Protocol V6 10th January 2025

Full project title: Quality, safety and clinical governance in NHS and independent hospitals: lessons from the interface

Short title: Quality, safety & clinical governance in NHS & independent hospitals

Duration: 36 months, 1st January 2023 – 31st December 2025

End of study: The end of study will be 31st December 2025.

Funding This study is funded (£977,551.33) by the National Institute for Health and Care Research (NIHR) HSDR programme (project reference NIHR135108). The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.

Research reference numbers:

NIHR HSDR Project reference number: NIHR135108

IRAS Project ID: IRAS 322163 (application pending)

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Signatures

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor's SOPs, and other regulatory requirement.
I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor
I also confirm that I will make the findings of the study publically available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

For and on behalf of the Study Sponsor:
Signature: Date:
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Name (please print):
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Position:
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Chief Investigator:
Signature: Date:
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Name: (please print):
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Version	Author	Purpose	Date
V1	Kieran Walshe		06/02/2023
V2	Kieran Walshe	• An amendment was made to specify the inclusion and exclusion criteria across work packages. • Detail was added on the accessing of datasets and the recruitment of case study sites. • The research ethics section was developed to outline relevant approvals required, key ethical concerns and considerations and data collection and storage.	15/03/2023
V3	Kieran Walshe	• Detail was added on the monitoring of the diversity of samples under work packages 2, 3 and 5.	03/05/2023
V4	Kieran Walshe	• An amendment was made to clarify detail regarding how data obtained from NHS England would be processed, and to provide additional information on contact information for survey respondents.	03/11/2023
V5	Kieran Walshe	• An amendment was made to the planned analysis using the ADAPt dataset, which is no longer available, and detail added on the recruitment of patients and carers as part of WP5.	29/07/2024
V6	Kieran Walshe	• An amendment was made to adjust the timelines of the project following a 6-month extension of the project. • Additional information was added regarding the use of the services of Be Part of Research to recruit patient and carers for interview as part of WP5.	10/01/2025

Detailed research plan

Plain English summary

Every patient has the right to expect safe, high quality care whether they are treated in an NHS hospital or an independent hospital. We propose new research to help understand and improve the quality and safety of patient care in NHS and independent hospitals. Independent hospitals are private sector organisations which provide health care to patients who pay, directly or through private insurance, and which are often also contracted to provide care for some patients funded by the NHS. We will learn about the systems which oversee the quality and safety of patient care, which are often termed “clinical governance”. Good clinical governance is the foundation of good patient care.

There are longstanding concerns among policymakers and leaders in both the NHS and independent healthcare sectors about the quality and safety of care, and the need for improvement has been highlighted. For the first time, in 2022, information about all patients treated in both NHS and independent hospitals will be brought together in one dataset, and we plan to use this to compare quality and performance and provide information for better clinical governance. The main aim of our research is to understand how quality and safety is monitored across both NHS and independent hospitals. To meet this aim, we will we will analyse the new national dataset covering all patients in NHS and independent hospitals. We will also send questionnaires to the staff who lead clinical governance in NHS and independent hospitals. Researchers will visit hospitals, which we will identify with our project advisory group and other stakeholders, to conduct interviews and focus groups with patients and carers who have experience of care in both settings, and to observe and interview doctors and other professionals who work across both NHS and independent hospitals.

This study is funded for two and a half years and will begin as soon as ethical approval is granted, which we hope will be by the 1st of May 2023.

Overview of the research

The overall aim of this research is to provide evidence on the quality and safety of patient care in NHS and independent hospitals and the effectiveness and impact of shared arrangements for clinical governance. There are longstanding concerns among policymakers and leaders in both the NHS and independent healthcare sectors, and reports such as the Paterson inquiry [3], the medicines and medical devices safety review [5], a recent Healthcare Safety Investigation Board report [6] and the Care Quality Commission state of care report [7]) have highlighted the need for improvement.

Empirical evidence on the quality and safety of care has been limited by the lack of comparable routine data across both NHS and independent hospitals, but that is now changing with reforms led by both NHS Digital and the Private Hospital Information Network. The importance of clinical governance has been recognised and we know that some important reforms have been initiated but not how well they are working, particularly to address the way clinical governance works across the interface and between organisations.

In this study, we address four main research questions:

1. What are the characteristics of the patient population and the care provision in NHS and independent hospitals in England, and what differences are observed by funding type (NHS or private), care setting (NHS or independent), specialty, procedure, geography and over time?
2. Can we map and measure the overall scope of practice of doctors providing care in both NHS and independent hospitals, and explore how well those organisations understand and oversee that scope of practice through the separate and shared arrangements for clinical governance that they have in place?
3. How does the quality and safety of care provided in NHS and independent hospitals differ, and what hospital, consultant, or other characteristics are associated with such variations?
4. How have the practice and working arrangements between NHS and independent hospitals changed during and after the COVID19 pandemic, and what effects have those changes had on clinical governance and the quality and safety of care?

This is a mixed methods study, combining the use of a survey of clinical governance leads in NHS and independent hospitals; in-depth qualitative research in some case study “clusters” of linked NHS and independent hospitals; quantitative analysis of existing and newly available routine data sets on inpatient care; and qualitative work with patients with experience of both NHS and independent hospital care.

The development of this proposal has had close involvement and support from colleagues in a range of stakeholder organisations (the Independent Healthcare Provider Network, the Care Quality Commission, NHS Digital, the Private Healthcare Information Network, the General Medical Council, NHS England) and we attach several formal letters of support from these organisations and one from Sir Bruce Keogh, formerly medical director of NHS England who previously chaired the DHSC review of cosmetic surgery and more recently chaired the group for IHPN which produced the Medical Practitioners Assurance Framework. Our Project Advisory Group will include representatives of all these organisations and others. We have also had extensive involvement from our PPI group. We have held two meetings with this group (consisting of five members) and have received written feedback from group members and lay reviewers at the NIHR Research Design Service. We have also consulted our PPI co-applicant throughout the design process.

We set out clear plans for the research to produce actionable research findings of real value to NHS organisations, independent healthcare providers, and the various stakeholder organisations outlined above in improving quality, safety and clinical governance, and for a programme of focused dissemination events and forums.

Background and rationale

We propose new research to help understand and improve the quality and safety of patient care in NHS and independent hospitals, through learning about the effectiveness and impact of shared arrangements for clinical governance. The funding and provision of acute hospital care in England is complex. Care may be publicly funded by the NHS or privately funded through health insurance or direct payment. Care may be delivered by NHS hospitals or by the independent sector. The diagram below illustrates the position.

Diagram 1. Funding and provision of elective acute inpatient care in England

		Funding source	
		NHS	Private
Care provision	NHS hospitals	A [88%]	B [0.6%]
	Independent hospitals	C [4.6%]	D [5.8%]

Note: figures in square brackets are the % of total elective acute inpatient care in England in 2020 (source – PHIN analysis).

The spread of patients across these four quadrants varies by specialty, by area/geography, and over time. A growing amount of NHS funded care has been provided in independent hospitals, particularly in elective surgical specialties, and NHS patients have had increasing opportunities to choose to be treated in the independent sector[1]. Many consultant medical staff work across both NHS and independent hospitals, usually employed by an NHS hospital but with admitting privileges at one or more independent hospitals. Independent hospitals have provided capacity to increase NHS funded service provision to improve access and reduce waiting times. During the current COVID19 pandemic, national arrangements to use the independent hospital sector to support the NHS in maintaining services have been put in place[2].

Why this research is needed now

There have been longstanding concerns about the quality and safety of care in both NHS and independent hospitals, and about the way clinical governance arrangements for assuring and improving quality and safety across this complex system of care have operated, but there has been very little empirical research in this area.

