**FULL/LONG TITLE OF THE STUDY**

Evaluating the safety and patient impacts of an Artificial Intelligence Command Centre in the NHS

**SHORT STUDY TITLE / ACRONYM**

Evaluating the safety and patient impacts of an Artificial Intelligence Command Centre in the NHS

**PROTOCOL VERSION NUMBER AND DATE**

| Version and date | Changes made |
|---|---|
| V4 2021 02 11 | Research process detail and protocol sections |
| V5 2021 02 17 | Corrected typos and duplications |
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# KEY STUDY CONTACTS

| | |
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| Joint-sponsor(s)/co-sponsor(s) | n/a |
| Funder(s) | National Institute for Health Research |
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# STUDY SUMMARY

| | |
|---|---|
| Study Title | Evaluating the safety and patient impacts of an AI Command Centre in the NHS |
| Internal ref. no. (or short title) | KRISTAL188684 |
| Study Design | Mixed-method evaluation, incorporating quasi-experimental and longitudinal qualitative research |
| Study Participants | Staff in key roles relative to the Command Centre |
| Planned Size of Sample (if applicable) | **Qualitative component**<br>Up to 40 NHS staff to take part in qualitative research interviews; Up to 20 NHS staff to take part in ethnographic observations; Up to 10 cross-industry experts to take part in qualitative research interviews; Up to 40 hospital information personnel to take part in a survey.<br>**Quantitative component**<br>Determined by the count of de-identified electronic patient health records from at least 6 months prior to the implementation of the Command Centre. |
| Follow up duration (if applicable) | n/a |
| Planned Study Period | From: 01/03/2021 to: 31/08/2022 (18 months) |
| Research Question/Aim(s) | Our four research aims are:<br>1. Evaluate the impact of the Staff in and around the Command Centre on patient safety, hospital operational efficiency and related organisational processes;<br>2. Understand the process of implementation and integration of the Command Centre;<br>3. Elicit cross-sector and cross-industry perspectives on command and control technologies, to contextualise our findings; *and*<br>4. Synthesise the research findings into practical outputs that will engage service stakeholders and inform future investment and practice |

## FUNDING AND SUPPORT IN KIND

| **FUNDER(S)**<br><br>(Names and contact details of ALL organisations providing funding and/or support in kind for this study) | **FINANCIAL AND NON FINANCIALSUPPORT GIVEN** |
|---|---|
| NIHR HS&DR Programme | |

## ROLE OF STUDY SPONSOR AND FUNDER

The role and responsibilities of the Sponsor are those set out by the NHS Health Research Authority, which comply with standards specified in the 2005 Research and Governance Framework. These responsibilities include ensuring that following are undertaken by the research team: peer review, supporting information, defined roles and responsibilities, monitoring and audit, risk assessment processes/tools, patient and public involvement, training, registration, and dissemination.

## ROLES AND RESPONSIBILITIES OF STUDY MANAGEMENT COMMITEES/GROUPS & INDIVIDUALS

This project will have a Study Steering Committee (called the Project Advisory Group) and a Project Management Group**.**

The responsibilities of the members of the Project Advisory Group have been adapted from NETSCC Research Governance Guidelines and are out in the Terms of Reference, summarised below.

- To provide advice, through its Chair, to the NIHR (Funder), University of Leeds (Sponsor and host institution), and the Project Co-Leads (Chief Investigators) on all appropriate aspects of the project;
- To concentrate on progress of the project, adherence to the protocol, patient safety and the consideration of new information of relevance to the research questions;
- The rights, safety and well-being of the participants are the most important considerations and should prevail over the interests of science and society;
- To ensure appropriate ethical and other approvals are obtained in line with the project plan;
- To agree proposals for substantial protocol amendments and provide advice to BTHFT and NIHR regarding approvals of such amendments; *and*
- To provide advice to the investigators on all aspects of the project.

The Project Advisory Group membership are independent, where independence is defined as follows:

- Not part of the same institution as any of the applicants or members of the project team.
- Not part of the same institution that is acting as a recruitment or investigative centre, including Patient Identification Centres, identifying and referring patients to a recruitment or investigative centre. (In both cases above ‘not part of the same institution’ means holding neither a substantive or honorary contract with said institution).
- Not related to any of the applicants or project team members.
- For the Chair only, not an applicant on a rival proposal.
- It is recognised that independence status may change during the duration of the trial.

The members of the Project Management Group are responsible for the day-to-day management of the project. The Group will be chaired by the Principal Investigator, Owen Johnson, and will include as members, representatives from each of the work-streams: project management (Owen Johnson), patient and public involvement and engagement (Naeem Sheikh), qualitative (Jonathan Benn), quantitative (Mark Gilthorpe), dissemination (all).

## PROTOCOL CONTRIBUTORS

Those who have contributed to the drafting of this protocol are:

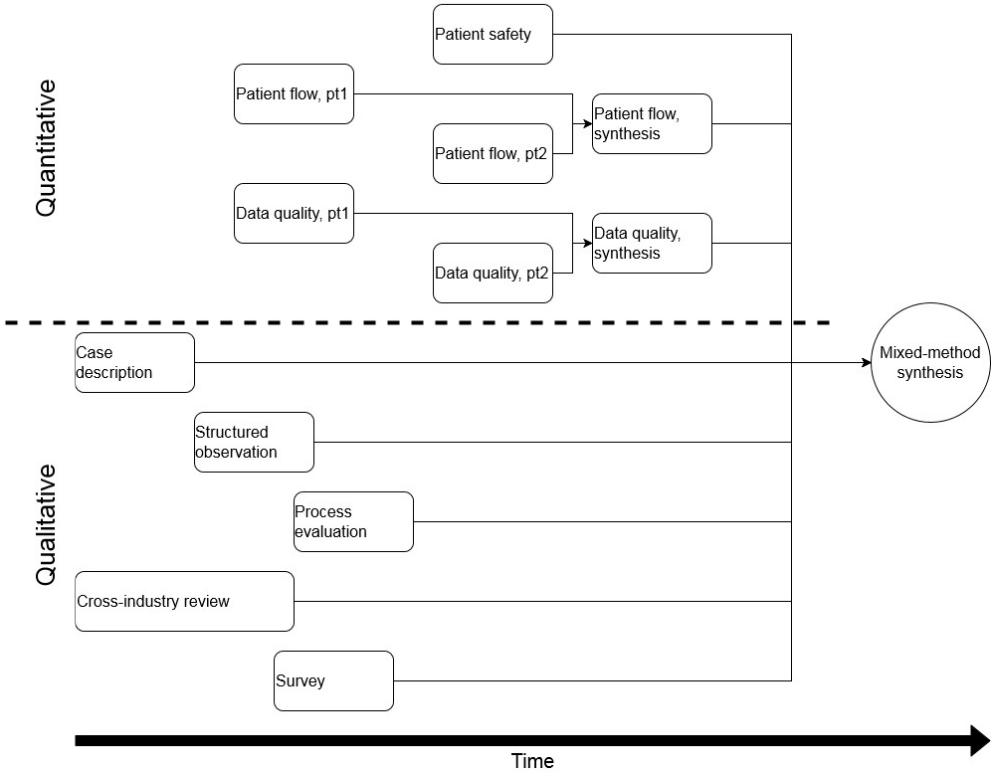
- Owen Johnson (Principal Investigator)
- Jonathan Benn (Qualitative lead)
- Mark Gilthorpe (Quantitative lead)
- Carolyn McCrorie (Co-applicant)
- Ciarán McInerney (Co-applicant)
- Naeem Sheikh (PPIE Co-applicant)
- Ibrahim Habli (Co-applicant)
- Tom Lawton (Co-applicant)
- Rebecca Randell (Co-applicant)
- Lay Leaders from the NIHR Yorkshire and Humber Patient Safety Translational Research Centre
- The Yorkshire Quality and Safety Research Group patient panel

## KEY WORDS

sociotechnical evaluation; health information technology; high-reliability organisation; care coordination

## STUDY FLOW CHART

A Gantt chart is provide in appendix 2. Below is a visualisation depicting how the research activities from the qualitative and quantitative work-streams combine in our mixed-method approach.


Quantitative
Patient safety
Patient flow, pt1
Patient flow, synthesis
Patient flow, pt2
Data quality, pt1
Data quality, synthesis
Data quality, pt2
Case description
Mixed-method synthesis
Qualitative
Structured observation
Process evaluation
Cross-industry review
Survey
Time

**STUDY PROTOCOL**

Evaluating the safety and patient impacts of an Artificial Intelligence Command Centre in the NHS

# 1 BACKGROUND

Poor healthcare service organisation, particularly in the complex environment of a hospital, can have serious impact on patients, patient care and safety, including problems such as deaths from untreated sepsis.[1] Targets such as the 4-hour wait in Accident & Emergency have been found to be unsuccessful in addressing priority cases.[2] A promising approach emerging from the USA has been to develop command centres that incorporate artificial intelligence to ensure patient services are delivered safely and effectively.[3] Command centres in safety critical industries are well-evolved and linked to reliability, resilience and shared situational awareness for operational control. In most UK NHS hospitals, the operational planning of health service delivery is fragmented across multiple departments and services with major implications for patient safety, efficiency and good patient care. There is growing interest in learning from other safety-critical industries and a need to translate concepts from safety critical industries to the unique challenges of healthcare. The UK is making major strategic investments in digital health technologies such as artificial intelligence in the belief this will lead to major improvements but there is an urgent need for research to inform these investments.

## 1.1 The implementation of an AI Command Centre at Bradford

Bradford Teaching Hospitals NHS Foundation Trust has pioneered an Artificial Intelligence Command Centre which is believed to be the first-of-type in Europe. The business case was based on the need to address limited situational awareness and pressure on staff, a common problem in all NHS hospitals. The Command Centre is now operational with permanent staff based in the operations room and work is now focussed on the development of Command Centre information tiles to display increasingly more relevant, actionable real-time information.


Figure 1: The AI Command Centre at Bradford – from design (left) to implementation (right)

The intention of the Command Centre is to create a ‘care’ traffic control centre that a) provides timely intelligence to those who need it; b) informs design and deployment of an efficient system of hospital management; and c) will evolve through use by engaging frontline staff in the design and re-thinking of digitally led service improvement. The Command Centre provides a 24/7 support system for front-line care givers by co-locating bed managers, EVS coordinators, transfer leaders, operation-room

schedulers, transport coordinators, and staffing coordinators with clinical and management leadership immediately available. The physical space of the Command Centre is an operations room focussed on a wall of eight large screens or “tiles” providing live information (Figure 1). The tiles will be evolved over time to meet the emerging needs of service delivery, improving patient flow, identifying bottlenecks, and safety and performance issues (Figure 2).

