SEISMIC-R

A REALIST EVALUATION

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A **S**tudy to **E**valuate the **I**ntroduction of new **S**taffing **M**odels in **I**ntensive **C**are: a **R**ealist evaluation (SEISMIC-R)

SEISMIC-R Study protocol

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Plain English Summary of Research:

Background: Staffing in intensive care units (ICU) has been in the spotlight since the pandemic. Having enough nurses to deliver safe, quality care in ICU is important. There is national guidance, re-issued in April 2021, on how many nurses should care for ICU patients. However, what the skill mix should be (how many should be qualified nurses or have an ICU qualification) is unclear. Very little research has been done to look at which nursing staff combinations and mix of skills works best in ICU to support patients (described as 'staffing models').

Across ICUs in UK, various ratios of qualified and unqualified nursing staff are being tried (staff ratios refer to the number of nurses caring for a set number of patients). Hospitals vary; some use a high proportion of non-registered nurses and others a low proportion of ICU qualified nurses. Research shows that there is a link between the quality of nurse staffing and poor patient outcomes, including deaths.

Aim: Our research plans to look at different staffing models across the UK. We aim to examine new staffing models in ICU across six very different Trusts. We will use a research technique called Realist Evaluation that examines what works best in different situations and helps us to understand why some things work for some people and not others. The design of this approach will help us to better understand the use of different staff ratios across different ICU settings.

We will examine what combinations of staff numbers and skills result in better patient care and improved survival rates. Our aim is to produce a template that every ICU unit can use. To do this, we will compare staffing levels with how well patients recover, and seek to understand the decisions behind staffing combinations.

Methods: We will:

1) carry out a national survey to understand the different staff models being used, comparing this against the current national standard (n=294 ICUs in the UK including Scotland)

2) observe how people at work in 6 hospitals (called ethnography), watching how they make decisions around staffing and the effect on patients. We will also conduct interviews (30 interviews plus 30 ethnographic observations) to understand staffing decisions.

3) look at ICU staffing patterns and models, and linked patient outcomes (such as whether people survive ICU) over 3 years (2019-2023) in those hospitals, including with a very different combination of staffing). We will then carry out some mathematical calculations to understand the best possible staffing combinations, and how this varies.

Patient Public Involvement/Engagement: The study develops on our previous NIHR development grant. JG was our public involvement co-applicant and she will continue in this role, along with another co-applicant JD, who has wide PPI/E experience in critical and acute care. We have discussed this proposal with other groups, including NP's local PPI/E group, and ICU charities. We plan to recruit public members to stakeholder and expert advisory panels to help provide insights around different staffing models, helping us consider wider implications from what we learn. Our PPI/E lead, SP, will support these members through bespoke training plans.

Dissemination: The PPI/E partners will help plan to explain to a wider audience what we learn. We plan to share with public groups, media (Science & Media centre) working with our PPI/E co-applicants, who are skilled at sharing the key messages in accessible language.

Summary of Research:

Background: Optimising deployment of the scarce nursing workforce in the intensive care unit (ICU) is paramount for patient safety, and staff wellbeing [1]. ICU staffing models are determined by NHS service specification, with 1:1 patient to RN ratios for the highest acuity patients [2,3]. A rapid expansion of ICU capacity during COVID19 led to adoption of alternative models, using more support staff, non-ICU qualified nurses and other professionals, reaching up to 70% at surge [7]. The strengths, weaknesses, costs and effects of these models, and benefits of retaining them, remain uncertain. Lower nurse-staffing levels, and high workload, have been associated with adverse outcomes for patients, staff and organisations [1,10-14] although ICU-specific evidence is limited [15,16]. Studies focus on levels of RNs, contributing little to understanding consequences of changes retained post-COVID, or to guiding adoption of alternative staffing models. It is unclear how changes in staffing or specific models affect various outcomes.

Aim: To identify the key components of an optimal nurse staffing model for deployment in ICU.

Objectives/Methods: Guided by a realist framework, we propose to interlink workstreams (WS) over 2 years to allow cross-fertilisation of ideas/hypotheses and inform emerging programme theories.

1) To identify and describe organisation of models, exploring intended mechanisms and outcomes for how different models work, we will conduct:

- a UK survey (WS 1) of all 294 ICUs in England/Wales/NI/Scotland that will identify staffing models emerging/retained since COVID19, compared with UK service specifications.
- a realist evaluation (WS 2, cross-cutting workstream) and detailed case studies involving six sites, and 30-40 interviews with: nurses/senior nurses; organisational leads; critical care network managers/commissioners; families/patients, to test emerging programme theories. Rapid ethnographies (n=30), will elucidate how staffing decisions are made.

2) To provide estimates of variability in demand for nursing staff and estimate associations between staffing patterns and patient outcomes, we will:

- use administrative e-roster (nurse staffing roster) data and patient data (WS 3) from the Intensive Care National Audit and Research Centre Case Mix Programme (2019-2023) to assess whether and how patient/staff outcomes vary with differing staff models between units/case study sites.

3) To develop simulation models to show the impact of models on capacity, cost and patient flow, we will use simulation modelling (WS 4) to explore scenarios for different staffing policies given case mixes of case study units, swiftly and with no patient impact.

Analysis: Data integration occurs across all workstreams in WS 5. Theories developed from WS2 case studies will be further tested against WS 3 observational data and inform WS 4 mathematical simulation models of ICU capacity, patient outcomes and patient flow, to inform emerging propositions for the realist evaluation programme theories as context-mechanism-outcome configurations.

Impact/Dissemination: Yielding vital information on where future efforts around ICU staffing models should be focused, in different contexts, we expect clear impact on practice. With expert advisory input we will create national guidance on staffing modelling. Engaging with stakeholders, policy-makers and PPI partners to input into publications/reports will help maximise impact from outputs.

The study team

Name	Position Held	Organisation
Professor Natalie Pattison (Chief Investigator) NP	Professor of Clinical Nursing	University of Hertfordshire
Professor Peter Griffiths (Co-Applicant; Workstream Lead) PG	Professor of Health Services Research	University of Southampton
Dr Chiara Dall'Ora (Co-Applicant) CDO	Lecturer, Nursing Workforce	University of Southampton
Dr Christina Saville (Co-Applicant) CS	Research Fellow	University of Southampton
Dr Lisa Whiting(Co-Applicant) LW	Associate Professor [Research], Professional Lead forChildren's Nursing	University of Hertfordshire
Dr Melanie Handley (Co-Applicant; Workstream Lead) MH	Research Fellow	University of Hertfordshire
Dr Susie Pearce (Co-Applicant; PPI Lead) SP	Associate Professor of Nursing (Research)	University of Plymouth
Dr Marion Penn (Co- Applicant; Workstream Lead) MP	Lecturer in Management Science	University of Southampton
Dr Paul Mouncey (Co-Applicant) PM	Head of Research	Intensive Care National Audit & Research Centre
Professor Thomas Monks (Co-Applicant) TM	Associate Professor of Health Data Science	University of Exeter
Mrs Clare Leon-Villapalos (Co-Applicant) CLV	Lead Nurse Practice Development and Innovation	Imperial College Healthcare NHSTrust
Professor Suzanne Bench (Co-Applicant) SB	Director of Nursing Research/ Professor of CriticalCare Nursing	Guys and St Thomas' NHS Foundation Trust/ London South BankUniversity
Professor Ruth Endacott (Co- Applicant) RE	Director of Nursing & Midwifery	NIHR Clinical Research Network
Mr Jeremy Dearling (Co-Applicant) JD	PPI co-applicant	Individual PPI member
Mrs Jennifer Gordon (Co-Applicant) JG	PPI	Individual PPI member

Signed

Date

10.1.23

Professor Natalie Pattison (Chief Investigator)

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Main Protocol

1. Background and rationale

Optimising the deployment of the scarce nursing workforce in the intensive care unit (ICU) is paramount for patient safety, and staff wellbeing [1]. The ICU staffing model in the UK has long been determined by NHS service specification, with 50% Registered Nurses (RNs) required to have ICU qualification and specified patient to RN ratios, which are linked to patient acuity/dependency levels [2, 3]. The umbrella term critical care encompasses ICUs and high dependency areas; the focus in service specification is on ICU (where 1 ICU nurse cares for 1 level 3 patient, the highest level of acuity)[3]. Patient acuity levels describe the level of severity of illness of patients, and in the UK this is based on organ failure, with most ICU patients classified as needing a one to one (1:1) nurse to patient ratio [4, 5]. However, nurses are in short supply. The UK has a low number of nurses (8.45 per 1000 inhabitants), below the median compared to much of Europe according to recent OECD data [6], and one of the lowest critical care bed numbers per 100,000 population [7], with deficits in overall capacity dependent almost entirely on critical care nurse numbers [8]. These conditions have led to chronic nurse understaffing in ICU, combined with ICU severe capacity strain. The impact on mortality is clear [1]. High vacancy rates before the COVID19 pandemic of 10-15% across the UK [9], and turnover reaching 42% in some areas [10] has prompted increased interest in more flexible alternatives as Trusts struggle to meet nurse: patient ratios outlined in NHS service specifications.

A national staffing framework was developed to meet exceptional ICU demand during COVID19 [11, 12]. Trusts also created internal solutions to extreme staffing issues. The rapid expansion of ICU capacity during COVID19 led to **widespread implementation of alternative models, with more support staff** (support workers and nursing associates), non-ICU qualified nurses and other professionals providing ICU nursing care, reaching up to 70% at surge [13]. These models are variations on the long-standing model of one critical care nurse for one level three patient (the sickest patient with highest acuity) and one nurse for two level two patients [4, 5]. Pre-pandemic the aforementioned nurse staffing goal of 50% with a specialist qualification was largely achieved (48.8%) [10, 14], however, post-pandemic, the situation is unclear. No national data have been reported since the pandemic on critical care vacancies or turnover. A national staffing crisis in critical care has been reportedly heightened by the pandemic [15-17].