The Paterson public inquiry report in 2020[3] examined the case of a surgeon who undertook inappropriate and unnecessary operations on hundreds of patients over many years in both NHS and independent hospitals. The case highlighted many gross failures of clinical governance – Paterson could have been stopped from harming patients eight years before he was eventually suspended in 2011. The inquiry report made many recommendations, particularly that “there should be a single repository of the whole practice of consultants across England, setting out their practising privileges and other critical consultant performance data” and that reforms should apply equally across both NHS and independent hospitals. The government accepted this and most other recommendations in its response to the inquiry report published in late 2021 [4]. Another inquiry report in 2020, into serious failings in the safety of medications and medical devices, also recommended that “hospitals should encourage clinical audit and should have robust systems for monitoring quality at Board level.”[5] A recent Healthcare Safety Investigation Board report on surgical care in independent hospitals, initiated because of a patient death, made recommendations to improve communication, safety and clinical governance for patient pathways across the NHS/independent sector interface [6].

In addition, the Care Quality Commission which regulates both NHS and independent hospitals published a report based on its inspections of 206 independent hospitals in 2018[7]. It found that the quality and safety of care was generally high but that monitoring of clinical governance was not consistently robust. In response, the Independent Healthcare Providers Network (IHPN) convened an expert group to develop the Medical Practitioners Assurance Framework (MPAF) published in 2019[8]. MPAF provides a framework for clinical governance in independent hospitals, and an evaluation of its implementation and impact in 2021[9] found that good progress had been made despite the COVID19 pandemic. IHPN plans to update MPAF during 2022.

Moreover, reforms to medical regulation introduced in 2012 require all doctors and their employing organisations to undergo a periodic review to ensure they are up to date and fit to practice (called medical revalidation)[10]. Research on the implementation of medical revalidation has highlighted the difficulties of reporting on the whole scope of practice for doctors who work across NHS and independent hospitals and the need for shared clinical governance arrangements[11, 12]. The creation of a single repository of data bringing together consultants' work across all sectors has been called for by the Royal College of Surgeons and others: “work in the independent sector is a legitimate endeavour, but it cannot and must not be a hiding place for bad practice. Surgeons who carry out hip surgery in the NHS should not suggest to patients that they have expertise in shoulder surgery in the independent sector, nor should the occasional procedure performed in the NHS form the basis for private practice.”[13]. Research is needed, however, to develop appropriate methods for defining, analysing and reviewing the scale and scope of consultants’ medical practice.

Until recently, there has been a paucity of data which would allow the quality and safety of care across NHS and independent hospitals to be analysed, but that is now changing. The NHS has long collected an extensive data set on all inpatients funded by the NHS and treated in NHS or independent hospitals (Hospital Episode Statistics) which covers quadrants A, B and C in Diagram 1. In 2014, a Competition and Markets Authority investigation into privately funded healthcare (in both independent and NHS hospitals) concluded that the lack of sufficient, independent, publicly available performance information was a barrier to competition[14]. To address this the Private Healthcare Information Network (PHIN), a not for profit organisation, was mandated to collect a wide range of data from all hospitals providing privately funded admitted inpatient care (quadrants B and D) and to publish a set of performance measures [15]. Since 2019, PHIN has been working with NHS Digital on ADAPt (the acute data alignment programme) to provide for the first time a combined data set covering all NHS and privately funded and provided admitted patient care (all four quadrants in Diagram 1) which was scheduled to be available from late 2022[16] but whose delivery has now been delayed by NHS England. ADAPt will, for the first time, permit tracking individual patient’s care over time and across all four quadrants. The Health and Care Act 2022 contained legislative provisions to give the Secretary of State powers to collect patient data from all independent health and care providers [17].

Overall, the importance of clinical governance across NHS and independent hospitals has never been more clearly recognised by government, regulators, providers, funders and patients and the public[18]. We know that some very important reforms have been initiated but not how well they are working, and new data will be available which allows the quality and safety of care across all hospitals to be explored and compared.

We have held discussions with our PPI group and PPI co-applicant when preparing this application. We heard about personal experiences of navigating the interface between the NHS and independent sector (examples including the challenges of navigating this interface, transfers between sectors, and how concerns or problems were dealt with). We also heard about experiences of inspecting NHS and independent providers as CQC Experts by Experience. This highlighted their interest in the research and their insights have shaped this application. We believe the research can be of real value to those involved in policy and practice on clinical governance across the interface, such as the General Medical Council, the Care Quality Commission, the Independent Healthcare Providers Network, NHS England and other stakeholders. We have consulted these organisations in developing our proposal. All have agreed to join our Project Advisory Group and are supportive of the proposed research. A number have provided letters of support for this application which are attached. We have worked closely with NHS Digital and the Private Healthcare Information Network on this proposal and the Chief Medical Officer of PHIN is a co-applicant.

Review of existing evidence

The UK policy context for this research is reviewed above, and here we focus on the relatively limited empirical literature on differences in clinical governance, quality and safety across the NHS and independent hospitals. An extensive international literature has explored the relationship between hospital ownership and performance. An overview of systematic reviews[19] compared the performance of hospitals with different models of ownership finding that patient mortality was higher in for-profit than not-for-profit private hospitals, but finding no clear differences between private and public providers. Many of the studies focusing on ownership originate from the US; evidence in the UK and Europe is less plentiful. A systematic realist review[20] comparing public and private hospitals in the EU found the existing evidence on quality of care too diverse to be conclusive. A recent scoping review[21] comparing public and private hospital services in Europe found numerous shortcomings in available studies, particularly failure to account for operational differences such as patient selection, and argued that future studies are needed to investigate the relationship between contextual circumstances and hospital performance. A robust analysis comparing NHS-funded elective care delivered in public and private hospitals found no observable difference in quality[22], but this study could not include data on privately funded patients.

Dual medical practice has long existed in most healthcare systems around the world, but it remains scantly debated and researched[23]. Studies of dual practice are mainly theoretical, and evidence reviews have largely focused on developing countries[24]. Its implications for performance of the health care sector are unclear, and evidence of the effects of dual practice on quality and efficiency in health care provision is scarce[25, 26]. Empirical evidence of the scale and scope of practice of doctors in the UK has been partial, and it has not been possible to observe practice over both the NHS and independent sectors. Studies have measured clinical activity of consultants in the NHS [27], but their activity over both sectors has so far only been inferred by observing their NHS and private income from tax records [28].

Theoretical framing of empirical research at the interface of public and private funding and provision is important[29, 30]. Health care in the UK (and elsewhere) is delivered in highly regulated markets with combinations of public and private actors[24]. Ideological perspectives can influence

evaluations of different ways of providing health care, and too frequently comparisons are made between idealised views of one sector and real-world failings of the other[31].

Research aims and objectives

We will study how clinical governance arrangements across both NHS and independent hospitals have developed and how they are working; and how newly available quantitative data can be used to analyse the quality and safety of care and to provide information to support clinical governance in practice.

We have four main research questions:

1. What are the characteristics of the patient population and the care provision in NHS and independent hospitals in England, and what differences are observed by funding type (NHS or private), care setting (NHS or independent), specialty, procedure, geography and over time? (RQ1)
2. Can we map and measure the overall scope of practice of doctors providing care in both NHS and independent hospitals, and explore how well those organisations understand and oversee that scope of practice through the separate and shared arrangements for clinical governance that they have in place? (RQ2)
3. How does the quality and safety of care provided in NHS and independent hospitals differ, and what hospital, consultant, or other characteristics are associated with such variations? (RQ3)
4. How have the practice and working arrangements between NHS and independent hospitals changed during and after the COVID19 pandemic, and what effects have those changes had on clinical governance and the quality and safety of care? (RQ4)

Inclusion/exclusion criteria

WP2 - Survey of clinical governance leads in NHS and independent hospitals in England

The principal inclusion criteria for participation in the national survey is involvement in leading clinical governance in NHS and independent hospitals including but not limited to medical directors, director of nursing/chief nurses and clinical governance leads at acute NHS trusts; and hospital directors, matrons and chairs of Medical Advisory Committees at independent hospitals providing inpatient care.

