PEER REVIEW HISTORY

BMJ Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form (**http://bmjopen.bmj.com/site/about/resources/checklist.pdf**) and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below.

ARTICLE DETAILS

TITLE (PROVISIONAL)	A qualitative process evaluation of the Perioperative Quality Improvement Programme (PQIP): Study protocol.
AUTHORS	Wagstaff, Duncan; Moonesinghe, S. Ramani; Fulop, Naomi; Vindrola-Padros, Cecilia

VERSION 1 - REVIEW

REVIEWER	Lee A Fleisher University of Pennsylvania Philadelphia, PA, USA
REVIEW RETURNED	21-Apr-2019

GENERAL COMMENTS	The authors describe their quality improvement program for perioperative care. They have done an excellent job laying out the study. General comments: 1. PQIP: It is unclear how the random patients will be chosen. It is also unclear how and to which datasets the program will be linked. Greater detail should be outlined on how the study will reduce the burden of perioperative complications. 2. PQIP activities: It would be useful to understand how much data is available for download to local collaborators. 3. Multi-site fieldwork: Please provide more information on the expertise of the team doing fieldwork. Given the description in the text, is there a bias in which sites and how they are assessed.

REVIEWER	Michael Avidan Washington University in St. Louis, United States
REVIEW RETURNED	27-Apr-2019

GENERAL COMMENTS	There is a strong tradition of 'audit' in the UK. But if audit is not incorporated into a quality improvement process, audit might have limited or no impact on practice. This is a protocol for a study using qualitative methods to analyze the Perioperative Quality Improvement Program (PQIP). The PQIP is designed to measure complications and then improve practice through feedback to clinicians. In order to be successful, the PQIP must (i) reliably measure complications and (ii) provide useful feedback to clinicians. This study will analyze the theory behind the PQIP initiative, assess barriers and facilitators to the success of PQIP, and examine wider contextual factors that impact the

	implementation of PQIP. It is difficult in for me to separate criticisms of this study from criticisms of PQIP, which this study is designed to evaluate. 1. Quality improvement requires specific skills and training. It is not obvious that the participants in PQIP or in this proposed study have the requisite skills and training. This could be elaborated. 2. The authors touch on this, but a key challenge is not just knowing what is wrong, but more importantly how to address the deficiencies. The following ingredients are all needed: (i) accurate knowledge of deficiencies, (ii) intentionality (motivation) to address deficiencies, (iii) adequate resources to address deficiencies, and (iv) ability (expertise and training) to address the deficiencies. Often clinicians only have intentionality or motivation. All four of these ingredients should be examined. 3. It is not clear whether PQIP is adequately conceptualized to address / provide all four of these ingredients. 4. Does the PQIP feedback reach individual clinicians or only individual hospitals? Ideally clinicians should be able to compare their practice and outcomes against national benchmarks. 5. If participation in PQIP is based on patient consent, is it likely that there will be a biased sample? 6. What is the basis for sites to be involved in PQIP? This seems to be a potential source of bias. There might be important differences (other than PQIP involvement) between PQIP and non PQIP sites. The same might apply to the specialties participating and not participating. 7. The qualitative methods used in this study are appropriate and are well described. The investigators have been thorough in detailing these. 8. Engagement with key stakeholders, including members of the public, is a strength. 9. The COREQ criteria have been used appropriately, and the checklist is included.

VERSION 1 – AUTHOR RESPONSE

Reviewer 1

The authors describe their quality improvement program for perioperative care. They have done an excellent job laying out the study.

It is unclear how the random patients will be chosen.

We have amended this paragraph:

Participating hospitals have the option either to try to recruit all eligible patients or to randomly recruit 3-5 eligible patients per week using an eight-day rolling sampling cycle. To evaluate potential bias within the sample of patients recruited to PQIP, patient characteristics and outcomes will be compared against those not recruited to PQIP by using an extract of administrative data from Hospital Episode Statistics (HES) held by NHS Digital.

It is also unclear how and to which datasets the program will be linked.

We have added this paragraph:

Patient-level PQIP data will also be linked with HES and the Office of National Statistics mortality register in order to track readmission and long term mortality rates. PQIP will also consider patient-level linkage with other relevant registries and National Clinical Audits in order to provide a comprehensive dataset at the lowest local data collection burden.

Greater detail should be outlined on how the study will reduce the burden of perioperative complications

We have added this paragraph:

PQIP hopes to provide local collaborators with sufficiently useful data to support quality improvement of structures or processes related to the incidence or severity of perioperative complications. This Process Evaluation will further elaborate the Programme Theories, as understood by either central or local collaborators, as to how this improvement might or does happen.

It would be useful to understand how much PQIP data is available for download to local collaborators.

We have added this paragraph:

Local collaborators are able to download anonymised versions of their entire local PQIP dataset, comprising patient characteristics, perioperative processes, clinical outcomes and patient related outcome measures.

Multi-site fieldwork: Please provide more information on the expertise of the team doing fieldwork.

We have amended this paragraph:

Fieldwork in two hospitals will be carried out by one researcher (DW) as part of a PhD thesis; he is an academic anaesthetist and member of the PQIP team. Fieldwork in the other four hospitals will be

carried out by a full-time qualitative researcher (CV). The positions of the researchers will be declared to all participants and consistently reflected upon during data collection and analysis.

Given the description in the text, is there a bias in which sites and how they are assessed.

The qualitative methods we will use do not claim to gather an unbiased sample of data, but rather an in-depth understanding of how local context(s) affect PQIP.

We have amended this paragraph:

The process evaluation aims to build a rich picture of how the context(s) of individual hospitals influence PQIP's impact. Participating hospitals will be NHS hospitals performing both Lower GI and Orthopaedic surgery and planning to start, or have recently started, recruiting patients to PQIP. One non-PQIP hospital will also be recruited to enable some comparison to secular trends. The same methods for data collection and analysis will be used at all sites.

