PQIP Perioperative Quality Improvement Programme

Participant Information Sheet

We may invite you to consent to taking part in a national study aimed at improving the quality of NHS surgical care. Please read the information below and ask any questions you would like to.

What is PQIP?

PQIP stands for the Perioperative Quality Improvement Programme. "Perioperative" refers to the time before, during and after surgery. Our aim is to improve the care and treatment of patients undergoing major surgery in the United Kingdom. We do this by collecting and studying information about you, your surgery, and then your recovery afterwards.

How does PQIP help patients?

The information collected by PQIP is used by doctors, nurses and medical researchers to:

- Produce information on the quality of care received by patients undergoing major surgery in NHS hospitals.
- Ensure that any changes or improvements to our services benefit patients
- Learn about the best ways in which doctors and nurses can use patient information to improve quality of care
- Understand better what happens to patients after they leave hospital after having a major operation, and whether the surgery has had a beneficial effect on their longer-term health.

What would taking part involve?

We collect information about you, your surgery, and then your recovery afterwards, both in hospital and at home. This information does not affect the care you receive. Some of this information is provided directly by you, about how you feel about your general health. Other information will be completed by your doctors and nurses, and includes information about the type of surgery, anaesthesia and care you receive before, during and after surgery.

If you consent, we would like you to complete three short questionnaires now, before your surgery. These will take about 20 minutes to complete. We will then contact you the day after your operation, and again on day 3 after surgery to answer some of these questions again (we will either visit you on the ward, or phone you at home if you have been discharged) – these questions should only take 10 minutes to complete.

We will also email and/or telephone you to ask some questions again 6 months and one year after your operation. These questions should take 10 minutes to answer. All of these questions are aimed at understanding how you feel about your general health and quality of life. This information will help us provide better information for future patients about what to expect from their surgery and how they will recover afterwards. If you later decide not to answer these questions, you do not have to.

Why does PQIP need my personal details?

To help PQIP provide an in-depth picture of your care, we send your personal details (NHS number, date of birth, postcode) to NHS Digital (England), NHS Wales Informatic Service (Patient Episode Database for Wales, Wales) or NHS National Services Scotland (Scotland). These organisations will link information to individual participants in the study which will tell us if you have (for example) been readmitted to hospital after you went home. In addition NHS Digital, NHS Wales Informatic Service, and National Services Scotland are able to provide us with information about people who may have passed away in order that we do not make contact and cause any distress to relatives. This information includes date and cause of death which is sourced from civil registration data on behalf of the Office for National Statistics. The linked information is returned to the PQIP study team in a digital file. The only identifiable details included in this file are your study ID and any information provided on the date and cause of death.

The personal details (listed below) are only shared with NHS Digital, NHS Wales Informatic Service (Patient Episode Database for Wales) or NHS National Services Scotland to enable the linkage to the information held by them. Your details will not be shared with anyone else outside the NHS or research team.

Personal details needed by PQIP are:

✓ Name ✓ Date of birth ✓ Postcode ✓ NHS number

The information collected by PQIP is only used for research after it has been made anonymous.

Legal basis for processing personal data

The RCoA collects your personal information in line with its charitable objectives, which can be found at https://www.rcoa.ac.uk/system/files/CharterOrdinances2018.pdf. Our use of your information is based on the legitimate interest we have to advance, promote and carry out study and research into anaesthesia and related subjects and disseminate the useful results of that research.

Who will be able to access my information?

Your information will be anonymised before it is analysed by the study team. Your personal details (detailed above) are only shared with NHS Digital, NHS Wales Informatic Service (Patient Episode Database for Wales) or NHS National Services Scotland to enable the linkage to the information held by them. Your details will not be shared with anyone else outside the NHS or research team.

Only doctors and approved researchers will be able to access the anonymised information which is collected through the PQIP study.

Is my information safe?

Yes. Very strict rules and secure procedures are in place to ensure that your information is kept safe. These systems and procedures comply with international standards and will be continuously monitored and adapted as necessary to maintain security over the lifetime of the project.

How long will the study last?

The study will last for 4 years but your involvement will only be for the 12 months following the time of surgery. Data collected by the PQIP study, and linked data from NHS Digital, NHS Wales Informatic Service and National Services Scotland will be kept for 30 years in order to track your long term recovery after surgery.

What are the possible benefits of taking part?

It is unlikely that you will benefit directly. Future patients may benefit from an improved NHS as a result of the information we have collected about you and your care.

What are the risks of taking part?

This is a very low risk study recording your routine care and your experience as a patient. There are no risks.

Can I stop being in the study?

You can decide to stop participating at any time – please contact a member of the research team at your local hospital or at the central office listed below.

What other choices do I have if I do not take part in the study?

You are free to choose not to participate in the study. If you decide not to take part in this study, there will be no penalty to you. Your care will not be affected either way.

What are the costs of taking part in the study? Will I be paid for taking part in this study?

There are no costs to you for taking part in this study. You will not be paid for taking part in this study.

Who is organising and funding this study?

The study is being led by the Royal College of Anaesthetists (RCoA). The RCoA will act as the data controller for this study which means we are responsible for looking after your information and using it properly. The RCoA has a Data Protection Officer - Sharon Drake who can help you with any queries about your information: dpo@rcoa.ac.uk. The details are being organised by a multidisciplinary project team consisting of anaesthetists, surgeons, physicians, nurses and patients. The research costs for the study have been supported by the RCoA and the Health Foundation.

Who has reviewed this study?

The study design has been reviewed by the South East Coast Research Ethics Committee before any patients were approached to participate.

What will happen to the results?
The results will be analysed and written up for publication in scientific journals, professional literature, social media and conference presentations. Participants will not be able to be identified in any publication.

What if there is a problem?
If you wish to complain, or have any concerns about any aspect of the way you have been approached or treated by members of staff you may have experienced due to your participation in the research, National Health Service or UCL complaints mechanisms are available to you. Please ask your research doctor if you would like more information on this. Your hospital's Patient Advisory Liaison Service (PALS), Community Health Council (CHC) in Wales or your local hospital's complaints team may also be able to help.

In the unlikely event that you are harmed by taking part in this study, compensation may be available. If you suspect that the harm is the result of the Sponsor's (University College London) or the hospital's negligence then you may be able to claim compensation. After discussing with your research doctor, please make the claim in writing to Dr Ramani Moonesinghe who is the Chief Investigator for the research and is based at University College London Hospital. The Chief Investigator will then pass the claim to the Sponsor's Insurers, via the Sponsor's office. You may have to bear the costs of the legal action initially, and you should consult a lawyer about this.

You also have the right to lodge a complaint with the Information Commissioner's Office (ICO), the supervisory authority in the UK responsible for the implementation and enforcement of data protection law, if you have concerns about the way your personal data is being handled. You can contact the ICO via their website - https://ico.org.uk/concerns/ or by calling their helpline – 0303 123 1113

Finding out more

PQIP Website
www.pqip.org.uk

Email
pqip@rcoa.ac.uk

PQIP Helpline
0207 092 1678

Mon-Fri, 9am to 5pm (excluding public holidays)

PQIP Centre
National Institute for Academic Anaesthesia's Health Services Research Centre,
Royal College of Anaesthetists, Churchill House, 35 Red Lion Square, London, WC1R 4SG

Giving your consent is voluntary and more information is available if you are unsure.