Roles and Adoption of Medical Associate Professionals (ROADMAP)

How might Physician Associates help (or not) address the workforce crisis in the NHS?

Study Title: How might Physician Associates help (or not) address the workforce crisis in the NHS?
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We declare no potential conflict of interest.

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1. KEY STUDY CONTACTS

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2. LAY SUMMARY

The NHS workforce is in crisis. The profession "Physician Associate" (PA) was introduced in the early 2000s in the UK, but despite this both the general public and the NHS workforce are unfamiliar with the work they take on. Nevertheless, almost 1,300 new PAs are now graduating every year expecting to work in UK health care, and the role has been emphasised in the latest NHS long-term workforce plan. In our recent systematic scoping review of research on PAs in the UK, which included 60 papers, some studies showed that PAs can deliver similar care outcomes and processes to General Practitioners (GPs) when undertaking less complex tasks. Similarly favourable comparisons to second-year Foundation Doctors in emergency departments was also found. However, PAs working in the NHS experience frustration in their work due to a lack of recognition, termed by some an "identity crisis", with their value and clinical credibility even questioned on social media and in recent television programmes. Literature also suggests that integrating PAs into the medical workforce in the NHS is challenging, with confusion and contestation around roles. This might be improved through both innovative recruitment and efforts to improve familiarity of other medical professionals and the public. Coming after investment in the PA profession, our research addresses major challenges identified around the introduction of the PA profession in the NHS, particularly in hospitals.

i. Nationally, information on how many PAs are working, where, and in what roles is held by various statistical agencies of the NHS across the four UK nations, and this prevents the use of data to evaluate the effect changes to PA-related policy and planning have on the NHS.
ii. There are no systems that track employment and career progression of PAs and very little is known about their recruitment, retention, or career evolution. No regulatory body for PAs exists, only a voluntary PA register. This, however, is evolving.
iii. Although data suggests that 70% of PAs work in hospitals, the use of them there varies across different regions of the UK and many NHS hospital trusts have relatively

little experience of employing PAs. Presently, it is difficult for trusts to share their experiences and this may prevent planning for using PAs.

Our research team combines individuals with different skills, and aims to tackle these gaps in the knowledge while engaging important stakeholders at all levels of the health system, from regulators to patients. Under this research project titled: "Roles and Adoption of Medical Associate Professionals (ROADMAP) - How might Physician Associates help (or not) address the workforce crisis in the NHS secondary care?" we aim to:

1. Identify improvements required in UK workforce databases to support national reporting on PAs' current roles and distribution in NHS hospital care settings across the four UK nations. We will then start to analyse the data and develop methods to track PAs as they enter, work in, and leave the NHS. As we do this, we will examine which healthcare roles PA graduates would like to work in.
2. Conduct a Realist Review of literature from upper-middle and high-income countries to understand how, in different contexts, professionals with similar qualifications to UK PAs have helped countries address hospital workforce challenges in the long-term.
3. Examine with eight NHS hospital trusts or health boards:

- the current roles of PAs in the trusts or health board and what managers think about the work they do, both now and in the future. As we do this, we will look at other groups of healthcare workers who may be involved in similar work or face similar challenges. These include but are not limited to Anaesthesia Associates (AAs); Surgical Care Practitioners (SCPs); Advanced Nurse Practitioners (ANPs) and Advanced Critical Care Practitioners (ACCPs) who also work in specific NHS teams.
- the development of a series of detailed stories that show some of the different roles PAs play in hospital care. As we do this, we will identify the key conditions that enable the successes and failures of PAs working in hospitals.
- how the people from institutions that govern health (e.g. regulators), other professionals, patients, and the public, understand PAs' potential contribution to the UK NHS workforce. This will be done by sharing the stories and other research findings in workshops to help us learn their opinions.

