IMPLEMENTATION OF THE NON-MEDICAL PRACTITIONER WORKFORCE INTO THE EMERGENCY AND URGENT CARE SYSTEM SKILL-MIX IN ENGLAND: A MIXED METHODS STUDY OF CONFIGURATIONS AND IMPACT

The SkillMix-ED study

PROTOCOL V 2.0

25th May 2023

This protocol has regard for the HRA guidance and order of content

Explanatory note on contents

This protocol (master v2.0) is an amalgamation of two protocols:

1 The master protocol 1.0 to the end of the methods for Phase 1 of the study (page x of this v2.0)

2 The Phase 2/3 protocol v3.1 submitted to HRA, including background and summaries in order to illustrate the context (of Phase One outputs) leading to the slightly revised Phase2/3 protocol.

The contents page therefore contains some duplication of section headings across Phase One and Phase 2/3

RESEARCH REFERENCE NUMBERS

IRAS Numbers:	294203 (Phase One), 319755 (Phases Two and Three)
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CONTENTS

LIST OF ABBREVIATIONS

ACP	Advanced Clinical Practitioner
ANP	Advanced Nurse Practitioner
APR	Annual Progress Report
CEM	College of Emergency Medicine
CI	Chief Investigator
CRN	Clinical Research Network
ED	Emergency Department
ENP	Emergency Nurse Practitioner
EP	Emergency Practitioner
GCP	Good Clinical Practice
GP	General Practitioner
HEE	Health Education England
HRA	Health Research Authority
HS & DR	Health Services & Delivery Research
IRAS	Integrated Research Application System
MeSH	Medical Subject Headings
NETSCC	NIHR Evaluation, Trials and Studies Coordinating Centre
NHS	National Health Service
NIHR	National Institute for Health Research
NP	Nurse Practitioner
NMP	Non medical practitioner
PA	Physician Associate
PP	Paramedic Practitioner
PPI	Patient and Public Involvement
PPI REG	Patient and Public Involvement Research Expert Group
RCEM	Royal College of Emergency Medicine
RCN	Royal College of Nursing
RCP	Royal College of Physicians
REC	Research Ethics Committee
SMG	Study Management Group

SOP	Standard Operating Procedure
SSC	Study Steering Committee
TBA	To be appointed
UK	United Kingdom
UTC	Urgent Treatment Centre
WP	Work Package

KEY STUDY CONTACTS

Study role	Name and contact details
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STUDY SUMMARY

Study Title	**IMPLEMENTATION OF THE NON-MEDICAL PRACTITIONER WORKFORCE INTO THE EMERGENCY AND URGENT CARE SYSTEM SKILL-MIX IN ENGLAND: A MIXED METHODS STUDY OF CONFIGURATIONS AND IMPACT**
Short title	The SKILLmix-ED study
Study Design	Mixed methods
Study Participants	National and regional NHS senior clinicians, managers, commissioners and lay representatives Emergency Department (ED) and Urgent Treatment Centre (UTC) non-medical practitioners (NMPs) and other clinical staff ED/UTC patient records ED/UTC patients
Planned Size of Sample (if applicable)	National and regional NHS senior clinicians, managers, commissioners and lay representatives n= 20 ED/UTC NMPs and other clinical staff n = 132 NHS Trusts with ED/UTC patient records n=124 ED/UTC patients n=995
Planned Study Period	March 2021 to August 2023
Research Question/Aim(s)	• What is the impact of different non-medical practitioner skill-mix in EDs and UTCs in NHS acute hospitals on patient and service processes and outcomes? (Phase 1, 2 & 3) Secondary research questions: • What is the research literature and policy evidence regarding the effectiveness, acceptability, levels of

	supervision and independence of NMPs in EDs/UTCs in NHS acute hospital settings? (Work package [WP]1) • What is the current workforce profile including NMPs in EDs/UTCs in acute NHS trusts in England, and what strategic aims exist for its development? (WPs 1, 2) • How independently or with what level of supervision do NMPs work in EDs/UTCs? (WP2 and WP5) • What recommendations can be made to inform clinicians and managers in deciding skill-mix that includes NMPs in staffing EDs and UTCs in NHS acute hospitals? (Phase 4, WP 7)

PLAIN ENGLISH SUMMARY

Demand for urgent and emergency care services is growing every year, especially urgent treatment centres (UTCs). People are going to Emergency Departments (ED) with more complicated issues and many patients are admitted to hospital. There are not always enough doctors for these departments, and staff are leaving or going off sick in high numbers. One solution is to employ 'non-medical practitioners'. These are qualified staff from other healthcare backgrounds who work at the same level as doctors. Some research shows that patient results are the same if they see a non-medical practitioner as if they see a doctor. We need to know what balance - known as 'skill-mix' - of nonmedical practitioners, doctors and nurses in a team and service achieves the best results.

This study will explore the result of different skill-mix in ED/UTCs in England, to make recommendations about the best balance.

Patient and public involvement (PPI) representatives have helped design the study. There will be an independent PPI panel who can feed in their views and experiences to all parts of the study. The panel will be run by an experienced patient and public involvement expert, who is a member of the core study team.

We will split the study into four phases over two-and-a-half years.

Phase One (months 0-12) will find out in detail what the staffing models are in EDs/UTCs. We will look at published research evidence and at NHS public documents, and we will interview regional and national senior NHS clinicians, managers, commissioners and lay representatives. Then, we will look for patterns in information about staff which is already collected regularly across England. We will look at what non-medical practitioners do and how independently they work in two different ED/UTCs. We will ask the panel of patient and public involvement representatives and a panel of non-medical practitioners to help us to understand these findings. We will develop a system for classifying 'skill-mix' in each organisation. We will also think of a way to measure how much support and supervision non-medical practitioners need.

Phase Two (months 13-18) will use look at figures regularly collected from all NHS Trusts in England between 2017 and 2021, to assess whether different skill mixes lead to different patient outcomes. We will look especially at the number of patients who return again to the ED within a week.

Phase Three (months 13-24) will involve looking in detail in six ED/UTCs. We will collect in depth local data to add to the national data we looked at in Phase Two. This will include looking closely at staff records and patients' clinical records to tell us more detail about skill-mix in the organisations and the outcomes for patients. We will gauge how independently the types of practitioners assess and treat patients. We will also survey and interview patients so that we can understand their experience, and we will interview staff for their views.

Phase Four (months 25-30) will pull all of the results together. We will ask our panels of patient and public involvement representatives and non-medical practitioners to help us again. We will make recommendations on skill-mix and levels of independence that will deliver the best outcomes for patients, for staff and for the NHS.

We will publicise our findings and evidence-based recommendations with professional, patient and public groups. We will use presentations, summaries, web-based video and social media to share our findings with patients, staff and employers.

SCIENTIFIC ABSTRACT

Primary research question

What is the impact of different non-medical practitioner skill-mix in Emergency Departments (ED) and Urgent Treatment Centres (UTC) in acute hospitals on patient and service processes and outcomes?

Background

Increasing demand for emergency and urgent care has occurred alongside staffing shortage, particularly of doctors. Re-shaping of the workforce has resulted, including the introduction of non-medical practitioners (NMPs), such as nurse practitioners and physician associates. Despite 20 years of NMPs in EDs, there is limited evidence of effectiveness of individual roles, and none as to appropriate skill-mix of staff, at what level of independence from senior medical staff.

Aim

To explore how NMPs are being deployed and the impact of different skill-mix including NMPs in EDs and UTCs on patient experience, quality of care, clinical outcomes, activity, staff experience and costs in acute NHS trusts in England, in order to inform workforce decisions of clinicians, managers and commissioners.

Methods

We will conduct a mixed methods study in three phases.

Phase One (months 1-12) aims to describe the rationale for, and configurations of, the NMP workforce in EDs/UTCs in England, and to develop analytical tools.

- We will undertake and publish a scoping literature and policy review on NMP development and skill-mix outcomes, informed by interviews with national workforce and professional leaders (Work package [WP] 1)
- We will describe quantitatively the NMP and other clinical workforce (skill-mix) using NHS Digital and NHS Benchmarking national data, 2017-2021; and qualitatively the level of independence/supervision of NMPs and doctors, through observation (WP2)
- We will triangulate WP1 and WP2 results in consultative activities with patient and public and NMP representatives, and the independent study steering committee, to develop three

analytical tools: a skill-mix ratio classification, a quantitative measure of independence and supervision, and a logic model for NMP skill-mix (WP3).

Phase two (months 13-18) aims to utilise the analytical tools to assess the impact of skill-mix ratios on national ED/UTC indicators of quality.

- We will conduct and publish a quasi-experimental study of associations of skill-mix ratio classifications with our primary outcome (rate of unplanned return to the ED/UTC in seven days, a proxy for clinical safety), secondary outcomes (national indicators of ED/UTC quality and performance), and cost-effectiveness. (WP4)

Phase three (months 13-24) aims to explain the effectiveness and acceptability of skill-mix ratios through investigation in six local-level case study sites.

- We will repeat WP4 analysis with added precise local quantitative data on NMP types (trust management information), controlling for level of independence/supervision of the clinician (collected via structured observation). We will add patient satisfaction as an outcome, collected prospectively via questionnaire (WP5).
- We will investigate the experience of including NMPs in the skill-mix through qualitative interviews with patients and staff (WP6).

In *Phase four* (months 25-30) we will prepare a synthesis of findings, using our logic model, for structured discussion at a stakeholder event to prepare recommendations and outputs.

Timelines for delivery

The study will take place from March 2021 to August2023.

Anticipated impact and dissemination

The research will generate new knowledge and understanding of optimum/most effective/impact of different skill-mix outcomes to translate into workforce models with our NHS partners. Commissioners, clinicians and managers will be able to assess their local skill-mix in relation to the guidance on (optimum) skill-mix outcomes. Dissemination throughout the study will include policy briefings, academic outputs, bite-size findings, conference presentations and social and mainstream media routes accessible to stakeholders.

FUNDING AND SUPPORT IN KIND

FUNDER(S)	**FINANCIAL AND NON FINANCIALSUPPORT GIVEN**
NIHR Health Services & Delivery **NETS Post Award Setup Team** NIHR Evaluation, Trials and Studies Coordinating Centre (NETSCC) University of Southampton, Alpha House, Enterprise Road, Southampton SO16 7NS netspostawardsetup@nihr.ac.uk	£770,796.54

ROLE OF STUDY SPONSOR AND FUNDER

The sponsor for the study will be Kingston University, assuming overall responsibility for the initiation and management of the study under contract with the NIHR.

This study/project is funded by the National Institute for Health Research (NIHR) Health Services and Delivery Research (HS&DR) Project:131356. The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.

ROLES AND RESPONSIBILITIES OF STUDY MANAGEMENT COMMITEES/GROUPS & INDIVIDUALS

Study management group (SMG)

The study management group will be responsible for the delivery of the study, against its timetable, under the overall leadership of the joint CIs. The study management group will be formed of all co-applicants and will meet in alternate virtual and in-person (if able) on a quarterly basis throughout the study, commencing at month 1. The study management group will be guided by an independent study steering committee and two stakeholder panels.

Study Steering Group (SSC)

The SSC will be appointed by NIHR, with at least 75% of its membership independent of the investigator team. The role of the SSC will be:

- To provide advice, through its Chair, to the Project Funder, the Project Sponsor, the joint CIs, the Host Institution and the Contractor on all appropriate aspects of the project
- To concentrate on progress of the trial/project, adherence to the protocol, patient safety (where appropriate) and the consideration of new information of relevance to the research question
- The rights, safety and well-being of the participants are the most important considerations and should prevail over the interests of science and society
- To ensure appropriate ethical and other approvals are obtained in line with the project plan
- To agree proposals for substantial protocol amendments and provide advice to the sponsor and funder regarding approvals of such amendments
- To provide advice to the investigators on all aspects of the trial/project.

The SSC will meet three times during the study, as well as being invited to join co-design and stakeholder synthesis meetings.

Advisory panels

Panel 1. Patient and Public Involvement (PPI) – we will invite members of PPI groups from our university and later from our participating UEC case study sites to form a panel

Panel 2. Non-medical workforce - we will invite medical, NMP, nursing and Allied Health Professional (AHP) clinicians from the ED/UTC setting to form a second panel.

Each of these panels will report into the study management group via the PPI lead and joint CIs and onto the study steering committee; the panels however will allow adequate time to be given to hearing the PPI and clinician voice before this is consolidated into a 'representative view' on the formal committees via two members of each panel. We will meet with both panels separately at four points in the 30 months with the following purpose: orientate to the study and dissemination

planning; question the research team and steer the direction of the scoping review; discussion and interpretation of findings as part of stakeholder activities.

PROTOCOL CONTRIBUTORS

The contributors to the protocol have been the joint CIs and the co-applicant team, with support from the following:

- The Faculty of Health, Social Care and Education of Kingston University and St George's, University of London Peer Review College
- The NIHR peer reviewers and funding committee
- The South London Clinical Research Network (CRN) and the Joint Research and Enterprise Office of St George's University Hospitals NHS Foundation Trust
- The Patient and Public Involvement Research Expert Group (PPI REG) of the Faculty of Health, Social Care and Education of Kingston University and St George's, University of London, under the leadership of co-applicant Mrs Sally Brearley. We consulted with this laypersons group twice during the development of the proposal:

Development of the stage one bid. We met with 11 members of the PPI REG once the research team had drafted an outline of research questions and methods, but with six weeks still before date of submission to allow for PPI recommendations to be fully considered. The group raised a number of issues they considered we could focus on: team configurations, who decides who will see whom, who in the team assesses patients, number of staff required to 'operate' (of which level, agency, vacancies), skills for the caseload, speed of change in multiplying workforce roles, need for cost-benefit analysis, staff retention, case studies including those who think they have 'got it right' and those who suggest they may be struggling, communication and understanding of role amongst the skill mix.

The group also suggested the following outcomes should be collected: inter-staff communication, teamwork, being seen as a person, thoroughness of history taking, being treated without harm, recommending the ED to others, provision of health education to avoid the need for ED in future, communication with patient, and satisfaction with the end result, whilst taking into account different levels of public understanding of non-medical practitioner roles. These discussions influenced our thinking about the research tools (e.g. the patient questionnaire) to be utilised and

are all able to be collected in our quantitative and qualitative methods involving patients and staff in Phase three of the study.

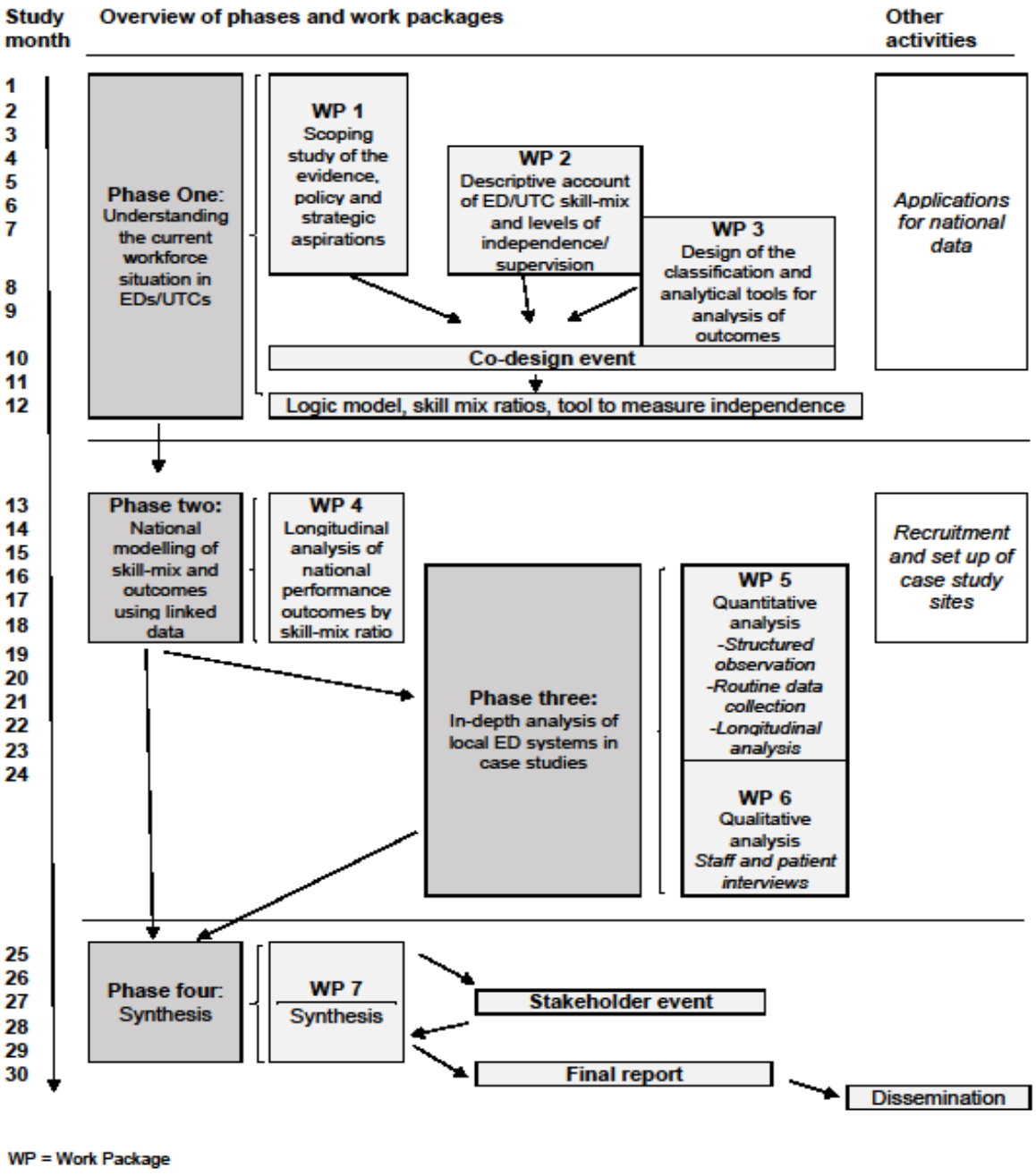
In preparation of this stage two bid we worked with eight members of the same PPI REG. The points we noted from the discussion, all of which have influenced the detailed research plan, are as follows: carefully define what we mean by skill-mix, noting that this would be measured at the level of the emergency department, not by who is actually on duty, and may vary by time of day; acknowledge the impact of COVID-19 on ED attendance patterns; the importance of considering the case-mix of patients seen by the practitioners; strengthening how we will address issues of diversity and inclusion, noting how different people's experiences of caring can be, and particularly ensuring we will not only recruit English-speaking participants; for patient interviews, consider offering an interview at a later time point (not while in the emergency department).
The PPI REG also advised us to broaden our approach to PPI in the proposal, expanding the PPI role to include data collection, around patient experience and satisfaction, and thinking about other opportunities to increase PPI through e.g. opportunities for the PPI and NMP panels to meet and ensuring diversity within the PPI panel.