The principal exclusion criteria for participation in the survey are professionals who do not have experience of or involvement with clinical governance in the NHS and independent sector.

WP3 – In depth case studies of clinical governance in a number of clusters of NHS and independent hospitals

The principal inclusion criteria for case study selection for independent hospitals is the treatment of NHS patients. The principal inclusion criteria for NHS hospitals is a relationship with a geographically proximate independent hospital where NHS patients are treated and NHS doctors are working. The principal exclusion criteria are independent hospitals that do not treat NHS patients and NHS hospitals that have no relationship with local independent hospitals (i.e. patients treated or doctors working).

The principal inclusion criteria for participation in qualitative interviews is: involvement in leading clinical governance in NHS and independent hospitals, including but not limited to; clinical governance leads, medical directors, registered managers, hospital directors, matrons, chairs of Medical Advisory Committees, medical performance leads, clinical directors/clinical leaders, responsible officers and appraisers, other health professionals with an interest in clinical governance, those leading on patient experience/complaints/PALS, and local Healthwatch representatives.

The principal exclusion criteria for participation in an interview are professionals who do not have experience of or involvement with clinical governance in the NHS and independent sector.

The inclusion criteria for meeting observations will be meetings about clinical governance in either NHS and independent hospitals and particularly when the meetings are concerning governance across the two sectors. Principal exclusion criteria for meeting observations are meeting that are not related to clinical governance in the NHS and/or independent sector.

WP5 – Analysis of the quality and safety of care

The principal inclusion criteria is patients and carers who have direct experience across both sectors with a particular focus on patients who have experience at the interface (e.g. patients who have been transferred between settings).

We are interested in patients and carers who have direct experience of care in both the independent and NHS hospitals, and would exclude patients who only have experience of one sector.

Project plan

We will organise the project into five main work packages, which are listed below (with the principal research questions they link to in brackets) and are then described in detail:

- WP1 – Variations in hospital volume, case-mix and coding practice (RQs 1, 4)
- WP2 – National survey of clinical governance leads in NHS and independent hospitals in England (RQs 2, 4)
- WP3 – In depth case studies of clinical governance in a number of linked pairs or clusters of NHS and independent hospitals (RQs 2, 4)
- WP4 – Analysis of the scale and scope of consultant clinical practice (RQs 2, 3, 4)
- WP5 – Analysis of the quality and safety of care (RQs 3, 4)

Sample size summary

In WP1, WP4 and WP5 hospital admitted patient care will be used. The data used cover the majority of the English population and the sample size will be very large.

In WP 2, we will survey medical directors, director of nursing/chief nurses and clinical governance leads at all 169 acute NHS trusts; and with the support of IHPN we will survey hospital directors, matrons and chairs of Medical Advisory Committees at 342 independent hospitals providing inpatient care.

In WP3, we anticipate interviewing approximately eighty staff across all four case study sites.

In WP5, we aim to recruit around forty patients and carers to take part in around six focus groups. If patients or carers prefer, we can conduct one-to-one interviews.

Patient datasets

The quantitative analyses for this project will use four main patient-level datasets provided by NHS Digital and PHIN. We set out here a brief description of each dataset and our rationale for its use in the research. Details of our methods and analytic approach are given in the workpackage descriptions.

- *Hospital Episode Statistics (NHS Digital):* hospital data covering all NHS provided or NHS funded care. This includes private patients treated in NHS hospitals and NHS patients treated in independent hospitals (quadrants A, B and C from Diagram 1). Data cover patients admitted to hospital and A&E attendances. Data include information on patient characteristics; diagnosis and treatment codes; where the treatment is delivered; cost of treatment; the consultant responsible for each episode of care; length of stay; and how the patient was discharged. Data are of good quality, as they relate to how hospitals are funded for the care they deliver. We will use admitted patient data from 2014 to 2024 for WP1, WP4 and WP5 and A&E attendance data from 2021 to 2024 for WP5.

- *Independent sector admitted patient care (PHIN):* hospital data covering all admitted patient care that is privately funded (quadrants B and D from Diagram 1). The data items collected and data definitions are based on those in Hospital Episode Statistics for admitted patients. Note that no data are collected for privately funded outpatient care. The Competition and Markets Authority order mandates that *all* providers submit admitted patient data to PHIN. We will use aggregated data from 2017 to 2024 for WP1 and WP4.

- *Patient-reported outcome measures (PROMs) for hip and knee surgery (NHS Digital):* patient-level data collected using pre- and post-operative questionnaires completed by patients undergoing hip or knee replacement. All patients are invited to complete these questionnaires however their treatment is funded or provided. Patients report on changes in their health following surgery using validated condition-specific measures of self-reported health status (Oxford Hip Score and Oxford Knee Score). Aggregated PROMs data are available from PHIN

for privately funded treatment. NHS Digital will provide patient level PROMs data for NHS-funded treatment (quadrants A and C) and treatment in NHS private patient units (quadrant B). We will use data from 2022 to 2024 in WP5.

As providers of these datasets, NHS Digital and PHIN support the work and have been consulted in the planning of our research questions and work packages. PHIN have further been involved in developing the proposal. The research team has considerable experience in applying for and analysing hospital data and has long standing working relationships with NHS Digital.

Data storage

Data from NHS Digital will be stored within an access restricted data share on the University's network storage infrastructure which is the recommended location for storing sensitive or critical University data. The storage infrastructure is hosted across two data centres for resilience and disaster recovery purposes. The data will be hosted on a strictly controlled data share within the University's network storage infrastructure to which only designated members of the research group staff will have access permissions. The data share will only be accessed via a mapped network drive initially on Thomas Allen's PC for secure transfer (winscp) to the iCSF , and thereafter from the iCSF which has been identified for research data processing. The NHS Digital data will be accessed locally at the University of Manchester and via remote access to the University of Manchester system. Remote access will process NHS England Data in line with NHS England's remote access conditions. Data from PHIN will be stored only in PHIN's storage infrastructure and not in University of Manchester servers. Access to PHIN data will be via Virtual Desktop Infrastructure (VDI) technology to ensure the data is only processed within, and never leaves the PHIN virtual environment.

WP1 – Variations in hospital volume, case-mix and coding practice (RQ1, RQ4 - lead: Allen)

Patient level data from Hospital Episode Statistics covered quadrants A, B and C. Aggregate data from PHIN covered quadrant D. These data will be analysed together to provide coverage of all four quadrants in Diagram 1. This combination will allow volume to be observed over a long time period covering both pre- and post-pandemic periods (2017 to 2024). Case-mix and coding practice will be analysed across quadrants A, B and C using Hospital Episode Statistics.

PHIN and Hospital Episode Statistics both contain information relating to quadrant B (private funding in NHS hospitals). Within Hospital Episode Statistics, activity from quadrant B can be identified using the fields relating to administrative category code and provider code. Within PHIN, identification is made using the provider code alone. Data from both sources will be compared to determine if volume is influenced by who collects the data. If differences are found, the most complete source of data will be used.

Access to data from external providers will be negotiated with NHS Digital and PHIN and data processing agreements will be signed with both organisations. We will follow the information governance processes of the University Manchester to make sure that the data is transferred, stored, managed and analysed safely, and we will work closely with the UoM information governance team. Our team has extensive experience of analysing HES data as four members (TA,

CG, NG, KB) of the team have previously negotiated and obtained access to Hospital Episode Statistics from NHS Digital.