Workforce configurations are at the centre of consideration of critical care nurse staffing model use; critical care nurse staffing remains a complex phenomenon determined by a range of factors, including nurse: patient ratios, environment, workforce availability and skill mix. Numbers of RNs with critical care qualification, types of nursing assistant or support workers in place, and skill mix variation are undefined in much of the existing evidence; and subsequent inconsistency in measuring staffing means no clear conclusions can be drawn for practice. There are no studies to guide deployment of staffing in critical care, and no evidence to support one staffing model over another [1]. Most studies focus on reporting observed variation in staffing within otherwise stable systems [1]. As is widely known in general staffing literature, more RNs are positively associated with a range of patient outcomes [18] and decreased omissions in care [19]. Changes made during the pandemic, to provide emergency staffing models, run the risk of becoming business as usual, in the context of longer-term staffing shortages. By using Pawson and Tilley's realist evaluation approach, our study will enable us to draw from the data across the four interlinked workstreams (WS), cross-fertilise ideas/hypotheses, inform developing programme theories about current practice and provide evidence regarding the future system resilience of ICU staffing models.

The COVID19 pandemic has forced a shift in thinking, with rapid decisions needed on staffing at both operational and policy levels [20]. While at present policies on staffing remain the same as pre-pandemic, guided by national service specifications [2, 3], Trusts are increasingly using different critical care nurse staffing models to address deficits. This has piqued NHSE interest and commands

engagement, as these will undoubtedly affect broader future NHS policy when further expansion of critical care beds gains traction [21]. Alongside the move towards greater staffing flexibility as a result of the increase in enhanced care areas that bridge the gap between ICUs and wards [22]. Health Foundation, The Kings Fund and Nuffield Trust collectively called for better workforce planning to address not just surge crisis needs but to focus on longer-term staffing [23], with similar views expressed specific to ICU [24]. Modelling around staffing in critical care has gained interest since the onset of COVID19, and the need to plan for surge activity taken high priority, but with little evidence to underpin [25-27]. The pandemic has also shone a light on how contextual and situational factors are highly important [20] in relation to models. Variation in ICU skill mix is now widespread[28], but little detail on the impact of different models is available. Interviews with critical care networks and senior managers indicated that nurse staffing models need to be adaptable to the local context of care, and indeed the local historical context was also found to be important [29].

Staffing will always be of high interest to the NHS, given related costs and staff/patient outcomes. Nurse staffing accounts for the largest component of cost in ICU [30]. Chronic shortages in ICU nurses [31], with high intention to leave [32] and poor nurse well-being [33, 34], warrant examination of the impact of different staffing models, a pressing concern because of COVID19. Ratios were altered significantly up to 1:6 (one critical care nurse overseeing six patients with support from non-critical care nurses and non-RN support workers) across the world [11, 35-37]. Early evidence points to the mental health crisis, and burnout, for NHS staff as a result of the pandemic [38], particularly in ICU [33]. Human costs of recent staffing pressures are clear, with a predicted exodus of ICU nurses [33], and increase in solutions such as using more support staff, such as nursing assistants and other support workers, in ICU [39], which risks further dilution of the available skill mix. Critical care services currently remain partially under specialist commissioning, and partially the Clinical Reference Group, under the new Health and Care Bill[40]. The expectation is that this will increasingly devolve to integrated care boards (ICBs) [41] within integrated care systems (ICSs) [42]. Expert input from regional critical care operational delivery networks to local ICSs and ICBs will continue to be highly important, and will influence this shifting landscape in commissioning, with system-wide solutions to staffing crises increasingly being explored.

2. Research and linked study SEISMIC (NIHR reference: 200100)

2.1 SEISMIC foreground work

As part of the Staffing to Evaluate the Introduction of alternative nurse Staffing Models in Intensive Care (SEISMIC, NIHR 200100, 2019-2021) study we reviewed evidence demonstrating that lower RN staffing levels, and high workload, were associated with adverse outcomes for patients, staff and organisations [1], with similar findings in the general staffing literature [1, 43-47] although ICU specific evidence is limited [48, 49]. It also identified key factors that influenced how the pre-pandemic staffing models and pandemic emergency staffing models worked in individual ICUs[1, 50]. Alongside the systematic review, the study involved focus groups (conducted in 2019-2020), interviews, and a stakeholder event. The qualitative data that examined the organisation of ICU nurse staffing models yielded three key themes: the constraining or enabling nature of ICU and hospital structures; whole team processes to mitigate nurse staffing shortfalls; and the impact of nurse staffing on patient, staff and ICU flow outcomes[50]. Seven focus group interviews (two with patients) revealed the importance of patients/families needing to feel safe, and prioritising patient and family-centred needs. Nurses managed the organisational complexity of staffing to ensure safety, but iterated the relationships between having the right skill mix impacted on education, stress, burnout, moral injury and staff turnover. Most staff expressed how the number and skill mix of nursing staff was dependent on nursing care requirements other than those directly related to

medical acuity, reiterating findings from a review of ICU nursing activity and workload scores commissioned by the Royal College of Nursing [51]. Nurse models and staffing were adapted to manage the fluctuating nature of patient acuity and needs. Interviews emphasised the primacy of soft intelligence over hard outcomes and the importance of retaining nurse:patient ratios (1:1 for level 3 and 1:2 for level 2) in the absence of an evidence-based alternative [29]. Our SEISMIC systematic review of 55 observational studies in ICU, undertaken as part of the SEISMIC study [1], found evidence with strong internal validity across two fifths of the observational studies reported, for analysing and measuring staffing outcomes. Of those demonstrating high internal validity, 15 studies measured mortality outcomes reporting statistically significant associations between higher staffing levels and lower mortality rate in ICU [48, 52-60]. Other studies found statistically significant associations between higher levels of staffing and lower rates of infection [55, 61-64] and fewer adverse events [55, 62, 65, 66]. Meta-analysis was not possible due to heterogenous outcomes. Although not current, meta-analysis of 5/9 observational studies showed significantly reduced patient mortality risk (unadj. risk ratio 0.65 [95% CI 0.47-0.71]) where there was high ICU nurse staffing [67], and subsequent systematic reviews without meta-analysis have reported trends in observational study data to support this [1, 68, 69]. No evidence was found to support one ICU staffing model over another [1]. In the studies reviewed, staffing was commonly treated as a demographic characteristic of the ICU, with no acknowledgement of the fluid, within-shift, staffing decisions uncovered in our qualitative work[70].

2.2 Observational evidence: nursing staffing and patient outcomes

In the broader literature outside ICU, systematic reviews have consistently shown a link between nurse staffing and patient outcomes [43, 71-73], and nurse outcomes [18, 46, 47, 73], primarily using nurse to patient ratios and numbers of nursing hours per patient day to link to mortality, and nurse-sensitive indicators [71]. Similar findings were found in recent Chinese survey data of staffing and COVID19 mortality across 58 ICUs that linked low critical care nurse staffing establishments with hospital groups reporting high mortality rates [74]. Similarly, a longitudinal observational Korean study using insurance data from 14 million patients, emphasised the association between higher ICU nurse staffing and improved patient mortality [75].

Very few nurse sensitive patient outcomes (such as ventilator-associated pneumonia; nosocomial infection; length of stay, readmission [49, 68]) have been explored in observational studies in ICU beyond infection and mortality [1, 49]. Patient and family-centred outcomes such as satisfaction are rarely reported in critical care staffing studies, however an observational study of English acute hospitals (as part of the RN4CAST consortium) that included survey data from over 66,000 patients in 2010, showed a clear association between poor perception of care and missed care, which in turn linked to lower levels of staffing [76]. The impact of outcomes beyond mortality in relation to nursing workforce configuration (number of RNs, critical care specialty and support workers) is not reported. As identified previously [77], limited evidence still remains on the safety and effectiveness of different nursing workforce models in critical care. Importantly, while staffing numbers are a critical factor, it remains only part of the broader understanding for optimal staffing, including environment, model configuration, skill mix and patient acuity.

2.3 Staffing models configuration

Reviews have outlined the need to further examine model configurations [78], including skill mix/acuity and environment factors [72],demonstrating that skill mix with more RNs had a positive effect on 12 patient outcomes [18]. Similarly, PG's group linked low RN levels to increased omissions in care [19]. Heterogeneity exists in defining skill mix (e.g. % of nurses that are RN; % of care

provided by RN), suggesting a need for clarity [73, 78]. Skill mix is one factor within models and does not account for context and how care is organised (e.g. shift patterns/patient flow). Previous modelling work in ICU [79] examined the effect of discharge delays on patient flow, although staffing effects were not specifically explored.

Clear associations exist between ICU nurse staffing and patient outcomes, hospital costs and family satisfaction as well as improved outcomes for staff and service [1]. However, 'nurse staffing' as an entity is not well described in studies. Numbers of registered nurses, with ICU qualification, and skill mix variation were often undefined and inconsistency in measuring staffing lead to vague conclusions for practice. Despite the overall association, the fixed 1:1 nursing model was not clearly supported. The simplistic 1:1 approach does not address the nuances of ICU requirements, compelling the need for closer examination of model configuration [78], particularly in times of surge crisis. Lack of scrutiny of critical care nurses' roles in differing models also warrants examination [20], given variations in practices/roles. The relatively few ICU simulation models that have focused on staffing have assumed that the ideal nurse-patient ratio is known and acts as a limit on the number of patients who can be admitted [80-83]. Similarly, other Operational Research approaches to modelling ICUs, queuing theory [84] and mathematical programming [85] have also taken the staff-to-patient ratio as a given.

