Royal College of
Obstetricians and Gynaecologists

Bringing to life the best in women's health care

Project Report

May 2012

Hospital Episode Statistics as a source of information on safety and quality in gynaecology to support revalidation

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Academy of Medical Royal Colleges

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Executive summary

The General Medical Council (GMC) is introducing revalidation in the UK. This will change the way doctors are regulated. Doctors will need to demonstrate that they are keeping up-to-date and that they are participating in activities which evaluate the quality of their work.

The project presented in this report was funded by the Academy of Medical Royal Colleges as part of the development of performance indicators that can be used for revalidation.

The aims of this project were two-fold:

- to assess whether routinely collected administrative data could be used as part of the evaluation of gynaecologists' practice
- to compare measures of activity and outcome derived from administrative data with measures derived from data in two specialist societies' clinical databases. The source of administrative data used by the project was the Hospital Episode Statistics (HES) database, which captures information on all admissions to English NHS trusts.

The project had two major components:

- a literature review of studies that used HES data to assess the performance of inpatient gynaecological practice in the English NHS
- an analysis of performance measures derived from HES data and the clinical databases maintained by the British Society of Urogynaecology (BSUG) and the British Society of Gynaecological Endoscopy (BSGE).

Literature review

The literature review identified five studies that had used HES to examine gynaecological care. They had derived a range of performance indicators at a regional level (e.g. strategic health authority), at an organisational level (e.g. NHS trusts), and by clinicians. Process-based indicators tended to be based on procedure rates standardised for case mix. Outcomes were based on case fatality rate and emergency readmission rates.

The performance indicators observed in the literature review were combined with the list of performance indicators described in the RCOG report Recertification in Obstetrics and Gynaecology. This combined list was reviewed by the project's clinical reference group, who then chose three potential performance indicators for use in the comparative analysis: readmission to hospital, return to theatre and length of hospital stay.

Comparison of Hospital Episode Statistics with clinical databases

An extract of the HES database was used that included women who had relevant gynaecological diagnosis (ICD-10) codes. Clinical datasets were obtained from databases maintained by the BSUG and BSGE. These clinical databases allow gynaecologists to record detailed information about their patients' conditions, treatments and clinical outcomes.

The comparative analysis of HES and BSUG data focused on the surgical treatment of women with urinary incontinence between January 2008 and December 2009. The analysis of HES and BSGE data focused on women who had undergone surgery for recto-vaginal endometriosis during

the same time period. The analyses compared the number of patients and procedures in each data source, the patients' characteristics, and their outcomes.

The comparison of female urinary incontinence surgery investigated transvaginal tape (TVT) and transobturator tape (TOT) procedures. There were 9439 women in HES having a TVT procedure compared to 3474 in the BSUG database. The number of TOT procedures in HES and BSUG were 5562 and 621 respectively. Readmission and return to theatre rates derived from both data sources differed considerably. Readmission rates derived from HES and BSUG datasets for TVT procedures were 7.6% and 2.5% respectively; corresponding rates for TOT procedures were 5.7% and 2.3% respectively. Data on readmissions were only captured in the BSUG database if women attended a follow-up clinic. The higher readmission rates according to HES reflects the ability of administrative data to follow patients over time. Length of hospital stay could not be derived from the BSUG data for the analysis period, but was available from HES data.

The comparison of the HES and the BSGE datasets investigated women who had surgery for recto-vaginal endometriosis between January 2008 and December 2009. There were 950 women treated by a gynaecologist or obstetrician according to HES, compared to 671 women according to the BSGE database. None of the performance indicators could be derived from data in the BSGE database. In the HES data, the readmission rate within 30 days was 1.3% and return to theatre rate for laparoscopic procedures was 0.8%.

Conclusions

The comparison of the HES database with the clinical databases demonstrated that:

- the HES database can be used to study the treatments and outcomes of women with incontinence or recto-vaginal endometriosis
- HES can only be used to produce generic performance indicators (e.g. readmission, return to theatre and length of stay)
- the clinical databases contain more detailed data on the nature and severity of the women's symptoms, the underlying clinical condition, the clinical procedures, and the outcomes. However, their low case ascertainment and level of missing data, especially with respect to outcomes, are a current concern.

These results are not unexpected. The ICD-10 and OPCS4 coding systems used in HES lack clinical detail and also do not allow the coding of more recently introduced procedures. On the other hand, the clinical databases are designed by clinical experts who aimed to collect detailed information about the patients they treat and the outcomes they achieve. However, participation in the clinical databases is currently voluntary, which explains the problems with case ascertainment and data completeness.

1. Introduction

1.1 The RCOG and revalidation

The General Medical Council (GMC) is introducing revalidation of doctors in the UK which will change the way doctors are regulated to practice medicine (www.gmc-uk.org). Doctors will be required to demonstrate that they remain up to date and fit to practice. The aim of revalidation is to assure patients and the general public, as well as employers and healthcare professionals, of the quality and safety of medical practitioners.

As part of revalidation, doctors will be expected to collect data related to their clinical practice as part of their professional work. The GMC has asked the Medical Royal Colleges to establish appropriate criteria for measuring the quality of practice in their respective areas of medicine. The RCOG has responded to this challenge by publishing a set of outcome performance indicators for specialists in obstetrics and gynaecology in the working party report Recertification in Obstetrics and Gynaecology (RCOG, 2009).

1.2 Background on administrative data

Administrative healthcare databases are a potential source of data for the purpose of revalidation. These data are increasingly being used in studies of activity and the quality of care and, because of their complete coverage of hospital activity, are being linked with ongoing national clinical audits throughout the UK. Administrative data on hospital admissions are collated into the Hospital Episode Statistics (HES) in England, the Patient Episode Data for Wales (PEDW) in Wales, the Hospital Inpatient Statistics (HIS) in Northern Ireland, and the Information Services Division (ISD) in Scotland.

