Consequences, costs and cost-effectiveness of different workforce configurations in English acute hospitals: a longitudinal retrospective study using routinely collected data

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Griffiths P. (Health Sciences)

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* Full names of change authors
PG – Peter Griffiths
FL – Francesca Lambert

Project Personnel

Peter Griffiths	Principal Investigator
Chiara Dall'Ora	Deputy Principal Investigator
Jane Ball	Co-investigator – nursing workforce
David Culliford	Co-investigator - statistics
Jeremy Jones	Co-investigator – health economics
Francesca Lambert	Co-investigator – patient and public involvement (lay researcher)
Paul Meredith	Co-investigator – health informatics
Bruna Rubbo	Senior Research Assistant / Research Fellow
Paul Schmidt	Co-investigator – clinical medicine
Christina Saville	Research Fellow

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1 Summary of Research

Background: The NHS is facing significant challenges in recruiting and retaining staff, particularly registered nurses (RNs). Recruiting unregistered staff is often adopted as a solution to the RN shortage; however, our recent research - the first in England to use longitudinal routinely collected data – found a negative effect of low RN staffing levels on mortality with no evidence that high levels of assistant staff could mitigate the increased risk. Our economic modelling suggested that increases in skill mix were potentially cost-effective, but these findings derive from a single NHS hospital Trust with limited cost and outcome data.

Aims and objectives: This project aims to estimate the consequences, costs and cost effectiveness of variation in the size and composition of the staff on hospital wards in England. We will build on findings from our previous study, where we looked at staffing on wards in a single hospital. In order to provide estimates that are more likely to apply across the NHS, this study will include at least four hospitals and consider a wider range of outcomes and sources of costs, including death within 30 days of admission, adverse events such as infections, length of hospital stay, readmissions and rates of staff sickness. In order to determine if results are likely to be sensitive to staff groups not on ward rosters we will use national routine data to explore the associations with staffing levels of other groups including medical and therapy staff.

Methods: Study 1 will be a panel study using routine national workforce data and outcomes (standardised mortality indicators, patient experience) to consider all staff groups including medical and therapy staff at the hospital level. This study will generate hypotheses about staffing for other groups, confirm the independence (or otherwise) of nurse staffing effects and fill a significant gap in international literature about the association between hospital safety and non-nursing staff levels.

Study 2 will be a retrospective longitudinal observational study with routinely collected data on ward and shift level nurse staffing, and patient outcomes. Data will be derived from the E-Roster systems, used by hospitals to record all planned and worked shifts. We will consider all rostered direct care staff. These data will be linked to patient data derived from the hospital patient administration system (PAS); and other clinical systems and databases of adverse events (e.g. datix). Relationships between RN and assistant staffing levels and outcomes will be explored using survival models incorporating mixed effects. We will use the results of these analyses to model the costs and consequences of different staffing configurations and to estimate the incremental cost-effectiveness associated with change. We will estimate cost per Quality Adjusted Life Year gained or lost (QALY), associated with each staffing configuration using the DANQALE approach.

Our study will provide evidence to inform staffing levels and skill mix planning in the NHS, highlighting potential cost savings, and offering improved patient safety and reduced adverse staff outcomes.

2 Background and Rationale

Adequately staffing hospital wards is challenging for England's National Health Service (NHS). A number of inquiries, NHS guidance, and an extensive body of research show that adverse patient and staff outcomes are associated with lower Registered Nurse (RN) staffing levels.[1-5] In the aftermath of the Francis inquiry and the publication of guidance for safe staffing in adult wards in acute hospitals by the National Institute for Health and Care

Excellence (NICE) in 2014, demand for RNs appeared to increase.[5,6] Because the increased demand for staff has not been matched by increases in supply, many hospitals are now facing difficulty recruiting and retaining sufficient RNs.[7,8] In the face of such scarcity and the need to manage expenditure on staff, care providers and policy makers face difficult decisions as they plan how to provide adequate nurse staffing levels.

The potential consequences of RN shortages are demonstrated by the extensive body of evidence showing that better patient outcomes are associated with higher nurse staffing levels. Patient and care outcomes associated with lower nurse staffing include increased risk of death,[9] hospital acquired infections,[10] falls,[11] poor patient experience,[12] and omissions in nursing care.[13] Adverse nurse outcomes include burnout, reduced job satisfaction and intention to leave.[14] The evidence remains largely cross-sectional and primarily shows hospital levels associations, leaving some to question the causal significance of these associations.[1]

Unsurprisingly, as RNs are in short supply, alternative approaches to meeting patient need are being considered. Hospitals already deploy significant numbers of unregistered health care assistants to deliver much “hands on” care to patients in hospital wards.[15] There is currently substantial variation in both absolute staffing levels and the composition of the nursing team (generally referred to as ‘skill-mix’) both between and within hospitals, and the support workforce has grown at a faster rate than the RN workforce in recent years.[15-17] For some time workforce policy has advocated an expansion of the workforce at ‘band 4’, the grade below a registered nurse and most recently the NHS in England has introduced a new role, regulated by the Nursing and Midwifery Council, the nursing associate (https://www.hee.nhs.uk/our-work/nursing-associates). Two thousand trainees commenced in 2017 and have started entering the register since early 2019 with numbers set to increase rapidly.

While the evidence indicates the potential adverse effects of reductions of registered nurses, there is no clear support for increasing the number of support workers as a strategy. Results from our pan-European RN4CAST study found that benefits from increases in team size associated with adding support staff was offset by reduced skill-mix, which was associated with worse outcomes.[18,19] Our cross-sectional study in England found some evidence that hospitals that employed more nursing support staff per patient had increased mortality, after controlling for the number of registered nurses and doctors.[15]

Estimates from published economic analyses of cross-sectional studies give highly variable estimates of cost effectiveness for increases in nurse staffing. Cost effectiveness estimates for increases in nurse staffing range from millions of $US per life saved to a potentially favourable estimate of AU$8907 per life year.[20,21] One US study concluded that increases in skill mix while holding team size constant were associated with reduced mortality and net cost savings.[22] However, when reviewing evidence for the development of safe staffing guidelines by NICE we found no UK based economic evidence.[1] An economic analysis using UK data, commissioned by NICE, estimated a cost per fall averted of £1,412 from a 10% increase in RN skill-mix.[23] The data for these studies were cross-sectional and the UK data is over 15 years old. The context of care has changed significantly, with new groups of staff such as nursing associates being introduced into the workforce.

