Information Governance Procedures for PQIP

DOCUMENT AIMED AT:
TRUST INFORMATION GOVERNANCE DEPARTMENTS AND CALDICOTT GUARDIANS

Title
Perioperative Quality Improvement Programme

Description of project
The National Perioperative Quality Improvement Programme (PQIP) is led by the National Institute for Academic Anaesthesia's Health Services Research Centre (NIAA-HSRC), based at the Royal College of Anaesthetists. PQIP measures care delivered, complications and outcome from 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. PQIP has received ethics approval from the National Research Ethics Service. The Baseline PQIP research study will use the data collected into the PQIP database to establish complications, mortality and failure-to-rescue rates in UK hospitals. Health Research Authority approval has been applied for (outcome pending mid-September 2016) and NIHR portfolio adoption also applied for.

The PQIP web-based data entry system will include features to facilitate 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.

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 of a comprehensive group of stakeholder representatives including surgeons, anaesthetists, physicians, nurses and patients.

Overview of the PQIP research database and the Baseline PQIP research study

The aim of PQIP is to comprehensively measure, report and improve outcome from major surgery in the United Kingdom.

Approval for the PQIP database has been granted for 5 years, at which point a routine re-application will be submitted. The baseline PQIP study will run for 3 years, with the potential for extension.

PQIP will begin data collection in November 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. A 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.

All participating hospitals will contribute patient and hospital level data which will be used in the quantitative analyses. Data will be analysed to compare risk-adjusted outcomes between participating hospitals and to identify variation in processes and outcomes.

PQIP data will be linked to other sources of routine data, including ONS mortality data from the Health and Social Care Information Centre (HSCIC) and Hospital Episode Statistics (HES) data.

Reporting
PQIP will provide near-real-time feedback to sites and regular site reports tailored to investigators' requirements. A full PQIP report and executive summary will be produced annually.

In addition, research manuscripts using PQIP data will be submitted to open access peer reviewed journals. Wider dissemination to the surgical and anaesthetic profession will be achieved 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.

Governance
The day-to-day delivery of PQIP is led by the Project Team which is chaired by the Chief Investigator and will meet monthly.

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 2017. The CRG will meet every 3-6 months.

Identify purpose
1. Healthcare Medical Purpose (Primary)
2. Non-Healthcare Medical Purpose (Secondary)

Data items requested
1) Demographic data: Date of birth, sex, postcode of place of residence
2) Patient identifiers: NHS number
3) Procedure data: Date & time of admission, date & time of surgery, procedure type, record of medical interventions performed, personnel involved in delivery of care, processes of care
4) Physiological data to enable risk adjustment
5) Process measures (e.g. compliance with enhanced recovery indicators)
6) Outcome data: Date of hospital discharge, date of death

Time period for data required
Start date: 7/11/2016 - End date: 6/11/2021 with potential to extend
Data is collected contemporaneous via web-based data collection platform.

Receiving Organisation/individual

Organisation Name: Royal College of Anaesthetists
Address: Churchill House, 35 Red Lion Square London WC1R 4SG

Appointed person responsible for data: Ms Sharon Drake

Contact details: 020 7092 1681 **Email address:** sdrake@rcoa.ac.uk

Recipient's location for receiving and processing Trust data: UK, Non-NHS organisation

Who else will have access to the data?
The RCoA will oversee the collection of patient level data for patients undergoing the included procedures. The source data will be entered by local hospital teams into the PQIP web-based data entry tool (webtool) hosted by NetSolving. The PQIP webtool will house the full dataset in a secure environment, including the patient identifiers.

The full identifiable dataset will be retained in their original format within the PQIP webtool. Only the registered Data Protection Controller for the Royal College of Anaesthetists will have access to the

full dataset. The Project Team and its subcontractors will not have access to the full set of patient identifiers. Pseudoanonymised data will be used for data analysis by the RCoA and its approved sub-contractors. In the pseudoanonymised dataset, patients will be identified by a computer-generated label. It will not contain NHS number, date of birth or full postcode. The local hospital users will only have access to their own hospital's data.