This study has made use of data captured by the HES database, its data being compared to two clinical databases run by specialist gynaecological societies. HES is a data 'warehouse' that captures details of all admissions and day cases in English NHS hospitals. It is managed by Northgate Information Solutions on behalf of The NHS Information Centre for Health and Social Care.

Each patient record in HES defines a Finished Consultant Episode (FCE), which corresponds to the care delivered under a particular consultant (a patient may have one or more consultant episodes during their stay in hospital). There are around 11 million new episodes of care each year.

Each HES record contains information about the patient (e.g. age, sex, ethnicity, postcode), the episode of care (e.g. hospital name, emergency/elective admission, date of admission and discharge) and clinical information. Diagnoses for each patient are recorded using the standard system of International Classification of Diseases, 10th edition (ICD-10) (WHO 2007). Procedures performed during an episode are coded using the Office of Population, Censuses and Surveys Classification of Surgical Operations and Procedures, 4th revision (OPCS) (NHS Connecting for Health, 2007).

One reason for HES being used to investigate patterns of hospital care and outcomes is its complete coverage of inpatient activity. In addition, because each patient is assigned a unique

identifier, it is possible to study longitudinal patterns of care such as rates of unplanned readmissions within 30 days after a surgical procedure. Nonetheless, concerns have been raised about its suitability for these studies. One of the main issues that has been consistently raised has been concern over the accuracy and completeness of the clinical coding. Encouragingly, the most recent annual report on the Payment by Results assurance programme by the Audit Commission (2010/2011) indicated that coding errors are fewer than in 2007, when the assurance programme was first introduced (Audit Commission, 2010). The 2010 report, Improving data quality in the NHS, reported that the average clinical coding error rate had dropped from 16% to 11% in three years. However, there was significant variation locally with an error rate ranging from 1% to 30% across NHS acute trusts (Audit Commission, 2010).

There is a general agreement that wider clinician involvement would improve the accuracy of HES records. The Royal Colleges have supported this. The Royal College of Physicians published a guide on how to improve data quality for clinicians (RCP, 2007). Training of local coders has also been identified as a priority, as has local programmes to assure data quality.

Because some conditions and procedures are more difficult to code using current ICD-10 and OPCS classifications, the quality of administrative data is thought to vary between clinical specialties. For example, data quality will depend on whether care involved acute or long-term conditions, whether the data items capture elements of the care process or outcomes, and whether outcomes being measured become apparent in or out of hospital. Therefore, it is important for each specialty to investigate the usefulness of HES data in capturing patient conditions, procedures, and outcomes within its own area.

1.3 Purpose

The project described in this report was designed to investigate the utility of administrative data for the purposes of revalidation within two subspecialties of gynaecology: urogynaecology and gynaecological endoscopy. The project was funded by the Academy of Medical Royal Colleges as part of the development of revalidation protocols. The overall aims of this project were two-fold:

- to assess whether routinely collected administrative data, such as HES, can be used as part of the evaluation of gynaecologists' practice, and
- to compare measures of activity and outcome derived from HES data with measures derived from data in two specialist-owned clinical databases.

In order to compare the HES data to clinical databases, we collaborated with two specialist societies who are currently managing clinical databases within their subspecialties: the British Society of Urogynaecology (BSUG) and the British Society of Gynaecological Endoscopy (BSGE). These society databases were chosen because they were thought to be the best sources of national clinician-collected data on gynaecology patients.

The components of the project were:

- a review of published studies which used HES data to evaluate the performance within gynaecology in England
- an analysis of performance measures derived from HES data and from specialist gynaecology databases in which data is voluntarily entered by clinicians
- the development of recommendations regarding the use of HES and clinical databases for revalidation of gynaecologists.

2. Literature review

The first phase of the project was to undertake a review of other studies that have used HES data to evaluate the quality of inpatient gynaecological care. The aim of the literature review was to discover what performance indicators had been derived from HES data as well as to document the analytical approaches. In fulfilling this aim, the literature review would describe what indicators had been used to compare services across regions, hospitals or clinicians, the patients included in individual studies, the methods used for risk adjustment, issues of clinical acceptability, and the extent of implementation.

2.1 Methodology

Relevant publications were identified through an explicit and structured search strategy. Searches were undertaken using the major electronic abstracting databases including Medline, Embase, Web of Science and CINAHL. We also searched the internet using Google and Google Scholar to locate any additional initiatives from the grey literature and conference proceedings. The reference lists of publications were also reviewed for additional relevant studies.

Equivalent search terms were used in each abstract database and typically combined the following:

- (hospitals OR hospital) AND (episode OR episodes) AND statistics
- gynaecology OR gynecology OR urogynaecology OR urogynecology.

The literature review included publications that met the following inclusion criteria:

- HES was used as the major source of data on the management of individual women receiving gynaecology care
- the study had a national perspective or covered large regional areas
- the study investigated the organisation, process or outcome of care. Studies that only reported on incidence or aetiology of disease were excluded.

There were 18 articles considered for the review. Abstracts were used to eliminate six studies that were not based on English HES data or were in specialties other than gynaecology or urogynaecology. After reading the full text of the remaining twelve articles, a further seven articles were eliminated as they were observational studies on a national level which looked at the frequency of procedures or diagnoses over time but did not offer an evaluation of quality of care or regional comparisons.

2.2 Results

The five studies that could be included used data from the 1990s and the early 2000s. An overview of the articles is presented in table 2.1. In summary:

- Three of the five studies compared regional variations in treatment patterns; one study looked at variation between trusts (Bottle, 2005) while another study compared hospitals

(Mason, 2006). Two studies evaluated either individual clinicians (Hilton, 1997) or consultant-led teams (Harley, 2005).

- Four studies defined the patient populations as a combination of relevant gynaecological diagnostic codes (ICD-10) and procedure codes (OPCS). In two studies, populations were further restricted by age. The patient population was not stated in one study.
- Process-based indicators tended to be based on standardised procedure rates. Outcome indicators included case fatality rate and emergency readmission rates.