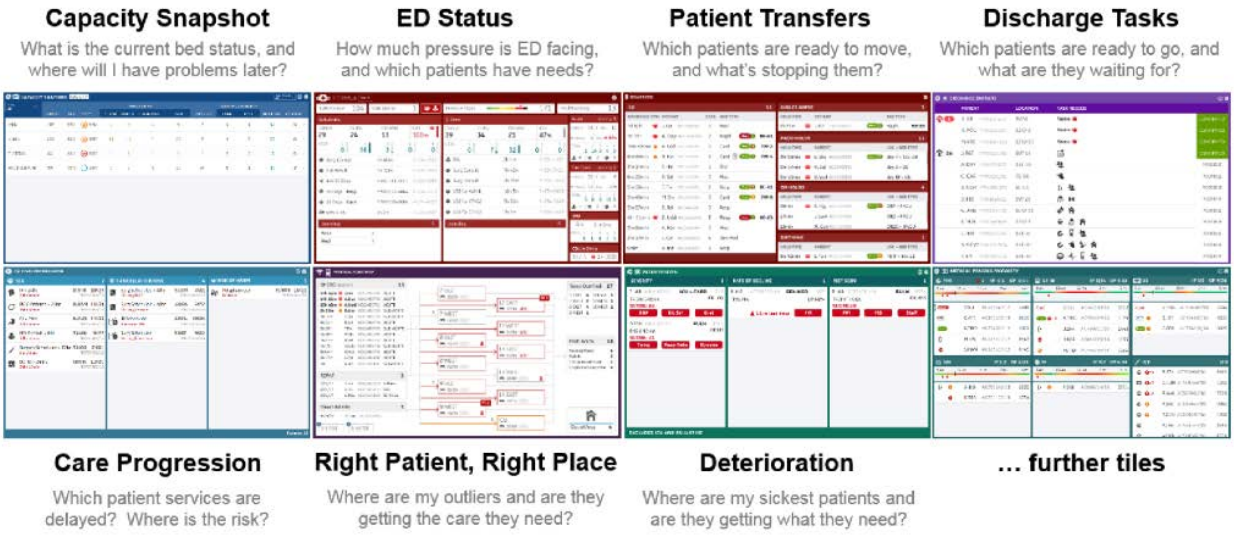


Figure 2: Command-Centre tiles at Bradford Teaching Hospitals NHS Foundation Trust

The development of the tiles has been based on extensive consultation between systems designers, human factors, workflow and usability experts, clinical and operational staff at all levels and this has included patient and public involvement and engagement. Over the duration of our proposed study we expect the tiles, the systems, their use and operations to evolve and improve following the approaches envisaged in the learning health systems literature. Initial design of the tiles and the algorithms to determine, for example, alert thresholds, was based on data analytics and machine learning from the underlying hospital information systems. The developers expect to implement increasingly smarter AI algorithms as usage generates data that the system can learn from. The hospital’s future plans for the Command Centre include further development of the Deteriorating Patients tile with specific focus on sepsis, chronic obstructive pulmonary disease and frailty. Further work will connect the system with partners in the community, primary care and other nearby hospitals.

## 1.2 **Readiness for an artificial intelligence command centre approach in the UK NHS**

In preparation for this application we have conducted a conceptual review of the literature. The following section provides an overview of the relevant evidence.

Digitisation of health information systems in secondary care services has been slow and the introduction of electronic patient records has been met with varying levels of success.[4] It has been estimated that more than half of all systems fail, or fail to be properly utilised.[5] Successful implementation depends on a combination of both technical and socio-organisational factors.[4] A recent review of barriers to implementation reported that around 95% of studies found issues with resistance, lack of education and training and lack of awareness of electronic patient records and

associated benefits.[6] There is a mismatch between the factors required for successful implementation, end users and provider perspectives.[7] The disruption to workflow and changes required are significant challenges for users, particularly in systems that have limited modularity and configurability.[7] There have been very few published attempts at evaluating effectiveness, with the exception of use as a clinical decision-making tool.[8] Most of the evidence originates from North America.[9] Given the major differences in the social, political and economic foundations of their healthcare system, it is important to explore whether these issues are relevant to the UK context.[10] Even less is known about the potential of electronic patient records developments to improve patient outcomes. Patient journeys are poorly understood as what really happens is often lost in aggregate statistics. What has not been achieved is real-time command and control using the data generated by routine systems, despite a rise in the number of state-of-the-art dashboards, flow and simulation models. An Artificial Intelligence Command Centre has the potential to improve future patient flow and safety. Research to understand the health service delivery, safety and operational factors that should be considered is an area of major importance for hospitals and our research should generate learning that will be of great utility to the wider NHS.

### 1.3 **Learning health system perspectives**

Strengthening health systems requires dealing with their complexity and taking into account not only their components but also their complex interrelations, and adopting new ways of thinking to close the knowledge–action gap, where each innovation in health systems constitutes a learning opportunity.[11] In healthcare in the USA the combination of people, processes and digital technologies into organisational structures that generate and implement continuous learning has been articulated as ‘learning health systems’,[10,11] a key interest for our group and a key theme for this call. Our research group is has a strong interest in the use of artificial intelligence within digital technologies from a safety perspective, as part of our theme leadership in the NIHR Yorkshire & Humber Patient Safety Translational Research Centre, and from a technology perspective, through our newly awarded Centre for Doctoral Training in Artificial Intelligence in Medical Diagnosis and Care where we will train 50 PhDs in practical applications of artificial intelligence within hospitals in the UK NHS. A recent review of evaluative frameworks concluded that the learning organisation concept can be a powerful mode of organisational reform to promote learning within the health sector[12]. We see the learning health systems literature as key to understanding the evolving nature of technology and operational services.

### 1.4 **Patient safety perspectives**

Many of the current patient safety measures collected within the NHS lack validity, are collected unreliably, with almost all being ‘lagging’ indicators of retrospective harm.[13] For example, mortality data is seen as a ‘zombie statistic’ lacking sensitivity to detect avoidable harm.[14] Patient safety thermometer data is a retrospective ‘snapshot’ audit from one day during the previous month. Patient safety incident data suffers from major reporting biases and lack of feedback.[15] In 2013, Vincent and colleagues presented a framework for measuring and monitoring patient safety, with a view to moving healthcare organisations away from the current hegemony of ‘past harm’, towards a more holistic and nuanced assessment of safety and prevention of future harm.[13] Safety is complex and multi-faceted, reflecting rapidly changing individual, team and organisational contributory factors. New measurement

approaches are required to capture this complexity and flux in order to support clinical teams in identifying unsafe environments before harm occurs. The Complex Adaptive System model describes healthcare systems as dynamic networks in which multiple agents (staff, patients, and technology) are continuously interacting. The ‘Safety 2’ model of organisational safety suggests that safety is an emergent outcome dependant on the interactions within a Complex Adaptive System. ‘Safety 2’ has its origins in industrial safety work but has been applied to healthcare safety analysis.[16] In contrast to a retrospective focus on harm, our research will explore the practical application of prospective approaches to understanding how safety is maintained, through the ‘Safety 2’ concept of “resilience”, to evaluate command centre processes, the interaction between supporting digital technologies, dynamic use of hospital systems and the whole system.

### 1.5 Reliability and resilience perspectives

A considerable amount of literature has been published on how High Reliability Organisations, such as nuclear power plants, air traffic control systems and emergency medical services maintain safety despite the complexity of their organisational systems.[17]. High Reliability Organisations utilise a set of organising processes that allow them to respond to the unexpected, detect the presence of dynamic risks and respond proactively to avoid harmful outcomes.[18] This is referred to as ‘mindful organising’.[19–23] The processes and practices of mindful organising are associated with sensitivity to operations and resilient coping processes.[18,24–26] In mindful organisations, resilience is sustained by timely human actions supported by specific organisational and technological systems which, for example, compress hierarchical decision making at times of crisis for direct operational control in response to emerging situational intelligence. These actions are affected by organising processes that increase the quality of attention. This increased attention in turn, enhances alertness to details of operations, thereby enabling them to detect subtle changes in contexts and respond as appropriate.[19]

### 1.6 A weak evidence base for Artificial Intelligence

The sociotechnical requirements for effective command centres have been studied in transport and military situations,[27] and there have been bold attempts to use AI principles within command centres since Project Cybersyn in Chile as early as 1971.[28] Within healthcare there is a very limited evidence base for this form of digital technology although some successes have been reported in the USA. For example, The Johns Hopkins Hospital reported that since it began operating a similar Artificial Intelligence Command Centre to that used in Bradford, patients from other hospitals have been transferred 60% faster, emergency room wait times were cut by 25%, and time waiting in operating theatres for post-surgical beds decreased by 70%.[3] Alternative approaches include technologies such as Splunk (www.splunk.com), which is linked to dashboard displays, and the retrospective review of business intelligence and analytics reports, but these approaches do not extend to include co-locating central control or raising and managing alerts. The UK is still dealing with the legacy of unsuccessful electronic patient record implementation where the impact of socio-technical factors had been underestimated.[29] We need to understand the pathway by which hospitals manage their operations through advances in digital technology. There is a limited evidence base for this form of digital technology but an increasing belief, supported by the Government’s Life Sciences Strategy, that artificial intelligence should play a key role in transforming and modernising

the NHS.[30] History demonstrates the risk of large-scale changes in practice without a robust evidence base.[5]

# 2 RATIONALE

Bradford Royal Infirmary is implementing the first hospital Artificial Intelligence Command Centre in the UK and Europe, working with partners from the USA. The Bradford Artificial Intelligence Command Centre aims to provide faster and safer care by reducing unnecessary waiting through anticipating and avoiding slow-downs in care delivery before they cause problems. System implementations such the Bradford Artificial Intelligence Command Centre are complex interventions that may have many benefits but can also have multiple emergent unforeseen consequences. There is a compelling case for research to develop the evidence base for these new digital technologies to inform safe and effective adoption by the NHS.

Our proposed research will make an important contribution to the speed at which emerging AI based digital technologies can be safely adopted by NHS hospitals. It is of national importance to understand the potential utility of this technology to inform its safe and effective adoption and use. Our proposal will address this evidence gap through a mixed methods study to evaluate the Bradford Artificial Intelligence Command Centre drawing on learning health system, sociotechnical, and patient safety frameworks. We will use a nearby hospital of similar size, systems and complexity that has not implemented a Command Centre approach, as a comparator.

