Research Protocol for application to NIHR SDO Call 11/1015 on Quasi-Experimental Designs

Evaluation of a continuous monitoring and multi-level feedback initiative to improve quality of anaesthetic care and perioperative work flow efficiency.

REVISED FOLLOWING SDO COMMISSIONING BOARD COMMENTS: CHANGES TRACKED IN RED TYPE

1. Aims and objectives

Primary aim:
To evaluate the impact of a departmental continuous quality monitoring and multi-level feedback initiative upon the quality of anaesthetic care and efficiency of perioperative workflow within a London teaching hospital over a two year period. Data will be analysed at multiple time-points over the course of the project in order to generate both formative and summative information to support development and evaluation of the initiative.

Secondary aims:

- To employ a quasi-experimental time-series design to provide robust evidence concerning the impact of a serial data feedback intervention upon anaesthetic quality indicators whilst controlling for baseline variance.
- To contribute to the evidence base for valid and reliable quality indicators for anaesthetic care including effective patient experience measures.
- To document the main features of the data feedback intervention as it develops through the CLAHRC programme for replication at other sites, including definition of metrics, data processes, feedback format and action mechanisms.
- To assess the perceived acceptability and utility of this information system for individual end-users, the clinical department and other organisational stakeholders, using a formative, mixed methods design.
- To provide summary research evidence and recommendations for use by relevant specialty groups, including the Royal College of Anaesthetists, Association of Anaesthetists of Great Britain and Ireland, and the National Institute of Academic Anaesthetists, to support the revalidation and quality indicators working groups that have been convened within this specialty.
- To build upon the current study to develop a research protocol and practical arrangements for a multi-site trial of a programme to support quality monitoring and multi-source feedback for anaesthetists, in collaboration with the newly formed Health Services Research Centre at the Royal College of Anaesthetists.

2. Background and rationale

The NHS Next Stage Review Report (Dept Health, 2008) called for continuous improvement in the quality of care for patients and reduction of variations in care based upon improved monitoring and reporting of quality indicators for patient experience, clinical safety and outcomes. Though recent policy has focused upon organisational level reporting of quality indicators using quality accounts, other research has suggested that robust measurement systems to evaluate progress in improving the quality and safety of care at the clinical systems level are lacking (Walley et al., 2006, Vincent et al., 2008). The conventional clinical audit model often fails to deliver sustainable, effective change (Johnston et al., 2000, Bowie et al., 2010) and clinicians do not routinely use or engage in quality improvement (Audet et al., 2005, Davies et al., 2007, Parand et al., 2010).

Recent focus upon revalidation processes for Doctors, driven by the GMC and professional bodies such as the Royal College of Anaesthetists, offers one potential mechanism for the use of intelligence on quality of care at the clinical service level, through improving professional practice of individual clinicians (Moonesinghe and Tomlinson, 2011, Rubin, 2010). Local ownership and confidence in the information systems that support personal professional monitoring processes are critical issues for the success of such efforts. Myerson (2001) emphasises the need for doctors to engage with the processes to ensure that appraisal based upon multi-

source feedback from patients and peers is used to provide constructive feedback to support professional development and is separate from the assessment process used to judge doctors. The definition of quality indicators and outcomes for monitoring is another area around which there is considerable debate within the anaesthetics specialty. Recent work in this area has highlighted the importance of establishing the reliability and validity of proposed indicators, methodology for data collection and reporting, appropriate levels at which to set targets and the case for improving standards of care (Moonesinghe and Tomlinson, 2011).

There is mounting economic pressure for productivity in the perioperative workflow, which focuses effort upon the intra-operative stages of care and theatre utilisation efficiency. Anaesthetists have substantial patient contact with little post-operative feedback on patient experience to improve processes or professional practice. There is a need for anaesthetists to receive quantitative feedback from the post-operative stage on the quality of care they deliver to patients and the patient experience. A recent systematic review of quality indicators in anaesthesia, however, identified few commonly agreed and validated indicators for this area (Haller et al., 2009). A large body of established evidence, linked to national guidelines, supports the impact of various anaesthetist perioperative practices such as patient temperature control, antibiotic administration and management of anaesthesia, upon care quality and periop outcomes (e.g. NICE, 2008). Work has also been undertaken to identify the important components of a positive patient experience of anaesthetic care (Myles, 2001, Myles et al., 2001). Capable systems for routine monitoring of quality of anaesthetic care as experienced by perioperative patients lags some way behind research-based development of patient satisfaction measures, however, representing a clear gap for operationalisation and translation of research evidence into clinical practice.

In addition to the issues involved in deciding what quality indicators to monitor and how to collect the data, the question of what to do with the resulting data and how best to utilise it to drive improvement, is an equally complex problem against which there is currently only limited guidance or research evidence. In the UK and elsewhere, a number of national and local initiatives have been launched to improve care through the application of industry-derived quality improvement methods e.g. Quality Collaboratives, The Safer Patients Initiative, The Productive Series, CLAHRC. Such programmes often employ Process Control as a measurement and evaluation model to guide improvement activities (Mohammed, 2004, Carey, 2003, Benneyan et al., 2003) and the approach has received some attention to monitor variations in clinical practice at the individual, unit and organisational levels (Runcie, 2009b, Mayer et al., 2009, Coory et al., 2008). The dominant rationale for this approach is that only continuous, longitudinal monitoring of local clinical processes and practices, in near real-time, can detect and correct variations in care in a timely manner. Whilst some evidence exists supporting the efficacy of such an approach in monitoring and improving care (Thor et al., 2007), a robust evidence base is currently lacking and reviews of quality improvement models in healthcare generally have suggested that the effects of the dominant improvement models in health care are too heterogeneous to synthesise and likely to be highly context-specific (Powell et al., 2009, Boaden et al., 2008). There is a clear need to investigate what features of quality monitoring and improvement models are therefore effective within specific service contexts and for specific purposes.

In terms of the effects of performance feedback on individual clinicians and clinical units, research evidence suggests that positive changes in systems and practice can result, especially where feedback from quality indicators is sustained and linked to a quality improvement framework (Jamtvedt et al., 2006, Jamtvedt et al., 2005, van der Veer et al., 2010, Bolsin et al., 2003). Other reviews of the evidence linked to the efficacy of professional behaviour change interventions have found that there are "no magic bullets" (Oxman et al., 1995), that dissemination alone was rarely effective and that moderate positive results can be achieved using more complex interventions. Similarly, synthesis of evidence on professional education and quality assurance interventions aimed at changing professional behaviour found that passive intervention approaches were generally ineffective and unlikely to result in behaviour change (Grimshaw et al., 2001). Multi-facetted interventions involving educational components were found to be more likely to be effective. There is generally a lack of evidence in this area underpinning the understanding of the causal mechanisms that drive professional behaviour change in health care and a clear need exists for future work in this area to identify the effective modifiers, barriers and facilitators (Grimshaw et al., 2002).

Case studies suggest that the requirements for effective feedback to support improvement in care are that it should be sustained/continuous, timely, locally relevant, credible, non-punitive and support remedial action (Bradley et al., 2004). Similarly, the characteristics of effective quality indicators have been described as being:

transparent, reliable, evidence-based, measurable and improvable (Wollersheim et al., 2007). The common theme in all of this work is that quality monitoring or performance feedback systems are sociotechnical in nature, with success subject to a range of technical design issues but additionally subject to the influence of human factors, end-user expectations of utility and purpose of the system and the local organisational culture or climate into which the system is introduced (Benn et al., 2009b).

3. Need

Drawing upon the rationale and past research outlined above, there is a clear need for work in this area to support the current national service agenda to promote improvement in quality of care and revalidation for clinicians across the professions. International studies have found broad variations in care quality and well-publicised examples of the consequences for quality of care and patient safety exist, where unreliable systems and variable professional practices are inadequately monitored. From both the health services and research perspectives, there is a need to build upon existing work on effective use of data and quality indicators to drive local service improvement and to better understand the requirements for effective quality monitoring and feedback processes at the clinical departmental level to support personal professional development amongst doctors. Within anaesthetics in particular, there is a lack of reliable, evidence-based quality indicators to quantify quality of care, patient experience and process efficiency and capable of guiding service development efforts and improvement in professional practice.

A growing body of research across a range of diverse areas suggests that selection of appropriate quality indicators and providing actionable feedback linked to quality improvement mechanisms can support detection of problem areas and timely action to improve effectiveness, efficiency, safety and the patient experience. Various models for feedback from quality indicators have been proposed and implemented, yet there is little robust evidence for the efficacy of any one specific model or its fit within the local clinical service context. Anaesthetists as a professional group have a high degree of patient contact in the perioperative pathway yet receive little routine feedback on patient experience or outcomes specific to the quality of the anaesthetic care process.

With UK acute care trusts now required to produce quality accounts to report on quality of care delivered to patients, there is a need to support specific clinical service areas in the development of criteria for monitoring quality of care. The GMC's work towards the development of revalidation processes for doctors has seen broad consultation and the establishment of task groups in the national clinical bodies to develop criteria and processes that are acceptable to each clinical profession.

Within the anaesthetics specialty, the Royal College of Anaesthetists, Association of Anaesthetists for Great Britain and Ireland, and National Institute of Academic Anaesthesia are engaged in work to support the evolving revalidation agenda. This work is being driven by a number of specialist working groups, coordinated by the newly formed Health Services Research Centre hosted by the Royal College. A committee has been set up to investigate and develop national frameworks for revalidation of anaesthetists, including specific working groups in the areas of Patient and Peer feedback (Multi-source feedback), and Quality Indicators and Outcomes. There is a clear need for health services research to support these activities and the development of the revalidation agenda through understanding how an effective quality indicators framework, data feedback process and the necessary service organisation structures can promote continuous improvement in clinical practice. A quasi-experimental evaluation of the introduction of a robust quality monitoring and feedback process for the anaesthetics service area as a model for modern audit and revalidation processes would therefore be of broad generalisable value to multiple research and service stakeholders.

