JRMO Research Protocol for Research Studies

Full Title	**Process Evaluation of the PRISM and OPTIMISE II trials: Understanding complexity in the implementation and delivery of interventions within perioperative care**
Short Title	**Process Evaluation of the PRISM and OPTIMISE II trials**
Sponsor	▪ Queen Mary, University of London

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List of sites

1. Royal London Hospital
2. Royal Gwent Hospital
3. Antrim Area Hospital
4. Royal Alexandra Hospital, Paisley
5. North Cumbria University Hospital

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2. Glossary

<Please insert any abbreviations and key terms>

3. Signature page

Chief Investigator Agreement

The study, as detailed within this Research Protocol, will be conducted in accordance with the principles of Good Clinical Practice, the UK Policy Framework for Health and Social Care Research, and the Declaration of Helsinki and any other applicable regulations. I agree to take responsibility for the statistical analysis and oversight of this study.

Chief Investigator Name: **Timothy Stephens**

Signature:

Date: **27-06-18**

4. Summary and synopsis

Short title	Process Evaluation of the PRISM and OPTIMISE II trials
Methodology	Process Evaluation (mixed methods)
Objectives / aims	1) To understand barriers to intervention delivery throughout the trial and strategies employed to overcome these; 2) To understand how teams adapted their working practices to accommodate the intervention and how this may have changed over time 3) To understand the how contextual factors within the peri-operative care environment, influenced the ability of trial sites to deliver the intervention as planned 4) To understand how patients responded to and perceived the intervention (PRISM trial only)
Number of participants	Up to 100 staff participants Up to 30 patient participants
Inclusion and exclusion criteria	**Inclusion criteria** For patients: • Enrolment in the PRISM trial and randomisation to the intervention group, For healthcare professionals • Any staff member involved in delivery of the PRSIM trial intervention or the OPTIMISE II intervention in any peri-operative area (e.g. recovery nursing and anaesthetic staff, critical care staff) **Exclusion criteria**

	For any participant: • Unwilling or unable to give consent • Inability to understand written and/ or verbal English
Statistical methodology and analysis (if applicable)	N/A
Study duration	12 months

5. Introduction

5.1. Background

There are approximately 310 million surgical procedures carried out worldwide each year for which effective peri-operative care is required to deliver good surgical outcomes.(1) Peri-operative care encompasses the patient journey from the surgical ward (pre-operative), to the operating theatre (intra-operative) to recovery, critical care and ward areas (post-operative) and crosses professional, team and departmental boundaries. Understanding how to improve the safety and quality of peri-operative care is a global health priority, and in recent years there have been several international attempts to do so e.g. the WHO Safer Surgery Checklist, implementation of Enhanced Recovery programmes. (2,3) The need to improve the quality of care is particularly relevant for the subset of surgical patients who, due to age and co-morbid disease, are at high-risk for post-operative critical illness.(4–6) In addition to post-operative critical care admission, these patients may require other specific interventions, for example pre-habilitation prior to surgery or organ support interventions in the intra- and post-operative setting. (7–9)

There has been an increasing recognition over the past decade that surgical and peri-operative interventions operate on the spectrum of complexity, sometimes being 'simple', but often being defined as complicated or complex. (10,11) The more components an intervention has, the greater the number of people involved and more levels at which the intervention operates the more complex it is. (11) Furthermore, the greater the degree of freedom of both intervention components and the actors involved to act independently or inter-dependently to influence outcomes, the more complexity increases. This often makes it hard to define the

"active ingredients" and to be sure which component or combinations of components is more important. This in turn influences outcome and our ability to predict these: a simple intervention should have predictable outcomes; a complicated intervention will often have a predictable outcome but there are a greater number of 'known unknowns' that require a deeper analysis to understand outcomes; and complex intervention have emergent outcomes that often require detailed multifaceted evaluations to understand what has contributed to the outcome achieved. (12)

