FULL/LONG TITLE OF THE STUDY

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

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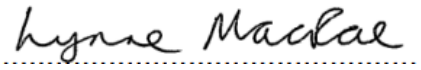
SIGNATURE PAGE

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: 17/04/2023

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ROLES AND RESPONSIBILITIES OF STUDY MANAGEMENT COMMITEES/GROUPS & INDIVIDUALS

Study Steering Groups

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.

PROTOCOL CONTRIBUTORS

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KEY WORDS: Clinical governance, NHS hospitals, independent hospitals, quality and safety, scope of practice, mixed methods

STUDY PROTOCOL

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

1 BACKGROUND

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 [1], the medicines and medical devices safety review [2], a recent Healthcare Safety Investigation Board report [3] and the Care Quality Commission state of care report [4]) have highlighted the need for improvement.

The terms quality, safety and clinical governance are often used somewhat loosely, and it is helpful to be clear about their meaning in this study. Patient safety refers generally to the prevention of avoidable harm to patients, but has a wider intellectual foundation in safety science in other industries and settings [5]. Quality of care refers to a wider set of attributes of care - safety, but also efficiency, effectiveness, acceptability, access, equity and relevance [6]. Clinical governance refers both to the systems that organisations put in place to assure and improve the quality of clinical care and the accountability of organisations for how those systems function – what has been termed corporate or managerial accountability for the quality of care [7].

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.

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 [8]. 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 [9].

2 RATIONALE

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 [1] 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 [10]. 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.”[2] 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 [3].

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 [4]. 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 [11]. MPAF provides a framework for clinical governance in independent hospitals, and an evaluation of its implementation and impact in 2021 [12] 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) [13]. 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 [14, 15]. 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.” [16]. 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 [17]. 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 [18]. 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 is scheduled to be available from late 2022[19]. ADAPt will, for the first time, permit tracking individual patient's care over time and across all four quadrants. The Health and Care Bill currently in parliament contains legislative provisions to give the Secretary of State powers to collect patient data from all independent health and care providers [20].

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 [21]. 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.

3 THEORETICAL FRAMEWORK

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 [22] 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 [23] 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 [24] 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 [25], 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 [26]. Studies of dual practice are mainly theoretical, and evidence reviews have largely focused on developing countries [27]. 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 [28, 29]. 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 [30], but their activity over both sectors has so far only been inferred by observing their NHS and private income from tax records [31].

Theoretical framing of empirical research at the interface of public and private funding and provision is important [32, 33]. Health care in the UK (and elsewhere) is delivered in highly regulated markets with combinations of public and private actors [27]. 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 [34].

4 RESEARCH QUESTION/AIM(S)

4.1 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)

5 STUDY DESIGN and METHODS of DATA COLLECTION AND DATA ANALYIS

This is a mixed methods study incorporating qualitative and quantitative methods to provide a better and deeper understanding of our research questions. The broad timetable for the stages of the research e.g. preparation will be in the first four to six months, conducting interviews and observing meeting will take place from month six and last for around twelve months, interpreting and analysing findings, preparing the final report will begin as soon as data collection begins with focussed attention on the final report in the last three months.

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

Admitted patient care data from PHIN and Hospital Episode Statistics will be analysed together to provide coverage of all four quadrants in Diagram 1. This combination will allow volume, case-mix and coding practice to be observed over a long time period covering both pre- and post-pandemic periods (2017 to 2024) and thereby contribute to answering RQs 1 and 4.

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, case-mix or coding 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

We will compare the case-mix of patients treated across NHS and independent hospitals using 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 and independent hospitals), funding source, geographical region and over time. We will also calculate the variation in these characteristics by clinical specialities and summarise the specialities with the greatest differences across our four quadrants. All differences will be established using appropriate statistical tests. Findings from this analysis will inform WP4 and WP5.

Coding practice

Quality, safety & clinical governance in NHS & independent hospitals

NHS-funded hospital care is reimbursed through the national Payment by Results tariff system which incentivises detailed recording of comorbidities, but privately funded care 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, depth, consistency 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.

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

We plan to undertake a survey of individuals involved in leading clinical governance in NHS and independent hospitals. After consultations with our stakeholders, 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 will be emailed a link to an online survey which they will be asked to complete once. This is not a survey of organisations but a survey of individuals who will be identified using publicly available email addresses. Potential survey participants will identified by their publicly available profiles and will be contacted directly by the researcher via their publicly available email addresses. Potential participants will also be approached indirectly as the survey will be undertaken with the support of NHS England and the Care Quality Commission who will assist in recruitment by cascading an email invitation to their networks. 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. 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. 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 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. Informed consent will be sought from all participants prior to participation. Participants are free to complete a questionnaire if they wish and will be advised that completion is entirely 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).