4. Methods

4.1 Conceptual framework

The main research question addressed by this proposal is concerned with determining the effects of introducing a longitudinal quality monitoring and multi-level feedback initiative upon the quality of anaesthetic care and efficiency of perioperative workflow within a large London teaching hospital, over a two year period. A variety of secondary research questions concerning acceptability and utility of the programme for local end-

users and the broader anaesthetics specialty agendas for revalidation and anaesthetic quality indicators, as described in the detailed research aims (Section 1), will additionally be investigated using a comprehensive qualitative research workstream.

The key features of the NIHR CLAHRC-supported quality monitoring and data feedback intervention under consideration are described in more detail in the sections which follow, along with the timescales for the CLAHRC programme. The overriding concept of the project is centred upon how to use data on quality and efficiency of care processes, to support continuous improvement at the level of the clinical department, perioperative system and individual clinician. It aims to evaluate the utility of implementing information systems and processes that draw upon what are presumed to be progressive principles from research and theory in the area of quality improvement in healthcare, reliability and improvement science. Most notably:

- Continuous quality monitoring in an industrial/total quality management/six-sigma paradigm, as opposed to periodic "snapshot" clinical audits, to provide a longitudinal perspective upon variation as opposed to stationary comparisons with best practice targets.
- Near real-time monitoring and feedback to permit timely detection and correction of potentially harmful variations and identify adverse effects of process and system perturbations that are usually invisible until it's too late.
- Local ownership of data and disaggregation of data onto a level that is meaningful to the individual clinician and clinical unit (i.e. not using data for judgement or organisational level reporting, but using data to drive local improvement efforts and individual professional development).
- Monitoring and analysis using Statistical Process Control principles that are sensitive to baseline trends in small longitudinal samples as opposed to summative aggregated analysis of large sample datasets in the clinical evaluative tradition.
- Data feedback processes and utilisation linked to local quality assurance and improvement mechanisms/frameworks, so that measurement and reporting is linked to action using defined and commonly understood methods and tools.
- A desirable shift towards an open culture (rather than blaming culture) for review of operational variations in order to learn lessons and incrementally reduce system vulnerabilities (rather than punish individuals) and hence develop into a "high reliability organisation".

The research model upon which the intervention is based is depicted within Fig 1 below which depicts the relationship between outcome, process factors and proposed interventional elements within the CLAHRC anaesthetics programme. The model is based upon established guidance for best perioperative practice and preliminary work within the local perioperative service undertaken since April 2011 under CLAHRC funding.

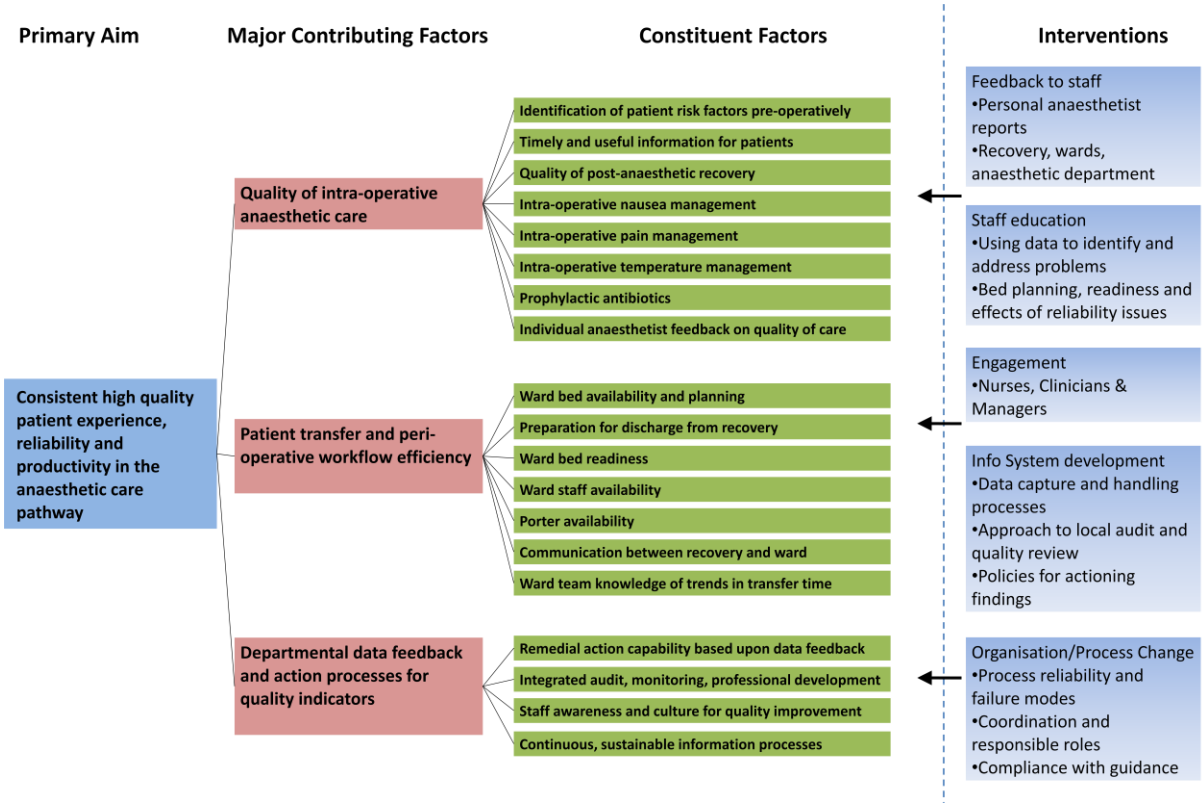

Figure 1: Conceptual model demonstrating hypothesised causal links between desired outcome and contributory factors. The CLAHRC quality monitoring and feedback initiative is represented by the intervention factors in the diagram which are designed to have a generic and cumulative effect upon quality of anaesthetic care, perioperative efficiency and departmental quality monitoring and information capability.

The proposed SDO-supported evaluation will both test the hypothesised causal mechanisms within the research model and seek to describe the nature of specific interactions within the model using qualitative enquiry into the perceptions and experience of system end-users and stakeholders. Within the research model, the three principal aims of improving quality of anaesthetic care, perioperative workflow efficiency and departmental monitoring/feedback capability are represented as separate streams. The research metrics that quantify the various elements within Fig 1 are described in a subsequent section (4.5).

4.2 Research design

We propose an evaluative, quasi-experimental research design using interrupted time series (ITS) analysis and mixed methods components to analyse the effects of the CLAHRC anaesthetics programme. ITS is a quasi-experimental design applicable to single group analysis of improvement programmes, organisational and policy interventions which are expected to have a cumulative or serial impact over a longitudinal time-frame and in which random assignment is problematic (Wagner et al., 2002, Gottman, 1981). This design derives statistical power from the ability to control for baseline variation and any periodicity, cyclical trend or autocorrelation in the time series, prior to examination of intervention effects. Segmented regression analysis may then be used to model shifts in level and trend between multiple time-periods representing successive interventional phases of a programme. This approach is versatile, resilient to threats to validity associated with extraneous factors and strong in terms of its ability to model dynamic temporal variations in a real world setting. The main arm of the study will comprise statistical analysis of longitudinal data collected against each quality and efficiency metric and perioperative outcome in order to assess serial effects of different intervention phases representing introduction of data feedback and escalation of programme intensity, whilst controlling for baseline trends. Temporal hypotheses concerning the abruptness of onset and sustainability of changes observed from baseline will be statistically modeled by fitting interrupted time series models using segmented regression.

The data feedback initiative represents a complex intervention with multiple components and as such is likely to be subject to a range of sociotechnical implementation factors. Qualitative work will therefore be undertaken to document the intervention timeline and iterative development of the information system. End-user surveys will be undertaken to quantify perceptions of the utility of the programme and changes in attitudes and capability regarding use of data to support continuous improvement. The evaluation will therefore employ periodic end-user surveys at key project time-points and a qualitative workstream to capture experience of end-users of the programme and perceptions of acceptability and utility. Survey data will be analysed using standard univariate models for repeated measures and multivariate analyses as appropriate. Qualitative data will be coded and subjected to categorical content analysis drawing upon principles of qualitative research that move between inductive theory and deductive frameworks (e.g. constant comparative method).

4.3 Definition of the intervention

4.3.1 OVERVIEW

The intervention for evaluation is a NIHR CLAHRC-supported quality monitoring, feedback and improvement programme for perioperative services and is principally an information system linked to service delivery and organisational processes. As such it comprises a complex, serial intervention at the organizational and departmental level, targeted at healthcare professionals. The data feedback component is multi-level in the sense that data will be reported at both the department/ward level and disaggregated and reported on the level of the individual clinician to support both systems improvement and individual professional development goals.