The methods of analysis were also variable. Most studies used regression models to adjust for case-mix, with women's age being a common factor in these models (Bottle, 2005, Cromwell, 2009, and Mason, 2006). Nonetheless, few confounding variables were typically included in the models. One study (Cromwell, 2009) used a multilevel approach and incorporated factors defined at different regional levels (Index of Multiple Deprivation by Primary Care Trust and the number of whole time equivalent consultants by strategic health authority).

2.3 Identifying potential performance indicators

The process and outcome indicators from the literature review were combined with the list of performance indicators described in the RCOG report Recertification in Obstetrics and Gynaecology. The latter list of indicators was developed by the RCOG in conjunction with the relevant subspecialist groups. The combined list described possible measures for the comparative analysis phase of this study and was reviewed by the project's clinical reference group. Because the available data sources for the analysis phase of the project were from the BSUG and BSGE, the list of indicators was restricted to general gynaecology, urogynaecology and gynaecological endoscopy.

Each indicator was assessed for its ability to be calculated based on the data items in the HES dataset. During the meeting of the clinical reference group, the following criteria were used to assess the indicators and identify potential measures for the analysis phase of the project:

- data quality and completeness
- methodological robustness
- clinical validity
- acceptability
- potential for implementation.

A collective decision was then taken as to what performance indicators could be used for the project.

The list of performance indicators is shown in table 2.2. The indicators that are highlighted in blue in the table are those identified by the clinical reference group as appropriate measures for the analysis phase of the study. These indicators included:

- length of hospital stay in days;
- unplanned readmission to hospital within 30 days; and
- unplanned return to theatre within 48–72 hours.

The indicators were chosen for various reasons. Firstly, they had a reasonable level of clinical validity and were generally accepted as being reliable to derive. Secondly, the required data items

Table 2.1 Summary of literature review

Study	Time period	Patient population	Diagnoses (ICD-10)	Procedures (OPCS)	Levels of analysis	Outcome or process measure
Bottle, 2005	FY 1998 – 2000	Women, aged 18+ years, with one of five diagnostic codes	Endometriosis (N80); uterine fibroids (D25); genital prolapse (N81); malignancies (C51–C57, D06, D07); menstrual irregularities (N92–N94)	Hysterectomy: abdominal (Q07), vaginal (Q08), laparoscopically assisted (Q07 or Q08, with Y508 in any of the three secondary procedure fields)	Regions (SHAs) and NHS trusts	Proportion of abdominal hysterectomies, adjusted for age and diagnosis
Cromwell, 2009	FY 2003 – 2005	Women, aged 25 to 59 years, who had surgery for menorrhagia	Menorrhagia (N92.0, .1,.4–.9; (N93.8, .9) or other abnormal uterine and vaginal bleeding (N93.8, .9)	Hysterectomy (Q07 and Q08) or endometrial ablation (Q16 and Q17)	Regions (SHA) and primary care trusts	Age-standardised procedure rates, adjusted for deprivation (PCT-level) and no. of consultants (SHA-level)
Harley, 2005	FY 1991 – 1995	Women treated by the 143 consultant-led teams	Not stated	Complications of surgical and medical care not elsewhere classified (ICD-9, 996–999 or ICD-10, T80–88)	Teams, a single consultant and the junior doctors that deal with his or her patients	7 process and outcome indicators (see table 2.2)
Hilton, 1997	FY 1990 – 1995	Women with vesico-vaginal or urethra-vaginal fistula repairs	Vesico-vaginal and other female urinary-genital tract fistulae (N82.0, .1) or Fistulae involving genital tract- other (N82.8) or unspecified fistulae (N82.9)	Vesico-vaginal fistula repair (P25.1) or urethra-vaginal fistula repair (P25.2) or construction of ileal conduit or other urinary diversion (M19.1, .2)	Regions and individual clinicians	Fistula repairs per surgeon per year (incl. whether urinary diversion performed)
Mason, 2006	FY 1999 – 2001, follow-up until June 2001 (90-day)	Women with gynaecology admissions	Included episodes coded as being in the specialty of gynaecology. Excluded cases with a cancer diagnosis (C00–97, D37–48 and z51.1)	Hysterectomy (Q07)	Hospitals	Case fatality rates (CFRs) at 30 and 90 days, emergency readmissions (ERA) at 30 and 90 days

KEY: FY = financial year, SHA = strategic health authority, PCT = primary care trust

were available in HES and the society clinical databases. Finally, there was potential to implement the indicators across all clinicians.

It was agreed by the clinical reference group that data quality, completeness, and methodological robustness for these particular measures in relation to gynaecological procedures should be assessed as part of the study.

Table 2.2 List of possible performance indicators

Source	Possible performance indicators
From the literature review	**From Harley, 2005** ● % of finished consultant episodes with complications (recorded) ● Mean length of spell (days) ● % of finished consultant episodes with more than two operations (recorded) ● % of finished consultant episodes where spell is longer than episode ● % of finished consultant episodes for dilatation and curettage on women aged <40 ● % of finished consultant episodes for sterilisation on women aged <25 ● % of finished consultant episodes for hysterectomy on women aged <30 **From Mason, 2006*** ● 30 day emergency readmissions following day case care ● 30 day emergency readmissions following elective admissions for abdominal hysterectomy ● length of hospital stay ● total time spent in hospital ● return to theatre ● postoperative infection rate.
From recertification in obstetrics and gynaecology, a working party report (measures with information available in HES)	**General gynaecology** ● all women with damage to structures (e.g. ureter, bowel, vessel) ● all cases of unplanned returns to theatre within 48 hours ● all cases of unplanned return to hospital within 30 days. **Urogynaecology** ● all women with prolapse and incontinence treated surgically ● all women returning to theatre within 48 hours ● all women returning for a further unexpected procedure (subset would have to be defined by type of procedure). **Gynaecological endoscopy** ● all cases of examination under anaesthesia/dilatation and curettage performed under ● general anaesthesia for dysfunctional uterine bleeding/post menopausal bleeding, ● where hysteroscopy is not undertaken ● all cases of visceral or vascular injury occurring at operative hysteroscopy or ● endometrial ablation ● all cases of visceral and vascular injury at operative laparoscopy.