The group also suggested that we include Walk-in-Centres as these can be wholly staffed by NMPs. As these facilities are no longer classified as EDs, we fed back that we would not include these facilities.

Members of the group also reviewed the Plain English Summary close to the application submission date, as did the South London RDS rapid PPI review team

Emergency Service, Hospital; Workforce; Professional Autonomy; non-medical practitioners; skill-mix; mixed methods

STUDY FLOW CHART



WP = Work Package

Implementation of the non-medical practitioner workforce into the urgent and emergency care system skill-mix in England: a mixed methods study of configurations and impact

1. BACKGROUND

Numbers of people attending emergency departments (EDs) in England have increased significantly in recent years.[1] The Care Quality Commission reported this increased demand was negatively impacting on operational performance and the quality of care.[2] The year 2019 saw the worst annual performance for the proportion of patients spending over four hours in the ED.[3] The ED workforce has some of the highest turnover, vacancy and sickness rates in the NHS,[4] with high levels of reported staff burn out,[5] assaults from patients [6] and consultant intention to retire early.[7]

In the National Health Service (NHS) there are four types of ED: Type 1 is consultant-led 24 hours, every day for general conditions; Type 2 consultant-led 24 hours every day for specialist conditions, Type 3, Urgent Treatment Centres (UTCs) GP-led 12 hours every day for patients not requiring Type 1 or 2 ED, and Type 4 walk-in-centres providing primary care by appointment (no longer defined as EDs/UTCs).[3] In 2020 there were 124 acute hospital trusts in England providing both Type 1 or 2 and Type 3 services, comprised of 183 individual providers.[8]

One policy solution to both patient demand and workforce problems has been the introduction of new roles and different skill-mix.[7] Determining the ‘‘right’’ mix of health disciplines is a major challenge for health care organisations.[8] To address the medical workforce shortages the Royal College of Emergency Medicine (RCEM), with NHS England, proposed solutions for increasing the medical workforce and also a strategy for greater skill-mix with NMPs to undertake some of the medical work.[9]

The RCEM, with NHS Health Education England (HEE), planned for growth of the NMP workforce with a national framework for the ‘emergency care-advanced clinical practitioner’.[7] NHS England workforce plans now include a range of NMPs in the emergency care system [10]: Advanced Clinical Practitioners (ACPs)[11] who come from professional groups registered with the Health Professions Council, including Pharmacists; advanced nurse practitioners (ANPs); and Physician Associates (PAs)[12], and Emergency Practitioners (EPs), many of whom are nurses (ENPs)[13] who vary in the

extent to which they work at advanced practice levels. NMPs work alongside medical staff of all grades as well as with nurses; some bodies emphasise that they are not direct substitutions for doctors.[7] There is a 20 year history of ENP employment in the English EDs; 70% of UTCs in acute hospital trusts in England have nurse-led models of care while 7% of the nursing workforce are nurse practitioners (NPs) and 2% ANPs.[4] However, there is currently no guidance concerning ED staffing ratios of any health discipline to patients, or guidelines on accreditation of the variety of NMPs against medical grades.

Our literature review searched Medline and Cinahl Plus databases (2000 to 2020), using the key word, MeSH and Subject Heading search terms ('skill-mix' OR 'skill-mix' OR 'substitution' OR 'staffing mix' OR 'Health Workforce') AND ('Emergency Service, Hospital' OR 'emergency department' OR 'accident and emergency department' OR 'A&E'). Four hundred and seventy-five entries were identified. The majority of these studies and reviews investigated the impact of a single type of NMP rather than the impact of a mix of disciplines in staffing of EDs. Dall'Ora et al's (2017) review of the evidence for skill-mix and new roles in urgent and emergency care settings, concluded that the evidence was very limited, with most support for improved patient experience with the use of ENPs and NPs.[14] A review of pharmacists in the ED reported that they eased pressure through undertaking prescribing roles and patient assessment.[15] Two reviews, one of the evidence of the impact of physiotherapists,[16] and the other of PAs, [17] reported mostly positive findings, but from limited studies in number and level of evidence. Our own study [18] found no differences between PAs and junior doctors-in-training for the outcome of re-attendance at the ED within seven days and that PAs were valued by the medical team, enabling release of junior doctors for training, although some professional resistance was noted. A review of paramedic roles in American EDs reported them influential in decreasing the nursing workload and improving patient flow.[19]

Literature referring to skill-mix is more scant, with studies mostly within nursing.[20]. One review of overall staffing reported evidence of the positive impact of increasing the proportion of senior decision makers at the time of a junior doctor strike, and of utilising NPs and junior doctors in 'fast track' or minor treatment services; the overall conclusion was "a large gap in current literature that looks at what combinations of staff work best across an ED."[21] Dall Ora et al's more recent review reports that the evidence base has not changed.[14]

The studies and reviews we identified generally considered 'grade-mix' rather the the "combinations of activities or skills needed for each job within the organization"[22], which is the focus of this study. The definitions for NMPs in the ED refer to the concept of autonomy or working

autonomously within a dependent relationship to a physician.[12,23,24] However, not all NMPs exercise the same degree of autonomy. The College of Emergency Medicine (CEM) argues that NMP staff are not direct substitutes for medical staff, and that the correct medical staffing varies dependent on the extent of supervision required for individual NMPs, as well as senior decision making for the patients.[13] The NMP level of equivalence has been reported to vary from foundation year 1 doctor-in-training to specialist training registrars as they develop over two to five years.[9] The CEM noted variation in the way NMPs were utilised,[13] and our research on PAs in EDs [25] and ACPs [26] identified differing levels of independence and supervision from senior medical staff. Our second literature search was of Cinahl Plus and Medline from 2000-2020, using the terms 'non-medical practitioner' OR 'paramedic' OR 'nurse practitioner' OR 'pharmacist' OR 'physiotherapy practitioner' OR 'physician assistant/associate' AND 'independence' OR 'supervision' OR 'autonomy'. We found only three studies. One study described NMPs as 'eventually' reaching autonomous practice.[27] Another study described various forms of supervision and its impact on costs, credentialing to avoid risk, and medicolegal considerations of NMPs.[28] A third study reported that modelling of resource need and costs required taking account that, "In many EDs, physicians supervise delegates such as residents, physician assistants and nurse practitioners each with different skill sets and levels of independence."[29] We located no literature examining outcomes of different skill-mix in the ED/UTC.

Our proposed research is designed to provide evidence to address the knowledge gaps on optimal skill-mix, in a mixed methods study. We will investigate how NMPs are being deployed in EDs and UTCs within the acute hospital sector.

2. RATIONALE

Timely, safe and effective emergency and urgent care provision is a key public, patient and NHS priority [30] but rising patient demand, missed performance targets, overcrowding and delays have been of increasing concern. In this context, emergency and urgent care workforce problems are identified as a major NHS England issue [30] requiring attention, as well as a 'Top 10' research priority.[31]

ED team failures have been attributed to inadequate resources and skill-mix,[32] and skill-mix is a known influencer on patient flow.[33] The Covid-19 pandemic offers further impetus for an ongoing commitment to good patient flow through the hospital to avoid ED crowding.[34] Systematic review

evidence also points to a strong association of social and organisational work factors with staff mental well-being in EDs.[35] Our patient and public involvement (PPI) Research Expert Group, contributing to this research plan, offered general support for the focus on skill-mix, with concern for the impact on patients of team configurations, queues, who decides who will see whom, who in the team assesses, the number of staff required to 'operate', skills for the caseload (e.g. mental health), speed of change in multiplying workforce roles, need for cost-benefit analysis, staff retention, communication and understanding of role amongst the skill-mix, whilst taking into account different levels of public understanding of NMP roles. Despite pressing and enduring health service need, there is little evidence to guide clinicians', managers' and commissioners' decision-making regarding skill-mix.

Ongoing research identified through our search of ClinicalTrial.gov, of NIHR, and of the Open Science Framework highlighted studies of the ED/UTC workforce in terms of GP models in the ED [36,37] but none on the NMP workforce. In primary care, skill-mix/team composition is currently being studied in three studies, [38-40] offering methodological learning, but no evidence from the ED/UTC setting. We are also aware of scoping review protocols of the evidence for advanced clinical practice in the UK, though this is not specialty-specific [41] and of how uncertainty influences healthcare professionals and service users in the ED;[42] while these have some relation to our topic, they will not answer questions on skill-mix in the ED/UTC.

There are notable gaps in the evidence about NMPs in the skill-mix in ED/UTC and therefore information is lacking for patients and the public, clinicians and managers to make decisions as to the optimum safe, effective and acceptable staffing mix and associated costs. This study takes the first steps to addresses this evidence gap. The information derived from the study will have utility in providing an understanding of the current context and paving the way for the later proposed phases of our overall funded study.

3. THEORETICAL FRAMEWORKS

As an applied, health services research study, an overall theoretical framework for judging health services developed by Donabedian (1988)[43] and expounded in the United Kingdom (UK) setting by Maxwell (1992)[44] will be used. This frames the contribution made by NMPs, as new types of personnel within different skill-mixes, in terms of effectiveness, patient safety, acceptability, equity

(fairness), efficiency, and costs.[43,44] The study will also be cognisant of theories concerning innovation in health care,[45] together with theories of substitution and supplementation in reassignment of work from one group of professionals to another [46,47] and the potential for contest between professional groups.[48]

Since level of independence in practice afforded to NMPs can vary significantly and needs to be considered in an analysis of processes and outcomes, we will additionally take account of theories concerned with levels of medical supervision of the non-medical workforce. Supervision in the health professions takes a number of forms, from managerial checking through to a more developmental encounter, which aims to enhance capability and clinical judgment plus increase the clinician's ability to cope with the complexity of clinical practice.[49] The degree of autonomy, that is the authority to make decisions within the domain of an individual's profession and to act accordingly, is also linked to the level of supervision received.[50] In this study we are using theories that the degree of autonomy can be measured as a function of practice independence behaviour,[52] focussing on: concepts of readiness (taking responsibility and being accountable for actions); empowerment (providing quality services through one's actions); actualisation (having a sense of professionalism), and valuation (accepting the consequences of choices made).[52]

4. AIMS AND OBJECTIVES

4.1 Aim

To describe the configurations of the NMP workforce in the ED/UTC in NHS acute hospitals and to develop analytical tools for skill-mix.

4.2 Research questions

- What is the current workforce profile including non-medical practitioners in emergency departments and urgent treatment centres in acute NHS trusts in England, and what strategic aims exist for its development?
- How independently or with what level of supervision do non-medical practitioners work in emergency departments and urgent treatment centres?

5. STUDY DESIGN

We will conduct a pragmatic, sequential, mixed methods study [53] to investigate the research questions, as recommended for the evaluation of complex interventions.[54]

Phase 1 will be undertaken in three work packages (see study flowchart).

6. SETTING/CONTEXT

We will carry out this study in the context of the ED/UTC workforce in NHS acute hospital services classified as Type1, 2 or 3 EDs in England, excluding Type 4 (walk-in-centres that do not accept emergency patients). Nationally, there were over 4 million Type 1 and 1.5 million type 3 patient attendances per quarter in 2019.[1]

We will utilise data from 2017 onwards as the marker for the advanced practice NMP policy implementation, following HEE's financial investment in the two-year training programmes for ACPs and PAs in 2015.[55]

7. PHASE ONE METHODS of DATA COLLECTION AND DATA ANALYIS

In Phase 1 we will undertake three WPs, the first two concurrently. WP1 will seek to describe the evidence, policy and aspirations at organisation leader level held for the non-medical workforce, answering research question 2. WP2 will investigate NMPs' level of independence/supervision (research question 4).WP3 will use data from WP1 and 2 , together with evidence from an updated literature review to create two classification tools upon which the next phases of the study are. The tools will be: a classification of the types of skill-mix in ED/UTC workforces which include NMP for Types 1 (general), 2 (specialist) and 3 (minors) patient attendances; and a measure of the level of NMPs' independence of working.

We describe each work package to include information on eligibility, recruitment, consent, data sources, data collection tools, outcomes and analysis presented within each work package.

7.1 WORK PACKAGE 1 (WP1): AN INVESTIGATION OF SENIOR NHS CLINICIAN, MANAGER, COMMISSIONER AND LAY REPRESENTATIVE VIEWS ON THE EVIDENCE, POLICY AND STRATEGIC ASPIRATIONS HELD FOR THE NON-MEDICAL WORKFORCE

We will investigate in-depth the factors and rationale influencing current and future ED/UTC workforce configurations and the inclusion of different types of NMPs. We will undertake qualitative semi-structured interviews in the interpretivist tradition [56] with a purposive sample of 20 regional and national leaders in ED/UTC workforce from senior NHS clinician, manager, commissioner and lay representative perspectives, aiming for a balance of numbers by stakeholder type. We will recruit these participants through direct email approach following our policy mapping, and through contact networks. Our interviews will be conducted by telephone or on MS Teams by a co-applicant member of the research team. We will construct a topic guide from our literature and policy mapping and informed by our PPI and NMP representatives, but we anticipate it will focus on expected benefits and risks, anticipated mechanisms for change and important outcomes regarding use of NMPs in ED/UTCs and the wider system. In this way we aim to understand the hypotheses underpinning the developments. We will record and transcribe the interviews and conduct a thematic analysis [57] with at least two members of the research team involved in reading, developing an index, coding and interpreting the interview data iteratively. Analysis will be first by stakeholder participant type and then across stakeholder types using constant comparison methods. We will use DEDOOSE software package to assist in this.

We will compare and contrast the findings with our literature review to a) inform WP3 and b) prepare a publication for a journal.

7.2 WORK PACKAGE 2 (WP2): A DESCRIPTIVE ACCOUNT OF NMPS' LEVEL OF INDEPENDENCE/SUPERVISION

We will undertake a qualitative observational study to describe how independently NMPs are working and their level of supervision.

1. Conduct a qualitative descriptive study of the level of independence / supervision of NMPs in EDs/UTCs to inform development of a measurement tool

We will carry out a small-scale study, using non-participant observation in an ethnographic approach.[58] The purpose of these observations is to directly inform the development of a tool, in WP3, for measuring levels of independence/supervision of NMPs. We will work at this stage of the study in two NHS acute trusts with EDs/UTCs where our co-applicants Jarman and Webb are the clinical leads, to be able to ensure early access. These sites also represent one where NMPs are well-established in a trust with a strategy for their development, and one where NMPs other than ENPs are a newer addition to the ED/UTC workforce. We will observe a small number of NMPs and doctors-in-training in their patient-facing roles in the ED/UTC, purposively selecting NMPs in various roles (e.g. PA, ACP, PP) and different grades of doctors-in-training, advised by the study sites at the time of the study as to the equivalence of NMPs and doctors (according to the type of rota on which the NMPs in those EDs/UTCs are placed).

We will invite staff to volunteer, ensuring that the research team members in leadership positions in these organisations maintain a distance from direct recruitment activities and are not privy to identifiable data on participants. We will advertise potential participation through information leaflets in staff workspaces and staff rooms and by email from line managers with a participant information sheet. We will select up to 12 participants purposively by role and grade, should we be over-subscribed. We will gain informed consent from participants, and the assent in advance of the planned observed session of the clinician-in-charge as well as other staff providing supervision for NMPs. One researcher (of FT and Researcher 1 TBA) will follow each of the participant clinicians for a short period of time (approximately two hours each, anticipated to involve the treatment of at least two patients in the 'majors' stream, or several in the 'minors' stream of ED/UTC)(n=24 hours

observation in total). Patient consent will be gained as previously used in our previous PA study [20] by the clinician requesting permission of the patient, in the same way as when accompanied by a student. Information notices of the observation periods will be displayed for patients, carers and other staff in the ED.

We will take detailed notes of what we see; notes will be unstructured but guided by Spradley's (1980) nine dimensions of social situations (space, actors, activity, object, act, event, time, goal and feelings) as applied to the clinical decision-making independently and levels of supervision.[59] We will analyse the notes using the constant comparative approach, indexing and coding the observed dimensions iteratively, against the apriori assumption that different levels of independence / supervision will be observed in different practitioners, within practitioners according to the clinical case complexity, and within the context of different senior clinical decision makers present. We base these assumptions on our own previous observations of PAs in their ED roles.[25] We will also write a narrative account of the context and content of our observations. We will use the coding and the narrative account to discuss and interpret with our study NMP and PPI advisory panels in WP2.

