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1. Summary of Research

The overall aim of this research is to provide evidence on the extent, quality and safety of medical locum practice and the implications of medical locum working for health service

organisation and delivery in primary and secondary care in the English NHS. The use of locum doctors in the NHS has grown rapidly over the last decade, and there have been widespread and sustained concerns among policymakers, healthcare providers, professional associations and professional regulators about the quality/safety, cost and effective use of locum doctors. There is little prior research on locum practice/performance or working arrangements to confirm those concerns or to inform the development of working arrangements for locums which will assure safety and the quality of care.
In this study, we address three main research questions:

- What is the nature, scale and scope of locum doctor working in the NHS in England?
- How may locum doctor working arrangements affect patient safety and the quality of care?
- How do the clinical practice and performance of locum and permanent doctors compare?

This is a mixed methods study, combining the use of a national survey of NHS organisations, in-depth qualitative research in some case study organisations/sites, and quantitative analysis of existing routine data sets to address these questions in both primary and secondary care.

Our project has letters of support from colleagues in NHS England and Health Education England responsible for locum doctors' policy/practice and guidance, and our prior work on this topic has been very positively received when we have presented it to audiences such as Responsible Officer network meetings and other practitioner forums.
We set out clear plans for the research to produce actionable research findings of real value to NHS organisations, to stakeholders such as NHS England/NHS Improvement, Health Education England, medical Royal Colleges and the General Medical Council, and of course to locum doctors themselves.

2. Background and Rationale

Internationally, there is an increasing shift towards non-standard forms of work such as temporary work(1) and more people have 'portfolio' careers which involve them working for shorter periods or concurrently across different organisations, often without a conventional employment relationship.(2) In the healthcare sector, doctors working in temporary positions are usually referred to as locums, and the numbers and proportions of doctors working as locums in the NHS in England have grown substantially over the last decade. Between 2009 and 2015, the use of locums in NHS hospitals almost doubled(3) and between 2015 and 2019 the number of locums working in primary care increased by 250%.(4) In 2018, 8,810 doctors were registered with the GMC as working primarily as a locum, representing 3.6% of all registered doctors, but many more undertake some locum work alongside more conventional permanent employment.(5)

Locum doctors are essential for maintaining continuity of service as healthcare organisations use them to cover gaps in rotas due to absence or recruitment and retention problems, and also to fill service gaps in underserved or shortage specialties and areas. However, rising locum numbers and the associated increase in cost has led to a growing concern among policymakers, employers and professional associations about locum use.(6-

8) Medical agency staff were estimated to have cost the NHS £1.1 billion in 2015/16,(9) and a locum pay cap was introduced in 2015 to curb expenditure.(10)

Some high profile examples of locum failures in care over recent years have contributed to widespread concerns about the quality and safety of locum doctors.(11-13) Locum doctors are often perceived negatively by patients,(6) other healthcare professionals (7) and NHS leaders.(8) They are often regarded as less professional (14) or as untrustworthy 'outsiders' who lack commitment and have poor intentions toward the organisation.(15, 16)

However, empirical evidence that locum doctors provide care which is of a lower quality or less safe than permanent doctors is very sparse.(17) But we do know that locum doctors are more likely to be the subject of complaints, more likely to have those complaints subsequently investigated, and more likely to be subject to sanctions by the GMC.(5) Locum doctors may present a greater risk to quality and safety because they often work in unfamiliar teams and settings, and are less likely to receive proper oversight and necessary support from colleagues and employing organisations.(5, 18) The presence of locums in the work environment has been described as an 'error producing condition'.(19) On the other hand, the shift towards locum working may represent a wider societal change in attitudes to careers and work-life balance and may provide employers with greater flexibility in staffing and greater externality of perspectives from locums who work across multiple organisations, while it may give locums reduced work pressures/risk of burnout, increased autonomy, and new career opportunities/flexibility.

NHS Employers, NHS England and NHS Improvement have all produced guidance on locum working and employment for NHS organisations, locum agencies and locums themselves.(20-22) However, evidence suggests that some basic requirements (such as adequate induction and familiarisation with organisational systems and procedures) are often lacking, communication especially about locum performance between organisations and locum agencies is poor, and locum doctors often are not included in or given access to systems for clinical governance and professional development.(23-25)

We have just completed an international review of the empirical and "grey" literature on locum doctors and the quality and safety of patient care (17), in accordance with PRISMA guidelines, including a comparative analysis of the use of locums in five countries. We found no prior systematic literature reviews. Overall, locums were generally regarded as necessary but potentially problematic, in that they may allow healthcare organisations to maintain appropriate staffing levels and flexibility, but they may also adversely affect continuity of care, patient safety, team functioning and costs. This literature also suggests that there is often a lack of robust systems for managing/overseeing locum doctors including inadequate pre-employment checks and induction, unclear line management structures, poor supervision and reporting of performance, and a risk that locums with performance problems move from organisation to organisation.