We hypothesise that the implementation and integration of a real-time, centralised hospital command and control centre will improve patient flow, reduce bottlenecks and delays, enhance situational awareness to support operational decision-making and facilitate identification and timely mitigation of threats to patient safety. Due to the evolving sociotechnical nature of the systems and processes we will be studying, we will use a mixed methods research approach that combines qualitative process evaluation with a quasi-experimental study (interrupted time series analysis). Our analyses and synthesis will be theoretically informed by contemporary safety science theory concerning system resilience[16,31] human factors models of situational awareness[32] and command and control in high reliability organisations[19,33,34]

# 3 RESEARCH QUESTION/AIM(S)

## 3.1 Main study

We have four aims:

1. Evaluate the impact of the Artificial Intelligence Command Centre on patient safety, hospital operational efficiency and related organisational processes.

2. Understand the process of implementation and integration of the Artificial Intelligence Command Centre and associated data infrastructure and organisational processes within the primary study site.

3. Elicit cross-sector and cross-industry perspectives on hospital command and control technologies to contextualise the findings from the primary study site for broader application.

4. Synthesise the research findings into practical outputs that will engage service stakeholders and inform future investment and practice.

## 3.2 Objectives

Each aim has two to four objectives:

**Aim 1:** Evaluate the impact of the Artificial Intelligence Command Centre on patient safety, hospital operational efficiency and related organisational processes.

a) Describe (qualitatively) and evaluate (statistically) any effect on patient safety, including monitoring of deteriorating patients and sub-optimal care pathways, risk of harm due to cancellation/delays and situational awareness in safety-critical areas such as the emergency department.
b) Describe (qualitatively) and evaluate (statistically) any effect on patient flow, including capacity-demand ratio, transfer delays, bed utilisation, timely discharge and cancellations of scheduled care.
c) Qualitatively investigate any effect on organisational processes, such as situational awareness, operational decision-making, risk and coordination/communication across organisational units, from multiple stakeholder perspectives.

**Aim 2:** Understand the process of implementation and integration of the Artificial Intelligence Command Centre and associated data infrastructure and organisational processes within the primary study site.

a) Using qualitative methods, describe the process of development and implementation of the Artificial Intelligence Command Centre, including critical implementation factors and any unintended consequences.
b) Through ethnographic methods, investigate the process by which the Artificial Intelligence Command Centre system and outputs are embedded at all levels of the organisation, from frontline operations to strategic quality and safety governance.
c) Develop and validate a logic model for this health informatics intervention that maps system preconditions, processes, technology and outcomes, at the primary study site.
d) Describe (statistically and qualitatively) the effect of the Artificial Intelligence Command Centre implementation on the local data environment, including data infrastructure, quality and integration (i.e. system interoperability).

**Aim 3:** Elicit cross-sector and cross-industry perspectives on hospital command and control technologies to contextualise the findings from the primary study site for broader application.

a) Review and understand command and control processes in non-healthcare safety critical operations and the key principles and contextual factors that may influence transferability of these models into a hospital setting.
b) Survey the perceptions of senior health informatics professionals on current command and control processes, viability of novel "mission-control" systems, data readiness and potential implementation barriers.

**Aim 4:** Synthesise the research findings into practical outputs that will engage service stakeholders and inform future investment and practice.

a) Share learning concerning cross-industry and empirical findings on the costs-benefit of investment within NHS management and Chief Information Officer networks.
b) Construct an empirically-informed implementation framework that describes contextual factors and implementation pathway for development of centralised, data-driven mission-control systems in acute care, including data infrastructure maturity.

# 4 STUDY DESIGN and METHODS of DATA COLLECTION AND DATA ANALYIS

This study uses a mixed-methods design, combing ethnographic and quasi-experimental approaches.

## 4.1 Qualitative

The qualitative study will comprise a theoretically-informed, longitudinal process evaluation to study the process of integration of digitally-supported command and control within an acute care organisation and evaluate outcomes from clinical, organisational and patient perspectives. It will therefore address aims 1c, 2a, 2b and 2c. We will undertake an in-depth case study [54] , with data collected through ethnographic observation [55] and qualitative interviews [56] in order to map the AI Command Centre's integration with hospital systems, study the process of implementation/ development and evaluate the effectiveness of the AI Command Centre in achieving its aims. As part of our work, we will construct a formal logic model [57] to describe mechanisms of impact of the command centre as a complex, organisational health informatics intervention. In a parallel work stream that will address aims 3a and 3b, we will seek diverse perspectives on the functioning of command centres from a cross-industry perspective, through literature review, consultation with international hospital and high-risk industry sites as exemplars of successful command centre/mission control implementation and a national survey of hospital Chief Information Officers (CIOs) to assess broader practice and investment in this area.

### 4.1.1 Fieldwork guide

The fieldwork guide developed to support the qualitative work will include the site visit preparation schedule, site visit schedule, field notes form, participant information sheets and consent forms, informal and formal interview topic guides and agenda for team debriefings.

The longitudinal qualitative study will consist of 4 components:

### *4.1.2* Qualitative scoping work: Case description and unstructured observation

*Months 3-6*

As an initial step in developing our case study of the AI Command Centre implementation and in order to immerse and sensitise the research team to the context of hospital operational command and control, the first phase of our work will involve unstructured ethnographic observation and system mapping. The AI Command Centre is intended to bring together multiple sources of real-time electronic data into intelligence to support action and we will study this process of transformation using a sociotechnical framework [58, 59]. Ethnographic enquiry has been selected in order to facilitate deep understanding of the technology in its broader social and organisational context, including human experience, engagement and interaction [60, 61]. We aim to achieve a comprehensive description of how the AI Command Centre is integrated and embedded within the broader sociotechnical hospital system through observation of enacted working practices, communication, decision-making and operating culture. In this sense, we won't simply be relying upon the model for the system implementation, as planned by programme leads, but will explore the differences between work as intended and work as done [18], and describe any unintended consequences and implementation barriers as they emerge.

**Data collection:** Data collection will be opportunistic within pre-specified observation periods, comprising participant observation (documented as researcher field notes) and short interviews with staff in and around the AI Command Centre, in order to understand events and actions as they unfold from the actor's perspective (and the meanings that AI Command Centre users attach to them). In addition, the researchers will record incidents of observer effects (e.g. participants asking 'What are you writing?') to allow analysis of whether participants' awareness of the researchers' presence changed over time [62].

**Sampling:** Sampling of observation periods will be based on opportunistic access provided by key personnel and as agreed with AI Command Centre Leads so as not to overburden staff. It is anticipated that observations will take the form of up to 4-hour windows with sampling of observation periods be stratified in order to ensure representation of varied days of the week (including weekends), time of day and AI Command Centre conditions (e.g. team handovers). A minimum of three shifts and three handovers will be observed [20]. Sampling will be informed by findings from the preliminary work. In this sense, and in accordance with standard qualitative research practice, sampling will be theoretically-informed, and data collection will proceed until saturation is achieved on key themes emerging from inductive analysis. In addition to general observation in the observation windows, we will explore behaviour and meaning around specific events, drawing upon the Critical Incident Technique [63]. Two researchers will undertake the observations and 36 researcher hours of observation will be conducted in this initial period.

#### 4.1.2.1 Recruitment

Staff working in the AI Command Centre during unstructured observation periods will be made aware of that the observations for research purposes will be taking place prior to their working shift. This will be communicated to them through the AI Command Centre Lead. Personnel present in the Command Centre will be provided with an information sheet about the study and will be asked to give their

informed consent to take part in the research, through indicating that they have read, and agreed with the information contained in the aforementioned sheet.

#### 4.1.2.2 Observation guide

An observation guide will be developed, informed through literature on ethnographic methods in acute care settings, and more broadly in healthcare and safety critical industries. Iterations to the guide will be made throughout the research process.

#### 4.1.2.3 Short, opportunistic interviews

Short, opportunistic interviews during periods of observation will be 10-15 minutes duration. An informal interview topic guide will be developed through established literature and informed by findings from the preliminary work. The guide will be iterated throughout the research process. Detailed researcher notes will be compiled from the interviews, both during and as soon as possible after the interviews have taken place.

#### 4.1.2.4 Researcher field notes

Three sets of researcher notes will be generated through observations: Substantive, reflective and analytic (Lowdes et al 2018). Detailed research notes will be entered into NVivo (Version 12) to facilitate data management and analysis.

#### 4.1.2.5 Document review

We will review emerging hospital policies and guidance related to the AI Command Centre (e.g. meeting minutes and organisational policies) where practicable as an alternative to data collection involving staff to capture the ongoing implementation and monitoring process. Documents relevant to the AI Command Centre (e.g. Evidence logs, Workbooks for key decisions, issues arising, roles and actions, New standard operating procedures, Risk assessments and meeting minutes) will be analysed for emergent themes.

A sampling framework to guide collection of documents (key documents and dates) will be informed through earlier qualitative interviews with AI Command Centre leads and iterated during the research process. Documents that meet inclusion criteria will be recorded in a document inventory and a data extraction template will be created to obtain the necessary information from the documents. The extracted data will be analysed through an inductive process to capture key developments in design and functioning of the AI Command Centre. The data will be analysed in parallel to interview data and will inform lines of questioning for subsequent interviews (e.g. analyse the “official” story vs. what happens in practice).

#### 4.1.2.6 Data analysis

We will adopt an inductive qualitative analysis approach drawing upon concepts from Grounded Theory [64]. We will capture the way in which the AI Command Centre system integrates within the broader hospital information and operational planning systems (e.g. bed management, escalation, A&E patient flow) in a formal model grounded in our data.

### *4.1.3* Structured observations

*Months 7-12*

Following our initial observation period, ethnographic data collection will move to a more structured approach in order to explore the impact of the AI Command Centre beyond the operations room and at all levels of the organisation, including micro-level (frontline clinical workflow in specific

specialties), meso-level operational planning (e.g. bed management) and macro-level strategic planning (e.g. use of data in quality and safety governance). Our approach to structured observation will draw upon engineering "use case" methodology [65] to understand usability of the system in context. Our approach will be twofold: a) following key information through the system from modules in the AI Command Centre visual displays (i.e. understanding the impact of the AI Command Centre on certain "tracer issues" at hospital level, such as detection and escalation for the deteriorating patient), and b) formal shadowing of key professional roles, such as bed managers, risk management/quality assurance, clinical leads and others, as they utilise, act upon and make decisions based upon command centre data and intelligence. We anticipate producing six use cases or vignettes, based upon 10 hours observation each of specific tracer issues/professional roles that represent interaction with AI Command Centre processes and outputs. In our interview work across the experimental and control sites, we will utilise the use cases as a probe to compare operational planning, control and decision-making in specific priority areas, with and without the support of a centralised AI Command Centre function, in order to enrich our understanding of how a AI Command Centre operates within a health service context.