Recent developments in e-rostering software have opened up opportunities to move beyond cross-sectional research to explore longitudinal relationships between daily staffing experienced by individual patients on wards and outcomes. However, until recently a single

study performed in a single US hospital has been the only notable example that has used these rich data, removing a significant objection to causal inference by establishing a direct association patient exposure to low staffing on wards and demonstrating that increased risks of mortality occurred after low staffing was experienced.[24] This study demonstrated that the risk of death is increased when patients experience staffing below the planned level. However, this study did not include an economic analysis, nor did it consider assistant staffing levels.

In an attempt to fill this evidence gap, our research group recently undertook the first longitudinal study using electronic rostering data to evaluate how the mix of staff in the nursing team was associated with the outcomes and cost of care (HS&DR ref 13/114/17). We found that additional hours of RN care per patient, relative to the norm for each ward was associated with reduced risk of death and shorter hospital stay. Patients exposed to low levels of assistant staffing had higher death rates, but as assistant staffing increased above the ward norm, the risk of death was also increased. Ward norms closely corresponded to planned staffing levels determined by a widely used and recognised staffing methodology [25] and for assistant staff it appeared that current levels might be nearly optimal. We calculated that a small reduction in assistant staff and a small increase in RNs (i.e. an increase in skill mix) would improve outcomes with no overall increase in costs.[17] Findings such as these have implications for how hospitals and the NHS as a whole respond to nurse shortages, but so far our results come from one hospital and use limited costs and outcomes. Furthermore, previous studies included RNs and care assistants only, so that the effect of different workforce configurations including therapy staff is still unclear.

Why this research is needed now?

Decisions about the size and composition of the nursing workforce in hospitals have major implications for both the costs and quality of care delivered to patients. Each year there are approximately 9 million admissions to hospital in England.[26] Although the risk of death is low, nearly 300,000 people (3.3%) die while in hospital or shortly after discharge. Consistent with a large body of evidence, the Mid Staffordshire enquiry and Keogh Review highlighted the potential for inadequate nurse staffing levels to cause harm to patients, including avoidable death.[2,3] Investment in nurse staffing, specifically RNs, is advocated by many professional bodies as a key strategy to reduce avoidable harm.[27,28]

While the association reported between nurse staffing and rates of death is typically small, many people are affected and so the potential benefits are great.[1] Taking an estimate derived from our recent NIHR study, each additional hour of RN care per patient day available over the first 5 days of a patient's stay was associated with 3% reduction in the hazard of death.[29] If the relationship observed in this research was a causal one and generalised across the English hospital population, increasing RN care available by one hour per patient per day could be associated with approximately 24,000 fewer deaths per year.

On the other hand, changes in nursing workforce have substantial cost implications and RNs are currently in short supply. Workforce accounts for 65% of all NHS spending.[30] There are approximately 175,000 RNs employed in English hospitals, with an additional 90,000 nursing support staff.[31] Training a RN takes three years and is estimated to cost £75,000.[32] In our recent study, we estimated that providing one additional hour of RN care per patient per day would increase labour costs for a large (800 bed) general hospital by about £10.1 million per year, some £219 per patient and 2% of the hospital's budget.[17] We estimated the cost per

life saved of a one RN hour per patient per day increase to be £47,376. Increasing skill mix by making small reductions in support staff and small increases in RN staffing was potentially cost neutral once the value of hospital bed days saved was considered.

Because of the curvilinear relationship we observed between support staff levels and patient mortality, there appeared to be no benefit from increasing their number from current levels. This presents a major challenge to current initiatives to increase the recruitment of support staff, although the effect of addition of nursing associates to the skill mix has an uncertain effect, which has not yet been studied.

While our recent NIHR study has gone some way to address the lack of economic evidence, identified by NICE, it is limited to a single site. Furthermore, while the staffing / outcome association we found is consistent with other evidence, studies showing longitudinal relationships at the patient level remain rare and have been limited to single hospital studies. Our findings on support staff provide a more nuanced picture of the contribution of support staff compared to previous research, but so far, this is the first study to find such a relationship. We considered only staffing and bed day costs and considered a limited range of outcomes. We did not consider the costs of treating adverse events nor costs associated with readmission. Additionally low nurse staffing has been associated with adverse staff outcomes including burnout and intention to leave.[14] While important in themselves, these factors also have implication for the costs and / or effectiveness of the ward team as sickness absence and staff turnover may arise as a result. Finally, while we estimated cost per life saved, we were unable to consider the likely length or quality of lives saved, making comparison with the value of other investments in health care difficult. As the challenge to maintain a safe nursing workforce increases, it is essential to further our understanding of the costs and consequences of nurse shortages and strategies to remedy them, such as substituting assistant staff.

As part of the dissemination of this recent study, we organised a gathering of interested NHS leaders, researchers and members of the public. We took the opportunity to discuss future research priorities with this group. In addition to addressing the gaps outlined above, they identified the importance of up to date data in the light of changing profiles within the nursing care workforce and the importance of considering the contributions of a wider range of professional and non-professional staff. This is particularly important, as shortages of registered nurses may not be easily remedied in the short or even medium term. Evidence that can suggest alternative potential ways of addressing safe staffing is vital and, furthermore, it is important to ensure that focussing on nurse staffing does not have unintended consequences by implicitly encouraging disinvestment in other staff groups who may make an equally important contribution to safe and effective care on wards.

3 Aims and Objectives

This study aims to provide evidence to support decision making about cost-effective deployment of nursing and other care staff on hospital wards in England and, therefore, strategic decisions about policy to address current nursing workforce shortages. We address the question of which combinations of care staff employed by hospitals and deployed on hospital wards provide the most cost effective care in terms of patient safety, experience and efficient use of resources.

Because staffing inputs at a patient level by some important groups (e.g. doctors, therapy, pharmacists) are not readily tracked at a ward / patient level in routine data, we will initially explore the impact of different workforce configurations (including medical and therapy staff) on risk adjusted mortality rates and patient experience at a hospital level, using nationally reported hospital level staffing and outcome data to undertake a panel study (study 1).

In Study 2 (longitudinal, patient level) we will model how variation in daily care staffing levels and skill mix are associated with:

- Death in hospital and within 30 days of admission
- Length of hospital stay
- Readmission within 30 days of discharge
- Other adverse outcomes (e.g. pressure ulcers, hospital acquired infection, falls)

We will also use e-roster data to determine how staffing levels and configurations are associated with

- Staffing costs
- Staff sickness absence and turnover
- Cost arising from staff sickness/absence
- Other service costs associated with adverse outcomes
- Incremental cost per life saved and per quality adjusted life year

We will explore data in order to identify staffing thresholds associated with adverse outcomes by modelling non-linear effects between staffing variables and outcomes. In order to inform decision making about staff deployment at a ward level, we will explore whether there is evidence for different thresholds in different ward types or for different patient groups.