7.3 WORK PACKAGE 3 (WP3): DESIGN OF THE CLASSIFICATION AND ANALYTICAL TOOLS FOR ANALYSIS OF OUTCOMES

We will conduct WP3 in two stages with the aim of producing three tools for utilisation in Phases two and three of the study. The first stage is a synthesis of evidence from the different activities. The second stage will be the collaborative design activities of three tools

We will draw on the principles of 'lead user design' in product development [60] to develop three tools: a skill-mix ratio classification, a quantitative measure of independence and supervision, and a logic model [61] which is a summary depiction of the resources, activities, outputs, participation, anticipated outcomes and moderators associated with NMPs in EDs/UTCs. To develop these tools we will invite members of the PPI advisory panel, the NMP advisory panel, and the external steering committee to participate in a collaborative event. A summary synthesis will be sent to participants prior to the event, followed by a presentation of this synthesis by the research team at the start of the event along with options for the content of the three tools. At this event we will employ a modified Nominal Group Technique [62] (used previously by the joint lead applicant [63]) to allow participants to put forward responses to the data analysis and content options, individually, then in groups, before moving to consensus, avoiding dominance within the group.[64] In this way we will 'design with' [65] PPI and staff representatives, and workforce experts.

The outputs of WP3, that is, the skill-mix ratio classification and the measure of level of independence/supervision tools will be used in data collection and/or analysis in Phases two and three, to be undertaken in 2022 and 2023.

The methods for Phases Two and Three of the study commence after the references to Phase One.

8. STUDY MANAGEMENT

8.1 Study timetable

Phase One will run for 12 months, commencing March 1st 2021, with some concurrent and some sequential research activities.

Reporting timetables to the approvers and to NIHR as funder will be adhered to, and accruals reported monthly/as required by central portfolio management services and the CRN.

8.2 Chief and co-investigator expertise and roles

The study has been developed, and will be led by, the experienced applicant team, many of whom have already successfully delivered and/or are currently leading studies both together and separately on the healthcare workforce to the NIHR. Each member brings different expertise and contribution:

- Health services research of workforce, both in recent NIHR HS&DR studies on PAs (Drennan and Halter), and in NMP evaluations across specialties and settings for other funders, including invited applications for HEE on the Medical Associate Professions and Advanced Clinical Practice (Drennan, Halter, Taylor), with qualitative and mixed-methods research expertise.
- Patient and public involvement (Brearley), with expertise as co-applicant on our previous NIHR-funded studies on PAs, alongside her many roles as an advocate for PPI at national and local level. Sally's role as a 'PPI fellow' at Kingston University and St George's, University of London involves providing PPI guidance one day a week to the Centre for Public

Engagement, including leading a panel of lay persons who form a Faculty of Health, Social Care and Education's PPI Research Expert Group, whose input has been integral to the development of this protocol, and some members of which will continue to help embed PPI throughout this study.

- Health economics (Gage), with expertise in directing health economics studies, including projects related to general practice and NMPs
- Statistics (Wang), with expertise in the merging and analysis of large datasets, including HES data
- Medical sociology (Gabe), with a focus on the underpinning concepts – such as autonomy and levels of independence - for this study
- ED/UTC lead clinicians with nursing (Jarman) and medical (Webb) perspectives, and with (Jarman) roles for the research development of the nursing workforce.

9. DATA MANAGEMENT

The CI (Mary Halter) will be responsible for data handling and record keeping. The sponsor organisation will maintain SOPs for the use of the system wherein data are handled and records kept and maintain a security system to protect against unauthorized access. The CI will maintain an audit trail of data changes ensuring that there is no deletion of entered data, maintain a list of the individuals authorised to make data changes, maintain adequate backup of the data, safeguard the archiving of any source data (hard copy and electronic). With the statistician, an audit trail will be kept in order that, if data are transformed during processing, it should always be possible to compare the original data and observations with the processed data. We will use an unambiguous participant identification code where the participant's identifying information is replaced by an unrelated sequence of characters that allows identification of all the data reported for each participant. This will be applied immediately upon recruitment or on receipt of data. The linking code will be stored in separate locations to the data or signed consent form using encrypted digital files within password protected folders and storage media, and any original personal data. Access to these folders will be restricted to the joint CIs, the research project manager and researchers employed onto the study.

The sponsors will ensure compliance with the requirements outlined above when tasks are subcontracted, with data sharing agreements to be put in place.

Interview recordings and observation notes will be destroyed at the end of each Phase of the study to which they were collected in. All other data will be electronically archived by the sponsor for 10 years after completion of the study, on university network drives.

Direct access will be granted to authorised representatives from the Sponsor, host institution and the regulatory authorities to permit trial-related monitoring, audits and inspections- in line with participant consent.

All investigators and study site staff will comply with the requirements of the Data Protection Act 1998 with regards to the collection, storage, processing and disclosure of personal information and will uphold the Act's core principles.

The data custodian will be the CI Mary Halter.

The data arising from the study is owned by the sponsor, Kingston University.

On completion of the study, the data will be analysed and a Phase One report prepared for the NIHR. The participating investigators have rights to publish any of the trial data with the permission of the sponsor (via the Joint Chief Investigators). The funding body (NIHR) needs to be acknowledged within the publications and must be informed of study outputs at least 30 days prior to their publication.

Participants will be notified of the outcome of the study, by provision of a specifically designed summary document, where they have requested to receive this and consented to the retention of their personal data for this purpose up to one year following the end of the study.

10. ETHICAL AND REGULATORY CONSIDERATIONS

10.1 Regulatory approvals and reports

This study will require regulatory approvals, in preparation for data collection. The study will be conducted in line with Health Research Authority (HRA), NHS Research Ethics Committee (for WP2-3) and local Capacity and Capability research governance approvals.

Substantial amendments that require review by REC will not be implemented until the REC grants a favourable opinion and have been reviewed by NHS R&D departments.

All correspondence with the REC will be retained in the study master files.

An annual progress report (APR) will be submitted to the REC within 30 days of the anniversary date on which the favourable opinion was given, the Chief Investigator will notify the REC of the end of Phase One, and, within one year after the end of Phase One, the Chief Investigator will submit a final report with the results, including any publications/abstracts to the REC.

10.2 Payment

There are no intended payments to participants.

10.3 Consent

The Joint Chief Investigators will ensure that the researchers delegated responsibility to participate in the informed consent process are duly authorised, trained and competent to participate according to the ethically approved protocol, principles of Good Clinical Practice (GCP) and Declaration of Helsinki. The joint CIs take responsibility for ensuring that all vulnerable participants are protected and participate voluntarily in an environment free from coercion or undue influence.

Informed consent will be gained from all staff interview and observation participants and patient interview participants. Participants will remain free to withdraw at any time from the study without giving reasons and without prejudicing their employment or treatment; data collected up to the point of withdrawal will remain in the study.

11. PUBLIC AND PATIENT INVOLVEMENT

We have approached PPI involvement in the research plan in two main ways, the aim of each of which is to embed PPI into the study's design and conduct from beginning to end.

11.1 PPI lead on the research team

Mrs Brearley is a core member of the research team, and is costed to work on the study for 5% wte, an agreed amount of time based on attending all core meetings, training and leading the PPI panel, training and supporting the PPI researcher and having time to read and contribute to study outputs, and taking into consideration Mrs Brearley's considerable other commitments to PPI and her other paid employment. We will ensure we work within the hours paid by the study.

11.2 PPI panel with links to PPI groups in case study sites

We will form a panel of 10 members of patients and the public, invited from within our networks in the university and our first two case study sites. We will ask the PPI leads for those organisations to advertise involvement in our study to their networks and we will invite expressions of interest in being a member of the panel. If over-subscribed we will select on the basis of creating a diverse group on demographic characteristics. The panel will meet on three occasions during the study on its own, as well as its members attending our two study collaborative design events. Travel to these events will be paid and reimbursement of time is costed in the Stage two application at NHS Involve rates. The purpose of the panel will be to provide patient and public perspectives on the research plan and proposed data collection tools (first PPI panel meeting, close to study commencement), and to play an active role in the development of the analytical tools arising from the synthesis of Phase one of the study (collaborative design event at month 12). Two members of the panel will be invited to join the membership of the study steering committee.

12. PROTOCOL COMPLIANCE

Accidental protocol non-compliances will be adequately documented and reported to the Chief Investigator and Sponsor immediately. Any serious breaches to GCP and/or the protocol will be notified to the CI and the sponsor and the funder (by the CI) where the breach is likely to effect to a significant degree the safety or physical or mental integrity of the participants of the study or the scientific value of the trial.

13. DISSEMINATION Outputs and anticipated Impact

We have designed this study in order to achieve impact through the collaboration and engagement with the NHS and the patient and public perspective. In particular, we anticipate a role for and with our PPI and NMP advisory panels and study steering group to contribute to and guide our communication and dissemination activities throughout the study. We intend to disseminate and generate impact throughout the study, initially sharing discrete academic outputs and undertaking knowledge transfer activities arising from Phase One. We intend for these dissemination and

discussion activities to use multiple methods and media, with key stakeholder groups' (e.g. NHS Employers, RCEM, HEE, RCN, Healthwatch); conference presentations, and journal articles. We will maintain a web site and use social media – we will work closely with our advisory panels (PPI and non-medical workforce) and the study steering group to achieve the best fit of materials to networks.

We will also share the specific output of our tool for the measurement of independence and supervision appropriate to its stage of validation and cognisant of its intellectual property.

We will ensure we focus on impact by having it as a standard agenda item at all of our planned research team, steering group and advisory panel meetings; impact will be documented using the University's impact tracker software, monitored by the impact manager.

14. REFERENCES (Phase One)

1. NHS. A&E Attendances and Emergency Admissions 2019-20. Accessed 10 August 2020 at: https://www.england.nhs.uk/statistics/statistical-work-areas/ae-waiting-times-and-activity/ae-attendances-and-emergency-admissions-2019-20/
2. Care Quality Commission. Under pressure. Safely managing increased demand in emergency departments. 2018. Accessed 10 August 2020 at: https://www.cqc.org.uk/sites/default/files/20180716_underpressure-winterpressures.pdf
3. Baker C. Briefing paper Number 7281, 16 October 2019. NHS Key Statistics: England, October 2019 House of Commons Library Accessed 10 August 2020 at: https://researchbriefings.parliament.uk/ResearchBriefing/Summary/CBP-7281#fullreport
4. NHS Benchmarking Network & Royal College of Emergency Medicine. Emergency Department Workforce Benchmarking Research Report. 2018. Accessed 10 August 2020 at: https://s3.eu-west-2.amazonaws.com/nhsbn-static/Emergency%20Care%20(Providers)/2019/RCEM_NHSBN_Staffing_Report_09-2019.pdf
5. Stehman CR, Testo Z, Gershaw RS, et al. Burnout, Drop Out, Suicide: Physician Loss in Emergency Medicine, Part I. *West J Emerg Med* 2019;20:485-494. **doi:** 10.5811/westjem.2019.4.40970
6. Ashton RA, Morris L, Smith I. A qualitative meta-synthesis of emergency department staff experiences of violence and aggression. *Int Emerg Nurs*. 2018;39:13-19. doi:10.1016/j.ienj.2017.12.004
7. Royal College Emergency Medicine and NHS. Securing the future workforce for emergency departments in England NHS Improvement (October 2017) Publication code: P 06/17 NHS England Publications Gateway Reference: 07340. Accessed 10 August 2020 at: https://improvement.nhs.uk/documents/1826/Emergency_department_workforce_plan_-_111017_Final.3.pdf
8. The World Health Report, 2000 Health systems: improving performance. Geneva: World Health Organization; 2000.
9. Crouch R, Brown R. Advanced clinical practitioners in emergency care: past, present and future. *Br Journal Hosp Med*, 2018;79:511-15. doi: 10.12968/hmed.2018.79.9.511.
10. NHS Improvement. Interim NHS People Plan. 2019. Accessed 10 August 2020 at: https://www.longtermplan.nhs.uk/wp-content/uploads/2019/05/Interim-NHS-People-Plan_June2019.pdf
11. NHS Health Education England. Multi-professional framework for advanced clinical practice in England. 2017. Accessed 10 August 2020 at:

https://www.hee.nhs.uk/sites/default/files/documents/Multi-professional%20framework%20for%20advanced%20clinical%20practice%20in%20England.pdf

12. Faculty of Physician Associates. Who are physician associates? 2019. Accessed 10 August 2020 at: https://fparcp.co.uk/about-fpa/Who-are-physician-associates
13. The College of Emergency Medicine. Non-medical Practitioners in the Emergency Department. 2015. Accessed 10 August 20202 at: https://www.rcem.ac.uk/docs/Workforce/Non%20medical%20practitioners%20in%20the%20ED.pdf
14. Dall'Ora C, Pope C, Crouch R, et al. Skill mix and new roles in Emergency and Urgent care: what is the evidence? Health Work: Evidence Briefs, 4, University of Southampton, 2017. Accessed 10 August 2020 at: http://eprints.soton.ac.uk/id/eprint/406806
15. Greenwood D, Tully MP, Martin S, Steinke D. The description and definition of Emergency Department Pharmacist Practitioners in the United Kingdom (the ENDPAPER study). *Int J Clin Pharm*. 2019;41(2):434-444. doi:10.1007/s11096-019-00799-2
16. Ferreira GE, Trager AC, Maher CG. Review article: A scoping review of physiotherapists in the adult emergency department. *Emerg Med Australas*. 2018;31:43-57. doi: 10.1111/1742-6723.12987
17. Halter M, Wheeler C, Pelone F, et al. Contribution of physician assistants/associates to secondary care: a systematic review. *BMJ Open*. 2018;8:e019573. doi: 10.1136/bmjopen-2017-019573
18. Drennan VM, Halter M, Wheeler C, et al. The role of physician associates in secondary care: the PA-SCER mixed-methods study. *Health Serv Deliv Res*. 2019;7(19). DOI: 10.3310/hsdr07190
19. Oglesby R. Recruitment and retention benefits of EMT--paramedic utilization during ED nursing shortages. *J Emerg Nurs*. 2007;33(1):21-93. doi:10.1016/j.jen.2006.10.009
20. Wise S, Fry M, Duffield C, Roche M, Buchanan J. Ratios and nurse staffing: the vexed case of emergency departments. *Australas Emerg Nurs J*. 2015;18(1):49-55. doi:10.1016/j.aenj.2014.08.001
21. Callander EJ, Schofield DJ. Emergency Department Workforce Models: What the literature can tell us. *Emerg Med Australas*. 2011;23(1):84-94. doi:10.1111/j.1742-6723.2010.01378.x
22. .Buchan J, Dal Poz MR. Skill mix in the health care workforce: reviewing the evidence. *Bull World Health Organ*. 2002;80:575-580
23. Department of Health. Advanced level Nursing: A Position Statement. 2010. Accessed 10 August 2020 at:

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/215935/dh_121738.pdf

24. Royal College of Nursing. Advanced nurse practitioners– an RCN guide to the advanced nurse practitioner role, competences and programme accreditation. 2008. Accessed 10 August 2020 at: http://aape.org.uk/wp-content/uploads/2015/02/RCN-ANP-guidance-document-2008.pdf
25. Halter M, Drennan VM, Wang C, et al. Comparing physician associates and foundation year two doctors-in- training undertaking emergency medicine consultations in England: a mixed-methods study of processes and outcomes. *BMJ Open* 2020;10:e037557. doi:10.1136/bmjopen-2020-037557
26. Drennan VM, Halter M, Taylor F. Development of Advanced Clinical Practice roles in acute, community and emergency care services in London. Health Education England (London). 2019.
27. Swann G, Chessum P, Fisher J, et al. An autonomous role in emergency departments**. *Emerg Nurse***, 2013;21:12-5. doi: 10.7748/en2013.06.21.3.12.e1164.
28. Clark A., Amanti C, Sheng AY. Supervision of Advanced Practice Providers. *Emerg Med Clin North Am*, 2020;38:353-361. DOI:https://doi.org/10.1016/j.emc.2020.02.007
29. Lim ME, Worster A, Goeree R et al. Simulating an emergency department: the importance of modeling the interactions between physicians and delegates in a discrete event simulation. *BMC Med Inform Decis Mak*, 2013;13:59. doi:10.1186/1472-6947-13-59
30. NHS England. The NHS Long Term Plan. 2019. Accessed 10 August 2020 at: https://www.longtermplan.nhs.uk/
31. James Lind Alliance. Top 10 Emergency Medicine Research Priorities 2017. Accessed 10 August 2020 at: http://www.jla.nihr.ac.uk/priority-setting-partnerships/emergency-medicine/downloads/Emergency-Medicine-PSP-Top-10.pdf
32. Grover E, Porter JE, Morphet J. An exploration of emergency nurses' perceptions, attitudes and experience of teamwork in the emergency department. *Australas Emerg Nurs J*. 2017;20:92-97. doi:10.1016/j.aenj.2017.01.003
33. Van Vaerenbergh C. Using mixed methods to identify factors influencing patient flow. *Health Serv Manage Res*. 2009;22(4):170-175. doi:10.1258/hsmr.2009.009006
34. The Royal College of Emergency Medicine. COVID-19: Resetting Emergency Department Care 6 May 2020. Accessed 10 August 2020 at https://www.rcem.ac.uk/docs/Policy/RCEM_Position_statement_Resetting_Emergency_Care_20200506.pdf