Qualitative considerations around context and organisation of care are also important. The influence of hidden work of critical care nurses around the daily decisions they make that are affected by, or that have consequence for staffing (and subsequent nurse and patient outcomes) are unaccounted for [86]. Important conceptual contributions from ethnographic research of nurses in acute hospitals outline how nurses undertake 'organising of work' [87], viewed as 'invisible' work (information location, interpretation, sense-making and checking to translate into narratives), when not involving direct patient care, such as supernumerary nurses in charge of ICU organising staffing and contributing to patient flow in the hospital through discharge discussions. Effect on nurses were examined in a recent systematic review of nurse outcomes and ICU nurse staffing [88] drawn from a small number of predominantly single-centre observational studies (n=6), indicated that while there was an association between poor staffing and increased burnout, a significant relationship to staffing levels and job dissatisfaction were not found. Despite this finding, larger scale evidence in acute care has demonstrated that there is a clear link between nurse outcomes, including satisfaction and nurse staffing ratios [78, 89, 90]. The heterogeneity of workforce models on both patient and nurse outcomes, however, is not yet understood.

Adopting different configurations where non-ICU trained staff are increasingly deployed, such as the Health Education England London Transformation and Learning Collaborative approach [39], also has potential implications for wellbeing, satisfaction and retention. A French study described a greater incidence of anxiety and depression in non-ICU trained staff [91], iterating the need for an appropriately trained workforce to deal with crisis situations like COVID19, and consideration of implications of applying different workforce models, such as on-call models as one way to meet fluctuating demand and capacity [92], but the impact on this on potential adverse impacts of work/life-balance and nurse satisfaction remains unknown, and there is still limited application in practice[94]. Previous simulation work also identified how flexible models (retaining a low number of core staff) led to high rates of understaffing and more deaths, even where temporary staff were available [93]. Building on SEISMIC, this study aims to address shifts away from traditional models, which limit equipoise and engagement in trials, and address the new questions that have emerged around creating agile, locally responsive staffing models, and their associated outcomes [1, 29, 70]. Whether the simplistic ratio approach to staffing, predicated on RN numbers, and levels of care through organ system failure, rather than patient acuity and dependency, and skill mix, as advocated in national guidance, sufficiently addresses the nuances and complexity of critical care requirements is questionable. This further compels the need for closer examination of model configuration [78].

Moreover, a lack of understanding of the impact of different critical care nurse roles, variations in skill mix, patient flow, working patterns - particularly given increasingly wide variations in practices and roles, leads to the principle research question: ***What are the key components of an optimal nurse staffing model for deployment in critical care?***

3. The study

3.1 Aims:

Through realist evaluation and modelling, this study aims to establish the key components of different ICU nurse staffing models, including the context, organisation and delivery, actual and required staffing, and patient/service/nurse outcomes.

This will inform explanations of the key factors (contexts and mechanism) most likely to lead to flexible staffing models that maintain safety and/or improve patient and nurse outcomes.

3.2 Research Objectives

1) to identify different models through a national survey and in-depth case studies for critical care nurse staffing, describe how the staffing models are organised and explore the mechanisms for how different models work to achieve their intended outcomes, or not.

2) Through an observational study using routine administrative and audit data provide estimates of variability in demand for nursing staff under a 1 to 1 model and estimate associations between nurse staffing patterns and patient/staff outcomes.

2) To develop simulation models to show the impact of different nurse staffing models in terms of capacity, cost, patient flow and outcomes.

3) To develop programme theories of deployment of new nurse staffing models in ICU and produce evidence-based recommendations.

3.3 Design and theoretical conceptual framework

3.3.1 Realist evaluation

The study employs Realist Evaluation [94], which navigates evaluations of complex interventions through theory building and provides a framework to draw together evidence from **four overlapping workstreams (**WS), allowing for cross-fertilisation of ideas/hypotheses and inform developing programme theories. A UK survey will identify and be used to describe the diversity of staffing models emerging or retained since COVID19. Detailed case studies will build the initial programme theories, set out as context-mechanism-outcome configurations, of a selection of different staffing models and organisational contexts and continue to test and refine these theoretical propositions from evidence collected within and across case study sites. Data from the observational study and simulation modelling of ICU staffing and outcomes will further inform and refine the programme theories for the nurse staffing models.

Realist evaluation recognises that interventions, in this case models of critical care nurse staffing, will have different degrees of success [94, 95], which are influenced by the context and explained through mechanisms. **Nurse staffing models are complex interventions** that have been set up in different ways reflecting local need, national staffing guidance and available staff to meet patient

dependency and acuity needs. Investigation of such diverse applications of staffing/outcomes requires a methodology that can navigate this complexity. Realist methodology incorporates complexity through theory building and refinement to explain the characteristics of contexts and mechanisms considered important to achieve the intended outcomes. We will use realist evaluation to set out the theories that explain how staffing models are organised and work across varied settings with different skill mix, patient dependency, environmental factors and with what outcomes, with integration of findings across WSs. As a result of the pandemic, post-pandemic staffing models are rapidly and necessarily being adapted to create flexible models that can cope with future surge requirements, and as such have a limited evidence-base. Realist evaluation will elucidate **understanding and help explain how differing nurse staffing models in ICU, with variations in organisation, structures, processes and available people resources, can best meet patient requirements**. This framework will also provide a structure for integrating findings across work streams. We will compare outcomes (including unintended consequences), and explore relationships between causal mechanisms and how context impacts outcomes via case studies [96, 97]. Theories developed from WS2 case studies will be further tested against WS3 observational data and inform WS4 mathematical simulation models of ICU capacity, patient outcomes (from national ICU case-mix data) and patient flow. The study will be reported against the RAMESES framework [98].

4. Work Streams (WS)

4.1 WS 1: Survey

This WS will provide **a detailed overview of staffing models used and context for variation** to inform theoretical development in WS2. A survey of UK NHS ICUs (n=270 + 24 Scottish ICUs, whole sample) on staffing models will be conducted, including reported variation in the context of vacancy rates, retention, skills mix and training (% ICU qualified, % RNs). The baseline UK-wide survey will be conducted via Intensive Care National Audit and Research Centre (ICNARC), the Clinical Trial Unit organisation leading the national ICU Case Mix programme (CMP), and SICSAG (Scottish Intensive Care Society Audit Group, with whom we are working closely and who have given their agreement and support).

ICNARC will circulate the survey to the 270 ICUs in England, Wales and Northern Ireland as an electronic link, with follow-ups as required. SICSAG will similarly circulate a link to the 24 Scottish ICUs. The survey will explore current models in use; changes since the pandemic, daily and total nurse staffing establishments, changes to establishments post-COVID19 and desires/suggestions for new models. Additionally, we will seek information on turnover, development of new non-RN roles (an emerging phenomenon) and examples of models in use. Assessment of representativeness of ICUs will be made by comparing responses to publicly available information.

The ICNARC-proposed platform is widely used and accessed by all ICUs in the NHS. We will use a secure online platform (e.g. Microsoft forms) to circulate the survey, export the data for analysis into SPSS (IBM), and will identify unit leads (nursing matron or similar level) at the outset for targeted responses.

- Output: detailed overview of staffing models used across England and identification of a pool of key informants to support building of theories in WS2.

Analysis WS1

- Anonymised data will be exported from the secure platform into IBM SPSS (IBM) and analysed descriptively using proportions, means, medians and SDs. We will undertake free-text analysis[99] of data from the open-ended questions, and derive coding categories directly from the questionnaire data.

4.2 WS2: Realist evaluation using a multi-site case study approach

This workstream involves a realist evaluation of nurse staffing in the ICU using six sites as case studies to:

i) understand how the staffing models have been organised locally
ii) understand variation in staffing models,
iii) establish factors associated with optimal staffing models,
iv) **build, test and refine programme theories**.

For the purposes of this multi-site case study [96], the case will be defined as the site or Trust where the model is being implemented. Case study data collection will comprise of formal interviews (ascribed time and place for interviews), participant observation, including the use of rapid ethnographies [100, 101], and organisational documentary review (e.g. policies and guidelines). We will build on work from our existing review of patient, family, staff and organisational outcomes related to nurse staffing levels in ICU [1] to develop and refine programme theories by exploring:

- the local criteria and impact of different models on nurses and patients;
- how and why decisions are made for staffing allocation and redeployment;
- perceptions of the adequacy of staffing;
- adverse event reporting;
- ability to deliver optimal care;
- staff wellbeing.

The outcomes of interest for the case study have been identified from our previous SEISMIC work and include: **time for appropriate and regular communication, achieving a sense of personhood for the patient, early mobilisation, team cohesion and time for self-care** [102], alongside nurses' perceptions of staffing adequacy and ability to plan staffing and care. Initial programme theories and refinement of the theories during the case study may also identify additional outcomes as important with the different staffing models. To ensure evidence collected can incorporate additional outcomes, data collection will be iterative and responsive.

4.3 Sample/setting case studies

Using data from the survey in WS1, and our earlier scoping survey, we will recruit six sites that represent a range of the characteristics of the nurse staffing models and organisational contexts. We elicited interest from several sites through preparatory survey work and discussions at CC3N fora, and the HS&DR study 128056 (led by PG), and as such we are now pursuing involvement from sites large metropolitan centres, which have adopted alternative staffing models, contrasting this with smaller centres (rural ICUs/district general hospitals) to be reflective of both diversity in staffing approaches and in broader population needs.