However, our review found only eight empirical studies comparing locum and permanent doctor practice and performance (three of which were from the UK), generally with small sample sizes and weak methodologies. The most substantial study we identified was from the USA and compared 30day mortality, costs of care, length of stay, and 30-day

readmissions for a random sample of 1,818,873 Medicare patients treated by locum tenens or permanent physicians between 2009 and 2014. There were no significant differences in 30-day mortality rates between patients treated by locums compared to permanent doctors. However, cost of care and length of stay were significantly higher when patients were treated by locums. Furthermore, in subgroup analyses, significantly higher mortality was associated with treatment by locums when patients were admitted to hospitals that used locums infrequently, perhaps due to hospitals being unfamiliar with how to support locums. Only locum doctors who provided 60 days or more of care were included in the analysis, meaning that shorter term locums, who might have had less opportunity to become familiar with the organisation, may have been excluded.(26) Overall, we concluded that there is limited empirical evidence to support the many commonly held assumptions about the quality and safety of locum working.

Our recent qualitative research on the experiences of and attitudes towards locum doctors, involving interviews with locum doctors, locum agency staff, and representatives of healthcare organisations who use locums,(25) showed that locums were often perceived to be inferior to permanently employed doctors in terms of quality, competency and safety. Despite their relatively high occupational status as medical professionals, locum doctors experienced many of the difficulties seen in research on temporary workers in other sectors, such as marginalisation, stigmatisation and limited access to opportunities for training and development. Our findings suggest that the treatment and use of locums may have important potential negative implications for team functioning and patient safety.

3. Evidence explaining why this research is needed now

We outlined above the increasing use of locum doctors in the NHS in England and growing concerns about the costs and quality/safety of locum doctors among NHS leaders, policymakers and the wider public – in part in response to some high profile examples of poor care – and the limited existing evidence base. There is therefore a vital need for high quality research to examine the realities of locum working in the NHS to inform policy and practice.

In addition, the introduction of medical revalidation in 2012, requiring all doctors to demonstrate that they are up to date and fit to practise, has highlighted the lack of robust arrangements for clinical governance for locum doctors.(27) Locums had difficulties in arranging annual appraisals and collecting the portfolio of supporting information about their practice that was required for revalidation (for example patient and colleague feedback, details of adverse events and complaints/compliments, records of CPD, etc). As a result their rates of deferral were higher than for any other group of doctors apart from trainees.(28) A review commissioned by the General Medical Council highlighted a number of concerns and recommended that the GMC and UK health departments should reform the arrangements for overseeing locum doctors.(28)

We believe there is a strong expressed need for this research. We have presented our existing research findings on locums (17, 25, 27) to stakeholders in NHS England and the General Medical Council, and to a number of Responsible Officer network meetings which bring together senior medical leaders from NHS organisations in England and from locum agencies, where they have found a receptive and very engaged audience. We have already

had discussions with some key stakeholders including staff in NHS England, NHS Improvement and Health Education England who lead on locum doctor working and who are willing to join our project advisory group and have provided letters of support for this proposal.

As our international review of the literature has shown,(17) the problems of locum doctor working have been widely and repeatedly identified over at least the last ten years by the General Medical Council, some medical Royal Colleges, NHS England, NHS Employers, the Care Quality Commission and many NHS organisations and there is likely to be continued and sustained interest in this topic. However, we have also shown that the empirical evidence base is sparse and weak, and so there is a real opportunity to generate new knowledge and to add to understanding and learning for the NHS.

We believe the actionable findings from the proposed research are likely to be useful to national stakeholders (such as NHS England, NHS Improvement, Health Education England, the General Medical Council, and medical Royal Colleges) in revising and updating the guidance that they offer to NHS organisations, locum agencies and locums themselves and in contributing more broadly to future workforce policy in this area. We also think that our findings will be used to help NHS organisations working locally to improve the use of locum doctors and to assure and improve the quality and safety of patient care, and by locum doctors themselves. Our plans for a project advisory group and for the dissemination of findings and engagement with these stakeholders are designed to promote the uptake of findings.

4. Aims and Objectives

The overall aim of this research is to provide evidence on the extent, quality and safety of medical locum practice and the implications of medical locum working for health service organisation and delivery in primary and secondary care in the English NHS. Our three main research questions are:

RQ1 – What is the nature, scale and scope of locum doctor working in the NHS in England? Why are locum doctors needed, what kinds of work do they undertake, and how is locum working organised? RQ2 - How may locum doctor working arrangements affect patient safety and the quality of care? What are the mechanisms or factors which may lead to variations in safety /quality between locum and permanent doctors? What strategies or systems do organisations use to assure and improve safety and quality in locum practice? How do locum doctors themselves seek to assure and improve the quality and safety of their practice? RQ3 – How do the clinical practice and performance of locum and permanent doctors compare? What differences in practice and performance exist and what consequences may they have for patient safety and quality of care?

This research is grounded in three main existing bodies of literature/theory which we have used to plan and frame our proposed empirical work: that related to temporary workers in organisations and the causes/consequences of precarious employment;(29-31) the wider literature on the sociology of the medical profession and particularly theories concerned with restratification and intraprofessional hierarchy and the nature and construction of professional identity; (32-34) and theories concerned with social identity and intergroup

relations, group identity and behaviours.(35, 36). The peripatetic nature of locum working may mean that locums practice on the periphery of healthcare organisations and of the profession, and may consequently have a weaker connection to organisational and professional norms and values. This raises questions about how locum doctors' professional autonomy and identity is constructed and legitimised relationally, how group identities and intergroup relationships are constructed and enacted, and the nature of intraprofessional group relationships and behaviours.