35. Schneider A, Weigl M. Associations between psychosocial work factors and provider mental well-being in emergency departments: A systematic review. *PLoS One*. 2018;13(6):e0197375. doi:10.1371/journal.pone.0197375
36. Morton K, Voss S, Adamson J, et al. General practitioners and emergency departments (GPED)-efficient models of care: a mixed-methods study protocol. *BMJ Open*. 2018;8(10):e024012. Published 2018 Oct 3. doi:10.1136/bmjopen-2018-024012.
37. Edwards E. Evaluating effectiveness, safety, patient experience and system implications of different models of using GPs in or alongside Emergency Departments. Research in progress. Accessed August 10 2020 at: https://www.journalslibrary.nihr.ac.uk/programmes/hsdr/1514504/#/
38. Spooner S. An investigation of the scale, scope and impact of skill mix change in primary care. Research in progress. Accessed 10 August 2020 at: https://www.journalslibrary.nihr.ac.uk/programmes/hsdr/170825/#/
39. Gage H. How general practice team composition and climate relate to quality, effectiveness and human resource costs: a mixed methods study in England. Research in progress. Accessed 10 August 2020 at: https://www.journalslibrary.nihr.ac.uk/programmes/hsdr/170834/#/
40. Walsh N. First Contact Physiotherapy in Primary Care (FRONTIER): A Realist Evaluation of effectiveness and costs. Research in progress. Accessed 10 August 2020 at: https://www.journalslibrary.nihr.ac.uk/programmes/hsdr/1611603/#/
41. Evans C, Poku B, Pearce R, et al. Characterising the evidence base for advanced clinical practice in the UK: **a** scoping review protocol. *BMJ Open*, 2020;10:e036192. doi: 10.1136/bmjopen-2019-036192
42. Parker E. Mapping the evidence on how uncertainty influences healthcare professionals and service users in the emergency department: a scoping review protocol. Accessed 10 August 2020 at: https://osf.io/4hfyd/
43. Donabedian A. The quality of care. How can it be assessed? JAMA 1988; 260:1743-1748. doi: 10.1001/jama.260.12.1743
44. Maxwell R. Dimensions of quality revisited: from thought to action. *Quality in Health Care* 1992:1:171-177. DOI:10.1136/qshc.1.3.171
45. Greenhalgh T, Robert G, Macfarlane F, Bate P, Kyriakidou O. Diffusion of innovations in service organizations: systematic review and recommendations. *Milbank Q*. 2004;82(4):581-629. doi:10.1111/j.0887-378X.2004.00325.x

46. Laurant M, Harmsen M, Wollersheim H, et al.The impact of non-physician clinicians: do they improve the quality and cost-effectiveness of health care services? *Med Care Res Rev*, 2009;66:36S-89S. doi: 10.1177/1077558709346277.
47. Nancarrow SA, Borthwick AM. Dynamic professional boundaries in the healthcare workforce. *Sociol Health Illn*. 2005;27:897-919. doi: 10.1111/j.1467-9566.2005.00463.x.
48. Abbott A. The System of Professions – a Study of the Division of Expert Labour. London: University of Chicago Press. 1988
49. Tomlinson J. Using clinical supervision to improve the quality and safety of patient care: a response to Berwick and Francis*. BMC Med Educ*. 2015;15:103. doi:10.1186/s12909-015-0324-3
50. Skar R. The meaning of autonomy in nursing practice. *J Clin Nurs*. 2009;19: 2226–34. doi: 10.1111/j.1365-2702.2009.02804.x
51. Bahadori A, Fitzpatrick JJ. Level of autonomy of primary care nurse practitioners. *J Am Acad Nurse Pract*. 2009;21(9):513-519. doi:10.1111/j.1745-7599.2009.00437.x
52. Dempster JS. Autonomy in practice: Conceptualization, construction, and psychometric evaluation of an empirical instrument. Dissertation Abstract International, 1990;50, 3320A. (UMI No. 9030752)
53. Tashakkori, A. and Teddlie, C. (2003). Handbook of Mixed Methods in Social and Behavioral Research. Thousand Oaks: Sage
54. Moore GF, Audrey S, Barker M, et al. Process evaluation of complex interventions: Medical Research Council guidance. *BMJ*. 2015;350:h1258. doi:10.1136/bmj.h1258
55. Health Education England. Workforce Plan for England. London, 2015
56. Kvale S. Doing Interviews. London: Sage Publications, 2007.
57. Braun V, Clarke V. Using thematic analysis in psychology. Qual Res Psychol. 2006;3:77-101. doi.org/10.1191/1478088706qp063oa
58. Hammersley M, Atkinson P. Ethnography: Principles in practice Third edition. Abingdon, Oxon: Routledge, 2007.
59. Spradley J. *Participant observation*. New York: Holt, 1980.
60. Herstatt C, Von Hippell E. From experience: developing new product concepts via the lead user method: a case study in a `low-tech' field, *Journal of Product Innovation Management*, 1992;9: 213-221. doi.org/10.1016/0737-6782(92)90031-7
61. W.K. Kellogg Foundation. Using logic models to bring together planning, evaluation and action: logic model development guide. Michigan: W.K. Kellogg Foundation, 2004.
62. Delbecq AL, Van der Ven AH. A group process model for problem identification and programme planning *J Appl Behav Sci* 1971;7:466-492. doi.org/10.1177/002188637100700404

63. Drennan V, Walters K, Lenihan et al. Priorities in identifying unmet need in older people attending general practice: a nomjnal group technique study. *Fam Pract*. 2007;24:454-460. doi:10.1093/fampra/cmm034

64. Islam R. Group decision making through nominal group technique: An empirical Study. *Journal of International Business and Entrepreneurship Development*, 2010;5:134-153. doi.org/10.1504/JIBED.2010.036998

65. Kaulio MA. Customer, consumer and user involvement in product development: A framework and a review of selected methods. *Total Quality Management*,1998;9:141-149. DOI: 10.1080/0954412989333.39

EXPLANATORY PAGE: PHASES TWO AND THREE

This Phase two and three section of the protocol is the equivalent of version 3.1 for the HRA/REC submission, bar removal of administrative sections which duplicate those of Phase One, e.g. study team, funder details

There are no substantive changes to the contracted protocol (Master v1.0), beyond a brief explanation of changes made following completion of Phase One, and additional detail arising from that.

STUDY PROTOCOL PHASES TWO AND THREE

Implementation of the non-medical practitioner workforce into the urgent and emergency care system skill-mix in England: a mixed methods study of configurations and impact: Phases Two and Three

STUDY PHASES TWO AND THREE SUMMARY

Study Title	IMPLEMENTATION OF THE NON-MEDICAL PRACTITIONER WORKFORCE INTO THE EMERGENCY AND URGENT CARE SYSTEM SKILL-MIX IN ENGLAND: A MIXED METHODS STUDY OF CONFIGURATIONS AND IMPACT
Short title	The SkillMix-ED study PHASES TWO AND THREE
Study Design	Mixed-methods
Study Participants	Emergency Department non-medical practitioners and other clinical staff Patients in the Emergency Department
Planned Size of Sample (if applicable)	Emergency Department non-medical practitioners and other clinical staff n = 110 Patients 1043 (inc. 995 questionnaires distributed); 274 (inc. 226 required questionnaire responses) Patient data n= approx. 23,865,348 (attendances over five years)
Planned Study Period	October 2022 to August 2023, inclusive
Research Question/Aim(s)	What is the impact of different non-medical practitioner skill-mix in EDs and UTCs in NHS acute hospitals on patient and service processes and outcomes?

PLAIN ENGLISH SUMMARY: PHASES TWO AND THREE

Demand for urgent and emergency care services is growing every year, especially at Urgent Treatment Centres (UTCs). People are going to Emergency Departments (ED) with complicated issues and many patients are admitted to hospital. There are not always enough doctors for these departments, and staff are leaving or going off sick in high numbers. One solution is to employ 'non-medical practitioners' (NMPs). These are qualified staff from other healthcare backgrounds who undertake some of the work of doctors. Some research shows that patient results are the same if they see a non-medical practitioner as if they see a doctor. We need to know what balance - known as 'skill-mix' - of nonmedical practitioners, doctors and nurses achieves the best results. This study will explore the result of different skill-mix in EDs in England, to make recommendations about the best balance.

Patient and public involvement representatives have helped design the study. We have also recruited an independent panel who feed in their views and experiences to all parts of the study. The panel is run by an experienced patient and public involvement expert, who is a member of the core study team.

We have split the study into four phases over two-and-a-half years. This protocol is for Phases two and three. Phases two and three use the work of Phase one in which we produced skill-mix ratios for all NHS organisations in England, a tool for measuring the level of interdependence of NMPs and other clinical staff. We have also developed a logic model or 'road map', to be further tested, of the ways in which different mixes of staff, in different contexts, impact on the care of patients and staff well-being.

Phase two will use NHS nationally-held information collected from all NHS Trusts in England between 2017 and 2021, to assess whether different skill mixes lead to different patient outcomes. We will look especially at the number of patients who return to the ED within a week (work package [WP]4 of the whole study). This analysis will not be able to include detailed information of the context or staffing of each ED/UTC and this is what Phase three will do.

Phase three will involve looking in detail in up to six ED/UTCs. We will collect in depth local data, as well as use the nationally-held data of Phase two for these sites. These local data will include pseudonymised staffing information and pseudonymised patients' clinical records of their ED

attendance. This will give detail about the staffing skill-mix and the outcomes for patients. We will gauge how inter-dependently the types of practitioners work when they assess and treat patients with different levels of urgent or emergency problems. We will also survey and interview patients so that we can understand their experience, and we will interview staff for their views (WP5 and 6 of the whole study.)

Following our analysis of all these different pieces of information, we will draw conclusions against our research questions, aided by our different advisory panels. We will then provide information and evidence to those in the NHS who make decisions about staffing in EDs and UTCs.

We will share and publicise our findings with professional, patient and public groups.

SCIENTIFIC ABSTRACT PHASES TWO AND THREE

Primary research question

What is the impact of different non-medical practitioner skill-mix in Emergency Departments (ED) and Urgent Treatment Centres (UTC) in acute hospitals on patient and service processes and outcomes?

Background

Increasing demand for emergency and urgent care has occurred alongside staffing shortage, particularly of doctors. Re-shaping of the workforce has resulted, including the introduction of non-medical practitioners (NMPs), such as nurse practitioners and physician associates. Despite 20 years of NMPs in EDs, there is limited evidence of effectiveness of individual roles, and none as to appropriate skill-mix of staff, at what level of independence from senior medical staff.

Methods

This is a mixed-methods, four phase study conducted over two-and-a-half years. This protocol is for Phases two and three, comprising work packages [WP] 4, 5 and 6. It uses tools developed in Phase one (21/NE/0071): skill-mix ratios for all NHS organisations in England, a tool for measuring the level of interdependence of NMPs and other clinical staff and a logic model to be further tested of the ways in which different mixes of staff in different contexts impact on the care of patients and staff well-being.

Phase two (WP4) aims to utilise the analytical tools to assess the impact of skill-mix ratios on national ED/UTC indicators of quality.

We will conduct and publish a quasi-experimental study of associations of skill-mix ratio classifications with our primary outcome (rate of unplanned return to the ED/UTC in seven days, a proxy for clinical safety), secondary outcomes (national indicators of ED/UTC quality and performance), and cost-effectiveness.

Phase three aims to explain the effectiveness and acceptability of skill-mix ratios through investigation in six local-level case study sites.

We will repeat the phase two (WP4 of the whole study) analysis with added precise local quantitative data on NMP types (trust management information), controlling for level of

independence/supervision of the clinician (collected via structured observation). We will add patient satisfaction as an outcome, collected prospectively via questionnaire (WP5 of the whole study).

We will investigate the experience of including NMPs in the skill-mix through qualitative interviews with patients and staff (WP6 of the whole study).

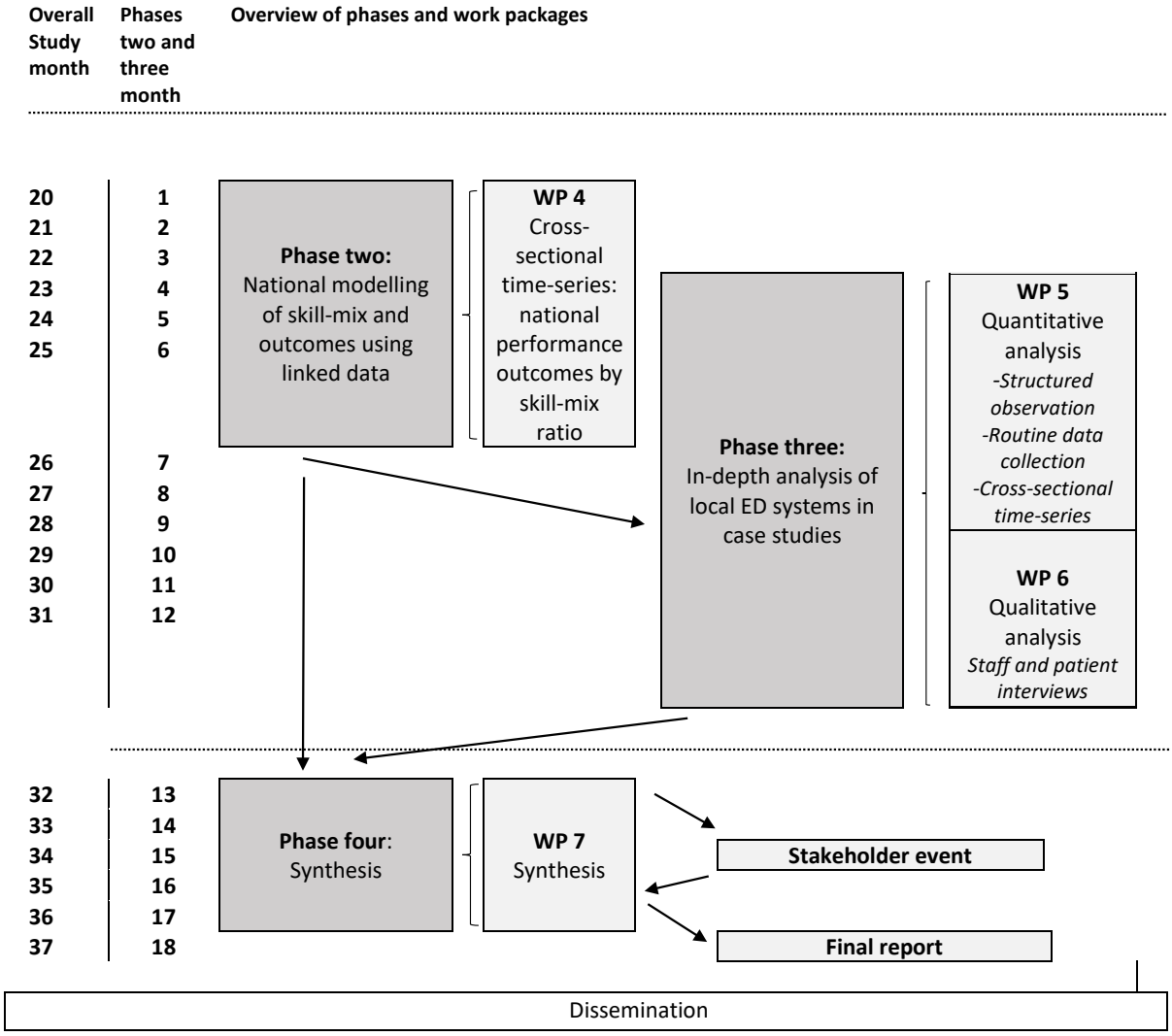
Timelines for delivery

The study will take place from October 2022. The study end date is 31 August 2023.

Anticipated impact and dissemination

The research will generate new knowledge and analytical tools through which the optimum/most effective/impact of different skill-mix outcomes will be able to be measured. Dissemination will include academic outputs, bite-size findings, conference presentations and social and mainstream media routes accessible to stakeholders.

STUDY FLOW CHART PHASES TWO AND THREE



WP = Work Package

1. BACKGROUND

Numbers of people attending emergency departments (EDs) in England have increased significantly in recent years; while year on year comparisons since 2019 are not advised due to the fluctuating impact of COVID-19 in EDs and changes to systems including booked appointments int eh ED replacing some walk-in attendances, growth over the 12 months to August 2022, compared to the preceding 12 months, for EDs treating all types of patients is 13.0%.[1] The Care Quality Commission reported this increased demand was negatively impacting on operational performance and the quality of care.[2] The number of patients waiting over 4 hours in EDs have risen further since the pandemic and a new record high of 41.3% was reached in March 2022.[3] Prior to the pandemic, the ED workforce had some of the highest turnover, vacancy and sickness rates in the NHS,[4] with high levels of reported staff burn out,[5] assaults from patients [6] and consultant intention to retire early.[7]

In the National Health Service (NHS) there are three types of ED: Type 1 is consultant-led 24 hours, every day for general conditions; Type 2 is consultant-led 24 hours every day for specialist conditions, Type 3 or Urgent Treatment Centres (UTCs) is GP-led at least 12 hours every day for patients not requiring Type 1 or 2 ED, and Type 4 walk-in-centres providing primary care by appointment (no longer defined as EDs/UTCs).[1] In 2022 there were 196 individual providers of Type 1, 2 and/or 3 ED/UTC services.[8]

One policy solution to both patient demand and workforce problems has been the introduction of new roles and different skill-mix.[7] Determining the ‘‘right’’ mix of health disciplines is a major challenge for health care organisations.[9] To address the medical workforce shortages the Royal College of Emergency Medicine (RCEM), with NHS England, proposed solutions for increasing the medical workforce and also a strategy for greater skill-mix with NMPs to undertake some of the medical work.[10]

The RCEM, with NHS Health Education England (HEE), planned for growth of the NMP workforce with a national framework for the ‘emergency care-advanced clinical practitioner’.[7] NHS England workforce plans now include a range of NMPs in the emergency care system [11]: Advanced Clinical Practitioners (ACPs)[12] who come from professional groups registered with the Health Professions Council, including Pharmacists; advanced nurse practitioners (ANPs); and Physician Associates (PAs)[13], and Emergency Practitioners (EPs), many of whom are nurses (ENPs)[14] who vary in the extent to which they work at advanced practice levels. NMPs work alongside medical staff of all grades as well as with nurses; some bodies emphasise that they are not direct substitutions for

doctors.[7] There is a 20 year history of ENP employment in the English EDs; 70% of UTCs in acute hospital trusts in England have nurse-led models of care while 7% of the nursing workforce are nurse practitioners (NPs) and 2% ANPs.[4] However, there is currently no guidance concerning ED staffing ratios of any health discipline to patients, or guidelines on accreditation of the variety of NMPs against medical grades.