4.3.2 HISTORY OF THE INITIATIVE AND CLAHRC SUPPORT

The programme was initially developed as a pilot audit at St Mary's Hospital, Imperial NHS in early 2010 and has grown through strong local clinical leadership and the involvement of a research team from the NIHR Centre for Patient Safety and Service Quality at Imperial College. The project was the subject of a successful application for support from the NIHR CLAHRC programme for North West London in late 2010. The CLAHRC programme rationale draws upon the Cooksey report findings concerning the need to close the "second translational gap" and focuses upon translation and implementation of evidence-based research findings into routine practice through a systematic approach to the adoption of new interventions (CLAHRC Rnd 3 Guidance, 2010). It aims to achieve this through "improvement driven research" using a rapid-cycle development and implementation methodology based upon quality improvement methods. The approach focuses upon "evidence-based implementation" with specific emphasis upon evidence for what to implement, evidence for how to implement and evidence for effects of implementation. An industrial process control model is used to measure the effects of implementation within any specific area. CLAHRC work is driven through a collaborative methodology including collaborative learning events for project teams, patient and public involvement and a specific project structure that involves use of established and newly developed quality improvement methods and tools (e.g. Process Mapping, Action-Effect/Casual Diagrams, Plan-Do-Study-Act cycles, Comprehensive stakeholder management and Web-based reporting). CLAHRC NW London funds a broad portfolio of projects but the overriding theme is: "Improve the patient journey across professional and organisational interfaces of care".

The 18 month CLAHRC-supported programme at St Mary's Hospital began in April 2011 with the dual aims of: 1) improving quality, patient experience, reliability and productivity in the anaesthetic care pathway, through 2) developing and implementing a robust and sustainable quality monitoring, feedback and improvement system within perioperative services. Progress to date within the CLAHRC programme has included intensive work to improve the reliability of the data collection mechanisms and to integrate and clean a number of datasets that comprise the baseline data for the programme in preparation for subsequent interventional work. As of January 2012 the project will move into the active development phase of the CLAHRC project in which the monitoring and feedback system will be further developed through active engagement and multidisciplinary collaboration. The local implementation and sustainability of the initiative will be monitored and evaluated using measures taken at the project level, submitted to the CLAHRC programme's Web Reporting Tool, which has in-built functionality for analysis of trends using process control principles. This current SDO proposal is for a formal, mixed methods evaluation of the intervention and local programme

itself, using in-depth qualitative enquiry and a robust quasi-experimental statistical design which controls for potential sources of baseline, extraneous and sub-unit variance in the determination of main intervention effects. It is intended to produce robust and detailed research evidence that will be of generalisable relevance to health services research and national specialty stakeholders. The methods proposed represent a significant addition to those used for monitoring and evaluation within the CLAHRC programme methodology and are designed to deliver high quality study findings for publication, above and beyond case-based quality improvement reports.

In terms of the opportunity for improvement inherent within the context for this intervention, illustrative preliminary baseline data from the project is included within appendix A. Our preliminary examination of the baseline data (appendix A) suggests that perioperative pain management (e.g. use of analgesics), individual variations in patient-reported quality of recovery dependent upon attending anaesthetist and trends in perioperative temperature control warrant further investigation using a quality improvement framework (note that analysis of baseline data trends as a formative exercise to plan later phases of the interventional work, is incorporated into the work plan for this evaluation). Significant variation in the reliability of ward transfer processes dependent upon receiving ward represents a further clear target for remedial efforts.

4.3.3 INTERVENTION COMPONENTS

In terms of the information system and data process, metrics relating to a range of perioperative process and outcome parameters relevant to anaesthetic care and theatre utilisation are collected continuously from theatre administration systems and through manual data collection in the Post Anaesthetic Care Unit (PACU) by recovery nurses enrolled in the programme. All metrics are monitored continuously over time using statistical process control principles (Benneyan et al., 2003). The intention is then to use this data in a structured feedback programme to support personal professional development for anaesthetists and service/department-level improvement work across the post-surgical perioperative pathway. The work is planned to build from initially simply presenting individuals and units with periodic summary data relating to quality of care delivered over the preceding period to comprehensive, tailored feedback reports that provide timely, relevant information on variance in quality if care using statistical process control principles and accompanied with educational content, guidance and interactions based upon review of the data at departmental level. The CLAHRC programme therefore represents a serial intervention of escalating intensity, structured in two main phases: 1) passive feedback and 2) active feedback/user engagement.

Passive feedback of quality data (Sept 2010 - Oct 2011):

Starting in September 2010, personal data has been passively fed back to individual anaesthetists in a monthly report comprising simple summary and descriptive statistics. Summative data is additionally posted in the PACU, distributed to surgical wards and nurse audit leads on at least two occasions, but not regularly. The reports comprise summary descriptive statistics for current and preceding months (e.g. mean and median rates) and cross-sectional breakdown of overall rates to compare wards or de-identified anaesthetists on key metrics. Passive feedback in PACU focuses upon patient transfer delays and quality of recovery scores, the feedback that surgical wards receive focuses upon patient transfer delays and the individualised anaesthetist reports comprise data on personal case load, post operative pain and nausea scales and temperature upon arrival in recovery (as an indicator of compliance with perioperative normothermia guidance).

Active feedback/end-user engagement (Nov 2011 onwards):

In the active feedback and user engagement phase, the content and functionality of the data feedback will be developed through active engagement and participation of end-users in an iterative development process. The research team will develop candidate report formats utilising statistical process control principles and more specific breakdowns of case data according to the requirements of the end user. The reporting formats will be implemented and evaluated in iterative cycles with input from stakeholders and end-users, supported by the qualitative research workstream from the evaluation (see section 4.6 below). In addition to the metrics included in the passive feedback phase, patient reported quality of recovery scores will be added to the individualised anaesthetist feedback reports and presented using control chart formats. The design philosophy for development in the active feedback phase will be to present data in such a way as to maximise its usefulness for process improvement and improvement of personal professional practice. The feedback reports will therefore include guidance on data use and interpretation and educational components linking data feedback to established quality improvement methods and practices. This component will be reinforced through interactions with the research team at audit meetings, which will include presentation of rationale for

the initiative, interim findings and interactive workshops to discuss design and effectiveness of the programme. Where variation is detected in departmental, ward and individual level measures, support for improvement work utilising quality improvement methods will be provided through the research team and CLAHRC programme.

Final version of the intervention for evaluation:

Although an outline for the elements of the data feedback intervention has been established along with core measures and data collection processes, the system will continue to be developed iteratively within the CLAHRC programme, with broad end-user consultation and input from local consultation and focus groups. The subsequent design of the system will be informed through collaboration with external specialty research groups focused upon the quality indicators and revalidation agenda for anaesthesia and perioperative care. Taken as a whole, the planned CLAHRC anaesthetic monitoring and feedback programme is designed to deliver the following data utilisation capability for this service area:

1) Continuous/real-time visualisation of the current level of quality/safety/reliability of care delivered to patients by individual clinicians and the service as a whole.
2) Prioritisation of targeted areas for remedial action including the ability to link data trends to candidate processes, personal practices, training areas, systems and environmental factors, organisational policies and changes to structure, so that potential vulnerabilities and opportunities for improvement can be identified and addressed.
3) Continual monitoring of progress towards personal and department level targets set for improvement work (eg. compliance with new protocols, productivity or patient experience goals) in order to deliver the capability to actually evaluate the impact of activity upon quality and efficiency of care.

We hypothesise that delivering the functional aspects outlined above will have a positive impact upon patient-reported quality of recovery, at the individual anaesthetist and service level, will improve compliance with best perioperative practices (e.g. perioperative normothermia guidance) and reduce excessive patient stay in recovery. At the individual level, implementing an effective personal professional monitoring programme for anaesthetists should reduce variation between individuals and drive up overall standards of care. We additionally hypothesise that implementing and supporting a multi-component programme comprising quality monitoring, feedback and linked educational and collaborative improvement work will impact upon local operating culture, attitudes towards personal professional monitoring and revalidation and the climate in which performance-related data is used and discussed to support individual and organisational learning, as represented by the multiple causal streams within the research model (figure 1).

4.4 Study sample

There are multiple local stakeholders for the anaesthetics quality monitoring and feedback system that are classifiable as end user groups for the purposes of evaluation. Due to the emphasis upon personal professional data for revalidation, the principal end user group for the programme consists of 35 consultant anaesthetists within the anaesthetics department at St Mary's Hospital and the service leadership function. For the quality of recovery and process efficiency metrics, there are additional service user stakeholders including the PACU nursing function, surgical ward teams, perioperative service and ward managers.

The target patient population comprises all surgical cases, both elective and emergency, that pass through St Mary's Theatres and PACU, including both general and regional anaesthetic cases but excluding Day Surgery cases. In the later phases of the CLAHRC programme, as part of roll-out work, similar samples will be defined at the other Imperial NHS hospital sites. The sampling strategy is inclusive in order to provide full information concerning perioperative temperature control, quality of post-operative recovery and patient transfer delay from the PACU, which are applicable quality indicators for all patients that undergo some form of surgery in the same surgical unit. Descriptive and contextual data is additionally accessed to allow sub-analyses to be run for specific surgical populations, based upon procedure type, attending anaesthetist and other categories.

4.5 Data collection and analysis

Quantitative research project data will be derived from several principle sources for evaluative purposes, including: local theatre administration systems and recovery registry, data collected on specially developed forms completed for each patient by recovery nurses (appendix B), an end-user evaluative survey for anaesthetists (appendix C) and standard hospital episode statistics.

The metrics used as dependent measures within the evaluation and time series modeling will include key parameters associated with anaesthetic process quality, quality of recovery, perioperative outcomes and perioperative process efficiency metrics. In addition an end-user evaluative survey will be employed to quantify perceptions of capability and acceptability of the monitoring and feedback system. Project quality indicators and research measures for the evaluation are outlined within Table 1 below, with scope to add additional metrics as the local information system evolves through CLAHRC development work. Of primary interest to the evaluation is the effect of the programme upon anaesthetic process and quality of recovery indicators, which we anticipate represent the most likely direct areas of impact from providing feedback on anaesthetic process compliance and anaesthetic-relevant outcome data. We will review hospital level perioperative outcome data for trends related to the programme timeline as we believe it is important to provide this perspective for the sake of completeness, but it is likely that a high proportion of variance in these metrics will be attributable to surgical processes and post-operative care, relative to the anaesthetic process.

