PQIP guidance on applying for data for secondary research or quality improvement

Introduction

The PQIP team are keen for PQIP data to be used for patient benefit. So, in addition to formal output by the central Project Team (quarterly reports, dashboards etc.), and our planned research outputs (protocol in submission) we actively encourage and support external proposals for secondary research. The intended purpose of the data is to provide clinicians at participating sites with a data resource they can use to investigate, analyse and improve the quality of care of their perioperative patients.

The purpose of this guidance is to:

1. Explain the general principles for PQIP data release
2. Explain how to apply to PQIP for access to anonymised patient-level and/or hospital-level aggregated data from multiple hospitals

1. General principles for Data Release

In compliance with Good Medical Practice 2017, the Data Protection Act 2018 and the General Data Protection Regulation (GDPR), 'data protection principles' will be followed. It is essential that the anonymity of research participants are protected and the data are used in an ethical way.

PQIP data must be used with the following principles in mind:

- **No Identification of Person(s)**: No effort to determine the identity of any individual (including but not limited to patient, surgeon, anaesthetist, and other health care providers). PQIP will omit from the dataset all patient identifiers, in compliance with the Data Protection Act 2018. It may be possible, in limited situations, through deliberate technical analysis, and with outside information, to ascertain from the de-identified data set the identity of persons. This could result in considerable harm. Any attempts to identify individuals is prohibited. Any information that could identify individuals directly or by inference must not be released or published.

- **No Identification of Hospital(s)**: No effort to determine the identity of hospitals. No direct comparison of hospital structure, processes and outcomes. PQIP will omit from the dataset all hospital identifiers. Any information that could identify hospitals directly or by inference must not be released or published.

- No use or disclosure of the PQIP data other than that as permitted for research activities and/or quality improvement analysis.

- No use of the PQIP data to identify or contact individuals who are the subject of the information.

- Only applicants who are (at the time of application) working in a hospital which is recruiting patients to PQIP will be eligible to apply for data before the main study is published by the PQIP team.

2. Applying to PQIP for access to anonymised patient-level and/or hospital-level aggregated data from multiple hospitals

Accessing local PQIP data

For access to your local data, please contact your local PQIP Principal Investigator.

All PQIP collaborators who have been given access to their local data by their local Principal Investigator can access patient-level data without need for any further permissions. Local teams have access to their own data, as entered into the web-tool, with downloadable excel spreadsheets. Automated run-charts are produced by the web-tool in real time, for selected key metrics, and compared against national data.

Data accessed at local level will not be anonymised. It is therefore the responsibility of those who access the data to adhere to information governance regulations to ensure that these data are secure.

Do I need to inform PQIP if I use my hospital's local data for quality improvement projects or research?

No. However, please attribute PQIP as the source of the data in posters, publications or reports. We are keen to hear about any quality improvement projects using PQIP data, and may be able to help you share and showcase your work. Please let us know how you are using the data to improve care by emailing pqip@rcoa.ac.uk.

What further PQIP data can be requested?

You can apply to the PQIP team for access to the following data for all PQIP patients / hospitals or a sub-set of patients / hospitals (e.g. by specialty or geographical region)

1. Hospital level aggregate data
2. Patient-level anonymised data

Can I request patient level data that includes patient identifiers?

No.

How do I request anonymised hospital and/or patient level data?

Complete the 'PQIP Data Access Request' application form and send it to pqip@rcoa.ac.uk with 'Data Request' in the subject line. Requests need to demonstrate a clear rationale for using the data and how they will be used in an ethically sound and scientifically robust manner. A clear justification is required for each data item requested, explaining how it will contribute to answering the research question. If you would like to make an informal query or request feasibility counts prior to submitting an application, then please email pqip@rcoa.ac.uk.

What does the application process involve?

The first step is to complete an application form detailing the proposal for using patient level data. This will be reviewed by the PQIP Project Team. The PQIP Project Team will then respond to say whether the application is suitable or not, or if further information is required. Applications will be reviewed at team meetings which take place every two months (list of dates and deadlines for consideration are on the website).

Will you let me know if someone else is carrying out a similar study?

We will publish accepted applications on the PQIP web site and keep a list of all ongoing and completed projects.

Can I collaborate with the PQIP project team on a project or proposal?

Yes. This will depend on the nature of the project and the capacity of the PQIP team. Our team includes the Chief Investigator, several clinical research fellows, surgical fellows, QI fellows, a data analyst, social scientist and a statistician. If you wish to collaborate with the PQIP project team then please email pqip@rcoa.ac.uk.

Is there a cost to requesting data?

There may be a cost, depending on the level of data cleaning that the PQIP team need to do before releasing it to you. Please see the Data Sharing Cost Recovery Policy for further details

Is ethical approval required for my study?

Separate Health Research Authority (HRA) approval will be required for your study. This includes ethics and sponsorship. The necessary permissions should be obtained in liaison with your local Research & Development department. If your require any help, please get in touch. All our ethics / HRA approval documents are available on the PQIP website.

Can I use extracts of anonymous patient level data for other studies?

No. Data can only be used in the manner described in the agreed research protocol. If you wish to carry out further studies not specified in the protocol then approval will need to be granted.

What about publishing my findings?

We hope that all studies using anonymous patient level data will be published in a peer-reviewed publication. Wherever possible, publications should be Open Access, and researchers should include the cost of open access publication in funding applications for studies using PQIP data. Appropriate statistical disclosure control measures should be implemented to prevent re-identification with the data included in publications. We encourage you to inform us of your study's outputs.

Do I need to include PQIP collaborators on publications?

The PQIP team intends to include all local investigators as collaborators on publications using PQIP data. We therefore request that all applicants for PQIP data do the same. Authorship is guided by the ICJME publication guidance.

How do I attribute PQIP in publications or reports?

Please attribute PQIP as the 'Perioperative Quality Improvement Programme (PQIP), Health Services Research Centre, Royal College of Anaesthetists.'

How long can I keep data for?

In accordance with the study protocol, local data should be kept for a period of 10 years from the end of the study (end of study currently forecast to be 31 October 2023). Anonymised aggregate and patient-level data will be kept for a period of time agreed with the PQIP Project Team – typically two years – after which it will need to be securely destroyed. Researchers will be required to formally inform PQIP that the data have been securely destroyed. We may contact you on an annual basis for an update on your study's progress.