in this format because consultants do not individually perform enough procedures to make the analysis meaningful. Individual unit results may be influenced by case mix (which have not been adjusted for) and implant usage, therefore they should be seen as a tool for audit rather than an absolute value. We have only included those units performing more than 1300 cases during the study period. Indeed, the limited number of knee replacements performed in some units has precluded the publication of the unit knee survival curves until we can review the statistical and case mix issues.

6. Further investigation of complication rates

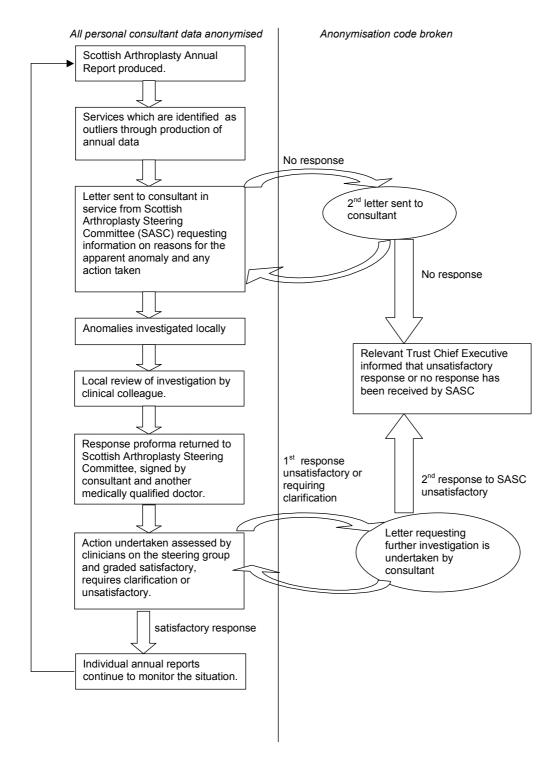
6.1. Background

The 2003 annual report contained control charts for complications following hip or knee arthroplasty. These charts identified consultants and NHS Boards whose complication rates lay outside normal values. The Scottish Arthroplasty Steering Committee (SASC) felt there was a need to investigate these outliers further. Following approval from the Scottish Orthopaedics and Trauma Committee (SCOT), it was agreed that these outlying figures should be reviewed under the umbrella of clinical governance, with the emphasis on quality improvement and not on attributing blame.

SAP provided consultants and NHS Boards with relevant case lists to allow them to investigate their outlying data. A process was set up for the review of these data as outlined in the flowchart (Figure 42). Consultant and patient anonymity was maintained throughout the process, with only one member of the ISD staff having access to named data for administrative purposes. The consultants and NHS Boards were asked to return an action plan, detailing the investigations they had undertaken and any action taken as a result.

Scottish Arthroplasty Project Annual Report 2004

Figure 42 - Flowchart to Illustrate the Procedure for Reviewing Consultant Data Outwith Normal Variation



6.2. Outlying Consultant and NHS Board data

6.2.1. Consultant Data

From the seven control charts presented for individual consultants in the 2003 annual report, 33 consultants were identified as having outlying data. The elimination of consultants who had retired or moved outwith Scotland reduced the outlying number to 17. It was decided to concentrate on the charts for dislocation, infected prosthesis and revision and not to follow up those for deaths, as the Scottish Audit for Surgical Mortality (SASM) reviews every death following elective surgery. This meant that 15 consultants remained outliers. These 15 consultants were written to and asked to return an 'action plan' co-signed by a senior colleague (appendix 5) to the SAP Committee for review.

Role of the co-signatory

The co-signatory gives the arthroplasty project evidence of:

- local knowledge of the situation other than from the originating surgeon;
- local action being taken (if necessary by other than the originating surgeon); and
- local ownership and responsibility for the data.

Outlying data were often the result of data quality and case mix, and these explanations were wholly acceptable. The purpose of using the control charts to identify outliers was not to extrapolate that the clinical practice of these consultants was in question; the purpose was to use these figures as a starting point for local investigation into the reasons for the outlying data, with emphasis placed on systems and processes of care and not just individual practice.

All 15 consultants returned an action plan, and the review committee (a clinical sub-group of the Steering Committee) reported that the majority of the replies were of a high standard. Several consultants pointed out that the data contained inaccuracies, and consultants were asked to pass corrections to their hospital clinical coding departments so that records could be appropriately amended and resubmitted to ISD. The majority of these inaccuracies were in the coding of the data at the hospital, rather than in the analysis of the data. Table 4 details the content of the responses in the returned action plans (each action plan may contribute to more than one theme).

Theme	Number
Data incorrect in some way (of which two placed the individual above the	7
upper control limit)	
Local medical records department asked to correct SMR01 records	4
Consultant to implement change in practice	4
Consultant no longer performing elective hip or knee surgery (stopped	2
prior to receiving information from arthroplasty project)	
Problems already identified locally and change implemented	2
Case mix issues	3

Table 4 – Themes identified through action plans

The action plans returned by the individual consultants were reviewed by a clinical sub-group of the Steering Committee, and a response returned to each consultant concerned, with a copy being sent to each cosignatory. Several pertinent points were raised by the replies, and these have led to some further investigation of the dataset (see section 6.2.3 below).

