Patient Outcomes in Surgery

A report comparing Independent Sector Treatment Centres and NHS providers

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Executive Summary

Background

Independent Sector Treatment Centres (ISTCs) provide elective diagnostic and surgical treatments to NHS patients. Private sector companies operate these centres. The ISTC programme was created to increase the capacity available to the NHS, and but also to give patients a greater choice of provider for their treatment and to improve outcomes. However, concerns have been raised that ISTCs may have worse outcomes and higher complications rates than NHS-run providers and that they may siphon off the easier cases that are essential for surgical training.

The Patient Outcomes in Surgery (POiS) Audit was established to compare pre-operative patient characteristics and the case-mix adjusted patient-reported outcomes and the complication rates of four elective surgery procedures (hip and knee replacement, inguinal hernia repair and varicose vein surgery) undertaken by ISTCs against those in NHS providers.

This report describes the results of the Audit.

Development of methodology and datasets

The Audit used the methodology and datasets recommended in the London School of Hygiene and Tropical Medicine (LSTHM) feasibility study which investigated the routine collection of patient-reported outcome measures (PROMs) after elective surgery. Additional datasets were developed for the recording of patient-reported co-morbidities and surgeon-reported information on patient characteristics, treatments and operative complications.

The Audit data were linked to the Hospital Episodes Statistics (HES) and the National Joint Registry (NJR) databases at the level of individual patients.

Enrolment of providers

All ISTCs undertaking any of the four procedures were invited to join the Audit, and at least two NHS providers were invited for each ISTC. A total of 14 ISTCs and 51 NHS providers participated in the hip and knee replacement arm of the Audit, and nine ISTCs and 21 NHS providers participated in the inguinal hernia and varicose vein arm.

Patient recruitment and response rates

Patient recruitment started on 1st June 2008 and ended on 30th September 2009 for hip and knee replacement, and started on 1st December 2008 and ended on 30th September 2009 for inguinal hernia repair and varicose vein surgery.

A total of 9,009 hip patients (2,510 in ISTCs and 6,499 in NHS), 10,954 knee patients (3,161 in ISTCs and 7,793 in NHS), 2,663 inguinal hernia patients (640 in ISTCs and

2,023 in NHS) and 1,584 varicose vein patients (248 in ISTCs and 1,336 in NHS) consented to join the Audit and met inclusion criteria.

The recruitment rates were higher in ISTCs than in the NHS providers: 57% vs 45% for hip replacement, 58% vs 48% for knee replacement, 37% vs 27% for inguinal hernia repair, adn 36% vs 33% for varicose vein surgery. Recruited patients were similar in age, sex, adn socioeconomic status compared with all eligible NHS patients based on Hospital Episode Statistics for all four procedures

Response rates to the postoperative questionnaires were higher in ISTC patients for hip (90% vs 84%) and knee replacement (88% vs 81%) but higher in patients treated by NHS providers for inguinal hernia repair (77% vs 71%) and varicose vein surgery (69% vs 64%).

Outcome measures

The following patient-reported outcome measures (PROMs) were collected in the Audit:

- EQ-5D score used for all procedures as a generic measure of health-related quality of life. EQ-5D scores range from -0.59 (worst health) to 1.00 (best health).
- Condition-specific PROMs
    - Oxford Hip and Oxford Knee Scores that measure impact of joint disease on health-related quality of life. The Scores range from 0 (worst outcome) to 48 (best outcome).
    - Aberdeeen Varicose Vein Questionnaire (AVVQ) that measures impact of the varicose veins in the legs on health-related quality of life. The score ranges from 100 (worst outcome) to 0 (best outcome).
    - No condition-specific PROM could be identified for patients with inguinal hernias.
- Complication rates (allergy or reaction to drugs, and urinary, bleeding or wound problems).
- General health
- Quality of life due to symptoms
- Overall result of operation
- Additional surgery on site of first operation.

Statistical Methods

Initially, simple descriptive statistics were used to investigate the data. Subsequently, multivariable regression models were used to adjust for differences in case-mix related to age, sex, pre-operative PROMs scores, general health, socio-economic

status, number of co-morbidities, whether the patient had help completing questionnaire, duration of problem, living circumstances, and length of follow-up.

Results

For both hip and knee replacement, it was found that:

- Patients treated by ISTCs were on average more affluent. They were also fitter for surgery and had fewer co-morbidities. The patients treated by ISTCs also reported a better pre-operative general health and better generic and condition-specific quality of life than those treated by NHS providers.
- Post-operative outcomes were better in ISTCs. With adjustment for case-mix, it was found that patients treated in ISTCs reported a better result of the operation, a better generic and condition-specific quality of life. They reported fewer complications and less frequently had another operation.
- The differences in post-operative outcomes of patients treated by ISTCs and NHS providers that were found after adjustment for case-mix were small. The adjusted difference in the EQ-5D score was - 0.03 for hip replacement and -0.02 for knee replacement. The adjusted difference in the Oxford Hip Score was -1.7 and in the Oxford Knee Score -0.9. These differences are unlikely to be clinically significant. The complication rate after hip or knee replacement was about a third higher in the NHS according to the adjusted figures.

For inguinal hernia repair, it was found that:

- Patients treated by ISTCs were on average younger and more affluent and they had fewer co-morbidities. They also reported a better pre-operative general health and generic quality of life.
- Most outcomes of patients treated by ISTCs or NHS providers were similar. The only difference was that patients treated in the NHS reported more frequently that the operation results were poor: the risk of a poor operation result was about 40% higher when differences in case-mix were taken into account.

For varicose vein surgery, the Audit results showed that:

- Patients treated by ISTCs were on average younger and more often had mild varicose vein symptoms.
- Most outcomes of patients treated by ISTCs or NHS providers were similar. Patients treated in the NHS reported more frequently that they had undergone another operation. The risk was about three times higher in the NHS when difference in case-mix were taken into account. However, this is most likely due to NHS providers treating more severe cases that required multi-stage procedures.

Conclusion

The POiS Audit was established to compare the case-mix adjusted patient-reported outcomes and complication rates of elective surgery undertaken by ISTCs and by NHS- providers. Patients treated by ISTCs had a case-mix profile that made them likely to have better outcomes than those treated by NHS providers. The results of the Audit show a number of differences in post-operative outcomes in favour of ISTCs. However, most differences are small and their clinical relevance is uncertain, especially when compared with the impact ISTCs could have on the provision of elective services.

Limitations in the case-mix adjustment model – due to differences in the pre-operative patient characteristics that could not be adjusted for – may account for part of the differences that were found.

Chapter 1 - Introduction

1.1 Independent Sector Treatment Centres

Independent Sector Treatment Centres (ISTCs) provide elective diagnostic and surgical treatments to NHS patients. Private sector companies own and operate these centres. The ISTC programme was created in 2002 to increase the capacity available to the NHS in order to reduce waiting times.[1]

Whilst the concept of establishing treatment centres to increase capacity has been welcomed,[2;3] the use of independent-sector companies and 'overseas' surgeons to achieve this aim was criticised by politicians and some healthcare bodies.[3] Some of the main criticisms of ISTCs were that:

- they may have significantly worse patient outcomes and increased complications rates when compared with NHS providers.
- they may impact on surgical training and long-term provision of surgical care in the UK by siphoning off the easiest cases who are essential for surgical training.

1.2 Previous investigations

As a result of these criticisms, two major investigations of the ISTC programme were initiated:

- In 2006, the House of Commons Select Committee for Health (HoCSC) undertook an inquiry that gathered evidence on all aspects of the ISTC programme. The Committee highlighted that it could not properly investigate issues related to the quality of care due to the lack of available data. The Committee recommended that more comparative data should be collected.[3]
- Based on the recommendations of the HoCSC report, in 2007 the Healthcare Commission undertook a review of the ISTC programme.[4] This review focused not only on analysis of existing data but included a survey of 2,000 orthopaedic patients being treated in ISTCs. The results of the survey were compared with results from the NHS In-patient Survey undertaken in NHS providers. This showed that 96% of patients in ISTCs compared to 78% in the NHS rated their overall care as 'excellent' or 'very good'', and that ISTCs had higher ratings than NHS providers for almost all aspects of patient experience.

  However, the Healthcare Commission report highlighted the lack of comparative outcome data collected by ISTCs. The Healthcare Commission concluded that without such data outcomes achieved in ISTCs and NHS providers could not be compared.

The only published study that has directly compared patient outcomes of treatment in ISTCs and NHS providers was part of a wider feasibility study ('London School of

Hygiene and Tropical Medicine (LSTHM) feasibility study') examining the routine collection of patient-reported outcome measures (PROMs).[5]

The study recruited 2,664 patients (769 ISTC and 1,895 NHS) across 24 providers (7 NHS Treatment Centres, 13 NHS acute hospitals, two ISTCs, one NHS General Practice and one private hospital) covering five procedures (cataract, inguinal hernia repair, varicose vein, hip and knee replacement). It found that patients who had undergone hip replacement or cataract surgery in ISTCs reported slightly better outcomes than patients treated by NHS providers, with the opposite being found for hernia repair. No differences in outcomes were found for knee replacement and varicose vein surgery. The study reported that patients treated in ISTCs reported fewer complications than those treated in NHS providers for cataract surgery, hernia repair and knee replacement. The study concluded that patients treated by ISTCs reported slightly better outcomes than patients treated by NHS providers, but urged caution in the interpretation of these results due to the small number of ISTCs that were included and the influence of unmeasured case-mix factors.[5]

1.3 Patient Outcomes in Surgery (POiS) Audit

In 2007, the Department of Health (DH) commissioned the Clinical Effectiveness Unit, a collaborative unit of the Royal College of Surgeons of England (RCS) and the LSHTM, to undertake a prospective audit of the outcomes of treatment achieved in ISTCs and comparator NHS providers using the methodology and outcomes outlined by the LSHTM feasibility study.[5-7]

As a result, the Patient Outcomes in Surgery (POiS) Audit was established to compare the case-mix adjusted outcomes and complication rates of four elective surgery procedures (hip and knee replacement, inguinal hernia repair and varicose vein surgery) undertaken in ISTCs and in NHS providers, as well as the patient pre-operative characteristics. Data collection started on the 1st June 2008 and was planned to continue until 30th September 2009.

The DH defined a number of key attributes for the Audit. The most important were:

- The Audit needed to focus on outcomes that are directly relevant to patients.
- The Audit should consider aspects of the process of care so as to provide feedback to ISTCs that can contribute to performance management and improvement.
- Prospective data needed to be collected for individual patients.
- The provider-specific results needed to include adjustments for differences in case-mix between providers.
- The analysis needed to include comparisons of outcomes achieved by the ISTCs against those achieved by the NHS providers.

A development that had a major impact on the POiS Audit was the start of the NHS PROMs Programme on 1st April 2009.[8] This programme was established in order to obtain pre-operative and post-operative PROMs from all patients undergoing hip or knee replacement, inguinal hernia repair and varicose vein surgery in the NHS or funded by the NHS in England. The design of the NHS PROMs Programme matched closely that of the POiS Audit and incorporated many of the developments from the POiS Audit, but it did not collect data on the process of care.

To avoid overlap between the POiS Audit and the NHS PROMs Programme, it was decided that the POiS Audit would continue recruiting patients undergoing hip or knee replacements until 30th September 2009 in the providers that it had recruited. However, the POiS Audit would stop recruiting patients undergoing inguinal hernia repair and varicose vein surgery on 31st March 2009. It was agreed that data collected by the NHS PROMs Programme on all patients recruited between 1st April and 30th September 2009 in the providers that had agreed to participate in the POiS Audit would be made available for analysis to the POiS Audit.

1.4 Scope of the report

In this report, a description is provided of the case-mix adjusted comparisons of outcomes achieved by ISTCs and NHS providers for patients undergoing a hip or knee replacement recruited between 1st June 2008 and 30th September 2009 and for patients undergoing inguinal hernia repair or varicose vein surgery recruited between 1st December 2008 and 30th September 2009. All post-operative outcomes are based on information reported by patients. The presented outcomes include generic and condition-specific health status measures, the patient's direct assessment of their general health and the results of the operation, and whether post-operative complications occurred.

In addition, we also compared the pre-operative characteristics of patients treated by ISTCs and NHS providers. These characteristics were included in risk models that were developed in order to adjust the comparisons of outcomes achieved in ISTCs and NHS providers for differences in case-mix. The pre-operative characteristics were either based on patient-reported data or derived from the Hospital Episode Statistics (HES), the administrative database of all admissions to the English NHS.

The analyses of differences in the process of care between ISTCs and NHS providers was based on surgeon-reported data and will be described in a separate report. We did not include the results of these analyses in this report for two reasons. First, the NHS PROMs Programme did not collect data on the process of care, so it is unavailable for the majority of general surgery patients. Second, the completeness of data on the process of care reported by the surgeons to the POiS Audit was relatively low. As a result, analyses of differences in the process of care would have been

based on a small sub-group of patients who would not be directly comparable to the group for whom PROMs data were available.

Chapter 2 - Background

2.1 ISTC programme

The ISTC programme started in 2003 and was an extension of the existing NHS Treatment Centre programme that began in 1999. The aim behind the introduction of Treatment Centres was to separate routine elective treatment from complex and emergency care in order to improve outcomes and efficiency in elective care.[2;3;9] The Middlesex Ambulatory Care and Diagnosis (ACAD) was the first such facility to open in July 1999, and by 2005 a total of 46 NHS-run Treatment Centres had been established.[3]

In 2002 the *NHS Plan* was published, which outlined the government's vision for the modernisation of the NHS, including commitments to cut waiting lists and to reduce waiting times for inpatient care to 3 months by 2008.[10] In order to meet these aims the DH planned to accelerate the existing Treatment Centre programme by working in partnership with the independent sector to create new 'Diagnostic and Treatment Centres'. The main justification for using the independent sector rather than continuing with a NHS-run model was the need to rapidly expand services, which it was argued could not solely be met by the NHS.[3]

There were two main routes via which the independent sector would become directly involved in providing services.[11]

- "clinical teams" – where staff would be made available to supplement clinical capacity in existing NHS providers, and
- "international establishments" - where independent health service providers would set up and run new health care facilities i.e. ISTCs.

2.2 ISTC building programme

In October 2002, the DH undertook a capacity planning exercise with all Strategic Health Authorities and Primary Care Trusts in England in order to identify where ISTCs would be required. Since then two phases of procurement have taken place. Phase 1 started in December 2002 with requests for bids to operate one of the 29 planned schemes. The first scheme opened in Daventry in October 2003, and by April 2009, 27 schemes were operational and 2 were under construction.[3] In March 2005, a second phase of procurement was announced. It was originally planned that another 24 schemes would be awarded. However, after a series of reviews it was decided that the additional capacity was not needed and the number of schemes was cut.[3] By September 2008 (the latest date for which published figures are available), a total of 11 Phase 2 schemes were operational.

Phase 1 procurement focused on the creation of new capacity in dedicated sites, whilst Phase 2 schemes focused more on using existing capacity within the

independent sector. As a result, a variety of facilities are used by the ISTC programme:

- New stand-alone facilities separate from existing NHS sites
- New stand-alone facilities on existing NHS sites
- New capacity within existing NHS facilities
- New mobile facilities
- Existing private hospitals

ISTCs provide a range of elective diagnostic (i.e. x-rays, MRI) and short-stay or day-case treatments (including general surgery, orthopaedic surgery, ophthalmology, ENT, gynaecology and renal dialysis). Some ISTCs provide a full range of these services, whilst others focus on specific areas.