Our recent international review of the literature on locum working (17) identified eight key factors through which locum working may affect the quality and safety of patient care and which may also provide the basis for mechanisms or interventions designed to improve the quality and safety of locum working. These factors are summarised in table 1, and we plan to use this framework to structure and guide our fieldwork and analysis.

Table 1 Factors which may affect the quality and safety of locum medical practice

Theme	Theme description
Governance and patient safety	Locums are on the fringes of governance. Gaps in the oversight of locums continue to be a patient safety risk e.g. background checks. The short-term nature of locum work means that locums are less likely to take part in clinical governance activities, such as audits and continuing professional development (CPD).
Policies, procedures and continuity of care	Locums are less likely to be aware of contextual issues and local policies and procedures that are relevant to providing safe and effective care, especially if they do not receive adequate induction and briefing when they take up a locum role in a new/unfamiliar organisation. Locums are not prepared for practise in the same way as permanent staff – for example, inductions are often poor or absent meaning locums are unable to carry out their duties safely and efficiently. Other risks include not knowing how to escalate concerns, and being placed in challenging environments where staffing is an issue. Procedures may be less likely to be carried out when a locum is on duty. The use of locums presents a patient safety issue and may have a negative impact on continuity of care.
Impact on the healthcare team – scope of practice	Locums (particularly short-term locums) can place burden on other members of the healthcare team, such as nurses and junior doctors, who could be expected to perform outside of their scope of practice to compensate for a locum's lack of contextual/local knowledge/competencies.
Impact on the healthcare team – workload	Locum working can increase workload for other members of the healthcare team, for example, extra support for the locum who is unlikely to be familiar with policies and protocols and patients returning to see their regular GP.
Information exchange – patients	The quality and quantity of patient information may be reduced when locums are employed as locums are less likely to be familiar with the patient group and how to report and handover information about patients to other healthcare professionals.
Information exchange – locum practise	The quality and quantity of information exchange about locum doctor practice is poor meaning that potentially relevant information about locum practice may not be shared with their regulator, employing agency or organisation where they are employed.
Professional isolation and peer support	Locums may become professionally isolated and may be less likely to establish/maintain their professional networks and to have good informal networks of peers to turn to for advice, support or social interaction.
Professional motivation and commitment	Locums' moral purpose and vocational commitment are often called into question and it is suggested that they may be more motivated by financial rewards/incentives than other doctors, and less committed to medicine as a vocation.

5. Research Plan/Methods

This study will consist of four main workpackages designed to address the three main research questions outlined above, as follows:

- **WP1 (RQ1 and RQ2)** will involve a national survey of medical directors/medical staffing leads in all NHS trusts and Clinical Commissioning Groups (CCGs), undertaken with the support of NHS England/NHS Improvement colleagues to examine the

nature, scale and scope of locum doctor working, why locums are needed, what work they undertake and how their work is organised.

- **WP2 (RQ1 and RQ2)** will involve four largely qualitative case studies in selected NHS organisations – two focused on secondary care in mainly acute care providers, and two focused on primary care in clinical commissioning groups (CCGs). Each case study will be a detailed and in depth exploration of locum doctor working arrangements with a particular focus on understanding how locum doctor working may affect the safety and quality of care and what strategies or systems organisations use to assure or improve quality and safety.

- **WP3 (RQ1)** will involve the collection and analysis of existing/routine quantitative data sets on locum doctor working in primary care (where we will use quarterly workforce returns to NHS Digital) and in secondary care (where we will draw on weekly locum usage returns from NHS trusts/NHS foundation trusts to NHS Improvement). These analyses will provide for the first time a quantitative analysis of the nature, scale and scope of locum doctor working in the NHS and how it has changed over time.

- **WP4 (RQ3)** will involve the collection and analysis of existing/routine quantitative data sets on doctors' practice/performance which identify whether doctors are locum or permanent staff and so allow us to compare the practice/performance of locums and permanent doctors. We will use the Clinical Practice Research Datalink (CPRD) linked to Hospital Episode Statistics (HES) to examine these issues in primary care. We will use data from the Electronic Patient Record (EPR) for Salford Royal Hospitals NHS trust to examine these issues in secondary care, and if feasible will extend this analysis to other hospitals with similar EPR configurations.

In addition, we describe a fifth workpackage (WP5) for project management and dissemination activities. A detailed description of the methods for each workpackage is set out below, and we have uploaded a Gantt chart showing the project timeline and the timelines for each workpackage and its components.

WP1: National survey of medical directors/medical staffing leads in NHS trusts and clinical commissioning groups (CCGs) in England (RQ1 and RQ2)

There is some routinely collected data on the nature, scale and scope of locum usage in the NHS which we plan to analyse in WP3 (see below) but this tells us relatively little about why locums are needed, what work they undertake, and how their work is organised by NHS employers. We have very little information on locum working arrangements and adherence to national guidelines on locum working produced by NHS England and NHS Employers. For this reason, and with the support of NHS England and NHS Improvement, we will first conduct a national census survey of medical directors and medical staffing leads in all NHS trusts/foundation trusts and medical directors in all clinical commissioning groups (CCGs) to establish a consistent and comprehensive dataset on the use and management of locum doctors in the NHS in England. We have recent experience of undertaking similar surveys of medical directors in 2015 and 2016 with satisfactory response and completion rates.(24)

We found it helped that medical directors themselves see these issues as important and want to know how their organisations compare to others, and we will provide respondents with feedback on the findings from the surveys.