We aim to estimate the costs and the consequences of variation in nurse staffing. We will estimate other service costs associated with adverse outcomes and, in order to inform strategic decision-making we will also estimate incremental cost per life saved and per quality adjusted life year associated with changes in staffing configurations that are suggested by the results of the analyses above.

4 Research Plan / Methods

Design

Study 1 is a hospital level national panel study using routinely reported hospital level staffing and outcome data. Study 2 is a patient/ward level retrospective longitudinal observational study using routinely collected data on ward and shift level nurse staffing, and patient outcomes.

Study 1

This study addresses a series of key questions to address our aim including:

- Which staff groups (in terms of staff per bed) are associated with patient outcomes at the hospital level?
- Do any nurse staffing effects appear to be attenuated when considering the association between outcomes and staffing by other groups?

Although measuring longitudinal associations between exposures to ward rostered staffing levels mitigates many of the limitations of cross-sectional research, the potential contribution of other members of staff who are not ward based cannot be readily measured in this way using these data. A longitudinal design focussing on individual patient exposures (see study 2), coupled with our adjustment for weekend effects (known to correlate with staffing levels by other groups) and use of individual ward norms to standardise staffing levels means that inferences about variation in staffing levels within wards are largely immune from this issue. However, our ability to make inferences about differences between wards, especially across different hospitals, remains limited by this.

A panel study of associations between staffing levels by all staff groups (nursing, medical, therapy etc.) at a hospital level can generate hypotheses about staffing, confirm the independence (or otherwise) of staffing effects and fills a significant gap in international literature about the association between hospital safety and non-nursing staff levels. We will model our approach on our previous cross-sectional studies where we considered the association between medical, nursing and assistant staffing levels and mortality,[15] extending the analysis to cover more staff groups and multiple years, applying longitudinal difference in difference models where data series allow.

Sampling and Data sources

Hospital staffing data for the cross-sectional national study will be obtained from the annual NHS staff census (for all staff groups) and NHS improvement published care hours per patient day (for ward staffing). Outcomes will be extracted from the published standardised mortality rates (HSMR, SHMI), safety thermometer data (NHS Improvement, reporting monthly nursing related safety events such as incident pressure ulcers based on a point of care survey) and national inpatient survey results. For patient experience, we will use anonymised respondent level data from the UK Data Archive via the UK Data Service. Sample size varies by year but for 2017, the survey contains responses from over 70,000 people who spent one or more nights in an acute or specialist hospital. We expect to be able to link Trust level staffing, bed occupancy and outcomes for approximately 130 acute Trusts.

Data analysis

For mortality based outcomes, analysis will be undertaken at a hospital level with the standardised mortality rate regressed onto hospital level staffing (expressed as staff per occupied bed) with other hospital level variables (e.g. size, teaching status) included as covariates. For patient experience data derived from the national inpatient patient survey we will calculate standardised hospital level response rates (standardised for age, sex and other demographic characteristics) for global ratings of experience (e.g. Q68 in the 2017 survey) and key nursing specific items (Q26-30 in the 2017 survey) and then apply a similar modelling framework. In our previous work applying a Poisson distribution with the local population size (admission / responses) as an offset has proved to be a parsimonious approach providing good model fit.[15] For patient safety thermometer data we are able to link ward level staffing to outcomes with other staff variables modelled at a hospital level (included as level 2 variables) in a multi-level modelling framework in which hospital is included as a random factor. As we potentially have multiple time periods for all outcomes

we can extend the modelling framework to include the multiple observations and outcome measures per Trust (and ward) and potentially apply difference in difference models should the necessary assumptions for such models be met.

We believe the potential for bias in this level of analysis means that we should treat the results as hypothesis generating rather than definitive and so we do not propose using the results directly in the economic modelling. However, we will use the results to determine if there is evidence that inclusion of other staff groups might alter estimates of nurse staffing effects and use such results to inform our sensitivity testing for the economic analysis of Study 2.

Study 2

This study addresses a series of key questions to address our aim including:

- What level and mix of staff on hospital wards is associated with improved outcomes for patients?
- Are relationships between staffing and outcomes linear or are there thresholds and, if so, are these similar or different in different patient groups?
- What are the consequences, costs and cost effectiveness of different staffing combinations?

Setting/context

The study will take place in at least four acute general hospital Trusts. Trust will be selected for eligibility based on willingness and ability to provide anonymised patient data and the ability to provide electronic roster data for a minimum period of 1 year prior to the commencement of the study. Over and above this, should we have the ability to select from willing and able participants, we will seek to maximise variation with consideration of trust type, regions and base staffing / vacancy rates.

We have informal expressions of interest and ability to provide suitable data from six additional Trusts. These Trusts display large variation covering a diverse geographical area with mixed urban rural catchments, covering areas of affluence and deprivation in the South East, South Central, South West and East Midlands. They also exhibit variation in Trust type, size, average staffing levels, and population health indicators, making the sample heterogeneous. For example, CHPPD on general surgical wards range from 5.37 to 11.29 between different Trusts. RN Skill mix in general surgical wards ranges between 52% and 73%.[36] Assuming all six Trusts participate there will be a total of approximately 5,300 beds on six Trusts with over 200 wards.

Sampling and data sources

Data for the study will be derived from a database of records of all staff rostered to work on a ward on a given shift (e-rostering); supplementary records of bank and agency staff working on the ward (if held separately); patient data derived from the hospital patient administration system (PAS etc.), clinical databases of vital signs observations and adverse events register (Datix). Shifts worked will be used to quantify hours of care available and staff costs, while shifts not worked will be used to identify sickness absence and additional staff costs.

The data have a complex hierarchical structure requiring linkage at different levels. Data about shifts worked by staff members from the roster must be aggregated over a period of time within a ward to give a measure of staff deployed on a ward (e.g. nurse hours per day).

This must be linked to patient data which provides the source of the caseload on the ward on a given day (e.g. patient days). The resulting staffing levels (e.g. hours per patient day) provide an 'exposure' variable that must be linked to individual patients and their demographic and clinical details (including prognostic factors and outcomes) as they move through the hospital experiencing varying staffing levels on one or more wards over the period of their hospital stay (see flow chart).

The team has considerable expertise in dealing with and linking such data. Patient caseload on the ward will be derived from admissions, discharges and transfers recorded in PAS, linked to staffing data derived from the e-roster. These will be linked to derive patient data based on wards for each day of their stay. We will use diagnostic and demographic (including age and comorbidity) data from PAS to determine rates of mortality and other outcomes and to adjust for patient level variation in risk of death. Data from other clinical and administrative databases will be linked to patients in order to determine other outcomes and adjust for patient level variation in risk.