4.4 Expert advisory group for the realist evaluation

Consistent with a realist approach [103], and distinct from the independent steering committee, we have approached and recruited expert stakeholders to act as an advisory group for the project. Up to twelve people will represent a range of content experts in ICU staffing through:

i) their roles in the health service (Senior ICU lead, large London hospital/CC3N Chair),
ii) as patients with experience of being in ICU (recruited via ICU Steps, the ICU charity, with a specific emphasis on diversity and inclusion to ensure diverse patient/family needs are met),
iii) as commissioner/providers of services (a Chief Nurse representing an Integrated Care System perspective),
as academics studying nurse staffing.

Further potential stakeholders will be identified from knowledge from WS1, from within the project team, online searches and snowballing of contacts. These experts will be asked to comment on the developing programme theories, help identify potential gaps in knowledge and support theories refinement.

4.5 Case study data collection

4.5.1 Interviews

Interviews will be carried out with staff and patients across all sites (n=30-40 in total). Six to eight people in each group who represent participants from groups a to d (below), will be recruited, using purposive sampling[104] across the case study sites:

a) **nurses** working in those models, ensuring diversity in sampling;
b) **senior nurses** making day-to-day staffing decisions;
c) **care recipients** (families/patients to test emerging theories, we will purposively sample to ensure under-represented groups are included);
d) **organisational leads** responsible for forecasting; and
e) regional (ICU operational delivery network) **managers/commissioners** (recruited via national fora as few in numbers).

Semi-structured interviews will: i) explore experiences of working with or receiving care from the different nurse staffing models, ii) identify the factors influencing staffing decisions and iii) test initial programme theories using a teacher/learner approach [105]. This will provide information on the variations in experiences and the assumptions for how staffing models are thought to achieve their intended outcomes (or not) for patients, nurses and services. **Documentary review** will be conducted at case study sites to contextualise the nurse staffing model within strategic decisions and organisational constraints evident in documents such as local policies and guidelines, staff satisfaction (using routine PICKER data) comparing these across cases and with national documents. We will also explore other staff groups and the effect on ICU/nurse staffing. This qualitative and documentary data will provide contextual data in a specialist area.

4.5.2 Rapid Ethnography

We will conduct around 6 clinically-based **rapid ethnographic observations** [101, 106] at each of the six case study sites (n=30 approx in total) to generate data on specific phenomena related to nurse staffing decision-making.

We will purposively sample [104], and target observations to capture data from meetings and clinical activities for nurse staffing decision-making, including but not limited to: the allocation and redeployment of nurses in local surges; at times of ICU strain; and as part of day-to-day within shift working. As part of these ethnographies we will be observing decision-making, including examining how decisions are made, by observing key meetings, such as staffing huddles, forecasting meetings and conducting formal and informal interviews [100]. We will also draw out observations around team interactions in relation to staffing decisions, including cohesion and explore nurses' senses of how staffing feels at that time. From this we will gain understanding of local processes for **how decisions are taken and individual rationales for why decisions are taken in situ**. Our PPI contributors will also help refine the observation schedules. These data will be used in combination with other data sources to characterise why decisions are made in certain contexts, and how their outcomes affect nursing care provision. Periods of observation will last between two to four hours and encompass different time points across the hours of a typical day shift. Field notes will be taken as per standard ethnographic practice [107].

4.6 Ethical issues

Ethical approval for the study will be gained through the Health Research Authority via IRAS with local R&D approval, following confirmation of C&C.

For WS2, the main issues for interviews and rapid ethnographies include: informed consent; ensuring the researcher's presence is not intrusive; observing the work of clinical teams; and taking account of patients' (where they have capacity) and families' perspectives if volunteered (only if or as appropriate).

Including the clinical team in the rapid ethnographies as the key research participants is crucial, focusing on their actions and interactions. This reduces the emphasis placed on families and patients, which could be too intense at this sensitive time [108]. In this way, we will gain a rich picture of the professional culture required to deliver safe staffing in ICU and augment our understanding from multiple perspectives [109]. Key staff will be purposively sampled for the rapid ethnographies (such as nurses-in charge, section leads and direct care nurses) and will be approached at the beginning of a shift to gain consent. Staff will be informed about how they can ask to not be observed at any time, and we will not directly observe those who do not consent.

4.6.1 Ethics of approach, timing, and safety-netting

The focus is on staffing and if families are present during data collection, we will be respectful of their privacy at all times offer them the opportunity to opt-out of observations at any point (if they are present during that episode of observation). Ethnographic research we conducted previously in challenging situations [108, 110-112] and our studies into recruitment in critical care studies suggest families will often be happy to participate, even when a person is critically ill and even when at high risk of dying [113, 114]. Family-reported benefits of taking part in research, including those who have been bereaved [115, 116], include catharsis and the opportunity to be listened to. As per usual practice for ethnography where the patients/families are not the primary focus we will

have visible posters in the ICUs explaining in plain English that data collection is being conducted. Where it may be beneficial to include patients/families in observations, we will; 1) consult the clinical team in relation to the appropriateness, 2) ask the clinical team to make the initial contact with the families about the research [117]. Observations will mainly occur around nurses' stations or nurse-in-charge offices. As conversations around staffing tend to occur away from the bedside observations of brief bedside discussions may be included, but extended observation of patient bedspaces will not be necessary. Observational data collection would take place over several weeks to capture various patient presentations, pinch points in staffing and staff involved in decision making. We will ensure all interviews (formal and informal, post-observation) are conducted at a convenient time/place or mode (online/phone) and we will be as flexible as possible. Staff can also opt-out.

We would also ensure support was in place for anyone participating and those who wish to withdraw. Should bereaved families be involved we will offer bereavement information leaflets from CRUSE, which outlines some of the feelings people may encounter and who to contact for support. For staff participants and non-participants, supportive information will be available, such as signposting to Professional Nurse Advocates, in-house and external psychological services and Intensive Care Society/local wellbeing resources in case the research raises any personal concerns related to staffing or other issues.

Ethical challenges may also present for researchers[117], who must balance confidentiality with participant safety. We will have 'safety nets' in place to ensure physical and emotional well-being of researchers [118, 119], including a distress protocol and lone worker guidance. Researchers will maintain reflexive research diaries [116, 120], and have regular (fortnightly) scheduled contact between the interview/research team to discuss any issues. Additional ad hoc support will be available as necessary and workstream leads/local PIs will be able to support these issues with regular meetings. Researchers will have regular team supervision.

4.6.2 Interviews

Interviews will be conducted face-to-face or by telephone (or video call), and audio-recorded, depending on participants' preferences, at a time and location convenient to participants [116, 117]. The CI has led research in this area and would ensure the interviews (or if families were involved in ethnography) were conducted in line with a published UK bereavement research framework [116], balancing ethical and research integrity [121]. For all participants, options regarding support will also be mentioned at the start and end of the interview [116]. For families/patients, additional family members may also wish to join in dyadic/triadic interviews. Telephone interviews can yield equally rich information [116, 122], and allow control over their stories and their social space, enabling private accounts of experiences to emerge. For families who have been bereaved, interviews will occur around 2-6 months post-bereavement, in line with good practice [116] and PPI input. We will also schedule interviews as soon as possible after expression of interest in participation to avoid people waiting [116].

Anonymised, generalised feedback will be provided to ICU teams involved at the end of the research to enhance practice.

4.6.3 Observation conduct/ Researcher considerations

The team, and specifically NP/SP/MH will work closely with an experienced researcher recruited to support this work stream (including providing supervision and training). Depending on our post-doc fellow's professional background, we have planned for either participant observation (PO) or non-

participant observation (NPO). In PO, the researcher adopts a 'participant-observer' role, the 'privileged observer' role [123], attempting to share in the daily life of the clinical setting by helping with general and simple tasks whilst observing and talking informally to clinical staff during their working day. In NPO, they simply observe; both try to be as unobtrusive as possible. In PO, having experienced clinicians helping with basic care can mitigate family concerns of having an outsider present. In both NPO and PO, experienced researchers are sensitive to the effects their presence may have [110]. It will be stressed to the participants (patients, families, healthcare team) that they may ask the researcher to leave or not be present at any time during the observation. For each episode of observation, verbal consent is re-established. Participants (staff) will be given sufficient information and time to consider the study prior to written or recorded consent being given. Staff rather than families/ patients are the focus of the ethnographies.

4.6.4 Adverse events and reporting

For this study, although very unlikely, AEs could potentially arise from disclosure of sensitive information in the interviews. An AE for this study would relate to **psychological wellbeing** or **information governance/data breaches.** When an AE occurs, the lead researcher responsible at the site will assess whether the event is an AE, and escalate to the CI as needed. Where any issues arise from the study, we will liaise in the first instance with the clinical teams and local principal investigators. Data breaches in later workstreams are covered in the data management plan (v1 10.10.22).