Our study was funded by the National Institute of Health Research (NIHR) to address the evidence gap.

We are conducting a mixed-methods, four phase study (NIHR131356 Implementation of the non-medical practitioner workforce into the urgent and emergency care system skill-mix in England: a mixed methods study of configurations and impact. - NIHR Funding and Awards). This protocol is for Phases two and three.

In Phase one (21/NE/0071) we conducted scoping and systematic reviews, interviews with key national clinicians and managers, and analysis of NHS workforce statistics that confirmed: a) variation in the involvement and types of NMPs in ED/UTC;[15] (b) limited evidence of effectiveness of individual roles, and none as to appropriate skill-mix of staff, at what level of independence from senior medical staff, despite 20 years of NMPs in EDs.[16] Just seven studies were identified that offered insights into skill-mix in the setting [17-23]. Ongoing or recently published research identified through our search of ClinicalTrial.gov, of NIHR, and of the Open Science Framework highlighted studies of the ED/UTC workforce in terms of GP models in the ED [24,25] but none on the NMP workforce. In primary care, skill-mix/team composition is currently being studied in three studies, [26-28] offering methodological learning, but no evidence from the ED/UTC setting.

In Phase one we also developed three tools to be taken into the investigations of phase 2. Based on a literature review, clinical observations of NMPs and doctors in EDs, and consultation with our study panels, we developed a prototype tool for assessing levels of independence/interdependence (Appendix 1). We analysed national NHS workforce data and developed a range of skill-mix ratios (i.e. across all NHS ED/UTC organisations the proportions of staff groups to each other; see examples in Appendix 2). In addition, we developed a preliminary logic model of the relationships between the context, the staffing ratios and the patient outcomes (Appendix 3). This logic model is informed by the theoretical frameworks of the overall study including that of Donebedian (1988) of criteria for judging quality in health services [29], theories concerning innovation in health care,[30] and theories regarding degrees of autonomy can be measured as a function of practice independence behaviour,[31] focussing on: concepts of readiness (taking responsibility and being accountable for

actions); empowerment (providing quality services through one's actions); actualisation (having a sense of professionalism), and valuation (accepting the consequences of choices made).[31]. These tools are being used within phase 2 and 3.

2. AIMS AND OBJECTIVES

2.1 Study Aim

To explore how NMPs are being deployed and the impact of different skill-mix including NMPs in EDs and UTCs on patient experience, quality of care, clinical outcomes, activity, staff experience and costs in acute NHS trusts in England, in order to inform workforce decisions of clinicians, managers and commissioners.

2.2 Research questions (Phases 2 and 3)

Primary research question:

- What is the impact of different NMP skill-mix in EDs and UTCs in NHS acute hospitals on patient and service processes and outcomes? (Phase 2 & 3)

Secondary research questions:

- How independently or with what level of supervision do NMPs work in EDs/UTCs?

3. STUDY DESIGN

We are conducting a pragmatic, sequential, mixed methods study [32] to investigate the research questions, as recommended for the evaluation of complex interventions.[33]

Phase 2 is a quasi-experimental study of associations of skill-mix ratio classifications with our primary outcome (rate of unplanned return to the ED/UTC in seven days, a proxy for clinical safety),

secondary outcomes (national indicators of ED/UTC quality and performance), and cost-effectiveness. It addresses the primary research question at the national level.

Phase 3 is a comparative case study design of six ED/UTCs, utilising mixed methods in two work packages (WP5 & 6). It addresses the primary research question at local level and the secondary research question.

4. SETTING/CONTEXT

We will carry out this study in the context of the ED/UTC workforce in NHS acute hospital services classified as Type1, 2 or 3 EDs in England, excluding Type 4 (walk-in-centres that do not accept emergency patients). Nationally, there were over 4 million Type 1 and 1.5 million type 3 patient attendances per quarter in 2019.[1]

We will utilise data from 2017 onwards as the marker for the advanced practice NMP policy implementation, following HEE's financial investment in the two-year training programmes for ACPs and PAs in 2015.[34]

5. METHODS of DATA COLLECTION AND DATA ANALYIS

5.1 PHASE TWO (P2): (months 1-6) National analysis of the impact of configurations of the NMP workforce (skill-mix ratios)

Leads Halter, with Wang and Gage, in one work package, with the Researchers 1 and 2.

Phase Two (Work package 4), addressing research question 1 at national level will use established, large, national data sets to explore associations between ED/UTC skill-mix and indicators of performance and, provide generalisable evidence. We will do this in a quasi-experimental study,[35] whereby we will proceed as if the skill-mix composition in each trust had been introduced as an experiment. Our measurement of the size of effect will rely upon two national datasets, from which we will draw our skill-mix, organisation characteristics, and indicators of performance variables.

Skill-mix

We will utilise the NHS Digital Workforce (from ESR) standard data reports [36] (as analysed in Phase One [P1]), to define the skill-mix composition of each ED/UTC in England (examples in Appendix 1). The expected sample based on current numbers of NHS trusts with EDs and UTCs is n = 124, utilising four years (2017-2021) of data. We will utilise (as constructed in Phase One) our assignment of the contextualised classification of skill-mix against the staff type ratios at each of the 48 monthly time points in the Workforce dataset. We are currently constructing the skill-mix classifications from the Phase One data – we may utilise these as continuous data or/and classify into low, medium and high proportions of NMPs within the clinical workforce. The specific data items we will use are detailed in Table 1.

Organisation characteristics

We will collect data from NHS Digital open access data sources at provider-level (expected sample based on numbers of individual EDs and UTCs n = approximately 200), and from the Data Access Request Service at patient record-level, for the four-year period 2017-2021.

We will add to our database other variables describing the ED/UTC organisations, such as number of attendances or patient characteristics, as well as additional workforce data such as the Stability Index. Trust-level data are available from two NHS Digital open access reports, sourced from the A&E Hospital Episode Statistics (HES) data and the Emergency Care Dataset (ECDS). These are the provider-level analysis within the 'Annual Latest Hospital Accident and Emergency Activity Summary Report' monthly 'Acute Trust Attribution File',[37] utilising the latest report available at the time of the study (2018-19 annual report and March 2020 monthly reports available at time of the Stage two application, respectively.) The variables assumed at this point to be required are listed in Table 1, but the selection for inclusion in the analysis will be partially informed by the policy and strategy data collected during Phase One.

We will also utilise patient-level data from the ECDS [CDS Type 011 – Emergency Care Data Set (ECDS), from 31st March 2019, and CDS Type 010 A&E within CDS v6.2, from 2017] [38] and from HES if required by NHS Digital to supplement data from the implementation years (2017-2019) of ECDS. These data will allow us to create organisation-level descriptions of patient demographics, as well as episode, clinical, injury and referral/discharge information, enabling the measurement of outcomes with knowledge of the patient case-mix, particularly the assigned patient acuity (the five level 'ECDS Emergency Care Acuity [SNOMED CT]' variable [NHS Digital), and diagnosis, which can be grouped; see Table 1 for detail on data

items. We will apply the trust-level data we have collated to each piece of record-level data in a database for analysis. These national data sets are subject to quality issues including incomplete data and variable use of coding,[39] but hold the advantage of utilising consistent monitoring of data locally and nationally.[40]

Outcomes (*national indicators of performance)*

Data on indicators of ED/UTC performance at trust-level will also be sourced from the two above NHS Digital reports, as well as from the 'Provisional Monthly Accident and Emergency Quality Indicators for England',[41] again open access via NHS Digital and sourced from HES data, and from the Care Quality Commission Urgent and Emergency Care Survey,[42] and NHS Staff Survey Results.[43]

Our primary outcome will be the rate of unplanned return to the ED within 7-days; a proxy for clinical safety. Our secondary outcomes are the five nationally collected indicators of ED/UTC health system quality,[1] used in previous studies comparing the performance of NMPs with the others in the ED workforce[44] and include measures of throughput and time (e.g. time to assessment and treatment, and time in the ED). These are detailed in Table 1.

Table 1: Variables to be used in the Phase Two national analysis of outcomes by skill-mix

Independent variable: ED/UTC workforce	Descriptives / potential confounders: ED/UTC-level characteristics	Outcomes
Skill-mix ratio classification, including: - Total Full Time equivalent (FTE) care staff per head of ED/UTC attenders[1, 2] - Ratio of NMP to whole ED/UTC clinical workforce FTE - Ratio of NMP to medical workforce FTE[3] - Ratio of NMP and medical workforce to non-medical, non-practitioner FTE[3]	Trust-level data: - HEE region - Patient Experience Scores[4] - Stability Index[2] - NHS Staff Survey results[5] ED/UTC-level data: - Type/level of ED/UTC[6] - Number of ED/UTC attendanc (and by gender, age group, ho of arrival, day of arrival)[2] - Number of emergency admissions from ED/UTC[6] Record-level data:[7] - Patient case-mix (Emergency Care Acuity; First diagnosis code), HES diagnosis - Patient age at activity, gender, ethnicity	Primary outcome: Re-attendance rate (within 7 days)[8] Secondary outcomes: • Left department before being seen for treatment rate[8] • Time to initial assessment[8] • Time to treatment[8] • Total time in A&E[8] • Clinical investigation[7] • Treatment code[7] • Onward referral /treatment complete[7] • Cost

Data source:

[1] Workforce (Electronic Staff Records) (monthly); [2] Annual Latest Hospital Accident and Emergency Activity (annual); [3] Phase One analysis; [4] NHS Patient Surveys Urgent and Emergency Care Survey (annual); [5] NHS Staff Survey Results (annual); [6] Acute Trust Attribution File (monthly); [7] Emergency Care Dataset; [8] Provisional Accident and Emergency Quality indicators for England

Analysis

We will assess the data for incompleteness and for missing data. We will investigate whether the data are missing completely at random (MCAR) by using Little's test [45] for the MCAR assumption. Appropriate statistical methods will be used if the MCAR assumption is violated, such as the full information maximum likelihood or multiple imputation method.

We will analyse data at aggregate (provider) level. The variables in the database will initially be analysed descriptively using frequencies, measures of central tendency and variability. We will utilise patient

record-level data to create provider-level values for descriptive/potential confounder variables from continuous data within each provider (for example, mean or median age for trust A), and provider-level percentage composition of categorical variables (for example, percentage within case-mix groups for provider B).

We will then test for any association of skill-mix classification, including the potential for the use of the skill-mix ratio as a continuous variable, as per the approach of Aiken et al (2017)[46] in examining the impact of nursing skill-mix ratios, before and after controlling for other provider-level characteristics, including case-mix. We will model against our primary and secondary outcomes.

Our Phase one analyses indicate that skill-mix differs between providers over both ED type and over time due to the gradual enactment of policy and training opportunities for NMPs and that there is the potential for this to produce different outcomes. We will therefore test our hypothesis by using data providing repeated information by provider and looking for potential time-varying effects using a difference-in-difference approach.[47] Given the multilevel data structure, we will conduct a longitudinal data analysis [48] over three to four years, controlling for temporal effects. We have the option to utilise up to 48 monthly time-points, or another time unit (groups of months or years), dependent upon policy developments, enactment of policy, or NHS Benchmarking data changes in the proportions of NMPs in the ED/Type 3 UTC workforce over the course of the data period. From what we know about the history of NMP development [9] we do not anticipate identifying time points before the first introduction of any NMP workforce into the skill-mix, but we may identify times when the skill-mix ratios including NMPs were emerging, and once NMPs had been implemented and were appearing in the Workforce dataset in more stable or larger numbers – we continue to analyse this in our Phase One datasets. We will, however, ensure that any time points used can be matched in both the skill-mix (workforce data) and outcomes, as we anticipate that potentially unusual patterns of ED or UTC attendances and skill-mix will be observed in the data collection period as a consequence of the Covid-19 pandemic.[49]

Since our outcomes are continuous variables, multilevel linear regression models will be employed. Our analysis at aggregate (provider) level will give us a macro level picture of effects; confounders such as repeat users of the ED will not be included in our models. If any associations are identified between skill-mix classification/ratios and our measured outcome, we will conduct a cost-effectiveness analysis of skill-mix composition using the coefficient of the regression and attributing a cost for the skill-mix

classification or ratio unit change associated with any differences in outcomes, relative to the average provider skill-mix.

If the results of the analysis suggest that particular workforce characteristics are associated with better outcomes (focus on primary outcome of ED/UTC re-attendance), the analysis will be taken further to consider the potential additional costs (savings) to changing staff configurations. The results (regression coefficients) of the analysis will be used to assess costs (savings) of staffing mix and ED/UTC ratio associated with changes to the average ED. These staffing levels will have unit costs assigned to provide an estimate of the resource costs for the average provider and other configurations. Costs for staffing grades and configurations will be identified based on national sources such as Agenda for Change pay scales and Personal Social Service Research Unit (PSSRU), inclusive of all on costs and overheads [50]. Sensitivity analysis will be conducted varying the input parameters of staffing levels within reasonable upper and lower bounds to account for uncertainty in these estimates. These upper and lower bounds will be defined as part of the analysis.

We will not require a sample size calculation as we will use secondary data for the whole population (England), and the existing evidence on the ED/UTC skill-mix is insufficient for us to assume an effect size (and variance of the data) and thereby provide an estimate of power. In including the whole population, we anticipate inclusion of organisations and ED/UTC attenders across geographical location, age, ethnicity, sex, socioeconomic status (proxy Index of Multiple Deprivation [IMD] by local authority) (as measurable within the national datasets), as well as having no selection criteria that would exclude patients according to other characteristics. These would include disability, marital status, gender, pregnancy status, religion or belief, sexual orientation, or level of access to health or social care.

We will produce and publish a report of the Phase Two analysis of the impact of skill-mix ratio classifications on national outcomes.

5.2 PHASE THREE (P3): (months 4-2) Local analysis for refining and explaining the impact of configurations of the NMP workforce (skill-mix ratios and level of independence/supervision)

Lead Halter, with Gage, Taylor and Wang; and Researcher (Brice) and the PPI co-researcher, conducted in two work packages (WP5 and WP6).

In Phase Three, addressing the primary and secondary research questions, we will enhance the specificity of Phase Two's national modelling, through an in-depth investigation at the micro level, using locally-observed processes and outcomes. We will undertake quantitative and qualitative analysis in up to six case study sites.[51]

To recruit the six sites we will invite ED clinical and research leads of EDs/UTCs from Phase One and others via our NMP panel with different levels of NMP staffing to participate. This recruitment activity will include trust agreement via research governance procedures. In addition to the skill-mix classifications, we are aiming to ensure that we include ED/UTCs which, across the up to six case studies, represent a diverse population on characteristics we can measure in the data: geographical location, age, ethnicity, sex, socioeconomic status (proxy IMD by Local Authority) (as measurable within the routinely-collected datasets). We will ensure that the research team members as Clinical Leads in these organisations maintain a distance from direct recruitment activities and are not privy to identifiable data on participants.

Phase 3 will be conducted in two work packages, WP5 and WP6. WP5 will collect locally-available quantitative data to add to those available for the case study site within the national data, and WP6 will seek to enhance understanding of this analysis through qualitative data collection with staff and patients. We will stagger data collection dates across the sites.

5.2.1 Work package 5 (WP5): Investigation of patient safety, clinical and service outcomes of different skill-mix through quantitative methods

WP5 will build from the longitudinal analysis undertaken in Phase Two WP4, repeating this to include further layers of data detail on NMP staffing, processes and outcomes of care, through local data collection. The two differences are:

- The addition of variables available through local data collection (detailed below) to supplement the ECDS and support the measurement of outcomes in the emerging logic model developed during Phase one (see Appendix).