The surveys for NHS trusts and CCGs will differ given the very different organisational arrangements in primary and secondary care but will include data on: main areas of locum usage and reasons for/need for locum working; line management and clinical governance arrangements for locums; use of and views on locum agencies and internal staff/locum banks; implementation of NHS Employers guidance on the management of locums (including pre-employment checks, induction, appraisal, CPD, clinical governance and performance concerns); local initiatives to improve efficient and effective locum use; and medical director/senior officers' views on the quality and safety of locum doctor working and how it could be improved. We note that in primary care the operational arrangements for locum working rest largely with practices (or groups of practices such as federations) but our consultations indicate that in many CCGs medical directors have a substantial involvement in workforce strategy/planning including policies on locum working. We will pilot the surveys first with a small number of NHS trusts and CCGs, and conduct them online using SelectSurvey software. We will, of course, not collect any data which is already available from routine sources (see WP3) but we will be able to link the survey returns to that routine data.

These surveys will provide for the first time a comprehensive and detailed cross-sectional analysis of the use and management of locums in the NHS in England, and will link to and complement the quantitative analyses from WP3. It will provide important evidence on the extent to which locum working arrangements conform with national guidance from NHS England and NHS Employers, and useful data on the nature and range of local initiatives used by NHS trusts and CCGs to improve the use of locums and the quality and safety of locum working.

WP2: Qualitative case studies in four NHS organisations (RQ1 and RQ2)

The survey dataset from WP1 will be used with other intelligence from stakeholders including our project advisory group to select and recruit the four case study sites for WP2. We plan to recruit two acute care providers (NHS trusts or foundation trusts) and two CCGs as case study sites. In keeping with standard case study methodologies which focus on theoretic rather than empirical generalisation, we will seek to recruit a maximum variety sample of organisations on dimensions including size/complexity, geographic location, and self-reported or measured levels of locum. We would note that our case study sites will not be intended to provide a "representative" sample empirically, and that our surveys in WP1 will provide that wider empirical, generalizable findings and context for the case studies which will involve a more in-depth exploration of the research questions in the particular context of those cases.

For each case study site we will first collect and analyse documents such as policies, reports, minutes of meetings and other existing data sources on locum doctor working to familiarise ourselves with the organisation and its arrangements for the use of locums, and to establish working relationships with some key individuals involved in medical staffing, clinical

governance/quality and safety, and medical leadership whose help in providing access and information is important. We will write brief document summaries to synthesise key information for each case study site.

We will adapt the fieldwork plan outlined below to the characteristics of the case study sites, and will need especially to take into account the organisational differences between NHS trusts and CCGs in our approach. We anticipate that in CCGs our research fieldwork will involve some CCG staff and fieldwork in 3-4 practices with practice staff (GPs, practice managers and other staff as appropriate). The issues arising in relation to the organisational of locum working are likely to vary across case study sites, and be different in primary and secondary care.

At each case study site the research team will undertake fieldwork over 4-5 days probably split across two visits to each organisation. Our fieldwork will combine interviews with key informants; observation of meetings or other relevant activities; focus groups with patients and PPI representatives; and a critical incident study with key informants.

We will conduct about 24 qualitative semi-structured interviews in total at each case study site with: locum doctors; permanently employed doctors; nurses and other health professionals; clinical directors/clinical leaders; responsible officer(s) and appraisers; leads for medical staffing, clinical governance, PALS and patient complaints; the medical director; local Healthwatch; and, via PALS/Healthwatch with some representatives of patient/public groups with an interest in locum doctors. We will aim to undertake interviews face to face during our fieldwork visit(s), but where interviewees are not available at that time we will undertake interviews by telephone at a mutually convenient date/time. Our interview topic guide will cover: interviewees' experiences of locum doctor working; how locum doctor working may affect patient safety and the quality of care; what strategies or systems organisations use to assure and improve safety and quality in locum practice; how other staff describe their experiences of locum doctor working; and how patients or their representatives describe their experiences of locum doctors. Interviews will be audio-recorded with permission and fully transcribed.

We will arrange and conduct two focus groups with patients and PPI representatives, recruited through existing patient/public involvement or participation groups at each case study site. The purpose of these focus groups will be to seek to understand patient/public views of locum doctors and experiences of locum doctor working. The topics to be covered will be codesigned with our PPI forum and we will welcome PPI forum members helping to lead focus groups if they are able and willing to do so. Each focus group will consist of around 8-10 members with two researchers, one facilitating the focus group and the other keeping contemporaneous observation notes. Focus groups will be audio-recorded with permission and fully transcribed.

We will attend and observe meetings during our fieldwork visits which are relevant to locum doctor working and related medical staffing matters, including where possible induction meetings for locums, clinical director/leader/practice meetings where medical staffing/locum staff issues may be discussed, and relevant HR/workforce/clinical governance related meetings. We will take contemporaneous fieldnotes from meetings and write up an

observation note immediately afterwards rather than seeking to record them as we have found this approach is less intrusive and is successful in capturing meeting content and dynamics/interrelationships.