6.2.2. NHS Board Data

From the eight control charts presented for NHS board areas in the 2003 annual report, four NHS boards were identified as having outlying data in a total of seven points. The chief executives from each board were written to and asked to ensure that the orthopaedic service reviewed the data and returned an action plan, signed by the chief executive. Each consultant whose data contributed to the outlying point were sent patient listings so that the data could be investigated. Data belonging to consultants who had left the board or retired were sent to the chief executive. Only one of the NHS boards replied in the time requested, and the data were resent to the remaining three boards in February 2004.

6.2.3. Further investigation

- Do rheumatoid arthritis sufferers have a higher than average rate of prostheses infection following joint replacement?
- Do patients receiving an elective hip replacement following a fractured neck of femur have a higher dislocation rate than average?

Infected prosthesis rates in patients suffering from rheumatoid arthritis

Analysis of hip and knee joint replacements carried out between April 1997 to March 2002 was carried out to investigate the rate of infection in patients suffering from rheumatoid arthritis. The results can be seen in Table 5. The rate of infection in patients diagnosed with rheumatoid arthritis does not appear to differ significantly from the rate for all patients. Espehaugb et al have shown that revision due to infection is more common amongst diabetics, patients taking steroids, male patients, high alcohol intake and those doing heavy work. This may well explain why there is no difference in the rates in Table 5 based on rheumatoid arthritis diagnosis only.

Groups	total operations	infected prosthesis within 365 days	% infected prosthesis
All Patients			
Hip arthroplasty	19581	294	1.5
Knee arthroplasty	14445	224	1.5
Rheumatoid Arthritis			
Hip arthroplasty	847	9	1.1
Knee arthroplasty	1278	23	1.8

 Table 5 – infected prosthesis rates

The Pan Celtic Collaborative Orthopaedic Surgical Site Infection Surveillance Report 2001-2003 was produced through the collaboration of the Northern Ireland Healthcare Associated Infection Surveillance Centre, the Scottish Surveillance of Healthcare Associated Infection Programme and the Welsh Healthcare Associated Infection Programme. This report indicated that the surgical site infection (SSI) rate within 30 days is 1.4% for patients undergoing a hip replacement and 1.1% for patients undergoing a knee replacement. The report estimated that 19.4% of these hip infections and 21.2% of these knee infections are deep, (the rest being superficial wound infections) making the deep SSI rates 0.27% and 0.23% respectively. The higher rates calculated by the Scottish Arthroplasty Project using the SMR01 dataset are probably due to the longer time period of follow-up of the patients. There is also evidence from the previous STAG audit that infections may be cautiously identified as deep infections, coded as such, but later identified as superficial infections.

The dislocation rate for patients having an elective hip replacement following a fractured neck of femur is still under investigation.

6.3. The effect of case mix on control charts

In this year's and last year's report control charts have been presented to illustrate complication rates for consultants (Scottish Arthroplasty Annual Report 2003, sections 2.5.3, 2.5.4). The complication rates have been presented without standardisation for case mix. Investigatory work was undertaken in 2003/2004 to examine the effect of standardising the data; would standardisation have an affect on the number and/or identity of the consultants identified as outliers?

6.3.1. Method

For simplicity, it was decided to use only two of the consultant data analyses performed in 2003 in the investigation of case mix;

infected prosthesis at 365 days following hip replacement and dislocation at 365 days following hip replacement.

Both of these analyses are based on patients undergoing a hip replacement between March 1996 – April 2001.

Logistic regression was performed to identify which factors had a significant influence on a patient developing a particular complication. Using the statistical package SPSS, all the available variables which were thought to have an influence on whether a patient developed a complication or not were fitted to the regression model. These variables were all derived from the SMR01 episode in which the patient underwent a hip replacement. They are;

age;

sex;

admission to hospital from home or another place of residence (e.g. nursing home);

whether or not they suffered from osteoarthritis;

whether or not they suffered from rheumatoid arthritis; and

deprivation category.

Table 6 illustrates which variables were found to significantly influence (at the 10% level) whether or not a patient is likely to suffer a complication. A significance level of \leq 0.1 (10%) demonstrates that the probability of a variable affecting the outcome by chance only is relatively low. Therefore, those variables with a significance of \leq 0.1 affect a patient's chances of developing a complication.

Variable	Significance level			
	Infected Prosthesis - 365 days	Dislocation - 365 days		
Age Group (≤ 60 and ≥ 61)	0.70	0.19		
Age Group 2 (10-year age bands)	<0.0001	<0.0001		
Sex	<0.0001	0.05		
Deprivation category	0.91	0.38		
Admission from home	<0.0001	<0.0001		
Osteoarthritis	<0.0001	<0.0001		
Rheumatoid Arthritis	<0.0001	<0.0001		

Table 6 – V	Variables	influencing	complication rates
-------------	-----------	-------------	--------------------

This process (logistic regression) essentially identified which factors had an influence on a patient developing a particular complication. A separate process – indirect standardisation - is then used to adjust for case mix. There are two main methods of standardisation: direct and indirect. Direct standardisation is often the preferred method, especially in epidemiological contexts. However, in the context of case mix adjustment it has one overwhelming drawback. Direct standardisation is inadvisable if the number of cases in any of the combinations of the variables used to standardise is small. Thus if one is standardising for age, sex and deprivation and there is a possibility of very low numbers in any combination of the age, sex and deprivation categories, direct standardisation should be avoided. For a full explanation of indirect standardisation, please see annex 7 of the 2002 Scottish Clinical Outcome Indicators Report:

http://www.show.scot.nhs.uk/indicators/Outcomes/OutcomesReport2002.pdf .