#### *4.1.4* Longitudinal stakeholder and process evaluation (formal interview study)

*Months 5-7 and 12-14*

To complement our observational work, we will undertake a formal stakeholder evaluation, using qualitative research interviews at multiple timepoints within the AI Command Centre programme, to evaluate the efficacy of the AI Command Centre system from multiple user perspectives. Sampling will be theoretically-driven, based upon emerging insights from the structured observations, and will include AI Command Centre programme leads, key roles working in the centre, clinical leads in frontline areas interacting with the AI Command Centre, and organisational level stakeholders representing senior information systems, operational strategy, clinical governance and financial interests. Up to 20 interviews will be undertaken at the experimental site focusing on two timepoints: one during the early phase of the project and the second towards the end of data collection. Representation of comparable roles will be sought at the control site, for comparative analysis of how the implicated functions are delivered in conventional operational planning processes.

In terms of data collection, we will draw upon a process evaluation framework [66] in order to understand intervention mechanisms, implementation processes, interaction with context and overall outcomes. In this sense, a key feature of our analysis will be production of the logic model to describe the AI Command Centre as a complex health informatics intervention. Our process evaluation will systematically explore the experiences, beliefs and expectations of users in relation to operational planning and delineate the trajectories by which patient safety, operational and other intermediary outcomes are impacted by AI Command Centre processes. This will include building upon the ethnographic work to explore interactions with prior theory concerning how the command centre may "work" as an intervention. The evaluation will address the factors that govern engagement with and use of this technology, using technology adoption theory [67], and the efficiency and effectiveness of processes for generating new intelligence for decision making and quality improvement at the level of the hospital. Data analysis for the qualitative interview component will comprise both inductive and deductive analyses, employing frameworks derived from prior theory and a comparative perspective across the two study sites [68, 69]. We will additionally describe the financial business case for

implementation of hospital command centres, linked to our logic model, and report the costs and benefits associated with this initiative, as perceived by stakeholders. Relevant theoretical frameworks for sense making in our analysis will include: models of situational awareness [70], operational command and control [26-28], sociotechnical evaluation [71], High Reliability Organisations [1, 2, 35] and resilience in healthcare [72, 73]. From the perspective of Situational Awareness theory, for example, we will seek to understand how the AI Command Centre enhances human perception of the environment and events within time and space, including projection of future states, and facilitates comprehension of meaning [70]. The extent to which the Bradford AI Command Centre differs from the approach at the control site will be mapped out, to understand how and in what ways the AI Command Centre impacts on patient safety.

#### 4.1.4.1 Recruitment

The first approach will be used to ask staff about whether they would be interested in taking part in the study by verbally explaining the key aspects of the study. If they are interested in taking part, the researcher will provide written information and will review this with the staff. Staff will be given some time to review the information and ask questions, according to their need and preference. The researcher will invite staff to participate in the research. Potential participants will receive an information leaflet about the study. If they decide to take part, the researcher and participant will complete a written consent form. A copy of the consent form will be retained by the member of staff and also by the researcher. In instances where interviews are conducted over the telephone, the interviewee will have sight of the information sheet and will be asked to confirm that they have read it and be given the opportunity to ask any questions. In accordance with the University of Leeds Verbal Consent Protocol, the participant will be asked to verify their verbal consent at the beginning of the recording of the interview and this conversation will be recorded as part of the transcript for the participant. Interviewees will be contacted at least one week prior to the interview date. Interviews will be audio-recorded, transcripts will be anonymised and entered into the qualitative data analysis tool Nvivo (Version 12.0) to facilitate data management.

#### 4.1.4.2 Interview topic guide

An iterative process will inform the ongoing development of the interview topic guide (including PPIE input).

### *4.1.5* Cross-industry review and survey study

*Months 3-14; with survey data collection in months 11-14*

We will complement insights gained from empirical work at the study sites with cross-industry and cross-sector perspectives on the use of, and strategy for implementing, command and control centres to improve quality and safety within high-risk operations. Integrating information systems within centralised command and control structures within safety-critical industries such as air traffic control, rail transport, nuclear power and military/naval applications. In order to facilitate transfer of this knowledge into the health care sector, we will undertake a cross-industry review as part of our work, comprising qualitative literature review and consultation with subject-matter experts in a range of safety-critical domains. Such an approach has been applied successfully in previous work, which sought to elicit and apply knowledge from high risk industry to the development of incident reporting systems in healthcare [74]. Data collection will involve scoping the literature in a range of domains for conceptual and empirical models of causal mechanisms for centralised command and control. We will

additionally consult with up to 10 industry experts, including representatives of similar command centre programmes in other health systems, accessed through UK health care human factors and other professional networks. The results will be synthesised to inform analysis and interpretation of our qualitative and ethnographic data. We will seek to produce evidence-based criteria or a maturity framework for command centre implementation at hospital sites.

In order to understand variations in electronic data-facilitated command and control within hospitals beyond the two research sites we will conduct a survey of the perceptions of Chief Information Officers in acute care across England and Wales. The survey instrument will capture views on current practices in data-supported operational planning and control, the costs-benefits of investment in centralised command and control "centres", information/data readiness, implementation barriers and perceptions of the need for further development in this area. The sampling target will be a census of CIOs, who will be contacted through relevant professional networks (accessed through our team of collaborators which includes senior CIOs) and invited to complete and return either an online or paper-based survey

#### 4.1.5.1 Interviews with subject-matter experts

*Months 11-14*

We will additionally consult with up to 10 industry experts, including representatives of similar command centre programmes in other health systems, accessed through UK health care human factors and other professional networks. An interview topic guide will be developed, informed through the literature review and qualitative work.

#### 4.1.5.2 Survey study

*Months 11-14*

In order to understand variations in electronic data-facilitated command and control within hospitals beyond the two research sites we will conduct a survey of the perceptions of Chief Information Officers (CIO) in acute care across England and Wales (minimum n=40). The survey instrument will be developed through literature review and informed by the qualitative interviews. The survey will capture views on current practices in data-supported operational planning and control, the costs-benefits of investment in centralised command and control "centres", information/data readiness, implementation barriers and perceptions of the need for further development in this area. The sampling target will be a census of CIOs, who will be contacted through relevant professional networks (accessed through our team of collaborators which includes senior CIOs) and invited to complete and return either an online or paper-based survey (developed and captured through UoL Online surveys). Once the survey is developed, it and all of the recruitment material for the survey will be sent to the University of Leeds Research Ethics Committee for review and the HRA for their approval before it is used.

Data collection will take place at a single time-point. (months 11-14). Potential survey participants will receive an email with an invitation to complete the survey and up to two reminders will be sent out close to the close of the survey data collection period (4 weeks). Personnel that are invited to complete the survey will be provided with an information sheet about the study and will be asked to

give their informed consent to take part in the research, through indicating that they have read, and agree with the information contained in the aforementioned sheet, at the first stage of completing the survey itself. Completion and submission of the survey online will be taken as consent for participation in the study.

## 4.2 Quantitative

For the quantitative work-stream, we will address aims 1a, 1b and 2d. The initially-proposed quantitative research plan consisted of three components:

1. An interrupted time-series analysis of patient safety metrics;
2. Process mining of patient flow; *and*
3. Assessment of data quality.

The work defines three consecutive periods under investigation:

1. Before the implementation of the Command Centre;
2. During the implementation of the Command Centre;
3. The Command Centre from onset of the COVID-19 pandemic.

The start of subsequent periods must be informed by clinical and administrative input. Ideally, we will have equal durations for each period, which will likely be constrained by period 2.

### *4.2.1 Evaluation of patient safety*

4.2.1.1 Descriptive statistics

The purpose of this work is to describe the data. The measures of interest will partly be informed by early qualitative scoping work but will at least include common Safety-1 measures like count of falls, and the AHRQ Patient Safety Indicators (Appendix 1; Table A4). We will compute summary statistics to populate the output table (Table 1). For the trend plots, provide the best fit from either a linear GLM or a 2$^{nd}$-order polynomial GLM For the trend plots, all measures will be aggregated by month.

**Table 1** Descriptive summary of patient-safety measures for the periods before implementation, during implementation, and the onset of the COVID-19 pandemic, for both sites (exposed and unexposed to the Command Centre). Est' = estimate of regression coefficient, S.E. = standard error of regression coefficient.

| | | <measure 1> | | <measure 2> | | <measure 3> | |
|---|---|---|---|---|---|---|---|
| | | Exposed | Unexposed | Exposed | Unexposed | Exposed | Unexposed |
| Mean | *Before* = | | | | | | |
| | *During* = | | | | | | |
| | *COVID* = | | | | | | |
| Median | *Before* = | | | | | | |

| | | |
|---|---|---|
| | *During* = | |
| | *COVID* = | |
| Minimum | *Before* = | |
| | *During* = | |
| | *COVID* = | |
| 1st Quartile | *Before* = | |
| | *During* = | |
| | *COVID* = | |
| 3rd Quartile | *Before* = | |
| | *During* = | |
| | *COVID* = | |
| Maximum | *Before* = | |
| | *During* = | |
| | *COVID* = | |
| Distribution plot, before implementation | | |
| Distribution plot, during implementation | | |
| Distribution plot, onset of COVID-19 pandemic | | |
| Trend plot, before implementation | | |
| *Intercept* [*Est' (S.E.)*]*:* | | |
| *Slope* [*Est' (S.E.)*]*:* | | |
| Trend plot, during implementation | | |
| *Intercept* [*Est' (S.E.)*]*:* | | |
| *Slope* [*Est' (S.E.)*]*:* | | |
| Trend plot, onset of COVID-19 pandemic | | |
| *Intercept* [*Est' (S.E.)*]*:* | | |
| *Slope* [*Est' (S.E.)*]*:* | | |

4.2.1.2 Interrupted time-series analysis

We will model trends using a three-phase, two-arm, interrupted time-series analysis of variations in aggregate dependent variables,[35] to capture the pre-, during and post-implementation of the AI Command Centre. We will approach the analysis in a responsive manner, adding or removing interrupts in response to unfolding understanding of the AI Command Centre's implementation from our qualitative process evaluation.