METRICS FOR PROGRAMME EVALUATION STUDY	
Anaesthetic process and quality of recovery indicators:	
Patient core temperature upon arrival in recovery	As measured upon arrival in PACU. Acceptable temperature classified as above 36.0 in accordance with standardised perioperative guidance.
Quality of Recovery (QoR) Score	Standardised and validated scale (Myles et al., 1999, Myles et al., 2000b). 8 questions to be answered by the patient, or by nurse when ready for discharge. Overall composite scale score calculated.
Postoperative pain	Worst pain on 11 point scale 0-10 within 30 minutes of waking and as QoR sub-item.
Postoperative nausea/vomiting	Classed as nausea versus vomiting/retching with or without nausea and as QoR sub-item.
Perioperative process efficiency indicators:	
Ward Wait Time WWT	Ward transfer delay: Time difference between time of first contact with ward and time patient leaves recovery unit. Reasons for transfer delays over 30 minutes are recorded.
Perioperative patient flow metrics	Various primitive metrics representing key perioperative timepoints (e.g. anaesthetic induction, knife to skin time) are logged in theatre administration system and used to calculate cycle times.
Hospital level perioperative outcomes:	
In-hospital mortality	Standard HES data
Surgical site infection rates	Standard HES data
Unplanned admissions to ICU	Standard HES data
Length of stay	Standard HES data; Trimmed mean and proportion of long stays
Unplanned readmissions within 28 days	Standard HES data
Patient demographics and contextual information:	
Patient ID, age & gender	Available through theatre administration system and PACU data form
Procedure type	Available through theatre administration system and PACU data form
Attending anaesthetist	Available through theatre administration system and PACU data form
End-user evaluative survey:	
Focus of current feedback upon quality of care	Quality dimensions and level of feedback

Effectiveness of current quality feedback	Reliability, validity, credibility, utility of quality indicators
Culture for effective use of data to drive improvement	16 item Likert scale

Table 1: Summary of quantitative metrics for research and evaluation

In terms of the main hypothesis-driven time points for data analysis, these will follow the two main intervention phases passive and active feedback and analysis of the effects of each phase will therefore begin in April 2012 and Oct 2012 respectively. This will allow at least 11 months of time series data under each feedback condition to have accumulated. Comparisons will be performed between each intervention condition and baseline (i.e. summative effect of the programme) and for each incremental escalation of the project compared with the preceding period (incremental effect of adding intervention components). Separate models will be fitted for anaesthetic quality indicators and other types of data delivered to additional stakeholders (e.g. ward transfer delay metrics). In addition to the project quality metrics, an evaluative end-user survey will be administered at two time-points Nov 2011 and July 2012, corresponding to the end of the passive and active phases of feedback and analysed using a repeated measures design in the main SDO-supported analytic work streams (note that the first survey time-point will be administered prior to SDO programme onset as the timepoint is critically dependent upon the CLAHRC programme timeline). Analysis and compilation of evaluative data from the quality indicators will be continuous, performed on a monthly basis from April 2012 as part of the active phase of the data feedback programme. This will provide an additional source of information concerning the effects of any practice changes or external perturbations in processes.

In order to evaluate the effects of a longitudinal, complex intervention, upon data collected continuously over time, we will employ Interrupted Time Series analysis. This is an uncontrolled, quasi-experimental design in which internal validity will be achieved through comprehensive baseline and post-intervention repeated measurements to control for trends over time. In addition to conventional statistical significance tests we will employ Statistical Process Control methods to identify significant changes in the degree of variation and level of performance in anaesthetic quality indicators and outcomes. Survey data will be presented using simple descriptive statistics and compared statistically between time-points using paired t-tests or similar.

4.6 Qualitative research work stream

The effectiveness of any form of reporting and performance monitoring system in an organisational environment will be sociotechnical in determination and hence acceptability and adoption of the proposed intervention will be shaped by a range of attitudinal and cultural factors, in addition to technical process factors, associated with the local professional environment, perceptions of the workplace and organisation. These issues represent the influence of the soft human factor in organisational change and successful development and implementation of new information technologies and processes (Eason, 1988).

In order to study soft factors surrounding the development of this system and strengthen the evaluation, we have developed a qualitative work stream to parallel the main active feedback development and end-user engagement phase of the project (qualitative research to begin Feb 2012). Support for a full time social sciences researcher has been requested for the period March 2012 - Feb 2013 to support qualitative analysis along with resource for transcription of interview recordings. The qualitative study will comprise a longitudinal investigation to account for processes specific to the local context for implementation of the intervention and to provide rich information and deep analysis of end-user acceptability and organisational change issues. The research approach will draw upon action research and case study methodologies (Pope and Mays, 2006, Yin, 2003), with data collected through participative ethnography and interviews from end users and system stakeholders. The principle aims of the qualitative component are as follows:

QUALITATIVE RESEARCH AIMS:

1. To provide a comprehensive requirements analysis for the sociotechnical design of the system based upon multiple end-user and broader stakeholder perspectives and in so doing provide formative input to the development of the project.

2. To document the main features of the data feedback intervention as it develops through the CLAHRC programme for replication at other sites, including definition of metrics, data processes, feedback format and action mechanisms.
3. To assess the perceived acceptability and utility of this information system for individual end-users, the clinical department and other organisational stakeholders and feed into the synthesis of evaluation findings. Assess perceptions of the impact of the programme upon local culture and attitudes towards quality of care and quality improvement.
4. Explore the mechanisms by which individuals and groups use the data to change practice by capturing specific narratives and use case scenarios. Evaluate the impact of the programme upon staff capability to use data from quality indicators effectively.
5. To identify key barriers and enablers to the successful development, implementation and utilization of this type of quality monitoring and feedback system within a specific service context, and assess any associated organizational change issues.

Within the 12 month qualitative work package, in accordance with grounded research practice, data collection and analysis will be iterative and largely concurrent, with two main periods of data collection. The first will take place in the Feb 2012 – April 2012 period and will focus upon end-user evaluation of the initial phase of the programme and establishing the requirements for the subsequent design of the programme from a broad range of stakeholders. The second phase will take place in the Aug – Oct 2012 period and will be focused upon summary evaluation (perceptions of usability and utility) of the programme.

The data that will be collected for the qualitative analysis will be from a range of sources, including researcher field notes at programme development and user evaluation sessions, semi-structured qualitative research interviews with project stakeholders and ethnographic field notes from interactions with nursing teams in recovery. The development and user evaluation sessions are planned to take place as part of an engagement workstream and comprise project-related activity and feedback in a focus group set-up as part of dedicated time within the regular anaesthetics department audit meeting. Three such sessions with group participation will be undertaken during the course of the 18 month project.

The qualitative research interviews will comprise more targeted semi-structured interactions with individuals representing key project stakeholders and end-user perspectives. Sampling will be stratified initially in order to seek representation of a range of perspectives and end-user requirements for the programme. Subsequent sampling will be theoretically driven to develop sufficient depth of understanding and theory related to the research aims. Interviews will be around 30 minutes in length and will be recorded for transcription prior to qualitative analysis. We anticipate obtaining and analyzing around 30 hours of transcribed interview footage in total. The initial sampling framework for the qualitative research interviews will comprise the following roles:

- Consultant and trainee anaesthetists (actual and potential end-users for the anaesthetic quality indicator feedback component of the programme and recipient of targeted feedback reports)
- Perioperative clinical service leads (representing department and clinical programme group level perspectives on the project)
- Perioperative service managers (end-users for the service efficiency and effectiveness dimensions inherent within the metrics and recipient of targeted feedback reports)
- PACU nursing leads and surgical ward leads (end-users for the ward transfer efficiency data feedback component and recipient of targeted feedback reports)
- PACU nurses (experiences of nurses responsible for data collection in recovery and recipient of targeted feedback reports)
- Expert advisors to the project (representing expert input into the requirements definition for the programme from surgical, anaesthetic and health services research expertise in related academic fields; see section 10)
- National specialty level development leads (representing specialty interests in quality indicators for anaesthetists and the revalidation working group agenda)

Qualitative data analysis will proceed using established methods of qualitative analysis, supported by qualitative research software. Data will be coded and categories derived through hierarchical and relational coding and constant comparisons. The process will be iterative and move between inductive (grounded) and

deductive (framework-driven) reasoning. Quantification will be applied where practicable (content analysis). To account for subjectivity in the research process, the analysis will incorporate reflexive dialogue amongst the research team to ensure multiple researcher input and input from varied clinical and research perspectives in interpretation of meaning. In terms of the qualitative research frames which will inform the analysis, the following conceptual frameworks have been identified as relevant and will be investigated in terms of their ability to provide useful explanations for observed and emergent processes:

- Theory of Planned Behaviour (TPB) (Ajzen, 1991)
- Normalisation Process Theory (May and Finch, 2009, May et al., 2007, Murray et al., 2010)
- Adoption of Innovation model and Diffusion of Innovation theory (Greenhalgh et al., 2004, Rogers, 2003)
- Technology Acceptance Model (TAM) (Chuttur, 2009, Davis, 1989, Holden and Karsh, 2010)
- Organisational change theory and resistance to change (Gollop et al., 2004, Gustafson et al., 2003, Iles and Sutherland, 2001, Pettigrew et al., 2001, Scott et al., 2003).
- Sociotechnical systems theory as applied to information systems development and implementation, including unintended consequences (Harrison et al., 2007, Eason, 2007, Ammenwerth et al., 2003).
- Theories of Professional Behaviour Change (Ashford et al., 1999, Grimshaw et al., 2002, Grimshaw et al., 2001, Oxman et al., 1995)