We will avoid collecting any data which is already available, for example data collected by IHPN through its impact review or by CQC through its inspections. 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.

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

WP3 will involve in-depth case studies in four “clusters” of geographically close 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. 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 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 will submit an amendment to the ethics committee when we have identified sites.

Informed written consent will be obtained from all interview and focus group participants and will involve a signed consent form that will be completed prior to participation. Verbal consent will be sought by meeting organisers prior to meeting observations and ongoing consent will be reaffirmed before the meeting.

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.

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 interview 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. Interviews will take place either over Zoom/Teams if this is more convenient or on hospital premises. 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.

Observations

We will observe meetings related to clinical governance. The purpose of the observation will be to learn how clinical governance processes are working across the NHS and independent sector. We will seek permission to observe the meeting from the meeting organiser and give advanced notice to all attendees that the meeting will be observed and the purpose of the observation, along with a copy of the PIS. We will ask attendees to indicate if they would not wish it to be observed or if they have any concerns. If none are received we 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. We will make contemporaneous notes during the meeting. When taking field notes, we will only record the details that necessary to answer the research question and code any personal identifiable information. We will ensure that we store our fieldnotes securely and have a back-up of the content electronically.

Researchers will minimise data collection and avoid including indirect identifiers (such as gender and ethnicity) that could be triangulated with direct identifiers (such as job role and organisation) to mitigate against the risk of re-identification. 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.

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 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.

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

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 both the Hospital Episode Statistics and PHIN datasets, each patient record includes a variable which identifies the consultant responsible for that episode of care.

In both datasets, the consultant identifier is based on the consultant's 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, and NHS workforce statistics) to derive other information about the consultant (such as their demographic characteristics, training, length of practice, and whole-time equivalent work in the NHS). Data like this have been used to describe and analyse the clinical workload, productivity, quality and safety of hospital consultants' practice in the NHS [30, 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.

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

Quantitative analysis of hospital data

We will compare standardised indicators of quality and safety across the four 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 four quadrants (see Diagram 1) 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.

Quality, safety & clinical governance in NHS & independent hospitals

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 from private 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).

Indicators 1-4 are constructed by linking index admissions to subsequent episodes of hospital care within the ADAPt dataset, 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 ADAPt to the Hospital Episode Statistics A&E dataset, which captures all emergency department attendances in English hospitals.

Indicator 5 is constructed by linking ADAPt 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 ADAPt (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). ADAPt does not include PROMs data and 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. Similarly, we will request PHIN to supply us with PROMs data linked to hospital admission data for privately-funded patient care. The datasets will be analysed separately, i.e. no linkage will be attempted.

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 four 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 ADAPt, 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 [25, 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/). 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 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 MS Teams/Zoom/telephone (depending on preference). We will also invite patients to submit written accounts of their experiences if this is more accessible for them.

The research has been assessed at various stages throughout the application process by experts and lay people in relation to the application and appropriateness of the methods undertaken. We will combine theories, methods and observers to help ensure that fundamental biases arising from the use of a single method or a single observer are overcome. Our findings and interpretations will be shared with our project advisory group at regular intervals who will provide feedback and alternative perspectives.

6 ETHICAL AND REGULATORY CONSIDERATIONS & ASSESSMENT AND MANAGEMENT OF RISK

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. Work on ethical approval and data sharing applications will commence in advance of the project start date to minimise the likelihood of any delays.

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 and observations.

We are yet to identify our case study sites and will identify these with our project advisory group and other stakeholders. We will apply for an amendment when we have identified these sites.

We plan on observing meetings relating to quality, safety and governance and will seek permission from meeting organisers and share the PIS with meeting attendees prior to the meeting. Informed consent will be requested from meeting attendees in advance of meeting observations. Ongoing consent will be reaffirmed by the chair at the meeting and 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 these meetings.

The identity of study sites will remain confidential. Disclosure risk will be assessed on a case-to-case basis, with recoding, 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 on 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, without giving 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.

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

- Before the start of the study, a favourable opinion will be sought from a REC

For NHS REC reviewed research

- Substantial amendments that require review by NHS REC will not be implemented until that review is in place and other mechanisms are in place to implement at site.
- All correspondence with the REC will be retained.
- It is the Chief Investigator's responsibility to produce the annual reports as required.
- The Chief Investigator will notify the REC of the end of the study.
- An annual progress report (APR) will be submitted to the REC within 30 days of the anniversary date on which the favourable opinion was given, and annually until the study is declared ended.
- If the study is ended prematurely, the Chief Investigator will notify the REC, including the reasons for the premature termination.
- Within one year after the end of the study, the Chief Investigator will submit a final report with the results, including any publications/abstracts, to the REC.