Surgical interventions and peri-operative care are also often introduced within complex systems, introducing a further layer of complexity.(13) A complex system is one that is adaptive to changes in its local environment, is composed of other complex systems (for example, the human body), and behaves in a non-linear fashion (change in outcome is not proportional to change in input). Schools, urban metro systems and hospitals are all examples of complex systems. The type of intervention introduced into a particular setting will vary in terms of its level of complexity (i.e. simple, complicated or complex) and, whatever the case, a complex systems approach makes us consider the wider ramifications of intervening and to be aware of the interaction that occurs between both components of the intervention and between the intervention (with all its components) and the context in which it is introduced. Context includes the operations, structures, and relations that exist in each setting; in most scientific papers it is briefly described as 'the study setting'. However with a growing interest on the influence of context on the introduction of new interventions, guidance recommends considering that anything that is not the intervention, but is of relevance to the introduction of that intervention, is studied as context. (14) And understanding context is key to appreciating complexity. For example, contextual factors such as the operating theatre and peri-operative care environment, availability of equipment and even peri-operative and overall hospital workload can all influence outcomes associated with an intervention within peri-operative care and therefore contribute to

complexity. The increased complexity created by contextual factors may be further compounded by interventions occurring in multiple locations in the patient's journey and across multiple professional boundaries i.e. across a range of contexts within a hospital. Through the lens of complexity theory an intervention that may seem relatively 'simple' may be complex in the peri-operative setting due to the complexity of the system into which it is introduced. (15,16)

The peri-operative community is faced with the challenge of implementing interventions that are efficacious in improving patient outcomes in the controlled research environment into the real and complex environment of peri-operative care. Pragmatic trials are concerned with the effectiveness of an intervention in relation to existing practice. They are becoming increasingly popular as a method of helping policy makers and clinicians alike understand whether interventions that have proven efficacious can produce similar patient (and other) benefits when implemented into 'near to normal' practice. (17) As the number of 'moving parts' within the intervention increases (increased complexity) so do the associated challenges in achieving fidelity to the trial intervention(s), and accounting for variations in intervention delivery across trial sites. For example, the introduction of robotic surgery involves components that are not only technological (the robot itself) but also organisational and social. Collaboration amongst staff from different professional groups, including surgeons, anaesthetists and nursing staff is altered in surgery using robotics, as are the training needs of both surgeons and the wider peri-operative team. These issues that lead to increased complexity can all impact the extent to which the technology is successfully introduced, as well as subsequent process and patient outcomes.

5.2. Rationale

Recent guidance has promoted greater rigour in the planning and design of such interventions as well as reporting. (10,18) The Medical Research Council (MRC) also offers guidance on evaluating complex interventions through a process evaluation approach. (19) Although a new and evolving area of health services research, process evaluations are typically designed to illuminate in depth how the intervention was delivered in reality (compared to the plan in the study protocol), how and why modifications or changes were made and how this may influence the interpretation of the main trial outcomes. The influence of local contextual factors can also be identified within a process evaluation and this may be especially useful within a pragmatic clinical trial where delivery of the intervention is less tightly controlled and contextual factors may exert stronger influence than in a traditional RCTs.

In this protocol we describe a process evaluation to run concurrently with two trials of complex intervention within peri-operative care: 1) the Prevention of Respiratory Insufficiency after Surgical Management (PRISM) trial; and the OPtimisation of Peri-operaTive CardIovascular Management to Improve Surgical outcome II (OPTIMISE II) trial (7,8) The PRISM trial is an international, multi-centre, pragmatic, randomised controlled trial with open study group allocation, to determine if routine continuous positive airway pressure (CPAP) for four hours immediately after major abdominal surgery is effective prophylaxis against postoperative pneumonia, re-intubation or death. The OPTIMISE II trial is an international, multi-centre, pragmatic, randomised controlled trial with an open study group allocation, to determine whether cardiac output-guided fluid therapy, with a low dose inotrope infusion is clinically effective when compared to usual care in patients undergoing major gastrointestinal surgery. Although the patient groups and clinical contexts are similar, patient acceptance of the intervention is only an issue within the PRISM trial, due to the nature of the intervention interface (see below for more details on the interventions).

When testing clinical interventions within a pragmatic trial (i.e. integrated within health care delivery systems) it is important to make the distinction between the

design of the intervention and the operational elements required for effective delivery. Thus, the aim of this evaluation is to describe what influences the ability of trial sites to deliver the intervention as planned, focussing particularly on the role of complexity (at both intervention and system level) and on the contextual factors that may support or challenge intervention delivery.

5.3. Risks / benefits

This process evaluation poses no risks to patients or staff.

The primary benefit will be a greater understanding of how to effectively introduce the delivery of interventions into complex systems such as peri-operative care pathways.