4.7 WS2 Analysis

Analysis will be conducted iteratively throughout WS2. We will use qualitative data analysis software (e.g. NVivo) to manage and support analysis [124, 125]. A realist logic of analysis (contexts plus mechanisms = outcomes) will be applied to interpret and judge the contribution to building theories and refinement from each data source both within and across sites. We will combine three approaches to data analysis: i) deductive (informed by experience and assumptions for how staffing 'works'), ii) inductive (informed from the data) and, iii) retroductive (to understand the cause of the outcome beyond what can be seen [126] (making inferences of causation). Along with our expert advisory group input, these will help to confirm, refute, extend and refine the initial programme theories from WS2. The initial programme theories' context-mechanism-outcome configurations will provide the framework for analysis. Analysis will be iterative, using the different data sources to develop our understanding of the relationships between context, mechanisms and outcomes within and across the sources [103]. In this way, we will be able to test if conjectured mechanisms from one source can explain how contexts led to outcomes in a different source. Data sources are likely to be partial in the evidence they provide for testing Context-Mechanism-Outcome configurations, therefore cross-case comparison will be used to determine if mechanisms impacted outcomes differently in different contexts. For example, we can compare how variation in a specific outcome of the nurse staffing models relates to differences in contexts or mechanisms. Analysis strategies will include juxtaposition, reconciliation, adjudication and consolidation of data across and within data sources [127]. We will also draw on an available existing logic model that relates to staffing [128] to inform our thinking.

We will adopt a realist analysis approach in terms of drawing together all the data (outlined in section 4.6). The first step will be to develop tentative explanations (initial programme theories) of what works for whom in terms of nurse staffing configurations. MH/NP will draw on our previous work [129] to develop '*if… then*' statements which will be debated with the project team in up to two workshops in the first month of the project. Agreed statements will inform, but not limit, data collection and data analysis to test explanations and search for those not yet articulated by combining inductive, deductive and retroductive analysis approaches. For example, rapid

ethnographic data will be developed using an inductive-iterative approach to analysis, based on an inductive thematic analysis (ITA), and aided by reflexive notes. Interview data will also be analysed using ITA [124], to draw out reoccurring patterns (in an iterative process of moving between codes, categories and sub-themes) from the events and outcomes that arise from the data/field notes. Patterns will be arranged into themes through an iterative process of moving between codes, categories and sub-themes and then reaching final themes, with team and stakeholder peer-review (via the advisory group) for verification of themes. Themes will be used to extend, refute or refine the initial programme theories. Coding will be conducted independently by the post-doc researchers initially, with subsequent meetings of team members (SB, RE, NP, LW, MH, and post-docs) and the stakeholder group to enhance trustworthiness and dependability of the data, verify analysis and develop the themes. The Initial Programme Theories will be used as the framework for an NVivo database, with '*if… then*' statements forming the initial codes. Data sources and themes will be assessed for their contribution to theory development, by asking if and how it relates to the programme theories. Extensive researcher notes will be made, utilising the 'memo' function in NVivo, to track how and why analysis evolves and support transparency in the process. Additionally, informal interview data and field notes will add depth to the observation analysis and support theorising and reflexivity, as opposed to being respondent validation [130].

This process will be supported by regular discussions of interpretations with the project team and expert advisory group to challenge and suggest alternative explanations for the data.

Outputs:

a) nurses' experiences of working within and implementation of described models
b) ethnographic descriptions around staffing and staffing decision-making
c) description of the model variants in those cases
d) Initial programme theories, set out as context-mechanism-outcome configurations, grounded in evidence that explain the factors within and across the staffing models and the related decision-making leading to nurse and patient outcomes. The theories will inform sampling of participants, data collection and analysis in WS3, and data synthesis across all datasets (WS5).

4.8 WS3: Observational study

We will undertake a retrospective longitudinal study in intensive care units across multiple NHS Trusts, linking electronic roster data to estimate nurse staffing levels and patterns with Intensive Care National Audit and Research Centre (ICNARC) Case Mix Programme (CMP) patient data. We will explore **changes in staffing over time and estimate associations between the staffing models and outcomes** for both patients and staff, exploring variation within and between units. These data will also provide empirical data to estimate parameters to populate OR models to be developed in WS4.

4.8.1 Sample/setting

We will recruit six Trusts to provide variety in ICU configurations and staffing patterns arising from both planned and natural variation due to (inter-alia) variation in patient flow, staff sickness/absence, vacancies, and crisis response due to COVID19 surges. To mitigate potentially significant challenges and delays associated with data governance we will initially purposively select and recruit six Trusts to participate in the study at an early stage (pre-project commencement). This recruitment will be based on established relationships (including Trusts participating in NIHR 128056) and known variety of approaches to ICU staffing during the pandemic and will include at least one Trust that has explicit plans to maintain a novel staffing model with a high proportion (>30%) of non-RNs in ICU that emerged during COVID19.

Data gathered will cover pre-COVID19 (pre-2020) and 'peri-COVID19' periods. We plan to include all patients, not limited to COVID patients, across time-periods that reflect pre-pandemic [March 2019 to March2020], intra-pandemic [March 2020 to March 2021] and post-pandemic [March 2022 to March 2023] peaks in ICUs. Taking a highly conservative estimate of occupancy (50%) and mean length of stay (5 days) we estimate having at least 403,500 nurse days of staffing data; 197,500 patient days; 39,750 admissions based on our experience of Trusts participating in NIHR 128056 and a large metropolitan NHS Trust, covering the years 2019 (pre COVID19) 2020 (early pandemic waves) 2021 (late pandemic waves), 2022 (endemic COVID19). The six proposed Trusts have approximately 310 ICU beds (NHS England sit rep Nov 20-April 21 and Trust site-reported bed numbers).

The sites are proposed will reflect large metropolitan centres, working to a very different staffing model sustained post-pandemic, areas of multiple indices of deprivation in the UK, small rural ICUs and large regional centres.

4.8.2 Data Sources & linkage

De-identified patient data will be sourced from the ICNARC CMP and staffing data will be derived from shift level records of staff deployed on intensive care (including bank and agency staff) derived from e-roster systems (supplemented by additional sources such as records of temporary staff supplied by NHS Professionals where these are not integrated into the e-roster). **E-roster data** will be used to determine the daily staffing deployed on each unit by band, grouping unregistered assistant staff (bands 2&3), assistant / associate nursing practitioners (band 4), and junior (band 5) and senior (band 6) registered nurses and registered nurse leaders / managers (band 7+). If data recorded in e-rosters allow, we will further differentiate staffing provided by ICU trained RNs. Where new models include integrated rostering with other professional groups these will also be considered in the study, and we will remain sensitive to potential effect modifiers associated with the configuration of other workforces and how they interact with nursing. Staffing will be further grouped and used to derive additional variables to represent the typical staffing model used on the unit. E-roster data will also be used to identify the daily incidence of sickness/absence among staff. Hourly staff costs will be estimated using the most recent tariffs published in the PSSRU Unit costs [131].

ICNARC CMP data will be used to derive patient demographic data (including pre-ICU hospital stay), prognostic factors, adverse events, resource utilisation, patient outcomes and to determine the unit occupancy for each day. For patients who die we will use the discounted and quality-adjusted life expectancy (DANQALE) tariffs [132] to estimate QALYs lost. Costs of post ICU hospital stay will be estimated using NHSE reference costs per day of stay [133]. ICU stays will be costed using the reference cost after deducting a value to reflect typical staffing (which are otherwise included in these national averages).

We will **link staffing and patient data** to calculate achieved daily nurse staffing levels in hours per patient day) and relative measures of daily patient turnover (daily admissions / discharge per nurse). These daily staffing levels and other derived variables describing staffing patterns will be linked to patient data for each day of their ICU stay to determine staffing levels (in staff hours per patient day) and patterns patients were exposed to on each day of their stay.

Data Ethics: We will apply to the Data Access Advisory Group (DAAG) at ICNARC in order to access the necessary CMP data for the periods outlined for each of the six sites. Data access requests for WS3 and 4 will be additionally submitted through Trust information governance channels and data access processes. A lead for data in each Trust will be identified and is responsible for ensuring data extraction data from the case study site hospital systems. Data extracts (Feb 2019-20; Mar 2020-

2021; Mar 2022-23) from each site (ICNARC CMP and e-roster) will be provided by each pf the six sites via a secure file transfer service to Southampton. All data will be pseudo-anonymised at source. Data will be stored on secure encrypted servers at the University of Southampton with access restricted to PG, CDO, TM, MP, NP, CS and PM (the data group for WS3 and 4 within the project team). (See separate Data Management Plan v1 10.10.22 for data management and flow).

4.8.3 Outcomes

The primary patient outcome for the study will be **death from all causes within 30 days of ICU** admission. *Secondary outcomes / resource use* measures include:

- Discounted quality adjusted life years lost
- Length of hospital stay

- Composite death/discharge to long term -care
- Length of ICU stay
- ICU acquired infection

- Death in ICU
- Days of organ support in ICU (per organ)

- Dependency on ICU discharge
- Cost of ICU and post ICU stay

Staff outcomes

- Staff sickness absence
- Staff costs including costs arising from sickness / absence

4.8.4 Staffing exposures and models

For each day of the patient stay we will calculate the staffing level in terms of hours per patient day and characterise the predominant staffing model in operation in that period. Our primary focus will be on registered nurse hours per day with additional derived variables used to indicate skill mix both within the RN team and between RNs and assistant staff. Key staffing variables to be considered include:

- RN (bands 5+) Hours per patient day
- RN skill mix (junior: senior RNs)
- Healthcare support worker (HCSW) and nurse associate hours per patient day
- Assistant skill mix (bands 2, 3, 4)
- Temporary (bank / agency) staffing hours per patient day
- Temporary staff mix (permanent staff: temporary staff)

We will infer staffing models that can be characterised from patterns in the data based from both the overall staffing level and the composition of staff used to achieve the hours. As a simplified example, staffing could vary in terms of the RN hours per patient day (high or low) and support worker hours (high or low) generating four hypothetical models of staffing (high RN high support / high low etc,) reflecting variation in skill mix, labour substitution and overall staffing resource. We will divide the time sequence into intervals and characterise the staffing model for each unit in each period.