- The use of a smaller dataset, utilising 12 months' national and local retrospective (three months from each of 2017-2021) data, and three months' local prospective (2022/3) data. Accepting that NMPs may work on rosters alongside a number of grades within 'doctors-in-training', we have elected to utilise data only from the last month of each FY2 doctor four-month training

rotation period to allow for their rapid experiential transition during that training period, and thereby also to avoid the use of data from the first months of those commencing their specialty training in Emergency Medicine (at ACCS, CT/ST3 or DRE-EM[ST3] levels. In this way, we aim to reduce the level of ED/UTC experience bias otherwise hidden within the skill-mix ratios, albeit recognising that many NMPs have longer experience in their profession.[52]

We will consider any limitations to our statistical analysis and statistical power of our selected months' data once we have assumptions from our Phase 2 analysis on which to base a sample size calculation. However, at this point we have specified the sample size we anticipate requiring for the prospectively collected patient self-report data (see IV. below)

We will utilise the following data for the specified time periods:

- The nationally available Workforce Dataset, ECDS and HES data (if required) for our case study sites
- Site-specific data on staffing and outcomes specified as important in the emerging logic model, from four sources of data collection:

I. *NMP staffing data*.

We will work closely with ED/UTC managerial staff to understand the precise breakdown of NMP staff over the period 2017-2021, and with trust IT/business analysts to achieve anonymised outputs from locally-collected data (see Phase Two and Phase Three Data Flow diagram, Appendix 4)

II. *Level of NMP independence and supervision*.

Using the tool developed in Phase One (see Appendix 1), we will derive a grading of interdependence (independence and supervision within the ED/UTC team) for each type of NMP and doctors-in-training for each of the sites. We will pilot the tool in the lead site. The grading will be derived from structured observation,[53] of a purposive sample of up to five NMPs (with at least one year of experience in the ED/UTC), and five other members of clinical staff (ideally in the last month of any individual's training rotation in the case of Foundation Year doctors) who have been allocated specific patients to assess and treat, in each of the case study sites. They will be observed for one two-hour period per clinician, in each of the case study sites (total observation hours up to n=120). Two researchers will be involved during each two-hour observation period. One researcher will follow the participant clinician and their interactions with patients and colleagues. Patient agreement will be gained by the clinician requesting permission of the patient, in the same way as when accompanied by a student. If the participant

clinician or their patient consider procedures to be intrusive or issues to be sensitive they may ask the researcher to leave at any point, without impact on the remaining observation period, should it continue.. Patients who do not have capacity to agree to the observation will also be excluded. Information notices of the observation periods will be displayed for patients, carers and other staff in the ED. The researcher will use the tool for observation measurement to code, using a tally/hash mark, each observed task and action against the different listed interdependence options, for the clinician's treatment and assessment of each patient. At the end of the observation period, the researcher will ask the observed clinician a small number of questions with pre-coded answers in the tool, on the clinician's perspective of the observation period context e.g., time pressure, team member familiarity.

The second researcher will be present in the ED/UTC during the observation period to record contextual issues. They will not closely follow the participant clinician and their interactions with patients but may observe the clinician from a distance when noting contextual issues. The second researcher will record in the researcher-completed contextual section of the tool, specific contextual details observed e.g., patient waiting time, staff on duty. They will also take additional handwritten notes on contextual details observed to enable further development and refinement of the tool. All observation data will be transferred to an Excel spreadsheet. Neither of the two researchers record any patient identifiable information.

The initial invitation for volunteer NMPs and other member of clinical staff will be via posters placed in the ED/UTC staff bases and staff room, and by direct email from the clinical lead, with response directly to the research team. Clinicians will be selected purposively by role if we are over-subscribed, and informed consent will be gained following sharing of a participant information sheet. Researchers will agree a specific time period for the observation and seek the consent in advance of the clinicians in charge (medical and nursing) rostered for that time. As in our previous study using observation [44] and Phase one of this study, individual consent will not be obtained from each member of the team as the focus of the observation is on the NMP/doctor in training and their supervisor.

III. *Patient records data*.

We will work with business information analysts in each of the case study sites to obtain pseudonymised outputs from patient records, for example the Getting It Right First Time (GIRFT) supplementary metrics associated with patient flow.[54]

IV. Patient self-report data - satisfaction and further health service use (Patient Questionnaire One).

Patients in the ED/UTC of each case study site, at points (defined by each site according to patient throughput, NHS research nurse availability and required sample size) within the three-month 2022/23 prospective data collection periods, will be invited by an NHS research nurse to complete a validated structured quality of care questionnaire, [55] that has been anglicised by the research team for use in this study. The NHS research nurse will assign a study ID to each potential patient participant to be given a questionnaire. The NHS research nurse will hold securely in the case study NHS Trust a list of the study ID numbers and their respective patient's hospital number. The NHS research nurse will offer each patient at the point of their discharge from the ED/UTC, a paper copy of the Patient Questionnaire with the patient's study ID added. In the questionnaire cover sheet patients will be offered the option of completing the questionnaire in electronic format with an online link provided to which they will be asked to add their study ID number (found on the paper version of the questionnaire).

At the end of the questionnaire questions, patients will be invited to take part in three further research activities:

1) Consent to receive a second questionnaire sent out by the NHS trust research nurse (who will be given their study ID number [on response to the first questionnaire] by the research team to be able to identify their contact details. No information about their views expressed in the questionnaire will be shared with the NHS research nurse.)
2) Consent for the NHS organisation they visited, for NHS research and/or analyst staff to add the study ID to the pseudonymised information from their clinical record, including the type of staff attending them on the episode of care to which the patient questionnaire pertains, already provided (see section III above) to the research team at the University The benefits of doing this will be explained – that it will enable the study researchers to link the patient's anonymous questionnaire responses to the type of skill-

mix of the staff team that was on duty when the patient was treated in the ED/UTC, and to be able to analyse if any differences observed by skill-mix are impacted by patient acuity, patient characteristics and other factors such as time of day. It will also be explained that the study research team will not know the patient's identity or anything else about their health record, and nd that the NHS staff will not know the patient's questionnaire responses.

3) Consent for the NHS research nurse to use their contact details to send them an invitation to volunteer to be interviewed about their experiences in the ED/UTC (detailed below in WP6.)

Patient participants will be asked to return the completed questionnaire by post in a reply-paid envelope or by email, direct to the research team at Kingston University.

In addition to the records of numbers of distributed questionnaires and their ID numbers, the NHS research nurse will keep a tally sheet of reasons for decline of the questionnaire in the ED/UTC to enable monitoring (on a weekly basis) of the distribution of questionnaires against patient characteristics, for the purposes of monitoring our sample selection processes (to ensure no systematic or unconscious bias in distribution of surveys and allowing us to make changes as required). The questionnaire will also request some demographic data to allow us to assess inclusion by diversity, alongside pseudonymised information in the patient records data.

V. Patient follow up (Patient Questionnaire Two).

The research study team will send to the NHS research nurse, a list of study IDs of patient participants who have returned the first patient questionnaire, consented to receive a second questionnaire and for the NHS research nurse to use their contact details to send this questionnaire. The NHS research nurse will identify the patient linked to each study ID and then send them the second patient questionnaire and participant information sheet (provided by the university team). The research study team will not know the identity of patient participants sent a second questionnaire. The second questionnaire will re-assess satisfaction and capture subsequent service use, for descriptive analysis of any impact on health system use, including costs. This questionnaire will also collect free text information to provide more contextual information to understand better their responses.

Support for patient completion of questionnaires one and two

Translation of the two questionnaires into the languages of the ED/UTC patient attendees will not be possible within the funding for this study, but we will place emphasis on increasing the inclusion of patients for whom the written questionnaire may pose difficulties, whether by language, literacy, disability, or being acutely unwell or distressed at the time of questionnaire administration in the ED/UTC - the research nurse will explain the survey and if a patient needs help to complete the questionnaire, encourage the patient to ask the assistance of a family member or carer, and the patient will complete it in the seven days after discharge from the ED/UTC. The two questionnaires will be routinely available in a large font, on coloured paper and will be able to be completed in an online version. The cover sheet is written in plain English.

Analysis

Analysis will take place in several steps:

Locally-collected patient and staffing data will be collated into a database in the NHS Trust sites, pseudonymised and sent directly via a secure data transfer service to the research team by the NHS research nurse or NHS analyst.

The research team will carry out descriptive statistics on each of the datasets: the structured observation data to derive measures of central tendency and dispersion for each staff member observed, and to then translate into a value for each of the NMP and doctor-in-training; the patient survey data; and the patient records-level data achieved locally.

We will regress the service and patient processes and outcomes against the locally-detailed skill-mix ratios, using the same multilevel modelling approach as detailed in Phase Two WP4, although now analysed at the individual patient level, taking account of clustering at the individual clinician and the aggregate provider level. In addition, there will be an adjustment made for the level of interdependence of the type of clinician allocated to see the patient. The additional (to Phase Two WP4) data to be included in the descriptives/potential confounders, and in outcomes are shown in Table 2. Care will be taken to ensure the models that are fitted are sensitive to the nature of the problem, and that full consideration is taken of confounding and omitted variable bias. Interpretation of the modelling results will take into account possible unobserved heterogeneity that is not controlled for in the model.

Table 2: Additional (to WP4) variables to be used in the Phase Three?, *local* analysis of outcomes by skill-mix

Independent variable: ED/UTC workforce	Descriptives / potential confounders: ED/UTC-level characteristics	Outcomes
Skill-mix ratio classification	ED-level data: Staff sickness level Record-level data: - Clinician seen - Clinician role - Level of interdependence (independence/supervision) of the clinician seen - Assigned level of interdependence of the clinician role	• Patient satisfaction measured within seven days of the ED/UTC visit • Patient satisfaction at 30 days following the ED/UTC visit • Patient onward service use in 30 days post-index event • Getting It Right First Time (GIRFT) patient flow indicators

Outcomes will be grouped in three sets of importance to the ED/UTC agenda: the Emergency Quality indicators (as WP4), the patient experience and patient use of services.

To assess patient satisfaction, we have defined a required sample size, to enable planning for the administration of the patient questionnaire. A linear regression will be used, with the outcome variables (overall patient satisfaction within seven days and at 30 days) as dependent variables and other variables as independent or control variables (Tables 1 and 2). The regression coefficients will be estimated along with their confidence intervals for statistical inference. Given the number of coefficients to be estimated (113 with dummy coding for categorical variables), a minimum of two participants were required per parameter (the parameters being the coefficients of the independent 'skill-mix ratio' variable and the potential confounding variables listed in Tables 1 and 2) [56], which suggests 226 questionnaire responses. Due to the questionnaires being distributed whist the patient is in the ED/UTC we assume a relatively low response rate of 50% to the first questionnaire, and a further 50% loss to follow- up on the second questionnaire. In addition, assuming a missing data rate of 10% on returned questionnaires, we will distribute 995 questionnaires, spread across the six case study sites.

As in Phase Two WP4, an economic analysis will be performed to explore the impact of changes in skill-mix, using outputs from regression analyses performed on the patient-level data collected in WP5. Dependent on the set of outcomes chosen, this approach could either focus solely on costs

(using indicators such as re-attendance or collected data on onward service use), or additionally take a cost-consequence framework (e.g. cost for unit changes in patient satisfaction). Costs for staffing grades and configurations will be identified based on national sources such as Agenda for Change pay scales and PSSRU unit costs, inclusive of all on costs and overheads [50]. Sensitivity analyses will be performed to characterise uncertainty in estimates.

5.2.2 Work package 6 (WP6): Exploration of the impact on staff and patients of NMP skill-mix through qualitative methods

We will embed an interpretive qualitative inquiry using semi-structured interviews into our natural experiment, in order to provide contextual understanding and a potential framework for the interpretation of the modelling results, addressing the primary research question. This inquiry will include two participant groups - patients and staff.

Participants

Patients. We aim to recruit a sample of up to 48 patients (eight from each site). We will recruit a convenience sample to ensure that can interview people as close to their ED visit as possible. We will ask participants if they are willing to share any demographic information with us to be able to analyse the diversity of participants we have recruited.

*Staff***.** We will also interview up to 50 staff (approximately eight from each site), purposively sampled from a range of roles relating closely to NMPs, to include junior to senior clinical staff (particularly junior doctors in training), as well as any relevant managerial/administrative roles in each ED/UTC.

Recruitment.

The NHS research nurse will send to those expressing interest via the consent form at the end of the patient questionnaire an invitation letter, participant information sheet and a consent form. Those interested in participating in an interview will get in contact directly with the research team and an interview data be agreed. Potential participants will be able to choose an interview with a study researcher by telephone, online call, or live text chat, dependent on participant choice. Our PPI advisors have suggested these multiple means to enable those who may be hard of hearing, have language barriers or any other reason for wishing a family member or carer to be present.

Staff: Staff will be recruited when the researchers are in-situ in the ED/UTC for the observations (Phase Three WP5) through a combination of recruitment posters placed in the ED/UTC staff areas and an all-eligible staff email from an ED/UTC senior clinical manager (again maintaining separation from the research team Clinical Lead members), with a participant information sheet and consent form provided. Staff expressing a willingness to participate will be able to choose an interview in their own personal time with a study researcher by telephone or online call, according to the participant's preference. Interviews will take no longer than 60 minutes. A £35 voucher will be offered to staff participants for undertaking an interview in their own personal time.

All potential participants (patients and staff) will be provided in advance with a consent form and a participant information sheet explaining the reasons why they are being asked to take part in an interview, and what participation will involve. This will give them an opportunity to consider whether they wish to participate and to raise questions. Additionally, the information sheet will provide the study researchers' contact details if the potential participant has any queries. It will be made clear that participation is entirely voluntary, individual participants are not named, responses are confidential, and taking part/withdrawing will have no influence on their treatment or employment. They will also be informed of their right to withdraw from the study without consequence, up to the point at which data have been entered for analysis, dates of which will be provided at the time of data collection. No payment has been scheduled. Potential interview participants will have the option to either return an initialled and electronically signed Consent Form via email, or to give digitally recorded consent verbally against the consent form prior to the start of the interview, and with the interview recording to commence separately, or in paper form before the start of a face-to-face interview. The voluntary nature of participation will be stressed at all times including the ability to withdraw from the study at any time, stop an interview, withdraw from the interview, or disregard a question as the participant wishes. Should any patient or staff participant experience distress at the time of the interview, the researchers will provide immediate support through listening and directing appropriately for further support via already-established sources of support for patients or for staff in the organisation. Contact details for these organisations will also be provided in the Information Sheet.

Data collection

The patient interviews are anticipated to be no longer than 40 minutes each and the staff interviews no longer than 60 minutes each, and will be audio recorded with permission, or field notes taken if not, and transcribed. Each participant will be given a study ID number and all personal identifiers will

be removed from the transcript, and the recording deleted after the transcript has been pseudonymised and checked by the research team.

An interview schedule will be used with open-ended questions. As advised by our PPI representatives, patients will be asked about inter-staff communication, communication with the patient, being seen as a person, thoroughness of history taking, being treated without harm, recommending the ED/UTC to others, and satisfaction with treatment. Staff will be asked about their experiences and perspectives on NMPs in the skill-mix team and their interdependence (independence/supervision), what works well and what works less well, whether there are any perceived benefits and/or problems, and where improvements could be made.

Analysis

The transcripts and/field notes will be analysed with at least two members of the research team involved in reading, developing an index, coding and interpreting the interview data iteratively. Inductive and deductive analysis methods will be used in a combination of thematic[57], and framework analysis techniques [58]. We will use DEDOOSE software package to assist in this.

6. RESEARCH OUTPUTS

A report on Phases 2 and 3, with plain English versions, will be written to carry forward to the overall study synthesis phase and for the NIHR.

All participants will be asked via questionnaire, interview and observation participant information sheets if they wish to be kept informed of the study's progress and its final results, and if so, to share their contact details with us for that purpose only. We will maintain a digital record of these contacts and store it securely (complying with General Data Protection Regulations), but separately to the data. We will produce study newsletter-style updates and distribute via email or post, at the participant's preference.

7. STUDY MANAGEMENT

7.1 Study timetable

Phases Two and Three will run for 11months, commencing October 2022, with some concurrent and some sequential research activities.

Reporting timetables to the approvers and to NIHR as funder will be adhered to, and accruals reported monthly/as required by central portfolio management services and the CRN.

7.2 Chief and co-investigator expertise and roles

The study has been developed, and will be led by, the experienced applicant team, many of whom have already successfully delivered and/or are currently leading studies both together and separately on the healthcare workforce to the NIHR. Each member brings different expertise and contribution:

- Health services research of workforce, both in recent NIHR HS&DR studies on PAs (Drennan and Halter), and in NMP evaluations across specialties and settings for other funders, including invited applications for HEE on the Medical Associate Professions and Advanced Clinical Practice (Drennan, Halter, Taylor), with qualitative and mixed-methods research expertise.
- Patient and public involvement (Brearley), with expertise as co-applicant on our previous NIHR-funded studies on PAs, alongside her many roles as an advocate for PPI at national and local level. Sally's role as a 'PPI fellow' at Kingston University involves providing PPI guidance one day a week to the Centre for Public Engagement, including leading a panel of lay persons who form a PPI Research Expert Group, whose input has been integral to the development of this protocol, and some members of which will continue to help embed PPI throughout this study.
- Health economics (Gage), with expertise in directing health economics studies, including projects related to general practice and NMPs
- Statistics (Wang), with expertise in the merging and analysis of large datasets, including HES data
- Medical sociology (Gabe), with a focus on the underpinning concepts – such as autonomy and levels of independence - for this study

- ED/UTC lead clinicians with nursing (Jarman) and medical (Marton) perspectives, and with (Jarman) roles for the research development of the nursing workforce.

8. DATA MANAGEMENT

The CI (Mary Halter) will be responsible for data handling and record keeping. The sponsor organisation will maintain Standard Operating Procedures (SOPs) for the use of the system wherein data are handled and records kept, and maintain a university security system to protect against unauthorised access. The CI will maintain an audit trail of data changes ensuring that there is no deletion of entered data, maintain a list of the individuals authorised to make data changes, maintain adequate backup of the data, safeguard the archiving of any source data (hard copy and electronic). With the statistician, an audit trail will be kept in order that, if data are transformed during processing, it should always be possible to compare the original data and observations with the processed data.