5. Contribution to collective research effort and utilisation

The theme of this research proposal focuses upon effective use of data at the level of the clinical anaesthetic department, to improve anaesthetic care and perioperative process efficiency through timely feedback to individual clinicians and clinical units. Evaluative quasi-experimental work in this area will contribute to the research evidence base in a number of related health services and perioperative knowledge areas, including: effectiveness of models for local audit and departmental quality monitoring (Bowie et al., 2010), methods of effective feedback from quality indicators (Wollersheim et al., 2007, Benn et al., 2009b, De Vos et al., 2009, van der Veer et al., 2010), the role of "knowledge of results" in improving personal professional practice (Jamtvedt, 2005; 2006; Foy, 2005) (Foy et al., 2005, Jamtvedt et al., 2006), revalidation processes for Doctors (Moonesinghe and Tomlinson, 2011, Runcie, 2009a, Rubin, 2010), the selection of valid and reliable quality indicators for anaesthetic practice (Haller et al., 2009, Schuurhuis et al., 2007), evaluation of quality improvement methods and programmes (Speroff, 2004, Eccles et al., 2003, Benn et al., 2009a) and measurement of the patient experience of post-operative recovery (Wu and Richman, 2004, Myles et al., 2000a) and service efficiency metrics (Hussey et al., 2009, Wong et al., 2010).

The proposed research is designed to deliver evidence for the efficacy of a clinical departmental level intervention to improve quality monitoring and feedback processes within anaesthetic services, including information concerning impact upon process efficiency, process quality and patient reported outcomes of anaesthetic care. As such it will be of high relevance to a range of end-users and stakeholders in local services, national specialty groups, health policy and health services research, including anaesthetists and their patients, health service managers, anaesthetic professional bodies and national policy development agencies concerned with quality reporting and revalidation.

This project will deliver generalisable knowledge and formative information to support a “proof of concept” case for quality monitoring and feedback processes in anaesthetic services linked to the quality improvement and revalidation agenda. In collaboration with the Royal College and Health Services Research groups within the anaesthetic specialty, both of whom have offered this project their support, we anticipate the project will contribute the following to collective knowledge in this area:

a) Requirements analysis and recommendations for effective continuous quality monitoring systems for anaesthetic services and how locally useful and accepted data collection and feedback processes link to the revalidation framework and agenda. Specifically, this will include research evidence for the validity, reliability and usefulness of a range of perioperative process, outcome, patient experience and efficiency metrics from the anaesthesia specialty perspective.

b) Proof of concept case study of how data can be used to drive improvement and support linked analysis and improvement action for enhanced organisational and individual learning within this service area.
c) Understanding of how such a system can be implemented, integrated within existing governance/audit structures and supported to achieve long-term sustainability, including understanding of the likely sociotechnical and cultural barriers and enablers encountered along the way.
d) Empirical evidence of the impact of such a system upon local quality and efficiency of anaesthetic care and upon local service structure and professional culture. Specifically, learning regarding the utility of an industry-derived process control and continuous quality improvement approach within this clinical service area.

At the local departmental level, the effects of monitoring and using data on process quality and efficiency to improve services will be of interest to a variety of stakeholders, including service leads and service managers interested in improving the cost effectiveness of care. These groups represent our target end-user group. For the anaesthetic professional community, the study will investigate the requirements for effective systems to monitor and provide performance feedback or "knowledge of results" for anaesthetic care, including investigation of the acceptability and perceived utility of the process. In its focus upon measurement of quality of anaesthetic care, the study will generate information concerning what are effective quality indicators to provide anaesthetists with feedback on the quality of care they have delivered to patients and how this may vary over time.

The NIHR CLAHRC for North West London provides a further collaborative network of stakeholders for the deliverables from this research. The CLAHRC programme aims to support translational research using quality improvement methods and structured collaboration. The proposed study will provide evidence concerning the role of data and information in service improvement and support development of related CLAHRC aims. Our proposed formal quasi-experimental evaluation of the CLAHRC anaesthetics initiative will provide

Through the CLAHRC programme, local Trust liaison and our patient representatives at the Centre for Patient Safety and Service Quality at Imperial College, we will pursue patient and public involvement in the research process to feed back the results to patient groups and gain patient perspectives on the relevant research and service issues. The issue of what constitutes satisfactory anaesthetic care is critical to patient's experience of the surgical care pathway and we will utilise this information to inform our monitoring and feedback system.

In terms of end-user involvement in this research, the Chief of Service in the Trust WHG (co-applicant) in which this process will be implemented is the executive sponsor for our CLAHRC project and has been involved in this work from an early stage, along with the local theatre management structure and departmental clinical governance leads. These stakeholders represent interests in improving theatre utilisation efficiency under limited resource conditions and this project will contribute knowledge regarding how process efficiency metrics can be used effectively to monitor and respond to variation at the departmental level. The local group of anaesthetists and trainees have demonstrated their support for the process by completing preliminary consultations for the CLAHRC programme and providing consent to participate in the data feedback initiative. Our project team includes senior anaesthetists involved in National policy development around revalidation for anaesthetists using multi-source feedback and senior members of the Association of Anaesthetists for Great Britain and Ireland (AAGBI), Royal College of Anaesthetists and National institute of Academic Anaesthetists which hosts this working group, along with the newly formed Health Services Research Centre for perioperative care. The anaesthetics working groups for revalidation and quality metrics will be important stakeholders for knowledge gained concerning how data on quality of anaesthetic care can be used effectively to support personal professional development and in the experience of the anaesthetics department in implementing, embedding and resourcing continuous quality monitoring and feedback processes. We have formed effective links with these groups and the new Health Services Research centre at the Royal College through collaboration with research leads (Prof Andrew Smith (co-applicant); Dr Ramani Moonesinghe (collaborator)) and senior figures within the specialty and revalidation committees (Prof Andrew Tomlinson, Vice President of RCoA and Revalidation lead, Dr Peter Nightingale, President Royal College of Anaesthetists; Dr William Harrop-Griffiths, Vice President AAGBI, Professor Mike Grocott, Director of NIAA HSRC). We attach a letter of support for the project from the Royal College of Anaesthetists, Health Services Research Centre and Revalidation working groups. Our research team additionally includes members of the CLAHRC NW London

programme team to facilitate dissemination and use of the findings through the CLAHRC research network to related programmes in the CLAHRC portfolio.

In terms of dissemination, academic publications will be produced to report the findings from the work for both clinical and health services research and management audiences. At the policy and national professional level (Royal College/AAGBI/NIAA/HSRC), the research report will include practical findings and recommendations concerning effective use of data to support quality monitoring in anaesthetic care and specifically regarding development of criteria and data processes to support local personal professional appraisal and revalidation. Opportunities to join meetings and present the research findings to relevant national professional bodies and at conference will be sought as well as dissemination through CLAHRC networks and events. The workplan will additionally involve comprehensive dissemination of data feedback on quality of care and results from the proposed research evaluation to the local clinical and service management community.

6. Plan of investigation

6.1 Planned deliverables and knowledge mobilisation

Planned output from the project consists of research reports of empirical evidence and practical, formative contributions to the specialty agenda on revalidation of clinicians and quality monitoring in anaesthesia. Academic papers and a report detailing the results of the analysis and recommendations for practice at different levels and for the various policy and professional project stakeholder groups will be produced. Comprehensive description of the intervention as it develops will yield a model and practical guidance with templates for implementation of multilevel monitoring and feedback, with supporting evidence. This will support broader implementation in the NHS, multi-site roll-out as part of the CLAHRC programme and future multi-site trial and will inform policy development on quality measurement and revalidation processes for the anaesthetic professional body stakeholders.

The planned output from the work will comprise the following specific types of research product, specified as project deliverables. The project will culminate in a main report to the SDO (due July 2013). An interim progress report will be prepared for the SDO and submitted in Oct 2012.

Deliverable 1: SDO Interim Report (end Oct 2012)
The interim report will summarise activity and preliminary findings from the Feb 2012 – Sept 2012 project period. Findings from the following research activity and specific research outputs will be summarised in the report:

- WP1: Report on baseline variation from retrospective analysis of quality indicator data including case for reliability of the data collection process and effects of any specific CLAHRC work to improve compliance and accuracy of the data processes that will feed the monitoring and feedback system.
- WP2: Report on evaluation of passive feedback phase for the anaesthetist group from analysis of intervention effects upon project baseline measures.
- WP3: Qualitative description of development of the programme in the initial phase of the active feedback and engagement period, including detailed programme timeline and perspectives of end-users and stakeholders from early phase qualitative work.
- WP3: Preliminary technical specification of the information system developed with end-user input during the active feedback and engagement phase of the project, including metric definitions, data processes, and feedback formats for multiple end users, with design rationale.
- WP4: Report on quantitative survey data from passive feedback phase survey time-point.
- Summary of progress to date against the research plan and outline of the future work-plan.