6. Study objectives

6.1. Evaluation aim

The aim of this study is to understand what influences the delivery of two complicated interventions, continuous positive airway pressure (CPAP) for four hours immediately after major abdominal surgery and cardiac output-guided fluid therapy, plus a low dose inotrope infusion intra and post-operatively, within a pragmatic clinical trial setting in peri-operative care (the PRISM and OPTIMISE II trials).

6.2. Evaluation objectives

1) To understand barriers to intervention delivery throughout the trial and strategies employed to overcome these;
2) To understand how teams adapted their working practices to accommodate the intervention and how this may have changed over time
3) To understand the how contextual factors within the peri-operative care environment, influenced the ability of trial sites to deliver the intervention as planned
4) To understand how patients perceived and responded to the intervention (PRISM trial only)

7. Study population

This evaluation will focus on efforts to deliver the trial interventions (CPAP or cardiac-monitor guided fluid therapy) within the peri-operative care areas of a sample of sites within the two trials.

The PRISM trial is a pragmatic, randomised controlled trial, to determine if routine continuous positive airway pressure (CPAP) for four hours immediately after major abdominal surgery is effective prophylaxis against postoperative pneumonia, re-intubation or death. CPAP is a form of non-invasive ventilation that is delivered to patients either via a tight fitting mask or hood device. Due to the intervention interface patient co-operation is required for the intervention to be delivered. CPAP as a therapy has been used within critical care areas for more than 20 years; however it has not been used in peri-operative care, as preventive therapy, before. CPAP needs to be prescribed as a therapy by a competent medical professional and requires continuous patient monitoring by a trained member of nursing staff. The trial opened in early 2016, and now has more than 50 sites in Italy, Norway, South

Africa, Spain, Sweden and the UK. The target sample size is 4800 patients and currently the trial is on course to finish, on time, by the end of 2019.

The OPTIMISE II trial is an international, multi-centre, pragmatic, randomised controlled trial with an open study group allocation, to determine whether cardiac output-guided fluid therapy, with a low dose inotrope infusion is clinically effective when compared to usual care in patients undergoing major gastrointestinal surgery. Advanced cardiac monitoring technologies are often used in critical care areas to guide the use of fluid and inotrope therapies but currently, at most only one third of eligible surgical patients currently receive this treatment because there is ongoing debate about the clinical equipoise for such interventions. Cardiac output monitoring does not need to be prescribed but the therapies it is used to guide (fluid and inotropes) do need to be prescribed by a competent medical professional and requires ongoing monitoring by a trained member of nursing or medical staff. The trial opened in January 2017, with over 30 participating centres in Australia, Canada, Germany, Jordan, Poland, Romania, Spain, Switzerland, US and the UK. The target sample size is 2500 patients, with a proposed end date of October 2020.

This evaluation will focus on trial sites in the United Kingdom only. The study population will be drawn from eight purposively selected trial sites, using a maximum variation sample. Site selection will ensure a mix of hospitals based upon their ability to deliver the intervention effectively, as indicated by analysis of trial management data, and to reflect the differences in the types of hospital within the trials overall (e.g. differences in surgical volume, number of critical care beds, population served (urban/rural)).

7.1. Inclusion criteria

For patients:

- Enrolment in the PRISM trial and randomisation to the intervention group,

For healthcare professionals

- Any staff member involved in delivery of the PRISM or OPTIMISE II trial interventions in any peri-operative area (e.g. recovery nursing and anaesthetic staff, critical care staff)

7.2. Exclusion criteria

:

- Unwilling or unable to give consent

- Inability to understand written and/ or verbal English

8. Study design

This study is a mixed-methods process evaluation, using a combination of naturally occurring trial management data, and a collective case-study design, focussed on a purposive sample of trial sites. Combining low-burden quantitative and more in-depth qualitative methods in this way provides feasible possibilities to understand the complexity of healthcare delivery and how this 'fits' within a clinical trial context. (20) A collective case study design provides a structure to gain insight into the issue of interest across settings as it allows comparison within and between cases. (21) Therefore this approach will be useful in identifying and studying influences the delivery of complicated interventions within peri-operative care across a number of participating trial sites. We will select a purposive sample of eight trial sites to ensure a range of settings and experiences in delivering the intervention. Collection and analysis of qualitative and quantitative data will be conducted in parallel to the PRISM and OPTIMISE II trials.