Volume

The annual volume of patients treated in each quadrant will be summarised from 2017 to 2024. Graphical and regression analysis will determine time trends over this period, seasonal effects, the impact of the COVID19 pandemic and how volume varies by geographical region and deprivation. Spatial maps will be used to identify areas with the greatest proportion of total care that is privately funded (quadrants B+D); and that is provided in an independent hospital (C+D). We will model how access to publicly-funded care, measured by NHS referral-to-treatment waiting times, varies with both private funding and care provision. To do so we will use waiting times data which are published each month for all NHS hospitals and furthermore broken down by treatment speciality. These waiting times will be matched to the volume of privately funded and provided care in the same speciality. This matching will first be done on hospitals closely located to each other, which assumes patients are less willing to travel for care, and then repeated for all providers regardless of location.

We will observe the procedures (and their clinical speciality) which are most commonly performed in each quadrant and identify the specialties/procedures with the greatest overlap across the NHS and independent sector. Together with our project advisory group, which includes our PPI co-applicant, we will select a set of procedures and specialties that will be the focus of our analyses for WP4 and WP5. The Competition and Markets Authority order, which mandates what data on privately funded care must be collected, does not cover outpatient care and such data are not collected by PHIN. Direct comparisons of volume between the NHS and independent sector will therefore only be made for procedures that are normally carried out as inpatient care.

For WP2, data on volume will be linked to responses to our national survey of governance leads in NHS and independent hospitals. For WP3 we will provide information on potential clusters of NHS and independent hospitals to inform case study selection. For WP4 and WP5 we will provide information on volume, case-mix and coding practice for areas of overlap across the NHS and independent sector. This list is likely to include procedures in specialties such as general surgery, urology, trauma and orthopaedics, ENT, ophthalmology and cardiology.

Case-mix

Using patient level data from Hospital Episode Statistics we will compare the case-mix of patients. This will include patients whose treatment is NHS funded regardless of where the treatment occurs, and privately funded care in NHS private patient units. We will compare patient socio-demographic characteristics (gender, age, ethnicity, deprivation of the patient's local area) and medical characteristics (length of stay, presence and count of comorbidities). These case-mix variables will be summarised by provider type (NHS hospital, NHS private patient unit), funding source, geographical region and over time.

For our analysis of case-mix we will estimate a prediction model for patients in quadrants A, B and C using mortality as the outcome for each patient. We will compare expected vs actual outcomes for patients in each quadrant after performing adjustment for casemix variables and provider characteristics. We will summarise the mean risk ratios for patients in each quadrant to identify

differences that may arise due to differences in casemix. We will repeat the analyses for the clinical specialties with the highest volumes across the three quadrants. Findings from this analysis will inform WP4 and WP5.

Coding practice

NHS-funded hospital care (quadrants A and C in Diagram 1) is reimbursed through the national Payment by Results tariff system which incentivises detailed recording of comorbidities, but privately funded care in NHS private patient units (quadrant B) is reimbursed/charged according to the price schedules of insurers and hospitals. This may lead to differences in coding practice across sectors influencing comparisons of scope of practice (WP4) and performance (WP5). We will assess differences in the coding of comorbidities in terms of completeness and depth, across sectors and how coding changes over time. NHS funded patients in NHS hospitals vs independent hospitals offer an opportunity to compare coding in different providers but where the incentives for coding are the same. Similarly, comparing patients treated in NHS hospitals vs NHS private patient units offers an opportunity where the setting is the same but coding incentives and payments differ.

- Completeness: We will explore completeness of data fields, in terms of patient demographic characteristics (ie. age, gender, ethnicity, LSOA of residence) by quantifying the proportion of missing/unknown values for each demographic characteristic across the 3 quadrants and make comparisons between the quadrants over time.
- Depth: Diagnoses and procedures from HES are coded using International Classification of Diseases 10th revision (ICD-10) and OPCS-4 codes. Up to 20 diagnosis and 24 operation codes are recorded for each. Information in the first diagnosis position reflects the primary diagnosis, with subsequent positions documenting other comorbidities. Comorbidities will be extracted from all diagnosis and operation codes from hospital admissions between April 2017 and February 2024. To compare coding depth, we will calculate the mean and standard deviation number of diagnoses codes for each patient, and calculated the mean number and standard deviation of diagnoses codes in each quadrant and make comparisons across age groups and over time.

WP2 – Survey of clinical governance leads in NHS and independent hospitals in England (RQ2, RQ3, RQ4 - lead Ferguson)

We have some information about the clinical governance arrangements in the NHS and independent sector [7, 9] but we know little about how those governance processes work in practice and are experienced, particularly at the interface between organisations/hospitals. As noted earlier a number of reports have made recommendations concerning the way NHS and independent hospitals should work collaboratively to improve clinical governance but we do not know whether or how those recommendations have been taken up and enacted in practice.

We plan to undertake a survey of individuals involved in leading clinical governance in NHS and independent hospitals. After consultations with our stakeholders noted earlier, we think there is value in securing a range of different perspectives at an organisational level if we are to really understand how clinical governance works in practice. For that reason, and with the support of NHS England and the Care Quality Commission we will survey medical directors, director of nursing/chief nurses and clinical governance leads at all 169 acute NHS trusts; and with the support of IHPN we

will survey hospital directors, matrons and chairs of Medical Advisory Committees at 342 independent hospitals providing inpatient care.

We will undertake extensive pre-survey development and engagement work where we will consult with stakeholders to develop a survey that captures data that is meaningful, relevant and useful to respondents. During this time we will also develop our sampling frame of contacts from NHS and independent hospitals to identify individuals who are best placed to complete the survey. We carried out similar pre-engagement work with stakeholders for our current NIHR funded project about locum doctors and a previous NIHR-funded project on medical revalidation. In both cases we engaged with stakeholders, such as, medical directors and responsible officer networks to develop our survey and identify potential respondents. In our experience, this helps not only to develop a survey that will be of interest and use to respondents but also helps respondents understand why we are doing the survey and be supportive of its completion. Our piloting work will also include cognitive interviewing to uncover whether the questions work as intended, and whether the survey takes sufficient account of differences in organisational context/setting and respondents' roles, knowledge and expertise. Our national survey of responsible officers in both NHS and independent healthcare providers secured a response rate of 63% [32] and our current survey of medical directors about locum doctors has an interim response rate of 48% to date. We will offer to provide all respondents with the results of the survey so they can see how their own experiences relate to those of others, and we find this also helps to secure engagement.

We will conduct the survey online using Qualtrics survey software and will include questions on: respondents' experiences of the process of clinical governance at the interface; how clinical governance is understood, developed, implemented and operationalised across the NHS and independent hospitals; and how recent reforms (such as the implementation of the revised MPAF in independent hospitals) have been received and enacted. We will explore how respondents understand and oversee scope of practice through the separate and shared arrangements for clinical governance in their organisations and how whole practice appraisal is supported. We will examine how information in areas like patient complaints, serious incidents, engagement in continuing professional development, early performance concerns, and other matters are gathered, reviewed, shared and used in clinical governance. We will also explore experiences of changes to clinical governance processes during and after the pandemic. To monitor how diverse our sample is, we will collect information on the respondents' job role, place of work and demographic data (age, ethnicity and gender). We will also collect respondents' contact details should they wish to receive a copy of the survey report.

We will avoid collecting any data which is already available, for example data collected by IHPN through its impact review[9] or by CQC through its inspections[7]. This survey will complement the qualitative fieldwork and analyses in WP3 and provide important evidence on how clinical governance arrangements are understood, implemented and operationalised between and across NHS and independent hospitals and useful data on the nature and range of local initiatives used by NHS and independent hospitals to improve clinical governance across the interface.

Consent

Informed consent will be sought from all participants. Participants are free to complete a questionnaire if they wish, and will be advised that completion is voluntary. Participants will be provided with information on the research using a participant information sheet to help them decide

whether they want to take part in the study and will be informed of how their data will be used and stored. A tick box at the beginning of the questionnaire will be included to capture consent as per the HRA guidance on proportionate approach to consent for the completion of surveys (i.e. completion is consent).