*Mason et al reported results on case fatality rates at 30 and 90 days and emergency readmissions at 30 and 90 days. However, they suggested that the other measures as seen in this table may be appropriate performance indicators as well.

2.4 Discussion

The literature review identified a small number of studies that had used HES data to evaluate and compare inpatient gynaecology services. They demonstrated that it is possible to use HES data to produce robust information about patterns of care and outcomes.

However, the literature review also confirmed some of the limitations of using HES data for performance measurement. The articles noted the following:

- HES data might underestimate rates of complications due to incomplete coding
- HES included a limited number of variables related to patient case mix
- HES did not contain data from independent hospitals
- HES did not contain clinically important information such as physical function that would be useful to understand disease severity and treatment outcomes
- there is currently a lack of clinical information on patients attending outpatient appointments, although it should be noted that the quantity and quality of outpatient data is improving
- clinician-level assessment is limited because of the lack of a 'gold standard' by which to measure clinical performance and difficulties in setting threshold values to identify cause for concern.

The results of the literature review, together with the work that had already been done by the RCOG in compiling a list of performance indicators (RCOG, 2009), provided a foundation for a list of possible performance indicators. Based on the recommendations of the clinical reference group, a small set of indicators (readmission to hospital, return to theatre and length of stay) was explored during the next phase of the project.

3 Comparative analyses of HES and society databases

3.1 Overview of the clinical databases

British Society for Urogynaecology (BSUG) database

The British Society for Urogynaecology was founded in April 2001 following a request from the RCOG for a urogynaecology society which might assist the College in matters pertaining to the subspecialty. The Society now has over 200 members. The Society's main function is to set and raise standards by providing guidelines, training, research and clinical meetings (in conjunction with the RCOG).

Bsug.net is an online database tool provided by the BSUG audit committee to gather data on a voluntary basis relating to specific operative procedures of this subspecialty for the purposes of providing the BSUG members with statistical reports on patients' outcome. The database began collecting data in 2007 and has gained users each year.

Each record on the database describes clinical details about a woman who has undergone surgery for incontinence and/or genital prolapse. Details are captured on the centre performing the surgery, patient age, various pre-treatment assessments including urodynamic diagnoses and POP-Q scores (a clinician-reported description of pelvic organ prolapse), surgery performed and treatment outcomes. Outcomes include various short-term complications (e.g. bladder injury) as well as longer-term follow-up scores from instruments used prior to treatment (e.g. POP-Q at 6 months post-surgery). The database also includes the patient-reported International Consultation on Incontinence Questionnaire-Short Form (ICIQ-SF) and the Patient Global Impression of Improvement (PGI-I).

British Society for Gynaecological Endoscopy (BSGE) database

The British Society for Gynaecological Endoscopy was founded in 1989 and currently has over 500 members. The BSGE was formed to promote the benefits of minimal access ('keyhole') surgery to clinicians, patients and those responsible for the formulation of healthcare policy.

The BSGE has set up criteria for tertiary referral centres to gain accreditation from the Society in carrying out laparoscopic treatment of recto-vaginal endometriosis. These include a dedicated endometriosis clinic, at least 12 recto-vaginal cases surgically treated laparoscopically per year, and working with a named colorectal surgeon. Accredited centres should also submit all preoperative, operative and postoperative data to the secure national database for all patients treated by the centre with recto-vaginal endometriosis.

The BSGE database began in 2007. Each record on the database represents a woman who has undergone surgery for recto-vaginal endometriosis.

3.2 Comparison of HES and clinical data sources

For the purposes of this project, an extract of anonymised HES data was obtained. HES contains multiple records for each patient. The records correspond to a period under a named consultant (referred to as an episode of care). For many patients, an episode of care corresponds to the whole time a patient was admitted. However, for some, two of more episodes of care will occur while a patient is admitted. Each record was allocated a unique patient identifier which allowed records of all admissions and day cases related to an individual to be identified and linked.

The diagnosis fields in HES were used to define the two patient populations. Women with urinary incontinence were identified from records that contained an ICD-10 diagnostic code for incontinence (N39 or R32) in any of the diagnosis fields. The dataset included all episodes from January 2008 to December 2009 that met these criteria plus any other episode of care record for these women between 2007 and 2009.

For the HES sample of women with endometriosis, records were selected if an ICD-10 diagnostic code for endometriosis (N80) was in any of the diagnosis fields. The dataset included all episodes from January 2008 to December 2009 that met these criteria and all other HES records for these women between 2000 and 2009.

Compared to the Society databases, HES has a higher number of contributing trusts/centres. This is understandable because NHS trusts must submit data to HES to fulfil Payment by Results requirements. Participation in the Society databases is voluntary, although consultants are recommended to submit details of all eligible patients.

There were various differences in the type of pre-treatment and diagnostic information captured by HES and the Society databases. HES is restricted to a limited number of demographic variables such as age and ethnicity. The Society databases are able to capture additional data such as height and weight for BMI (BSUG) and whether the woman is 'trying to conceive' (BSGE).

The differences in information captured also reflect the coding structures of the databases. In HES, the ICD-10 classification provides a comprehensive set of codes for specifying the type of primary condition and comorbidities experienced by a patient in a number of 'diagnosis fields'. However, these are less able to capture disease severity and symptoms. Both Society databases record details of the specific symptoms and pre-treatment test results. In the BSUG database, data is captured from standard, validated examinations, such as urodynamic results (urodynamic stress incontinence [USI], detrusor overactivity [DOA] and overflow, chronic retention) and the pelvic organ prolapse quantification (POP-Q) exam, which is used to quantify and describe the degree of prolapse.