Regulatory Review & Compliance

For any amendment to the study, the Chief Investigator or designee, in agreement with the sponsor will submit information to the appropriate body in order for them to issue approval for the amendment. The Chief Investigator or designee will work with sites (R&D departments at NHS sites as well as the study delivery team) so they can put the necessary arrangements in place to implement the amendment to confirm their support for the study as amended.

6.3 Patient & 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. 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. As an experienced researcher and lecturer who has taught qualitative methods, JF has previously provided training to the PPI forum for our current NIHR funded project which included our co-applicant MM. This training covered what focus groups are and why they are used, group composition, ethical considerations, establishing ground rules and guidance for facilitation. Ethical considerations were discussed in detail, such as: disclosure and the adequacy of the information given by the researcher; comprehension and the extent to which this information is understood by the participant; and competence and the participant's cognitive or emotional capacity to give or withhold agreement. PPI forum members were also guided on facilitation and how to respond sensitively should a participant become distressed, including how to support participants and withdrawal from the study. Similar training will be provided by JF for any PPI members who wish to carry out qualitative interviews. PPI members will be supported during the interview process by JF or an RF who has undertaken the appropriate training in good research practice.

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.

6.4 Protocol compliance

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. KW (20%) as PI will lead the project and have overall responsibility for oversight of all work packages 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%) and KW (plus research fellow to be appointed 100%) will be primarily involved in the more qualitative work packages (WP2, WP3, WP5), while TA (20%), CG (100%), KB (5%) and NG (15%) will be primarily involved in the quantitative work packages (WP1, WP4, WP5) but all will meet regularly as noted above – this is essential in order to support learning and analysis across the work packages 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.

6.5 Data protection and patient confidentiality

Research data will be:

- fairly and lawfully processed for the purposes detailed in the PIS, which will state the limits of anonymity and confidentiality afforded to research participants
- not be shared with any researcher or organisation other than in ways detailed on the PIS and the ways in which it will may be used will be clearly described on the PIS and addressed in the consent process
- securely stored for the duration of the study. All computers used for storing data will be firewall and pass-word protected
- confidentiality will be preserved with respect to stored data by use of ID-numbers for research participants, which will only be known and available to custodians of the data (researchers)
- Personal information will be stored and kept securely in a locked drawer (accessed only by the researchers) and separate from any data collected
- The data will be stored for five-years and then deleted

Hard and electronic copies of data (such as consent forms and audio files) will be kept in locked UoM offices or on encrypted password protected UoM network drives. Audio files will be deleted as soon as possible after transcripts have been checked. These will only be access by the CI and three members of the research team. The pseudonymisation key will be kept on a password protected file, on an encrypted and password protected computer and will only be access by the CI and members of the research team (JF, GS and EG). Personal data will be stored separately to research data. Reports and other publications from the study may contain direct quotations from participants, these will be anonymised and will not be traceable back to individual participants or organisation. During interviews, audio recording will be used, subject to the participants giving permission. Recordings will be used only to facilitate transcription by a University approved transcriber. Transfer of audio files to the transcription service will be via a secure file upload. Digital audio files and their transcripts will be password protected and stored in an encrypted university research data storage (RDS) file. NVIVO project files containing these data will also be password protected and stored on the same university encrypted network area. Hard copies of consent forms will be kept in a locked filing cabinet in a locked office on University premises. The key will be held by the CI and data will only be accessed by the CI and three researchers working within the research team. All data will be deleted or destroyed after a 5 year period.

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 only and no remote access or transfer of the data to other locations (inside or outside the UK) will be possible. 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.

6.6 Access to the final study dataset

Only researchers on the project team will have access to the data (with access granted by the CI Walshe). All interviews and survey results will be confidential and anonymised 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 only accessed by the CI and other members of the research team. 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.

7 DISSEMINATION POLICY

7.1 Dissemination policy

This project and its five main work packages will produce a large volume of findings, and our approach to reporting and dissemination is designed to integrate those findings and provide effective synthesis for a wide range of audiences. Outputs will largely relate to the project as a whole rather than to individual work packages. 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.

7.2 Authorship eligibility guidelines and any intended use of professional writers

All those designated as the final study report authors will meet all 4 criteria for authorship recommends by the International Committee of Medical Journal Editors (ICMJE). The ICMJE recommends that authorship be based on substantial contributions to the conception or design of the work and/or the research conducted; drafting the work or critically revising the work for intellectual content; approving the final version of the work to be published and agreeing to be accountable for all aspects of the work, appropriately investigating and resolving any questions relating to the accuracy or integrity of the work where required.

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