Our initial model specification for the interrupted time series analysis is detailed below:

$$Yt = \beta 0 + \beta 1Tt + \beta 2Xt(1) + \beta 3Xt(2) + \beta 4(Tt - t1)Xt(1) + \beta 5(Tt - t2)Xt(2) + \beta 6G + \beta 7GTt + \beta 8GXt(1) + \beta 9GXt(2) + \beta 10G(Tt - t1)Xt(1) + \beta 11G(Tt - t2)Xt(2) + \epsilon tG$$

where $Y_t$ is the aggregate patient-safety metric, $G$ is a binary indicator for the Command Centre site ($G$ = 1), $T_t$ is the time from the start of the pre-implementation phase, $X_t(_{1)}$ is a binary indicator for the start of the implementation phase, $X_t(_{2)}$ is a binary indicator for the start of the post-implementation phase, $t_1$ is the starting time-point of the implementation phase, $t_2$ is the starting time-point of the post-implementation phase, and $\epsilon_{tG}$ represents the error term for both sites (which will be modelled with an appropriate autoregressive structure). The coefficients represent the starting and changing intercept (level) and slope (trend) changes in the dependent variable (Table 2).

**Table 2:** Coefficients in the three-phase, two-arm, interrupted time-series regression model and their representation.

| Coefficient | Representation |
|---|---|
| $\beta_0$ | Pre-implementation intercept for the control site. |
| $\beta_1$ | Pre-implementation slope for the control site. |
| $\beta_2$ | Difference between pre-implementation and implementation intercept for the control site. |
| $\beta_3$ | Difference between implementation and post-implementation intercept for the control site. |
| $\beta_4$ | Difference between pre-implementation and implementation slope for the control site. |
| $\beta_5$ | Difference between implementation and post-implementation slope for the control site. |
| $\beta_6$ | Pre-implementation intercept for the Command Centre site. |
| $\beta_7$ | Pre-implementation slope for the Command Centre site. |
| $\beta_8$ | Difference between pre-implementation and implementation intercept for the Command Centre site. |
| $\beta_9$ | Difference between implementation and post-implementation intercept for the Command Centre site. |
| $\beta_{10}$ | Difference between pre-implementation and implementation slope for the Command Centre site. |
| $\beta_{11}$ | Difference between implementation and post-implementation slope for the Command Centre site. |

Rather than relying on null hypothesis significance testing as proxy for the clinical significance of the output of our statistical models, we will interpret our analysis primarily on effect sizes and their precision, carefully selecting the autoregressive structure to minimise bias, and critically appraising the stability of confounders pre-, during and post-implementation, which might also bias estimates. The effect sizes of interest are:

1. Total effect size – the sum of all intercept and slope changes, standardised by the standard deviation of the error term.
2. Level effect size – the sum of all intercept changes, standardised by the standard deviation of the error term.
3. Trend effect size – the sum of all slope changes, standardised by the standard deviation of the error term.

No clinical guidelines exist for a clinically meaningful change in the metrics being considered, and any such guidance is likely conditional on other clinical characteristics. The effect sizes quoted above are statistical, not clinical. All quoted effect sizes are standardised to units of the error term and thus express how many multiples of our uncertainty the observed "effect" is. The larger the number, the great the "effect"–to–uncertainty ratio and the more persuaded we can be that the "effect" is meaningful, assuming larger changes are more meaningful.

All interrupted time-series analyses will be bootstrapped for 500 repeats to inform a distribution of effect-size estimates.[36] This will help to assess the effect of homogeneity of the data informing the aggregate-data points used in proposed interrupted time-series analyses. This analysis will permit us to make comments about the effect of the variation in patient data on the modelled effect sizes for the AI Command Centre's implementation.

### *4.2.2 Evaluation of patient flow*

This component of the quasi-experimental study will compare process-mined patient journeys through their hospital care between hospitals before and after the ethnographic study, to support a mixed-method evaluation of the effects of a Command Centre.

#### 4.2.2.1 Descriptive statistics

We will calculate descriptive summary statistics common to process mining, adopting multi-level descriptions as per Kurniati et al [37], excluding the model-level statistics (Table 3).

Table 3 Multilevel descriptive statistics of process models.

| Level | Statistic | Description |
|---|---|---|
| Trace | Duration | The length of time, in hours, from the first to last events in patients' event sequences |
| | Variant proportion | The proportion of variants that were one of the most frequent variants in the complete log of patients' event sequences. |

| | | |
|---|---|---|
| Activity | Frequency | The number of patients sequences undergoing an event. |
| | Percentage | The percentage of patient sequences undergoing an event out of all patient sequences. |

#### 4.2.2.2 Choosing a process model

We want to construct a process model that will be representative of the event log from each hospital site. The model will be our best understanding of the dynamics of patient flow, in that hospital. We will determine the best model by comparing the performance of process models constructed using multiple process-mining algorithms. We will measure performance of these models across three, model-level measures [38]:

1. *Replay fitness* is a measure of how many traces from the log can be reproduced in the process model, with penalties for skips and insertions; range 0 – 1.
2. *Precision* is a measure of how 'lean' the model is at representing traces from the log. Lower values indicate superfluous structure in the model; range 0 – 1.
3. *Generalisation* is a measure of generalisability as indicated by the redundancy of nodes in the model. The more redundant the nodes, the more variety of possible traces that can be represented; range 0 – 1.

These statistics are not currently available in R so I will have to write my own based on the information in Van der Aalst, Adriansyah and Van Dongen (2012).

Distributional parameters of these measures will be informed by bootstrapping. The bootstrapped estimates will inform a one-way MANOVA to help inform the choice of the most-representative process model, for each hospital site.

For each site independently, the process-mining algorithms will be constructed from site-specific event logs to discover a representative process model. The mining algorithms of interest will be:

I. Alpha miner
   a. A petri net model.
   b. The R syntax for that model is

```
pm4py::discovery_alpha(myEventlog_<exposed/unexposed>) %>% render_PN()
```

II. Inductive miner
   a. A petri net model.
   b. The R syntax for that model is

```
pm4py::discovery_inductive(myEventlog_<exposed/unexposed>) %>% render_PN()
```

III. Heuristics miner
   a. A causal net model [39]
   b. The R syntax for that model is

```
heuristicsmineR::causal_net(myEventlog_<exposed/unexposed>) %>%
render_causal_net()
```

IV. Fuzzy miner
   a. A fuzzy model.

b. Not on CRAN. Available on GitHub.
c. The R syntax for that model is

```
devtools::install_github("nirmalpatel/fuzzymineR")

fuzzymineR::mine_fuzzy_model(myEventlog_<exposed/unexposed>) %>%
viz_fuzzy_model()
```

For each site independently, for each process model, measures of replay fitness, precision and generalisation will be calculated. The miners will be ranked according to each performance measure, independently. We will use the arithmetic mean rank of the miners across the three performance measures to create the final ranking of the miners. The highest-ranking process model produced by the mining algorithms will be used as our process model, for that site.

For each site independently, for each process model, measures of replay fitness, precision and generalisation will be calculated. The miners will be ranked according to each performance measure, independently. We will use the arithmetic mean rank of the miners across the three performance measures to create the final ranking of the miners. The highest-ranking process model produced by the mining algorithms will be used as our process model, for that site.

For each site and for each mining algorithm, 500 estimates of the performance measures will be calculated using 500 bootstrapped samples cases from the event log. In the R syntax below, it is assumed that the `procMod` argument will be supplied to the `statistic` argument to specify which process model to test. The `statistic` argument refers to my functions for computing the performance measures, which will have arguments for an eventlog and a process model.

The `data` object supplied to the `boot::boot()` command will have to be an R list object, with each element referring to a case and each case containing an R dataframe object of the portion of the eventlog to which that case refers. This is because the `boot::boot()` command samples elements/rows from the `data` object and, since we need it to sample entire cases rather than sample random activities, the `data` object must have entire cases as its element/rows.

For each site independently, we will build a one-way MANOVA model to test whether the vector of mean values of the performance measures are the same for each mining algorithm. Assuming multivariate normality of the dependent variables (as opposed to their residuals), we will use the Mahalanobis distance, *D*, as a difference-in-means type effect size [40]. A $D > 0.5$ will be interpreted as a sufficient standardised multivariate difference in means because it indicates that the combined means are half a standard deviation away from each other. If $D < 0.5$, then we will conclude that the performance of the mining algorithms are not sufficiently different to note. The R syntax for the Mahalanobis distance is:

```
psych::cohen.d(subset(MANOVA_data["SiteID"=="<exposed/unexposed>",], select =
-SiteID) ~ Miner)$M.dist
```

If multivariate normality of the dependent variables (as opposed to their residuals) cannot be assumed, then I will use Grissom and Kim's (2012) multivariate omega-squared to report the effect size for the MANOVA. This is a variance-based approach and so is less intuitive. We will adopt a threshold of $\omega^2_{multi} > 0.5$ because it indicates something like the proportion of variance in the dependent variables that remains after accounting for the variance in the independent variable(s). A

$\omega^2_{multi}$> 0.5 indicates that at least half of the variation in the dependent variables might be due to the independent variable. The R syntax for the multivariate omega-squared is below, which will need amending for the adjusted case.

```
wilks <- summary(MANOVA_mod_<exposed/unexposed>, test = "Wilks")$stats[1,'Wilks'] # Extract Wilks' lambda.

omega_sqrd <- 1 - (( nrow(MANOVA_mod_<exposed/unexposed>$model) * wilks ) / ((nrow(MANOVA_mod_<exposed/unexposed>$model) - 4) + wilks)) # Compute multivariate omega-squared for the site variable.
```

If the MANOVA suggests insufficient effect sizes, then no further analyses of variance will be conducted. If the effect sizes are sufficient, then one-way ANOVAs will be conducted on pairs of algorithms

If the all-miner MANOVA does not satisfy the Mahalanobis threshold, then the previous ranking protocol will determine the process model to be used in further work. If the all-miner MANOVA does satisfy the Mahalanobis threshold, then for the purpose of selecting the best performing process model, we will build one-way MANOVA models to test whether the vector of mean values of the performance measures are the same for pairs of mining algorithms. The only difference in the protocol from the all-miner MANOVA is that multiple models will be built with subsets of the MANOVA_data R dataframe object. The subsetting of the data is defined by the six pairs of miners:

| | *Inductive* | *Heuristic* | *Fuzzy* |
|---|---|---|---|
| *Alpha* | 1 | 2 | 3 |
| *Inductive* | - | 4 | 5 |
| *Heuristic* | - | - | 6 |

The Mahalanobis distance will used to rank the algorithms (higher scores rank higher) and the process model from the highest ranking algorithm will be selected.