3. SYNOPSIS

Study Title	How might Physician Associates help (or not) address the workforce crisis in the NHS?
Internal ref. no. / short title	Physician Associates & the NHS workforce crisis
Sponsor	University of Oxford Research Governance, Ethics and Assurance Boundary Brook House, Churchill Drive, Headington, Oxford, OX3 7GB RGEA.Sponsor@admin.ox.ac.uk
Funder	National Institute for Health and Care Research Health and Social Care Delivery Research (HSDR) Programme NIHR153324

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Study Design, including methodology	A multiple methods study including secondary administrative data analysis, survey and longitudinal cohort design, discrete choice experiment, qualitative semi-structured interviews and focus group discussions, participatory video approach, as well as stakeholder collective-sensemaking
Study Participants, including sampling strategy	• For survey and longitudinal cohort and discrete choice experiments, physician associate (PA) students who are studying in their final years of the PA programme of participating schools at the time of the survey in 2024. • For qualitative semi-structured interviews and focus group discussions, at the eight participating NHS Trusts and Health Boards, senior trust managers and divisional directors, people in the clinical team (PAs, Consultants, nursing staff, junior doctors, non-clinical support staff), and patients with experience of interaction with PAs • For participatory videos, PAs at two of our selected NHS Trusts and Health Board • For stakeholder and patient collective-sensemaking, stakeholders from the General Medical Council, Nursing and Midwifery Council (NMC), the Faculty of Physician Associates, Health Education England, the Royal College of Physicians, the Royal College of General Practice, the Royal College of Nursing, and the British Medical Association, alongside PA Schools Councils and individual training programmes, Trust management and staff representatives; patients representatives will be selected from participating NHS Trusts and Health Boards' existing patient and public involvement structures
Sample Size	• Survey, longitudinal cohort and discrete choice experiment: Likely a range of 300 - 600 PA students • Semi-structured interviews, focus group discussions, participatory videos: likely 150 NHS Trust and Health Board staff (20 senior managers, 20 consultants, 40 PAs, 20 junior doctors, 20 nursing staff and 10 other clinical or non-clinical team staff, 20 patients) across eight sites or until data reach theoretical saturation • Stakeholder and patient collective-sensemaking participants: likely 10 national stakeholders, 50 NHS Trust and Health Board staff and PA training programmes representatives, and 15 patient representatives or until data reach theoretical saturation
Planned Study Period	This project last from 1 May 2023 to 30 April 2026.
Planned Recruitment period	1 May 2024 to 30 April 2026
Aim/Research Questions/Objectives	
Primary	How could Physician Associates address the workforce crisis in the NHS secondary care?

Secondary	• Where are PAs working and in what roles across the UK? - UK data systems and routine analyses must improve to inform specific policies and wider NHS workforce planning in the UK • What can we learn from successful as well as challenging/unsuccessful examples of PA work in hospitals, how are hospitals planning to use PAs in the future, what are their current practice, appraisal, clinical governance, job description, scope of practice, line management structure, how might demand for and use of PAs be informed by sharing examples of success or challenges, and how can this thinking inform future NHS workforce planning and public understanding of this new cadre?

4. ABBREVIATIONS

AA	Anaesthetic Associate
ANP	Advanced Nurse Practitioner
CI	Chief Investigator
CRF	Case Report Form
DCE	Discrete Choice Experiment
ESR	Electronic Staff Record
HR	Human resource
HRA	Health Research Authority
ICF	Informed Consent Form
NHS	National Health Service
RES	Research Ethics Service
PA	Physician associate
PI	Principal Investigator
PID	Personal identifying data
PIL	Participant/ Patient Information Leaflet
R&D	NHS Trust R&D Department
REC	Research Ethics Committee
RGEA	Research Governance, Ethics and Assurance
ROADMAP	Roles and Adoption of Medical Associate Professionals
SCP	Surgical Care Practitioner
SID	Study Identification Number
SOP	Standard Operating Procedure