WP3 – In depth case studies of clinical governance in a number of clusters of NHS and independent hospitals (RQ2, RQ4 – leads Ferguson/Walshe)

WP3 will involve in-depth case studies in four "clusters" of geographically proximate and connected NHS and independent hospitals to understand how clinical governance processes develop and how they are working at the interface of NHS and independent hospitals. Each case study will be a detailed exploration of governance processes with a particular focus on understanding shared processes across the sectors to provide information to support continuous improvement in clinical governance in practice. We will explore clinical governance in a variety of ways including documentary analyses, meeting observations, semi-structured qualitative interviews and structured review and engagement focused on selected practice profiles and other data we will provide to case study sites.

Case study definition and selection

Having discussed case study selection with colleagues from IHPN and CQC we plan to work with them and our Project Advisory Group to identify four "clusters" of NHS and independent hospitals intended to reflect the diverse and heterogeneous landscape of acute care provision in England:

- Two *simple clusters* – typically involving one NHS hospital and one or two geographically proximate independent hospitals, and likely to be located in a large town or a mixed urban/rural setting. In these simple clusters, there is likely to be a fairly straightforward mapping/relationship between the set of consultant medical staff at the NHS hospital and those who have admitting privileges at the independent hospital.
- Two *complex clusters* – typically involving one or two NHS hospitals and two or more independent hospitals, and likely to be located in a large city/urban setting (eg London, Manchester, Birmingham) where there may be a number of other hospitals which are geographically proximate. In these complex clusters, there is likely to be a much less straightforward mapping/relationship between the consultants working at hospitals within the cluster – with some doctors working at multiple hospitals, both NHS and independent – and clinical governance arrangements are likely to be similarly more complex.

Within these case study clusters, we also want to reflect the diversity of independent hospital provision, and involve both some independent hospitals which are part of a larger chain (such as Spire, HCA etc) and some which are standalone organisations.

Case study recruitment

It is essential that prospective case study clusters and the organisations within them are willing to participate in the research and understand what it involves. We will seek advice from CQC and IHPN in our case study selection and recruitment process, and will bring together senior leaders in clinical governance from potential case study sites to agree on involvement and collaboration. We think that the opportunity to have access to pilot scope of practice profiles and other bespoke quantitative analyses from WP4 and WP5 will be attractive to potential participating organisations.

For WP3, intelligence from stakeholders including IHPN, CQC and our project advisory group will be used to identify four "clusters" of NHS and independent hospitals intended to reflect the diverse and heterogeneous landscape of acute care provision in England. It is essential that prospective case study clusters and the organisations within them are willing to participate in the research and understand what it involves. We will seek advice from CQC and IHPN in our case study selection and recruitment process, and will bring together senior leaders in clinical governance from potential case study sites to agree on involvement and collaboration. We think that the opportunity to have access to pilot scope of practice profiles and other bespoke quantitative analyses from WP4 and WP5 will be attractive to potential participating organisations. The medical director or clinical governance lead at potential case study sites will be invited to take part in the study via email and fully briefed on what participation will involve. We will ask a staff member at participating case study sites to cascade an email invitation to professional networks and use publicly available email addresses in order to recruit professional participants.

Desk based exploratory work

We will carry out desk-based exploratory/descriptive work so we can develop a detailed understanding of clinical governance at our case study sites by analysing documents such as policies, CQC reports and other existing data sources on clinical governance. We will familiarise ourselves with the organisations and their arrangements for clinical governance and generate issues of importance that we can further explore in our qualitative work.

Qualitative field work

We will seek to recruit clinical governance leads, medical directors, registered managers, hospital directors, matrons, chairs of Medical Advisory Committees, medical performance leads, clinical directors/clinical leaders, responsible officers and appraisers, other health professionals with an interest in clinical governance, those leading on patient experience/complaints/PALS, and local Healthwatch representatives. We anticipate interviewing approximately eighty staff across all four case study sites.

The topic guide will cover: scope of practice for doctors providing care in both NHS and independent hospitals to explore how organisations understand and oversee scope of practice through the separate and shared arrangements for clinical governance; how clinical governance is understood, developed, managed, implemented and operationalised in NHS and independent hospitals; what similarities and differences in processes exist; how communication across the interface of the sectors works; and how mutual learning can be shared. We will explore how governance processes have been changed by the pandemic and what has been learned from that experience. To monitor how diverse our sample is, we will also collect information on the respondents' job role, place of work and demographic data (age, ethnicity and gender). We will also collect respondents' contact details should they wish to take part in further research.

Consent

Informed written consent will be obtained from all interview participants by the researcher, and will involve a signed wet ink signature prior to participation. Where interviews are conducted via Zoom/Teams, consent forms will be completed electronically. The consent form will be emailed to

participants and they will email the completed and signed form back to the research team prior to participation.

For meeting observations, consent will be sought from the meeting organiser in advance of the meeting. A PIS will be shared with attendees and they will be asked by the meeting organiser if they are happy for the meeting to be observed. If attendees are uncomfortable for any reason with researchers observing the meeting, the meeting will not be observed. Where meetings are observed, we will ask the chair at the beginning of the meeting to confirm ongoing consent with attendees. We will record in our field notes whether the attendees have confirmed their consent to be observed

Development of clinical governance resources

We will provide bespoke analysis and feedback which has the potential to be of benefit to participating sites. Case study sites will have access to pilot scope of practice profiles, generated using Hospital Episode Statistics, PHIN and ADAPt datasets in WP4 and WP5 for consultants who work across both the NHS and independent sectors in selected specialties (see WP1). We will develop and share selected consultant- and hospital-level reports and explore the utility of these (see WP4). Our quantitative team could also provide other forms of bespoke focussed analysis in areas of interest (for example data on PROMS, transfers and readmissions from WP5). This will be the first time that organisations will have had access to such whole scope of practice information and we will carry out small group workshops and/or interviews to explore how these profiles and information are or can be used in clinical governance.

Data collection

We will aim to undertake interviews and group workshops face to face where possible as we envisage visiting sites on a number of occasions over several months to collect data and develop scope of practice resources. Where COVID19 restrictions are in place, or interviewees are not available at that time, we will undertake interviews by Zoom/MSTeams. We will do our best to accommodate participants who are working and offer interviews during evenings and weekends. All interviews will be audio-recorded with permission and fully transcribed. Where possible we will attend and observe meetings during our fieldwork visits which are relevant to clinical governance and take contemporaneous field notes.

Analysis

Our qualitative analysis will use a template approach [33] using NVivo computer software. We will hold regular team meetings, including our PPI forum, to compare coding, explore alternative framings and diverse insights within and across our case study sites. We will undertake pilot coding with a sample of data to iteratively develop and review our coding framework to identify significant broader patterns of meaning and review the viability of themes by checking potential themes against the dataset, to determine if they tell a convincing story of the data, and one that answers the research question. As this work progresses, new second order themes will be developed, abstracting from our data and using a pragmatic approach, namely abductive analysis, to construct empirically based theorisations [34].

WP4 – Analysis of the scale and scope of consultant clinical practice (RQ2, RQ3, RQ4 – lead: Bloor)

In order to contribute to improvements in the quality and effectiveness of governance arrangements, and to enabling patients to make informed choices, in this work package we will develop methods to assess and inform providers about overall consultant activity. Using routine data, we will map the scale and scope of practice of doctors who provide care across the NHS and independent sectors (RQ2). We will explore trends in clinical practice over time, and before and after the COVID19 pandemic (RQ4) and we will explore which characteristics of consultants and their scale and scope of practice are associated with measures of quality and safety of care (RQ3, in conjunction with WP5).