#### 4.2.2.3 Sensitivity analysis of mining algorithm

We want to understand the sensitivity of performance measures to the choice of mining algorithm to quantify the differences that might have occurred if we chose a different mining algorithm. . Performance will be measured using the same three performance measures previously used to choose the 'best' model: replay fitness, precision, and generalisation [38]. Distributional parameters of these measures will be informed by bootstrapping. The bootstrapped estimates will inform a two-way MANOVA (site and miner).

#### 4.2.2.4 Inferential statistical analysis of exposure and period

If data are available from the exposed site for all periods, then we will conduct appropriate inferential statistical analyses to infer whether the patient-flow measures were similar across periods and sites.

### *4.2.3 Evaluation of hospital data quality*

This study will compare the quality of data between hospitals before and after the ethnographic study, to support a mixed-method evaluation of the effects of a Command Centre. The data-quality assessment (DQA) has four parts:

1. Variable identification
2. Scope identification
3. Quality measurement
4. Descriptive statistics
5. Inferential Statistics

#### 4.2.3.1 Variable identification

The case-description work in the qualitative work-stream will define the Command Centre tiles of interest. The data presented or used to inform variables that are presented on these tiles will be requested as data abstracts, from both sites.

We will require clinical input to determine the expected attributes of the variables of interest. The output from this step will be a table with the following columns:

1. Variable name
2. Associated Command Centre tile
3. Expected completeness
    - Clinical- and Administration-informed rule(s) that describes the sufficient quantity for the variable, e.g. if a patient has a weekly timestamp in their record but blood pressure is only expected to be taken fortnightly, then we should not consider empty entries every other week as incomplete.
4. Plausible range
    - The typical maximum and minimum values of the variable.
5. Inferred variables
    - The other variables whose values can be inferred from this variable's value, e.g. a diabetes diagnosis may imply abnormal glucose values.
6. Inferred variable value
    - The value of the other variables whose values can be inferred from this variable's value.
7. Plausible trend rule(s)
    - This column relates only to variables whose values can change over time but only in expected ways. It describes the clinical- and administration-informed rule(s) for identifying implausible trends, e.g. height should not increase drastically for adults.
8. Expected timeframe
    - Clinical- and Administration-informed rule(s) describing the period within which this variable's data should be recorded.
9. Expected sequence
    - Where appropriate, clinical- and administration-informed rule(s) that specify which other variables are expected to precede and follow this variable.
10. Regularity
    - Where appropriate, the expected regularity of the variable, e.g. hourly or weekly.

From this variable-identification stage, we will determine how far back in the EHR we will need to extract data to inform the DQA. Importantly, this duration defines how far *back* we will extract data *before* the ethnographic study, and how long we will have to wait *after* the end of the ethnographic study to extract the post-ethnographic study data. For example, if three-months of data are needed to assess the data quality, then we will not be able to request a data extract for the second DQA until three months after the end of the ethnographic study, i.e. June 2022. It might be a tight squeeze to finish the work on time depending on the length of this extract period, the time taken to receive the extract, and the time taken to conduct the DQA.

#### 4.2.3.2 Scope identification

In line with the 3x3 DQA guidelines [42], the following Level-1 questions must be answered:

- Does your study involve more than one patient?
- Does your study involve more than on variable?
- Does your study require information from more than on point in time for each patient?

Our answers to these Level-1 questions are 'Yes', so the only relevant Level-2 question is:

- Does your study involve following more than on variable for multiple patients over time?

It is expected that the answer is 'Yes', so the relevant Level-3 questions are:

12. Do you have a specific time frame(s) of interest?
13. Do you require or expect that variables be recorded in a certain order?
14. Do you require more than one data point for one or more of your variables?
    a. Do you require that your data be recorded with a certain frequency or regularity over time?

The Level-3 questions will be answered by the research team as the information becomes available. This will inform a guideline table that instructs which elements of data quality will need to be assessed.

#### 4.2.3.3 Quality measurement

Data will be aggregated by month. We will use Weiskopf *et al.*'s (2017) 3x3 matrix to assess the quality of healthcare data, which maps Patient, Variables and Time data items in terms of Completeness, Correctness and Currency. Further detail on how to implement the 3x3 matrix is available in [42]:

| | A: Complete | B: Correct | C: Current |
|---|---|---|---|
| 1: Patients | 1A<br>There are sufficient data points for each patient | 1B<br>The distribution of values is plausible across patients | 1C<br>All data were recorded during the timeframe of interest |
| 2: Variables | 2A<br>There are sufficient data points for each variable | 2B<br>There is concordance between variables | 2C<br>Variables were recorded in the desired order |
| 3: Time | 3A | 3B | 3C |

| | | | |
|---|---|---|---|
| | There are sufficient data points at each time | The progression of data over time is plausible | Data were recorded with the desired regularity over time. |

#### 4.2.3.4 Descriptive statistics

The purpose of this work is to describe the data. We will calculate descriptive summary statistics of the data-quality measures computed in the previous stage of the work.

#### 4.2.3.5 Inferential statistics

If data are available from the exposed site for all periods, then we will conduct appropriate inferential statistical analyses to infer whether the data-quality measures were similar across periods and sites.

# 5 STUDY SETTING

The experimental site is Bradford Teaching Hospitals NHS Foundation Trust (BTHFT) with its underlying electronic health record system and newly-developed AI Command Centre. The second site will be a suitable control within the Yorkshire and Humber region.

Bradford is typical of UK cities in terms of social deprivation indices, patterns of illness and characteristics of secondary care services. It is the fifth largest metropolitan district in the UK and the 8th most deprived health community in the UK, with high levels of morbidity. Approximately 20% of its 534,300 people are of South Asian origin. We envisage that the populations covered are sufficiently large and diverse to reflect practice in much of the UK. Both hospital trusts have recently implemented Cerner Millennium, a comprehensive electronic patient record system that is well established in the USA and in growing use in the UK and worldwide.

Our target population are therefore hospital patients, including those attending outpatients, and hospital-based staff at both trusts. We are asking the hospitals to allow us to collect aggregated, anonymised patient data and system use event logs for alerts and actions in order to explore patient safety outcomes. We will ensure that we adequately explain that we are interested in general patterns and trends, rather than individual, team or service activity.

# 6 SAMPLE AND RECRUITMENT

## 6.1 Eligibility Criteria

For the qualitative work-stream, we will recruit only staff at Bradford Royal Infirmary and the control site in key roles relative to the initiative under study. No other inclusion or exclusion criteria will be applied. The quantitative work-stream will not apply any specific inclusion criteria to its data extract.

### *6.1.1 Inclusion criteria*

See above.

### *6.1.2 Exclusion criteria*

See above.

## 6.2 Sampling

### 6.2.1 *Size of sample*

For the qualitative work-stream, up to 40 NHS staff will be asked to take part in qualitative research interviews, sampled evenly from both sites; up to 20 NHS staff will be asked to take part in ethnographic observations at the Bradford site; up to 10 cross-industry experts will be asked to take part in qualitative research interviews; and up to 40 hospital information personnel will be asked to take part in a survey, sampled evenly from both sites.

For the quantitative work-stream, the studies on data quality and patient flow do not require sample-size estimations or power calculations because they are descriptive studies and neither involve null hypothesis significance testing. Our proposed interrupted time-series analysis of patient-safety metrics uses regression analysis that can involve null hypothesis significance testing of the regression coefficients. Given that the dependent variables in the interrupted time-series analyses are aggregate metrics, the power of the models is determined by the count of time-points in each phase rather than the count of data supporting each time-point's summary estimate.[35] The duration of each phase in the proposed three-phase analysis will be determined by scoping work so the exact count of time-points for each phase cannot be determined in advance for power estimation. Here, we assume the same count of time-points in each phase of the interrupted time-series analyses. Alongside the actual analysis, we will use simulation methods to estimate the power of our regression model specifications, given the count of time-points used in the final models. Should the implementation phase of the three-phase model not contain sufficient time-points (i.e. approximately less than eight[44]), we will censor the implementation phase and conduct a disconnected, two-phase analysis.

### *6.2.2 Sampling technique*

For the quantitative work-stream, we will use complete sampling of electronic patient records. The duration of relevant periods will be informed by the initial case description and unstructured observations in the qualitative work stream, which will sensitise us to the information handled by the Command Centre. At a minimum, our patient safety study will require data from patients with electronic health records entries six months prior to the implementation of the Command Centre. This is to satisfy statistical requirements for a minimum number of data points per period, where our data points are monthly aggregates.

For the qualitative work-stream, sampling will be theoretically informed in accordance with qualitative research practices, to maximise variation in stakeholder perspectives. We anticipate that this number of interviews will allow us to achieve data saturation on key themes emerging from inductive analysis.

## *6.3* Recruitment

### *6.3.1 Sample identification*

For the quantitative work, we will use secondary data of de-identified electronic patient health records from at least 6 months prior to the implementation of the Command Centre.

For the qualitative work, we will recruit only staff at Bradford Royal Infirmary and the control site in key roles relative to the initiative under study. Posters detailing that the observations are being conducted will be placed around the AI Command Centre at the time of the observations. For formal interviews, potential participants will be identified through the clinical lead. Further details for each of the qualitative research activities are below.

#### 6.3.1.1 Interviews

We will recruit staff in key roles relative to the AI Command Centre initiative to participate in semi-structured interviews during our preliminary COVID-19 related work. We will recruit staff at the hospital sites in key roles relative to hospital-operational planning to participate in qualitative interviews with the research lead. Data collection will take place across the course of the project. Interview participants will be contacted at least one week prior to the interview date.

Staff in key roles relative to the initiative will be invited to participate in qualitative interviews with members of the evaluation team. Data collection will take place across the course of the project. Interview participants will be contacted at least one week prior to the interview date.

#### 6.3.1.2 Ethnographic observations

Staff working in the AI Command Centre during unstructured observation periods will be made aware of that the observations for research purposes will be taking place prior to their working shift. This will be communicated to them through the AI Command Centre Lead. Any staff member that does not wish to be involved in the data being collected can contact the researcher to request that the researcher does not record any information concerning them.