Deliverable 2: SDO Final Report (end July 2013)
The primary purpose of the final report is to present the completed research study and findings, including rationale, aims, scientific description of methodology, presentation of qualitative and quantitative findings from each evaluation phase including overall assessment and evidence-based recommendations. The report will adopt the recommended SDO report format and will incorporate the preliminary findings from the interim

report to create a definitive report from the project work. Specifically and relating to the main work packages undertaken within the project, the final report will detail the following output following research activity across the entire Feb 2011 – June 2013 period:

- WP1, WP2 & WP4: Full statistical evaluation of effects of the monitoring and feedback initiative upon: 1) quality of anaesthetic care indicators, 2) perioperative outcomes, and 3) end-user perceptions of adequacy of local quality feedback arrangements and local climate for open use of data to improve care. This will include a full scientific description of the research design and methodology used.
- WP3: Final specification of the information system developed within the CLAHRC work as an organisational-level intervention, including development timeline, critical functionality, design rationale, summary of end-user requirements and sociotechnical factors (barriers/enablers) for successful implementation and adoption.
- WP3: Full report on the qualitative component of the work, including description of the process of enquiry and output from the qualitative analysis process linked to established theory and prior research questions. The write-up will detail the inductive and deductive interpretation of the data to develop grounded theory. It will include illustrative case examples and interviewee quotations, along with reflexive accounts from the research team, in line with best practice in reporting qualitative research.
- WP5: Full statement of practical implications and recommendations from integrative synthesis of the various research work packages to form a coherent overall summary of practical findings and feasibility case for broader implementation of the initiative. Recommendations for practice will be sub-divided according to key stakeholder group, with specific emphasis upon implications at the anaesthetics national specialty level (linked to the clinician revalidation and quality metrics agendas), the implications for perioperative service leads and managers running local services and the broader implications for future research and development in relevant health services delivery and organisational research areas.
- WP5: A technical appendix to the main report comprising a research protocol for a follow-on multi-site trial of the initiative to investigate broader generalisability and investigate the applicability of the multi-level and multi-source feedback model in a broader sample of specific service contexts.
- WP6: Summary of research output delivered during the course of the project, both in terms of academic outputs, local summary reports and dissemination of intermediary findings to the specialty working groups at the Royal College of Anaesthetists and any other key external stakeholders, along with any feedback received from this activity.

In addition to the two main project research reports to be submitted to the SDO, the following further deliverables are planned for production during the course of the project (and due by July 2013):

- **Submissions of research papers to peer reviewed scientific publications.** As a minimum, we will produce one high quality scientific report of the main evaluation of the initiative and one conceptual article detailing the rationale and design for the initiative (and relevant preliminary findings). These two main papers will adopt a health services research perspective and will be aimed at general UK anaesthetics journals such as *Anaesthesia* and the *British Journal of Anaesthesia*. In addition to this core output, we will produce more specific output based upon findings from the specific work packages undertaken, such as a full report of the qualitative sub-study for a Health Services Research journal (e.g. *BMC Health Services Research/Health Services Research and Policy*), analysis (and case studies) of our experience of using data to drive improvement for *BMJ Quality and Safety* or *Int J for Quality in Health Care* and publication of the broader trial research protocol in *Implementation Science*.
- **Broad dissemination activities for local, national and international stakeholders.** This project has been designed to be of strong interest to external stakeholders at the professional level such as the Royal College of Anaesthetists, Association of Anaesthetists of Great Britain and Ireland and other professional associations for perioperative practitioners. Evaluation of this type of data feedback intervention for quality indicators is additionally topical both in terms of NHS policy (e.g. Next Stage Review agenda) and for broader international health services research, as well as for local CLAHRC programme stakeholders who are interested in evaluative outputs. During the course of the project, we will undertake a number of dissemination activities as key deliverables, for both intermediary, formative findings and the overall evaluation at the end of the project. These will include:

1. Dissemination through anaesthetic and perioperative specialty channels and websites, including participation in specialty working group activity on revalidation/quality indicators, presentation of findings at specialty sessions for AAGBI/RCoA meetings, presentation at specialty research conferences such as that of the Association for Perioperative Practice (AfPP) and other scientific seminar programmes.
2. Dissemination through CLAHRC collaboration and specifically contributions to CLAHRC conferences and events involving a broad range of service development projects in the North West London area. The topic of use of data for quality improvement is a key one at these forums.
3. Dissemination through collaboration with other specialty, health services and care quality research centres that are associated with this project through contributions by co-applicants who are research leads in these Centres (Lancaster Patient Safety; Imperial CPSSQ & Perioperative Research) and through the support of the National Institute for Academic Anaesthesia's Health Services Research Centre.
4. Maintenance and regular update of a multi-media website hosted by Imperial CPSSQ with information on the research aims and rationale, a summary of output and a short film produced about the project from earlier CLAHRC work. The web-page will be updated periodically as a source of information and resource for researchers, healthcare professionals and the public.
5. Dissemination through international collaboration with Imperial Centre for Patient safety and Service Quality partners, including the IQ Institute for Quality of health care, University Medical Centre, St Radboud, Nijmegen in The Netherlands. We are collaborating with a team led by Prof Hub Wollersheim (expert advisor to this project) and colleagues on establishing an evidence base for feedback from quality indicators.

6.2 Project timeline and workflow

The initiative builds upon a pilot programme that has been running since March 2010, including baseline data collection, which has been expanded from April 2011 under NIHR CLAHRC funding for the practical aspects of development, data collection and programme implementation. The proposed SDO-supported component of the work will begin in Feb 2012 and will last for 18 months. Figure 2 below depicts the main phases and planned activity work packages (WP) for the SDO-supported evaluation. It additionally includes an outline of the main CLAHRC phases beginning in April 2011 in order to illustrate how the two parallel projects correspond. The SDO evaluation will comprise a mixed methods design with analysis of several study time-points corresponding to key milestones in the CLAHRC-supported work. The main study time-points representing onset of important phases of intervention work are as follows:

1. Passive feedback to anaesthetists (April 2011 - Oct 2011). The effects of this period in which simple personal data is provided on a regular basis to clinicians will be assessed against baseline variation in quality of care metrics in the first five months of the SDO work (WP1 & WP2). An evaluative survey will additionally be undertaken in Nov 2011 corresponding to the end of this initial period of the intervention (as part of prior work to the onset of the SDO-supported evaluation).
2. Active feedback and engagement (Nov 2011 onwards). This period represents iteration of the basic feedback report in line with emerging practice in use of data for continuous improvement and in response to end-user input and evaluation. In this phase, the research team will actively engage clinicians, nurses and managers to develop the requirements for a useful, effective and acceptable system. The feedback package will include guidance/education on effective use of the data at individual, unit, ward and departmental levels. Targeted feedback will be initiated beyond the immediate consultant group, to main recovery unit, surgical wards and senior departmental stakeholders. In terms of the SDO evaluation, the impact of the final iteration of the feedback packages for each stakeholder group will be evaluated in the six month period Oct 2012 – Mar 2013.

The main and intermediary reports planned for submission to the SDO based upon the work are scheduled to follow the end of evaluative activity corresponding to the two main study time-points indicated above. Due to the evolving nature of the CLAHRC project and iterative plan for the development and implementation of the intervention in the active feedback phase which uses a quality improvement programme design, the plan for

the SDO evaluative work has been designed to allow a degree of flexibility, in which the effects of emerging iterations and additional project milestones can be evaluated as intermediary study time-points. The proposed SDO work will additionally incorporate responsive, formative monitoring of the initiative in the form of a longitudinal qualitative (WP3) and continuous statistical review (part of WP2) component.

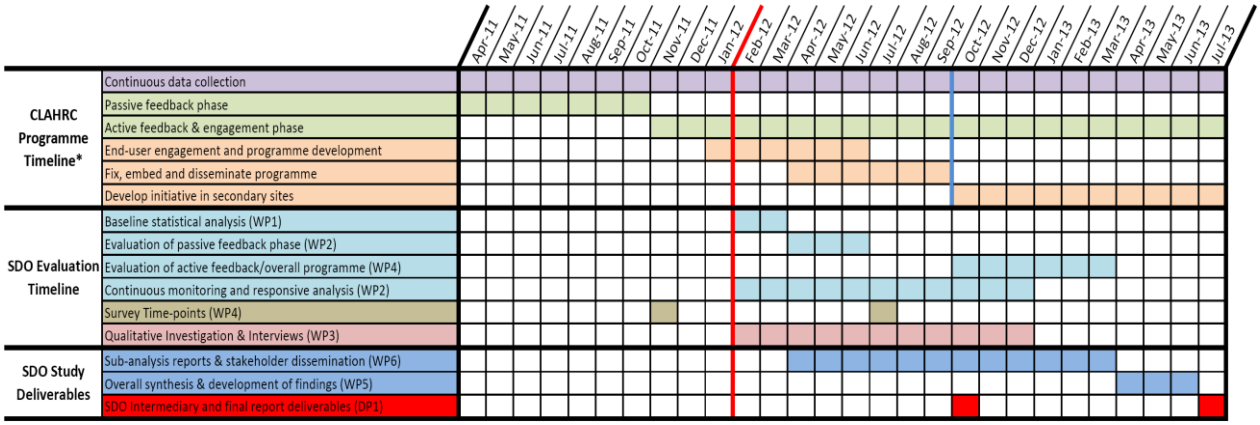

Fig 2: Project timeline depicting proposed SDO-supported activity, CLAHRC project timeline and main study deliverables.

The main work packages corresponding with activity on the project timeline are described in table 2 below. Note that the NIHR CLAHRC anaesthetics programme will support development and implementation of the intervention itself, including collection and administration of the majority of the data that will be analysed within the evaluation. The SDO-supported work will therefore involve predominantly analysis, qualitative enquiry, synthesis and dissemination of findings. Reporting to local clinical, service and managerial stakeholders on trends and implications of the observed quality indicators will occur continuously throughout the project as part of the data feedback component of the CLAHRC project intervention and as such is not included here. In contrast, the SDO-supported work is oriented towards reporting to broader research and evaluation stakeholders.