A summary of proposed data collection and analysis methods is provided in Table 1. Detailed description is provided below relating to each evaluation objective.

Data collection and sampling

For objective 1, data for objective 1 will be collected from all UK trial sites. Protocol deviation reports, filed as part of the normal running of the trials will be collated and analysed. These data are submitted online by all participating trial sites, by either research nurses or clinicians directly involved in intervention delivery. The reports are filed when there is a problem with intervention delivery and provide data on what happened (in terms of deviations from the planned intervention delivery and a reason (or reasons) for this. As such, they provide a rich source of data regarding the challenges of implementing these interventions in practice. Reports will be analysed at two time-points, mid-trial and end of trial, to identify whether familiarity with the intervention over time led to a change in the frequency of or type of challenges documented by teams.

For objectives 2-4, data will be collected from eight purposively selected case study sites, using a maximum variation sample. Site performance data (collected routinely as part of the trial procedures) will be analysed to identify UK sites in terms of successful implementation of the interventions, e.g. those with the most eligible patients receiving the intervention as planned to those where the fewest eligible patients receive the intervention. From this , eight sites will be purposively selected to represent a range of implementation success of the interventions across the two trials, with four sites per trial . Additional considerations for site selection will ensure a mix of hospitals that reflect the hospitals in the trial cohorts overall (e.g. surgical volume, number of critical care beds, population served (urban/rural)).

For objective 2 & 3, collation and analysis of documented barriers (as part of the protocol deviation report analysis – see above) will provide some broad themes for discussion within the qualitative element of the evaluation. One day of observation in the peri-operative care areas of each of the eight selected case study sites where the intervention is delivered will be undertaken to capture a snapshot of key

potential influences e.g. team working, inter-professional working, flow of patients through. (22) Go-along interviews' with relevant frontline staff (i.e. informal, but guided, discussions with staff as they go about their everyday work) will be used. (23) All data will be recorded using contemporaneous field notes. Focus groups will be convened for each case study site, involving 8-12 peri-operative professionals (e.g. surgeons, anaesthetists and nurses) in order to gain a group perspective on the local influences on intervention implementation. Focus groups will use a semi-structured format with a topic guide to focus discussion. Data will be audio recorded (with consent) and transcribed.

For objective 4, we will work with research colleagues within the four selected case study sites in the PRISM trial to recruit patient participants, aiming for up to 10% of a sites patient intervention arm cohort (this is likely to range between 2 to 10 patients per site, depending on each sites recruitment rate). Selection will use purposive maximum variation sampling to ensure representation by age, gender, ethnicity and patients' tolerance for the full intervention (some patients request that the intervention stops before the full four hours – detailed in the trial protocol - has been completed) . Wherever possible, patients will be invited to participate during one of the routine trial follow-up phone calls. If interested and willing to take part, a patient information sheet and consent form will be sent to them either by post or email, depending on their preference. If consenting, patients will be invited to discuss their experience of the PRISM intervention in a short telephone interview. Interviews will be short, semi-structured (using a pre-defined topic guide) and will continue until theoretical saturation is reached. These interviews will be carried out by the evaluation team (i.e. not the trial sites own research team) to allow patients to speak freely about their experiences and minimise burden on case study sites. Interviews will be audio recorded (with consent) and transcribed.

<u>Data analysis and synthesis</u>

Quantitative data will initially be analysed deductively to answer specific objectives, using descriptive statistics. Site performance regarding ability to deliver the intervention as planned will already be known (see above).

Protocol deviation reports will be analysed using content analysis (24,25). Following published guidance, this will involve becoming familiar with the data through reading / re-reading all content and then applying an inductive approach, using an open framework to group verbatim comments. Open coding will further group and abstract data to generate overarching themes. These themes will be of interest in themselves and will also act as sensitising concepts for further analysis of qualitative data.

Fieldnote, interview and focus group data will be electronically transcribed and added to the data analysis programme (Nvivo 11), This data will first be analysed descriptively to build up a case-study of each site in the study (focusing particularly on of notions of successful implementation), before undertaking within and cross case analysis searching for common challenges and influences on implementation success(26). Sensitising concepts from analysis of protocol deviation reports will be used to organise potential candidate themes. Relevant literature relating to complexity and diffusion of innovation will also be drawn upon to provide sensitising concepts, to maximise the usage of accumulated knowledge in this field already and facilitate transferability of the results of the current study (15,16,27,28). This process will be led by TS with regular supervision meetings with the senior researcher for the study (SS) to minimise researcher bias and ensure appropriate rival candidate theories are considered for the themes within each case.