We will include all acute inpatient wards / admissions units (including HDU and ICU). Our recent HS&DR study used three years of data from Portsmouth Hospital Trust. In order to ensure currency and to avoid duplication we will use the end of this study as our starting point (March 2015) and seek at least four years of data (to March 2019) although there may be opportunity to extend the time period, while recognising that some source of data may not be available for the entire period. Based on this 4-year period and the sample of 'interested' Trusts we estimate up to 6.5 million 'bed days' of patient exposure to ward staffing levels will be available. Assuming mean length of stay in the order of 7 days, the study will involve close to 1 million admissions.

In order to provide nationally representative cost estimates we will apply standard reference costs for staff where available, for example for nursing staff costs we will use hourly staffing costs derived from the unit costs for health and social care.[32] For other costs, we will assess the availability of local patient level costing and the potential to use this to estimate other (non-workforce) costs such as the costs of treating adverse events.

Outcomes

The primary outcome for the study will be death from all causes within 30 days of admission.

Secondary outcomes will include:

- Length of hospital stay
- Readmission within 30 days of discharge
- Other adverse outcomes (e.g. pressure ulcers, hospital acquired infection, falls)
- Staff sickness absence and turnover
- Staff costs including costs arising from sickness / absence
- Other service costs associated with adverse outcomes
- Incremental cost per life saved and per quality adjusted life year

We will estimate quality adjusted life years (QALY) as the primary economic outcome based on the discounted and quality-adjusted life expectancy (DANQALE) approach.[37] This is a method to quantify effects of service interventions in terms of QALYs in absence of primary data collection on Health Related Quality of Life or preferences, which is not feasible in this study. Staff sickness will be estimated by identifying shifts that are rostered but recorded as not worked due to sickness/absence. Staff turnover will be estimated based on linked records of staff shifts to identify when staff leave a ward or the hospital.

Staffing variables

Our primary approach to measuring staffing will be to calculate hours per patient day (HPPD) (i.e. a 24-hour period starting at midnight) for rostered staff.

For each ward, the rostered hours for each day will be calculated from the E-Roster with all hours between the shift start time and end time contributing (i.e. from midnight to midnight). Staff shifts that are not worked due to sickness will be removed from the calculation of hours provided but retained for calculation of staff costs and ward sickness rates. We will focus our analysis on registered nursing hours (registered nurses bands 5+) and assistant hours (health care assistants, assistant / associate practitioners etc.). Within each group, we will consider the 'skill mix'. Final decision will depend upon the observed distribution but we provisionally propose using proportion of more highly qualified band 4 (vs others) for assistant hours and proportion of senior (band 6+) vs junior (band 5) for registered nurses. Where other staff groups are rostered on the ward in significant numbers, we will take a similar approach.

For each day, we will also calculate 'patient-days', with 1 patient-day equivalent to one patient occupying one bed for 24 hours. The daily number of patient-days for each ward will be calculated using the admission, discharge and transfer information during a 24-hour period (i.e. from midnight to midnight). For example, a patient occupying the bed for 12 hours would be assigned a value of 0.5 (patient hours / 24). Consequently, patient-days represent the average number of occupied beds in a 24-hour period. By combining these data with the staffing hours, we will calculate hours per patient day as the sum of hours worked by each group divided by patient-days. Shifts that are recorded as sickness absence will be retained for the purposes of costing and calculating rates of sickness but removed from hours worked.

Using the same approach, we will calculate hours provided by temporary nursing staff employed via the hospital's bank or from an outside agency and calculate the proportion of such staff on each day. Additionally we will derive a measure of workload associated with patient admission and discharges, the number of admissions per nursing hour, shown to be associated with patient outcomes in our own and other previous research. [17,24] If we are able link staff members across multiple shifts we will use this to estimate staff turnover within the ward, differentiating leavers from the hospital from those who change wards within the organisation.

Using this approach, we are also able to derive staffing levels at a more granular level, approximating nursing shifts, although the diversity of shift patterns in operation makes exact matching to shifts challenging.

Data analysis

We will assess patient outcomes at the individual level, with patients being exposed to varying staffing levels throughout their stay in hospital. The primary clinical outcome will be death within 30 days of admission.

Staffing levels for each day of each patients stay will be linked to the patient records. Because baseline ward staffing levels vary based on assessed patient need, following the approach taken in our previous study, our primary staffing measures will be based on staff hours per patient day relative to norms for each and every ward. We will explore a variety of approaches to determining ward norms including using establishments (planned staffing) determined by an evidence-based tool as the norm.[25] Where Trusts are able to provide daily

patient acuity / dependency assessments derived using an evidence-based tool, we will use deviation from the assessed staffing requirement as a criterion, although this may not be available for all wards / Trusts over the entire study period.

We will model exposure to varying staffing levels from each major staff group. Patient turnover (admissions, discharges) per staff member will also be included as a measure of workload. We will add variables to account for skill mix within the main staff groups and the proportion of temporary staff to the models to determine the contribution of these additional variables, using criteria for model fit (see below) to determine whether these additional variables add to the overall explanatory power of the models. We will consider staffing in a variety of ways including, as absolute deviations from norms and cumulative shortfalls over the stay. Our primary analysis will use staffing level (in hours per patient day) relative to the ward mean, a continuous variable which will allow us to explore and identify non-linear effects and thresholds.

In order to control for patient level variation in risk we will include variables based on the nationally validated SHMI model,[26] supplemented by measures of acuity risk based on clinical vital signs (early warning scores) shown to be strongly predictive of mortality (AUROC for death within 24 hours 0.89).[38]

For death and other adverse events we will use we will use survival models incorporating mixed effects to account for the hierarchical nature of the data. We have repeated observations on the same patient over a period of time from the admission (i.e. onset of risk) until death/adverse event or the discharge date. Covariates of interest (such as ward and staffing levels) change over time and, thus, we specify a survival model to account for repeated measurements, time-varying covariates, and unobserved patient-specific characteristics. Based on the results of our previous research a parametric, (exponential) distribution is assumed for the baseline hazard function, as it provided superior model fit to the Cox Proportional Hazards, where no distribution is assumed. Such parametric modelling requires careful consideration. We will use appropriate diagnostic methods to assess distributional fit and other relevant measures throughout the modelling process. Length of stay is measured on a continuous scale, which exhibits a right-skewed distribution with mode near zero and heavy tails. Therefore, to better represent length of stay data features, the gamma distribution will be used.

