Perioperative Quality Improvement Programme Database

Short Title: PQIP Database

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Protocol version number and date	Amendment type and nature	Responsible person
1.2: 26 September 2016	Minor amendment: a. change from HSCIC to NHS Digital b. Clarification that TDLS will be NHS Digital c. Removal of RCS-CEU from page 11	SR Moonesinghe

Lay abstract

We propose to establish a National Perioperative Quality Improvement Programme (PQIP), led by the National Institute for Academic Anaesthesia's Health Services Research Centre (NIAA-HSRC), based at the Royal College of Anaesthetists. PQIP will measure care delivered, complications and outcome from the patient perspective after major surgery. Patients will be approached at random, in participating hospitals, to give consent to have their data collected and used for research. The data collected will include information about patients, the surgery that they undergo, and the care that they receive. Patients will be asked to complete questionnaires before, and at several points up to one year after surgery, so that we can measure health and quality of life from their perspective, in order to understand whether or not the surgery has provided benefit to them.

The database is being funded by the Royal College of Anaesthetists. The programme is being managed by the National Institute for Academic Anaesthesia's Health Services Research Centre with support from a steering committee comprising a comprehensive group of stakeholder representatives including surgeons, anaesthetists, physicians, nurses and patients.

1. Background

i. Setting the scene: perioperative outcome is a public health issue

Over ten million operations take place in the UK NHS every year. [1] The number of patients which are at high risk of adverse postoperative outcomes has grown substantially in recent years: this is attributable to a combination of an ageing population, the increased numbers of surgical options available for previously untreatable conditions, and the increasing numbers of patient presenting for surgery with multiple comorbidities. Estimates of inpatient mortality after non-cardiac surgery range between 1.5 and 3.6% depending on the type of surgery and patient related risks. [2] [3]. Major or prolonged postoperative morbidity (for example, significant infections, respiratory or renal impairment) occur in up to 15% of patients, and is associated with reduced long-term survival and worse health-related quality of life; this signal has been consistently demonstrated across different types of surgery, patient and healthcare system. [2] [4, 5]

Data from the US [6] [7] demonstrate wide variation in risk-adjusted mortality & morbidity rates between healthcare providers, suggesting that at least some complications after surgery could be avoidable if standards of care were improved. It is likely that the same is true in the UK; however, there is currently no unified national system for measuring complications or patient reported outcomes across different types of major surgery in the NHS. In order to address this gap, the National Institute for Academic Anaesthesia's Health Services Research Centre (NIAA-HSRC) proposes the development and implementation of a **Perioperative Quality Improvement Programme (PQIP**) for the UK. PQIP will measure risk-adjusted morbidity and mortality, as well as process and patient-reported outcome data in patients undergoing major surgery (lower GI resection, upper GI resection, liver resection, cystectomy, major head and neck reconstructive surgery, thoracic resection). Our dataset has been informed by previous systematic [8] and structured reviews, [9] and over 60 UK NHS hospitals have volunteered to take part. Our clinical reference (steering) group has met and comprises representation from all key stakeholder groups: patient representatives, the Royal College of Surgeons (Eng), Royal College of Physicians, Royal College of Nursing, Faculty of Intensive Care Medicine, Faculty of Pain Medicine, and a wide range of national surgical specialist societies.

ii. Not just another counting exercise?

A number of national audit and quality improvement initiatives already exist in the UK. These range from short-term evaluations of specific clinical areas, as undertaken

by the National Confidential Enquiry into Patient Outcome and Death (NCEPOD) or longer-term continuous national audits which are funded by the Healthcare Quality Improvement Partnership (HQIP) and managed usually by a research team working on behalf of a medical Royal College (e.g. the National Emergency Laparotomy Audit, which is delivered by the NIAA-HSRC on behalf of the Royal College of Anaesthetists).

However, it has been acknowledged that the use of data from national audits to drive local quality improvement activity, which should be the purpose of these audit exercises, varies considerably. This variation is related both to aspects of programme delivery by the lead organisations, and local to issues related to culture, resources and clinician engagement. A report [10] which was commissioned by HQIP to provide information on how to address these issues included the following key messages:

- Support with how to analyse and interpret data and present findings to others in user-friendly formats would help clinicians to engage better with audit findings

- The right resources, knowledge and skills are needed to encourage engagement. Dedicated time to interpret and act on findings, together with clinical audit team input were important

In perioperative care, we recently conducted a national survey which looked at the measurement, reporting and feedback of quality indicators. [11] 158 anaesthetic departments provided data and the following themes emerged:

- data collection and monitoring focuses on indicators of efficiency and productivity (such as operating theatre utilisation rates and surgical cancellation rates: measured and regularly reported in 100% of Trusts)

- safety indicators for which there is an established reporting system with national mandate were also commonly measured and reported (e.g. critical incident reporting)

- a striking volume of “quality data” is already collected by departments of perioperative care; however, current efforts are often sporadic and of little perceived local value, or are in response to external requests (e.g. NCEPOD), which may be of national importance but have little direct local benefit.