WP	Work Package

5. BACKGROUND AND RATIONALE

The National Health Service in the UK (NHS) has major workforce gaps with many unfilled positions (1). This increases pressure on existing staff, a situation exacerbated by the Covid-19 pandemic, and threatens the ability of the NHS to deliver care in the short and long-term (2). Integrating Physician Associates (PAs), Advanced Nurse Practitioners (ANPs) and other providers into the health care team as part of a broader workforce redesign agenda is one of the solutions proposed to solve the workforce crisis in the NHS (3). PA is a new profession introduced in the early 2000s in the UK. There are growing numbers in training and potential regulatory changes to grant PAs prescribing rights (4). These prospects make PAs an apparently attractive 'technical solution' to address the NHS workforce crisis as PAs represent an expansion in the supply of health workers to deliver clinical care. In the latest NHS -long-term workforce plan, there is an emphasis on advanced and associate roles including a planned increase of PA training places to over 1,500 by 2031/32 and registration of PAs and anaesthesia associates by the General Medical Council by the end of 2024 with the potential of giving them prescribing rights in the future (5).

To fully appreciate the nature of research on PAs in the UK and begin to compare this with research on Advanced Nurse Practitioners (ANPs), our team recently conducted a systematic scoping review and narrative synthesis on PAs in the NHS contrasting these roles with those of ANPs (6). The narrative synthesis of the literature provided insights into the competencies, career development, effectiveness, perceptions, and regulation of PAs in comparison to ANPs. The existing research characterised the development of the PA profession and articulated both the challenges and opportunities of the role in the UK (7). Some studies show that PAs can deliver similar care outcomes and processes to GPs when undertaking less complex tasks in primary care at a smaller cost per consultation (8,9). Similarly favourable comparisons to second-year Foundation Doctors in emergency departments are made (10). However, PAs working in the NHS experience frustration in their work due to lack of recognition, termed by some an 'identity crisis' (11–13), with their value and clinical credibility even being questioned on social media and recent high-profile investigative television programmes (14). Even in the US where PAs have been an established profession for 50 years they still experience "out-group disdain" and a lack of recognition from nurses and doctors due to "groupishness" (15). To better integrate the PAs into the medical workforce, our scoping review and narrative synthesis suggest that the integration and employment of PAs in the NHS can be improved through more innovative recruitment initiatives such as Trusts offering work experience placements, links with PA training programmes
and generally efforts to improve the socialisation of PAs so that familiarity and acceptability increases amongst other professional groups (6). There are also PA ambassador roles in England funded by NHS England to support and enable system-wide workforce transformation and integration (16). Importantly, efforts also need to be made to educate the public about PAs if they are to be an acceptable part of the solution to long-term workforce challenges in the UK. Other cadres such as Anaesthetic Assistants (AAs), Surgical Care Practitioners (SCPs) and ANPs have successfully integrated into NHS teams (17–20). A comparative study of other cadres with PAs may provide important insights into how professional identities and boundaries are negotiated in the workplace when introducing a new cadre of health professionals into existing clinical teams.

One of the major concerns for PAs is the absence of prescribing rights which limits their ability to work independently and efficiently (21). The need for supervision resulting from no prescribing rights also makes other medical workers view PAs as less productive (22). However, the General Medical Council (GMC) together with other stakeholders have been developing the regulatory framework for PAs planned in the second half of 2024 (during our planned research), which could be foundational for granting PAs prescribing rights later (23). The delays in PA regulation are in part linked to plans for additional public consultation and legislation needed before PAs could prescribe (24). This makes our planned research timely, especially our efforts to develop simple video descriptions of PAs and their roles (see WP 3.2). Another longer-term issue for the PA profession is the lack of career progression in clinical roles beyond the entry-level (6). As a result, currently, some PAs seek advancement by proceeding to medical training programmes or pursuing research and teaching opportunities in universities and hospitals (15,25). Such findings suggest PAs may not fulfil the generalist mid-level roles anticipated by policymakers. Interestingly although policymakers anticipated PAs would principally support primary care, more than 70% of PAs currently employed are in hospitals or other secondary or tertiary care settings rather than in primary care (6).