#### 6.3.1.3 Survey

We will recruit a representative sample of stakeholders across industries and across hospitals. Sampling will be drawn from a range of disciplines to maximise variation in stakeholder perspectives. Potential participants will be identified through our links with professional and safety science networks. Online survey administration will be used. Data collection will take place at a single time-point. Potential survey participants will receive an email with an invitation to complete the survey and up to two reminders will be sent out close to the close of the survey data collection period (4 weeks).

### *6.3.2 Consent*

The following subsection present details of our consent processes. In addition to these specifics, staff will be told that they do not have to take part in the research if they wish and that they can withdraw their participation up to the point where their data has been anonymised in the analysis process. Withdrawal will be possible for up to two weeks following the research interview and up to one week following completion of the survey.

Potential participants will be given as long as they need to decide whether to take part or not, as long as this is within the recruitment and data collection time frame (e.g. staff will be given enough time to decide whether to participate, up to the commencement of the interviews). Interview participants will be contacted at least one week prior to the interview date with an invitation to participate and may

subsequently decline up to the point of commencement of the interview. The data collection window for the survey will be four weeks from the initial invitation to complete the survey until survey close and participants will therefore have four weeks in which to decline. As the survey is voluntary, declining participants need simply not respond to the invitation.

Potential participants are members of staff employed through NHS trusts and cross-industries in the UK. We anticipate that they will adequately understand verbal and written information given in English.

The research does not involve any element of deception.

#### 6.3.2.1 Quantitative work-stream

The quantitative work stream will analyse existing data provided by the participating hospitals. The data of interest will be from patients with electronic health records entries within the time periods relevant to the three studies on patient safety, patient flow and data quality. We will not request patients' data that was entered outside of these time periods, nor will we request data from patients that do not have new entries in these periods.

The data of interest will have been de-identified and processed by the hospitals' data teams and submitted to the Yorkshire and Humber Care Record (https://yhcr.org; a regional integration of health and care records that can be used for research purposes). Our analysis of this data will not require us to approach patients whose data is being studied but will require a standard contract of use with Yorkshire and Humber Care Record. The quantitative work stream will not require any communication with the patients whose data is being studied.

#### 6.3.2.2 Ethnographic observations

Our approach to consent is for personnel that work in the Command Centre to be provided with an information sheet about the study and will be asked to give their informed consent to take part in the research, through indicating that they have read, and agreed with the information contained in the aforementioned sheet

#### 6.3.2.3 Interviews

Our approach to consent will be used to ask staff about whether they would be interested in taking part in the study by verbally explaining the key aspects of the study. If they are interested in taking part, the researcher will provide written information and will review this with the staff. Staff will be given some time to review the information and ask questions, according to their need and preference. The researcher will invite staff to participate in the research. Potential participants will receive an information leaflet about the study. If they decide to take part, the researcher and participant will complete a written consent form. A copy of the consent form will be retained by the member of staff and also by the researcher. In instances where interviews are conducted over the telephone, the interviewee will have sight of the information sheet and will be asked to confirm that they have read it and be given the opportunity to ask any questions. In accordance with the University of Leeds Verbal Consent Protocol, the participant will be asked to verify their verbal consent at the beginning of the recording of the interview and this conversation will be recorded as part of the transcript for the participant

#### 6.3.2.4 Survey

Our approach to consent is for personnel invited to complete the survey to be provided with an information sheet about the study and will be asked to give their informed consent to take part in the research, through indicating that they have read, and agree with the information contained in the aforementioned sheet, at the first stage of completing the survey itself. Completion and submission of the survey online will be taken as consent for participation in the study.

# 7 ETHICAL AND REGULATORY CONSIDERATIONS

## 7.1 Assessment and management of risk

A fieldwork risk assessment has been completed and approved for site visits by qualitative researchers. A risk register has been created and regularly updated during the start-up phase of the project. The risk register details risks and mitigations, and will be updated at monthly Project Management Group meetings.

## 7.2 Research Ethics Committee (REC) and other Regulatory review & reports

This protocol has been reviewed and approved by the University of Leeds Engineering and Physical Sciences Research Ethics Committee (# MEEC 20-016) and the Health Research Authority ('#)

## 7.3 Peer review

This protocol was developed by a multi-disciplinary team of expert co-applicants and by the NIHR as part of the NIHR 19/16 HSDR Digital Technologies to Improve Health and Care funding processes.

## 7.4 Patient & Public Involvement

As stated in our initial bid, we have developed the following activities to ensure active, meaningful and contributory involvement of patient and public perspectives.

### *7.4.1 Hospital visitor survey*

In the foyer of Bradford Royal Infirmary, there is a display wall showcasing the example screens from the Command Centre, with information leaflets available for visitors to find out more about the Command Centre. We have arranged for a short survey to be collected at the display wall to understand hospital visitors' acceptability and opinions of the Command Centre. This information will be used to sensitise subsequent qualitative work to the expectation of patients, which might impact the successful implementation of the Command Centre.

### *7.4.2 Grounding Workshops*

Two workshops will be held –one at each hospital –where patients and the public will be invited to discuss their perspectives on hospital management systems and their relationship to patient journeys. In light of COVID restrictions, we have prepared online workshops for remote participation.

In the grounding workshop, we will explore:

- What is important to you when you visit a hospital?
- What do you feel about a hospital management being carried out using the Command Centre?

- How do you feel about AI technology helping the way that patient care is prioritised within hospital?

The output of the workshops will sensitise the qualitative research team and directly inform the case vignettes that will comprise the qualitative work-stream. The workshops will be co-planned and co-led by our patient-and-public co-applicant and members of the research team. Advice will also be sought from our research Centre's PPI research fellow.

#### *7.4.3 Extending Workshop*

In a final workshop –hosted at a neutral site or online –the findings of the project will be discussed with patients and the public to:

- Report findings;
- Help interpret findings; *and*
- Inform non-academic communication plans.

The intention of the workshop is two-fold. On the one hand, it is to communicate the outputs of the research to the patients and public who not only have helped with the research but who are the ultimate beneficiaries of the work. On the other hand, the intention of the workshop is to continue the collaboration with patient and public by integrating their perspectives into interpretation and official communications.

#### *7.4.4 Co-development of case vignettes*

Based on the outputs from the workshops and the case descriptions, our patient-and-public co-applicant and the qualitative research team will co-develop the case vignettes that will form the topics of the qualitative work-stream.

#### *7.4.5 Academic communication*

Our patient-and-public co-applicant, who lead the Extending Workshop, will be a co-author in academic publications of the work. Specifically, our patient-and-public co-applicant will author a 'PPI perspective' section of the publications that will discuss the PPI activities related to the work, and, as co-author, will review the manuscript prior to submission. Additionally, we have budgeted for our patient-and-public co-applicant to present the patient and public perspectives of the research at an appropriate academic conference.

#### *7.4.6 Support*

Travel for patients attending the various workshops has been budgeted. Training for blog writing and presentation will be provided should the need arise for our patient-and-public co-applicant.

#### *7.4.7 Oversight groups*

Our Project Advisory Group / Study Steering Group includes an independent patient-and-public representative, and our Project Management Group includes our patient-and-public co-applicant.

### 7.5 Protocol compliance

Day-to-day compliance with this protocol is the responsibility of the Chief Investigator, will be managed by the Project Management Group, and will be overseen for the life of the project by the Sponsor.

## 7.6 Data protection and patient confidentiality

The electronic health records used in the quantitative work will not be copied for storage or back-up, by the research team. Instead, it will be hosted by the Yorkshire and Humber Care Record and accessed via their virtual research environment. The Yorkshire and Humber Care Record system is built on Google Cloud technology with Identity Access Management following the principle of least privilege, i.e. minimum permissions of access and functionality. Google Cloud technology is compliant with GDPR, ISO/IEC 27001, ISO/IEC 27017, ISO/IEC 27018, ISO/IEC 27701, NHS Digital Commercial Third-Party Information Governance Requirements, UK's Cloud Security Principles. Further details are available at https://cloud.google.com/security/compliance.

Toward the end of the project, summative research output for publications and all R scripts used for data processing will be exported from the Yorkshire and Humber Care Record portal and stored on the University of Leeds SAN (Storage Area Network), which comprises enterprise level disk storage and file servers located in physically secure data centres with appropriate fire suppression equipment. Snapshots are taken every day at 10pm (and accessible for 1 month). A second level of snapshots is taken every month and are kept for 11 months. Snapshots are user recoverable from the desktop.

A full back-up to tape is taken once every month and an incremental copy to backup tape is taken every night (and kept for 28 days). Every quarter, the most recent set of full dump tapes are moved to a long-term storage facility where they are kept for 12 months. Tapes are initially stored in on-campus fireproof safes and then moved to off-campus secure locations. The SAN is located behind the University's Institutional firewall to protect against external attacks.

During the life of the qualitative work, the data will be stored on the University of Leeds SAN. The audio-recording equipment will be encrypted. Survey data will be stored in UoL Online Surveys.

## 7.7 Indemnity

University of Leeds indemnity applies to the design and management of the research (see appendix 4). The NHS indemnity scheme applies to legal liability of investigators and collaborators arising from harm to participants in the conduct of the research on NHS sites.

## 7.8 Access to the final study dataset

Data studied as part of the quantitative work-stream will not be stored or shared by the research team, in accordance with the Data Sharing Agreement from the data controller, Yorkshire and Humber Care Record. Summary data that is permitted for extraction by the data controller for publication will be stored in association with respective publications in University of Leeds' Research Data Leeds Repository. All statistical code for generating the results will also be stored with the extracted summary data in the University of Leeds Research Data Repository (Research Data Leeds) or another appropriate data repository service in order to ensure the data can be shared, reused and cited beyond the end of the project. Research Data Leeds holds deposited data for a minimum of 10 years and datasets are associated with digital object identifiers (DOIs).

All data stored within the Research Data Leeds Repository (from all project work-streams) will only be accessible on request and following approval criteria that will be co-developed by the research team and the data repository service. Further details are available in the latest Data Management Plan in Appendix 3.

# 8 DISSEMINIATION POLICY

## 8.1 Dissemination policy

### *8.1.1 Publication review requirements*

For any publications involving work from the quantitative work-stream, draft publications must be submitted to the Director of Research at the Bradford Teaching Hospitals NHS Foundation Trust at least one month prior to submission. This is to comply with the Data Sharing Agreement from the data controller, Yorkshire and Humber Care Record.