In this analysis, the control charts look slightly different from the shewhart charts plotted last year and in sections 5.1.4 - 5.1.7 this year. The standardised rates are plotted on control charts and are often called 'funnel plots' (as they have a funnel shape to them). The charts have this appearance as the complication *rates* are plotted rather than the actual *numbers* of complications occurring. The rates have to be plotted as it is not possible to standardise actual numbers without converting them into rates.

6.3.2. Results

Figure 43 - Standardised rates: Consultant Surgeon Data for Infected Prosthesis within 365 days of elective hip replacement (April 1996 – March 2001)

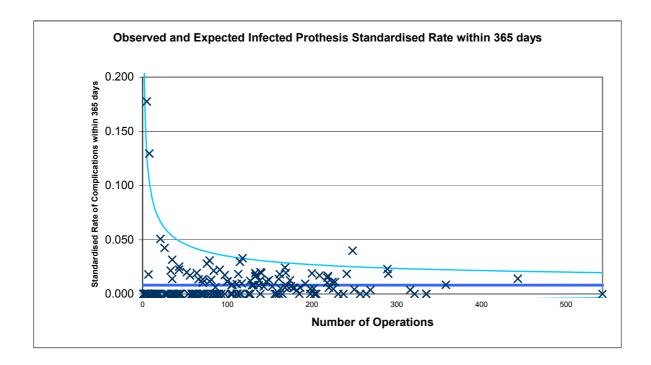
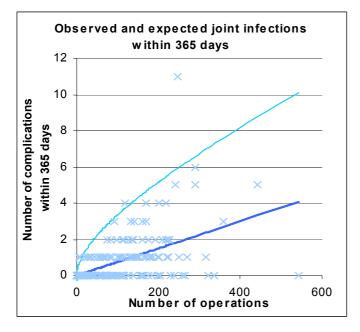


Figure 44 - Crude rates: Consultant Surgeon Data for Infected Prosthesis within 365 days of elective hip replacement (April 1996 – March 2001)



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Figure 45 - Standardised rates: Consultant Surgeon Data for Dislocations within 365 days of elective hip replacement (April 1996 – March 2001)

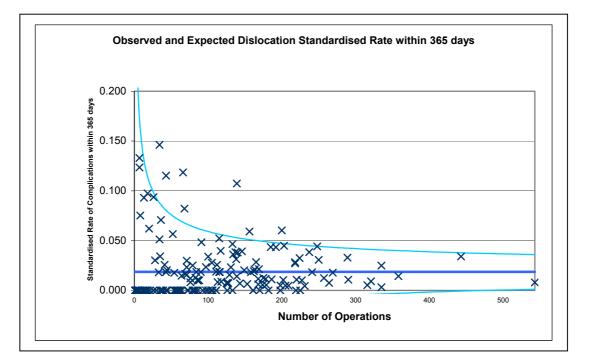
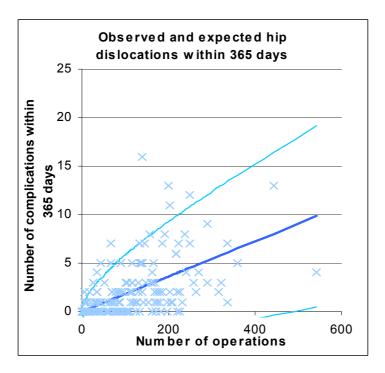


Figure 46 - Crude rates: Consultant Surgeon Data for Dislocations within 365 days of elective hip replacement (April 1996 – March 2001)



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Table 7- Numbers of outlying consultants

Type of analysis	Number of outliers: Infected Prosthesis 365 days	Number of outliers: Dislocations 365 days
Crude rates	5	12
Standardised rates	4	8

Table 7 shows that standardisation reduced the numbers of outliers for both complications. The consultants who are outliers on the standardised control charts (Figure 43 and Figure 45) are also outliers on the original crude rate control charts (Figure 44 and Figure 46). i.e. no new consultants were identified as outlying through standardisation.

The initial attempt at case mix analysis in sections 5.1.4 and 5.1.5 was fairly crude, as a particular patient group (i.e. patients 60yrs old and over suffering from osteoarthritis) was selected and their outcomes investigated. Subdivision of cases as a way of doing case mix analysis eventually leads to relatively small numbers in each group being investigated. Where patient factors are shown to contribute to the future development of complications, it must be ensured that those patients at greater risk of complication are not denied surgery because they may alter the complication rates of a unit or individual surgeon. Using standardisation means that the patient group doesn't have to be subdivided; the influence of different factors on a patient's outcome are instead adjusted for by standardisation. This year the analysis is based on the un-standardised control charts for consistency with the approach used in 2003. The standardised charts will hopefully be introduced in future reports.