2.3 Clinical Governance

At the time of this Audit both Phase 1 and Phase 2 ISTCs were governed by a regulatory framework different from NHS providers.[12] They were required to meet the 'national minimum standards'[13] for independent sector providers rather than the 'standards for better health' required from NHS providers at that time.

The differences in clinical governance arrangements between ISTCs and NHS providers resulted in differences in data collection that have acted as a barrier to the comparison of the two models of provision.

2.4 Impact of ISTCs

2.4.1 Reducing waiting times

The *NHS Plan* specified that the main aim for ISTCs was to reduce waiting times.[10] The available data shows that NHS waiting lists for hospital in-patient care fell from 972,294 in October 2003 to 556,015 in September 2008 and that waiting times improved, with 98% of patients waiting less than 18 weeks for treatment by 2008.[14;15] However, the Audit Commission report concluded that ISTCs have only contributed directly a small proportion (1.7% of total) to this reduction, for three reasons: first, waiting lists were falling before any ISTC had opened; second, the available capacity in ISTCs has only slowly become available; and third, this capacity has not been fully utilised.[4;16;17]

2.4.2 Quality of care

Much of the criticism of the ISTC programme from professional bodies has focused on the quality of treatment provided. However, both the HoCSC and Healthcare Commission reports highlighted the lack of data on quality of care collected by ISTCs that meant that comparisons could not be made with the NHS.[3;4]

As mentioned earlier, the only study to directly compare the outcomes of patients treated in ISTCs with those treated in NHS providers found little or no difference in results.[6]

2.4.3 Training

Phase 1 contracts did not include any obligation to undertake training, and a concern was raised that this could damage the medical training and long-term provision of services in the UK, as a result of easier cases that are essential for medical training being treated in ISTCs.[3] This concern was addressed in Phase 2 contracts which specified that at least one-third of all activity should be made available for the training of all clinical professions.[3]

2.4.4 Cost

The original estimated cost of the Phase 1 programme was £1.7bn[3]. By April 2008 (the latest published figures) with two facilities yet to open the cost had been £1.47bn.[16] The Phase 2 programme was originally predicted to cost £3.75bn[3], but due to reduction in scope by 2008 it had cost £1.2bn.[17] Phase 1 facilities had been contracted to undertake 355,156 diagnostic and 705,285 interventional procedures.[16] By 2008 the utilisation rate of these services had been 85%. Phase 2 facilities had been contracted to undertake 1,756,141 diagnostic procedures and 1,202,131 treatments.[16] By 2008 the utilisation rate was 25% for diagnostics and 85% for interventions.[16]

2.5 Future of ISTCs

The current ISTC contracts end between 2010 and 2017. New treatment centre services will be commissioned locally and providers will be paid NHS tariff prices, under the terms and conditions of the standard NHS acute contract.

Chapter 3 – Treatments

This chapter provides an overview of the four treatment areas that were examined by the Audit.

3.1 Hip replacement

Hip replacement involves the surgical removal of the hip joint and its substitution with an artificial one. National Joint Registry (NJR) figures show approximately 65,000 hip replacements were performed in England in 2009; 90% of these were primary procedures and 10% were revisions of existing replacements.[18] Osteoarthritis was the indication for surgery in 93% of cases.[19]

The average age of patients having a primary hip replacement was 66 years[18] and 56% were women. It is a highly effective procedure with 96% of patients reporting improvement in symptoms, but it also represents a major intervention with at least a 3-month recovery time.[20;21]

A variety of materials, prosthesis and surgical techniques are being used. For example, the 2010 NJR report states that over 151 brands of femoral stems and 127 brands of acetabular cups have been used in the previous year.[18] The choice of which brand and type of prosthesis to use in a patient depends on the diagnosis, patient risk-factors and the preference of the surgeon. However, the main choices are between:

- Different bearing surfaces
    - Metal-on-plastic
    - Ceramic-on-plastic
    - Ceramic-on-ceramic
    - Metal-on-metal
- Cemented versus uncemented fixation.

According to NJR figures, untoward intra-operative events are reported in 1% of procedures, such as calcar crack or trochanteric fractures.[18] Peri-operative problems are reported by approximately 25% of patients, including site infection, deep vein thrombosis, dislocation and joint stiffening.

3.2 Knee replacement

Knee replacement is the removal of the knee joint and its replacement with an artificial one. Approximately 77,000 knee replacements were undertaken in England in 2009/2010.[18] Of these, 93% are primary procedures and 7% are revisions. Osteoarthritis is the primary reason for a knee replacement in 97% of cases. The average age of patients having a primary knee replacement was 67 years and 57% were on women.[18] Like hip replacement, knee replacement is highly successful intervention that requires at least a 3-month recovery period.

A variety of materials, prosthesis and surgical techniques are used. The choice of which to use in an individual patient depends on the diagnosis, patient risk-factors and the preference of the surgeon. However, the main choices are between:

- Total or partial replacement
- Metal-on-plastic bearing surfaces
- Cemented versus uncemented fixation

According to NJR figures, untoward intra-operative events are reported in 1% of procedures, such as fracture, patella tendon avulsion and ligament injury. Peri-operative problems are reported by approximately 25% of patients, including site infection, deep vein thrombosis, dislocation and joint stiffening.

3.3 Inguinal hernia repair

An inguinal hernia is a protrusion of abdominal-cavity contents, usually intestine, through a weakened area of the lower abdominal wall.[22] Inguinal hernias may have few symptoms. However, there is a risk that the hernia becomes incarcerated (the intestine becomes trapped and blocked) or strangulated (the blood supply to the intestine is cut). Both incarcerated and strangulated hernias require emergency surgery.[22]

There is no internationally accepted clinical classification system for inguinal hernias. However, the classification system outlined by Kingsnorth[23] provides an example of how severity can be graded:

- H1. Groin only, reduces spontaneously on lying down
- H2. Groin only, reduces completely with gentle manual pressure
- H3. Inguinoscrotal, reducible with manual manipulation
- H4. Irreducible

The lifetime prevalence of inguinal hernias in men aged over 25 is 18 per 100.[24] In 2008, 74,472 inguinal hernia repairs were undertaken in the NHS (including 3,246 emergency cases).[25]

Treatments are grouped into three main categories [22;26;27]:

- Open “tension-free” repair. An incision is made and then mesh is used to reinforce the area of weakness and prevent any further protrusion. A number of variations of this technique are used: onlay mesh repair, plug only, plug and patch and open pre-peritoneal.
- Laparoscopic “tension-free” repair. Laparoscopic techniques are used to place mesh to reinforce the area of weakness. The two main methods used are - Transabdominal preperitoneal (TAPP) repair and Total extra-peritoneal (TEP) repair. Laparoscopic techniques are associated with more rapid recovery and less post-operative pain than open repair.
- Open “tension” repair or suture only repair. An incision is made and the sides of weakness in the abdominal cavity are sewn together without any other support.

This technique is now rarely used having been superseded by “tension free” methods.

3.4 Varicose vein surgery

Varicose veins are the result of non-functioning valves within the veins of the legs. Varicose veins are grouped into three main types.[28]

- Trunk varicose veins which are large and tortuous.
- Reticular varicose veins which are red and sometimes grouped close together.
- Telangiectasia varicose veins which are small clusters of blue or red veins.

Whilst appearance is often the main reason for seeking treatment, varicose veins can cause itchiness, pain, eczema and, in severe cases, ulcers. The main clinical classification system used for varicose veins, the Clinical Etiologic Anatomic Pathophysiologic (CEAP)[29], is based on the appearance and severity of symptoms:

- C0 no visible or palpable signs of venous disease
- C1 telangiectasias or reticular veins
- C2 varicose veins
- C3 oedema
- C4a skin changes due to venous disorders: pigmentation, eczema
- C4b skin changes due to venous disorders: lipodermatosclerosis, atrophie blanche
- C5 as C4 but with healed ulcers
- C6 skin changes with active ulcers

Varicose veins are very common and increase with age. Studies show the prevalence in women ranges from 20% to 32% and in men from 10% to 40%.[30-32] In 2009, 36,811 varicose vein procedures were undertaken in the NHS.[25]

The main interventions used to treat varicose veins are:

- Vein stripping which is used for the removal of large varicose veins. This involves two incisions being made, one above and one below the damaged vein. A wire with a modified end is passed down the vein from the higher incision. As the wire is pulled out of the lower incision the vein is pulled with it. The vein above and below the incision are then surgically ‘tied off’.
- Vein ligation which is used to reduce the appearance of varicose veins. This is achieved by stopping blood flow by surgically ‘tying off’ the veins.
- Ambulatory phlebectomy used for the removal of small surface veins. Small incisions are made in the skin. An endoscopic light is then used to highlight the veins that need to be removed. The veins are then removed via the incision using a hook or suction.
- Sclerotherapy which is the chemical shrinkage of small varicose veins. The chemicals are administered to the site using an injection.

- Endovenous thermal ablation which is used to reduce the appearance of varicose veins. This is achieved by thermally sealing the vein and thereby stopping the blood flow.
- Endovenous laser treatment where a laser is inserted in the vein and used to seal it.

Chapter 4 – Patients and Methods

4.1 Enrolment of providers

Participation in the POiS Audit was voluntary for both ISTCs and NHS providers.

The aim was to enrol all ISTCs undertaking hip and knee replacement, varicose veins surgery and inguinal hernia repair, as well as a minimum of two NHS providers to each ISTC. A list of ISTCs that performed these procedures was obtained from the DH and a list of NHS providers was identified from the Hospital Episodes Statistics (HES) database. No matching of ISTCs and NHS-providers was undertaken. However, NHS providers were selected to give a representative sample of the types of provider and geographic spread of providers found in the NHS. It was estimated that about 50% of NHS providers invited to enrol in the Audit would do so. Therefore, four NHS providers were invited to enrol per ISTC.

A letter of invitation was sent to the Chief Executive and Medical Director of all identified ISTCs and the selected NHS providers. As participation in the Audit was voluntary, the letter focused on the benefits of the data collection to individual providers and stressed that the workload involved for local staff had been minimised. A reminder was sent to ISTCs and NHS providers that failed to respond to the initial letter. The DH contacted ISTCs that still failed to respond to outline the importance of the Audit. No further contact was made with NHS providers who failed to respond.

Providers that expressed an interest in joining the Audit were asked to nominate two members of staff to act as local contacts for the POiS Audit. A visit to the provider by a member of the Audit Team was arranged to meet staff who would be involved in the administration of the Audit. At the meeting, a presentation on the background of the Audit was given, training in administration of the Audit was provided, and any questions that staff had were answered. Those providers that joined the Audit were asked to complete a data sharing agreement and were sent all the relevant documentation (user manuals, patient leaflets, questionnaires and envelopes). A start date for the Audit was agreed between the provider and the Audit Team.

The Audit Team stayed in contact with all providers via the nominated members of staff in order to monitor the local progress of the Audit. Two newsletters were sent to each provider that summarised the progress of the Audit.

4.2 Patient Recruitment

The Audit aimed to recruit consecutive patients aged 15 years and above undergoing an elective primary hip or knee replacement (Appendix B). Bilateral operations were excluded as the outcome of bilateral replacement are expected to be different.

Revision surgery was excluded as this is usually performed in NHS providers and its outcomes are expected to be worse than those of primary joint replacement.

The Audit also recruited consecutive patients aged 15 years and above undergoing any elective treatment for varicose veins or inguinal hernia repair (Appendix B).

Patients were eligible to be recruited if they had a hip or knee replacement between 1st June 2008 and 30th September 2009 for orthopaedics and an inguinal hernia repair or varicose vein surgery between 1st December 2008 and 30th September 2009. It was originally planned that recruitment for general surgery would last 10 months. However, the DH made a decision to transfer all providers from the POiS Audit to the NHS PROMs Programme from the 1st April 2009.[7;8] To compensate, the DH agreed to provide NHS PROMs data for operations carried out during the period April to September 2009. These data matched those collected by the POiS Audit although the questionnaires were not identical and were made available to the Audit Team in September 2010.

The participating providers were asked to follow a standard process when recruiting patients:

- Patients were invited to join the Audit by a member of staff either at pre-assessment clinic or on the day of admission for surgery.
- Patients were given a pre-operative questionnaire pack by the member of staff and were asked to read the information leaflet it contained.
- Patients were asked to read and sign a consent form.

4.3 Data sources and collection

Three data sources were used in the Audit.

- Patient-reported data
- Surgeon-reported data
- Existing routine data

4.3.1 Patient-reported data

Patients who agreed to take part in the Audit were asked to complete a pre-operative questionnaire and return it to a member of staff.

4.3.1.1 Pre-operative questionnaires

The content of the questionnaires was based on the recommendations made by the LSHTM feasibility study and is summarised here.[5]

- Patient identifiers - name, address, date of birth, sex, previous similar operations, length of symptoms and NHS number.
- Patient-reported outcome measures (PROMs). The minimally important clinical differences (MIDs) for each measure outlined in the LSHTM feasibility study are

also shown. MIDs are defined as "the smallest difference in score...which patients perceive as beneficial and which would mandate, in the absence of troublesome side effects and excessive cost, a change in the patient's management".[33] Whilst the use of MIDs should be treated with caution, the proportion of patients achieving a MIDS does provide the best available metric to judge clinical differences in outcomes.[5]

  - The EQ-5D score was used for all procedures. The EQ-5D is a generic measure of health status. The score contains five questions each covering a specific dimension of health: mobility, self-care, daily activities, pain and anxiety/depression. There are three responses to each question numbered from 1 (least severe) to 3 (most severe). The EQ-5D score is calculated by matching the pattern of responses to the five questions against existing weighted preference data derived from the general population.[34;35] Based on the UK EQ-5D population dataset, the score can range from -0.59 (worse than death) to 1 (perfect health). The EQ-5D also contains a visual analogue scale for recording overall health status, but this is not used to calculate the overall score. The MIDs outlined for each of the procedures included in the POiS Audit were from 0.12 to 0.32 for hips, from 0.12 to 0.25 for knees, from 0.06 to 0.08 for varicose veins, and from 0.02 to 0.07 for inguinal hernia.[5]
  - The Oxford Hip is a 12-item self-completed questionnaires designed to measure the impact of joint disease.[36;37] The items covered include pain and ability to undertake daily activities. Responses to individual questions are scored (from 0 to 4) and added together to provide an overall score of between 0 (severe arthritis) and 48 (satisfactory joint function). The MIDs outlined for Oxford Hip Score range from 2.7 to 13.1.[5]
  - The Oxford Knee Scores is a 12-item and in the same way as the Oxford Hip Score. The MIDs outlined for Oxford Knee Score range from 2.1 to 9.7.[5]
  - The Aberdeen Varicose Vein Questionnaire (AVVQ) is a 13-item self-reported condition-specific questionnaire.[38] It uses a variety of question formats, including a pictogram. The individual responses are weighted, depending on the severity of the specific symptoms, and added together to produce overall score of between 0 (no problems) and 100 (most severe problems).[38] The MIDs outlined for AVVQ range from 3.6 to 5.0.[5]

- Two summary health questions were included
  - General health status ('In general, would you say your health is') used in a number of health status questionnaires, such as the SF-36.