Models and data from WS3 will provide parameters for WS4 in three important ways.

1. Direct estimation of causal effects from staffing (with appropriate measures of uncertainty)
2. Parameters that can be used to judge plausible magnitude for other causal effects that cannot be directly estimated in WS3
3. Data to provide plausible baseline parameters for factors such as variation in case mix and patient flow

4.9 WS3 Analysis

We will describe changes in patient mix, patient flow and patient volume over time, noting peak activity and changes associated with COVID19 pandemic waves. We will describe changes in staffing levels and models over time, paying particular attention to periods where staffing models may have changed because of COVID19 demand. We will assess the association between staffing levels and outcome, using mixed effects to account for the hierarchical nature of the data, with staffing included as a time-varying covariate in survival models.

This analysis plan is supplemented by a **data management plan (v1 10.10.22)** that will inform the flow of data and management of data for WS3 and 4.

We will 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. Based on the results of our previous research, a parametric (exponential) distribution is assumed for the baseline hazard function. 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. Risk adjustment for patient outcomes will be based on the validated ICNARC model [134]. Our primary analysis will focus on **RN staffing level (hours per patient day)**. Because of varying trajectories for patients and the varying mechanisms of action for staffing levels (e.g. the overall effect of staffing provided on average vs specific adverse events associated with low staffing) we will consider alternative approaches to modelling staffing exposures to reflect deviations from RN hours/day relative to a 1:1 model (24 RN Hours per patient day). To reflect low staffing we will model the cumulative sum of days staffing below 1:1 and days with more than 15% below 1:1 staffing; a level of deviation providing a criterion of low staffing using the widely researched RAFAELA tool [135]; both as an absolute number and as a proportion of days thus avoiding immortal time bias [136]. We will also calculate and use the cumulative hours / proportion of hours relative to 1:1 staffing, a measure that reflects the average staffing experienced up to that point.

We will add variables to identify non-linear effects, effects from non-registered staff, effects from temporary staff use and effects related to the skill mix of staff. 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. We will add interactions terms to determine if effects of RN staffing are conditional on other staff groups. Finally, we will seek to estimate the **marginal effects of any distinct models we observe that vary from the standard 1:1 RN staffing model**. We will seek to build a parsimonious model and will use the Akaike criterion and the Bayesian information criterion to assess model fit [137], preferring models that minimise values. Because there are a number of structural factors that largely operate at a hospital level including levels of medical and other therapy staff, we will initially model each hospital separately. Dramatic shifts in case-mix and / or staffing models associated with COVID may also require a segmented approach to modelling before moving to a combined model with (if required) appropriate terms included to reflect varying relationships across sites and time periods. We will also model **the association of staffing with staff sickness absence** using the same broad approach. In these models we will treat staff sickness absence 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. If we identify staffing models that are associated with increased staffing costs but reduced mortality, we will seek to estimate the marginal cost per quality-adjusted life year gained by estimating the marginal staffing costs and costs / savings from any changes in resource use and the marginal reduction in mortality with the DANQALE tariff, based on the age / gender distribution of observed deaths, used to estimate QALYs saved.

4.10 WS4: Operational research modelling

Operational research modelling, in particular simulation modelling, will explore scenarios for different staffing policies given the case mixes of particular units, swiftly and without any impact on actual patients. Recent work in our group used this approach to evidence the need for sufficient baseline staffing numbers [138-140]. This will enable us to draw on findings from other WS and investigate how the findings translate to units. We will develop a generic *discrete event simulation model (DES)* [141] for ICUs to simulate potential impact of different *staffing models* on ICU capacity and patient flow [79].

We will base our DES model on the ICU modelling led by MP/TM [79]. A DES is a stochastic individual patient-level model. It enables us to accurately simulate the pattern of patient admissions to an ICU across a day/week and design the process that a patient follows during their stay. The existing model will be adapted and include staff availability, allowing testing of different rules on staffing models such as staffing ratios for different levels of care. Length of stay calculations will be adapted to take account of impact of staffing on this aspect of care explored in other WSs. The model output will be adapted to track staffing levels experienced over patients' stays, so expected adverse events associated with those staffing levels can be calculated. We will adopt the Turing Way [142] to achieve our open science objectives.

4.10.1 Model conceptualisation and parameterisation

We will follow a collaborative approach to conceptualising the model, building on work in other workstreams and the expertise of the team and other partners. The WS4 leads will take part in discussions in the earlier stages of the project to inform their understanding of the problem and available data, as well as working closely with the research fellow in WS3 who will be collating and analysing the data. Parameters will be derived from the data analysed in WS3 along with supplementary data provided from hospital Trusts/publicly available data sources as required. These will include:

- Admission rates per time period and number of open beds (inc. delay/transfers)
- Length of stay
- Ward size
- Relationship between staffing levels and length of stay/mortality/other adverse outcomes
- Staffing models defined by staff-patient ratios for different staff groups (e.g. ICU-specialist registered nurses, non-ICU registered nurses, nursing associates, HCSWs, etc.) and for different patient types (e.g. using critical care levels)

Figure 1. illustrates the high-level model logic for the ICU simulation model in Penn et al [79]. The model is a stochastic individual patient level simulation. Stochastic refers to notion of modelling variation in a process. Patients arrive to the simulation at random following a time dependent process (a non-stationary Poisson process [143]). This means that the model can simulate the general pattern of arrivals across a day (or week); for example, a lower arrival rate of patients at night or towards a weekend. This is achieved via sampling the time between arrivals from a set of Exponential distributions (e.g. one for each hour of a day) and correcting for periods of transition between them (for example, via the thinning algorithm or using a piecewise linear model). Variation in patient processing times, decision-making, acuity-dependency are incorporated into the model through probability distributions derived from empirical data.

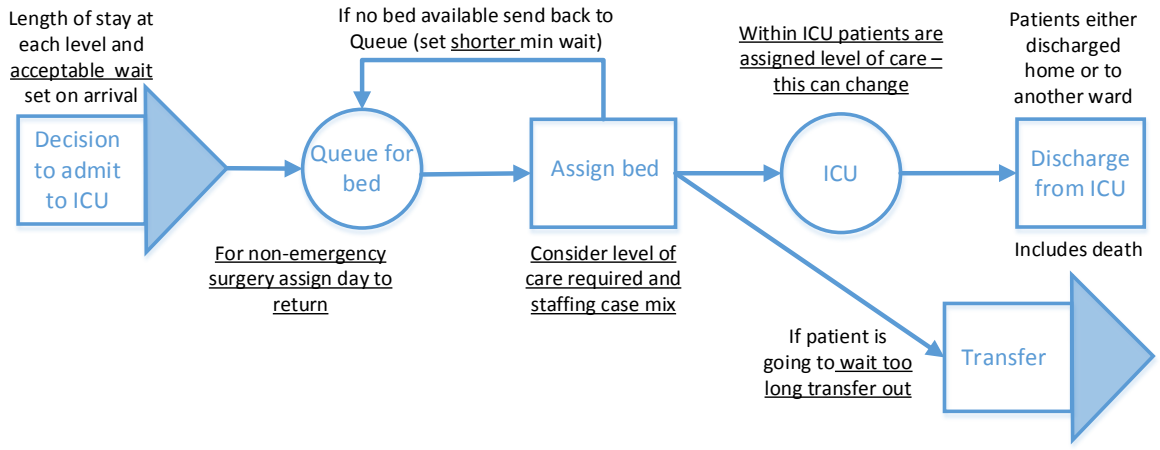


Figure 1: Model logic for ICU flow model in Penn et al[79]

4.10.2 Comparative analysis

We will compare the impact of different ICU staffing models on a range of outcomes. The staffing models considered will be informed by earlier workstreams but are likely to include:

- **Traditional ICU nurse-patient ratios** as recommended by the critical care society
- **Reclassification / tailored staffing model**: some patient beds are provided less than 1:1 staffing
- **Revised skill mix**: some care provided by:
  - non-ICU specialist registered nurses
  - pre-registration nursing students (relevant during the height of the pandemic)
  - junior registered nurses and/or associate nurses.
- **Combination scenarios:** Combining different skill mixes with higher or lower use of registered nurses/nursing associates/ nursing assistants.

4.10.3 WS4 Primary model outcomes

We will track the staffing levels each patient was exposed to in the simulation model (in hours per patient day for each staff group) and use the coefficients from regression models in WS3 to model the likely outcomes. For example, staffing models may be associated with lengths of stay for patients. The simulation model will deliver a range of outcomes for each scenario including:

- Length of stay
- Staffing costs based on hours worked by different types of staff and the corresponding national Agenda for Change pay-scales
- Adverse events including mortality
- Open beds (for admissions) and delay / transfer as outcomes

We will also investigate the feasibility of including other outcomes such as staff satisfaction, absences and number of moves between wards. Point estimates and 95% confidence intervals of the outcomes are estimated by running the model multiple times; in each run a different set of pseudo random numbers streams are used. This enables us to account for the variability seen in the real world. We will employ the confidence interval method to estimate the optimal number of simulation runs and will investigate the need to set a warm-up period and/or initial conditions. We will run the model separately for each hospital Trust's ICU , replicating the methods used in our NIHR-funded Safer Nursing Care Tool project [138] to produce overall general results across hospital Trusts.

4.10.4 Verification and validation

A rigorous process of verification and validation will be followed throughout [144]; for example extreme value tests, sensitivity analysis, tracing individual patient routes through the model and regular face validity checks with clinical members of the project team. We will follow the STRESS-DES reporting guidelines from the EQUATOR-Network to document the model in full [145] - a method we have used in previous projects [138].