In addition to our review of the literature, we have conducted preliminary analyses of UK health workforce databases. Such analyses support earlier suggestions that PAs deployment is very unevenly distributed across regions in the UK with more PAs working closer to PA training programmes (22,26). The Faculty of Physician Associates (FPA), with whom we collaborate, have conducted annual cross-sectional surveys of PAs based on their voluntary registration since 2014. As there is no legislation to regulate the profession this remains an 'opt-in' registration process with high but incomplete coverage (survey response rates are in the range of 40% to 60% of the voluntary registration database) (26). These surveys and wider literature (6) point to challenges in integrating PAs in the NHS workforce, particularly in recruitment, career progression, role transitions and retention. Yet the FPA surveys obviously do not capture data on PAs who are not members. Neither are they designed to link individuals' data across surveys, hence there are no large-scale longitudinal data for individual PAs in the NHS.

Our initial work therefore identified several key knowledge and evidence gaps:

1. Nationally, workforce statistics on PAs are incomplete and fragmented across various statistical agencies of the NHS in the four UK Nations preventing utilisation of such data to evaluate workforce policy changes on PAs or temporal shifts, a deficiency of considerable relevance as PA graduates grow in number and as they are poised to be fully regulated in 2024 and gain full prescribing rights.
2. While the UK has invested in systems to track employment and career progression of doctors no such system has been established to track PAs and very little is known about their recruitment and retention or, for those qualified for some years, how their careers have evolved.
3. Existing limited evidence suggests although 70% of PAs work in secondary care, there is highly variable recruitment across different regions of the UK. Thus, many NHS Hospital trusts have relatively little experience employing PAs and there is relatively little understanding of the current and likely future demand for PA roles from this sector, nor information on when they should be used, for what roles, to what extent, and how they might integrate into existing teams.

Our project aims to initiate work to address these NHS knowledge needs with a particular focus on secondary care to inform long-term workforce planning in the UK, a much-neglected concern.

6. AIM AND RESEARCH QUESTIONS

This project focuses on PAs, an innovation in the UK NHS workforce introduced twenty years ago, with an overall aim to generate the knowledge and approaches that will improve national and local NHS workforce planning. Specifically, we build on prior NIHR-funded research, and complement existing NIHR funded research, to undertake work guided by WHO's Health Labour Market approach (30). We examine supply and demand side issues in the education sector, labour market and wider society. Our work will address two outstanding and important questions to inform health workforce policy and planning.

- Where are PAs working and in what roles across the UK? - UK data systems and routine analyses must improve to inform specific policies and wider NHS workforce planning in the UK. (WP1)
- What has been learned about how to successfully integrate PAs into hospital teams in other countries who have had similar health workers for much longer than the UK (with an additional focus on licencing and regulatory aspects of the profession)? (WP2)
- What can we learn from successful as well as challenging/unsuccessful examples of PA work in hospitals, how are hospitals planning to use PAs in the future, how might demand for and use of PAs be informed by sharing examples of success or challenges, and how can this thinking inform future NHS workforce planning and public understanding of this new cadre? (WP3)

7. STUDY DESIGN, ACTIVITIES AND ANALYSIS

To address the above questions and provide national and local decision-makers with important evidence our multi-disciplinary team will undertake research activities in three work packages using different methods (See Table below). These will be conducted in collaboration with PA Schools Council (WP 1.2), eight selected NHS Trusts and Health Boards (WP 1.1, 3.1, 3.2, and 3.3) as well as involving national and regional stakeholders (WP 1.3 and 3.3).

To date, the following eight Trusts and Health Boards have agreed to participate. They will be referred to as study sites hereinafter.