Members of the PQIP Project Team employed by the NHS will be subject to standard NHS confidentiality agreements.

Non-NHS members of the PQIP Project Team are aware of their responsibilities and obligations to respect patient confidentiality. It is a condition of employment that all employees abide by their organisation's Data Protection Policy and confidentiality clause within their contract of employment.

Method of secure information / data transfer
Electronic File Transfer

Applicable security arrangements for the transfer
Data will be collected by a web-based data collection tool (PQIP webtool). This will be accessible via a secure website using SSL encryption. The Project Team will have access to data via data exports from the online data collection web tool.

The organisation responsible for hosting the data collection platform, UKFast, has attained ISO-27001:2013 certification for their Information Security Management System and ISO 9001:2008 for their Quality Management System. Further information about protection of data is given below.

NetSolving have been contracted to the project due to their track record in managing audit and patient data. The hardware service provider (UKFast) has a track record in delivery to many private and public sector clients, including the NHS and is a G-Cloud supplier. The contract with UKFast mandates stringent security processes in terms of the back-up and protection of data, including subsequent deletion of audit data. These providers already work with the Royal College of Anaesthetists on the National Emergency Laparotomy Audit.

Service Users (patients)
How will the service users be contacted?
Patients undergoing major surgery defined by our list of included procedures will be approached to provide informed consent for data collection and analysis. A participant information sheet will be provided either at the preoperative assessment clinic appointment or on the morning of surgery.

Patients will be asked to complete questionnaires before, and at several points up to one year after, surgery.

What information will be given to the service user about the purpose?
Patient and public information will be made available via specific information sheets and consent forms. These will be made available for download from the PQIP website, and also for distribution in paper format at hospital sites.

Will the service users' consent be obtained?
Yes, full consent will be obtained in advance of the procedure via a consent form.

How long will the data be stored?
PQIP will be collecting patient data for 5 years initially, from November 2016 until November 2021 (with potential extension). Individuals will be pseudoanonymised by assigning a unique identifier at the time of data entry; however data linkage to external databases will require provision of patient identifiable data. Long-term follow up of PQIP patients will be achieved through linkage to the Office of National Statistics mortality register, and will continue for 20 years after each individual patient has been recruited to the database and study.

Where will the data be physically stored?
On a server hosted by UKFast in a secure data centre. See below for additional details.

If the data is on a computer is there access via a local network or the internet?
Information for analysis will be exported from the PQIP data collection web tool as a pseudoanonymised dataset and held on a local network held within the RCoA. Access to this network is controlled by unique usernames and passwords. Furthermore, the exported files will be stored on parts of the network that are only accessible to the Project Team. Patient identifiable data will not be stored on the local network.

Only the registered Data Protection Controller for the Royal College of Anaesthetists will have access to the full dataset. The project team and its subcontractors will not have access to a dataset that contains both a full set of patient identifiers and patients' clinical information.

How will data be protected?
The server is hosted by UKFast in a secure datacentre. All traffic passes through Cisco equipment including Anomaly Detection Systems (ADS), Intrusion Detection Systems (IDS) and Intrusion Prevention Systems (IPS). This is clustered across multiple locations. The hardware is protected by a Cisco Firewall with full access controls enabled. UKFast will carry out an annual security audit. These audits will inspect the system for any vulnerabilities or threats that could allow hackers to destroy or damage the system. Each UKFast datacentre is fully powered, secure, resilient and equipped to meet the project demands.

The company has a track record in delivering to many private and public sector clients, including the NHS, and has demonstrated a strong awareness of the need to protect systems and data from both physical and virtual threats. The organisation responsible for hosting the data collection platform, UKFast, has attained ISO-27001:2013 certification for their Information Security Management System and ISO 9001:2008 for their Quality Management System. They are PCI compliant for all client transactions.