We will include code walk-throughs involving all of the WS4 team to identify logical bugs and potential improvements in the DES model, as we have done successfully elsewhere [146]. We will provide detailed instructions to reproduce the computational results: the WS4 leads will also independently verify that results of the modelling can be recreated without the aid of the research fellow who built the model. As the model will evolve over the study we will plan and write unit tests for individual components of model that will be used for regression testing (catching new bugs introduced to previously working code as the model is developed).

4.11 WS5 Data Synthesis

Our overall evaluation will focus on integrating all findings, underpinning this synthesis with a formal triangulation protocol [147, 148], and use a meta-matrix to corroborate across WS data [149], to ensure different aspects of realist evaluation findings are fully drawn out. Key findings informing context-mechanism-outcome will be followed as a thread across datasets [150], We will draw on existing logic models in this area [128] to develop our programme theories and our overall findings. As a core part of realist evaluation, stakeholders representing content experts through i) their NHS roles ii) as patients/families iii) as commissioners iv) as academics will advise on developing programme theories/data to improve the validity/usability of recommendations. Figure 1.(Appendix 1) outlines the overall workstream flow and summary.

5. Patient Public Involvement/Engagement (PPI/E)

Co- applicants JG and JD, alongside a local Trust PPI/EE group have influenced development of each proposal stream and will be supported to contribute throughout the project, and to support developing programme theories. We are also engaging with the key ICU charity ICU Steps, who commented on this work, and we are adopting a broader view of PPI/E, to also include nurses, as 'recipients' of models, alongside patients. PPI/E partners have helped us consider in-depth the patient implications of alternative staffing models, and what the public perception of that might be.

Our PPI/E partners will attend core team meetings, to ensure the patient voice, representativeness,and inclusion are at the centre of the project. As a team we will continue to ensure that:

(i) the impact of nurse staffing on how patients/families members experience care in critical care unitsremains paramount (reflected in data collection, analysis and outputs)
(ii) research materials for patient/families recruitment are fit for purpose, well-written and help reach families
(iii) study procedures are not unduly burdensome for patient/family participants.

We will continue to engage with national groups, including ICU charities, NHS England and professional bodies in the development of this study. The impact, and changes made following PPI/E input, has been outlined in the respective workstream descriptions and we have two formal co-applicants, JD and JG in the team. PPI/E partners are keen to support interview schedules, review of outcomes collected, and development of the programme theories in particular. Support to PPI/E participants provided includes:

• Training on realist methods and training by experts (team members MH/NP) on how to review participant documents, such as information sheets and consent form, and questionnaires. Also additional methodological training so they can advise on how to conduct the study in a participant-friendly and ethically acceptable way (e.g. https://www.learningforinvolvement.org.uk/an-interactive-course-for-new-and-experienced-patient- public-reviewers-of-health-and-social-care-research/)
• Providing a clear role description to enable them to provide a public perspective
• PPI/ E participants (in addition to co-applicants JG and JD) will be included on the advisory group reviewing the programme theories.
• Training and support to facilitate the involvement in the analysis of data (such as the qualitative analysis), with honorary contracts through the university to support this activity.

SP, as the project PPIE lead will carefully support the team, PPI/E partners, and PPI/E co-applicants inparticular, providing bespoke training as necessary, and facilitating access to national and regional training. The regional (East of England) NIHR Applied Research Collaborative PPI/E Lead is willing to support PPI/E partners by highlighting opportunities and support available. A clear feedback mechanism (newsletters, updates) is planned for PPI/E partners and the public throughout the study, using the new NIHR feedback framework. We plan to hold yearly update meetings (twice in the first year for concentrated activity around ethics application) for our PPI/E members (those on the core team and those on the expert advisory group convened for the realist evaluation workstream), and will keep in regular contact via email. We also plan to work with our PPI/E members to develop public-facing updates (e.g outputs from survey findings).

A flexible approach to facilitate PPI/E is adopted, which is particularly important with people affected by a stay in ICU, that works on an individual level and gives people several options for involvement.

6. Research Management

6.1 The Study Management Group comprising the Chief Investigator, co-investigators and research fellows, and two PPI representatives, and project support staff (admin/other) will be responsible for managing the project, and meeting milestones. This group will be chaired by NP and will meet via videoconference monthly to review progress against milestones, plan work, discuss methods/analyses, keep a risk register and anticipate/resolve any problems. Sub-groups for workstream leads will also meet as required.

The ***Realist Stakeholder Advisory Group*** will meet six times during the study (see GANTT) to advise on programme theories development, as well as policy and organisational engagement, and the overall development of outputs, dissemination and implementation.

An **Independent Steering Group** will meet four times during the study (five to six monthly) and in advisory and supervisory capacity to monitor progress of the study by advising on development and progress of the research.

Conflicts arising: Arising conflicts of interest within the team will be declared for each meeting, with signed declarations for the independent groups to be maintained on a yearly basis.

6.2 Organisation: The Chief Investigator (CI) has responsibility for the study. Day-to-day running of the study is by the PI and nurse researcher; the CI is responsible for ensuring that data acquisition is completed. The CI will facilitate application for NHS confirmation of capacity and capability from each site's Research & Development (R&D) department. The CI holds responsibility for ensuring study processes are adhered to. Workstream leads ensure eligibility at the outset of the workstream, gain written consent (where relevant) and organise data acquisition.

The audio recordings will be transcribed by an external transcription service via UH. Data storage, analysis and management are the responsibility of workstream leads, overseen by NP. All data will stored on university secure shared servers (at Hertfordshire and Southampton) and anonymised. All data will be coded and no identifiable reference to the participants will be held with the data. Paper data will be stored in locked, fireproof file cabinets. Coded data held electronically will be stored on password protected NHS computers. Data will be stored for fifteen years, in accordance to the Data Protection Policy and GDPR. Oversight of the intellectual property issues are the responsibility of the CI, NP. The IP arising from the data is held as per contract and collaboration agreements.

6.3 Timelines: Start date will be from the point of contract agreement (see GANTT in Appendix 2). Participant completion defined as end of ethnographic observation, interviews and/or questionnaires. No further follow-up anticipated. Study completion defined as recruitment of sufficient numbers for ethnography, survey and interviews (and completion of these), completion of realist evaluation and outputs from workforce data and CMP data linkage.

6.4 Protocol Compliance: All researchers taking part in the study will be required to attend a start-up meeting to ensure compliance with the proposal and to provide training on study procedures and data collection methods. The CI will monitor the compliance of researchers in the team on an ongoing basis, although workstream leads are responsible for compliance within their stream (such as data governance). Where non-compliance with the protocol is suspected, the CI will liaise with the research team and resolve the matter according to Good Clinical Practice (GCP) principles and the 2017 Policy Framework for Health and Social Care Research (particularly relevant for health service research such as this).

6.5 Monitoring/Inspection: Compliance will be monitored by the CI checking for compliance with the protocol, data consistency, missing data and timing. The CI will be in regular contact with team members (by phone/fax/email/letter) to check on progress and deal with any queries that they may have. This study is to be conducted according to EU and international standards of Good Clinical Practice and International Conference on Harmonisation guidelines, applicable government regulations and Ethics policies and procedures. This protocol and any amendments will be submitted to a properly constituted independent Research Ethics Committee (REC), in agreement with local legal and sponsor requirements, for formal approval of the study conduct. The REC approval decision will be provided to the sponsor before commencement of this study. There is the potential for inspection by government regulatory authorities and sponsor/R&D Compliance, and the CI maintain responsibility for complying with this. If the CI is notified of an inspection relating to the project by a regulatory or other official body, the CI will immediately notify all members of the team and the study steering committee.

6.6 Informed Consent: It is the responsibility of the CI to ensure informed consent is obtained as per REC and HRA submission from each participant prior to entering the study or, where relevant, prior to evaluating the participant's suitability for the study (see earlier sections for processes). The study should be discussed by one of the research team listed on the site responsibilities sheet (clinician or nurse) with the participant in detail and the participant provided with a copy of the information sheet to take away with them to consider further. Participants will be given sufficient time to consider the study, allowing time for discussion with other family/friends, and for the participant to ask questions of the research team prior to written consent being given. Copies of the PIS will be given to the participant. The original signed Participant Consent Form or verbal (audio-recorded) consent will be stored in the study site file or on secure servers, separate to the research data.

6.7 Project finance, indemnity and insurance and reporting: Funding costs for this study have been provided by the NIHR and it will be submitted for adoption onto the NIHR portfolio. Study insurance and indemnity is provided by UH who will act as sponsor and employs the CI. An interim report will be sent to the NIHR as per NIHR contract, and copied to the UH Research Office. A final report will be submitted to the NIHR, HRA (REC) and sponsor.

6.8 Regulatory Principles The team will conduct the study according to GCP guidelines and UH research policy. Participants have the right to withdraw from the study at any time for any reason. This study will be carried out in accordance with the World Medical Association Declaration of Helsinki (1964) and all subsequent amendments. Study data will belong to the University of Hertfordshire (as per collaboration/NIHR agreements) and the CI is the custodian of the data.