- NHS Grampian
- Oxford University Hospitals NHS Foundation Trust
- Norfolk and Norwich University Hospitals NHS Foundation Trust
- The Queen Elizabeth Hospital King's Lynn NHS Foundation Trust
- James Paget University Hospitals NHS Foundation Trust
- St. George's University Hospitals NHS Foundation Trust
- Lancashire Teaching Hospitals NHS Foundation Trust
- East Lancashire Hospitals NHS Trust

Overview of study activities

Activity	Study design	Participants and sampling	Data collection, management and consent
WP 1.1: Secondary NHS workforce database analysis	• Secondary data analysis from publicly available database e.g. National Workforce Dataset by NHS Digital and NHS Scotland Workforce by NHS Education, ESR and NHS trust and health board HR database, FPA census	• N/A, aggregate data	• All de-identified and aggregate data • Data stored securely on a university server accessible only by the research team
WP 1.2: Exit survey and discrete choice experiment	• Longitudinal cohort study, starting from end of training with a possibility for follow-up	• PA students who are studying in their final years of the PA programme of participating schools at the time of the survey in 2024. • Census-type sampling, sampled from participating PA training programmes • Participants will be asked to take part in longitudinal follow-ups	• Personal data (phone number and email address) direct identifier collected • Data stored securely on a university server accessible only by the research team, only aggregate data without identifier will be shared • Completing the survey and discrete choice experiment considered as consent
WP 1.3: PA workforce cohort data	• Collaboration and engagement with regulators and stakeholders	• N/A, aggregate data	• Exploring possibilities for data-linkage between all

			administrative databases
WP 2: Realist Review	• Realist review	• N/A, literature based	• Using secondary data drawn from the academic and grey literature
WP 3.1: NHS trust interviews and focus groups	• Qualitative interviews or focus group discussions	• Senior trust managers and divisional directors • People in the clinical team including: PAs, consultants, nursing staff, junior doctors • Patients with experience of interaction with PAs • Purposively sampling, sampled from eight participating NHS trusts and health boards	• De-identified data (transcripts will be saved with a sample identifier instead of someone's name) • Data stored securely on a university server accessible only by the research team • In-person or online consent form signed at interviews or focus group start
WP 3.2: Participatory video	• Participatory video through creating a short film	• PAs • Purposively sampling, sampled from PA from eight participating NHS trusts and health boards	• Video of agreed and copyright consented individuals • Footage stored securely on a university server accessible only by the research team, edited videos will be shared in public • In-person consent form and copyright

			forms signed at video workshop start
WP 3.3: Collective sensemaking workshops	• Workshops	• National stakeholders such as General Medical Council alongside Trust management and staff representatives • Purposively sampling, sampled from research team's contacts and stakeholder groups • Patient representatives from Trust/Health Boards' patient and public involvement groups	• De-identified data (field notes will be saved with a sample identifier instead of someone's name) • Data stored securely on a university server accessible only by the research team • In-person consent form signed at workshop start

WP1: Development of effective PA workforce information systems and tools (Ethical review: in process)

WP 1.1: Secondary NHS workforce database analysis

- **Methodology overview**

Our main objectives for WP 1.1 are to 1) explore available administrative statistics from four UK nations to understand historical and current trends and geographical distribution of PAs in secondary care, and to 2) explore "our local partners" (NHS Trusts/Health boards) workforce data to analyse changes in local demand for health professionals.

We would therefore use quantitative analysis of secondary NHS workforce data at the national and local levels, the latter based only on data of NHS Hospital Boards/Trusts participating in this study. The main outcomes are 1) Data structure and framework made available to organisations responsible for NHS workforce planning and statistics and professional bodies; 2) Illustrative cases from eight selected NHS study sites on numbers of posts and vacancies for PAs and related health professionals that help deepen our understanding on current trends and future PAs' hospital roles.

- **Data sources and data management**

For the regional and national level data, NHS statistical agencies and professional bodies will be approached for their permission for data access. At the participating NHS study site level, we will collaborate with the Human Resource (HR) and Research Governance team in each organisation for essential data access. Only aggregated data that strips personal data of sufficient elements to identify any individual will be presented in our case studies report. The research team will not keep or process any personally identifiable data outside the data framework used by these partner organisations. The organisations and types of data we plan to access and analyse are listed in the following table:

Types of data	Duration	Organisations
National and regional level data: - Numbers of PAs working in secondary care settings in each region by age-group (or years of working in the NHS), gender, ethnicity (to help understanding diversity in the workforce), specialty and pay-grade[1]	2010 – most updated data available	NHS Digital (England), NHS Education Scotland, Health Education and Improvement Wales, Department of Health Northern Ireland, NHS Electronic Staff Records (ESR), Faculty of Physician Associates, General Medical Council

[1] We will ensure that summary statistics presented based on cross-tabulations of these characteristics will not be small enough to risk re-identifying any individual with one's physical, physiological, genetic, mental, economic, cultural or social identity. The rule of thumb that no cell with fewer than 5 persons should be presented in the summary statistics.