In Hospital Episode Statistics, each patient record includes the responsible consultant's General Medical Council number. PHIN also publish aggregated data for each consultant showing the volume of procedures performed and the independent providers they practice in. These PHIN aggregated data also include the General Medical Council number which means that it can be used to specify and aggregate the patient care provided by each individual consultant across NHS and independent hospitals. The General Medical Council number can also be linked with other sources of data (including the General Medical Council register) to derive other information about the consultant (such as their demographic characteristics, training, length of practice). Data like this have been used to describe and analyse the clinical workload, productivity, quality and safety of hospital consultants' practice in the NHS [27, 35] and evaluate the effect of changes to consultants' working lives such as the introduction of revalidation [36]. Until now, though, we have not been able to identify the scale and scope of consultant clinical practice across both NHS and independent sectors. Such analysis is crucial to monitoring and managing consultant performance and improving the quality and safety of patient care.

We will use the Hospital Episode Statistics and PHIN datasets to identify consultants who work across both the NHS and independent sectors in selected specialties (see WP1) and to describe their scale and scope of practice. For each consultant we will quantify the total number of patient episodes treated in each of the four funding/provision quadrants, and identify differences between consultants' practice in NHS and independent sector hospitals. Working at increasing levels of detail (from treatment specialty to procedure group to individual procedure codes) we will map consultants' activity, comparing their scope of practice in the NHS and independent sectors. In particular, we will highlight procedures which are carried out by consultants in independent hospitals (B+D) but rarely or not at all in NHS hospitals (A+C).

We will conduct a brief methodological review to assess potential methods to measure variation in consultants' practice and their level of specialisation / diversification in each sector (for example using a Gini ratio [37], or information theory index [38]). We will consult our clinical advisors to determine patterns of activity which may potentially cause concern (e.g. low volume activities or consultants who may appear to be practising outside their main areas of expertise).

Using a measure of practice variation, we will describe and assess how scale and scope of practice varies over time and geographic region, in particular looking at changes during and after the COVID19 pandemic. We will explore the potential to analyse indicators of the quality and safety of care (WP5) linked with the scale and scope of consultant practice.

From our national analysis, we plan to share selected consultant- and hospital-level reports for our case-study sites and explore the utility of these for clinical governance through our case study site fieldwork. This will build on prior experience of analysis of consultant-level clinical activity in the NHS [39] and will permit detailed exploration of patterns of consultant practice within and between sectors, refining analytical methods as well as developing potential methods to inform future governance and regulation.

WP5 – Analysis of the quality and safety of care (RQ3, RQ4 – leads: Gutacker and Ferguson)

Quantitative analysis of hospital data

Using Hospital Episode Statistics, we will compare standardised indicators of quality and safety across the three quadrants of patients treated in England to test for differences in *average* quality and safety across the quadrants, and to derive performance estimates for *individual consultants and hospitals* (feeding into WP3). We will restrict our analysis to the set of surgical procedures identified in WP1.

The unit of observation in our empirical analysis is the *index hospital admission*, i.e. the admission spell in which the relevant surgical procedure was performed. Each index admission is assigned to one of the three quadrants (see Diagram 1, A, B and C) based on funding source and hospital type. Patients can have several index admissions during the study period, and can also have (non-index) health care use for other causes and treatments.

For each index admission we will calculate a set of quality and safety indicators, which have been validated for use with administrative data and are widely used for performance assessment in regulatory contexts (for example in monitoring against the NHS Outcome Framework, in CQC inspections/reviews, in clinical governance and appraisal/revalidation processes, etc) and for research purposes:

1) Unplanned readmission to hospital within 28 days of discharge (binary: yes/no),
2) Unplanned emergency department attendance within 28 days of discharge (binary: yes/no),
3) Emergency transfers to NHS hospitals at the end of the index admission episode (binary: yes/no),
4) Total length of continuous inpatient stay (accounting for transfers between hospitals) (continuous),
5) Death within 30 days of admission (binary: yes/no), and
6) Patient-reported health improvements within the first 6 months after surgery (for hip and knee replacement only) (continuous).

Each indicator will be summarised for index admission for quadrants A, B and C. Indicators 1-4 are constructed by linking index admissions to subsequent episodes of hospital care within Hospital Episode Statistics, which allows for such longitudinal follow-up through the use of a unique pseudonymised patient identifier (the Master Person Service ID). For indicator 2, we will additionally link admitted patient data to the Hospital Episode Statistics Emergency Care dataset, which captures all emergency department attendances in English hospitals from 2021.

Indicator 5 is constructed by linking Hospital Episode Statistics data to official Civil Registration data on date of death held by the Office for National Statistics. This linkage is performed by NHS Digital

based on the patient-identifiable data (e.g name, date of birth, NHS number) they hold. We will also consider an alternative outcome indicator based on in-hospital deaths as recorded in Hospital Episode Statistics (derived from the data fields discharge method & destination). This alternative approach captures mortality for the full patient population, including those that do not have an NHS number (e.g. patients not resident in England) or that for other reasons cannot be linked to Civil Registration data, but it necessarily fails to capture any deaths that occur after the end of the index hospital admission.

Indicator 6 uses patient-reported outcome measures (PROMs) data that are routinely collected in both NHS and independent hospitals for two surgical procedures: planned hip and knee replacement surgery (see section on datasets above). We will request NHS Digital to supply us with data from the national PROMs programme, which covers NHS-funded care only, linked to a corresponding Hospital Episode Statistics extract.

We will conduct separate multivariate regression analysis of the six indicators stratified by type of procedure. All regression models will include a set of indicator variables denoting the three quadrants, and the associated regression coefficients will be used to test for differences in quality and safety across hospital types and funding sources. All regression models will control for known confounders such as patient demographic characteristics (i.e. sex, age, ethnicity, area-level deprivation based on the index of multiple deprivation score for the patient's lower-layer super output area (LSOA) of residence), diagnosis, comorbidities, past healthcare utilisation as captured in Hospital Episode Statistics, and admission information (e.g. calendar month of admission). In specifying the case-mix adjustment we will draw on previous work [40, 41, 42] and insights from the data quality assessment conducted in WP1.

It is well known that administrative hospital data do not capture all patient factors that determine outcomes. If unobserved confounders are not equally distributed across admissions in the four quadrants, for example because patients with certain unobserved characteristics are more likely to self-fund their care or be treated in independent hospitals, then this may bias comparative assessments. To explore the impact of unobserved confounding, we will build on our previous work [22, 43, 44] and specify instrumental variable (IV) regression models in which the observed choice of funding source and hospital type (i.e. *selection into treatment* in causal inference terminology) for each admission is modelled as a function of exogenous variation in i) difference in the travel distances to the nearest NHS and independent hospital (as a proxy for ease of access), and ii) median house prices in the patient's LSOA of residence (as a proxy for relative wealth and, thus, affordability of private care). Under the assumptions that these two instrumental variables are not directly correlated with outcome of care (other than through the observed choice of funding source / hospital type) and are strong determinants of the observed choice, this IV approach permits achieving quasi-randomisation in observational data.

Using the result from our analysis we will calculate hospital-level reports for our case-study sites by means of indirect standardisation. For each hospital and indicator, we will calculate the case-mix adjusted outcome (e.g. the rate of unplanned readmissions following planned hip replacement surgery) and plot these using funnel plots; a presentational format of performance assessments that clinicians and managers are increasingly familiar with. We will explore the utility of these data for clinical governance through our case study site fieldwork in WP3.

Qualitative focus groups/interviews with patients and carers to explore quality and safety

We know very little about patient experiences of quality and safety when they are treated in both NHS and independent hospitals. We will carry out qualitative focus groups and interviews with patients and carers to understand their lived experiences of quality and safety of care in the NHS and independent sector. Patient and carer perspectives will provide an additional lens for viewing governance processes and patient pathways between sectors and complement the quantitative work by providing rich context to deepen our understanding of these complex systems.