The research team will not be required to submit advance notification of publication to NIHR via the NETSCC Management Information System, as stated in the Welcome Booklet sent to the research team in July 2020. NIHR policy has been updated since September 2020. Notification to NIHR will be via ResearchFish accounts associated with the project. Full guidance on NIHR research outputs and publications is available here, as of Feb 2021.

### *8.1.2 Acknowledgements*

In all publications relating to this project, the following acknowledgements must be made:

- This study/project is funded by the National Institute for Health Research (NIHR) Health Services and Delivery Research Programme (NIHR129483). The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.
- This research is supported by the National Institute for Health Research (NIHR) Yorkshire and Humber Patient Safety Translational Research Centre (NIHR Yorkshire and Humber PSTRC). The views expressed in this article / presentation are those of the author(s) and not necessarily those of the NHS, the NIHR, or the Department of Health and Social Care.

### *8.1.3 Access to final report*

The final report will be made available to the public via the NIHR Journals Library.

### *8.1.4 Access to materials generated by the project*

A plain-English summary and project abstract are available from the project's NIHR Funding and Award webpage. Author's accepted manuscripts of publications will be stored in the University of Leeds repository via researchers' Symplectic accounts, and publically available. Access to data generated by the research activities is specified in section 8.8.

## 8.2 Authorship eligibility guidelines and any intended use of professional writers

For both the final report and for peer-reviewed journal articles, we will follow the guidance form The International Committee of Medical Journal Editors.

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# 10 APPENDICIES

## 10.1 Appendix 1 – Agency for Healthcare and Research Quality Patient Safety Indicators.

**Table A4** Patient safety indicators.

| | Code | Measure | Explanation |
|---|---|---|---|
| 1 | AHRQ_PSI02 | Death rate in low-mortality diagnosis groups | In-hospital deaths per 1,000 discharges for low mortality (< 0.5%) Diagnosis Related Groups (DRGs) among patients ages 18 years and older or obstetric patients. Excludes cases with trauma, cases with cancer, cases with an immunocompromised state, and transfers to an acute care facility |
| 2 | AHRQ_PSI03 | Pressure ulcer rate | Stage III or IV pressure ulcers or unstageable (secondary diagnosis) per 1,000 discharges among surgical or medical patients ages 18 years and older. Excludes stays less than 3 days; cases with a principal stage III or IV (or unstageable) pressure ulcer diagnosis; cases with a secondary diagnosis of stage III or IV pressure ulcer (or unstageable) that is present on admission; obstetric cases; severe burns; exfoliative skin disorders |
| 3 | AHRQ_PSI04 | Death rate among surgical inpatients with serious treatable complications | In-hospital deaths per 1,000 surgical discharges, among patients ages 18 through 89 years or obstetric patients, with serious treatable complications (deep vein thrombosis/ pulmonary embolism, pneumonia, sepsis, shock/cardiac arrest, or gastrointestinal hemorrhage/acute ulcer). Includes metrics for the number of discharges for each type of complication. Excludes cases transferred to an acute care facility and cases in hospice care at admission |
| 4 | AHRQ_PSI05 | Retained surgical item or unretrieved device fragment count | The number of hospital discharges with a retained surgical item or unretrieved device fragment (secondary diagnosis) among surgical and medical patients ages 18 years and older or obstetric patients. Excludes cases with principal diagnosis of retained surgical item or unretrieved device fragment and cases with a secondary diagnosis of retained surgical item or unretrieved device fragment present on admission |
| 5 | AHRQ_PSI06 | Iatrogenic pneumothorax rate | Iatrogenic pneumothorax cases (secondary diagnosis) per 1,000 surgical and medical discharges for patients ages 18 years and older. Excludes cases with chest trauma, pleural effusion, thoracic surgery, lung or pleural biopsy, diaphragmatic repair, or cardiac procedures; cases with a principal diagnosis of iatrogenic pneumothorax; cases with a secondary diagnosis of iatrogenic pneumothorax present on admission; and obstetric cases |
| 6 | AHRQ_PSI07 | Central venous catheter-related blood stream infection rate | Central venous catheter-related bloodstream infections (secondary diagnosis) per 1,000 medical and surgical discharges for patients ages 18 years and older or obstetric cases. Excludes cases with a principal diagnosis of a central venous catheter-related bloodstream infection, cases with a secondary diagnosis of a central venous catheter-related bloodstream infection present on admission, cases with stays less than 2 days, cases with an immunocompromised state, and cases with cancer |
| 7 | AHRQ_PSI08 | In-hospital fall with hip fracture rate | In hospital fall with hip fracture (secondary diagnosis) per 1,000 discharges for patients ages 18 years and older. Excludes discharges with principal diagnosis of a condition with high susceptibility to falls (seizure disorder, syncope, stroke, occlusion of arteries, coma, cardiac arrest, poisoning, trauma, delirium or other psychoses, anoxic brain injury), diagnoses associated with fragile bone (metastatic cancer, lymphoid malignancy, bone malignancy), a principal diagnosis of hip fracture, a secondary diagnosis of hip fracture present on admission, and obstetric cases |

| | | | |
|---|---|---|---|
| 8 | AHRQ_PSI09 | Perioperative haemorrhage or haemotoma rate | Perioperative hemorrhage or hematoma cases involving a procedure to treat the hemorrhage or hematoma, following surgery per 1,000 surgical discharges for patients ages 18 years and older. Excludes cases with a diagnosis of coagulation disorder; cases with a principal diagnosis of perioperative hemorrhage or hematoma; cases with a secondary diagnosis of perioperative hemorrhage or hematoma present on admission; cases where the only operating room procedure is for treatment of perioperative hemorrhage or hematoma; obstetric cases |
| 9 | AHRQ_PSI10 | Post-operative acute kidney injury requiring dialysis | Postoperative acute kidney failure requiring dialysis per 1,000 elective surgical discharges for patients ages 18 years and older. Excludes cases with principal diagnosis of acute kidney failure; cases with secondary diagnosis of acute kidney failure present on admission; cases with secondary diagnosis of acute kidney failure and dialysis procedure before or on the same day as the first operating room procedure; cases with acute kidney failure, cardiac arrest, severe cardiac dysrhythmia, cardiac shock, chronic kidney failure; a principal diagnosis of urinary tract obstruction and obstetric cases |
| 10 | AHRQ_PSI11 | Post-operative respiratory failure rate | Postoperative respiratory failure (secondary diagnosis), prolonged mechanical ventilation, or reintubation cases per 1,000 elective surgical discharges for patients ages 18 years and older. Excludes cases with principal diagnosis for acute respiratory failure; cases with secondary diagnosis for acute respiratory failure present on admission; cases in which tracheostomy is the only operating room procedure or in which tracheostomy occurs before the first operating room procedure; cases with neuromuscular disorders; cases with laryngeal, oropharyngeal or craniofacial surgery involving significant risk of airway compromise; esophageal resection, lung cancer, lung transplant or degenerative neurological disorders; cases with respiratory or circulatory diseases; and obstetric discharges |
| 11 | AHRQ_PSI12 | Perioperative pulmonary embolism or deep vein thrombosis rate | Perioperative pulmonary embolism or proximal deep vein thrombosis (secondary diagnosis) per 1,000 surgical discharges for patients ages 18 years and older. Excludes discharges with a principal diagnosis of pulmonary embolism or proximal deep vein thrombosis; with a secondary diagnosis of pulmonary embolism or proximal deep vein thrombosis present on admission; in which interruption of the vena cava or a pulmonary arterial thromboectomy occurs before or on the same day as the first operating room procedure; with extracorporeal membrane oxygenation; with acute brain or spinal injury present on admission; and obstetric cases |
| 12 | AHRQ_PSI13 | Post-operative sepsis rate | Postoperative sepsis cases (secondary diagnosis) per 1,000 elective surgical discharges for patients ages 18 years and older. Excludes cases with a principal diagnosis of sepsis, cases with a secondary diagnosis of sepsis present on admission, cases with a principal diagnosis of infection, cases with a secondary diagnosis of infection present on admission (only if they also have a secondary diagnosis of sepsis), obstetric discharges |
| 13 | AHRQ_PSI14 | Post-operative wound dehiscence rate | Postoperative reclosures of the abdominal wall with a diagnosis of disruption of internal operational wound per 1,000 abdominopelvic surgery discharges for patients ages 18 years and older. Excludes cases in which the abdominal wall reclosure occurs on or before the day of the first abdominopelvic surgery, cases with an immunocompromised state, cases with stays less than two (2) days, and obstetric cases. Cases are included if they have a diagnosis code of disruption of internal surgical |
| 14 | AHRQ_PSI15 | Unrecognised abdominopelvic accidental puncture or laceration rate | Accidental punctures or lacerations (secondary diagnosis) per 1,000 discharges for patients ages 18 years and older who have undergone an abdominopelvic procedure; in which a second abdominopelvic procedure follows one or more days after an index abdominopelvic procedure. Excludes cases with accidental puncture or laceration as a principal diagnosis, cases with accidental puncture or laceration as a secondary diagnosis that is present on admission, and obstetric cases |

| | | | |
|---|---|---|---|
| 15 | AHRQ_PSI16 | Birth trauma rate - injury to neonate | Birth trauma injuries per 1,000 newborns. Excludes preterm infants with a birth weight less than 2,000 grams, and cases with osteogenesis imperfecta |
| 16 | AHRQ_PSI17 | Obstetric trauma rate – vaginal deliver with instrument | Third and fourth degree obstetric traumas per 1,000 instrument-assisted vaginal deliveries |
| 17 | AHRQ_PSI18 | Obstetric trauma rate – vaginal deliver without instrument | Third and fourth degree obstetric traumas per 1,000 vaginal deliveries. Excludes cases with instrument-assisted delivery |
| 18 | AHRQ_PSI90 | Patient safety for selected indicators (this is a composite score using some of the above) | The weighted average of the observed-to-expected ratios of PSI03, PSI06, PSI08, PSI09, PSI10, PSI11, PSI12, PSI13, PSI14, PSI15 |

## 10.2 Appendix 2 – Project Management Plan / Gantt chart

See attached 'Project plan.xlsx'

## 10.3 Appendix 3 – Data Management Plan

See attached 'v2.0 Leeds_DMP.docx'

## 10.4 Appendix 4 – University of Leeds Indemnity

See attached