7. Other current work

7.1. English and Welsh National Joint Register

In April 2003, a national joint registry was launched in England and Wales. The aim of this registry is to collect data pertaining to hip and knee replacements, including detailed information about the types of prosthetic joint implants used. At present the Scottish Arthroplasty Project does not collect these data, but ultimately the Scottish data will be added to the English and Welsh data.

SAP uses routinely collected SMR01 data to monitor hip and knee arthroplasty in Scotland. Presently all Scottish data are collected using existing systems (the England and Wales system uses a separate and dedicated data gathering system). Rather than start a new data collection, it was decided to build on the current data collection to include more detailed operation and prosthesis information by importing information gathered in theatre management systems or routine local audit systems. In March 2003, the Scottish Trauma Audit Staff (STAG) carried out a scoping study to investigate the feasibility of collecting these extra data from hospital theatre systems. Details of this study can be seen in appendix 6.

Following this study, SAP decided that a data collection system would be piloted in two/three hospitals in April 2004, with a view to rolling out this system across Scotland over the year. A dataset has been developed which is based on the English and Welsh National Joint Registry dataset (appendix 7). The dataset contains additional clinical information, and once linked to the SMR01 will produce a powerful and detailed dataset containing all the data items needed for a National Joint Register.

7.2. Website

In January 2004, the Scottish Arthroplasty Project (SAP) launched a website for the project. The principle aims of the site are;

- to provide an information point about SAP for all those involved in care of arthroplasty patients in Scotland; and
- to provide an information resource about SAP for patients and the public.

The site contains;

- summary information about the work of SAP;
- information for patients about arthroplasty and the possible complications following surgery;
- a list of questions patients may wish to put to their consultant;
- copies of annual reports and other papers produced by the project;
- links to other related websites; and
- a facility to e-mail feedback to SAP.

The website can be viewed at www.show.scot.nhs.uk/arthro .

7.3. Future Work

The work of SAP has grown considerably over the past year, and the project has expanded to include undertaking various pieces of developmental work.

A large part of the project's resources in the coming year will be devoted to the development of a Scottish National Joint Registry (see section 7.1). Aside from this project, SAP will continue to develop the clinical governance work in monitoring and following up those consultants and health boards whose complication rates are higher than expected (see section 6). We have been heartened by the decision of the Scottish Society of Anaesthetists to join us in the project exploring the outcomes following Arthroplasty and look forward to developing this section in future reports.

8. Appendices

8.1. Appendix 1 – Consent and Confidentiality

Consent

Consent issues for patients and participants have been discussed and opinion has been widely canvassed. The SMR01 dataset is firmly embedded in the administrative structure of NHSScotland and is used for audit and demographic description. Specific written consent is not formally required provided the rules for confidentiality and anonymity are rigorously applied. However, we have a duty to inform patients that this process is being carried out and that they have the right to refuse to take part. Trusts have already begun providing generic information to patients about this. As part of the evolving process a poster to inform patients about the Scottish Arthroplasty Project is available for orthopaedic departments to download from the SAP website.

Confidentiality

Throughout the process, no identifiable data linkable to individual consultant surgeons has been produced or reviewed outside ISD. Only the consultant surgeon concerned has the right to review these data in line with the guidelines on data access which apply equally to the patient and consultant surgeon. Other than one member of the ISD staff, no-one in the project has access to individually identifiable data and therefore cannot comment or release information on individuals. While this should reassure participants it also places considerable responsibilities on consultant surgeons to respond to the data supplied. It must be pointed out that the relatively small size of the consultant orthopaedic community in Scotland may occasionally make absolute anonymity difficult.

8.2. Appendix 2 - Distribution of Orthopaedic Consultants Across Scotland

In this report data covering the time period April 1997 to March 2003 are used. As at May 2003, there were 156.2 whole time equivalent (WTE) orthopaedic consultant posts in Scotland, filled by 163 orthopaedic consultants. 12 of these posts were vacant, with 5 of these vacant posts being temporarily filled by a locum consultant. These figures may seem confusing, however, each year some consultants retire and their place is taken by another which results in two consultants filling one post. In addition, one unfilled post may be filled by a number of locum consultants within the year. The data show that during the months of April and May 2003, 165 orthopaedic consultants performed elective hip and knee joint replacements. Table 8 illustrates the distribution of orthopaedic services around Scotland.

Health Board	Hospital	Total number of posts		Vacant (filled by locum)
NHS Grampian	Aberdeen Royal Infirmary and Woodend Hospital	14	12.5	1
NHS Highland	Dr Gray's	3	2.7	
	Raigmore Hospital	8	8	
NHS Western Isles	Western Isles Hospital	2	2	2(1)
NHS Tayside	Ninewells Hospital	12	10.5	
	Perth Royal Infirmary	5	5	
NHS Lothian	Royal Infirmary Edinburgh	6	4.3	
	New Royal Infirmary Edinburgh and RHSC Edinburgh	12	10.7	
	St John's Hospital	5	5	
NHS Borders	Borders General Hospital	4	4	
NHS Fife	Queen Margaret Hospital and Victoria Hospital	7	7	
NHS Forth Valley	Stirling Royal Infirmary	5	5	1
	Falkirk and District Royal Infirmary	4	4	
NHS Dumfries and Galloway	Dumfries and Galloway Royal Infirmary	5	5	
NHS Ayrshire and Arran	Crosshouse Hospital	6	6	
	Ayr Hospital	5	5	
NHS Greater Glasgow	Glasgow Royal Infirmary	9	9	1
	Western Infirmary	9	8.5	
	Victoria Infirmary	5	5	
	Southern General Hospital	5	5	1
	RHSC Yorkhill	5	5	
NHS Inverclyde	Inverclyde Royal Hospital	5	5	1
	Royal Alexandra Hospital	6	6	1(1)
NHS Lanarkshire	Wishaw General Hospital	5	5	1(1)
	Monklands General Hospital	5	5	1
	Hairmyres Hospital	5	5	2(2)
Golden Jubilee National Hospital	Golden Jubilee National Hospital	1	1	
Scotland	Total	163	156.2	12(5)