1. System Security
- Full Security patching;
- Dedicated firewall;
- Risk assessment and security consultation and auditing;
- Programmed evaluation and testing of all systems;

2. Physical and site security
- Unassuming facilities, unmarked and inauspicious;
- On site security 24/7/365;
- Electronic surveillance with continual monitoring/recording;
- Electronic access;
- Client access by appointment only;
- Dual power supply, UPS and onsite generator backup;
- Fire, power, weather, temperature and humidity monitoring systems;
- Diverse fibre routing via multiple carriers;
- Cross connection to a number of tier 1 carriers;
- 24 hour security patrol (NSI accredited security).

In reports containing large volumes of data patient identifiable data will not be included.

At the end of this period how will the data be disposed?
Hard drives are removed by UKFast and stored in a secure storage facility on site for 30 days. After 30 days the drives are wiped to HMG standard. Once wiped they are physically destroyed. A Certificate of Destruction can be created.

Printed copies will be securely shredded. Files will be securely deleted from computer systems (including any copies held on backup or archive media).

Caldicott Principles

Principle 1 - Justify the purpose(s).
Every proposed use or transfer of personal confidential data within or from an organisation should be clearly defined, scrutinised and documented, with continuing uses regularly reviewed, by an appropriate guardian.

The Perioperative Quality Improvement Programme is collecting data to improve the quality of perioperative care delivered to patients. It will collect only that data required for the published process and outcome measures. These have been specifically linked to evidence based published standards of care. It will also collect sufficient data to risk adjust cases in order to produce meaningful comparisons between hospitals. The data required for risk adjustment has also been subject to an evidence based review process. Documents will be produced that explain the explicit links between the data being collected and the process and outcome measures, and published standards of care. These documents will be in the public domain via the website.

All process and outcome measures and related data has been subject to peer review by a Clinical Reference Group that meets 3 times a year, consisting of key stakeholders including patient and public representation.

The data will be analysed at least annually by the Project Team to ensure that the dataset is fit for purpose.

Principle 2 - Don't use personal confidential data unless it is absolutely necessary.
Personal confidential data items should not be included unless it is essential for the specified purpose(s) of that flow. The need for patients to be identified should be considered at each stage of satisfying the purpose(s).

In accordance with the requirements of nationally funded HQIP audits, PQIP will not duplicate data collection where it is already being collected elsewhere, in order to minimise the burden of data collection on participants.

Linkage will be made with additional databases such as (but not limited to):
Hospital Episode Statistics (HES) for data validation
ONS mortality data from the Health and Social Care Information Centre (HSCIC)
Patient Episode Database for Wales (PEDW) for data validation
National Clinical Audit data (for example, the Intensive Care National Audit and Research Centre's Case-Mix Programme, or the National Bowel Cancer Audit)

In order to successfully link with these databases, personal confidential data is required. The only personal confidential data being requested is the minimum required in order to successfully link with these databases. Dataflows will be kept segregated wherever possible by using pseudoanonymised identifiers.

Among the patient identifiers, only sex is used for analysis. An anonymised dataset will be used by the RCoA for analysis. In this dataset:
• The NHS number will be replaced by a unique Audit patient identifier.
• Date of Birth will be converted to Age at diagnosis, 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.

Principle 3 - Use the minimum necessary personal confidential data.
Where use of personal confidential data is considered to be essential, the inclusion of each individual item of data should be considered and justified so that the minimum amount of personal confidential data is transferred or accessible as is necessary for a given function to be carried out.

Each individual item within the dataset has been peer reviewed by the Clinical Reference Group, and the minimum data necessary to draw adequate conclusions about the care provided is being collected. The dataset has been informed by evidence based reviews carried out by the National Institute of Academic Anaesthesia's Health Services Research Centre.

In order to successfully link with the relevant databases listed above, personal confidential data is required. The only personal confidential data being requested is the minimum required in order to successfully link with these databases.

Principle 4 - Access to personal confidential data should be on a strictly need-to-know basis. Only those individuals who need access to personal confidential data should have access to it, and they should only have access to the data items that they need to see. This may mean introducing access controls or splitting data flows where one data flow is used for several purposes.