Based on previous research we will focus analysis on exposures that occur during the first five days of the hospital stay – accounting for the majority of the stay for the majority of patients – although we will assess the sensitivity of results to staffing experienced over longer and shorter time periods.

As low staffing can be associated with particular times of year and days of the week, we will add variables to control for season and weekend stay / admission. In our previous study, we identified a linear effect for RN staffing levels (over the range observed) but a potentially curvilinear relationship for assistant staffing. We will explore the data to determine evidence of non-linear effects by adding cubic and quadratic terms for staffing variables. Should we find such evidence we will consider modelling the relationships using splines, depending on the shape of the curves we observe, although curves that are approximated by lower order polynomials match the likely relationships that can be hypothesised (e.g. curves flattening at higher staffing levels) may provide a sufficient and more readily interpretable approximation.[39] We will add interaction terms in order to determine whether the effect of

one staff group is contingent on the level of another – specifically exploring the hypothesis that adding assistant staff will improve the relative effectiveness of registered nurses.

Secondary analyses will consider low staffing as a qualitative variable using various thresholds to define 'low' staffing including below 15% of the established (daily) staffing requirement, a level of deviation assumed to be acceptable providing a criterion of low staffing using the widely researched RAFAELA tool,[40] and / or any thresholds suggested by our analysis of non-linear relationships.

We will undertake sub group analyses considering only particular patient groups (e.g. older patients, groups with high mortality risk) and / or exposure to staffing in particular types of wards. As the assumption of common baseline staffing requirements for similar ward types or patient groups is more tenable we will also undertake analysis using absolute as well as relative staffing levels although there is a substantial risk of confounding by indication (high staffing linked to higher risk) unless the risk model is well specified. Although we will include paediatric admissions and wards these form a largely distinct service and patient population with a low mortality risk and so our default approach will be keep models for this patient group separate for all analyses.

For staff outcomes, we will treat staff sickness absence or turnover in a manner that is analogous to adverse events occurring to patients, with the staff member's exposures to low staffing over the preceding period used to predict the event, although time windows are likely to be longer. In these models, we will also consider factors known or hypothesised to be related to sickness absence and turnover such as typical shift length and total hours worked, based on the approach taken in our previous research on shift length, using similar data.[41] Previously we were unable to include additional personal data derived from the electronic staff record to further control for individual differences in propensity for sickness / absence although adaptation of these analyses to account for repeated measures of individuals will mitigate this to some extent. However, we will explore the possibility of obtaining consistent additional demographic data.

Because there are a number of structural factors that largely operate at a hospital level, or are not easily linked to individual wards, including levels of medical and other therapy staff, we will initially model each hospital separately. Depending on the results, combined models with data from multiple hospitals will allow for random slopes in addition to random intercepts.

In the context of hierarchical generalized linear mixed models, the choice of the model structure is a crucial aspect of the model selection process. The prevailing approaches, which have been adopted to balance model fit and parsimony, are based on information criteria, obtained through penalizations of the maximum log-likelihood. As we build from our core model (patient risk and linear staffing exposure) we will consider additional factors and judge the extent to which the model is improved. We will use the Akaike information criterion (AIC) and the Bayesian information criterion (BIC) to assess model fit,[42] preferring models that minimise the values. We will consider non-linear effects before interactions as mis-specified linear main effects can generate spurious interactions.[43]

Economic analysis

We will use the results of these analyses to model the costs and consequences of changes in staffing and additionally to estimate the incremental cost-effectiveness associated with change. As employment costs fall upon hospitals we will take an NHS hospital provider cost

perspective. Our time horizon is from admission to 30 days post discharge with post discharge costs measured in terms of the cost of readmissions.

We will use national reference costs and unit values to estimate staff costs.[32] The unit costs will be applied to all nursing staff employed in the wards taking into account the agenda for change band. Additional charges will be included to account for costs associated with employing agency staff. Because staff on short term sick leave are still paid for by the hospital shifts recorded as sickness absence will be included in the daily staff costs, with appropriate adjustments made in the case of long term sickness absence where the person concerned remains on the roster.

Should we see that staffing levels are associated with other adverse events or changes in resource use, we will attribute costs (e.g. treatment of pressure ulcers extended stay, readmission, and staff sickness) using authoritative sources. Costs of extended stay will be based on NHS reference costs for excess bed days with any increment to the length of stay associated with staffing change costed as an excess bed day. Costs of readmissions will be based on the current HRG tariff for the condition associated with the readmission. For treatments of adverse events we will seek estimates of incremental costs, over and above the cost of the hospital stay, such as that used by NICE for the treatment of hospital acquired pressure ulcers.[44] We will explore with Trusts the availability and utility of patient level costing data although our preliminary exploration of this suggests that nurse staffing costs are included as a fixed rather than varying (daily) cost at the ward level, which may prove difficult to disaggregate and undermine our ability to identify the effect of varying nurse staffing levels on other costs.

In order to facilitate comparison with other investments, should changes in mortality be associated with changes in staffing, we will estimate a cost per QALY. Our approach will use the discounted and quality-adjusted life expectancy (DANQALE) approach.[37] The DANQALE tariff uses sex specific life expectancy estimates at each single year of age are, taken from the ONS life tables. Age-sex specific quality of life adjustments are sourced from mean values of the EQ-5D index reported by respondents to the most recent wave of the Health Survey for England with an annual discount rate based on the prevailing rate used by NICE for their reference case (currently 3.5%). [45] Because we will extrapolate from estimated mortality rates we will assume that estimated lives saved (or lost) associated with different staffing levels resemble the population of patients who die. We will calculate the expected QALY had these patients survived, using the DANQALE method and determine the population average. For our primary endpoint we will assume this population average applies to all lives saved (or lost) with changes in staffing. We will determine the sensitivity of conclusions to this assumption by applying alternative estimates of life expectancy and quality of life to explore the possibility that lives most likely to be “saved” are those with better than average life expectancy for the age / sex within the group (i.e. fitter patients more likely to be ‘saved’) or, alternatively, worse (i.e. there is additional unmeasured risk after survival relative to the general age / sex stratified population).

Plausible scenarios to be modelled will be identified informed by our stakeholder engagement, including engagement with patients and the public (see relevant sections) and by the results of our analyses. We will not calculate incremental cost effectiveness ratios (ICERs) for strategies that are clearly dominant or dominated, but anticipate estimating ICERs for single unit increases in staffing (in terms of hours per patient day) or adding a single member of staff to a typical ward and comparing incremental cost per QALY for

adding different members of staff or changing skill mix within and between the registered nursing and assistant staff groups.