Table 8 - Distribution of orthopaedic consultants across Scotland as at 30/09/2003

Data source: ISD Scotland workforce statistics

8.3. Appendix 3 – Committee Structure

The Project is overseen by the Scottish Committee for Orthopaedics and Trauma (SCOT), who elect a chair for the Project. The Project is then managed by the Scottish Arthroplasty Steering Committee, whose membership is as follows;

Mr Colin Howie, Orthopaedic Consultant, Chair; Mr Arthur Espley, Orthopaedic Consultant; Mr David Allan, Orthopaedic Consultant; Dr David Semple, Anaesthetic Consultant; Miss Harriet Hughes, ISD project co-ordinator; Mr Graham Mitchell, ISD senior programme lead; Dr Rod Muir, ISD Consultant in Public Health; Ms Christine Allen, Private hospitals representative; Ms Angela Donaldson, patient representative; and representative of the Scottish Association of Medical Directors acting in advisory capacity where necessary.

The orthopaedic consultants sitting on the Steering Committee, including the Committee chair, are nominated by the SCOT Committee and the organisational representative is nominated by the Scottish Association of Trust Medical Directors. The term of office for all nominees is 3 years, with an option to renew this term once. This does not apply to committee members who are not nominated, i.e. ISD staff.

Other health professionals (eg anaesthetists, nurses, physiotherapists) will be invited to join the steering committee as outcome indicators develop for areas of care to which these professions directly contribute.

The function of the Steering Committee is to plan the medium and long term strategy of the Project under the direction of SCOT. The Committee also directs the clinical content of the annual report and of any other data analyses produced and manages the clinical governance aspect of the Project. The Committee also provides clinical advice and guidance to the Scottish Arthroplasty

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Management Group whenever needed. The Management Group is responsible for the day to day running of the arthroplasty project.

The Scottish Arthroplasty Management Group reports to the Steering Committee. Its membership is as follows;

Mr Colin Howie, Orthopaedic Consultant; ISD staff;

- Dr Rod Muir, Consultant in Public Health Medicine;
- Mr Tim Varley, data intelligence group representative;
- Ms Katy Duff, data analyst;
- Miss Harriet Hughes, project co-ordinator;
- Mr Graham Mitchell, senior programme lead (chair); and
- Mr Tommy Pearson, IT representative (as required).

The Management Group meets monthly and is responsible for the operational management of the Project, including the production of the annual report and the quarterly patient listings produced for consultants.

8.4. Appendix 4 – Funding and Staffing

SAP is currently funded by the Common Services Agency (CSA). In 2003/2004, the project received £104 000. This money is principally to establish and run a Scottish National Joint Registry.

The project is managed on a day to day basis by staff at the Information and Statistics Division, which is a division of the CSA. Two whole time equivalents are dedicated to SAP, with input from several other members of ISD staff on a consultative basis. The clinical lead and chair of the project is a consultant orthopaedic surgeon and two further consultant orthopaedic surgeons sit on the steering committee, which meets three times per year. A member of the public and a representative from the private hospitals sector also contribute by sitting on the Steering Committee.

8.5. Appendix 5 – Action Plan

Scottish Arthroplasty Project:

Action Plan resulting from the identification of data outwith normal variation

Name Mr AN Other		
GMC 9999999]	

Outlier Indicator: dislocations within 365 days following hip arthroplasty Number of hip arthroplasties that you performed: 40 Number of expected dislocations for 40 cases: 1 +/- 2.33 Your value for 40 cases: 5 dislocations, which is greater than the upper control limit of 3.33

Comments concerning quality of information received from Scottish Arthroplasty Project pertaining to cases forming outlying data:

Have corrections been made to SMR01 records at a local level? Y/N

ve these corrections been forwarded to ISD? Y/N

Action Plan following review of cases (please continue on separate sheet if necessary).

Signed:

Co-signed:

(This signatory must be a GMC registered doctor with whom you have discussed this information and who will confirm what actions have been taken. This colleague may be your medical manager, medical director or a senior colleague and need not be employed within your Trust.)

The GMC of the co-signatory will be required on the action plans for 2004

8.6. Appendix 6 - Audit of Hospital Theatre Systems: Summary

Theatre systems

Theatres at 24 hospital sites in Scotland which carry out arthroplasty surgery were audited. Of these 24, 21 have electronic theatre management systems in which patient information is recorded. About half of these systems have been developed in-house, and half are commercial systems. Six different bought systems are in use (Table 9).