Reviewer 2

There is a strong tradition of 'audit' in the UK. But if audit is not incorporated into a quality improvement process, audit might have limited or no impact on practice. This is a protocol for a study using qualitative methods to analyze the Perioperative Quality Improvement Program (PQIP). The PQIP is designed to measure complications and then improve practice through feedback to clinicians. In order to be successful, the PQIP must (i) reliably measure complications and (ii) provide useful feedback to clinicians. This study will analyze the theory behind the PQIP initiative, assess barriers and facilitators to the success of PQIP, and examine wider contextual factors that impact the implementation of PQIP. It is difficult in for me to separate criticisms of this study from criticisms of PQIP, which this study is designed to evaluate.

We have tried to address all reviewer comments about PQIP within this manuscript but have also added two new references (21 and 22) which describe PQIP in more detail. Reference 21 is currently under review with BMJ Open.

1. Quality improvement requires specific skills and training. It is not obvious that the participants in PQIP or in this proposed study have the requisite skills and training. This could be elaborated.

The skills and training of local collaborators to implement successful QI will be explored during the Process Evaluation as part of Research Question 2 ('How did specific contexts shape PQIP and processes of implementation?)

We have amended this paragraph:

Fieldwork in two hospitals will be carried out by one researcher (DW) as part of a PhD thesis; he is an academic anaesthetist and member of the PQIP team. Fieldwork in the other four hospitals will be carried out by a full-time qualitative researcher (CV). The positions of the researchers will be declared to all participants and consistently reflected upon during data collection and analysis.

2. The authors touch on this, but a key challenge is not just knowing what is wrong, but more importantly how to address the deficiencies. The following ingredients are all needed: (i) accurate knowledge of deficiencies, (ii) intentionality (motivation) to address deficiencies, (iii) adequate resources to address deficiencies, and (iv) ability (expertise and training) to address the deficiencies. Often clinicians only have intentionality or motivation. All four of these ingredients should be examined.

3. It is not clear whether PQIP is adequately conceptualized to address / provide all four of these ingredients.

We agree that all stages of the local improvement process need to be understood. We will seek to do this by building Programme Theories of how PQIP is understood to work and exploring any differences between how these are perceived by central or local teams, of indeed whether change over time.

We have added this paragraph:

PQIP hopes to provide local collaborators with sufficiently useful data to support quality improvement of structures or processes related to the incidence or severity of perioperative complications. This Process Evaluation will further elaborate the Programme Theories, as understood by either central or local collaborators, as to how this improvement might or does happen.

4. Does the PQIP feedback reach individual clinicians or only individual hospitals? Ideally clinicians should be able to compare their practice and outcomes against national benchmarks.

PQIP feedback is delivered and accessible to all local collaborators. The feedback is analysed at the level of hospitals. The process evaluation will explore whether that is a useful and meaningful level of analysis for local teams to use for improvement.

We have amended this paragraph:

Local collaborators will also be able to download anonymised versions of their entire local PQIP dataset, comprising patient characteristics, perioperative processes, clinical outcomes and patient related outcome measures. These hospital-level data and dashboards, added to the quality improvement tools from the website, are intended to support local and national improvement in the perioperative care of patients.

5. If participation in PQIP is based on patient consent, is it likely that there will be a biased sample?

We have added this paragraph:

To evaluate potential bias within the sample of patients recruited to PQIP, patient characteristics and outcomes will be compared against those not recruited to PQIP by using an extract of administrative data from Hospital Episode Statistics (HES) held by NHS Digital.

6. What is the basis for sites to be involved in PQIP? This seems to be a potential source of bias. There might be important differences (other than PQIP involvement) between PQIP and non PQIP sites. The same might apply to the specialties participating and not participating.

Hospital participation in PQIP is on a voluntary basis. The Process Evaluation will explore the motivations and characteristics of why sites volunteered to participate. By conducting fieldwork at a site which is not participating in PQIP, and data from a speciality not included in PQIP, we hope to make some comparisons between PQIP and secular trends.

We draw attention of the reviewers to this paragraph:

Surgical Specialities

We will focus the multi-sited fieldwork on a single PQIP surgical speciality, Lower Gastro-Intestinal (GI), as this is widely performed, and therefore offers greater variety when exploring context. Orthopaedic surgery (not involved in PQIP) will be studied in comparison to Lower GI. Orthopaedics has been chosen because it is performed in a similarly broad range of hospitals to Lower GI surgery, and both specialties have established National Clinical Audit data for both elective and emergency surgical services. In addition, a recent initiative called Getting It Right First Time ('GIRFT') has been piloted in Orthopaedics. The GIRFT team aim to help hospitals improve quality by using site visits to support targeted self-assessment and peer review of local data, with the emphasis on reducing variation between hospitals. This approach for using data has gained traction within the Department of Health and is therefore a timely comparison to PQIP's approach, which has the same aim but different methods.

We have amended the following paragraph:

The process evaluation aims to build a rich picture of how the context(s) of individual hospitals influence PQIP's impact. Participating hospitals will be NHS hospitals performing both Lower GI and Orthopaedic surgery and planning to start, or have recently started, recruiting patients to PQIP. One non-PQIP hospital will also be recruited to enable some comparison to secular trends. The same methods for data collection and analysis will be used at all sites.

7. The qualitative methods used in this study are appropriate and are well described. The investigators have been thorough in detailing these.

8. Engagement with key stakeholders, including members of the public, is a strength.

9. The COREQ criteria have been used appropriately, and the checklist is included.

We thank the authors for these comments.