While QALYs facilitate comparison with other health investments, nurse staffing does not have a single effect. Other outcomes in our analysis such as readmission and adverse events are in themselves important to patients. Therefore, we will also present the consequences for each outcome we study – such as length of stay, readmission and staff sickness – arising from each staffing configuration modelled alongside the costs and the ICER.

We will undertake sensitivity analysis to determine the extent to which conclusions are sensitive to estimates of effect derived from regression models and to the assumptions made about costs. We will undertake both one way and multi-way sensitivity analyses to determine the sensitivity of models to key assumptions. For staffing costs and QALY we will seek to identify thresholds at which conclusions alter.

Approach to causal inference and generalisation

We will take a cautious epidemiological approach to assessing causality of the exposure-outcome relationship informed by the so-called Bradford-Hill criteria,[46] including the following elements: the strength of association between exposure and outcome; the temporal sequence between exposure and outcome; the dose response relationship between exposure and outcome; and the reproducibility of the association.

While there is now extensive cross-sectional evidence for an association between nurse staffing and a number of patient and staff outcomes, which is plausibly causal, longitudinal evidence is relatively sparse. Our study will be one of the view to determine temporal associations – that is determining whether the presumed cause (low nurse staffing levels) precedes or is simultaneous with the adverse outcomes. Our analyses will pay close attention to the shape of any relationship, and will consider whether there is evidence of a plausible ‘dose response’ relationship between nurse staffing and outcomes.

The aspect of reproducibility will be approached by investigating the relationship in diverse settings and patient groups. We will consider the consistency of the relationship across the settings in the study. The use of random effects models allows the gradient of the relationship to vary across hospitals but we would expect that it would be consistent in its direction.

We are able to adjust for potential confounders at the patient level and have established risk models for mortality, which have been shown to perform well. Because we do not have comparable staffing data for medical teams, it is not possible to directly consider medical staffing levels (or indeed other staff) as a potential confounding variable in the analyses. However, we will scrutinise the results of our longitudinal analysis in order to see if there are patterns that might be consistent with such confounding. For example, we will explore whether nurse staffing levels vary with periods where there are known variation in medical staffing levels (for example weekends). Assuming this to be the case, all our analyses will include day of week (or weekend vs weekday). Additionally our analysis of national data allows us to consider the influence of other staff groups, potentially confirming (or disconfirming) independent nurse staffing effects while at the same time generating hypotheses about the influence of other staff groups on key outcomes.

Data management

Depersonalised data will be provided by the Trusts in their original form, with direct patient identifiers replaced by a study identifier before transfer (pseudonymisation). Checks on validity will be undertaken to identify and rectify issues with source data. The data will be stored in encrypted form in a data repository that is subject to additional security checks and access control. Access to the database will be limited to members of the research team and designated support staff. From the repository, datasets will be generated that address particular aspects of the analysis. Final cleaning of the data, adjusting or excluding missing values will be done at this stage. Where convenient / required for analysis, synthetic categorisation (relating date/time to shift for example) will be performed. These data will be shared with the remainder of the analysis team. All transfers of individual patient data will use secure data transfer protocols.

We will follow the Information Commissioner's Office guidance, as set out in the managing data protection risk code of practice for anonymization and the use of anonymous data. In this case the risk of re-identification is managed and reduced to a level that it should be considered remote. Additionally, in the highly unlikely event that such identification occurred, the consequential risk to the individual is low. This is because

1. The research team will not have access to patient or staff identifiers (including names and patient / staff numbers) and no means of linking data to such identifiers in the hospital system
2. We do not seek any information such as address or postcode area that might make it easy to link these data to other records
3. We will not link patient data from hospital systems to any data other than ward staffing levels
4. Access to the data will be limited to members of the research team and named collaborators who manage databases, who are versed in confidentiality and data governance
5. Data will be stored in a secure digital environment with robust and tested security procedures.
6. Data files will be encrypted and password protected, making it highly unlikely that a motivated attacker could access it.
7. Even if a motivated attack occurred and succeeded, it is very unlikely to be sufficient to identify a living person unless the information contained is already known.
8. Identifiers for specific hospitals and wards will be suppressed in reports and descriptions made less distinctive to reduce the chance of their identification
9. Constellations of data that might result in reporting small numbers (<10) with rare circumstances (e.g. X people with diagnosis y on ward Z at date abc) will not be published.

5 Dissemination, Outputs and anticipated Impact

What this research will produce

We anticipate a number of papers for academic peer review journals that will contribute to the emerging literature on the mechanisms of the link between nurse staffing and patient outcomes. The 'core' papers that we anticipate are:

i) The association between hospital level staffing and outcomes
ii) Patient level associations between variations in ward staffing / skill mix and adverse events
iii) Association between nurse staffing levels and staff sickness / absence events
iv) The cost effectiveness of different staffing configurations

We will prioritise journals that are read by a broad audience of health researchers and professionals and which have options for gold open access. Our ability to deliver these papers will be partially determined by editorial policies in relation to the publication of results in the NIHR HS&DR journal, although we anticipate peer review papers preceding this publication. Additionally we will present findings at key national and international conferences with likely candidates being the US Academy Health annual research meeting, International Forum on Quality and Safety in Healthcare, RCN International Research Conference, as well as conferences targeted at NHS managers.

We recognise that these peer reviewed outputs provide a necessary foundation for dissemination but are not, in themselves, likely to be sufficient to reach and influence key decision makers. We are committed to dissemination to a wider audience of health service managers and will aim to disseminate summaries of findings and implications using a policy brief format, via journals such as the HSJ and Nursing Times, and using networks linked to bodies such as NHS Improvement and the Royal College of Nursing.

We will also prepare a number of accessible outputs to be used alongside other dissemination activities including a concise set of PowerPoint slides of the main findings, infographics and an animation that can help explain the research findings and engage the varying audiences. Depending on results we will also consider designing and deploying an interactive modelling tool allowing decision makers to change parameters from the economic models and consider potential effects.

Informing and engaging patients, NHS and the wider population about our work

Engagement and communication will be integral to the research from the outset. Our goal is to stimulate discussion and dialogue amongst a wide range of decision makers and stakeholders in order to help shape the research; to be aware of different contexts to tailor the communication strategy for different groups; and to prepare the ground in order to maximise the uptake of the research findings. We have an excellent track record of using traditional and social media to draw attention to key messages from our research and engaging both public and professional audiences. Our papers in top journals feature among the most widely reported / talked about as measured by Altmetrics. Our 2014 Lancet paper[9] was ranked as one of the most talked about of any papers in the year it was published and remains in the top 0.01% of papers ever tracked. Papers from our team are the highest ranked from leading journals in the field including BMJ Quality and Safety, and International Journal of Nursing Studies. Our publications also score highly in traditional citation metric and media reports of our work has provoked substantial debate and comment from the public via comment on news articles and similar. This is particularly important as it is relatively challenging to reach patients and the public through networks that are predominantly linked to interest and support for particular conditions.