TIMELINE	WORK PACKAGE	DESCRIPTION AND RATIONALE
Feb - Mar 2012	WP1 Retrospective analysis of baseline trends	Retrospective analysis of historical longitudinal data, dating back to early pilot data (March 2010). Purpose is to clean dataset, establish usefulness and reliability of early data and identify any temporal/periodic trends in the pre-intervention baseline, which will need to be controlled in subsequent stages of the analysis. Baseline variability and feasibility for different length baseline periods will be reported. From project onset throughout we will collaborate with anaesthetics specialty research groups to secure formative input into the evaluation and data analysis.
Apr - Jun 2012	WP2 Statistical analysis of serial effects from CLAHRC development/implementation phase	Interrupted time series models will be fitted to the longitudinal dataset with intervention timepoints specified corresponding to the incremental passive and active feedback intervention timepoints representing developmental milestones within the CLAHRC programme. Incremental analysis of intervention and other temporal effects will be supported by a near real-time Statistical Process Control approach using varied format control charts with control limits to identify significant special cause variation and contribute formative information to the programme.
Feb – Dec 2012	WP3 qualitative data collection and analysis	Main qualitative work stream to run concurrently with statistical analysis. Principle aims are to document the emerging quality monitoring and feedback system, end-user perceptions of utility and acceptability and experience with implementation. Causal mechanisms for any quantitative effects observed will be explored. Data collection and analysis will be iterative and largely concurrent, with two main periods of data collection. The first will take place in the Feb - Apr 2012 period and will focus upon end-user evaluation of the initial phase of the programme and establishing the requirements for the subsequent design of the programme from a broad range of stakeholders. The second phase will take place in the Aug – Oct 2012 period and will be focused upon summary evaluation (perceptions of usability and utility) of the programme.
Oct 2012 – Mar 2013	WP4 Final statistical programme evaluation	At the end of the CLAHRC programme implementation at the pilot site (St Mary's Hospital), the evaluation project will produce a summative retrospective statistical evaluation using the full longitudinal dataset. Cumulative intervention effects will be assessed along with post-implementation sustainability. The analysis will focus upon the two main project phases: passive and active feedback, along with evaluation of any major incremental milestones in programme development. Longitudinal survey data will additionally be analysed within this work package.

Apr – Jun 2013	WP5 Synthesis of data streams and development of final report	Following completion of the main qualitative and quantitative arms of the evaluation, this work stream will comprise a comprehensive research synthesis and write-up for final summative reporting and dissemination. Key findings from the intermediary and incremental analyses will be included from sub-stages of the project (WP6). Integration of qualitative findings with quantitative observations concerning intervention effects will allow the research team to address the main evaluative aims.
Apr 2012-Mar 2013	WP6 Development and dissemination of sub-analyses findings	Concurrent with the main analyses, from April 2012 the project will begin a continuous reporting work stream in which the emergent results from the intermediary stages of the evaluation will be prepared and disseminated in relevant briefing papers, forums and academic output. Output in this period is likely to include the results from sub-projects based upon improvement work to address specific areas. The results from sub-stages within the qualitative and quantitative work streams will additionally be reported to key stakeholder groups.

Table 2: Details of main project work packages from Gantt chart. All specified month periods are inclusive (e.g. Feb – Mar is equivalent to 2 month's effort)

The relationship between the proposed SDO-supported evaluative work streams and the main NIHR CLAHRC programme phases and development of quality monitoring and feedback system is depicted within the following project workflow diagram (Fig 3). Where possible, activities are depicted in chronological sequence, though some elements of the evaluation will be undertaken concurrently as depicted in the timeline (Fig 2).

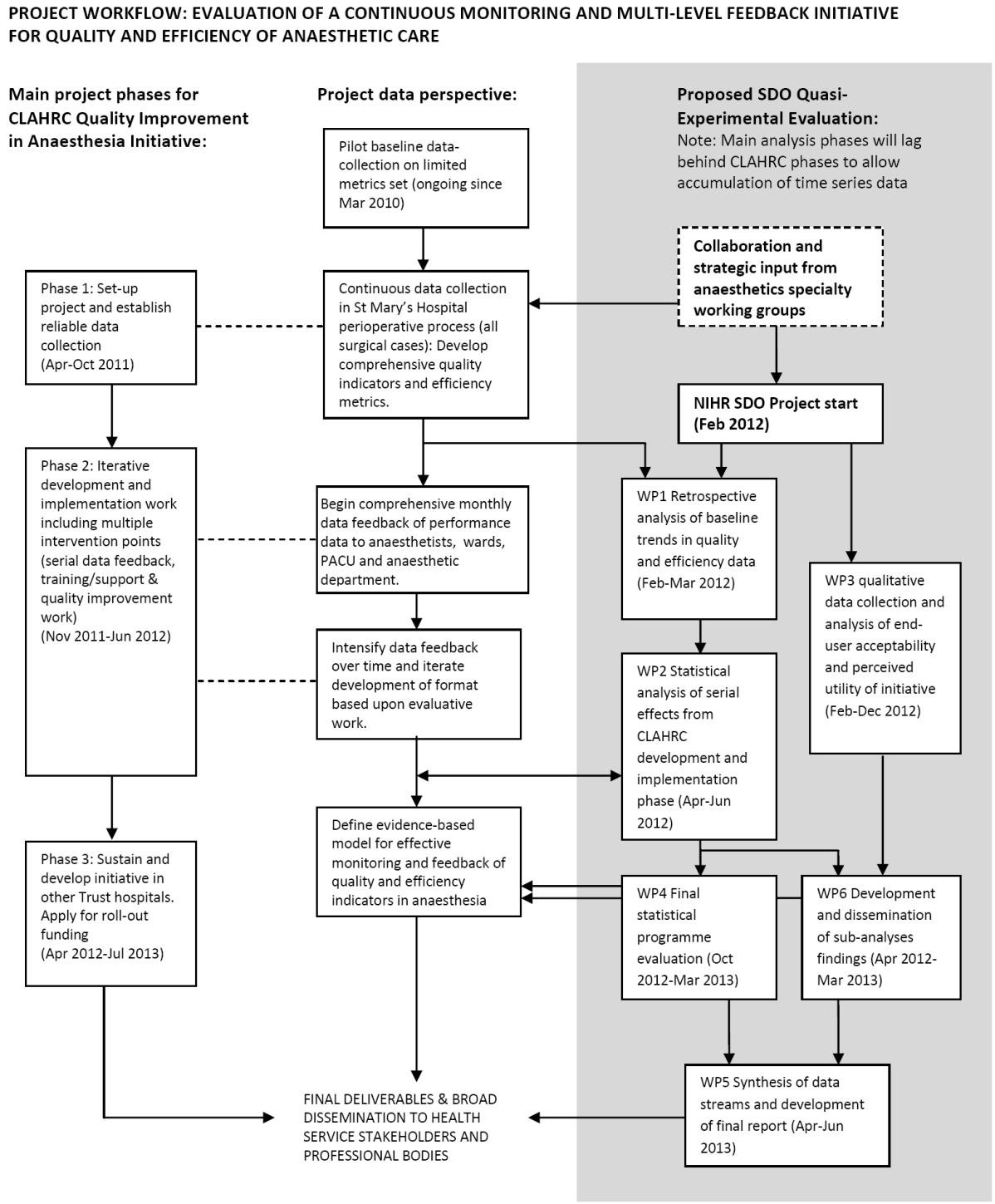

Fig 3: Project workflow diagram depicting relationship between proposed SDO evaluation, CLAHRC programme phases and development sequence for quality monitoring and feedback system.

7. Approval by ethics committees

Following advice from both local R&D (Imperial Healthcare Joint Research Office) and the National Research Ethics Service and in accordance with the harmonised "Governance Arrangements for Research Ethics Committees - GAFREC" (May 2011), the proposed study described in this protocol does not fall under the

requirement for review by a research ethics board, though does require local R&D registration and approval through the Integrated Research Application System (IRAS). The proposed project entails re-analysis of anonymised routinely collected data from Imperial College Healthcare NHS Trust, from staff surveys and interviews, and from publically available hospital episode statistics databases. The data upon which the feedback system is based ("the intervention") is routinely collected for local quality assurance and service development purposes and patients are therefore only involved as part of routine perioperative service audit and are not specifically recruited as research participants in this evaluation. The specific harmonised GAFREC criteria and considerations relating to this position are detailed in the following points:

- "**NHS Staff**: Under the 2001 GAfREC edition, REC review was required for research involving NHS staff recruited as research participants by virtue of their professional role. Such research, or equivalent research involving the staff of social care providers, is excluded from the normal remit of RECs under the harmonised edition of GAfREC. For example, a research project limited to administration of questionnaires or interviews with care staff or managers would no longer require review by a REC within the UK Health Departments Research Ethics Service."
- "**Non-identifiable data**: REC review continues to be required for research involving collection of information from patients or service users for research. However, REC review is not required under the harmonised GAfREC for research limited to use of previously collected, non-identifiable information. This exception also applies to research undertaken by staff within a care team using information previously collected in the course of care for their own patients or clients, provided that data is anonymised or pseudonymised in conducting the research. Such research would involve no breach of the duty of confidentiality owed by care professionals."

8. Project management

Project management for the proposed SDO-supported evaluation will be closely linked to the activities of the NIHR CLAHRC programme team and management arrangements and will benefit from having research governance and operational structures already in place under CLAHRC funding. At operational level, day-to-day project activity will be managed by the PI (JB) who will supervise the principal research staff time allocated to the project and the qualitative work, with input from the senior clinical and academic collaborators as required. The PI will additionally undertake a proportion of the research work linked to the statistical analysis and research synthesis, in collaboration with the allocated researcher and statistician (AB). Operational planning and supervision meetings will be combined with those for the NIHR CLAHRC work until its cessation in September 2012 and will take place on a weekly basis (monthly for the broader operational team dependent upon phase of work).