Synthesis will focus on integrating the quantitative and qualitative data from the different strands of the evaluation (see Table 1) and the focus will be on constructing a narrative synthesis of the process of delivery of this complex intervention, to contextualize the main trial findings and to inform judgments about external validity and generalizability, real-world implementation if appropriate, and further

intervention development. (20,29) Case studies will provide a rich understanding of how the intervention was perceived and delivered, by both patients and professionals, and how actual intervention delivery related to the model of how the intervention was intended to work in practice. (18)

9. Study procedures

There is no intervention associated with this study.
The data collection procedures for this Process Evaluation are:

1. Seeking consent from healthcare staff to participate in the evaluation. To be done by the Lead Researcher (TS)
2. Ethnographic observation in peri-operative care areas (1 day per case study site). To be done by Lead Researcher (TS)
3. Focus groups with healthcare staff, up to 60-mins in duration, to be held in case study sites. To be done by Lead Researcher (TS)
4. Seeking consent from participants of the PRISM trial to participate in this evaluation, by telephone. To be done by Lead Researcher (TS) or research nurses in local sites.
5. Patient telephone interviews, of up to 20 minutes duration. To be done by Lead Researcher (TS).

10. Statistical considerations

This work will use predominately qualitative data. Quantitative data will be analysed used descriptive statistics only

10.1. Sample size

Up to six sites will be purposively selected, using a maximum variation sample. This will enable 3 collective cases studies to be generated (the cases of 'strong, average and challenged' performance), drawing on 2 individual cases each. This is in line with recommend case study practice (26).

10.2. Method of analysis

N/A

11. Ethics

As the project design will involve human subjects (both patients and NHS Hospital staff), care will be taken to offer protection to these subjects. In particular, the principles of informed consent, privacy, anonymity and confidentiality will be considered and strictly adhered to.

Organisational consent: we will obtain written organisational consent from each participating case study site, explaining the study and ensuring opportunity for discussion from the outset. Expectations and roles in relation to the study will be made clear from the outset with written consent filed in a secure location at QMUL at the start of the project.

Individual consent: Informed consent will be a precondition for inclusion of individuals within the study It is important that all those who are invited to participate in the evaluation understand what involvement will mean and that they formally consent to that. We plan to do that by providing written information sheets to both the health professionals and patients invited to participate, and providing them with sufficient time (e.g. at least 24 hours) to read this and ask questions of the

research team. For patient interviews we will make it clear that a decision not to participate will not affect their current or future care in any way. And for staff, we will make it clear that a decision not to participate will not affect their involvement in the trial or their wider work. For interviews and focus groups, written consent will be obtained. For observations verbal consent will be obtained (ideally from all staff but otherwise a senior member of staff on behalf of the team).

Privacy: during periods of observations in clinical areas researchers will always maintain the privacy and dignity of patients and will step away from clinical situations where the researcher deems this necessary and / or whenever requested to by a patient or member of staff.

Equity

There is also the issue of equity and steps will be taken to ensure that no patients or relevant professional groups are unfairly excluded from the research. Using a maximum variation sample will help with this (in that maximum variation aims for representation across different groups) and final samples will be reviewed by the trial team to ensure this has been achieved.

There are no relevant conflicts of interest

11.1. Annual Safety Reporting

The CI will send an Annual Progress Report to the REC and the sponsor using the HRA template on the anniversary of the REC "favourable opinion".

12. Public involvement

We have involved the patient representatives from the main PRISM and OPTIMISE II trials in the design of this work, showing and discussing the trial protocol with them. In this way we have sought feedback about acceptability of our evaluation to patients but also whether this research is of interest to patients.

We will continue to work with these patients once we have our data, presenting them with emergent results to consider and analyse from their perspective. We will seek patient representation help in actively disseminating our findings at the end of the study period

13. Data handling and record keeping

13.1. Data management

Data storage: Data collection and storage will follow the QMUL data protection policy (e.g. records of personal details (names, addresses, telephone numbers) kept in a secure place and separately from research records). All data will de-identified with raw data stored on a non-networked, encrypted hard drive along with a 'key' (i.e. a list of ID numbers and names) which connects the identifiable and de-identified data. Potentially identifiable material will not be used in published or publicly accessible outputs unless express written consent has been given (e.g. permission to use direct quotes will be sought).