There were also differences in the procedure information captured by HES and the Society databases. Data on numerous procedures can be recorded in HES using the OPCS classification. The OPCS codes cover a comprehensive range of procedures but do not always correspond to the typical nomenclature used by clinicians and may also not capture specific details. The BSUG database allows for a single-incision short tape insertion procedure to be recorded; there is no corresponding OPCS code for this precise operation. For example, the database allows identification of the specific brands of devices used in the operations.

As with the patient characteristics and treatment information, the HES and Society databases differ in the outcome information collected, and consequently, their ability to support the derivation of outcome measures. The potential outcome indicators that can be derived from the data sources are summarised in Table 3.1. Indicators supported by HES tend to be fairly generic in nature. These include: return to theatre, readmission to hospital and death in hospital. These rely on the more

robust data items in HES, and can give a reliable overview of certain aspects of performance. The disadvantage is that these measures do not capture the outcomes of primary importance to gynaecologists and to patients, such as improvement in physical function or quality of life.

Table 3.1 Indicators that can be derived from HES, BSUG database and BSGE database in 2011

HES	BSUG database	BSGE database
Length of stay		**Length of stay**
Complications ● return to theatre ● readmission to hospital death in hospital ● able to use ICD-10 diagnostic codes for complications in primary or subsequent episodes	**Complications** ● ureteric injury ● bladder injury ● bowel injury ● vascular injury ● neurologic injury ● blood loss >500ml ● per-operative blood transfusion ● per-operative thromboembolism ● death ● return to theatre for procedure-related event within 72 hours ● catheterisation required for more than 10 days post-op ● return to hospital within 30 days for procedure-related event ● long-term problem identified	**Complications** ● ureteric injury ● unexpected bladder injury ● unexpected bowel injury ● unexpected vascular injury ● any perioperative haemorrhage >1 litre ● epigastric injury ● stoma ● death ● removal of any other organ ● any late complications ● pelvic haematoma ● pelvic abscess ● urinary tract leak ● bowel leak ● urinary tract fistula ● bowel fistula ● severe sepsis ● pulmonary embolism
Follow-up procedures ● able to look for OPCS procedure codes for certain follow-up procedures in primary or subsequent episodes	**Global impression of improvement** **Post-surgery quality of life score** **POP-Q assessment** **Long-term follow-up, including** ● graft problems ● change in stress incontinence ● change in urgency ● recurrent incontinence requiring surgery ● new incontinence requiring surgery ● graft erosion / infection	**Quality of life measures** ● baseline, 6 month, 1 year and 2 year

By being designed for specific patient populations, both the BSUG and BSGE databases provide a richer description of outcomes, both in terms of specific complications and improvement in patient wellbeing (table 3.1).

3.3 Analysis of female incontinence data

To prepare the BSUG and HES datasets for the comparative analysis, we undertook data cleaning (eliminating duplicates and blank records) and then restricted the datasets to only eligible patients: women who had surgery for incontinence between 1 January 2008 and 31 December 2009. With respect to the BSUG database, we identified 5939 women.

The HES sample was prepared in stages. First, women with incontinence were identified. Female incontinence was defined as stress incontinence (ICD-10 code N39.3); other specified urinary incontinence including overflow, reflex, and urge (N39.4); or unspecified urinary incontinence (R32). Second, we removed HES records which were missing values for key variables (age, admission, operation or discharge dates), had out-of-range values (ages <18 or >120 years, length of stay >183 days), and records for women who were resident outside of England. This produced a HES sample that contained 93 231 records for women with incontinence. Finally, the HES sample was restricted to women who had undergone a procedure and who were treated by a gynaecologist. This resulted in a final sample of 31 271 women.

Various analyses were performed. The first was a comparison of the number of women with incontinence in each dataset together with a description of the patients' characteristics such as age, diagnosis and whether or not genital prolapse was also recorded. The second analysis described the frequency of procedures in each sample, with the HES sample being restricted to those procedures being performed by a gynaecologist.

These descriptive results were presented to the clinical reference group. The group recommended further analysis of the most prevalent procedures for female incontinence, namely transvaginal tape (TVT) and transobturator tape (TOT) procedures. In the BSUG database, the procedures labelled as either 'mid-urethral sling' or 'TVT' were combined to form one TVT category, while 'single incision tape' and 'TOT' were combined to form one TOT category. In HES, TVT procedures were defined as those with OPCS code M53.3, and TOT procedures were defined as OPCS code M53.6.

Performance indicators for both TVT and TOT procedures were derived. These were: readmission to hospital within 30 days of initial procedure, return to theatre within 72 hours of initial procedure, and length of stay in days. The return to theatre indicator was limited to within 72 hours as this matched the BSUG database definition. All statistical calculations were performed in Stata 11 (StataCorp, 2009).

Number of patients and their characteristics

A description of each sample of women with incontinence identified from HES and BSUG is provided in table 3.2. There are many more patients captured in HES than in the BSUG database, and there were also a greater number of contributing trusts. However, HES may include women who had urinary incontinence as a concomitant rather than as the main diagnosis.

Despite the different level of coverage, the characteristics of patients were broadly similar. The mean age was 54 years in both databases. There was a larger difference in the proportion of

Table 3.2 Comparison of female incontinence in HES for England versus BSUG database (2008–2009)

	HES: patients admitted to hospital with a diagnosis of female incontinence*	BSUG: patients with surgery for incontinence
Complications	Complications	Complications
Number of records	31,271	5,939
Age mean (standard deviation)	53.79 (12.84)	53.89 (12.44)
Age categories		
≤35	1,596 (5.1%)	244 (4.1%)
36–45	7,545 (24.1%)	1,401 (23.69%)
46–55	9,205 (29.4%)	1,781 (30.0%)
56–65	6,762 (21.7%)	1,284 (21.6%)
>65	6,163 (19.7%)	1,108 (18.7%)
Missing	--	121 (2.0%)
Type of incontinence (ICD-10 | urodynamic diagnosis)		
Stress only (N39.3 | USI)	24,429 (78.12%)	3,817 (64.3%)
Urge only (N39.4 | DOA)	3,049 (9.75%)	314 (5.3%)
Unspecified only (R32 | -)	2,485 (7.95%)	886 (14.9%)
Stress + Urge (N39.3+N39.4 | Mixed DOA /USI)	1,236 (3.95%)	922 (15.5%)
Other combinations	72 (0.23%)	–
Genital prolapse (ICD-10) **		
Yes (N81)	8,411 (26.9%)	–
No	22,860 (73.1%)	–