We will also use our interviews to explore participants' experiences of locum working using the critical incident technique.(37, 38) This method has been widely used in healthcare and other settings to analyse complex phenomena where an informant's personal experience of a specific example of the phenomenon is used to help them reflect on the underlying circumstances, behaviours or attributes of the phenomenon. (39) The critical incident technique is sometimes thought of as a way to explore adverse events or untoward incidents (40) but it is important to recognise that the incidents recalled may have both positive and negative features and are intended to be emblematic or typical rather than extreme or atypical in nature. Informants will be asked to select a critical incident from their work experience related to locum working and then to describe it. We may use interview prompts based on the broad themes outlined in table 1 to aid recall and support abstraction from the specific incident to the wider phenomenon being studied.
Our qualitative analysis of document summaries, observation/field notes, interview transcripts, focus group transcripts and observation notes and critical incident data will use a template analysis approach,(41) starting with a priori codes drawing on the thematic framework set out in table 1, and using NVivo computer software to manage the qualitative data analysis. We will undertake pilot coding with a sample of data by all three members of the research team (JF, KW, RA) to test and iteratively develop our coding framework before then coding the main body of data, with regular team meetings to compare coding and test out emerging findings within and across our case study sites. As this work progresses, new second order themes will be developed, abstracting from our data and linking where appropriate to themes drawing on the wider literature outlined in section 4 (such as temporary working, the sociology of the medical profession, professional identity and socialisation, and group identity and intergroup relationships).

WP3: Collection and analysis of existing/routine quantitative data sets on the scale and scope of locum working in primary and secondary care (RQ1)

There are some existing routine data sets in both primary and secondary care which have not yet been used to analyse patterns of locum working/usage and how they have changed over time. While these routine data sources have some limitations, which we outline below, we think it is important to use them to provide a more definitive and comprehensive picture of locum working in the NHS in England.

Primary care

Since 2015, NHS Digital has produced a quarterly dataset on the general practice workforce.(42) Data are produced from practice submissions which are voluntary but coverage is high, for example only 5.7% of practices were not included in the most recent release (September 2018) due to incomplete submissions. The completeness of locum data declarations has been examined by NHS Digital and adjusted to ensure that short-term as well as long-term locum staff are being included in practice submissions.(43)These data will

be used to describe characteristics of the locum workforce compared to the non-locum GP workforce.

There are currently 13 quarterly time points available from September 2015 to March 2019. We expect the analysis to include up to March 2021 which should be released in May 2021, a total of 21 time points. Within each General Practice Workforce release GPs are categorised as GP Partners, Salaried GPs, GP Registrars, GP Retainers or GP Locums. The last category is of primary interest and comparisons will be made to numbers of all GPs in the other categories.

The data reveal the number of GPs working in each practice by GP type and will be used to measure the count and proportion of locums working in each practice over time. Characteristics of these locums are not provided at the practice level to avoid possible re-identification of locums. We will supplement these data by linking practice level characteristics of interest (mentioned below). At the CCG level additional characteristics are provided. We can determine the headcount to Full Time Equivalent (FTE) ratio for locums, the gender composition of locums and the age provide of locums (in 5 year bands). These characteristics will be compared to other GP types and over time.

Descriptive analyses (descriptive statistics tables, heat maps and distribution plots) of these data will used to determine the following:

1. The current number of locums employed in GP practices and how this figure has changed from 2015 to 2021
2. The age and gender of the locum work force compared over time and compared to other types of GP
3. The geographical patterns in locum employment: including areas of high/low employment and employment in urban/rural areas

Regression analysis will be used to determine the association between locum employment and practice characteristics. The dependent variable for this analysis will be the proportion of locums employed at each practice. Independent variables will be important practice characteristic, specifically: size of patient population, age and gender composition of patient population, QOF performance, patient satisfaction, contract type, chronic condition disease registers, rural/urban location, local area deprivation and mean deprivation of patients registered with the practice.

These associations will be modelled using two approaches: (1) a single cross-section of the data from the most recent year available, and (2) a panel of all available data. The first approach will benefit from more variation in the dependent variable due to low locum use in the early years of the data, plus it will provide more contemporary findings. Multiple linear regressions models will be used here. The second approach will benefit from repeated observations per practice which can be used to model changes in locum use and practice characteristics over time. Multi-level (random or fixed effects) multiple linear regression models will be used here to account for clustering. Time will be modelled in quarterly bins.

Secondary care

Since 2016, NHS Improvement has required all NHS trusts and foundation trusts to provide a weekly return detailing their use of locum medical staff, particularly high cost locums and adherence to locum pay caps. In addition, the three national procurement framework operators for NHS Improvement (Crown Commercial Services, Commercial Procurement Collaborative and Health Trust Europe) collect detailed information on all locum placements by suppliers registered on the framework through mandatory management information returns. This data has been used to produce some management statistics for NHS Improvement on locum usage/costs but otherwise has not been analysed to date. We have secured support and agreement in principle from NHS Improvement colleagues to us accessing this data, subject to necessary information governance approvals.