Table 9

Theatre system used	Source of theatre system		
	In-ho	useBought	Bought & customised
ORSOS		3	
RES 2			1
Theatre Management System	3		
PETS (Patient Electronic Theatre	1		
System)			
TheatreMan		2	
Sapphire		2	
GALAXY		1	
Hospital Utilisation System	1		
SASHA		1	
OASIS		1	
Not specified	3		
Stand-Alone	2		
total	10	10	1
No theatre system	3		

Data extraction

Data could be electronically extracted from 17 of the 24 theatres.

Data entry into theatre systems occurs in real time at 11 sites. The delay in data entry at the remaining 10 sites with a theatre system varies from 1 day to 7 - 8 weeks (Table 10).

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Table 10

Delay (days)	No. of sites
1	2
2 -4	2
2 -4 5 - 7	3
53	1
Not specified	2
Total	10

Data correctness

Table 11

% forms completed correctly	no. of sites
25	1
60	2
60 65 70	1
70	1
75	2
80	1
90	3
98	1
99.9	1
100	1
missing	10 24
total	24

Staff were asked about the correct completion of forms used to collect the data entered into theatre systems. This question was answered by 14 sites, who estimated that forms are correctly completed between 25 - 100% of the time (Table 11).

At 15 sites, there is some kind of mechanism in place for checking and amending incorrect information, either before entry onto the system or within the theatre system.

At the majority of sites, it is a combination of staff who complete theatre forms or enter information into the theatre system (Table 12). This includes;

- administrative staff;
- coding staff;
- nurses;
- operating department staff; and
- doctors.

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Table 12

	Number of hospitals at which this grade of staff fills in form
Nurse	20
Doctor	8
Op. dept staff	11
Sec staff	7
Other	4

The minimum dataset

A minimum dataset has been created for an English and Welsh National Joint Registry. In Scotland, a large number of the data fields in this dataset are collected from SMR01. The scoping study set out to discover if the 10 fields from the dataset that are not present on SMR01 could be extracted from existing theatre systems.

The 2 hospitals with stand alone systems and the hospitals without systems did not answer whether they could add the data fields to their existing system. Implant details are currently entered into 2 systems, and 10 of the remaining sites indicated that they could add implant information to their existing system (Table 13).

Table 13	le 13
----------	-------

data field	extractable at present			If not, could be added				
	Yes	No	Some- times		No	Not recorded	Don't know	No answer
Identity of lead surgeon		5						5
Grade of lead surgeon	13	11		3	3			5
Grade of first assistant	13	11		2	4			5
Implant manufacturer	2	22		10	6	1		5
Implant cat. no. &								
model	1	23		9	6	1	1	6
Implant batch/lot no	2	22		10	6	1		5
ASA grade	14	9	1	1	3			5
Type of anaesthetic	16	8		1	2			5
Anaesthetic times	16	8		1	2			5
Operation times	17	7		1	1			5

If sites could not add the data to their existing systems, the majority of information is to be found in written form; either in a theatre book, in case notes, on an operation list or held by the arthroplasty nurse.

Private patients

Table 14

Private	Number
patients	of sites
entered	
No	10
Yes	10
Maybe	1
Not	3
answered	
total	24

Under half of the sites enter information about private patients (Table 14). It would be useful if all hospitals could enter this information, as it is vital to gaining more complete picture of arthroplasty in Scotland .

Scottish dataset					
Position From To	Data Item	Size	Field type	description	Definition (if nationally agreed definition exists)

8.7. Appendix 7 – Proposed National Joint Registry Dataset for Scotland

Episode record key	11	Numeric	Single key to identify uniquely the patient episode	
Sending location	5	Alphanumeric in format ANNNA	Location code where these data was sent from	
CHI number	10	alphanumeric		The Community Health Index (CHI) is a population register which is used for health care purposes. The CHI number uniquely identifies a person on the index. Definitions and Codes Manual, 6th Update, April 2002
Hospital Patient Identifier	10	alphanumeric	Case Reference Number from hospital of treatment	The hospital patient identifier is a code which uniquely identifies a patient on the main index of a hospital (i.e. within the hospital health records system). Definitions and Codes Manual, 6th Update, April 2002
Surname	20	text	minimum of 2 characters	The surname of a person represents that part of the name of a person which indicates the family group of which the person is part. Definitions and Codes Manual, 6th Update, April 2002
1st Forename	35	text	minimum of 1 character	The first forename of a person represents that part of the name of a person which after the surname, is the principal identifier of a person. Definitions and Codes Manual, 6th Update, April 2002
Sex	1	numeric	0 – not known	(ISO Standard)

Scottish dataset	Joint Registry	Maximum Record Size =			
Position From To	Data Item	Size	Field type	description	Definition (if nationally agreed definition exists)