- An adapted version of the quality of life question from the International Prostate Symptom Score ('If you were to spend the rest of your life with your hip the way it is now, how would you feel about that?').[39]

- Patient-reported co-morbidities. A 12-item index ('LSHTM Patient-Reported Co-morbidity Index') was developed by the Audit Team. This was based on the results of a systematic review of existing patient-reported co-morbidity indices. A total of five indices were identified, but none were found to be suitable for use in the POiS Audit. Therefore, the Audit Team developed a new index based on the content of these existing indices. Items were included if they represented a commonly occurring co-morbidity and avoided the use of esoteric medical terminology.
- The patients' postcodes were used to calculate the Index of Multiple Deprivation based on 2007 rankings.[40]

For hip and knee replacement surgery, the questionnaire was returned to the Audit Team for data entry. For inguinal hernia repair and varicose vein, the questionnaire was retained as the surgeon-reported form was contained at the back of the patient questionnaire. Once this was completed the questionnaire was returned Audit Team for data entry.

4.3.1.2 Post-operative questionnaires

Before a post-operative questionnaire was mailed to a patient, a check was undertaken using the NHS Strategic Tracing Service (NSTS) to establish if the patient had died during the follow-up period. No follow-up questionnaires were sent to patients who were found to have died.

A member of the Audit Team mailed the post-operative questionnaires to the patient's home address 3 months after inguinal hernia repair and varicose vein surgery and 6 months after hip or knee replacement. The difference in timing of follow-up reflects the recovery periods for each of the procedures. Non-responders to the post-operative questionnaire were sent a reminder letter and a replacement questionnaire 5 weeks after the original mailing. Patients were asked to return the completed questionnaires in a pre-paid envelope to the Audit Team.

The content of the post-operative questionnaire was based on the recommendations of the LSHTM feasibility study.[5] The questionnaires contained the same measures as the pre-operative questionnaire, with the addition of questions on:

- Any additional surgery on the site of the first operation
- Re-admission to hospital for any reason
- Overall assessment of the outcome of surgery ('How would you describe the results of your operation?')

- Overall assessment of change in symptoms ('Overall, how are the problems now in the hip on which you had surgery, compared to before your operation?')
- Post-operative complications (allergy or reaction to drugs, urinary, bleeding or wound problems).[41]

4.3.2 Surgeon-reported data

As explained in Sections 1.3 and 1.4, the Audit Team was requested by the DH to collect data on the process of care that may demonstrate how the quality of care can be further improved. For this purpose, the Audit developed a dataset for each surgical procedure to be reported on by the surgeons. The content of the datasets were based on the results of systematic reviews of existing ones that were undertaken by the Audit Team as well as input from nominated members of the British Orthopaedic Association and Association of Surgeons of Great Britain and Ireland. The result of this process was a 19-item dataset for hip replacement, a 17-item dataset for knee replacement, a 14-item dataset for varicose veins, and a 20-item dataset for inguinal hernia repair .

Surgeons were asked to complete their questionnaire immediately after the patient was discharged. For orthopaedic surgery, the questionnaire was printed on the hospital copy of the consent form. Once completed a member of hospital staff then entered the information contained on the form onto a database via a secure website. For general surgery, the questionnaire was printed on the back page of the patient pre-operative questionnaire, and once completed returned to the Audit Team for data entry. The differences in collection procedures used were due to the varying length of stay after surgery. For inguinal hernia repair or varicose vein surgery, the questionnaire could be completed on the day of surgery and so could be safely incorporated into the pre-operative questionnaire for patients. This was not practical for hip and knee replacement given that the length of stay for these procedures is much longer.

4.3.3 Existing data

A key component of the POiS Audit is the linkage of patient-reported data with existing NHS databases at the level of individual patients. The Audit data were linked to three existing databases.

4.3.3.1 NHS Strategic Tracing Service (NSTS)

The NHS Strategic Tracing Service (NSTS) was used to provide information on whether a patient had died during the follow-up period and obtain missing patient identifier information, such as the NHS number.

4.3.3.2 Hospital Episodes Statistics (HES)

The HES database contains administrative, diagnostic and treatment details for all patients admitted to an NHS provider or to an independent provider but funded by the NHS.[42]

The Audit data on a patient were linked to the HES record of the admission in which the surgical procedure took place, as well as to HES records of all previous and subsequent admissions of that patient. The linked data were used to identify co-morbidities. They could also be used to validate the patient-reported and surgeon-reported data, and to obtain data on complications and revision surgery. Results of this validation process will be reported separately.

Originally, it was planned that the POiS Audit Team would undertake the record linkage. However, as part of the collaboration with the NHS PROMs Programme it was agreed that linkage of POiS Audit data to HES data would follow process planned by the NHS PROMs Programme. The linkage process is summarised in Appendix C.

4.3.3.3 National Joint Registry (NJR)

The National Joint Registry (NJR) of England and Wales was established in 2002.[43] It aims to collect detailed information on all patients undergoing hip or knee replacements as well as on the surgical procedure and the implanted prothesis.[44;45] As with the HES, the linkage was undertaken as part of the NHS PROMs Programme.

4.4 Statistical analysis

4.4.1 Recruitment and response rates

Recruitment rates were calculated for each provider as the number of eligible patients (see section 4.2) who consented to join the Audit and returned a pre-operative questionnaire divided by the number of eligible patients during the recruitment period according to HES.

Post-operative response rates were calculated as the number of returned questionnaires divided by the number of pre-operative questionnaires received from patients who had given consent.

4.4.2 Descriptive analysis

The data were explored using simple descriptive statistics and graphical methods in order to provide an understanding of the data and assess issues that may affect the main analysis, such as duplicate records.[46;47] Where necessary the database was up-dated to ensure accuracy and completeness (see Appendix C for details of this process).

4.4.3 Main analysis

Univariate methods were used to compare providers by means of chi-square or t-tests depending on the type of data.[46;47]

Extended complete case analysis was undertaken on all the outcomes recommended in the LSHTM feasibility study.[5] The main outcome measures were:

- Post-operative EQ-5D score
- Post-operative condition-specific PROM (Oxford Hip Scores, Oxford Knee Scores, AVVQ)
- Patient-reported complication rates
- Post-operative quality of life – ('If you were to spend the rest of your life with your hip the way it is now, how would you feel about that?')
- Overall result of operation ('How would you describe the results of your operation?')
- Additional surgery on the site of the first operation

Case-mix adjustment was undertaken using multivariable regression models. The case-mix adjustment was an extended version of that outlined in the LSHTM feasibility study[5], and aimed to cover all relevant pre-operative variables. Organisation-level and surgeon-level variables were not included in the case-mix model. No account was taken of type or complexity of surgery as this is likely to be based on surgeon preference and organisational decisions. Therefore, the case-mix adjustment models used in the POiS Audit included:

- Age (years; as a continuous variable)
- Sex (male or female)
- Pre-operative PROMs score (EQ-5D, Oxford Hip or Knee Scores or AVVQ)
- General health (5 categories – Excellent; Very good; Good; Fair; Poor)
- Quintile of the Index of Multiple Deprivation (IMD) rank for 2007 (5 categories: 0 to 8,121, 8,122 to 16241, 16,242 to 24,362, and 24,363 to 32,484)
- Number of co-morbidities (0, 1 or 2+)
- Received help completing questionnaire (yes or no)
- Duration of problem (categories varied depending on condition)
- Living circumstances (with family or not)
- Length of follow-up (months; as a continuous variable)

Ethnicity based on HES data and surgeon-reported American Society of Anesthesiologists (ASA) grade, [45]which is a measure of fitness for surgery, graded from 1 (normal healthy patients) to 6 (declared brain dead), BMI, and surgeon-reported severity of symptoms were not included in the multivariable regression model because of the high level of missing data (for example, data on BMI was missing for 66% of hip replacement patients). Moreover, missing data were often clustered within providers.

The main analysis combined all NHS providers, but these represent a variety of organisation types that treat different patient groups. Therefore, sub-group analyses were also undertaken comparing ISTC against NHS treatment centres, as these centres are most likely to treat a patient population comparable to the population treated in ISTCs.

All reported p-values are 2-sided, and p-values lower than 0.05 were considered to be statistically significant. Where appropriate mean averages and odds ratios are presented with 95% confidence intervals. Robust standard errors were used to allow for clustering of outcomes within providers. Results are shown as adjusted differences for continuous outcomes and adjusted odds ratios (OR) for binary outcomes.

Chapter 5 – Results

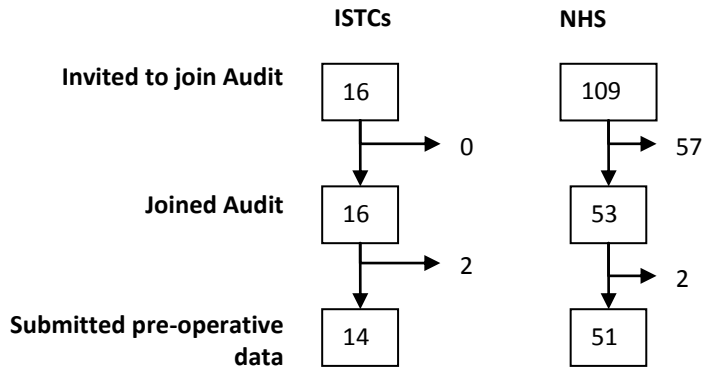
5.1 Hip Replacement

5.1.1 Provider Recruitment

Sixteen ISTCs were identified that undertook orthopaedic surgery and all were invited to join the Audit. Of the 16 ISTCs invited, all agreed to join the Audit but two subsequently did not submit any data. Some hospitals had stated before the Audit started that they would not participate and are not included in these figures.

Of the 109 NHS providers (representing 154 individual hospitals) invited to join, 53 representing 78 hospitals agreed with only two subsequently failing to submit any data.

Figure 1. Provider recruitment for hip replacement



5.1.2 Patient recruitment and response rates

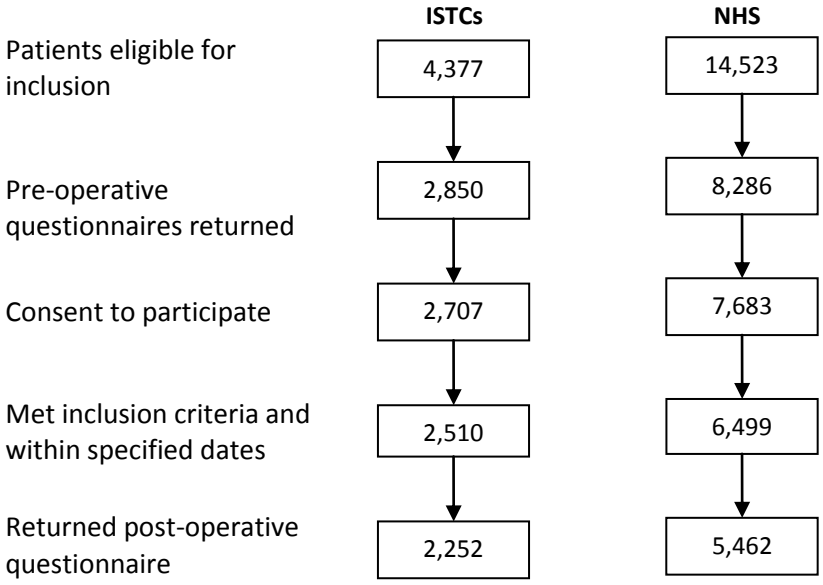
The overall recruitment rate for hip replacement was 48% (57% for ISTCs [2,510 of 4,377] and 45% for NHS providers [6,499 of 14,523]). The figures for individual providers ranged from 11% to 91%. The follow-up response rate was 86% (90% for ISTCs [2,252 of 2,510] and 84% for NHS providers [5,462 of 6,499])(see Figure 2).

The recruitment figures are lower than anticipated. There are three reasons for this:

- Data collection was voluntary and as a result, a number of providers failed, in essence, to participate even after agreeing to take part. Nine NHS providers had recruitment rates of less than 20% and therefore could be considered to have failed to participate.
- The 'soft' roll-out of the Audit meant that providers continued to join the Audit up until April 2009. After starting, providers needed 3 months to reach a good level of recruitment. This had the effect of lowering the overall recruitment rate.

- There is also evidence of a 'wind-down' period for some providers, where recruitment rates trailed off towards the end of the Audit period as they prepared to switch to the NHS PROMs Programme.

Figure 2. Patient recruitment for hip replacement



5.1.3 Comparison of POiS population and all NHS patients using HES

Comparing the patients who consented to participate with the NHS population (based on HES data) showed that they were similar in terms of age, sex and deprivation score (see Table 1).

Table 1. Comparison of POiS population with NHS population

Variable	POiS Audit	NHS
Age (mean, years)	67.4	68.1
Sex (% male)	41.0	40.0
IMD rank[a] (% in lowest quintile)	14.7	13.0

[a] IMD rank for whole of England divided into quintiles

5.1.4 Comparison of responders and non-responders to the post-operative questionnaire

Comparison of pre-operative data of patients who did or did not respond to the post-operative questionnaire showed that responders were more likely to be older, to live less often in deprived areas and to have better pre-operative symptoms than non-responders (see Table 2).

Table 2. Comparison pre-operative scores of responders and non-responders

Variable	Responders	Non-responders
Age (mean, years)	68.6	64.1
Sex (% male)	44.2	39.5
IMD rank[a] (% in lowest quintile)	13.7	24.1
Co-morbidities (% with co-morbidities)	83.9	82.3
Pre-operative EQ-5D score (mean)	0.32	0.21
Pre-operative Oxford Hip score (mean)	17.8	15.0

[a] IMD rank for whole of England divided into quintiles

5.1.5 Comparison of ISTC and NHS patients pre-operative characteristics

Comparison of the pre-operative characteristics of the ISTC and NHS groups shows that they are similar in terms of age, sex and BMI (see Table 3). However, all other pre-operative variables showed that the ISTC population has less severe symptoms and fewer health problems than the NHS population. For example, 50.9% of patients in the NHS group reported having two or more co-morbidities compared to 44.1% in the ISTC group. Furthermore, 17.9% of the NHS population had an ASA grade of 3 or more compared to 6.3% of ISTC patients.

5.1.6 Comparison of ISTC and NHS patient post-operative outcomes

The unadjusted post-operative results (see Table 4) show that ISTC patients have statistically better outcomes. NHS patients had on average a worse Oxford Hip Score (difference of 2.3, $p<0.001$), a worse EQ-5D score (difference of 0.05, $p<0.001$), and report more complications (difference of 6.5%, $p<0.001$).

The main case-mix model reduced the differences found between ISTC and NHS populations (see Table 5 and Table 6). However, differences between ISTC and NHS providers remained statistically significant. For example, the adjusted difference in Oxford Hip Score was -1.7 ($p=0.002$) and for EQ-5D it was -0.03 $p<0.001$). The only outcome where ISTCs did not have statistically adjusted outcomes that were better than NHS Trusts was for having an additional operation (OR 1.26, $p=0.234$).