13.2. Source Data

- PRISM trial management data
- OPTIMISE II trial management data
- Transcripts of focus groups and interviews

- Fieldnotes from observations

All will be stored in accordance with the above.

13.3. Confidentiality

Confidentiality and anonymity: digital recordings will be logged so that they will be identified with a participant number (or site number) only and all data are reported anonymously. Furthermore, participants will be reassured that any responses they give will not be attributed directly to them; if a direct quote is used in any research output, permission will be sought first and the quote not attributed directly. Observations and accounts of discussions recorded in fieldnotes will be documented in such a way as to maintain confidentiality and reported in research outputs in a way that will maintain confidentiality and anonymity.

13.4. Record retention and archiving

The data will be archived for 20 years in accordance with local standards and Barts Health NHS Trust procedures for quality & assurance. Accessed by members of the research study team.

14. Safety reporting

*"*Due to the nature and design of this study, safety reporting of adverse events will not occur.*"*

15. Monitoring and auditing

The Sponsor or delegate retains the right to audit any study, study site or central facility. In addition, any part of the study may be audited by the funders where applicable.

16. Study committees

This process evaluation would considered a small study; we will convene a study management group consisting of the CI, PIs, and study coordination team every 6 months of the lifetime of the project.

17. Finance and funding

Study is financed from within our department: Critical Care and Peri-operative Medicine Research group, WHRI

18. Insurance and indemnity

QMUL insurance policy will apply

19. Dissemination of research findings

The key output from the evaluation will be a detailed explanation of how and why (or how and why not) the interventions within the PRISM and OPTIMISE II trialS were delivered *as intended in the trial protocol* by site teams. If the intervention does not result in the hypothesised patient outcomes, as per the main trial findings, then the evaluation will help identify why this happened in terms of where the problem on the causal pathway may lie; with the intervention itself or with the operational

requirements necessary for intervention delivery or with issues of complexity in the clinical workplace more generally. If the intervention does impact upon patient outcomes positively, as per the main trial findings, then the process evaluation will provide information to inform judgments about likely generalizability and identify if improvement was general or restricted to some settings only, which may influence real-world implementation or identify targets for a modified intervention.

We plan dissemination through three main channels:

1. a publication in an open-access, peer-reviewed journal, reporting main findings;
2. use of our research group, trial network and other professional networks to promote emerging findings amongst professionals working in peri-operative care globally ; and
3. presentations during at least one speciality specific conference (e.g. EBPOM) and one improvement focussed conference (e.g. the BMJ International Forum on Quality and Safety).

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This protocol is based on JRMO Protocol template for Research Studies; version 1.0, February 2018.

Table 1 – Overview of method						
Objective	**Focus**	**Method**	**Data source**	**Sampling**	**Analysis**	**Synthesis**
1. To understand barriers to intervention delivery throughout the trial and the strategies employed to overcome them.	Barriers to delivery as planned; learning for the future	Protocol deviation analysis	Collation of trial protocol deviations, at mid and end points of the trial	All sites (data is from trial management)	Inductive content analysis – with qualitative and quantitative reporting	Overall, to create a narrative synthesis of the process of complex intervention delivery, using in-depth qualitative data to provide rich description and emergent themes related to the key influences on intervention delivery and quantitative data to test out the hypotheses arising from these themes across the trial cohort.
2. To understand how teams adapted their working practices to accommodate the intervention and how this may have changed over time	Adaptation	Ethnographic observation and focus groups	Fieldnotes from observations in peri-operative area Transcripts from focus groups of peri-operative professionals	Maximum variation purposive sample of 6 trial sites	Comparative analysis Pattern matching	
3. To understand the how the peri-operative care pathway influenced the ability of trial sites to	Complex system	Ethnographic observation and focus groups	Fieldnotes from observations in peri-operative area Transcripts from	Maximum variation purposive sample of 6 trial sites	Comparative analysis Pattern matching	

deliver the intervention as planned 4.			focus groups of peri-operative professionals			
To understand how patients perceive and respond to the intervention.	Patient response	Patient interviews	Transcripts of telephone interviews with patients	Maximum variation sample of patients within the 6 case-study sites	Comparative analysis Pattern matching	