We propose launching the study by hosting a one day engagement event to bring together a wide range of interested parties including senior nurses, policy makers and members of the public / public representative bodies to consider current knowledge on staffing levels and outcomes, and to outline the new study. The event, within six months of the study start, will

serve multiple purposes: to highlight that decisions about staffing levels may have patient outcomes implications, in order to sow the seeds for future diffusion of emergent messages, to stimulate awareness of the study itself, to better understand the context and perspectives of stakeholders, to engage stakeholders in thinking about the study design, and to identify an interested body of people that we can connect with throughout the study. Through advertising the event and achieving coverage of it via multiple media, we aim to prime interest in the study's findings more widely, across the UK. After the event, a stakeholder consultation report will be published as an "evidence brief" in a lay language.

A similar engagement event – which will include, but not be limited to, the participants from the study launch event – will be held in the last six months of the study. We will use this event to share key findings from the research with stakeholders, in order to 'sense check' the findings with people who have insight into the issues not only from staffing and professional perspectives but from our public contributors who have had direct experience in hospital care. We intend to listen and act on their views on how we can make sure the findings are readily accessible to staff in Trusts but to the wider community and public/patient body.

These two events will act as 'book-ends' to our communication and engagement strategy within the study. Between these bookends, we will have a series of engagements and outputs that target more specific audiences aiming to develop an active dialogue throughout the research process, targeting different audiences. We will undertake a series of consultations with public, patient and clinical experts / stakeholders (including health services managers and ward based nurses) in order to identify issues that should be considered when determining scenarios for economic models. We expect the exact approaches to be refined through close working with our public contributors, the study advisory group, and the initial launch engagement event.

a) Policy makers & national leaders: making the most of our established relationship with lead national bodies such as NHS Improvement, HSRUK and the RCN, we propose offering a series of face to face briefings to individuals and small groups of opinion leaders, building on the approach we have developed in our recent studies. We will extend this approach to other key decision makers/interested parties, such as the NHS Employers, RCN, Health Education England, and the CQC.

b) Patients & Public: As part of the NIHR Wessex CLAHRC, we set up an extensive network of members of the public, NHS staff, patients and carers that have helped determine our research priorities and shape our research. In 2015 'nurse staffing' was identified through a public consultation as the priority topic for research to improve fundamental care. A patient, public and practitioner workshop in June 2017 explored 'nurse staffing' and generated ideas for future research on nurse staffing. We have maintained our relationship with participants of these workshops, and would invite them to be involved in the proposed study (see also PPI section on application form).

c) "Traditional" media to reach Health service decision makers, managers and staff: We have an established relationship with Nursing Standard, Nursing Times, Nursing Management and Health Service Journal. Our research is frequently featured in these publications and our series of briefing papers entitled 'Evidence Briefs' is republished by Nursing.

Our Public Contributors/Representatives on the project advisory group will guide us in developing a dissemination strategy for these audiences as findings emerge. We will work closely with the University media team and ensure that members of the project team are

given full support and training in dealing with media enquiries. We will make active use of social media channels to amplify key messages, and to complement the use of traditional media (radio and television broadcasts, magazine, newspapers) as channels for reaching both public and professional audiences.

How outputs will enter our health and care system and society as a whole

Key stakeholders to facilitate transition of our outputs to healthcare and society will be national policy makers, especially NHS Improvement and local operational managers, especially senior nurse leaders. We already have strong links with them, and their unique leadership position in the NHS means that our findings have the potential to influence emerging policy and guidance around workforce development and safe staffing at local and national level. Our engagement with different stakeholders at various stages will enable us to shape our work and craft our messages appropriately for each audience, so that policy makers, patients and staff nurses will be engaged and not mere recipients of our outputs.

Possible barriers for further research, development, adoption and implementation

Our study has the potential to provide ward or speciality specific guidance about staffing levels and skill mix. It also has the potential to inform workforce development and in particular inform decisions about future investment and priority to train, recruit and retain registered nurses and assistant / associate practitioners. The current cost containment climate in the NHS and the current RN shortage mean that findings from our research may encounter barriers to implementation. For example, if we found that staffing wards with higher RN skill mix is more cost-effective, the translation of this finding into practice would require more RNs than those currently available in the labour market. In this context, the ability of the study consider the contributions from other staff groups is crucial as the potential for substitution and complementarity between different labour inputs can be assessed from the results of our analyses.

No protected background intellectual property is used in the project and we do not believe that any such IP is likely to be created. The research will generate know-how, a research database and a series of statistical and economic models. In addition to this IP there will be specific dissemination outputs, including PowerPoint slides, conference abstracts and potentially workshop materials as well as research publications. The research database and models will be made available to others under a suitable creative commons license, subject to resources being available to host data and the limits imposed by ethical approvals / data governance arrangements. It is conceivable but unlikely that the project may produce IP that could be commercially exploited, for example specific algorithms that can be used to identify safe staffing levels. We will work closely the University's Research and innovation Service, who have a long established record of protecting and managing IP with a portfolio of over 350 active patent families. We will seek to ensure that any such IP is managed to ensure benefit to the NHS arises from the IP that is generated. This may include licensing to a commercial partner who is in a position to exploit the IP.

Potential impact of the research

Guidance such as the NICE safe staffing guidance and subsequent 'improvement resources' produced by NHS Improvement have highlighted the limitations of current evidence for informing policy and practice in the UK. The need for and potential significance of such evidence is high.

Staffing costs are the largest variable cost incurred by the NHS and nurses are the largest group of staff. There are 174,343 Full Time Equivalent (FTE) registered nurses in the English NHS working in inpatient hospital care; they make up 50% of the clinical workforce.[31] Additionally, healthcare assistants, who provide much hands-on patient care, make up 50% of the support staff workforce.[31]

Consistent with a large body of evidence, the Mid Staffordshire enquiry and Keogh Review highlighted the potential for inadequate staffing levels to cause harm to patients, including avoidable death.[2,3,27] While absolute changes in the risk of death associated with nurse staffing are low, the number of people affected means that large numbers of people are potentially affected. Each year there are approximately 9 million admissions to hospital in England.[26] Although the absolute risk of death is low, nearly 300,000 people (3.3%) die while in hospital or shortly after discharge. Any effect on mortality is likely to be accompanied by effects on outcomes and experience that will affect many more people.