* patients with an ICD-10 code of N39.3, N39.4, or R32 who were treated by a gynaecologist

** figures not available for BSUG patients due to lack of corresponding diagnosis information

patients with specific types of incontinence and this probably reflects differences in the source of the information. In particular, the BSUG data had a higher proportion of women that had both stress and urge incontinence diagnoses. HES may have a lower proportion because coders select only one of the two diagnoses. It has to be noted in this context that diagnoses in the BSUG database are urodynamically proven which is not the case for the HES database.

In HES, 26.9% of women with incontinence were also coded as having genital prolapse (N81). The BSUG database was only used to identify women having surgery for prolapse and so a comparative figure was not derived.

Frequency of procedures

Transvaginal tape (TVT) and transobturator tape (TOT) were the most common procedures among women with incontinence (table 3.3). A proportion of these women also underwent concomitant anterior/posterior repair. In HES, there was a high degree of consistency with expected diagnosis and procedure combinations, with a diagnosis of genital prolapse entered for 5023 (93%) of these 5395 repair procedures.

Performance indicators

In the previous section, it was noted that some women with incontinence who had transvaginal tape (TVT) and transobturator tape (TOT) also underwent concomitant anterior/posterior repair. To avoid possible confounding due to this additional surgery, the performance indicators were derived for women who underwent TVT or TOT procedures that did not include a repair.

Readmission within 30 days

Table 3.4 shows the readmission rates for derived from the HES and BSUG data. Overall the readmission rates were higher in the HES sample compared to the BSUG sample. This may have been due to the BSUG database capturing mainly emergency readmissions, although readmission is not specified as elective or non-elective in the BSUG database. In HES, a readmission is categorised as non-elective/emergency or elective/planned. Of the 722 readmissions for TVT procedures, 415 readmissions (4.4%) were non-elective. Of the 316 readmissions for TOT procedures, 174 (3.1%) were non-elective.

When deriving the rates using the BSUG data, we found that a significant number of records did not have either the 'yes' or 'no' response. Of 3474 women with TVT only, there were 87 (2.5%) with 'yes' for readmission; 1914 (55.1%) with 'no'; and 1473 (42.4%) with this field 'unanswered'. Of 621 women with TOT only, there were 14 (2.3%) with 'yes' for readmission; 371 (59.7%) with 'no'; and 236 (38%) with this field 'unanswered'. In table 3.4, the rates were derived assuming that an unanswered response indicated 'no readmission'. An alternative approach would be to perform a complete case analysis and ignore these responses. This would have resulted in readmission rates for TVT and TOT only procedures of 4.3% and 3.6% respectively. These rates are still lower than those derived from HES.

Table 3.3 Comparison of three common procedures performed for female incontinence: HES for England versus BSUG database (2008–2009)

Operation recorded	HES: patients admitted to hospital with a diagnosis of female incontinence	BSUG: patients with surgery for incontinence
Transvaginal tape (TVT)	9439 (30%)	3474 (58%)
Transobturator tape (TOT)	5562 (18%)	621 (10%)
Transvaginal tape + AR/PR	2067 (7%)	800 (13%)
Transobturator tape + AR/PR	1449 (5%)	119 (2%)
Another procedure	12 754 (41%)	925 (15%)
Patients	31 271	5939

Return to theatre within 72 hours

Rates of return to theatre within 72 hours were low. Using the HES data, return to theatre rates for TVT and TOT only procedures were estimated to be 0.7% (69/9439) and 0.5% (26/5562) respectively.

Comparable rates of return to theatre were derived from the BSUG database, although it was not clear how patients with missing responses should be interpreted. As before, the return to theatre

field had responses of 'yes', 'no' and 'not answered'. Of 3474 women with TVT only, there were 10 (0.2%) with 'yes' for return to theatre; 2048 (59.0%) with 'no'; and 1419 (40.8%) with this field 'unanswered'. Of 621 women with TOT only, there were 6 (1.0%) with 'yes' for readmission; 388 (62.5%) with 'no'; and 227 (36.6%) with this field 'unanswered'.

Table 3.4 Readmission to hospital within 30 days of female incontinence-related procedure: HES for England versus BSUG clinical database (CY 2008–2009)

Procedure	Number readmitted within 30 days of initial procedure n (%)	Number of procedures by gynaecologists n
Transvaginal tape (TVT) (OPCS=M53.3)		
HES	722 (7.6%)	9439
BSUG	87 (2.5%)	3474
Transobturator tape (TOT) (OPCS=M53.6)		
HES	316 (5.7%)	5562
BSUG	14 (2.3%)	621

*CY = calendar years

Length of stay

Length of stay could not be derived from the BSUG data. Fields to produce this information have recently been added to the database but data was not available for 2008–2009.

From the HES data, the length of stay for these incontinence procedures was short:

- for transvaginal tape (TVT) procedures, 2909 (30.8%) were same-day admissions and among overnight admissions, the mean (SD) length of stay was 1.53 days (1.27)
- for transobturator tape (TOT) procedures, 1652 (29.7%) were same-day admissions and among overnight admissions, the mean (SD) length of stay was 1.35 days (1.22).

3.4 Analysis of recto-vaginal endometriosis data

The preparation of the BSGE and HES datasets followed the same process as before. A series of data cleaning stages were undertaken and then the datasets were restricted to patients who met the eligibility criteria: women who had surgery for recto-vaginal endometriosis between 1 January 2008 and 31 December 2009. With respect to the BSGE database, we identified 671 women.