- The measurement and local review of a number of other potentially important quality indicators (for example, postoperative morbidity and patient satisfaction) is low (<15% of trusts regularly review such data).

The reasons for these findings may include:

- a lack of clear guidance or understanding of which metrics may be of value for reporting, learning and improvement purposes; [12] [13]

- lack of resources to sustainably monitor and report quality indicators; [14]

- a focus on short-lived measurement exercises, and efficiency and productivity, rather than sustained quality improvement, which may in part relate to a poorly developed understanding of improvement science amongst healthcare professionals. [15]

In setting up PQIP, we are mindful of these issues, and also of those which have been raised in previous evaluations of large scale audit or QI efforts. [10] Therefore, our web-based data entry system will include the features which have been suggested by stakeholders to be important for facilitating the use of data for improvement, such as near-real time feedback, feedback provided in easily understandable and graphical formats, and explanations for statistical analyses and risk-adjustment techniques. [10] A key finding of several previous reviews of using audit data for improvement, [16] highlights the preference from clinicians for a management plan to be suggested to address the areas of need. Therefore, alongside the core dataset, we will provide evidence based bundles for local teams to implement if they find that they have a problem with a particular type of postoperative complication. For example, if a hospital find that they have a high rate of wound complications, relative to hospitals with comparable case-mix, they will be encouraged to use an evidence-based bundle to address this issue. The PQIP database will enable the recording of compliance with the bundle so that implementation can be reviewed locally and centrally.

2. Aim and Objectives

Aim

To comprehensively measure, report and improve risk-adjusted outcome from major surgery in the United Kingdom.

Objectives

1. To measure and report risk-adjusted complication, patient reported outcome and mortality rates after major surgery
2. To analyse variations in structure, process and outcome after major surgery between NHS institutions.
3. To support local quality improvement through feedback of data to clinicians and managers, using near-real time feedback

Methods

The Perioperative Quality Improvement Programme (PQIP) will begin data collection in October 2016. Adult (>18 years) patients undergoing major surgery defined by our list of included procedures will be approached to provide informed consent for data collection and analysis. The participant information sheet will be provided either at the preoperative assessment clinic appointment or on the morning of surgery. An 8-day target recruitment number of up to 5 patients per week will be agreed with each site prior to the start of the PQIP programme. Each 8-day recruitment cycle will start on a different day of the week and patients will be recruited consecutively until the target number is fulfilled [17] and the recruited patients will be approached for consent. As the process of patients' arrival to hospital for treatment can be treated as a random process, selecting patients consecutively as they arrive should not introduce substantial selection bias. Also, starting each period of selection on a different day should cover all days of the week (including weekends, where weekend elective surgery takes place).

All participating hospitals will contribute patient and hospital level data which will be used in the quantitative analyses.

Primary outcome: 7-day post-operative morbidity

Risk adjustment: We will include various patient level, hospital level and procedural factors as covariates in the mixed models to control for the effects of potential confounding variables that are likely to modify patient outcomes. The list of patient level characteristics we plan to control for in the mixed model analysis includes

patients' socio-demographics , physical & behavioural factors, medical history and procedural factors. In secondary analyses we will also adjust for potential hospital level confounding factors such as, hospital volume, whether the hospital is a teaching hospital, and staff (nurse)-to-patient ratio.

Variable selection for risk adjustment:

We will use the purposeful selection of covariates approach [18] for variable selection. The process begins by a univariate analysis of each variable and identifying those having a significant effect at a relaxed p-value cut-off point (typically, at p=0.25). Those identified are then entered simultaneously in the model and, following further iterative process of deleting, refitting, and verifying, the model will contain only factors that are important for risk adjustment.

Analyses

Data will be analysed to compare risk-adjusted outcomes between participating hospitals and to identify variation in processes and outcomes.

Secondary outcomes:

<u>Short-term patient outcome measures</u>

Clavien-Dindo classification of complications on discharge from hospital.

<u>Process measures of engagement with PQIP</u>

Case-ascertainment rates

Data completion

<u>Process measures related to patient care</u>

Changes in compliance with process measures

<u>Resource utilisation</u>

Critical Care admission (planned)

Critical Care admission (unplanned)

Critical Care Length of Stay

Hospital length of stay

Hospital readmission within 30 days of index procedure

<u>Longer-term patient outcome measures</u>

EQ5D (5L) at 6 months and one year post-surgery

World Health Organisation Disability Assessment Schedule 2.0 [19] at 6months and one year post-surgery

5. Ethics and data protection issues

5.1 Caldicott Guardian approval

All hospitals participating in PQIP will be required to provide written approval from their local Caldicott guardian.