We aim to recruit around forty patients to take part in focus groups/interviews through the NIHR funded organisation 'Research for the Future' (https://www.researchforthefuture.org/), Be Part of Research and other patient groups. Research for the Future has over 11,000 registered people who have consented to be approached about future research opportunities, holds data on diversity and can also pre-select patients on the inclusion criteria for our study, i.e patients and carers who have direct experience across both sectors with a particular focus on patients who have experience at the interface (e.g. patients who have been transferred between settings). We successfully recruited forty-five patients for our current project on locum doctors through Research for the Future, to explore patients' experience of and views on being treated by locums.

The purpose of the Be Part of Research Volunteer Service (BPORVS) is to allow members of the public to become volunteers by creating an account, specifying the areas of research that they are interested in and give consent to be contacted by the Be Part of Research team. Those who consent will receive information about BPORVS, in particular to alert them to specific BPORVS registered studies that they may be interested in, based on their volunteered details and study specific eligibility criteria, using an online self-registration service. The register is open to those that live in the UK, are over 18 and have an email address. At the time of registration, volunteers are made aware that they are not signing up to take part in a specific health study when they join this register and that they will only be signposted to studies that have NIHR funding or are listed on the NIHR CRN Portfolio. If the volunteer is interested in the study there will be a link in the email to take them to the study team (e.g. website, pre-screener) where they will move into the study teams screening process and consenting process if they take part in the study.

The topics to be covered will be co-designed with our PPI forum and are likely to include questions about experiences of quality and safety across the sectors; patient journey; patient history and sharing of information across providers; monitoring of patient experience and satisfaction; and what happens when there are concerns or problems (as suggested in our PPI group). We will carry out interviews/focus groups remotely through MSTeams/Zoom/telephone (depending on preference). We will also invite patients to submit written accounts of their experiences if this is more accessible for them. To monitor how diverse our sample is, we will collect information on the respondents' age, ethnicity and gender and their contact details should they wish to take part in further research.

Consent

Electronic informed written consent will be obtained from all focus group and interview participants by the researcher. Focus groups and interviews will be conducted via MSTeams/Zoom. The consent form and PIS will be emailed to participants and they will email the completed and signed consent form back to the research team prior to participation. For participants recruited via the BPORVS, there is an additional statement in the consent form that confirms their consent for the research team to report back to the BPORVS on who has taken part. This is for the purposes of ensuring that the participant will not be contacted about the study again.

Project monitoring, management, and project team expertise

We are an established team, with most key staff as co-applicants already in post and a strong record of prior research collaboration (for example on past NIHR funded research on medical revalidation, CQC inspections, and the quality and safety of locum doctors) and of delivering impactful research to time and target. We have made provision for one additional key member of the research team - a full-time qualitative researcher appointment at research fellow grade to work with JF and KW on WP2 and WP3 particularly. We have also made provision for a grade 5 project administrator particularly to support WP2 and WP3 but also to support KW with project management, stakeholder liaison, progress tracking, and knowledge mobilisation/dissemination.

We will hold regular project team meetings (either face to face or by Zoom/MSTeams) with action notes from each meeting. Weekly Teams meetings throughout the project mean it is easy for the team at Manchester and York to meet. We prefer regular business like project management meetings involving all team members to less frequent and lengthier engagements. Project team meetings will be used to get report backs on progress for each workpackage, monitor risks to progress, and take mitigating action if need be. The detailed content development related to each workpackage will be discussed separately in workpackage-level meetings scheduled to fit in with the timescale set out on the Gantt chart.

KW (20%) as PI will lead the project and have overall responsibility for oversight of all workpackages and delivery of project outputs, and we would note that he will not be PI on any other projects at our anticipated project start date. JF (40%), KW, and GS (research fellow at 100%) will be primarily involved in the more qualitative workpackages (WP2, WP3, WP5). TA (20%), CG (100%), KB (5%) and NG (15%) will be primarily involved in the quantitative workpackages (WP1, WP4, WP5) but all will meet regularly as noted above – this is essential in order to support learning and analysis across the workpackages for our final report and other outputs, and we have noted that the quantitative work from WP4, WP5 will form an important resource for WP3.

Patient and public involvement

We will establish a PPI forum with patient/public members recruited in part through the existing groups we have consulted in developing this proposal. Our PPI forum members will be involved in every stage of our research. We plan for the PPI forum to meet formally five times during the study. Forum members will be involved regularly in project design and planning, and will give us feedback and guidance on research materials and outputs (e.g. study protocol, participant information sheets, survey tools, interview schedules, emerging findings). Our PPI co-applicant MM will be involved in project team meetings to ensure that we have PPI involvement at regular and relevant intervals throughout the lifecycle of the project. As this is our PPI co-applicants first time as a co-applicant he will be mentored by an experienced PPI co-applicant and member of our PPI forum who will provide guidance and support to MM.

Our PPI forum members will also be invited to help lead our planned patient and carer focus groups and interviews (WP5). MM, our co-applicant successfully led three patient and carer focus groups in our current NIHR funded project. All PPI forum members were provided with training on conducting focus groups from JF. We encourage reflexivity and dialogue within our research team and plan for

the PPI forum to be involved in analyses of qualitative findings, as they have been in our current project.

JF, who has previous experience of PPI in research, will lead on PPI support and engagement and will monitor PPI experience including exploring training needs and feeding back on changes, outcomes and impact as a result of PPI involvement. JF will be supported by faculty PPI leads who are able to provide sustained support and training. PPI has been fully costed including the payment of meeting fees, training costs, reimbursement of travel and provision of subsistence in accordance with INVOLVE guidance.

More details of our PPI arrangements are contained in the REALMS form section on patient and public involvement.

Project advisory group

We have noted our strong existing engagement in developing this proposal with key stakeholder audiences (IHPN, PHIN, NHS Digital, CQC, GMC etc) and we plan to continue their involvement through our project advisory group. We will reach out to other stakeholders (such as the NHS England patient safety team, the Healthcare Safety Investigation Board, and NHS Resolution) to seek engagement.

We will invite Andrew Vallance-Owen, formerly Medical Director of BUPA Healthcare and chair of the DHSC Patient Reported Outcomes Stakeholder Group and who chaired the PHIN board until recently to chair the Project Advisory Group. He has expressed his strong support for the research. It will meet about every 4 months during the research, to provide guidance to the research team, to hear about and give feedback on emerging findings from the research, and to advise on dissemination and knowledge mobilisation.

Project audit and monitoring

The study will be subject to the audit and monitoring regime of the University of Manchester. The project will be managed by the chief investigator (KW) who has extensive experience of managing research projects to time and budget. He will be supported by Ellie Gee, our project co-ordinator based in Alliance Manchester Business School who will minute meetings and track/log actions, maintain a live critical path analysis document, and produce progress reports and other returns to NIHR.

Peer review

In addition to in-house reviews, the scientific quality of this research has been assessed by the National Institute of Health and Care Research.

Dissemination, outputs and expected impact

We plan to produce as outputs from this study both academic journal publications and a report aimed at the policy/practice community, as we have done on other similar projects. We place a very

high value on dissemination and engagement with relevant evidence user communities as is evidenced by our strong engagement with stakeholders throughout the development of this proposal, and we will prioritise opportunities to present findings and discuss their use with a wide range of policymaker and practitioner forums and meetings.

- We will share emerging findings and our reports with our project advisory group and PPI forum and through them with other key stakeholder organisations nationally
- We will use feedback from our survey in WP2 to raise awareness of the research relatively early in the project and to provide respondents with some benchmarking information about the practice of clinical governance
- We will use existing forums (like NHS England Responsible Officer networks)
- We will produce a practitioner-oriented summary of our final report and an accompanying Powerpoint presentation and make both available/promote them through social media/Twitter alongside a short video presentation from the research team on youtube/vimeo produced inhouse at Alliance Manchester Business School.
- We will produce a parallel summary of findings and video aimed specifically at a public and patient audience and involve our PPI forum members both in their production and in finding routes to dissemination. Our media team at Alliance Manchester Business school will assist in establishing opportunities for press/media coverage.
- We will work with HSR UK and some of their key partners (such as the NHS Confederation/NHS Providers and IHPN) to organise, convene and follow up on three regionally based half-day seminars for NHS and independent hospital staff involved in clinical governance setting our research in the wider system/organisational context
- We will produce academic papers for a number of high-impact peer reviewed journals in the fields of quality and safety and clinical governance. As a team we focus on early journal publication of findings which then form the basis of our final report.