As the data are currently used by the NHS we believe the quality to be sufficient for our planned analyses. However, we will first need to undertake work to evaluate data quality and completeness over the period available, assessing the consistency of data definitions and their application and writing and applying code to clean data and check for data errors/inconsistencies. Any issues involving quality or completeness will be fed back to NHS Improvement so the data may be corrected for future releases.

We will then link data to available trust-level characteristics of interest, such as bed availability/occupancy and CQC inspection ratings, as well as using published aggregated Hospital Episode Statistics (HES) data on inpatient and outpatient activity by specialty and month/year. We will produce descriptive analyses of variations in locum usage by specialty, trust type and geographic area over time. We will use regression analysis (mirroring the approach described for primary care) to examine associations between locum usage and specialty/trust characteristics.

WP4: Collection and analysis of existing/routine quantitative data sets to compare locum and permanent doctor practice/performance in primary and secondary care (RQ3)

Most routine/existing NHS datasets do not contain sufficient information to distinguish reliably between care provided by locum and non-locum doctors, and so our approach to quantitative analysis makes careful and informed use of selected datasets in which our pilot work has established this analysis is feasible, in order to address RQ3. Locum doctors can be identified either where the staff role is explicitly coded in the data set as a locum, or where records contain medical staff identifiers which can be linked to staffing/HR databases. However, especially in team settings where care may be provided by a number of medical staff including both locums and permanent doctors, it is difficult both to identify and to distinguish the distinctive contribution of locum doctors. For example, an activity (such as admission, discharge, test ordering, prescribing, operative procedure, etc) may be recorded by one member of a team (whether a locum or permanent doctor) but may have been initiated by another.

For this reason, out our quantitative analyses will focus primarily on primary care, where the quality of data is high, locum information is known to be reliably collected and available in CPRD, and the attribution of activities to individual doctors (whether permanent or locum) is less problematic. However, we also set out plans for a more limited feasibility study in

secondary care, using Electronic Patient Record (EPR) data from one NHS trust with the capacity to extend the analysis to others.

Primary care

We will use the Clinical Practice Research Datalink (CPRD) to access electronic health records (EHRs) from primary care practices. The database holds anonymised general practice records on all registered patients, including diagnoses, test, prescribed treatments and referrals. Each interaction with a health professional is recorded, through unique identifiers for patients, consultations and health professionals. The staff role field can be used reliably to identify the type of GP (partner, salaried, or locum) involved in any recorded interaction. In addition, linkage to Hospital Episodes Statistics (HES) data is available. This allows us to obtain detailed information on any form of hospital attendance for all patients in the practices that are part of this linkage scheme. Our proposal plans to use data from both CPRD Gold (practices using Vision software) and the more recent CPRD Aurum (practices using EMIS). In total we should be able to access data from about 1,100 practices for a median period of 10 years, involving millions of patient, the great majority of which have given permission for the practice data to be linked to HES.

We will analyse the data in bins of financial years. Within each financial year, our population will comprise of patients registered with a CPRD general practice for whole of the year. Preliminary analyses in CPRD have confirmed that the available staff role identifier is widely and reliably used across practices, and we will use it to identify locum and permanent GPs. This will be our key parameter of interest and we will evaluate its association with important patient outcomes. All analyses will be conducted at the patient level.

We will focus on service utilisation and patient outcomes. Our primary outcomes will be patients revisiting the general practice within 7 days or 15 days. Secondary outcomes will include: referrals to secondary care, unplanned hospital admissions within 7 days or 15 days (through HES linkage), A&E attendance within 7 days or 15 days (through HES linkage), ambulatory care sensitive conditions (ACSC) hospitalisations within 7 days or 15 days (through HES linkage), antibiotic prescriptions, and validated prescribing safety indicators (as established measures of clinical performance and quality of care) which we have already used in a prior study using the CPRD.(44)

All analyses will be controlled for available patient, general practitioner and general practice characteristics. Patient: age, sex, deprivation as measured by the 2015 Index of Multiple Deprivation (IMD, in quintiles),(45) years registered with the practice (if not collinear with age), number of practice visits in the previous financial year (or in the previous 12 months since the current consultation event) and numerous chronic conditions which are well recorded in these databases since they are part of the Quality and Outcomes Framework (atrial fibrillation, asthma, cancer, coronary heart disease, chronic kidney disease, chronic obstructive pulmonary disease, dementia, depression, diabetes, epilepsy, heart failure, hypertension, limiting disabilities, severe mental health, osteoporosis, peripheral arterial disease, rheumatoid arthritis and stroke).(46) General practitioner: sex/age are unavailable, but see analytical plan below). General practice: list-size, urban/rural location, practice location IMD (in quintiles), region, ratio of locum consultations over total within the

respective analysis year. We will also derive and describe consultation characteristics, like type, length and day of the week, although these will be used for descriptive purposes.

Our power calculation is based on the primary outcome, revisiting general practice within 7 days, and on the assumption that 10% of patients consulting a permanent GP return within that time period. Assuming 9 consultations with a permanent GP for 1 consultation with a locum, an alpha level of 5%, and an increase in the outcome to 15% for locum consultations (OR=1.59), we would need a total of 4330 patients to have 90% power to detect the association. Although this approach ignores between-practice variability in both the intercept and the association (e.g. varying return rates for permanent GPs and locus), it does demonstrate that we have many hundreds (if not thousands) times the numbers needed to detect a meaningful association.