The lack of robust economic models using UK data has been identified as a key limitation limiting the application of existing evidence to policy and practice. This study, by understanding how nurse staffing levels and skill mix are associated with factors such as staff costs, sickness absence, staff turnover, length of hospital stay, and readmission rates, has the potential to improve efficiency through direct and indirect effects arising from different staffing policies. Conversely, our research has the potential to avert changes in staffing policies that are driven by mistaken or untested assumptions about efficiency and effectiveness.

6 Project / research timetable [initial plan – updates will not be made to this version]

V 1.01 Feb 2020	Pre-project						Year 1												Year 2												Year 3					
	01-Sep-19	01-Oct-19	01-Nov-19	01-Dec-19	01-Jan-20	01-Feb-20	01-Mar-20	01-Apr-20	01-May-20	01-Jun-20	01-Jul-20	01-Aug-20	01-Sep-20	01-Oct-20	01-Nov-20	01-Dec-20	01-Jan-21	01-Feb-21	01-Mar-21	01-Apr-21	01-May-21	01-Jun-21	01-Jul-21	01-Aug-21	01-Sep-21	01-Oct-21	01-Nov-21	01-Dec-21	01-Jan-22	01-Feb-22	01-Mar-22	01-Apr-22	01-May-22	01-Jun-22	01-Jul-22	01-Aug-22
Approvals and study preparation activities																																				
CRN Application																																				
UoS ERGO																																				
UoS Data imact assessment (or review)																																				
Main NIHR contract																																				
Collaboration agreement																																				
Contract for data supply / management																																				
HRA approval (pre-project activity)																																				
Local R&D approval (pre-project activity)																																				
Recruit (Trusts)																																				
Revisit current candidates																																				
Recruit																																				
Recruitment (HR)																																				
Job spec																																				
Draft Job adverts																																				
Internal approvals																																				
Post 1 - advertise																																				
interviews																																				
Appoint																																				
Post 2 adertise																																				
interviews																																				
Appoint																																				
Advisory Group																																				
nominate																																				
Advisory / steering group meet																																				
Data extraction and analysis(National)																																				
(National) Data Extraction																																				
(National) data analysis																																				
Draft Paper1 (Hospital staffing -> outcomes)																																				
Data extraction and analysis(Trust)																																				
Specification for data extraction																																				
Trust Data extraction																																				
Build database and data cleaning																																				
Database complete																																				
Descriptive analysis																																				
Model mortality																																				
Model Readmissions/length of stay																																				
Model staff outcomes																																				
Economic modelling																																				
Data analysis complete																																				
Draft and submit paper 2 (patient level AE)																																				
Draft and submit paper 3 (staff outcomes)																																				
Draft and submit paper 4 (economics)																																				
Reports																																				
Periodic report to NIHR																																				
Final report to NIHR																																				

V 1.01 Feb 2020	Pre-project						Year 1												Year 2												Year 3					
	01-Sep-19	01-Oct-19	01-Nov-19	01-Dec-19	01-Jan-20	01-Feb-20	01-Mar-20	01-Apr-20	01-May-20	01-Jun-20	01-Jul-20	01-Aug-20	01-Sep-20	01-Oct-20	01-Nov-20	01-Dec-20	01-Jan-21	01-Feb-21	01-Mar-21	01-Apr-21	01-May-21	01-Jun-21	01-Jul-21	01-Aug-21	01-Sep-21	01-Oct-21	01-Nov-21	01-Dec-21	01-Jan-22	01-Feb-22	01-Mar-22	01-Apr-22	01-May-22	01-Jun-22	01-Jul-22	01-Aug-22
Engagement opportunities																																				
Stakeholder study launch event																																				
Stakeholder consultation report																																				
Engagement event with stakeholders																																				
Sharing early findings with Trusts																																				

Key milestones are marked in RED

7 Project management

The project will be overseen and managed by the principal investigator Peter Griffiths with day-to-day project management provided by a senior research fellow. With mentorship and support from senior colleagues Chiara Dall'Ora will act as deputy principal investigator, reflecting her contribution to developing the proposal and in order to provide a developmental opportunity to build future capacity.

The work of the project will be organised into five work streams with senior leads. 1) Project management (Peter Griffiths / Senior Research Fellow TBA); 2) Data acquisition and management (Paul Meredith / data analyst TBA); 3) Statistical analysis (David Culliford); 4) Economic modelling (Jeremy Jones); 5) Dissemination (Peter Griffiths) and engagement (Francesca Lambert / Jane Ball). Leads will hold regular research management group meetings to review and coordinate progress on each work stream. Project progress against key milestones will be monitored monthly. Because of the complexities of the dataset and the associated analyses, we have allowed significant periods of time for analysis and for write up following the building of the database. This timescale also gives some degree of contingency should we experience delays in accessing data or building the database.

Strategic oversight and advice will be provided by a steering / advisory group. The group will meet five times. The group will comprise of senior academics, NHS and other stakeholders and patient and public representatives.

8 Ethics

While the project draws on data from individual staff and patient records where explicit consent has not been gained from participants, all patient data used for the project will be depersonalised in order to maintain confidentiality while allowing the necessary records to be linked. Following guidance from the ICO, it is not classed as personal data and so use in this way is permissible and indeed encouraged in order to meet society's needs, in this case to address important questions about how best to provide care in the NHS. The risks of re-identification are extremely low, both in terms of the possibility of such an event occurring but also the potential consequences for any person. We have stringent procedures to minimise any residual risk. Because personal data is not involved we anticipate that ethical review is not required from the HRA although we will pursue such review internally at the University of Southampton.

9 Patient and Public Involvement

Patient and public involvement has been key in developing this project, to be mindful of the public perspective, and views around nurse staffing. Patient and Public Involvement will continue throughout the project including in our engagement events (see 0) and securing public engagement forms a key part of our dissemination strategy. We have a PPI co-applicant (Francesca Lambert) who has extensive experience of working alongside research teams and has extensive engagement as a service user of the NHS through personal experience on her own behalf as well as her family – she is carer for two teenagers with Down's syndrome. She will lead a work package on involvement and engagement and identify a further independent member of the public for the steering/advisory group. In addition to PPI involvement in our two engagement events and our steering/advisory group we will convene a regular group of interested patients members of the public as part of our research group's wider PPI strategy and we plan to consult our group at key points during the research, for example when launching the study, as well as plan dissemination with them

to be patient/public friendly and disseminate key messages. Key decisions around the research that these engagements can inform include the wider dissemination strategy and decisions in economic modelling. More details of our PPI within this project can be found in the dedicated PPI sections on the main application form.

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