6.10. Confidentiality, data handling and record keeping: Content arising from questionnaires, ethnographic data/interviews and WS3/4 workforce data will be regarded as confidential, and it will be iterated to participants the importance of confidentiality. Where any issues arise from the study, we will liaise in the first instance with those involved and potentially the clinical team (where appropriate). No one outside the research team will have access to data, unless there is safeguarding issue where we are required by law to share this data. Data related to the study will be kept in a locked cabinet in a secure office or on password protected University computer servers only accessible to the research team. Digital files will be destroyed at the end of the study and no identifying data will be attached to the file or transcriptions. Data will be presented to be accurate but also to protect participant's identities. As with all studies, limits of confidentiality, such as criminal practices, apply. Written and 'processual' (after the event) consent will be sought after the interviews, to ensure participants are happy to allow the interview data to be used anonymously in the research.

6.11 Modifying and maintaining data: Records of study sites and participating staff will be modified to maintain accurate details of personnel and status. The reason for such changes will be recorded in an audit trail.

6.12 Risk mitigation Table 1. outlines risk mitigation for the project.

Table 1: Factors mitigating risks and contingency plans

Risk	Factors mitigating risk	Contingency plan
Regulatory approvals/ethics delays	Precedent of successful ethics applications from previous studies involving investigator group.	Parallel activities on Gantt chart can be undertaken if delays to ethics approvals
Delays in recruitment and set-up due to ongoing COVID-19 pandemic	In addition to the specific issues outlined for each work packages below, we could see another surge (although modelling suggests this will not peak as it did in January 2021), which could threaten prioritisation of research via local R&Ds. The subject area is highly pertinent to COVID.	We would work with local sites to outline need for the research in terms of R&D support and prioritisation, as we have done successfully with other critical care focused research over the past 20 months.
Low recruitment to questionnaires (WP1)	We are confident of a good response rates and units are engaged in this issue. Option to complete online. Descriptive statistics only are sought – so not predicated on a given sample number.	Telephone follow-up of individual non-responding units
Low recruitment to ethnographies (WP2)	We are seeking a very small number, 6 on each site over 6 months and will work closely with clinical teams to see which staff, families and patients this might be possible with, and follow all due ethical processes.	We could recruit more than 6 from one site, or seek further ethical approval for in situ interviews rather than ethnography if recruitment becomes problematic (unlikely)
Lack of participation in qualitative interviews WP2	Precedents of successful conduct of interviews by investigator team in previous workforce research.	Participation rate will be monitored and methodology of participant recruitment adjusted if needed; We will recruit more from high-recruiting sites if needed.
Feasibility of the overall project	Investigator team have a strong track record of delivering successful research projects in critical care and workforce; Robust project management organisation.	Strong lines of communication have been planned with regular meetings to facilitate the mixed methods approach.
Lack of stakeholder engagement	Significant progress already made on engaging stakeholders from all relevant groups, including 3rd sector, health management, integrated care systems, PPI. All opportunities to raise the profile of the work and potential impact (including guidance) will be exploited (via clinical, policy and research avenues).	The team will capitalise on connections through professional bodies, clinical networks, strong PPI engagement and umbrella organisations (UKCCNA, Royal College of Nursing, and advocacy groups, HEE)
Transferability across different geographical locations	Conducting across England provides some diversity for implementation models and different health provider structures. We plan to continue to connect with national stakeholders to ensure wide applicability.	We will draw stakeholders and experts from across the UK.

Appendix 1. Figure 1.

Study flow and Participants: SEISMIC-R

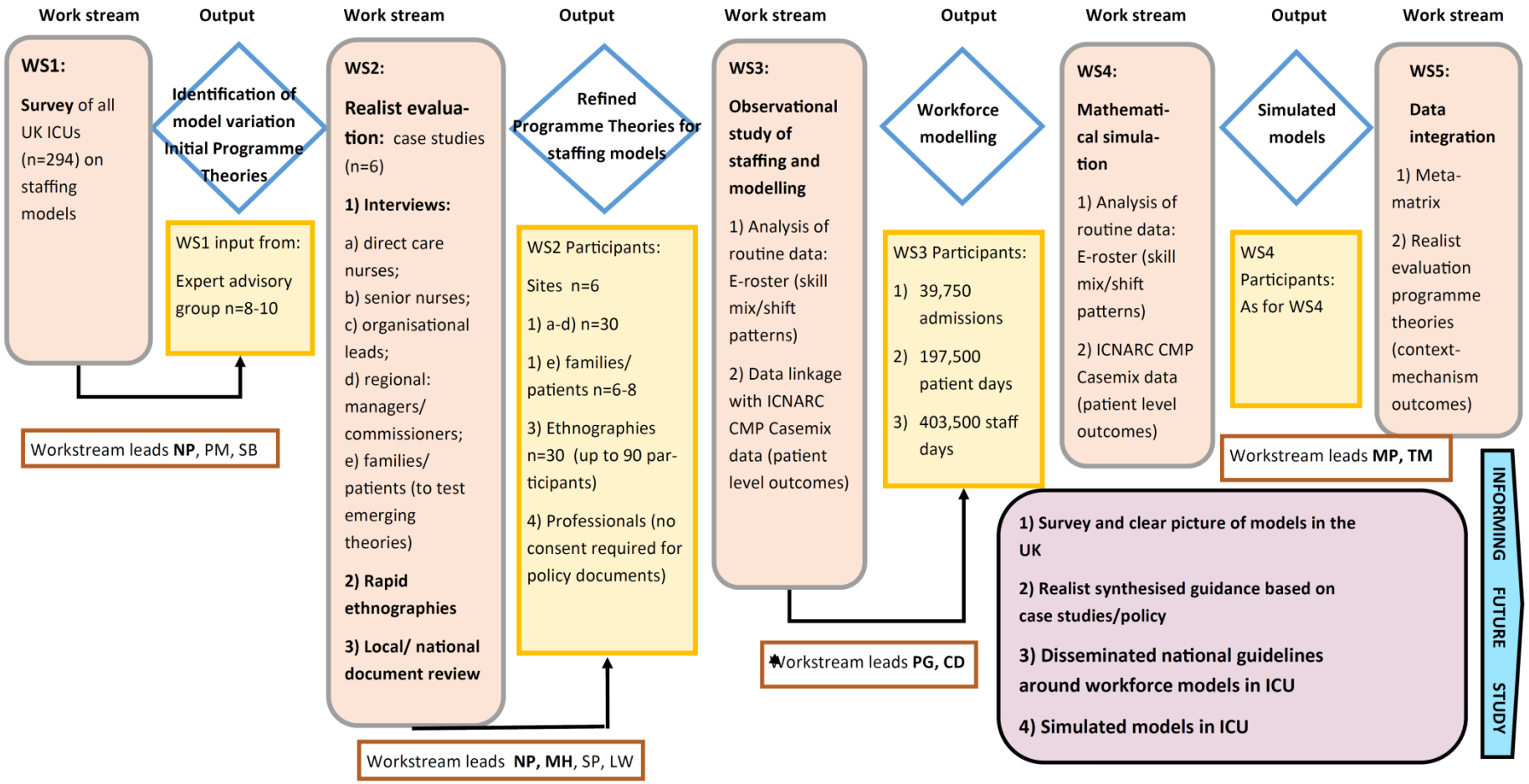
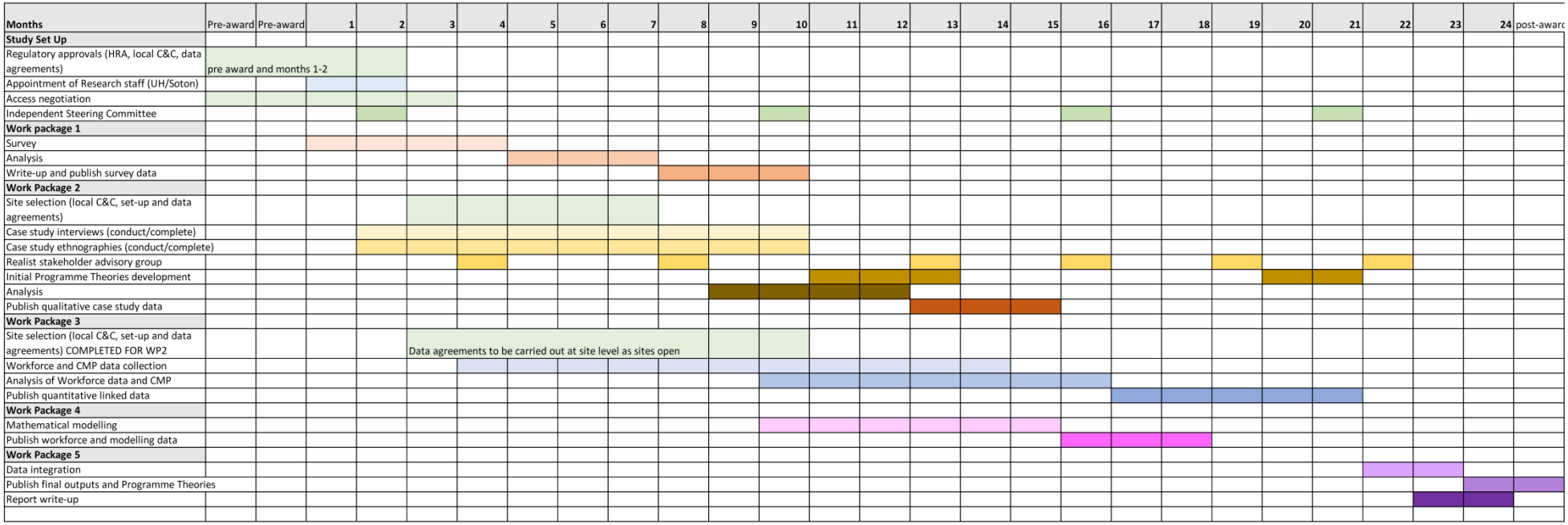


Figure 2. GANTT



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