All outcomes and key covariates of interest will be appropriately described over time, at the patient, GP and general practice level. For example, we will plot the percentage of revisits within 7 days by locum/permanent GP groups, across all practices, over time. We will use multi-level mixed effects logistic regression models to quantify the association between the exposure of interest (locum/permanent GP) and the outcomes of interest, controlling for all available covariates previously discussed. If an outcome (e.g. safety indicators) in better expressed as a count, e.g. if we identify that numerous indicators tend to apply to visits, we will use multi-level mixed effects Poisson or negative binomial regression models instead. Analyses will be conducted at the patient level, accounting for the nested structure of the data: patients within general practices, within regions. We will include random effects for practices and possibly for regions (alternatively a fixed effect for regions).

We will use two designs to reliably evaluate the association of interest. Within each financial year, we will randomly select one consultation for each patient, and then align all the outcomes and covariates to that specific event date for the patient. This will allow us to give equal weights to patients, and limit the potential for confounding introduced by patients with very poor health who may be visiting numerous times within a year. The first design, will involve a multi-level regression on all randomly selected consultation events, which will be used to obtain adjusted estimates for the exposure of interest. The second design will involve an additional step before the regression analysis, propensity score matching. This approach will attempt to select two patient samples for each exposure group (locum/permanent GP) that are as “close” and comparable as possible, in terms of all their available characteristics. We will use logistic regression to obtain the propensity score for each patient within a financial year, the probability of membership to each exposure group (locum/permanent GP) given the observed covariate values. The score will then be used to match patients in the two groups of interest, using their propensity scores (10 in the permanent GP group to 1 in the locum group – with no replacements). The propensity scores will be plotted over time and the performance of the matching process will be evaluated. Next, the matched sub-samples will be analysed with the multi-level regression models previously described. Our primary analyses will be the unmatched regressions, since our group has conducted methodological work that has demonstrated that matching can be detrimental in large samples (the methods work well for small and very small samples), while the recommended conditional regression approach for matched samples does not

confer any benefits (while it's less flexible when it comes to modelling the nested structure of the data).

Data will be complete (e.g. a patient either is coded as having diabetes or not) and of high quality since tied to financial incentives (e.g. QOF) or almost impossible not to record (e.g. consultation, or prescribing). Therefore, we will not need to use a multiple imputation framework or anything similar. Confounding is a concern, with urgent requests perhaps being more likely handled by locums – e.g. a patient cannot afford to wait for 2 weeks before his/her regular GP is back from holiday. We will partly attempt to control for that through the available patient characteristics, but we will also interpret our results with caution and use the recently suggested E-Value to assess the potential effect of unmeasured confounding.(47) The age of GPs is not available in the database, and another concern is that locums may be much less experienced that permanent GPs, hence any potential differences could be attributed to that rather than the locum status. Although we need to be careful not to "overcontrol" the analyses for the characteristics of locum GPs, since numerous GPs close to or in retirement choose to locum, we will conduct a sensitivity analysis where we will exclude more experienced permanent GPs (thus focusing on GP registrars, salaried GPs and GP retainers vs locums, repeating all analyses previously described).

Secondary care

For reasons noted earlier, our analysis in secondary care will be a more limited feasibility study. We plan to work with Salford Royal NHS Foundation Trust, who have agreed in principle to take part in the study and to provide data from their Electronic Patient Record system. Salford is a Digital Exemplar, and one of the highest scoring NHS trusts on the NHS Improvement digital maturity index. We have an established working relationship from prior research(48, 49)and we know they have comprehensive EPR datasets which capture a wide range of clinical activity at the patient level. The EPR contains specific information relating to prescriptions (BNF code, dosage details and if the prescription was changed or omitted) which is in addition to more standard information about the hospital admission (patient age, gender, admission type, days since admission). Importantly the EPR also includes a medical staff identifier which our feasibility work indicates can be used to distinguish between locum and non-locum doctors, and to describe how much of a patient's care/treatment was provided by locums.

We will use pseudonymised data extracted from the electronic inpatient record system (EPR) and linked to electronic and manual records that identify locum and permanent doctors through their EPR identity code. We will use this data to determine the scale and scope (RQ1) of locum use including how it varies between specialties/departments, across the working week and out of hours. As with previously described WPs this aspect will focus on descriptive analysis and the identification of time trends.

To understand how clinical practice and performance (RQ3) may differ for locums is complex because patients receive care from both locum and permanent doctors during an inpatient stay. To appropriately attribute activity and outcomes to care provided by a locum we will take two approaches.

First, we will focus on prescribing activity which can be linked to a single locum. Specifically, by comparing prescribing practices using both established prescribing safety indicators developed for primary care but adapted for this setting(50) and EPR data on rates and outcomes of clinical pharmacist reviews/interventions (i.e. if the prescription is changed). Multivariate regression analysis will be used and safety indicators /pharmacist review outcomes will be the dependent variable. The independent variable will be binary, indicating whether the activity was performed by a locum. We will control for patient and ward characteristics which may be prescribing outcomes and treatment by locum (for example age, gender, speciality).