The HES sample was prepared in stages. Women with a diagnosis of recto-vaginal endometriosis were identified as having a diagnostic ICD-10 code of N80.4. Then records were removed if they were missing values for key variables (age, source of admission, operation or discharge dates), had out-of-range values (ages <18 or >120 years or length of stay >183 days), or were for women who were resident outside England. This identified 1010 women with a diagnosis of recto-vaginal endometriosis. For the comparison to the BSGE database, the HES population was further limited to women who were treated by an obstetrician or gynaecologist, which resulted in a final sample of 950 women.

A sequence of analyses was performed. The first was a comparison of the number of women with recto-vaginal endometriosis in each dataset together with a description of the patients' characteristics such as age, diagnosis and whether or not genital prolapse was also recorded. The second analysis described the frequency of procedures in each sample. These results were presented to the clinical reference group. The group recommended further in-depth analysis of procedures for recto-vaginal endometriosis using three categories of procedure:

- laparoscopic procedures (OPCS code)
  - uni/bilateral ureterolysis/dissection (M25.3)
  - open excision of lesion of rectum (H34.1)
  - anterior resection (H33)
  - laparoscopic tubal adhesiolysis (Q38.1)
  - laparoscopic ovarian procedures Q49.1–4
  - laparoscopic procedures of the peritoneum T42.1–3
- laparotomy
  - unspecified opening of abdomen (T30.9)
  - laparotomy approach NEC (Y50.2)
- hysterectomy
  - abdominal hysterectomy (Q07.2)
  - total and subtotal abdominal hysterectomy (Q07.4–5)
  - vaginal hysterectomy (Q08.2).

For these procedures, performance indicators were derived from both samples including readmission to hospital within 30 days, return to theatre, and length of stay in days.

Number of patients and their characteristics

During this time period (2008–2009), we identified 671 women in the BSGE database from eight NHS centres. There were 950 patients captured in HES. There were 22 NHS trusts that treated 10 or more patients but, overall, 132 NHS trusts with obstetrics/gynaecology as a recorded specialty had admitted one or more women with endometriosis.

The median age of patients in HES was 35 years (inter-quartile range: 29 to 40 years).

Frequency of surgical procedures

In the BSGE data, patients' procedures can be recorded as laparoscopy (yes/no) or laparotomy (yes/no). There was also a field to record whether a planned laparoscopy was converted to a laparotomy. For this analysis, a converted surgery was recorded as a laparotomy.

Of the 671 women in the BSGE sample, 228 had a laparoscopy and 10 had a laparotomy (including one planned laparoscopy converted to laparotomy). In addition, 424 women had blank entries for both laparoscopy and laparotomy, and 9 women were recorded as 'no' for laparoscopy and blank for laparotomy and therefore had no surgery recorded. The total number of women missing surgery information was 433.

Among the 950 women in the HES sample, a higher proportion of women were recorded as having laparoscopy (table 3.5). In total, 476 had a laparoscopic procedure, 7 had a laparotomy, and 467 had other procedures that were not included in these categories.

Hysterectomy was recorded in both BSGE and HES. A hysterectomy could be performed at the same time as either a laparoscopic surgery or laparotomy. In HES, 79 (8.32%) women in the sample also had a hysterectomy, while in BSGE 9 (1.34%) women also had a hysterectomy.

Performance indicators

As decided by the clinical reference group, the performance indicators of readmission to hospital within 30 days of the initial procedure, return to theatre with 72 hours, and length of stay were evaluated. Each indicator could be derived from HES data. However, this was not possible for readmission to hospital within 30 days and return to theatre within 72 hours for the BSGE data as the required data items were not collected.

Table 3.5 Procedures for recto-vaginal endometriosis: HES for England versus BSGE database (CY 2008–2009)

	HES: patients with recto-vaginal endometriosis*	BSGE database
Sample size	950	671
Procedures		
Laparoscopic (M25.3, H34.1, H33, Q38.1, Q49.1–4, T42.1–3)	476 (50.11%)	228 (33.98%)
Laparotomy (T30.9 or Y50.2)	7 (0.74%)	10 (1.49%)
No procedure or other type of procedure	467 (49.16%)	433 (64.53%)

* Patients with an ICD-10 code of N80.4 who were treated by an obstetrician or gynaecologist
CY = calendar years

Remission within 30 days

Table 3.6 shows readmission to hospital within 30 days of the initial procedure for recto-vaginal endometriosis derived from HES data. Among the six readmissions of women who initially had a laparoscopic procedure, five readmissions were elective/planned. The two readmissions of women who initially had hysterectomies were both elective/planned.

Return to theatre within 72 hours

Among the HES data, few women were found to undergo a reoperation. There were four additional procedures for women who underwent a laparoscopic procedure and one woman undergoing a hysterectomy had a reoperation.

Length of stay

Using HES, the national mean length of stay for laparoscopic procedures for women with recto-vaginal endometriosis was 1.63 days (95% CI 1.46–1.81). For laparotomy procedures, the mean length of stay was 4.86 days (95% CI 1.68–8.04). For women undergoing a hysterectomy, the mean length of stay was 4.78 days (95% CI 4.18–5.38).

Table 3.6 Readmission to hospital by procedure for women with recto-vaginal endometriosis: HES for England (CY 2008–2009)

Procedure	Number readmitted within 30 days of initial procedure n (%)	Number of procedures by gynaecologists n
Laparoscopic (M25.3, H34.1, H33, Q38.1, Q49.1–4, T42.1–3)	6 (1.26%)	476
Laparotomy (T30.9 or Y50.2)	0 (0%)	7
Hysterectomy (Q07.2, Q07.4–5, Q08.2)	2 (2.53%)	79

CY = calendar years

4 Discussion

As part of its preparation for revalidation, the Recertification in Obstetrics and Gynaecology working party report highlighted a variety of measures that could be used as performance indicators for obstetricians and gynaecologists. The adoption of these indicators greatly depends on having ready access to complete and reliable data sources that contain the required information. A key finding from this study is that many of the proposed performances indicators for gynaecology cannot be derived from currently available databases, such as the routine administrative datasets like HES or the Societies specialist clinical registers. Yet, we did find that there is enough information available from these data sources to begin defining appropriate measures that are methodologically robust, clinically valid and could be implemented nationally.