			1 – Male 2 - female 9 - not specified	Sex not known - The sex of the person is not provided in the personal details i.e. the data have not been supplied and sex cannot be ascertained from the data provided. Sex not specified - The sex of the person cannot be determined for physical reasons, e.g. a new born baby. Definitions and Codes Manual, 6th Update, April 2002
Date of Birth	8	numeric	yyyymmdd	Field length 1.Year 4 2.Month 2 3.Day 2 Date Interchange Standard is YYYYMMDD. Definitions and Codes Manual, 6th Update, April 2002
Postcode	8	alphanumeric	Minimum 8 characters	The postcode is a basic unit for identifying geographic locations. A postcode is associated with each address in the UK. A postcode has two component parts. Part one of the postcode is known as the outcode, and part two is known as the incode. Outcode The outcode identifies the postal area and the postal district. The postal area is represented by 1 or 2 alpha characters and the postal district is represented by 1 or 2 digits. Therefore, part 1 contains 2, 3 or 4 characters. Incode The incode is of length 3 characters. The postcode

Scottish dataset	Joint Registry	Maximum Record Size =			
Position From To	Data Item	Size	Field type	description	Definition (if nationally agreed definition exists)

Date of operation	8	numeric	yyyymmdd	sector is represented by the outcode plus the first digit of the incode. The complete postcode represents the postman's walk. Definitions and Codes Manual, 6th Update, April 2002 Field length 1.Year 4 2.Month 2 3.Day 2 Date Interchange Standard is YYYYMMDD. Definitions and Codes Manual, 6th Update, April 2002
Type of theatre list	1	numeric	Coded list 1 - Emergency immediately life/limb threatening ; must be done within 2 hrs of decision to operate 2 - Urgent; within 24hrs of emergency admission 3 - Scheduled urgent; within 7 days of decision to operate 4 - Elective; all other planned surgery	

Scottish dataset	Joint Registry	Maximum Record Size =			
Position From To	Data Item	Size	Field type	description	Definition (if nationally agreed definition exists)

	1	1	
ASA grade	1	numeric	 1 - Fit and well 2 - Mild systemic disease 3 - Severe systemic disturbance 4 - Life threatening disease 5 - Not expected to survive 24 hours
Anaesthetic start time	4	numeric	24hr clock - hhmm
General anaesthetic	1	numeric	1-yes 0-no
Spinal Anaesthetic	1	numeric	1-yes 0-no
Epidural	1	numeric	1-yes 0-no
Peripheral nerve block (excluding infiltration)	1	numeric	1-yes 0-no
IV sedation given in theatre (excludes routine pre-operative medication)	1	numeric	1-yes 0-no
Lead anaesthetist	7	alphanumeric	GMC
Grade of lead anaesthetist	2	number	1 - Consultant 2 - SpR Years 5-6 3 - SpR Years 1-4 4 - SHO 5 - Staff grade or Associate specialist

Scottish dataset	Joint Registry	Maximum Record Size =			
Position From To	Data Item	Size	Field type	description	Definition (if nationally agreed definition exists)

Consultant responsible for care	8	alphanumeric	GMC	The health professional responsible for care (HCP) is the person who carries clinical responsibility for a patient's healthcare during an episode. Definitions and Codes Manual, 6th Update, April 2002
Grade of assisting anaesthetist	2	number	 6 - locum consultant 7 - locum SpR years 5-6 8 - locum SpR years 1-4 9 - locum SHO 10 -locum Staff grade or Associate specialist 11 - part of a visiting anaesthetic team 1 - Consultant 2 - SPR Years 5-6 3 - SPR Years 5-6 3 - SPR Years 1-4 4 - SHO 5 - Staff grade or Associate specialist 6 - locum consultant 7 - locum SpR years 5-6 8 - locum SpR years 1-4 9 - locum SHO 10 -locum Staff grade or Associate specialist 11 - part of a visiting anaesthetic team 	

Scottish Joint Registry dataset		Maximum Record Size =			
Position From To	Data Item	Size	Field type	description	Definition (if nationally agreed definition exists)

Lead scrubbed operating surgeon	8	alphanumeric	GMC	 This is the identification code of the clinician responsible for the procedure. For a doctor, it is the GMC Registration Number; for other health professionals, it is the unique identification number issued by the controlling authority of that discipline. The code entered may not necessarily be the code of the consultant responsible for the episode of care. SMR Data Manual, Version 1.3, November 2000
Grade of lead scrubbed operating surgeon	2	number	Coded list: 1 - Consultant 2 - SpR Years 5-6 3 - SpR Years 1-4 4 - SHO 5 - Staff grade or Associate specialist 6 - locum consultant 7 - locum SpR years 5-6 8 - locum SpR years 1-4 9 - locum SHO 10 -locum Staff grade or Associate specialist 11 - part of a visiting surgical team	
Grade first surgical assistant	2	number	coded list (same as lead scrubbed operating surgeon above) plus 12. non medically	