Table 3. Patient pre-operative characteristics: hip replacement

Characteristics	ISTC	NHS	p-value	Missing data	
			ISTC v NHS	ISTC	NHS
Total, n	2,510	6,499			
Patient characteristics					
Sex, n (%)					
Female	1,496 (59.6)	3,883 (59.9)	0.825	2	17
Male	1,012 (40.4)	2,599 (40.1)			
Age, years, mean (SD)	68.1(9.2)	68.0 (11.3)	0.857	2	53
IMD rank, % in bottom quintile	287 (11.5)	1,017 (16.0)	<0.001	25	128
Body Mass Index, kg/m^2, mean (SD)[a]	28.9 (11.7)	28.8 (12.0)	0.805	1,744	4,246
Patient ASA Grade, n (%)[b]					
1	248 (11.6)	564 (14.1)	<0.001	371	2,493
2	1,757 (82.1)	2,723 (68.0)			
3+	134 (6.3)	719 (17.9)			
Number of co-morbidities, n (%)					
0	443 (17.6)	960 (14.8)	<0.001	0	0
1	960 (38.2)	2,228 (34.3)			
2 or more	1,107 (44.1)	3,311 (50.9)			
Health and Quality of life					
General health, n (%)					
Excellent	122 (5.4)	295 (5.2)	<0.001	257	817
Very good	790 (35.1)	1,607 (28.3)			
Good	973 (43.2)	2,385 (42.0)			
Fair	326 (14.5)	1,135 (20.0)			
Poor	42 (1.9)	260 (4.6)			
If you were to spend the rest of your life with your hip the way it is now, how would you feel about that?, n (%)					
Delighted	20 (0.9)	16 (0.3)	<0.001	226	737
Pleased	14 (0.6)	28 (0.5)			
Mostly satisfied	15 (0.7)	25 (0.4)			
Mixed	36 (1.6)	120 (2.1)			
Mostly dissatisfied	137 (6.0)	328 (5.7)			
Unhappy	752 (32.9)	1711 (29.7)			
Terrible	1310 (57.4)	3534 (61.3)			
EQ-5D score					
Mean (SD)	0.35 (0.31)	0.30 (0.33)	<0.001	263	522
Median (IQR)	0.52 (0.59)	0.21 (0.60)			
Oxford Hip Score					
Mean (SD)	18.1 (7.8)	17.3 (8.2)	<0.001	161	329
Median (IQR)	18.0 (11.0)	17.0 (12.0)			

[a] From NJR only & BMIs of 0 excluded.[b] Combined surgeon-reported and NJR data.

Table 4. Unadjusted patient post-operative outcomes: hip replacement

Characteristics		ISTC	NHS	p-value ISTC v NHS	Missing data ISTC	Missing data NHS
Total, n (%)		2,252	5,462			
Length of follow-up, months		6.3	6.2	0.334		
Outcomes of the procedure						
Readmitted to hospital, n (%)						
	Yes	152 (6.8)	440 (8.2)	0.042	23	93
	No	2,077 (93.2)	4,929 (91.8)			
Another operation, n (%)						
	Yes	59 (2.6)	186 (3.5)	0.066	22	91
	No	2,171 (97.4)	5185 (96.5)			
Any complications, n (%)						
	Yes	564 (25.3)	1,708 (31.8)	<0.001	24	87
	No	1,664 (74.7)	3,667 (68.2)			
Results of operation, n (%)						
	Excellent	1,000 (44.8)	1,999 (37.1)	<0.001	20	76
	Very good	779 (34.9)	2,020 (37.5)			
	Good	336 (15.1)	961 (17.8)			
	Fair	84 (3.8)	303 (5.6)			
	Poor	33 (1.5)	103 (1.9)			
Died, n (%)		21 (0.8)	58 (0.9)			
Health & Quality of life						
General health, n (%)[a]						
	Excellent	260 (11.7)	465 (8.6)	<0.001	23	79
	Very good	908 (40.7)	1,924 (35.7)			
	Good	809 (36.3)	2,046 (38.0)			
	Fair	229 (10.3)	818 (15.2)			
	Poor	23 (1.0)	130 (2.4)			
If you were to spend the rest of your life with your hip the way it is now, how would you feel about that?, n (%)[a]						
	Delighted	1,014 (45.5)	1,973 (38.7)	<0.001	23	362
	Pleased	644 (28.9)	1,466 (28.7)			
	Mostly satisfied	324 (14.5)	896 (17.6)			
	Mixed	136 (6.1)	385 (7.5)			
	Mostly dissatisfied	35 (1.6)	116 (2.3)			
	Unhappy	49 (2.2)	167 (3.3)			
	Terrible	27 (1.2)	97 (1.9)			
EQ-5D score[a]						
	Mean (SD)	0.81 (0.23)	0.76 (0.24)	<0.001	311	630
	Median (IQR)	0.85 (0.31)	0.80 (0.36)			
Oxford Hip score[a]						
	Mean (SD)	40.4 (8.0)	38.1 (9.0)	<0.001	142	280
	Median (IQR)	43.0 (9.0)	41.0 (12.0)			

[a] Figures based on patients who completed both pre-operative and post-operative questions.

Table 5. Unadjusted score and robust adjusted difference: hip replacement

PROMs	Unadjusted mean (SD)		Adjusted		
	ISTC	NHS	difference	95% CI	p-value
EQ-5D score	0.81 (0.23)	0.76 (0.24)	-0.03	-0.05 to -0.01	0.002
Oxford Hip score	40.4 (8.0)	38.1 (9.0)	-1.7	-2.5 to -0.9	<0.001

Adjusted for: age, sex, pre-operative score, number of co-morbidities, general health, deprivation, received help with questionnaire, living circumstances, time from surgery to follow-up, and duration of problems.

Table 6. Unadjusted scores and adjusted OR: hip replacement

Outcome	%		Adjusted		
	ISTC	NHS	OR	95% CI	p-value
Another operation[a]	2.6	3.5	1.26	0.8 to 1.8	0.234
Poor operation result[b]	5.2	7.5	1.34	1.1 to 1.7	0.013
Poor quality of life[c]	5.0	7.0	1.31	1.0 to 1.7	0.041
Any complications[a]	25.3	31.8	1.31	1.1 to 1.5	<0.001

Adjusted for: age, sex, pre-operative score, number of co-morbidities, general health, deprivation, received help with questionnaire, living circumstances, time from surgery to follow-up, and duration of problems.

[a] Response - yes.

[b] Combined response – 'fair' or 'poor'.

[c] Combined response – 'mostly dissatisfied', 'unhappy' or 'terrible'.

5.1.7 Sub-group analysis

Sub-group analysis was undertaken comparing ISTCs with NHS Treatment Centres. The results showed no difference in outcomes between ISTCs and NHS Treatment Centres except for complications, which were more frequent in NHS Treatment Centres (complications 25.3% in ISTCs and 32.1% in NHS TCs, adjusted OR of 1.354, p<0.001).

5.1.8 Summary of hip replacement results

The pre-operative results for hip replacement show that ISTCs, on average, treat patients who have less severe symptoms and fewer health problems than those treated by NHS-providers.

The unadjusted post-operative results show statistically significant differences in favour of ISTCs compared to NHS providers for most outcomes. These are not unexpected findings given the pre-operative differences. The case-mix adjustment showed that there are a number of small but statistically significant differences in outcomes in favour of ISTCs compared to NHS providers. However, these differences are slight and not thought to be clinically or socially significant (Section 4.3.1.1).

The large number of providers and patients recruited from both ISTCs and NHS for hip replacement means the results of the Audit are likely to be consistent with those in the rest of the NHS. However, when interpreting the results one should take into account that the recruitment rate was higher in ISTCs than in NHS providers. In addition, the case-mix adjustment model was limited, given that variables such as BMI were not included. Therefore, residual confounding is likely to exist and this may

have reduced the differences in outcome that were found between ISTCs and NHS providers. This is demonstrated in the sub-group analysis, where there were no difference in outcome between ISTCs and NHS Treatments Centres, both of which use similar criteria for patient selection.

5.2 Knee replacement

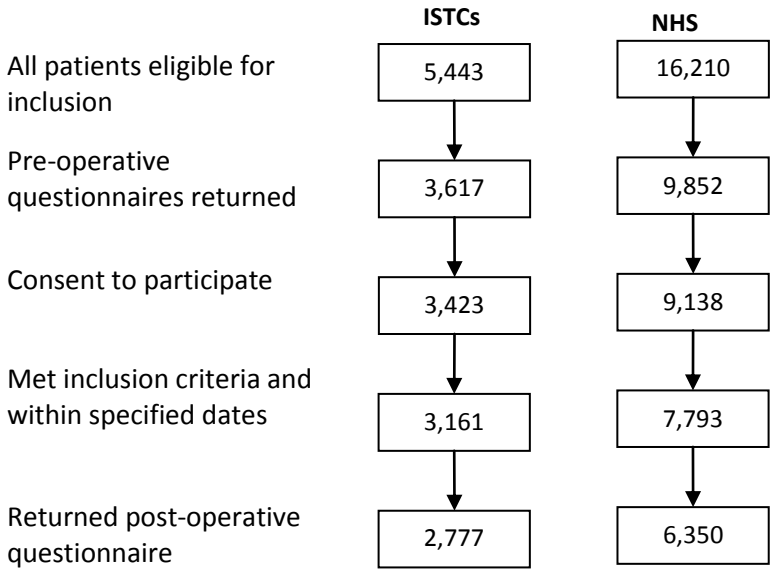
5.2.1 Provider Recruitment

The same providers were recruited for the knee replacement arm of the Audit as for the hip replacement (see Figure 1).

5.2.2 Patient recruitment and response rates

The overall recruitment rate for knee replacement patients was 51% (58% in ISTCs [3,161 of 5,443] and 48% in NHS providers [7,793 of 16,210]). For individual providers the recruitment rate ranged from 6% to 100%. The post-operative response rate was 83% (88% [2,777of 3,161] in ISTCs and 81% [6,350 of 7,793] in NHS providers)(see Figure 3). The same issues affected the recruitment rate for knees as for hips.

Figure 3. Patient recruitment for knee replacement



5.2.3 Comparison of POiS population with all NHS patients using HES

Using HES data to compare the Audit population with the NHS population, we found that they were comparable in terms of age, although there were more men and more patients with low deprivation scores in the Audit population (see Table 7).

Table 7. Comparison of POiS population with NHS population

Variable	POiS Audit	NHS
Age (mean, years)	69.6	69.6
Sex (% male)	45.6	42.1
IMD rank[a] (% in lowest quintile)	17.5	15.9

[a] IMD rank for whole of England divided into quintiles

5.2.4 Comparison of responders and non-responders

Comparison of the pre-operative results for people who did or did not respond to the post-operative questionnaire showed that responders were likely to be older, to live less often in deprived areas, and to have better pre-operative symptoms than non-responders (see Table 8).

Table 8. Comparison of responders and non-responders within providers

Variable	Responders	Non-responders
Age (mean, years)	69.5	66.6
Sex (% male)	44.5	44.4
IMD rank[a] (% in lowest quintile)	16.0	25.5
Co-morbidities (% with any co-morbidities)	88.0	86.8
Pre-operative EQ-5D score (mean)	0.38	0.27
Pre-operative Oxford Knee score (mean)	19.0	16.3

[a] IMD rank for whole of England divided into quintiles

5.2.5 Comparison of ISTC and NHS patient pre-operative characteristics

Comparison of the pre-operative characteristics of the ISTC and NHS groups shows that they were balanced in terms of age, sex and BMI (see Table 9). However, the ISTC population had less severe symptoms than the NHS population. For example, 17.6% of ISTC patients compared to 29.2% of NHS patients reported their general health to be poor or fair.

5.2.6 Comparison of ISTC and NHS patient post-operative outcomes

The unadjusted post-operative results showed that the ISTC patients had better outcomes (see Table 10), with the average Oxford Knee Score being 1.6 points higher ($p<0.01$) and the EQ-5D score being 0.04 higher ($p<0.001$), and the complication rate 7.3% lower ($p<0.001$) than NHS patients.

After case-mix adjustment the differences between the ISTC and NHS populations were reduced (see Table 11 and Table 12), with difference between ISTCs and NHS providers becoming non-significant for re-operation rate (OR 1.18, $p = 0.27$) and poor quality of life due to symptoms (OR 1.17, $p = 0.20$). However, statistically significant differences in favour of ISTCs compared to NHS providers remained for the EQ-5D score (adjusted difference -0.02, $p=0.009$), Oxford Knee Score (adjusted difference -0.90, p=0008), poor overall result of operation (OR 1.17, $p=0.020$) and complication rate (OR 1.35, $p<0.001$).

Table 9. Patient pre-operative characteristics: Knee replacement

Characteristics		ISTC	NHS	p-value ISTC v NHS	Missing data ISTC	Missing data NHS
Total, n		3,161	7,793			
Patient characteristics						
Sex, n (%)						
	Female	1,717 (54.3)	4,335 (55.8)	0.161	1	25
	Male	1,443 (45.7)	3,433 (44.2)			
Age, years, mean (SD)		69.1 (8.9)	69.1 (9.6)	0.826	10	78
IMD rank, % in bottom quintile		457 (14.8)	1362 (18.1)	<0.001	77	281
Body Mass Index, mean (SD)[a]		30.4 (6.3)	31.0 (10.3)	0.124	2,129	5,211
Patient ASA Grade, n (%)[b]						
	1	218 (8.2)	474 (10.1)	<0.001	493	3,121
	2	2,248 (84.3)	3,312 (70.9)			
	3+	202 (7.6)	886 (19.0)			
Number of co-morbidities, n (%)						
	0	470 (14.9)	797 (10.2)	<0.001	0	0
	1	1,094 (34.6)	2,339 (30.0)			
	2 or more	1,597 (50.5)	4,657 (59.8)			
Health and Quality of life						
General health, n (%)						
	Excellent	143 (5.0)	248 (3.5)	<0.001	290	806
	Very good	913 (31.8)	1,793 (25.7)			
	Good	1,308 (45.6)	2,980 (42.7)			
	Fair	455 (15.8)	1,676 (24.0)			
	Poor	52 (1.8)	290 (4.2)			
If you were to spend the rest of your life with your knee the way it is now, how would you feel about that?, n (%)						
	Delighted	20 (0.7)	20 (0.3)	<0.001	257	713
	Pleased	26 (0.9)	26 (0.4)			
	Mostly satisfied	23 (0.8)	38 (0.5)			
	Mixed	67 (2.3)	183 (2.6)			
	Mostly dissatisfied	229 (7.9)	573 (8.1)			
	Unhappy	1,116 (38.4)	2,620 (37.0)			
	Terrible	1,423 (49.0)	3,620 (51.1)			
EQ-5D score						
	Mean (SD)	0.40 (0.31)	0.35 (0.32)	<0.001	300	621
	Median (IQR)	0.52 (0.60)	0.52 (0.64)			
Oxford Knee score						
	Mean (SD)	19.3 (7.5)	18.5 (7.6)	<0.001	170	389
	Median (IQR)	19.0 (10.0)	18.0 (11.0)			

[a] From NJR only & BMIs of 0 excluded.
[b] Combined surgeon-reported and NJR data.