We will work closely with NHS Digital and the participating NHS trusts who will use an unambiguous participant identification code where the participant's identifying information is replaced by an unrelated sequence of characters that allows identification of all the data reported for each participant. This will be applied immediately upon receipt of data from the NHS Trust case studies. NHS Digital will supply pseudonymised data to the research team via a secure data transfer service under the terms of the Data Sharing Framework Contract and the Data Sharing Agreement. Access to the anonymised data will be restricted to the joint CIs, the research project manager, statistician, health economists and researchers employed onto the study.

The sponsors will ensure compliance with the requirements outlined above when tasks are subcontracted, with data sharing agreements to be put in place.

Interview recordings and observation notes will be destroyed at the end of each Phase of the study to which they were collected in. All other data will be electronically archived by the sponsor for 10 years after completion of the study, on university network drives.

Direct access will be granted to authorised representatives from the Sponsor, host institution and the regulatory authorities to permit trial-related monitoring, audits and inspections- in line with participant consent.

All investigators and study site staff will comply with the requirements of the Data Protection Act 1998 with regards to the collection, storage, processing and disclosure of personal information and will uphold the Act's core principles.

The data custodian will be the CI Mary Halter.

The data arising from the study is owned by the sponsor, Kingston University.

On completion of the study, the data will be analysed and a report prepared for the NIHR. The participating investigators have rights to publish any of the trial data with the permission of the sponsor (via the Joint Chief Investigators). The funding body (NIHR) needs to be acknowledged within the publications and must be informed of study outputs at least 30 days prior to their publication.

Participants will be notified of the outcome of the study, by provision of a specifically designed summary document, where they have requested to receive this and consented to the retention of their personal data for this purpose up to one year following the end of the study.

9. ETHICAL AND REGULATORY CONSIDERATIONS

Ethical considerations

This research will be conducted according to Medical Research Council principles and guidelines for good research practice [59].

9.1. Consent

The Joint Chief Investigators will ensure that the researchers delegated responsibility to participate in the informed consent process are duly authorised, trained and competent to participate according to the ethically approved protocol, principles of Good Clinical Practice (GCP) and Declaration of Helsinki. The joint CIs take responsibility for ensuring that all vulnerable participants are protected and participate voluntarily in an environment free from coercion or undue influence.

Informed consent will be gained from all staff interview and observation participants and patient interview participants. Participants will remain free to withdraw at any time from the study without giving reasons and without prejudicing their employment or treatment; data collected up to the point of withdrawal will remain in the study.

9.2 Regulatory approvals and reports

This study will require regulatory approvals, in preparation for data collection. The study will be conducted in line with Health Research Authority (HRA), NHS Research Ethics Committee and local Capacity and Capability research governance approvals.

Substantial amendments that require review by REC will not be implemented until the REC grants a favourable opinion and have been reviewed by NHS R&D departments.

All correspondence with the REC will be retained in the study master files, on University password protected networks.

An annual progress report (APR) will be submitted to the REC within 30 days of the anniversary date on which the favourable opinion was given, the Chief Investigator will notify the REC of the end of Phase 2 and Phase 3, and, within one year after the end of Phase 3, the Chief Investigator will submit a final report with the results, including any publications/abstracts to the REC.

9.3 Payment

There are no intended payments to participants.

10. PROTOCOL COMPLIANCE

Accidental protocol non-compliances will be adequately documented and reported to the Chief Investigator and Sponsor immediately. Any serious breaches to GCP and/or the protocol will be notified to the CI and the sponsor and the funder (by the CI) where the breach is likely to effect to a significant degree the safety or physical or mental integrity of the participants of the study or the scientific value of the trial.

11. DISSEMINATION OUTPUTS AND ANTICIPATED IMPACT

We have designed this study in order to achieve impact through the collaboration and engagement with the NHS and the patient and public perspective. In particular, we anticipate a role for and with our PPI and NMP advisory panels and study steering committee to contribute to and guide our

communication and dissemination activities throughout the study. We intend to disseminate and generate impact throughout the study. We intend for these dissemination and discussion activities to use multiple methods and media, with key stakeholder groups' (e.g. NHS Employers, RCEM, HEE, RCN, Healthwatch); conference presentations, and journal articles. We will maintain our study web site and use social media – we will work closely with our advisory panels (PPI and NMP) and the study steering committee to achieve the best fit of materials to networks.

We will also share the specific output of our tool for the measurement of independence and supervision appropriate to its stage of validation and cognisant of its intellectual property.

We will ensure we focus on impact by having it as a standard agenda item at all of our planned research team, steering group and advisory panel meetings; impact will be documented using the University's impact tracker software, monitored by the impact manager.

REFERENCES

1. NHS. A&E Attendances and Emergency Admissions August 2022 Statistical Commentary. Accessed 16 September 2022 at: Statistics » A&E Attendances and Emergency Admissions 2022-23 (england.nhs.uk)
2. UK Parliament/ Baker C and Kirk-Wade E. Research Briefing NHS Key Statistics: England June 2022 Published Thursday, 30 June, 2022. Accessed 16 September 2022 at: NHS Key Statistics: England, June 2022 - House of Commons Library (parliament.uk)
3. NHS Benchmarking Network & Royal College of Emergency Medicine. Emergency Department Workforce Benchmarking Research Report. 2018. Accessed 16 September 2022 at: https://s3.eu-west-2.amazonaws.com/nhsbn-static/Emergency%20Care%20(Providers)/2019/RCEM_NHSBN_Staffing_Report_09-2019.pdf
4. Stehman CR, Testo Z, Gershaw RS, et al. Burnout, Drop Out, Suicide: Physician Loss in Emergency Medicine, Part I. *West J Emerg Med.* 2019;20:485-494. doi: 10.5811/westjem.2019.4.40970
5. Ashton RA, Morris L, Smith I. A qualitative meta-synthesis of emergency department staff experiences of violence and aggression. *Int Emerg Nurs.* 2018;39:13-19. doi:10.1016/j.ienj.2017.12.004
6. Royal College Emergency Medicine and NHS. Securing the future workforce for emergency departments in England NHS Improvement (October 2017) Publication code: P 06/17 NHS England Publications Gateway Reference: 07340. Accessed 16 September 2022 at: https://improvement.nhs.uk/documents/1826/Emergency_department_workforce_plan_-_111017_Final.3.pdf
7. NHS England. A&E Attendances and Emergency Admissions 2022-23 Monthly A&E August 2022. Accessed 16 September 2022 at: August-2022-AE-by-provider-Ht6m3.xls (live.com)
8. The World Health Report, 2000 Health systems: improving performance. Geneva: World Health Organization; 2000.
9. Crouch R, Brown R. Advanced clinical practitioners in emergency care: past, present and future. *Br Journal Hosp Med*. 2018;79:511-15. doi: 10.12968/hmed.2018.79.9.511.
10. NHS Improvement. Interim NHS People Plan. 2019. Accessed 16 September 2022 at: https://www.longtermplan.nhs.uk/wp-content/uploads/2019/05/Interim-NHS-People-Plan_June2019.pdf
11. NHS Health Education England. Multi-professional framework for advanced clinical practice in England. 2017. Accessed16 September 2022 at: https://www.hee.nhs.uk/sites/default/files/documents/Multi-professional%20framework%20for%20advanced%20clinical%20practice%20in%20England.pdf

12. Faculty of Physician Associates. Who are physician associates? 2019. Accessed 16 September 2022 at: https://fparcp.co.uk/about-fpa/Who-are-physician-associates
13. The College of Emergency Medicine. Non-medical Practitioners in the Emergency Department. 2015. Accessed 16 September 2022 at: https://www.rcem.ac.uk/docs/Workforce/Non%20medical%20practitioners%20in%20the%20ED.pdf
14. Drennan et al. The non-medical practitioner workforce contribution in the emergency and urgent care system skill-mix: early findings from a stakeholder interview and policy analysis study in England. Accessed 21 September 2022 at: https://youtu.be/8na0FZjWoyc
15. Halter M. The non-medical practitioner workforce contribution in the emergency and urgent care system skill-mix: emerging findings from a scoping and systematic review. HSRUK conference presentation July 2022. Accessed 16 September 2022 at: https://youtu.be/04SB1fva4Ok
16. Aledhaim A, Walker A, Vesselinov R et al. Resource utilization in non-academic emergency departments with advanced practice providers. *West J Emerg Med*. 2019;20(4):541-548. doi: 10.5811/westjem.2019.5.42465
17. McDonnell WM, Carpenter P, Jacobsen K, Kadish, HA. Relative productivity of nurse practitioner and resident physician care models in the paediatric emergency department. *Pediatr Emerg Care*. 2015;31(2):101-106. doi:10.1097/PEC.0000000000000349
18. Morton S, Igantowicz A, Gnani S, Majeed A, Greenfield G. Describing team development within a novel GP-led urgent care centre model: a qualitative study. *BMJ Open*. 2016;6(6):e010224. doi:10.1136/bmjopen-2015-010224
19. Myers RA, Parikh PJ, Ekeh AP, Denlinger E, McCarthy MC. Scheduling of advanced practice providers at level 1 trauma centres. *J Trauma Acute Care Surg.* 2014;77(1):176-181. doi:10.1097/TA.0000000000000250.
20. Pines JM, Zocchi MS, Ritsema T, Polansky M, Bedolla J, Venkat A, US Acute Care Solutions Research Group. The impact of advanced practice provider staffing on emergency department care: Productivity, flow, safety, and experience*. Acad Emerg Med*. 2020;27:1090-1099. doi:10.1111/acem.14077
21. Wise S. The flexibility of healthcare teams. A mixed methods study of doctors and nurses in an emergency department. Faculty of Health at the University of Technology Sydney, 2018. Accessed 15 August 2022 at: https://opus.lib.uts.edu.au/bitstream/10453/129414/1/01front.pdf

22. Wise S, Duffield C, Fry M, Roche M. Clarifying workforce flexibility from a division of labour perspective: a mixed methods study of an emergency department team. *Hum Resour Health.* 2020;18(17). doi.org/10.1186/s12960-020-0460-7
23. Gaughan J, Liu D, Gutacker N, Bloor K, Doran T, Benger JR. Does the presence of general practitioners in emergency departments affect quality and safety in English Hospitals? A retrospective observational study. *BMJ Open*. 2022;12:e055976 doi.org/10.1136/bmjopen-2021-055976
24. Edwards E. Evaluating effectiveness, safety, patient experience and system implications of different models of using GPs in or alongside Emergency Departments. Research in progress. Accessed 16 September 2022 at: https://www.journalslibrary.nihr.ac.uk/programmes/hsdr/1514504/#/
25. McDermott I, Spooner S, Goff M et al. Scale, scope and impact of skill mix change in primary care in England: a mixed-methods study. *Health Soc Care Deliv Res*. 2022;10(9) doi.org/10.3310/YWTU6690
26. Gage H. How general practice team composition and climate relate to quality, effectiveness and human resource costs: a mixed methods study in England. Research in progress. Accessed 16 September 2022 at: https://www.journalslibrary.nihr.ac.uk/programmes/hsdr/170834/#/
27. Walsh N. First Contact Physiotherapy in Primary Care (FRONTIER): A Realist Evaluation of effectiveness and costs. Research in progress. Accessed 16 September 2022 at: https://www.journalslibrary.nihr.ac.uk/programmes/hsdr/1611603/#/
28. Donabedian A. The quality of care. How can it be assessed? *JAMA.* 1988; 260:1743-1748. doi: 10.1001/jama.260.12.1743
29. Greenhalgh T, Robert G, Macfarlane F, Bate P, Kyriakidou O. Diffusion of innovations in service organizations: systematic review and recommendations. *Milbank Q*. 2004;82(4):581-629. doi:10.1111/j.0887-378X.2004.00325.x
30. Dempster JS. Autonomy in practice: Conceptualization, construction, and psychometric evaluation of an empirical instrument. Dissertation Abstract International, 1990;50, 3320A. (UMI No. 9030752)
31. Tashakkori, A. and Teddlie, C. (2003). Handbook of Mixed Methods in Social and Behavioral Research. Thousand Oaks: Sage
32. Moore GF, Audrey S, Barker M, et al. Process evaluation of complex interventions: Medical Research Council guidance. *BMJ*. 2015;350:h1258. doi:10.1136/bmj.h1258
33. Health Education England. Workforce Plan for England. London, 2015Campbell DT, Stanley JC. Experimental and quasi-experimental designs for research. Chicago: Rand McNally; 1966

34. Kvale S. Doing Interviews. London: Sage Publications, 2007.
35. NHS Digital. NHS Workforce Statistics – August 2022. Accessed 16 September 2022 at: https://digital.nhs.uk/data-and-information/publications/statistical/nhs-workforce-statistics/august-2022
36. NHS Digital 2021. Hospital Accident & Emergency Activity 2020-21. 30 Sep 2021. Accessed 16 September 2022 at: https://digital.nhs.uk/data-and-information/publications/statistical/hospital-accident--emergency-activity/2020-21
37. NHS Digital 2020 DCB0092-2062: Commissioning Data Sets: Emergency Care Data Set Type 011: Emergency Care Data Set (ECDS) is the Commissioning Data Set (CDS) Type for emergency care services. Last updated 20 September 2020. Accessed 16 September 2022 at: https://digital.nhs.uk/data-and-information/information-standards/information-standards-and-data-collections-including-extractions/publications-and-notifications/standards-and-collections/dcb0092-2062-commissioning-data-sets-emergency-care-data-set
38. NHS Digital 2022. Provisional data quality report for Emergency Care Data Set (ECDS) supplementary information. Accessed 16 September 2022 at: https://digital.nhs.uk/data-and-information/data-tools-and-services/data-services/emergency-care-data-set-ecds-data-quality
39. NHS Data Model and Dictionary 2022. Emergency care acuity Accessed 16 September 2022 at: https://www.datadictionary.nhs.uk/data_elements/emergency_care_acuity__snomed_ct_.html
40. NHS Digital 2022. Provisional Accident and Emergency Quality Indicators for England - March 2022, by provider. Accessed 16 September 2022 at: https://digital.nhs.uk/data-and-information/publications/statistical/provisional-accident-and-emergency-quality-indicators-for-england/march-2022-by-provider
41. Care Quality Commission. NHS Patient Surveys Urgent and Emergency Care Survey 2020. Accessed 16 September 2022 at: https://www.cqc.org.uk/publications/surveys/urgent-emergency-care-survey-2020
42. NHS 2020. NHS Staff Survey. Benchmarking - Organisation overview 2021. Accessed 16 September 2022 at: https://www.nhsstaffsurveys.com/results/local-results/
43. Drennan VM, Halter M, Wheeler C, et al. The role of physician associates in secondary care: the PA-SCER mixed-methods study. *Health Serv Deliv Res*. 2019;7(19). doi:10.3310/hsdr07190
44. Little, R. J. A. 1988. A test of missing completely at random for multivariate data with missing values. *JASA*. 83: 1198–1202
45. Aiken LH, Sloane D, Griffiths P, et al. Nursing skill mix in European hospitals: cross-sectional study of the association with mortality, patient ratings, and quality of care. *BMJ Qual Saf*. 2017;26(7):559-568. doi:10.1136/bmjqs-2016-005567

46. Price S, Zhang X, Spencer A. Measuring the impact of national guidelines: What methods can be used to uncover time-varying effects for healthcare evaluations? *Soc Sci Med*. 2020;258:113021. doi:10.1016/j.socscimed.2020.113021
47. Rabe-Hesketh S, Skrondal A. Multilevel and Longitudinal Modeling Using Stata. 3rd ed. College Station, TX: Stata Press. 2012.
48. The Royal College of Emergency Medicine. RCEM – seriously ill or injured patients may be avoiding Emergency Departments due to Covid-19 fears. 9 April 2020. Accessed 16 September 2022 at: https://rcem.ac.uk/rcem-seriously-ill-or-injured-patients-may-be-avoiding-emergency-departments-due-to-covid-19-fears/
49. Curtis LA, Burns A. Unit Costs of Health and Social Care 2019. PSSRU, Kent, UK, 176pp. ISBN 978-1-911353-10-2. doi:10.22024/UniKent/01.02.79286
50. Yin RK. Case Study Research: Design and Methods. 3rd Ed. Thousand Oaks, California: Sage Publications .Inc, 2003.
51. Health Education England. What is advanced clinical practice? Undated. Accessed 16 September 2022 at: https://www.hee.nhs.uk/our-work/advanced-clinical-practice/what-advanced-clinical-practice
52. Bryman A. Social Research Methods. 4th Ed. Oxford, UK: Oxford University Press, 2012
53. NHS Getting It Right First Time (GIRFT) with the Emergency Care Intensive Support Team (ECIST). Getting It Right In Emergency Care. 1st Ed.2018. Accessed 16 September 2022 at: https://gettingitrightfirsttime.co.uk/wp-content/uploads/2019/12/Getting-it-right-in-emergency-care-Aug18.pdf
54. Weinick RM, Becker K, Parast L, Stucky BD, Elliott MN, Mathews M, Chan C, Kotzias V (2014). Emergency Department Patient Experience of Care Survey: Development and Field Test. RAND Corporation, RR-761-CMS.
55. Austin PC, Steyerberg EW. The number of subjects per variable required in linear regression analyses. *J Clin Epidemiol.* 2015; 68:627–636. doi.org/10.1016/J.JCLINEPI.2014.12.014
56. Braun V, Clarke V. Using thematic analysis in psychology. Qual Res Psychol. 2006;3:77-101. doi.org/10.1191/1478088706qp063oa58. Ritchie J, Lewis J. (eds.) Qualitative Research Practice: A Guide for Social Science Students and Researchers. Sage Publications, London, 2003.
57. Ritchie J, Lewis J. (eds.) Qualitative Research Practice: A Guide for Social Science Students and Researchers. Sage Publications, London, 2003.
58. Medical Research Council. Good research practice: principles and guidelines. Accessed 16 September 2022 at: https://www.ukri.org/about