Research ethics

The study will be conducted in full conformance with all relevant legal requirements and the principles of the Declaration of Helsinki, Good Clinical Practice (GCP) and the UK Policy Framework for Health and Social Care Research 2017.

This study will require NHS REC approval and coordinated research governance approval from the Health Research Authority as WP2 will involve a survey clinical governance leads in NHS and independent hospitals and WP3 will involve qualitative case studies in NHS and independent hospitals (note that the latter do not fall under the aegis of HRA and bespoke agreements with independent hospitals may be required); and WP5 will involve qualitative fieldwork with patients. Based on prior related work we do not anticipate that WP1, WP4 or the quantitative component of WP5 will require ethical approval as they involve work with data that will be pseudonymised, but appropriate data sharing applications and agreements will be required.

The key ethical concerns and considerations involved with this study include data protection, maintaining confidentiality and anonymity, obtaining informed consent, participants' right to withdraw from the study, and participants becoming distressed and/or revealing information that requires disclosure during the study. All data will be securely stored in accordance with the Data Protection Act and other relevant legislation.

Participants who complete surveys, take part in interviews, focus groups and observations will receive information about the study, including how their data will be stored, how their anonymity and confidentiality will be assured and how data requested will contribute to our investigations. During data collection (observations, interviews and focus groups) participants will be assured of confidentiality and anonymity, and specifically asked not to mention names of individuals or organisations during interviews or focus groups. Individual informed consent will be requested from those who participate in surveys and/or interviews and focus groups.

Interviews will be recorded via UoM encrypted Dictaphones or on MSTeams where they are carried out remotely. Audio files will be transferred securely on a UoM encrypted computer to a University approved transcription company. All electronic data will be stored on password protected and fire walled university network drives. Digital audio files will be destroyed as soon as possible after transcripts have been checked. All paper documentation will be stored in a locked filing cabinet in a locked office on UoM premises. Transcripts will be pseudoanonymised at the earliest opportunity and the key will be stored in a password protected file, on a password protected firewalled UoM computer and only accessed by the CI and three other members of the research team (JF, GS and EG). Once data linkage has been completed the pseudo key used to perform the data linkage will be destroyed. All findings reported in reports, papers and presentations will also be pseudoanonymised.

We plan on observing meetings relating to governance. We propose that we follow our normal practice and ask the meeting organiser to give advance notice that the meeting will be observed to all invited attendees along with a copy of the PIS and ask them to indicate if they would not wish it to be observed or if they have any concerns. If none are received, we will then ask the chair at the outset of the meeting to obtain verbal consent from attendees. If any attendees either raise concerns or do not consent in advance or at the outset of the meeting then we would not observe the meeting. Ongoing consent will be recorded by the study team in field notes and/or minuted formally. We feel that this approach is proportionate to risk, given that it is unlikely patient identifiable information will be shared at governance meetings.

The identity of study participants and study sites will remain confidential. Disclosure risk will be assessed on a case-to-case basis, with re-coding, pseudonyms or deletion of variables being used if necessary to preserve confidentiality depending on whether a combination of indirect identifiers could lead to the identification of a respondent or organisation. If this is the case, then variables will be recoded or deleted to avoid identification.

Interviews and focus groups will be led/coordinated by JF who is a highly experienced qualitative researcher who has undergone University training, attended workshops on qualitative interviewing and successfully completed the Research Integrity and Good Clinical Practice course. Participants will be given the opportunity to have interviews take place in the workplace, or by telephone or Zoom/MSTeams, or in a different neutral location away from the workface. The interviews will require participants to reflect clinical governance arrangements and practices. There is a small risk that may involve participants reflecting on potentially negative experiences and becoming distressed. If this happens, the researcher will handle this as sensitively as possible by not further probing the subject, changing the subject or asking the participant if they wish to take a break from the interview. If the participant wishes to carry on then the interview will resume. If not, the researcher will stop the interview and refer the participant to appropriate personnel if necessary.

Participants will also be reminded at this time that their participation is entirely voluntary and that they can withdraw at any time (either during or after participation), without having to provide a reason, and that this will not be disclosed to anyone. The research team will comply with requests by participants who are withdrawing from the research that any data they have contributed, including recordings, be destroyed. The research team will facilitate withdrawal up until the point that it is no longer practically possible.

There is a small risk that participants may disclose examples of serious unsafe practice that have not yet been reported through the usual procedures. Any information given by participants throughout the study indicating harm to patients or professional misconduct may be disclosed by the research team as part of a safeguarding process, in accordance with established good research practice and with the University of Manchester's own policy on whistleblowing and public interest disclosure. Of course, our participant information sheet and consent form will explicitly mention this issue. If this situation occurs, the interview will be stopped and the matter discussed with the participant making it clear what is happening, before discharging that responsibility. In the unlikely event of uncovering a previously unreported serious adverse event that directly resulted in patient harm, the researcher might be professionally obliged to report the incident through the normal risk management procedures. The terms on these issues will be clearly stated on the participant information sheet.

Statement of indemnity

The University has insurance available in respect of research involving human subjects that provides cover for legal liabilities arising from its actions or those of its staff or supervised students. The University also has insurance available that provides compensation for non-negligent harm to research subjects occasioned in circumstances that are under the control of the University.

Success criteria, potential barriers/risks to the research and risk mitigation

The main success criteria for this project are, straightforwardly, the delivery to time and target of the five main workpackages described above and the planned outputs already outlined. In the table below we set out our analysis of the potential risks to delivery of each workpackage and our approach to minimising and mitigating those risks.

ID	Risk description	WPs affected	Likeli-hood	Impact	Description of impact	Mitigating actions
1	Access to Hospital Episode Statistics /PHIN delayed	WP1 WP4 WP5	Low	Medium	Delay to quants analysis in WP1/4 and impact on case study work in WP3	Work on applications for data access to start as soon as funding approval and in advance of formal project start date. PHIN CMO is co-app, NHSD have expressed support and team have extensive experience of applications
2.	Access to ADAPt data delayed or not possible	WP5	Low	Medium	Delay or non-completion of quants analysis in WP5	Unlikely as ADAPt is central to deliver government commitment to Paterson inquiry recommendation 1 and pilots complete by March 2022. Team could seek CAG approvals to link Hospital

						Episode Statistics and PHIN data using patient identifiable data ourselves without ADAPt.
3	Data security breach	WP1 WP4 WP5	Low	High	Data access revoked.	UoM and UoY have strict data security protocols accepted by providers such as CPRD and NHS Digital. PHIN data could be analysed on PHIN servers eg without leaving PHIN secure environment.
4	Poor uptake of survey	WP2	Medium	Medium	Issues of generalisability and value of survey findings	Pre-survey engagement, strong support from PAG stakeholders and encouragement to complete,
5	Poor engagement with case studies	WP3	Medium	Medium	Difficulty undertaking or completing fieldwork	Careful case study selection and pre-engagement work, support from CQC/IPHN, good incentives to participate because of bespoke quants resources.
6	Research team changes or sickness/ absence	All	Low	Medium	Difficulties completing workpackages to time and target	Early start to recruitment of research fellow and administrator. Strong support from UoM HR and research office.

Acknowledgement and disclaimer

This study/project is funded by the NIHR [HSDR NIHR135108]. The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.

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