At strategic level, high level project planning and network/dissemination planning will be undertaken by a strategic advisory group comprising senior co-applicant, external collaborators and expert advisors to the project. This group represents local service interests, anaesthesia and surgical expertise, patient safety/service quality and related methodological research expertise, and professional specialty interests. Members of the strategic advisory group will meet periodically with the PI and core research team periodically over the course of the project and at least three times over the 18 month duration. The co-applicants are additionally members of various specialty research groups, including two highly relevant specialty working groups on revalidation-related topics within the anaesthetic specialty. Activities within these specialty groups will form strategic input and steering for the SDO-supported evaluation in addition to local project governance.

In terms of project initiation and reporting, the project team will engage with SDO representatives in orientation/output planning at the initiation phase. During the 18 month course of the project, two reports will be delivered to the funder: an interim report in Oct 2012 and the final report due in Jul 2013. Detailed specification of report contents are described in section 6.1 above, along with description of the other research deliverables and knowledge mobilisation activities.

9. Public involvement

As part of the CLAHRC programme that this proposal will evaluate, we will engage service users to elicit their views on: 1) criteria for positive patient experience of perioperative and anaesthetic care, 2) the acceptability of patient reported quality of recovery measures, 3) their views on how data should be used at the clinical unit level to support quality improvement and revalidation of clinicians, and 3) the relevance of the emerging findings to service users. We will additionally work with established CPSSQ patient representatives and Trust patient liaison groups to ensure patient and public involvement throughout the project, through development of the initiative, interpretation of study findings and communication and dissemination of results.

10. Expertise and justification of support required

The requested support for this proposal represents a low-cost evaluative research activity that capitalises upon existing NIHR investment through the CLAHRC North West London programme. Funding is sought specifically for analysis, synthesis, reporting and dissemination of pre-existing data, the collection and administration of which is currently being undertaken within the CLAHRC programme. As such, we believe this represents a high value proposal and unique opportunity to subject an existing service delivery and organisational innovation within the perioperative specialty to robust evaluative research. The CLAHRC anaesthetics programme and SDO Quasi-Experimental call come at an opportune time within the context of the GMC revalidation drive and intensive activity linked to this agenda within the anaesthetics specialty. This overlap of research and policy interest will ensure the work receives formative strategic input, has a receptive and relevant stakeholder group and is able to link to pre-existing networks for dissemination and translation into practice.

The majority of the requested financial support is allocated to costed project time for the research collaborators and dedicated social scientist researcher. For the PI (JB), Researcher, Statistician (AB) and clinical research lead (GA), the requested resource represents time for operational project management activity, execution of the qualitative work package, statistical data analysis and related tasks, and write-up and dissemination. Support for a full time social sciences researcher for 12 months from Mar 2012 has been requested to coincide with the period of most intensive work corresponding to development of the active feedback and end-user engagement phase of the project and the parallel in-depth qualitative research work stream. A small proportion of additional resource is requested for transcription of interview recordings for the qualitative component. The resource requested for the other co-applicants represents input into interpretation and write-up, membership of the strategic advisory group and professional communication activities to disseminate the project output within the relevant professional networks and act as a bridge between the evaluation and relevant stakeholder interests, including the Royal College of Anaesthetists, the National Institute of Academic Anaesthesia (NIAA), the Association of Anaesthetists for Great Britain and Ireland (AAGBI), the Perioperative Health Services Research Centre (HSRC) and the two working groups linked to the revalidation agenda within the specialty. Limited additional funds are allocated for attendance and dissemination at International conferences, including the BMJ International Forum for Quality and Safety in Healthcare and for travel and subsistence for attendance and presentation at specialty group meetings, such as those of the Royal College and Association for Perioperative Practice (AfPP).

In terms of expertise, the proposed project team is multi-disciplinary comprising research, service and policy-level expertise and with an established history of collaboration. JB (FTE 0.2) is PI for this proposal and as Lecturer in the NIHR Centre for Patient Safety and Service Quality (CPSSQ) has experience of leading various

statistical and qualitative research projects and research publication, including work on effective feedback from incident reporting in healthcare and research and evaluation of organisational level programmes such as the UK safer Patients Initiative. JB is a patient safety researcher and psychologist by background with PhD level research experience in analysing human and organisational factors in systems development projects. JB is lead on the NIHR CLAHRC anaesthetics project (£100,000) that this current application was developed to evaluate and will be responsible for research design, project management, data analysis and overall delivery. JB is linked to a programme focused upon evaluation of complex intervention programmes run by the Health Foundation, which comprises an ongoing series of roundtable discussions drawing upon national and international research and policy expertise in this area, which will inform the design and interpretation of the proposed evaluation.

GA (FTE 0.1) is a Consultant Anaesthetist and Clinical Lead for the local CLAHRC programme. GA will provide clinical input into the evaluation and represents the interests of the local anaesthetic department. SB (FTE 0.03) is Director of the Imperial Centre for Perioperative Medicine and Critical Care Research and contributes expertise in research design and data analysis. CV (FTE 0.01) is Professor of Patient Safety Research and Director of the NIHR Centre for Patient Safety and Service Quality which maintains an extensive portfolio of quality and safety research projects and themes, including use of data to support quality improvement, and has a comprehensive programme of translational research. CV will act as senior advisor to the project management team and will mentor JB in the PI role. DB (FTE 0.01) is Professor of Acute Medicine and Director of the NIHR CLAHRC programme for North West London. DB will form a bridge to the CLAHRC programme team which includes expertise in improvement methodology and statistics.

AS (FTE 0.01) is Honorary Professor of Clinical Anaesthesia at the School of Health and Medicine at Lancaster University, Chair of the Guidelines Committee of the European Society of Anaesthesiology and has a long-standing interest in care standards through leading the Royal College's Excellence project and more recent involvement in the Outcomes Working Group of the HSRC within the College. AS will form a bridge between this project and relevant specialty research networks and professional groups. AB is a lecturer in medical statistics and chief analyst at the Dr Foster Unit with expertise in risk modelling, development of indicators of quality and safety using routine data, and SPC. AB will contribute statistical expertise and facilitate access and analysis of HES datasets. AB's methodological work using CUSUMs underpins a national outcomes monitoring tool in use in 70% of acute hospitals in England. He is PI on an NIHR-funded project looking at comorbidity measurement and machine learning methods for benchmarking outcomes. WHG (FTE 0.01) is Chief of Anaesthetic Services at Imperial College Healthcare and Vice President of the Association of Anaesthetists (AAGBI) and will facilitate dissemination of findings and recommendations through the AAGBI.

In addition to costed co-applicants, the following collaborators have agreed to be involved in the project to form links to relevant anaesthetic specialty bodies. Professor Andrew Tomlinson, Vice President of the Royal College of Anaesthetists and lead of the revalidation committee will support the project and provide a link to the College agenda. Dr Ramani Moonesinghe, Consultant and senior lecturer in anaesthesia at UCH is a Council member of the Royal College of Anaesthetists, Board Member of the National Institute for Academic Anaesthesia (NIAA) and NIAA's Health Services Research Centre and as a lead on the specialty revalidation and quality indicators working groups, will link the project to these agendas (see attached letters of support for further details). We have additionally secured surgical input to the development of the project and research findings through the involvement of two academic surgeons that have agreed to act as expert advisors to the project from Imperial College's Dept Surgery and Cancer. Mr Krishna Moorthy is a senior lecturer and honorary consultant surgeon specialising in upper gastrointestinal surgery. Mr Moorthy is additionally a clinical lead within the CPSSQ's patient safety research work and studies factors affecting compliance with best surgical practice, such as with the WHO Safer Surgery checklist. Dr Erik Mayer is a surgeon and Clinical Research Fellow in the Dept of Surgery and Cancer. Dr Mayer's work on application of statistical process control principles, such as the use of Funnel Plots for surgical data, is extremely relevant to the current

proposal. Mr Moorthy and Dr Mayer will be consulted at key points during the project and will be interviewed as representatives of the surgical perspective on use of quality of recovery data to improve care.

Through established collaborations within and external to the Centre for Patient Safety and Service Quality (CPSSQ), located within the Department of Biosurgery and Surgical Technology at Imperial College, we are able to draw upon a broad range of health psychology, organisational sciences and surgical research expertise. CV is director of a large group of patient safety researchers including health psychologists, clinical researchers, organisational psychologists and human factors expertise. JB is a collaborator with Professor Mary Dixon-Woods and Dr Graham Martin at the Dept Health Sciences, University of Leicester, on an application for support to NIHR RfPB for a project entitled: "Clinical dashboards in action: driving improvements in quality and safety in inpatient care". If supported, this project will provide a further evaluation of use of data to drive improvement within the general ward care context. The overlap in methodology and research framework through the collaborators will benefit both projects. Professor Dixon-Woods has agreed to be an expert advisor for the currently proposed SDO project in anaesthesia to provide methodological input and support for the qualitative research component. Professor Hub Wollersheim, an existing collaborator with JB & CV at the IQ Institute for Quality at St Radboud Medical Centre, University of Nijmegen, is another expert advisor to this project and provides research expertise on quality indicators and multi-source feedback. JB is collaborating with Prof. Wollersheim in a systematic review of the evidence for the effectiveness of data feedback interventions in acute care, which will inform the currently proposed study.

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