Table 10. Patient post-operative outcomes: knee replacement surgery

Characteristics		ISTC	NHS	p-value	Missing data	
				ISTC v NHS	ISTC	NHS
Total, n (%)		2,777	6,350			
Length of follow-up, months		6.2	6.2	0.018		
Outcomes of the procedure						
Readmitted to hospital , n (%)						
	Yes	223 (8.1)	591 (9.4)	0.041	27	94
	No	2,527 (91.9)	5,665 (90.6)			
Another operation, n (%)						
	Yes	2,535 (92.4)	5,688 (90.9)	0.021	34	95
	No	208 (7.6)	567 (9.1)			
Any complications, n (%)						
	Yes	714 (26.1)	2,086 (33.4)	<0.001	41	112
	No	2,022 (73.9)	4,152 (66.6)			
Results of operation, n (%)						
	Excellent	744 (27.0)	1426 (22.7)	<0.001	26	80
	Very good	1,049 (38.1)	2,290 (36.5)			
	Good	617 (22.4)	1,591 (25.4)			
	Fair	275 (10.0)	729 (11.6)			
	Poor	66 (2.4)	234 (3.7)			
Died, n (%)		10 (0.4)	47 (0.7)	0.059		
Health and Quality of life						
General health, n (%)[a]						
	Excellent	242 (8.8)	365 (5.8)	<0.001	22	86
	Very good	1,034 (37.5)	1,919 (30.6)			
	Good	1,107 (40.2)	2,649 (42.3)			
	Fair	338 (12.3)	1,157 (18.5)			
	Poor	34 (1.2)	174 (2.8)			
If you were to spend the rest of your life with your knee the way it is now, how would you feel about that?, n (%)[a]						
	Delighted	602 (21.9)	1,327 (21.2)	<0.001	27	95
	Pleased	845 (30.7)	1,670 (26.7)			
	Mostly satisfied	614 (22.3)	1,535 (24.5)			
	Mixed	372 (13.5)	852 (13.6)			
	Mostly dissatisfied	100 (3.6)	261 (4.2)			
	Unhappy	144 (5.2)	393 (6.3)			
	Terrible	73 (2.7)	217 (3.5)			
EQ-5D score[a]						
	Mean (SD)	0.74 (0.23)	0.70 (0.25)	<0.001	353	701
	Median (IQR)	0.76 (0.31)	0.73 (0.23)			
Oxford Knee score[a]						
	Mean (SD)	35.5 (8.9)	33.9 (9.6)	<0.001	150	301
	Median (IQR)	37.0 (12.5)	36.0 (13.5)			

[a] Figures based on patients who completed both pre-operative and post-operative questions.

Table 11. Unadjusted score and robust adjusted difference: knee replacement

PROMs	Unadjusted mean (SD)		Adjusted		
	ISTC	NHS	difference	95% CI	p-value
EQ-5D score	0.74 (0.23)	0.70 (0.25)	-0.02	-.04 to -.005	0.009
Oxford Knee score	35.5 (8.9)	33.9 (9.6)	-0.90	-1.6 to -0.2	0.008

Adjusted for: age, sex, pre-operative score, number of co-morbidities, general health, time from surgery to follow-up, duration of problems, housing status, received help completing questionnaire, and deprivation score.

Table 12. Unadjusted scores and adjusted OR: knee replacement

Outcome	%		Adjusted		
	ISTC	NHS	OR	95% CI	p-value
Another operation [a]	7.6	9.1	1.18	0.87 to 1.60	0.276
Poor operation result [b]	12.4	15.3	1.17	1.03 to 1.33	0.020
Poor quality of life [c]	11.5	13.9	1.17	0.92 to 1.47	0.193
Any complications [a]	26.1	33.4	1.35	1.15 to 1.59	<0.001

Adjusted for: age, sex, pre-operative score, number of co-morbidities, general health, time from surgery to follow-up, duration of problems, housing status, received help completing questionnaire, and deprivation score.

[a] Response - yes.

[b] Combined response - fair or poor.

[c] Combined response - mostly dissatisfied, unhappy or terrible.

5.2.7 Sub-group analysis

Sub-group analysis was undertaken comparing ISTCs with NHS Treatment Centres. The results showed no differences in outcomes between ISTCs and NHS Treatment Centres except for poor operation results and complications, which were both more frequent in NHS Treatment Centres (poor operation results 12.4% in ISTCs and 13.7% in NHS TCs, adjusted OR 1.20, p=0.002; complications 26.1% in ISTCs and 31.7% in NHS TCs, adjusted OR 1.29, p=0.003).

5.2.8 Summary of knee replacement results

The pre-operative results show that ISTCs, on average, treat patients who have less severe symptoms and fewer health problems than those treated by NHS-providers.

The results for knee replacement show after case-mix adjustment that there are a number of small but statistically significant differences in the outcomes and complications rates in favour of ISTCs compared to NHS providers. However, these differences are small and are unlikely to be clinically and socially significant.

The large number of providers and patients recruited from both ISTCs and NHS providers means the findings of the Audit are likely to be consistent with those in the rest of the NHS. However, as explained before (see section 5.1.8), given the higher case ascertainment in ISTCs and the limitations of the case-mix adjustment model, residual confounding may explain at least a part of the observed differences between ISTCs and NHS providers.

5.3 Inguinal hernia repair

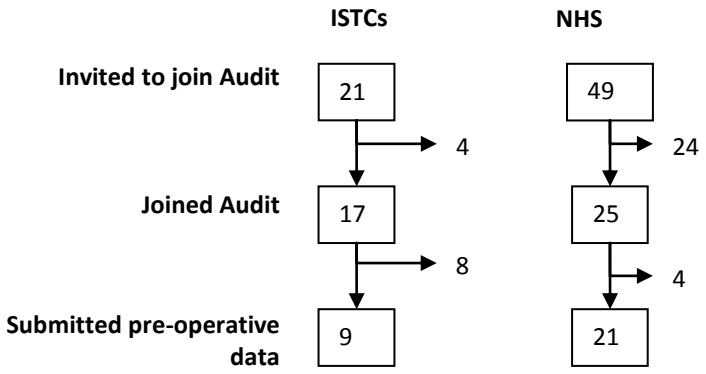
5.3.1 Provider Recruitment

Of the 21 ISTCs that undertook inguinal hernia repair, 17 agreed to join, but nine subsequently submitted data.

In total, 49 NHS providers (representing 74 individual hospitals) were invited to join, and of these, 25 (representing 40 hospitals) agreed to join the Audit with four providers failing to submit any data (Figure 4).

The primary reason for low recruitment of providers was the introduction of the NHS PROMs Programme by the DH. Many providers opted to wait until the commencement of the NHS PROMs programme in April 2009, rather than begin participation in the POiS Audit in December 2008 and then transfer to the DH-led programme.

Figure 4. Provider recruitment for inguinal hernias

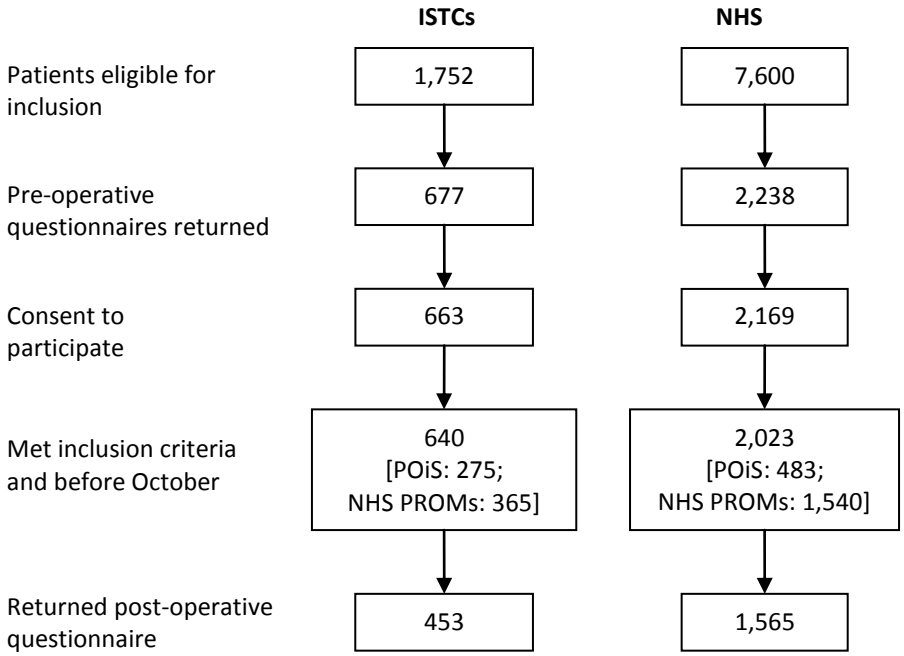


5.3.2 Patient recruitment and response rates

The overall recruitment rate for inguinal hernia repair was 30% (37% [640 of 1,752] for ISTCs and 27% [2,023 of 7,600] for NHS providers) and the follow-up response rate was 76% (71% [453 of 640] for ISTCs and 77% [1,565 of 2,023] for NHS providers) (Figure 5).

The recruitment figures are lower than anticipated. There are two reasons for this. Firstly, the Audit data collection was voluntary and the results show a number of NHS providers failed to participate properly. Secondly, inguinal hernias are treated as day-cases, and the time between arriving in hospital to undergoing surgery is short. This means there is little time to properly recruit patients and for patients to then complete the questionnaires.

Figure 5. Patient recruitment for inguinal hernias



5.3.3 Comparison of POiS population and all NHS patients using HES

A comparison of the Audit population with the NHS population showed that they were similar in terms of the percentage of patients living in deprived areas, but the Audit population tended to be slightly younger and more likely to be male.

Table 13. Comparison of POiS population with rest of NHS population

Variable	POiS Audit	NHS
Age (mean, years)	56.8	58.9
Sex (% male)	93.1	90.7
IMD rank[a] (% in lowest quintile)	15.4	16.0

[a] IMD rank for whole of England divided into quintiles.

5.3.4 Comparison of responders to post-operative questionnaire and non-responders

A comparison of patients who did and did not respond to the post-operative questionnaire showed that responders were on average older, lived less often in deprived areas and had more co-morbidities than patients who did respond (see Table 14).

Table 14. Comparison of responders and non-responders within providers

Variable	Responders	Non-responders
Age (mean, years)	60.8	45.9
Sex (% male)	92.9	93.7
IMD rank[a] (% in lowest quintile)	13.1	23.3
Co-morbidities (% with co-morbidities)	49.9	29.0
General Health (% fair or poor)	8.5	10.0
Pre-operative EQ-5D score (mean)	0.80	0.78

[a] IMD ranks for whole of England divided into quintiles.

5.3.5 Comparison of ISTC and NHS patients pre-operative characteristics

Comparison of the pre-operative characteristics of the ISTC and NHS groups (Table 15) shows they were balanced in terms of sex, clinical classification of inguinal hernia and quality of life. However, the patients treated in ISTCs were younger, lived less frequently in deprived areas and experienced less severe symptoms than the NHS population.

5.3.6 Comparison of ISTC and NHS patient post-operative outcomes

Unadjusted post-operative results show that there is little difference in outcomes between the ISTC and NHS groups except that patients in the ISTC group were less likely to have had another operation (8.3% vs. 13.5%, p=0.002) and reported better post-operative general health than those in the NHS group (91.7% vs. 86.2%, p<0.001) (Table 16).

After case-mix adjustment, the difference between ISTC and NHS groups increased in terms of the overall result of the operation (Table 17 and Table 18), where the ISTC group had less often a poor operation results than the NHS group (7.1% vs. 8.5, adjusted OR 1.40, p=0.042). However, there was little effect on the difference and significance levels of the other outcomes.

Table 15. Patient pre-operative characteristics: inguinal hernia repair

Characteristics		ISTC	NHS	p-value ISTC v NHS	Missing data ISTC	Missing data NHS
Total, n		**640**	**2,023**			
Patient characteristics						
Sex, n (%)						
	Female	39 (6.1)	145 (7.2)	0.349	0	1
	Male	601 (93.9)	1,877 (92.8)			
Age, years, mean (SD)		53.6 (15.6)	58.4 (16.6)	<0.001	32	9
IMD, % in bottom quintile		113 (17.8)	473 (23.5)	0.009	5	7
Body Mass Index, mean (SD)[a]		25.6 (3.3)	26.2 (4.4)	0.068	414	1,689
Patient ASA Grade, n (%)[a]				0.410	394	1,642
	1	141 (57.3)	231 (60.6)			
	2	101 (41.1)	135 (35.4)			
	3+	4 (1.6)	15 (3.9)			
Number of co-morbidities, n (%)				<0.001	0	0
	0	418 (65.3)	1,050 (51.9)			
	1	152 (23.8)	598 (29.6)			
	2 or more	70 (10.9)	375 (18.5)			
Surgical characteristics						
Presenting features, n (%)[a,b]				0.497	415	1,647
	H1	115 (51.1)	209 (55.6)			
	H2	80 (35.6)	126 (33.5)			
	H3	21 (9.3)	26 (6.9)			
	H4	9 (4.0)	15 (4.0)			
Previous similar surgery, n (%)				<0.001	10	19
	Yes	56 (8.9)	261 (13.0)			
	No	574 (91.1)	1743 (87.0)			
Health and Quality of life						
General health, n (%)				<0.001	14	32
	Excellent	85 (13.6)	243 (12.2)			
	Very good	271 (43.3)	797 (40.0)			
	Good	234 (37.4)	734 (36.9)			
	Fair	35 (5.6)	198 (9.9)			
	Poor	1 (0.2)	19 (1.0)			
If you were to spend the rest of your life with your hernia the way it is now, how would you feel about that?, n (%) [a]				0.584	17	26
	Delighted	3 (1.2)	1 (0.2)			
	Pleased	3 (1.2)	12 (2.6)			
	Mostly satisfied	14 (5.4)	31 (6.8)			
	Mixed	46 (17.8)	89 (19.5)			
	Mostly dissatisfied	62 (24.0)	119 (26.0)			
	Unhappy	94 (36.4)	156 (34.1)			
	Terrible	36 (14.0)	49 (10.7)			
EQ-5D score				0.001	47	85
	Mean (SD)	0.81 (0.17)	0.78 (0.21)			
	Median (IQR)	0.796 (0.24)	0.796 (0.28)			

[a] Only collected by the POiS Audit, not for NHS PROMs programme.

[b] Where:- H1=Groin only, reduces spontaneously on lying down; H2=Groin only, reduces completely with gentle manual pressure; H3=Inguinoscrotal, reducible with manual manipulation; H4=Irreducible.