Scottish Joint Registry dataset		Maximum Record Size =			
Position From To	Data Item	Size	Field type	description	Definition (if nationally agreed definition exists)

			qualified practitioner	
Operation start time Knife to skin	4	number	hhmm - 24hr clock	
principal operation (a)	4	Alphanumeric	OPCS4 codes	
principal operation (b)		Alphanumeric	OPCS4 codes	
Laterality of procedure	1	number	1 - Left 2 - Right 3 - bilateral	
Implant manufacturer –implant part 1			Code list to be supplied	
Implant cat no and model – implant part 1			Code list to be supplied	
Implant manufacturer –implant part 2			Code list to be supplied	
Implant cat no and model – implant part 2			Code list to be supplied	
Implant manufacturer –implant part 3			Code list to be supplied	
Implant cat no and model – implant part 3			Code list to be supplied	
Implant manufacturer –implant part 4			Code list to be supplied	
Implant cat no and model – implant part 4			Code list to be supplied	
Implant manufacturer - implant part 5			Code list to be supplied	
Implant cat no and model – implant part 5			Code list to be supplied	
Implant manufacturer –implant part 6			Code list to be supplied	
Implant cat no and			Code list to be supplied	

Scottish Joint Registry dataset		Maximum Record Size =			
Position From To	Data Item	Size	Field type	description	Definition (if nationally agreed definition exists)

model – implant part 6				
Implant manufacturer –implant part 7			Code list to be supplied	
Implant cat no and model – implant part 7			Code list to be supplied	
Implant manufacturer –implant part 8			Code list to be supplied	
Implant cat no and model – implant part 8			Code list to be supplied	
Implant manufacturer –implant part 9			Code list to be supplied	
Implant cat no and model – implant part 9			Code list to be supplied	
Implant manufacturer –implant part 10			Code list to be supplied	
Implant cat no and model – implant part 10			Code list to be supplied	
Intra-operative blood loss (mls) recorded during procedure	4	number	number	
Time out of theatre Time that the patient leaves theatre and enters recovery	4	number	hhmm - 24hr clock	

Fi	Fields recommended for inclusion. The following fields will not be initially collected, but it is							
foreseen that they will become part of the minimum dataset in two years time.								
	Time patient arrived in	4	hhmm - 24hr clock	numeric				
	anaesthetic room							
	Time patient taken	4	hhmm - 24hr clock	numeric				

Scottish Joint Registry dataset		Maximum Record Size =			
Position From To	Data Item	Size	Field type	description	Definition (if nationally agreed definition exists)

into theatre			
End of operation – time drapes removed from patient	4	hhmm - 24hr clock	numeric
Time out of recovery Time the patient leaves recovery, or if remaining in recovery for any reason other than a clinical reason (e.g. no ward bed available), the time that the patient's care changes and they are no longer monitored according to local recovery monitoring protocols.	4	hhmm - 24hr clock	numeric
Destination of patient on leaving recovery	1	Coded list: 1 - Ward 2 - HDU 3 - ITU 4 - Died in theatre 5 - Transferred to another hospital	numeric
HDU care delivered in recovery	1	1 – yes 0 - no	numeric
Incident occurred in theatre - An event or circumstance which could have, or did lead	1	1 – yes 0 - no	numeric

Scottish Joint Registry dataset		Maximum Record Size =			
Position From To	Data Item	Size	Field type	description	Definition (if nationally agreed definition exists)

to unintended and/or unnecessary harm to a person, and/or a complaint, loss or damage.			
Type of incident	1	Surgical – 1 Anaesthetic – 2 Nursing - 3 Process – 4 (eg delay in leaving theatre as no available ward beds)	numeric

Further Notes

- The codes for implant details will be supplied by the National Joint Registry for Scotland, and will be made electronically available to each site.
- The data set will be collected for every patient who undergoes a hip or knee replacement or a hip or knee revision operation.
- It is planned that the data will be collected from each hospital as a CSV file(comma separated file) and submitted to ISD electronically once a month via a secure web-based system.
- The data can hopefully be collected through the adaptation of an existing electronic data collection system that each hospital uses, be it the local theatre system or an arthroplasty audit database.

8.8. Appendix 8 – References

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8.9. Appendix 9 – Glossary

Arthroplasty	Surgical remodelling of a diseased joint. To prevent the ends of the bones joining together after the operation, a large gap may be created between them (gap or excision arthroplasty), a barrier of artificial material may be inserted (interposition arthroplasty), or one or both of the bone ends may be replaced by a prosthesis of metal or plastic (replacement arthroplasty). This operation may replace both joint surfaces (total arthroplasty) or only one (hemiarthropalsty).
Complication	Unexpected event arising as a result of an operation.
Deep Vein Thrombosis (DVT)	A blood clot blocking the deep veins of the calf of the leg.
Dislocation	The separation of the ball and socket parts of a prosthesis from their normal position of meeting at a joint.
Elective surgery	Surgery that is subject to choice (election). The choice may be made by the patient or doctor.
	For example, the time when a surgical procedure is performed may be elective. The procedure is beneficial to the patient but does not need be done at a particular time.
	As opposed to urgent or emergency surgery.
ISD	The Information and Statistics Division of NHSScotland. ISD is a national organisation that collects health service data in Scotland, and uses these data for a wide variety of purposes, including the production of national health statistics and providing feedback to health professionals.
Prosthesis	Any artificial device that is attached to the body as an aid, including joint implants.
Pulmonary Embolism (PE)	This occurs when a blood clot is carried in the circulation to lodge in an artery in the lungs (the pulmonary artery).
Revision	When an artificial joint fails, a second operation is required to replace the failing joint. This procedure is called a revision.
SAP	Scottish Arthroplasty Project.
SCOT Committee	Scottish Orthopaedics and Trauma Committee.