The issues that need to be addressed in the short term to make data useable for revalidation purposes are different for HES and the clinical databases. For HES, more detailed information is required regarding the primary condition, disease and symptom severity, the treatments and the outcomes.

While the Society databases provide a potential of wealth of clinical information, they currently function more as an electronic medical record system than as a national database, because they do not include the entire patient population and their records for patients who were included are not always complete. However, in trusts with a robust data collection system they can function as a valuable internal audit tool.

These issues are now discussed in more detail.

Case ascertainment and data completeness

HES has a high level of case ascertainment. Data completeness for many data items is also high. For example, few patient records in this analysis had missing values for age and for dates required to calculate the performance indicators. However, for the diagnosis and procedure fields, the level of missing data in HES is difficult to measure. Studies are required that compare HES data with a random sample of case notes to estimate of the level of miscoding in this patient population.

Participation in the Society databases is voluntary and increasing numbers of clinicians are now entering their data. Nevertheless, only a proportion of clinicians record their data in these databases. The voluntary nature of the Societies' data collection also affects data quality. Some fields have a high percentage of missing data. The level of detail and number of fields means that the databases can function as electronic case note system for these clinicians. It is important to note that support for making clinical databases mandatory is growing.

Validity of performance indicators

The performance indicators that could be derived from HES are simple in their construction and could be considered generic in nature. The gynaecology community will have to establish whether these performance indicators are valid measures of clinical performance and would be appropriate for revalidation. The interpretation of a performance indicator should be unambiguous. The use of readmissions as a performance indicator demonstrates this problem as a high readmission rate could be an indicator of poor as well as of good quality of care.

Statistical power

It is necessary to consider the statistical power to accurately report differences between trusts or individual consultants when evaluating a potential performance indicator. This comparison will rely on the ability to accurately calculate a clinician's true rate for indicators such as complications and readmissions.

There are two factors that need to be considered in power calculations: (1) the number of procedures performed over a defined time period, and (2) the frequency of the outcome (e.g. readmission within 30 days). In the case of TVT and TOT procedures, the readmission rates were 1.7% and 2.2% respectively. Formal statistical power calculations are required to set minimum number of procedures for individual clinicians or hospitals, below which a comparison against targets is not meaningful.

Technical specification and reliability of performance indicators

The technical specification of a performance indicator needs to be sufficiently robust to ensure that it is not unduly influenced by records with poor or inconsistent data. In HES, there is the possibility that indicators can be affected by omission or miscoding of diagnoses and procedures.

The performance indicators used in this report (readmission, return to theatre, and length of stay) have robust technical specifications because they are calculated from administrative data.

Comparability and fairness

Performance measurement should take into account the different populations and levels of disease severity treated by clinicians. This requires appropriate risk adjustment of performance indicators.

HES has the potential to support risk adjustment. Age and other socio-demographic variables are standard fields and comorbidities may be derived from the secondary diagnosis fields (Armitage, 2010). The gynaecological community will need to develop an agreed risk adjustment strategy for any revalidation performance indicator. This exercise was beyond the scope of the project reported here but should be considered prior to implementing any performance measurement.

Conclusions

The comparison of the HES database with the clinical databases demonstrated that:

- The HES database can be used to study the treatments and some outcomes of women with incontinence or recto-vaginal endometriosis.
- HES can only be used to produce generic performance indicators (e.g. readmission, return to theatre and length of stay).
- The clinical databases contain more detailed data on the nature and severity of the women's symptoms, the underlying clinical condition, the clinical procedures, and treatment outcomes. However, their low case ascertainment and level of missing data, especially with respect to outcomes, are a current concern.

Once potential indicators based on HES data are defined, their appropriateness should be evaluated by considering their validity, statistical power, robustness of the technical specification, and comparability and fairness.

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Appendix

Comparison of patients with female incontinence treated at Worcestershire Acute Hospitals NHS Trust: Hospital Episode Statistics (HES) for England versus British Society of Urogynaecology (BSUG) database (2008–2009)

	HES: patients admitted to hospital with a diagnosis of female incontinence	BSUG: patients with surgery for incontinence
Number of records	173	522
Age mean (standard deviation)	55.77 (12.6)	55.92 (12.5)
Age categories		
≤35	4 (2.3%)	16 (3.1%)
36–45	41 (23.7%)	103 (19.7%)
46–55	42 (24.3%)	145 (27.8%)
56–65	41 (23.7%)	134 (25.7%)
>65	45 (26.0%)	119 (22.8%)
Missing	–	5 (1%)
Type of incontinence (ICD-10 | urodynamic diagnosis)		
Stress only (N39.3 | USI)	160 (92.5%)	365 (69.9%)
Urge only (N39.4 | DOA)	5 (2.9%)	36 (6.9%)
Unspecified only (R32 | -)	7 (4.0%)	39 (7.5%)
Stress + Urge (N39.3+N39.4 | Mixed DOA /USI	1 (0.6%)	82 (15.7%)
Other combinations	0	–
Genital prolapse (ICD-10)		
Yes (N81)	68 (39.3%)	–
No	105 (60.7%)	–
Operation recorded		
Transvaginal tape (TVT)	100 (58%)	319 (61%)
Trans-obturator tape (TOT)	2 (1%)	3 (1%)
Anterior/Posterior repair (AR/PR)	12 (7%)	7 (1%)
Transvaginal tape + AR/PR	40 (23%)	127 (24%)
Trans-obturator tape + AR/PR	0 (0%)	1 (0%)
Another procedure	19 (11%)	65 (12%)

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