Table 16. Patient post-operative outcomes: inguinal hernia repair

Characteristics		ISTC	NHS	p-value ISTC v NHS	Missing data ISTC	Missing data NHS
Total, n (%)		453	1,565			
Length of follow-up, months		4.9	4.7	0.057		
Outcomes of the procedure						
Readmitted to hospital, n (%)				0.374	6	28
	Yes	17 (3.8)	76 (4.9)			
	No	430 (96.2)	1,461 (95.1)			
Another operation, n (%)				0.002	5	24
	Yes	37 (8.3)	208 (13.5)			
	No	411 (91.7)	1,333 (86.5)			
Any complications, n (%)				0.381	7	22
	Yes	100 (22.4)	377 (24.4)			
	No	346 (77.6)	1,166 (75.6)			
Results of operation, n (%)				0.504	4	20
	Excellent	153 (34.1)	540 (35.0)			
	Very good	183 (40.8)	574 (37.2)			
	Good	81 (18.0)	299 (19.4)			
	Fair	23 (5.1)	100 (6.5)			
	Poor	9 (2.0)	32 (2.1)			
Health & Quality of life						
General health, n (%)[a]				<0.001	8	43
	Excellent	45 (10.1)	172 (11.3)			
	Very good	218 (49.0)	573 (37.6)			
	Good	145 (32.6)	568 (37.3)			
	Fair	33 (7.4)	181 (11.9)			
	Poor	4 (0.9)	28 (1.8)			
If you were to spend the rest of your life with your hernia the way it is now, how would you feel about that?, n (%)[a,b]				0.436	9	16
	Delighted	71 (40.3)	156 (42.2)			
	Pleased	53 (30.1)	120 (32.4)			
	Mostly satisfied	30 (17.0)	44 (11.9)			
	Mixed	10 (5.7)	15 (4.1)			
	Mostly dissatisfied	1 (0.6)	18 (4.9)			
	Unhappy	9 (5.1)	9 (2.4)			
	Terrible	2 (1.1)	8 (2.2)			
EQ-5D score[a]				0.317	23	94
	Mean (SD)	0.89 (0.2)	0.88 (0.2)			
	Median (IQR)	1 (0.2)	1 (0.2)			

[a] Figures based on patients who completed both pre-operative and post-operative questions.
[b] Only collected by the POiS Audit, not for NHS PROMs programme.

Table 17. Unadjusted score and robust adjusted difference: inguinal hernia repair

PROMs	Unadjusted mean (SD)		Adjusted		
	ISTC	NHS	difference	95% CI	p-value
EQ-5D Score	0.89 (0.2)	0.88 (0.2)	0.005	-0.01 to 0.02	0.508

Adjusted for: pre-operative score, age, general health, any reported co-morbidity and deprivation score.

Table 18. Unadjusted scores and adjusted OR: inguinal hernia repair

Outcome	%		Adjusted		
	ISTC	NHS	OR	95% CI	Wald test
Another operation[a]	8.3	13.5	1.46	0.90 to 2.38	0.126
Poor operation result[b]	7.1	8.6	1.40	1.01 to 1.94	0.042
Any complications[a]	22.4	24.4	1.13	0.85 to 1.49	0.400

Adjusted for: pre-operative score, age, general health, any reported co-morbidity and deprivation score.
[a] Response - yes.
[b] Combined response - fair or poor.

5.3.7 Summary

The results for inguinal hernia repair show some differences between ISTCs and NHS providers in terms of pre-operative patient characteristics.

The unadjusted post-operative results suggest that patients treated by ISTCs were less likely to have another operation and reported a poor operation result less often. After case-mix adjustment, only the differences in frequency of having a poor operation result remained. Overall, the results suggest little difference in outcomes between ISTCs and NHS providers.

5.4 Varicose vein surgery

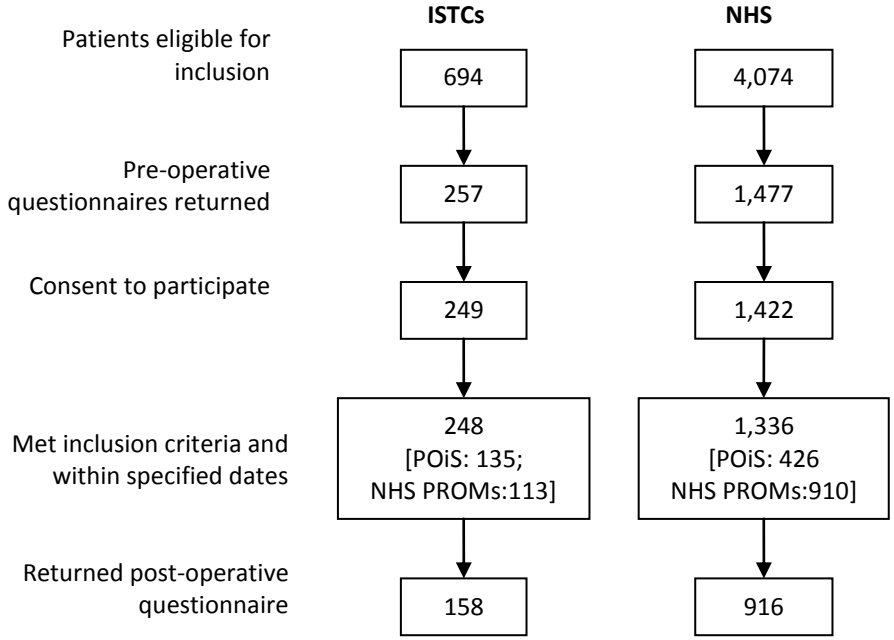
5.4.1 Provider Recruitment

The same providers were recruited for the varicose vein surgery arm of the Audit as for the inguinal hernia repair arm. The lack of provider participation was also due to the same issues experienced in the inguinal hernia repair (see section 5.3.1).

5.4.2 Patient recruitment and response rates

The overall recruitment rate for varicose vein surgery was 33% (36% [248 of 694] in ISTCs and 33% [1,336 of 4,074] in NHS providers). The response rate to the post-operative questionnaire was 68% (64% [158 of 248] in ISTCs and 69% [916 of 1,336] in NHS providers). The recruitment rates for varicose vein surgery were affected by the same issues experienced with the inguinal hernia repair.

Figure 6. Patient recruitment for varicose veins



5.4.3 Comparison of POiS population and all NHS population using HES

The patients in the POiS Audit were similar to the NHS population in terms of sex and levels of deprivation, but they were more likely to be younger (Table 19).

Table 19. Comparison of POiS population and rest of the NHS population

Variable	POiS Audit	NHS
Age (mean, years)	49.1	51.1
Sex (% male)	35.2	37.2
IMD rank[a] (% in lowest quintile)	20.6	19.94

[a]IMD rank for whole of England divided into quintiles.

5.4.4 Comparison of responders and non-responders

Patients who responded to the post-operative questionnaire tended to be older, to live less frequently in deprived areas and to have more frequently co-morbidities than those who did not respond (Table 20).

Table 20. Comparison of responders and non-responders

Variable	Responders	Non-responders
Age (mean, years)	52.8	42.8
Sex (% male)	36.8	34.3
IMD rank[a] (% in lowest quintile)	19.1	23.8
Co-morbidities (% with co-morbidities)	46.8	33.3
General Health (% fair or poor)	11.6	11.4
Pre-operative EQ-5D score (mean)	0.77	0.76

[a]IMD ranks for whole of England divided into quintiles

5.4.5 Comparison of ISTC and NHS patient pre-operative characteristics

Comparison of the pre-operative characteristics of the ISTC and NHS groups (Table 21) shows that the groups are similar for most characteristics. The results show that the patients in the ISTC group were younger (48.0 vs. 49.9 years) and more often had mild symptoms (83.5% vs. 78.6% with CEAP classification C1, C2 and C3).

5.4.6 Comparison of ISTC and NHS patient post-operative outcomes

Before case-mix adjustment, the post-operative results show that fewer patients in the ISTC group have had another operation or reported a ‘fair’ or ‘poor’ general health status than those in the NHS group (Table 22). However, after case-mix adjustment the differences between the groups were reduced and the only difference that remained statistically significant was that the NHS patients more often required another operation (Table 23 and Table 24) (5.2% vs. 13.7%, adjusted OR 2.83).

Table 21. Patient pre-operative characteristics: varicose vein surgery

Characteristics		ISTC	NHS	p-value ISTC v NHS	Missing data ISTC	Missing data NHS
Total, n		248	1,336			
Patient characteristics						
Sex, n (%)				0.293	0	1
	Female	168 (67.7)	858 (64.3)			
	Male	80 (32.3)	477 (35.7)			
Age, years, mean (SD)		48.0 (13.6)	49.9 (14.1)	0.048	7	7
IMD, % in bottom quintile		54 (22.3)	270 (20.2)	0.513	2	6
Body Mass Index, mean (SD)[a]		27.5 (4.9)	27.4 (5.2)	0.939	178	968
Patient ASA Grade, n (%)[a]				0.993		
	1	72 (68.6)	246 (68.5)		143	977
	2	31 (29.5)	106 (29.5)			
	3+	2 (1.9)	7 (1.9)			
Number of co-morbidities, n (%)				0.221	0	0
	0	154 (62.1)	757 (56.7)			
	1	62 (25.0)	359 (26.9)			
	2 or more	32 (12.9)	220 (16.5)			
Surgical characteristics						
CEAP clinical classification, n (%)[a]				0.050	950	145
	C1: Telanglectasia or reticular veins	0 (0.0)	6 (1.6)			
	C2: Varicose veins	78 (75.7)	247 (64.0)			
	C3: Oedema	8 (7.8)	50 (13.0)			
	C4a: Pigmentation or eczema	13 (12.6)	56 (14.5)			
	C4b: Lipodermatosclerosis or atrophie blanche	2 (1.9)	10 (2.6)			
	C5: Healed venous ulcer	2 (1.9)	13 (3.4)			
	C6: Active venous ulcer	0 (0.0)	4 (1.0)			
Health and Quality of life						
General health, n (%)				0.172	8	25
	Excellent	32 (13.3)	138 (10.5)			
	Very good	91 (37.9)	507 (38.7)			
	Good	98 (40.8)	507 (38.7)			
	Fair	17 (7.1)	138 (10.5)			
	Poor	2 (0.8)	21 (1.6)			
If you were to spend the rest of your life with your varicose veins the way it is now, how would you feel about that?, n (%)[a]				0.106	4	18
	Delighted	0 (0.0)	3 (0.2)			
	Pleased	0 (0.0)	1 (0.1)			
	Mostly satisfied	4 (1.6)	5 (0.4)			
	Mixed	8 (3.2)	54 (4.0)			
	Mostly dissatisfied	28 (11.3)	58 (4.3)			
	Unhappy	65 (26.2)	210 (15.7)			
	Terrible	26 (10.5)	77 (5.8)			
EQ-5D score				0.762	15	52
	Mean (SD)	0.77 (0.2)	0.77 (0.2)			
	Median (IQR)	0.80 (0.1)	0.80 (0.1)			
AVVQ score				0.890	23	128
	Mean (SD)	15.9 (8.7)	15.8 (8.2)			
	Median (IQR)	14.3 (10.1)	14.6 (10.1)			

[a] Only collected by POiS Audit, not for NHS PROMs programme.

Table 22. Patient post-operative outcomes: varicose vein surgery

Characteristics		ISTC	NHS	p-value ISTC v NHS	Missing data ISTC	Missing data NHS
Total, n (%)		158	916			
Length of follow-up, months		3.7	3.6	0.374		
Outcomes of the procedure						
Readmitted to hospital, n (%)				0.142	1	10
	Yes	5 (3.2)	58 (6.4)			
	No	152 (96.8)	848 (93.6)			
Another operation, n (%)				0.002	3	15
	Yes	8 (5.2)	123 (13.7)			
	No	147 (94.8)	778 (86.3)			
Any complications, n (%)				0.545	2	10
	Yes	43 (27.6)	229 (25.3)			
	No	113 (72.4)	677 (74.7)			
Results of operation, n (%)				0.860	1	12
	Excellent	38 (24.2)	198 (21.9)			
	Very good	60 (38.2)	343 (37.9)			
	Good	35 (22.3)	227 (25.1)			
	Fair	21 (13.4)	99 (11.0)			
	Poor	3 (1.9)	37 (4.1)			
Health and Quality of life						
General health, n (%)[a]				0.031	3	23
	Excellent	26 (16.8)	114 (12.8)			
	Very good	79 (51.0)	383 (42.9)			
	Good	42 (27.1)	310 (34.7)			
	Fair	7 (4.5)	75 (8.4)			
	Poor	1 (0.6)	11 (1.2)			
If you were to spend the rest of your life with your varicose veins the way it is now, how would you feel about that?, n (%)[a, b]				0.919	3	17
	Delighted	8 (9.1)	32 (11.6)			
	Pleased	15 (17.0)	49 (17.8)			
	Mostly satisfied	22 (25.0)	71 (25.8)			
	Mixed	17 (19.3)	54 (19.6)			
	Mostly dissatisfied	18 (20.5)	16 (5.8)			
	Unhappy	3 (3.4)	36 (13.1)			
	Terrible	5 (5.7)	17 (6.2)			
EQ-5D score[a]				0.385	9	62
	Mean (SD)	0.88 (0.18)	0.86 (0.20)			
	Median (IQR)	1 (0.20)	1 (0.20)			
AVVQ score[a]				0.92	18	138
	Mean (SD)	9.1 (8.1)	9.2 (8.1)			
	Median (IQR)	7.2 (9.1)	7.5 (9.6)			

[a] Figures based on patients who completed both pre-operative and post-operative questions.
[b] Only collected by POiS Audit, not for NHS PROMs programme.

Table 23. Unadjusted score and robust adjusted difference: varicose vein surgery

PROMs	Unadjusted mean (SD)		Adjusted		
	ISTC	NHS	difference	95% CI	p-value
EQ-5D score	0.88 (0.18)	0.86 (0.20)	-0.003	-0.02 to 0.02	0.809
AVVQ score	9.1 (8.1)	9.2 (8.1)	0.02	-1.61 to 1.64	0.984

Adjusted for: pre-operative score, age, general health, any reported co-morbidity and deprivation score.

Table 24. Unadjusted scores and adjusted OR: varicose vein surgery

Outcome	%		Adjusted		
	ISTC	NHS	OR	95% CI	Wald test
Another operation[a]	5.2	13.7	2.83	1.19 to 6.75	0.019
Poor operation result[b]	15.3	15.0	0.99	0.65 to 1.51	0.965
Any complications[a]	27.6	25.3	0.87	0.59 to 1.29	0.497

Adjusted for pre-operative score, age, general health, any reported co-morbidity and deprivation score.
[a] Response - yes.
[b] Combined response - fair or poor.

5.4.7 Summary of varicose vein surgery

The pre-operative results for varicose vein surgery show no differences between patients treated in ISTCs and NHS providers.

Both the unadjusted and case-mix adjusted post-operative figures show that similar results were achieved in ISTCs and NHS providers. The only major difference was the higher rate of having another operation found in NHS providers.

Chapter 6 – Conclusion

6.1 Summary of the results

The POiS Audit was established to compare a range of patient-reported outcomes achieved by ISTCs with those achieved by NHS providers.

For both hip and knee replacement, we found that:

- Patients treated by ISTCs were on average more affluent. They were also fitter for surgery and had fewer co-morbidities. The patients treated by ISTCs also reported better pre-operative general health and better generic and condition-specific quality of life than those treated by NHS providers.
- Post-operative outcomes were better in ISTCs. With adjustment for case-mix, we found that patients treated in ISTCs reported a better general health, a better result of the operation, a better generic and condition-specific quality of life. They less frequently had complications or another operation.
- The differences that we found after adjustment for case-mix differences were often small and are unlikely to be clinically or socially significant. The complication rate after hip or knee replacement was about a third higher in the NHS providers than in ISTCs according to the adjusted figures.

For inguinal hernia repair, we found that:

- Patients treated by ISTCs were on average younger and more affluent and they had fewer co-morbidities. They also reported a better pre-operative general health and generic quality of life.
- Most outcomes of patients treated by ISTCs or NHS providers were similar. The only difference was that patients treated in NHS providers reported more frequently that the operation results were poor: the risk of a poor operation result was about 40% higher when differences in case-mix were taken into.