Our second approach will consider each entire patient admission and approximate the proportion of care delivered by locum doctors. For example if during their admission a patient has two interactions (such as tests or prescriptions) recorded by a locum doctor but six ordered by a permanent doctor, the proportion would be 0.25. This measure will be used as the independent variable when examining length of stay, rates of emergency readmission and mortality. With this analysis occurring in one trust only we will carefully consider if we have the power to detect meaningful associations. If under-powered, the processes developed could be applied to more trust EPR data in the future. Indeed, having undertaken this work successfully with Salford Royal NHS Foundation Trust, we will if time and resources allow seek to extend it to other hospitals in the Northern Care Alliance Group with similar EPR capabilities.

6. Dissemination, Outputs and Anticipated Impact

We have noted earlier our strong existing engagement with key stakeholder audiences (NHS England and NHS Improvement, Health Education England, NHS Employers, the Care Quality Commission, the General Medical Council and networks of medical directors/responsible officers) and our plans for their continued involvement through our project advisory group are set out below in section 8. Our plans for outputs and dissemination are as follows:

- We will share emerging findings and our interim and final reports with our project advisory group and PPI forum and through them with other key stakeholder organisations nationally
- We will use feedback from our national survey to NHS trusts and CCGs to raise awareness of the research relatively early in the project and to provide respondents with some benchmarking information about locum working arrangements We will link in to the existing system of NHS England convened responsible officer networks to raise awareness of our research findings through presentations at relevant meetings We will produce a practitioner-oriented summary of our final report and an accompanying Powepoint 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 findng 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 in the NHS to organise, convene and follow up on three regionally based half-day seminars for NHS staff involved in overseeing/managing locum doctors, 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, workforce research and development, and the work, identity and socialisation of the medical profession.

We plan to engage in dissemination and outputs during and after the project life – details of timing can be found in WP5 (project management and dissemination) on our Gantt chart.

7. Project/Research Timetable

The Gantt chart shows the whole project timeline over 24 months (Jan 2020 to Dec 2021) and breaks each workpackage (1-5) down into tasks or components. There are relatively few interdependencies between workpackages. Staff recruitment will commence as soon as possible after the project is awarded, as will work on securing ethical approval, both before the formal project start date. We anticipate that dissemination and publication activities will continue well after the formal project end date.

8. Project Management

The project will be managed by the principal investigator (KW) who has extensive experience of managing research projects to time and budget. We would note that at the time of submission we anticipate this will be the only project for which he will be the PI, when this project is scheduled to start. He will be supported by an administrator based in the Institute for Health Policy and Organisation (IHPO) at 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.

The research team for the whole project is based in Manchester which will make it easy for us to meet fortnightly throughout the project – we prefer brief and 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. The project timeline is short and there is relatively little scope for slippage (see risks and barriers in section 12).

9. Ethics/Regulatory Approval

This study will require NHS REC approval and coordinated research governance approval from the Health Research Authority as WP1 will involve a national survey of medical directors/medical staffing leads and WP2 will involve qualitative case studies in secondary care and primary care organisations including fieldwork with patients and PPI representatives. We do not think that WP3 or WP4 require ethical approval as both involve work with data that will be anonymised or pseudonymised. Work on ethical approval 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.

At all study sites, all potential participants 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. For the national survey, no personal or identifying information will be requested about staff, medical directors or medical staffing leads. During interviews, participants will be assured of confidentiality and anonymity, and specifically asked not to mention names of individuals or organisations during interviews. Individual informed consent will be requested from those who participate in surveys and/or interviews. We will not require any personal or identifying information to be shared and the identity of study sites will remain confidential. Participants will have the opportunity to review their data that we plan to use/publish to solicit their feedback, giving them greater voice.

Interviews and focus groups will be undertaken by JF who is a highly experienced 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 in a different neutral location away from the workface. The interviews will require participants to reflect on how the employment of locums affects patient experience of care / working relationships. This 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, JF 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.

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 will 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 cover this issue and make provision for dealing with such disclosures. 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.

10. Patient and Public Involvement

This study has benefited from PPI throughout its development. From the outset, we have involved members of Primary Care Research in Manchester Engagement Resource (PRIMER - http://research.bmh.manchester.ac.uk/PRIMER/about/) and a local Patient and Public Advisory Board at the University of Manchester to inform the development of this proposal and to help frame our research questions.

We will establish a PPI forum with patient/public members recruited in part through the existing groups we have consulted in developing this proposal, but also through the NHS organisations we will work with as case study sites in WP2. We will seek 1-2 members of the PPI forum from each case study site who could be drawn from existing PPI groups at that organisation or from a partner organisation/agency such as local Healthwatch. We have found in the past that this arrangement helps to connect the work of the PPI forum with our fieldwork more directly. The chair of the PPI forum and one other member will also be on our project advisory group. We plan that the PPI forum will meet four times during the study, 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). We also propose enabling our PPI forum members to help lead our planned patient/PPI focus groups at case study sites if they are able and willing to do so. The PPI forum will also provide an invaluable resource for developing strategies for sharing the findings of the research with the wider community and the public. We also propose to continue attending the Patient Participation Group meetings based at the University of Manchester to update the group as we have found their feedback very useful to date, and they provide a different perspective drawing as they do on experience of working with quite a number of research projects.

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.

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