APPENDIX 1: TOOL FOR OBSERVATION

Tool for observation measurement of clinician interdependence in clinical practice in the ED/UTC skill-mix team

SECTION A	NO DISCUSSION	DISCUSSION WITH TEAM COLLEAGUE						DISCUSSION WITH DOCTOR/CONSULTANT IN CHARGE						DISCUSSION WITH SPECIALIST				
TASKS AND ACTIONS	No Discussion	No Change	Prompted Change	Directed Change	Peer Review	Un-clear		No change	Prompted change	Directed Change	Peer Review	Un-clear		No change	Prompted Change	Directed Change	Peer Review	Un-clear
Patient assessment and investigation																		
Patient history taking																		
Physical examination undertaken																		
Vital signs checked																		
Diagnostic procedures/ performed																		
Diagnostic test/s ordered																		
Online information seeking																		
Clinical guidelines/ protocol/ pathway/risk assessments checked																		
Clinical knowledge sought																		

TASKS AND ACTIONS	NO DISCUSSION	DISCUSSION WITH TEAM COLLEAGUE						DISCUSSION WITH DOCTOR/CONSULTANT IN CHARGE						DISCUSSION WITH SPECIALIST				
	No Discussion	No Change	Prompted Change	Directed Change	Peer Review	Un-clear		No change	Prompted change	Directed Change	Peer Review	Un-clear		No change	Prompted Change	Directed Change	Peer Review	Un-clear
Diagnosis and treatment																		
Test results interpreted																		
Different diagnoses considered on basis of information gathered																		
Certain diagnosis ruled out																		
Final diagnosis about treatment procedure/s																		
Treatment options considered																		
Decision made about treatment procedure/s																		
Treatment procedure/s performed																		
Medication prescribed																		

TASKS AND ACTIONS	NO DISCUSSION	DISCUSSION WITH TEAM COLLEAGUE						DISCUSSION WITH DOCTOR/CONSULTANT IN CHARGE						DISCUSSION WITH SPECIALIST				
	No Discussion	No Change	Prompted Change	Directed Change	Peer Review	Un-clear		No change	Prompted change	Directed Change	Peer Review	Un-clear		No change	Prompted Change	Directed Change	Peer Review	Un-clear
Information sharing and communication with patient																		
Need for investigations communicated																		
Test results explained																		
Confirmation of diagnosis communicated																		
Treatment recommendations explained																		
Patient's understanding of information ensured																		
Patient's questions about care handled																		
Patient's complaints about care handled																		
Plan of care confirmed with patient																		

TASKS AND ACTIONS	NO DISCUSSION	DISCUSSION WITH TEAM COLLEAGUE						DISCUSSION WITH DOCTOR/CONSULTANT IN CHARGE						DISCUSSION WITH SPECIALIST				
	No Discussion	No Change	Prompted Change	Directed Change	Peer Review	Un-clear		No change	Prompted change	Directed Change	Peer Review	Un-clear		No change	Prompted Change	Directed Change	Peer Review	Un-clear
Patient participation in decision making																		
Patient encouraged to participate in decision making																		
Discussion with patient of advantages/ disadvantages of different treatment recommendations																		
Any thoughts & concerns of patient discussed																		
Care plan adjusted to patient's needs, or rationale provided for why this is not possible																		

TASKS AND ACTIONS	NO DISCUSSION	DISCUSSION WITH TEAM COLLEAGUE						DISCUSSION WITH DOCTOR/CONSULTANT IN CHARGE						DISCUSSION WITH SPECIALIST				
	No Discussion	No Change	Prompted Change	Directed Change	Peer Review	Un-clear		No change	Prompted change	Directed Change	Peer Review	Un-clear		No change	Prompted Change	Directed Change	Peer Review	Un-clear
Disposition of patient																		
Disposition plan determined																		
Disposition plan communicated to patient																		
Patient provided with advice & education for ongoing care																		
Patient alerted to "red flag" issues																		
Follow-up organised with another hospital speciality																		
Referral/s made (e.g., to GP)																		
Patient handover																		
Patient handover received																		
Patient handover given to colleague																		
Advice/decision sought																		
Asked by colleague for advice on their patient																		
Asked by colleague for clinical decision on their patient																		
TOTAL																		

Section B
Context data collected during observation

Location **Time** _____ **Point in clinician's shift**
Triage Start Middle End
Majors
Minors
Resus
Fast-track
Paediatrics
Other_____

Proximity of consultant/doctor in charge
Where NMP working in ED
Wider area of ED
Outside of ED

Computer availability
Where NMP working in ED
Wider area of ED
Outside of ED

Room availability for patient assessment
Where NMP working in ED
Wider area of ED
Outside of ED
Patient waiting area

Locating patient
Where NMP working in ED
Wider area of ED
Outside of ED
Patient waiting area

Equipment availability for diagnostic tests
Where NMP working in ED
Wider area of ED
Outside of ED

Interruptions during patient assessment and investigation (e.g., request to use room, request for equipment in room)
None Some (1-3) Several (4+)

Wait time to access consultant/doctor in charge
None Short (under 15 mins) Long (15 mins+)

Clinician self-completion of tasks/activities wanted to delegate
None Some Several

Section C

i) Context data collected from Trust

Patients waiting
Number _____
Low Medium High

Patients in last hour
Number _____
Low Medium High

Wait time to treatment
Time (hrs/mins) _____
Low Medium High

Staff on duty
Assistants Number___
Low Medium High

Nurses Number___
Low Medium High

NMPs Number___
Low Medium High

Junior doctors Number___
Low Medium High

Senior doctors Number___
Low Medium High

Trust rules/protocols for supervision_____
_____
_

ii) *Context data – perspective of clinician observed*

Time pressure
Low Medium High

Workplace experience
Low Medium High

Experiential knowledge
Low Medium High

Knowledge of team members' skills/experience
Low Medium High

Team member familiarity
Low Medium High

Confidence around clinical decision making
Low Medium High

Managing risk
Comfortable Moderate Uncomfortable

Managing uncertainty
Comfortable Moderate Uncomfortable

APPENDIX 2: SKILL-MIX RATIO EXAMPLES

Ratios for clinician levels or titles grouped for the data (all trusts) as a whole

Ratio (Proportion)

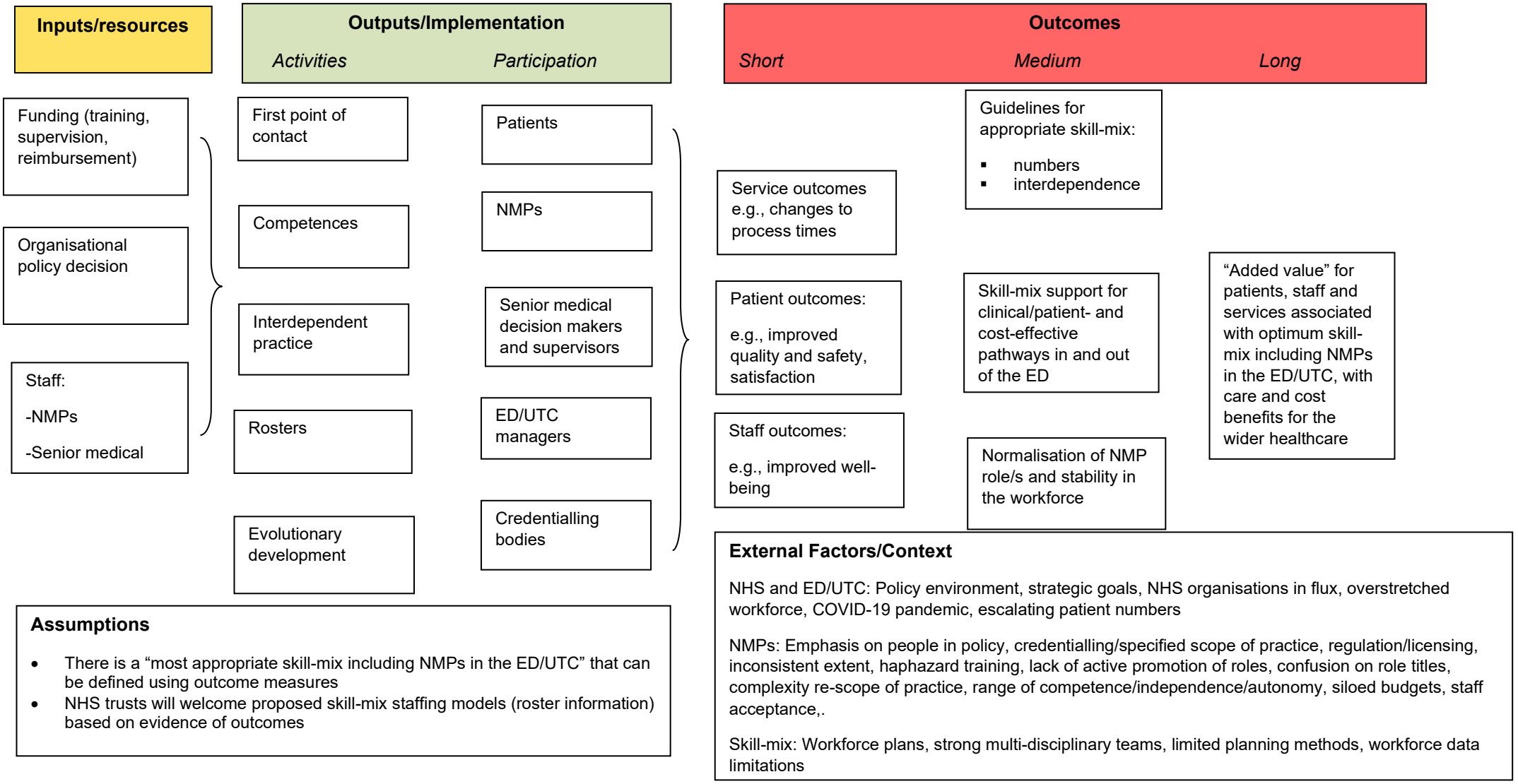
Clinician group	Year					
	2016-2017	2017-2018	2018-2019	2019-2020	2020-2021	Total
Subtotal: Medical workforce	0.27	0.27	0.27	0.26	0.28	0.27
Subtotal: Nursing workforce	0.66	0.64	0.65	0.65	0.64	0.65
Subtotal: NMP workforce	0.08	0.09	0.08	0.09	0.08	0.08

Ratio relative to NMP

Clinician group	Year				
	2016-2017	2017-2018	2018-2019	2019-2020	2020-2021
Subtotal: Medical workforce	3.54	3.21	3.39	2.76	3.34
Subtotal: Nursing workforce	8.74	7.48	8.11	6.88	7.64
Subtotal: NMP workforce	1.00	1.00	1.00	1.00	1.00

APPENDIX 3. THE LOGIC MODEL. PROGRAM: SKILLMIX-ED RESEARCH STUDY

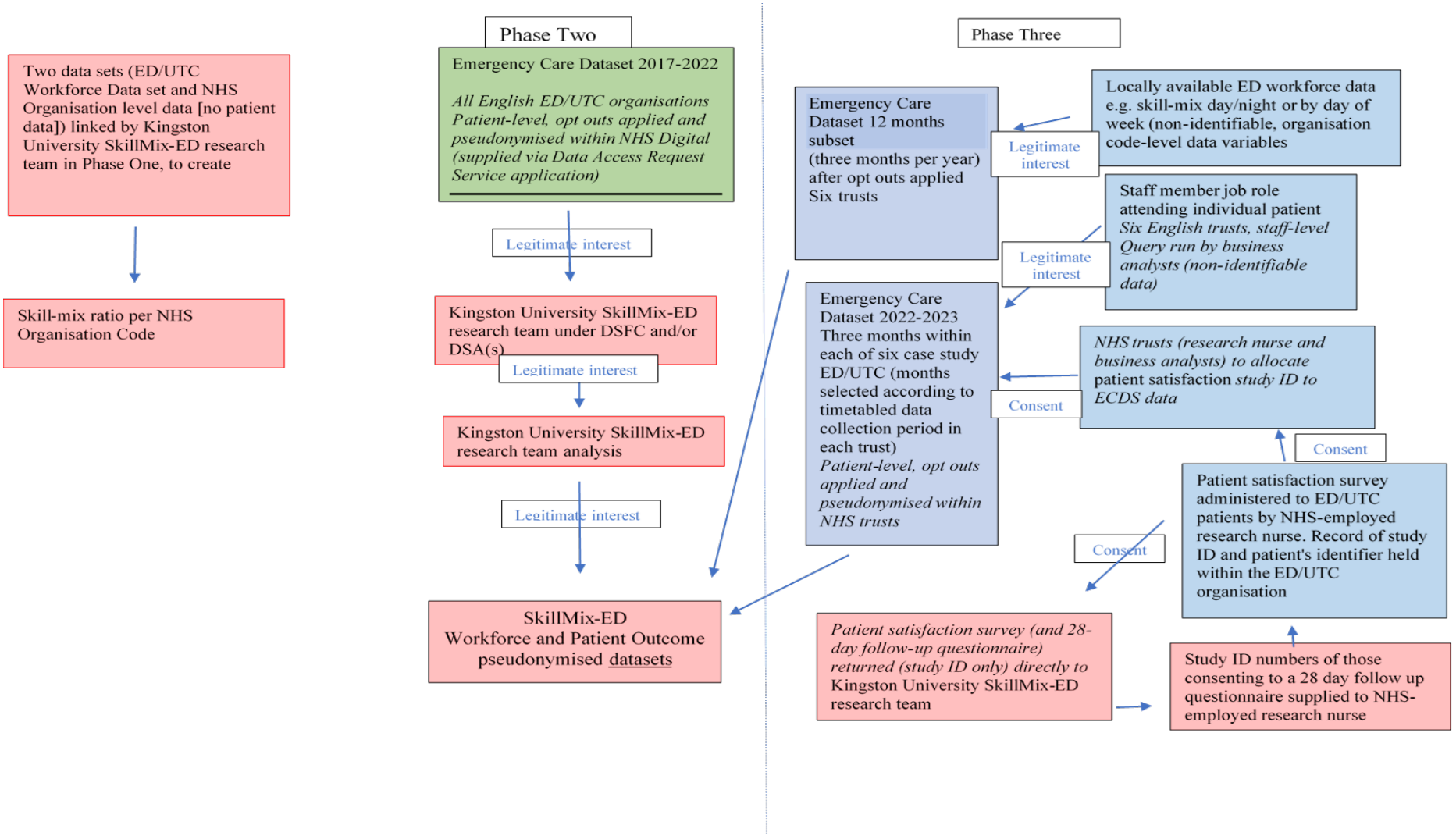
Situation: Skill-mix including non-medical practitioners in the emergency department and urgent treatment centre



Definitions used

1. Outputs/Implementation refers to how a service or intervention gets delivered and what gets delivered in practice.
2. Mechanisms of impact (Outcomes short-term) relate to the mechanisms through which the intervention works and produces changes in the intervention recipients.
3. Outcomes (long-term) are the changes that the intervention is ultimately trying to bring about for recipients, such as weight loss or diabetes prevention.
4. Context refers to factors external to the intervention that might influence how the intervention operates.

APPENDIX 4: PHASES TWO AND PHASE THREE DATA FLOW DIAGRAM



Data Flows Proposal_SkillMix-ED_v1.0_2023 March 5th_DARS submission.docx

Red=university (pseudonymised); Green = NHS Digital identifiable at source, supplied pseudonymised via DARS application; Blue = NHS Trust identifiable, supplied pseudonymised.

NO PATIENT-LEVEL LINKAGE IN PHASE TWO OR FROM PHASE THREE TO PHASE TWO

Data Access Request: anticipated ECDS data fields (from Enhanced Technical output Specification v3.0.0)

- Organisation Code (Code of provider)
- Emergency Care Attendance Category
- Emergency Care Department type
- Organisation Site identifier (of Treatment)
- *Local Authority*
- Organisation Identifier (Residence Responsibility) by Local Authority
- Age at CDS Activity Date
- Person Stated gender Code
- Ethnic category
- Emergency Care Acuity SNOMED-CT
- Emergency Care Chief Complaint (at grouped level)
- *Emergency Care Arrival Date **can be provided by MONTH and DAY OF WEEK if date renders data re-identifiable***
- *Emergency Care Arrival Time ** can be provided as DAY/NIGHT if time renders data identifiable***
- *Emergency Care Initial Assessment Time **can be provided as 'time to initial assessment (minutes') if provision of time stamps renders data re-identifiable***
- *Time Seen for Treatment **can be provided as 'time to treatment (minutes') if provision of time stamps renders data re-identifiable***
- *Emergency care Clinically Ready to proceed Timestamp **can be provided as 'time to clinically ready to proceed (minutes') a/a***
- Emergency care Clinical Investigation (grouped level)
- Emergency care Diagnosis (SNOMED-CT)
- Referred to Service
- Discharge Destination
- Care Professional Tier (Emergency Care)
- Care Professional Discharge Responsibility Indicator (Emergency Care)

- *Individual patient's Re-attendance within 7 days*