For varicose vein surgery, we found that:

- Patients treated by ISTCs were on average younger and had slightly less severe varicose vein problems.
- Most outcomes of patients treated by ISTCs or NHS providers were similar. Patients treated in the NHS reported more frequently that they had undergone another operation. The risk was about three times higher in the NHS when difference in case-mix were taken into account.

6.2 Limitations of the Audit

A number of limitations with the design and implementation of the Audit may have influenced the results.

6.2.1 Enrolment of providers

Participation in the POiS Audit was voluntary for both ISTCs and NHS providers. As a result, not all invited providers enrolled in the Audit. With respect to hip and knee replacement, most ISTCs participated (14 out of 16 invited ISTCs submitted pre-operative data), whereas only about 50% of the invited NHS providers did (51 of the 109 NHS providers submitted pre-operative data). Participation of ISTCs and NHS providers was even lower for inguinal hernia repair and varicose vein surgery (9 of the 21 invited ISTCs submitted pre-operative data compared to 21 of the 49 invited NHS providers). As a result, the ISTCs and NHS providers enrolled in the Audit may not be representative. However, for all four procedures, there were only small differences in terms of age, sex and deprivation between the patients who participated in the Audit and the wider population of patients undergoing a similar procedure in the NHS. In addition, the Audit had good geographical coverage, with at least one NHS provider from each of the 10 NHS strategic health authority regions.

6.2.2 Patient recruitment

The patient recruitment rates for the four procedures ranged from 30% to 60% among the four elective procedures. As a result, the patients included in the Audit may be a selected group and not be representative of the patients treated by ISTCs or NHS providers. This is a concern as the LSHTM feasibility study showed that providers that had lower recruitment rates included patients with less severe mean pre-operative scores. However, we aimed to limit the potential impact of selective inclusion by adjusting the comparison of outcomes in ISTCs and NHS providers for differences in case-mix.

6.2.3 Case-mix adjustment

The case-mix adjustment model was designed to account for pre-operative patient factors. Whilst the Audit did extend the outlined case-mix adjustment model in the LSHTM feasibility study, a number of important limitations remained. The opportunity to include BMI, ASA grade, ethnicity and surgeon-reported clinical severity measures in the case-mix model was explored, but given the high level of missing data for these variables they could not be included. It is therefore likely that part of the differences in the outcomes of patients treated by ISTCs and those treated by NHS providers are due to residual confounding (i.e. due to differences in the pre-operative patient characteristics that could not be adjusted for).

6.2.4 Data validity

We only used outcomes that were reported by patients. The validity of certain patient-reported outcomes need to be further explored. For example, we found that patients who had an inguinal hernia repair in the NHS reported a reoperation rate that was almost three times higher than those treated in an ISTC. This difference

may reflect a difference in operative management rather than a difference in the quality of care.

6.3 Audit developments

The Audit required the development of surgeon-reported clinical datasets and a patient-reported co-morbidity index.

6.3.1 Surgeon-reported datasets

The Audit Team was set the task to develop and collect surgeon-reported data on processes used in order to enhance the case-mix adjustment and to identify operative complications. The results of this development process were a 19-item dataset for hip replacement, a 17-item dataset for knee replacement, a 20-item dataset for inguinal hernia repair, and a 14-item dataset for varicose veins.

The completion rate of these forms was approximately 50% for hip and knee surgery and 87% for inguinal hernia repair and varicose vein surgery. There are two likely explanations for the low completion rate of surgeon-reported data for hip and knee replacement. Firstly, the orthopaedic surgeons could only complete their data forms after a patient had been discharged from hospital (and length of stay is on average more than a week). Secondly, the data had to be entered by the provider into a central database via the POiS Audit's website.

The collection of surgeon-reported data for inguinal hernia repair and varicose vein surgery was organised differently. The form that was used to collect these data was printed on the back of the patient questionnaire and returned to the Audit Team for data entry. Length of stay after both general surgery procedures is very short, which made it possible to complete the surgeon-reported data on the day of surgery. In addition, there is no data collection equivalent to the NJR for general surgery. Although the completion rate was good for both inguinal hernia repair and varicose vein surgery, these data was only collected as part of the POiS Audit (December – April 2010). When the general surgery data collection was transferred to the NHS PROMs Programme, the surgeon-reported data collection ceased, thus data was available only for a limited amount of patients.

6.3.2 Patient-reported co-morbidity index

A 12-item patient-reported co-morbidity index ('LSHTM Patient-Reported Co-morbidity Index') was developed by the Audit Team. This was based on the approach already used in the LSHTM feasibility study with the addition of results from a systematic review of existing patient-reported co-morbidity indices undertaken by the Audit Team. The Index was used throughout the Audit and has been adopted by the NHS PROMs Programme and incorporated in their case-mix adjustment model. The Audit Team is in the process of validating this patient-reported co-morbidity index.

6.3.3 Routine collection of PROMs data

The Audit demonstrates a number of challenges of carrying out a large-scale study collecting PROMs data in the English NHS:

- Recruitment rates varied among providers and in some cases providers failed to participate. This demonstrates the need to monitor patient recruitment against expected numbers from the start and to feedback their results to participating providers so they can be improved.
- Response rates were very good after hip and knee replacement and reasonable after inguinal hernia repair and varicose vein surgery. This is likely to reflect the differences in the patient groups. Also, the willingness of patients to participate may also be dependent on the nature and severity of the procedure and their potential impact on health.
- Linkage of POiS data to HES and the NJR was undertaken by the NHS Information Centre and augmented with additional linkage undertaken by the Audit Team (see Appendix C). It was found that linkage rates of 90% or more could be achieved for POiS Audit data and HES. This result highlights the potential of national clinical audits solely based on patient-reported data linked to existing administrative datasets. An important condition for such an approach is a complete and accurate collection of patient identifiers, including NHS number, date of birth and postcode.

6.4 Conclusion

The POiS Audit was established to compare the case-mix adjusted patient-reported outcomes of elective surgery undertaken by ISTCs and by NHS- providers. The results of the Audit show a number of differences in favour of ISTCs. However, most differences are small and their clinical relevance is uncertain. In addition, patients treated by ISTCs have a case-mix profile that makes them likely to have better outcomes than those treated by NHS providers and we may not have adjusted fully for this more favourable risk profile.

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- Mr Alun Davies
- Mr Michael Gough
- Professor Andrew Kingsnorth
- Mr Martin Kurzer
- Mr Tim Lees
- Mr Jonathon Pye
- Mr Keith Tucker

The Audit Team consists of:

- Dr Jiri Chard – Senior Audit Co-ordinator
- Ms Jo Clarke – Audit administrator
- Ms Maxine Kuczawski – Audit Co-ordinator
- Ms Tracey Tong – Audit administrator
- Professor Jan van der Meulen – Director of CEU

In addition, support has been provided by other members of staff at the CEU:

- Professor John Browne
- Ms Lynn Copley
- Ms Jackie Horrocks
- Mr Andrew Hutchings
- Dr Jenny Neuberger

Appendix A – Steering Committee

A Steering Committee was established to provide independent oversight and governance to the POiS Audit. Representatives from all the main stakeholder groups were invited to join the Steering Committee. The Steering Committee membership is as follows:

- Professor Mike Gill – Chair
- Mr Andrew Woodhead - National Joint Registry
- Ms Carolyn Naisby - The Chartered Society of Physiotherapy
- Dr Jean Jacques de Gorter – Spire hospitals & Independent Sector[a]
- Professor Nick Black – London School of Hygiene and Tropical Medicine
- Mr Timothy Wilton - British Orthopaedic Association
- Mrs Jo C Hawkes - Patient/ lay representative, BOA Patient Liaison Group[b]
- Mrs Beda Oliver - Patient/ lay representative, RCS Patient Liaison Group
- Mr John McIvor - NHS Confederation (on behalf of the Commissioners)
- Mr Neil Betteridge - Arthritis Care[c]
- Mr Paul Evans - Consultant Orthopaedic Surgeon, and Medical Director (Peninsula NHS Treatment Centre)
- Mr Brian Rees – Consultant General Surgeon & The Royal College of Surgeons of England

In addition, representatives from the DH act as observers for the sponsoring organisation:

- Dr Richard Dale – Medical Director, Commercial Directorate[d]
- Dr Jane Moore – Policy Advisor[e]
- Mr David Nuttall
- Mr Rob Moorhead

[a] Dr de Gorter stepped down from the Steering Committee and has been replaced by Sheila Peskett, Ramsay Health Care UK

[b] Jo Hawkes has retired from the BOA Patient Liaison Group, and a replacement has been requested

[c] Neil Betteridge stepped down from the Steering Committee and has been replaced by Jo Cumming, Arthritis Care

[d] Richard Dale has left the DH and has been replaced on the Steering Committee by Anna Casburn-Jones, Head of Clinical Care

[e] Jane Moore moved into a secondment post and has been replaced on the Steering Committee by Gerard Hetherington, Director Clinical Care

Appendix B – Patient inclusion and exclusion criteria

Hips replacements

Included

- Unilateral hip replacement procedures as defined by the OPCS-4.3 clinical procedure codes:
    - Total hip replacement, primary (W37.1, W37.8, W37.9, W38.1, W38.8, W38.9, W39.1, W39.8, W39.9);
    - Total prosthetic replacement of the head of the femur, primary (W46.1, W46.8, W46.9, W47.1, W47.8, W47.9, W48.1, W48.8, W48.9);
    - Hybrid prosthetic hip replacements, primary (W93.1, W93.8, W93.9, W94.1, W94.8, W94.9, W95.1, W95.8, W95.9);
    - Other Hip replacements, primary (W52.1, W52.8, W52.9, W53.1, W53.8, W53.9, W54.1, W54.8, W54.9 (with Z76.1 or Z75.6)
    - Hip resurfacing (W581 with Z84.6)
- Non-emergency procedure: HES ADMIMETH not between 21 and 28
- Patient type: HES ADMINCAT = 1 (NHS patient)
- Age: HES STARTAGE > 15
- Operation date between 1st June 2008 to 30th September 2009

Excluded

All HES linked records that did not meet these criteria were excluded; revisions excluded by omissions of their codes. Additional active exclusions were:

- Bilateral hip replacements Z94.1 or as a pair of unilateral hip replacements accompanied by both a code of Z94.2 (“Right-sided operation”) and a code of Z94.3 (“Left-sided operation”).
- Revision
    - POiS Previous operation = yes
    - NJR Procedure_type = Revision
- POiS - Age <=15

Knees

Included

- All unilateral knee replacement procedures as defined by the OPCS-4.3 clinical procedure codes:
    - Total knee replacements, primary (W40.1, W40.8, W40.9, W41.1, W41.8, W41.9, W42.1, W42.8, W42.9);
    - Unicondylar/Unicompartmental knee operations, primary (W52.1, W52.8, W52.9, W53.1, W53.8, W53.9, W54.1, W54.8, W54.9 (with Z76.5, Z77.1 or Z77.4 for dominator only);
    - Knee resurfacing (W581 with z843 or z902)
- Non-emergency procedure: HES ADMIMETH not between 21 and 28
- Patient type: HES ADMINCAT = 1 (NHS patient)
- Age: HES STARTAGE > 15
- Operation date between 1st June 2008 to 30th September 2009

Excluded
All HES linked records that did not meet these criteria were excluded; revisions excluded by omissions of their codes in inclusion. Additional active exclusions were:

- Bilateral knee replacements Z94.1 or as a pair of unilateral knee replacements accompanied by both a code of Z94.2 ("Right-sided operation") and a code of Z94.3 ("Left-sided operation").
- POiS - Previous operation = yes
- NJR - procedure_type = Revision
- POiS - Age <=15

Varicose veins
Included

- All Varicose Vein surgeries as defined by the OPCS-4.3 clinical procedure codes:
    - L84, L85, L86, L87, L88 where these are accompanied by ICD-10 Diagnosis codes of I83.0, I83.1, I83.2, I83.9, O22.0; and
    - L93 with Z39.5, Z39.9, Z93.9, Z98.3, Z98.4, Z98.7 or Z98.9 where this is accompanied by ICD-10 Diagnosis codes of I83.0, I83.1, I83.2, I83.9, O22.0.
- Non-emergency procedure: HES ADMIMETH not between 21 and 28
- Patient type: HES ADMINCAT = 1 (NHS patient)
- Age: HES STARTAGE > 15
- Operation date between 1st June 2008 to 30th September 2009

Excluded
All HES linked records that did not meet these criteria were excluded; revisions excluded by omissions of their codes in inclusion.

- POiS - Age <=15

Groin hernia

- All Groin Hernia surgeries as defined by the OPCS-4.3 clinical procedure codes:
    - T19, T20, T21, T22, T23; and
    - recurrent incisional groin hernia (T26 with Z49.8).
- Non-emergency procedure: HES ADMIMETH not between 21 and 28
- Patient type: HES ADMINCAT = 1 (NHS patient)
- Age: HES STARTAGE > 15
- Operation date between 1st June 2008 to 30th September 2009

Excluded
All HES linked records that did not meet these criteria were excluded; revisions excluded by omissions of their codes in inclusion.

- POiS - Age <=15

Appendix C – Data quality and linkage

This appendix outlines the methodology used to produce the final dataset used for analysis in the POiS audit. The aim of this process is to create single linked and 'cleaned' dataset for each of the four procedures: hip and knee replacement, inguinal hernia repair and varicose vein surgery.

Data sources

The POiS Audit is using data from six sources:

- POiS dataset–collected by the Audit Team and contains patient identifiers, demographics, and PROMs.
- Surgeon-reported dataset - collected by the Audit Team and contains diagnosis, procedure and in-patient complications.
- NHS PROMs – collected as part of the NHS PROMs Programme(DH) and contains PROMs data. This dataset is required for general surgery PROMs data as part of agreement for handover of general surgery providers to NHS PROMs.
- Hospital Episode Statistics (HES) – contains diagnostic, treatment and administrative data.
- National Joint Registry (NJR) – contains detailed treatment information, including ASA grade and BMI.
- The NHS Strategic Tracing Service (NSTS) - used to provide information on whether a patient had died during the follow-up period and obtain missing patient identifier information, such as the NHS number.

The original plan for the POiS Audit was that data collection for orthopaedic surgery would start on 1st June 2008 and finish on 30th September 2009, and for general surgery the dates would be 1st December 2008 to 30th September 2009. The POiS Audit Team would then link POiS records to NSTS, HES and NJR records in order to provide additional clinical information. This original plan was amended by the Department of Health due to the start of the NHS PROMs programme. The POiS Audit was required to transfer all general surgery providers to the NHS PROMs programme from 1st April 2009 which truncated data collection by 6 months, and to transfer all POiS data to the NHS PROMs programme for inclusion in their dataset. In return for the loss of primary data collection and sharing of data, the NHS PROMs programme agreed to make their data available and undertake the linkage to HES and NJR.

Assessing datasets

The following 4 stages needed to be completed before data analysis:

1. Test and improve linkage of POiS data, HES and NJR datasets
2. Adding NHS PROMs data to POiS for general surgery
3. Identify and remove duplicate records from POiS dataset
4. Identify and remove erroneous data from POiS dataset

This work was undertaken in Microsoft Access where the main POiS database is stored.