5.2 Ethics approvals for research using PQIP data

We will separately apply for ethics approval to use these data for research through the Integrated Research Application System. Approval will be sought for the study protocol, informed consent forms, patient and participant information sheets and patient-level dataset.

5.3 Risk Management

There are minimal potential risks to patients. No patient-level interventions are being tested. All data will be anonymised. There are minimal potential risks to investigators.

5.4 Data protection and patient confidentiality

All investigators and study site staff will comply with the requirements of the Data Protection Act 1998 with regards to the collection, storage, processing and disclosure of personal information and will uphold the Act's core principles.

Patient level data will be entered by local reporters directly into electronic CRFs on the web-based study database. The database will be hosted on servers managed by UK Fast on behalf of the Royal College of Anaesthetists (RCoA). Local investigators will have access to their own full datasets.

Among the patient identifiers, only sex will used for analysis. An anonymised dataset will be used by the central PQIP study team for analysis. In this dataset:

- the NHS number will be replaced by a unique study patient identifier.
- Date of Birth will be converted to Age on date of surgery, and trimmed to month and year of birth
- Postcode will be converted to PCT, SHA of residence, and the Office for National Statistics Lower Super Output Area, which allows the allocation of the Index of Multiple Deprivation.

The data items will be retained in their original format in the identifiable dataset which is retained within the PQIP IT system.

The following paragraphs describe the process of linkage, between the PQIP database and data held by NHS Digital (ONS mortality data and Hospital Episode Statistics (HES) data).

The minimum amount of patient identifiable data will be extracted from the study database by the central investigation team, onto a password protected Excel spreadsheet, and emailed securely to NHS Digital. These fields will be used to ensure individual patient records within the PQIP system are managed correctly, keeping distinct treatment episodes linked to the correct patient.

Four patient identifiers will be used to facilitate data linkage: patient name, date of birth, NHS number and postcode. The NHS number is not completely populated in the other routine datasets and the other patient identifiers are used when the NHS number is absent. In addition, by using these four identifiers in combination, possible erroneous record linkages are flagged.

A file (P) containing these patient identifiers only will be extracted from the full dataset hosted in the study database, and will be sent securely to the NHS Digital Trusted Data Linkage Service (TDLS). File (P) will contain the following identifiers:

- PQIP anonymised identifier
- NHS number
- Date of Birth
- Sex
- Postcode

For each patient in the file, the TDLS will identify the matching ONS or HES ID. The TDLS will then return to the Royal College of Anaesthetists a 'look-up' file (L) containing only the PQIP identifier and the HES or ONS ID identifiers, and a MATCH_RANK field which indicates the strength of the match.

An extract of anonymised ONS or HES mortality data will then be requested from the TDLS for all the list of IDs contained in file (L).

The file (L) will be placed in the secure RCoA server accessible only to the project data manager. It will then be used to link the anonymised ONS or HES data to the anonymised PQIP data for analysis. The anonymised PQIP extract will not contain NHS number, postcode or date of birth. Patients will be labelled with the PQIP identifier only.

The Data Custodian will be Ms Sharon Drake, Director of Quality and Research, Royal College of Anaesthetists. The full anonymised dataset will only be accessible to named members of the study team. Requests for access to the full dataset by external parties for secondary analyses will be considered by the Project team following a formal application which includes details of purpose, ethics, information governance and data management.

6. Study administration

6.1 Project management

The day-to-day delivery of PQIP will be led by the Project Team which will be chaired by the Chief Investigator and will meet monthly face-to-face or video-conferencing.

The Clinical Reference Group has been established to provide professional and lay representation into all aspects of the project. This is currently chaired by the Chief Investigator but this will be handed over to an independent chair during 2016-7. The CRG will meet every 3-4 months.

6.2 Patient and Public Involvement

Our clinical reference group has representation from the Royal College of Anaesthetists' Lay representation group and they have provided input into the study design since inception. The Chief Investigator has undertaken to present updates to the Lay Representation group at least twice-yearly for the duration of the study. Lay representatives will be integral members of the clinical reference group throughout the study including during dissemination of the results.

7. Impact and Dissemination

We expect analyses of data from this database to produce a number of high impact academic outputs. A full report and executive summary will be produced annually. Manuscripts will be prepared for submission to open access peer reviewed journals. Wider dissemination to the surgical and anaesthetic profession will be achieved through using the resources of the RCoA and other stakeholder Royal Colleges and the NIAA-HSRC, including websites, press releases, written and electronic communications. Different resources will be used to disseminate information to different stakeholders, using a multi-media approach and lay representation to ensure effective communication to the public. Authorship of all manuscripts will be

determined by the CI with the agreement of the Project Team and comply with ICJME standards.

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9. Appendices

1. Patient Information Sheet, consent form, and questionnaires v 0.5 20.07.2016
2. PQIP Data sharing agreement v1.0 26.07.2016