Each hospital will be assigned a lead user who will administer the user rights for staff within their hospital. Access will be via unique usernames and passwords issued to each user. This will ensure that only users who have a legitimate reason to use the data collection tool will be granted access. A database of users will be maintained by the Project Team. Local hospital users will only have access to their own hospital's data.

Only the registered Data Protection Controller for the Royal College of Anaesthetists will have access to the full dataset.

Dataflows will be kept segregated wherever possible by using pseudoanonymised identifiers, in order to limit the number of people who have access to patient confidential data.

The following paragraphs describe the process of linkage, using the English Hospital Episode Statistics (HES) database as the example of the national database to which the PQIP dataset will be linked.

A file (P) containing patient identifiers only will be extracted from the full dataset hosted in the webtool, and will be sent securely to a trusted Data Linkage Service. For HES data, this would be the Health and Social Care Information Centre (HSCIC). File (P) will contain the following identifiers:

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

For each patient in the file, the HSCIC will identify the matching HES ID. The HSCIC will the return to the RCoA a 'look-up' file (L) containing only the PQIP identifier and the HES ID identifiers. An extract of anonymised HES data will then be requested from the HSCIC for all the list of HES 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 HES data to the anonymised extract of audit data from the PQIP webtool for analysis. The anonymised PQIP extract will not contain NHS number, postcode or date of birth. All datasets used for analysis will have patients identified with the PQIP identifier only.

Principle 5 - Everyone with access to personal confidential data should be aware of their responsibilities.
Action should be taken to ensure that those handling personal confidential data - both clinical and non-clinical staff - are made fully aware of their responsibilities and obligations to respect patient confidentiality.

Members of the PQIP Project Team employed by the NHS will have completed Information Governance training in accordance with their own Trusts requirements.

Non-NHS members of the PQIP Project Team are aware of their responsibilities and obligations to respect patient confidentiality. It is a condition of employment that all employees abide by their organisation's Data Protection Policy and confidentiality clause within their contract of employment.

Clinical and non-clinical staff entering data will be reminded of their obligations surrounding the use of confidential data when registering to use the data collection tool and when signing in. These obligations will also be explicitly stated on a separate area of the data collection website.

Principle 6 - Comply with the law.
Every use of personal confidential data must be lawful. Someone in each organisation handling personal confidential data should be responsible for ensuring that the organisation complies with legal requirements.

Users submitting data will be subject to Information Governance training in accordance with their own Trusts requirements, which will set out their legal responsibilities and requirements.

Each hospital has a designated lead from the Clinical Audit Department who will be familiar with the legal requirements due to the nature of their role within an NHS Clinical Audit Department.

Members of the Project Team are aware of their obligations and legal requirements regarding personal confidential data. It is a condition of employment that all employees abide by their organisation's Data Protection Policy and confidentiality clause within their contract of employment.

The Director of Clinical Quality and Research is the Data Protection Controller for the Royal College of Anaesthetists. In lieu of a Caldicott Guardian for the RCoA, the Director of Clinical Quality and Research will act as the Caldicott Guardian. The Data Protection Controller has undergone Data Protection Training and Information Governance Training.

The Royal College of Anaesthetists both has Data Protection Registration. The Royal College of Anaesthetists has commenced the IG Toolkit: Organisation code 8J277.

Principle 7 – The duty to share information can be as important as the duty to protect patient confidentiality.
Health and social care professionals should have the confidence to share information in the best interests of their patients within the framework set out by these principles. They should be supported by the policies of their employers, regulators and professional bodies.

All NHS employees are appropriately supported in this way.

Medical staff will be aware of their responsibilities as part of the General Medical Council's guidance on Good Medical Practice and Duties of a Doctor. This will be augmented by specific Trust policies.

Other health care professionals will also be supported by their respective professional bodies (eg Nursing and Midwifery Council) and Trust policies.

RCoA staff are aware of their responsibilities as set out in the RCoA's Data Protection Policy.

If you require any further clarification please contact the PQIP Project Team: pqip@rcoa.ac.uk