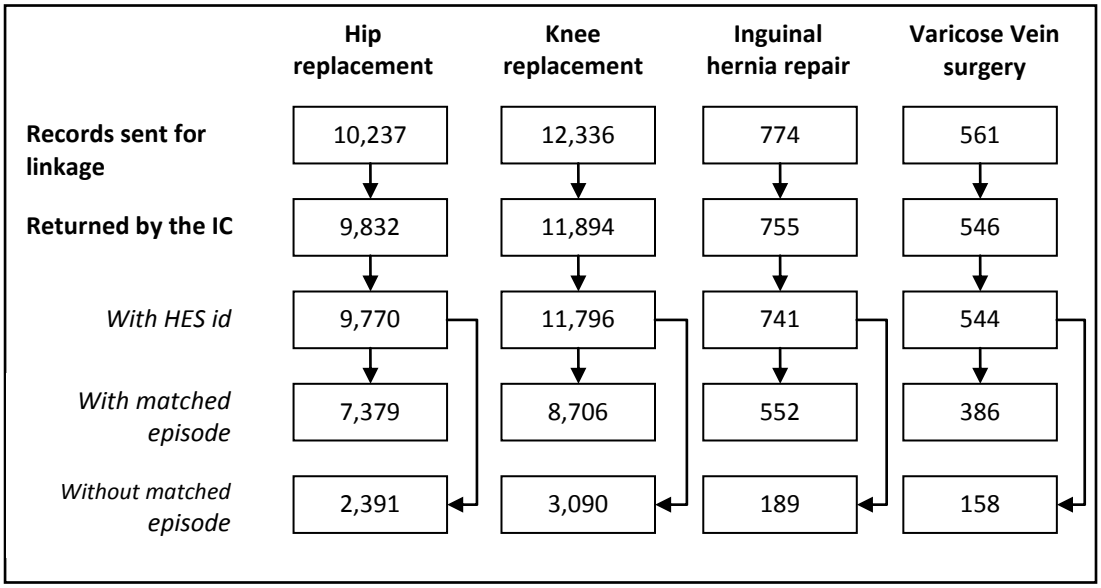
Testing and improving linkage of datasets

HES linkage

HES linkage for the POiS Audit was undertaken by the NHS Information Centre (IC) as part of the agreement with the NHS PROMs Programme. The POiS Audit team transferred data for all consenting patients to the IC in July 2010, and a HES linked dataset was returned in September 2010. Linkage of POiS data to HES data was undertaken by the IC using the same process as used for the NHS PROMs programme. It was assumed that the linkage undertaken by the IC is accurate and that the content of the records is correct. Therefore, this section focuses on investigating POiS records where no linkage has been achieved and determining why this has happened and if it can be improved.

Figure 7 provides a summary of the success of linkage. Assessment of the returned data show that linkage was not attempted where the patient consented but the pre-operative questionnaire was not completed (approximately 3% of questionnaires). Where linkage was attempted, the results show that the IC managed to match a POiS record to a HES ID in 99% of cases and to a specific episode in approximately 75% of cases. However, for about 24% of records in which a HES ID was found (the patient was found on the HES system) no matched HES episode was found (the specific procedure was not identified).

Figure 7 – HES linkage for POiS Audit



The POiS Audit Team used the HES IDs where no episode had been matched and linked these to a local HES data extract (securely held in the RCS CEU) for each specific procedure to determine if further episodes could be identified. Assessment of this showed a large number of potential matches; and that mismatches in provider codes and incorrect date of operation within HES were the main sources of episodes not being linked by the IC.

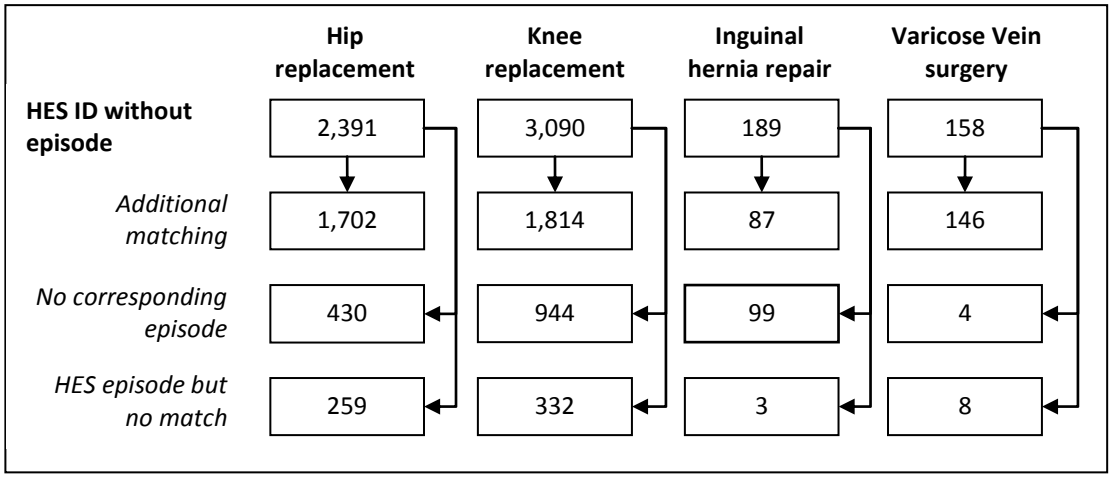
Therefore, the POiS Audit team adapted the published linkage algorithm used by the IC to overcome these issues. Firstly, the IC algorithm was based on questionnaire completion date. As the questionnaire could be completed several weeks before the operation and completion date is often missing from the dataset, these could be potential sources of problems. Therefore, operation date was used instead as this was available for all patients (for example only 28 of 10,237 hip patients did not have an operation date). The IC also required that both operation date and episode start date were within a specific period of the questionnaire completion date. Assessment of the HES linkage highlighted providers where the operation date was systematically incorrect. For example, for 524 of the unmatched hip replacement records, a HES episode was identified where the operation date was mistakenly entered as being after the discharge date. To overcome this problem operation date and episode start date were used separately to link records. Finally, the IC used only the main provider code. Assessment shows that most providers have several codes. For example, Care UK used a company-wide code (NTPC1) which accounted for 141 hip records not being matched. To address this problem the POiS Audit team created a merged provider code variable containing all provider codes. The following matching algorithm was then used:

- **HES Match Rank 1:** Exact match of PROVIDER, PROCEDURE GROUP and HES ID, where the POiS OPERATION DATE is up to *2* days before the HES PROCEDURE DATE. Then if no match found.
- **HES Match Rank 2:** Exact match of PROVIDER, PROCEDURE GROUP and HES ID, where the POiS OPERATION DATE is within (+ -) 2 days of the HES EPISODE START DATE. Then if no match found.
- **HES Match Rank 3:** Exact match of PROVIDER, PROCEDURE GROUP and HES ID, where the POiS OPERATION DATE is bet*w*een HES EPISODE START DATE and HES EPISODE END DATE.

Figure 8 shows the results of this adapted linkage process, with an additional 12% of POiS records being matched to a HES episode. Approximately 10% of the HES IDs supplied by the IC to the Audit Team did not have a corresponding record which appears to be due to HES records not being up-to-date for many providers, for example, Care UK ISTCs have no HES records for April 2009 onward. In addition, a

number of operations have been cancelled or postponed after completion of the pre-operative questionnaire. For example, POiS records showed that 0.5% of hip replacement patients reported their operation had been cancelled.

Figure 8 – Additional HES linkage



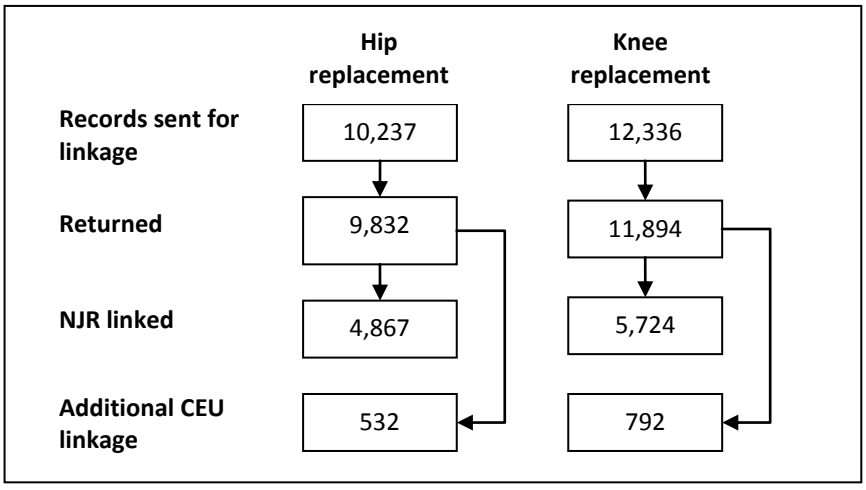
NJR linkage

NJR linkage (orthopaedics only)

NJR linkage was undertaken by the IC, with a success rate of 50%. The POiS Audit Team used the local HES data extract and available NJR data to improve the level of linkage. As the number of identifiers available within the NJR dataset was limited, only one level of linkage was undertaken (see below). Figure 9 shows the results of this process; Using this approach resulted in an additional 5% of records being linked.

- **NJR Match Rank 1** – Exact match on PROCEDURE and EPIKEY. With STARTAGE within +/- 1 year and DATE OF OPERATION: +/- 2 days.

Figure 9 – Additional NJR linkage



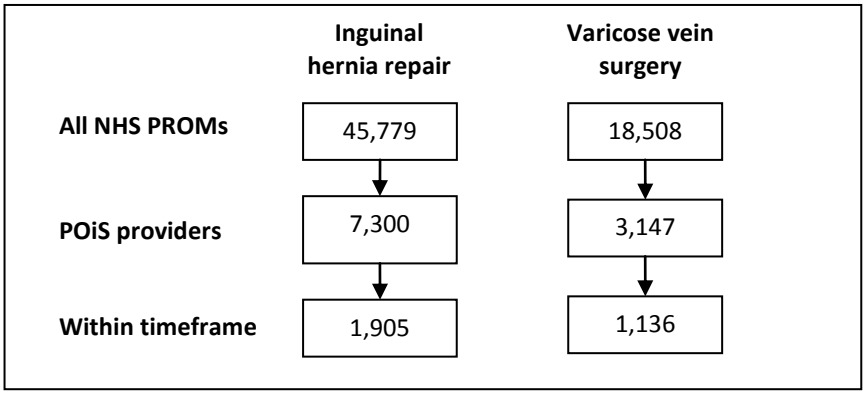
NHS PROMs data

As part of the agreement between the POiS Audit and NHS PROMs programme all general surgery providers in the POiS Audit were transferred to the NHS PROMs programme in April 2009. This meant that the POiS Audit data collection was truncated as it was planned to continue until October 2009. In order to compensate for this it was agreed that NHS PROMs data would be made available to the POIS Audit Team for analysis. The complete NHS PROMs dataset was transferred to the Audit Team in September 2010. The Audit Team then had to extract the records for the providers who were recruited into the POiS Audit and for the period of the Audit April 2009 to September 2009. The following algorithm was used to identify providers.

- NHS PROMs PROVIDER (SITETRET, PROCODE or Q1 PROCODE) matches PROCODES for providers recruited into POiS. Then
- COMPLETION DATE is between April 2009 to September 2009.

Using this method resulted in an additional 1,905 inguinal hernia and 1,136 varicose vein records being identified. These records were appended to the main POiS datasets for these procedures and flagged to allow identification (figure 10).

Figure 10 – Identification of NHS PROMs records



Removing duplicates

POiS Data

There is a potential for a patient to have completed more than one pre-operative questionnaire. This occurs in situations where an operation is cancelled, or a patient completes a questionnaire at a pre-assessment clinic and another on the day of surgery, or is having a bilateral operation. Identifying these records is important as duplication causes inaccuracy in recruitment rates and bias in statistical analysis.

A number of identifiers are available in the POiS Audit for use in de-duplication: NHS number, HES ID, surname, postcode, date of birth, gender, date of operation, side of operation and provider; and various combinations of these can be tested. After

discussion with the NHS PROMS Lot 3 group, the approach taken by the POiS Audit Team was to create strings of variables around the three main identifiers: NHS number, HES ID and surname. In combination with date of operation, it would be expected that NHS number or HES ID would be unique; whereas many surnames are very common and so additional variables have to be used to avoid false duplicates being identified. In addition, as these main identifiers are supplied by different sources (provider, NHS PROMs and patients, respectively) using these different groups means that the accuracy of the checking can be assured. The following sets of duplication strings were used:

- **Duplication 1** – Exact matches on NHS number, HES ID, surname, postcode, date of birth, sex, side operation, episode start date
- **Duplication 2** – NHS number, surname, postcode, date of birth
- **Duplication 3** – HES ID, side, episode start date
- **Duplication 4 -** Surname, postcode, date of birth, sex
- **Duplication 5 –** HES ID
- **Duplication 6 –** NHS number
- **Duplication 7 –** Surname, date of birth
- **Duplication 8 –** Surname, postcode
- **Duplication 9 –** Surname, date of birth, provider
- **Duplication 1 to 9 –** Plus date of operation (dop)

Table 25 shows the results of the duplication analysis. The various strings produce very similar results once the date of operation is included. Overall 0.7% of records were duplicates.

NHS PROMs data

Duplication may also exist in the NHS PROMs dataset. As fewer identifiers are available to the POiS Audit Team for the NHS PROMs dataset compared to the POiS dataset different criteria had to be used.

- **NHS PROMs –** HES ID, date of operation

Results show the rate of duplication is about 0.7%.

Table 25 – Duplicate records identified in POiS and NHS PROMs datasets

Duplication level	Hip replacement		Knee replacement		Inguinal hernia repair		Varicose vein surgery	
	String only	+ dop[a]	String only	+ dop[a]	String only	+ dop[a]	String only	+ dop[a]
Duplication 1	40	26	52	36	0	0	2	0
Duplication 2	332	48	430	60	0	0	18	0
Duplication 3	50	34	58	42	0	0	2	0
Duplication 4	376	54	517	70	0	0	18	0
Duplication 5	358	45	471	60	0	0	14	0
Duplication 6	361	55	464	64	0	0	18	0
Duplication 7	407	61	539	70	0	0	18	0
Duplication 8	392	56	558	72	0	0	18	0
Duplication 9	375	59	499	58	0	0	18	0
NHS PROMs (all dates)	-	-	-	-	38	26	53	0
Total		63		74		26		10

[a]dop = Date of procedure

A process was then needed for determining which duplicate record to remove, and the following two-step approach was adopted:

- Record with both pre-operative and post-operative questionnaires kept, then
- Record closest to operation date kept, then
- Random selection

Erroneous data

Where possible the POiS Audit database used input masks that prevented erroneous figures from being entered. The only variables where this was not possible were dates. Therefore, date variables were assessed based on being within expected limits. For example:

- Date of Birth – patients aged 16 years or above and less than 100 years
- Consent date – not before 2008
- Date of operation – within recruitment period of Audit and not before consent date
- Follow-up date - within period of Audit

A sample of records where erroneous dates were found manually were checked. It was found that a combination of data entry error and recording error were the cause of the erroneous results. Therefore, it was decided that erroneous dates should be deleted to avoid introducing bias into the dataset.

In addition, a random selection of 200 pre- and post-operative questionnaires were checked for data entry accuracy. It was found that 3% of questionnaires contained at least one error. In most cases there was only one mistake within a questionnaire. Therefore, the error rate per data item entered is less than 1%. This is well within the expected error rate for manual data entry.

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