NHS Trusts/Health boards - Numbers (head counts and Whole Time Equivalences) of PAs and related professionals (e.g. Advanced Nurse Practitioners (ANP), Surgical Care Practitioners (SCP), junior doctors and specialty doctors and specialist grade doctors) in particular wards/specialties as well as turn-over rates, vacancies, and total days of absence - Financial data related to workforce such as expenditure on Locum doctors and Agency nurses, pay-grade, and recruitment and training cost for new staffs	Most recent year and five years in the past	Participated NHS Trusts / Health Boards depending on data access given by each partner organisation

- **Data analysis**

Secondary data collected from national and local partner organisations will be cleansed, organised, and analysed using statistical programmes such as STATA or R. Summary statistics will be presented by cross-tabulation tables and visualised into diagrams and maps. We will analyse the data based on existing theories and frameworks, including the WHO's Health Labour Market framework (27) that covers supply, demand, employment, performance, etc. Drawing upon HR and financial data across several NHS Trusts / Health boards will enable us to compare the challenges and plans of local partners with different characteristics (e.g. urban and rural areas) and stages of PA adoption (i.e. early vs. late adopters).

WP 1.2: Exit survey and discrete choice experiment

- **Methodology overview**

For WP 1.2, our main objective is to develop and employ survey tools that help to better understand the experiences and career aspirations of qualifying PAs to inform NHS workforce planning. We would achieve these through co-designing the exit survey and DCE with key stakeholders. DCEs are survey-based relying on what respondents say they will choose or prefer between hypothetical options. One of the key strengths of a DCE is its ability to set up hypothetical jobs with attributes, e.g. salary ranges or career opportunities, that do not currently exist but could potentially influence the choice of job and inform human resources policy. Econometric models will be used to analyse data collected from the exit survey and DCE.

By the end of WP 1.2, we would:

- Have developed two survey tools: an 'exit' survey of PAs completing their training to explore their training experiences and DCE to examine the job preferences of PA graduates
- Better understanding of PAs' work intentions, expectations, challenges encountered, workload, well-being, and longer-term career plans as well as factors that attract or deter PAs to their first jobs and the trade-offs between these factors

- **Sampling**

All PA training programmes will be invited to participate in the survey through contacts and network of the PA Schools Council, a body representing Physician Associate training programmes across the UK. All PA students satisfying the inclusion criteria in these programmes will receive an email invitation from their institution to join the study. Although we strive to recruit as many included PA students as possible, we anticipate that 300-600 students (out of around 1,300 eligible students from the whole UK) will participate in the survey.

Participant Inclusion

Participants in the exit survey and DCE will be PA students who are studying in their final year of the PA programme of participating training programmes (all participants should be older than 20 years of age) at the time of the survey in 2024.

Participant Exclusion

PA students who are in other years of study or already graduated from the programme at the time of the survey.

- **Data collection**

We will conduct an online survey with PA students meeting the inclusion criteria, who have given their informed consent to participate in the study by clicking on the "agree" button before beginning the survey. The survey consists of a simple online questionnaire (the exit survey) followed by the DCE task at the end of it. The online survey will be collected and managed by the programme REDCap without IP address information. The collected data will be stored in a locally secured server by the research team in Oxford. We plan to recruit the participants by asking participating PA training programmes (with the support of the PA Schools Council) to share the survey link via their existing databases or communication channels. Hence, the research team will not have direct access to participants' contact information at recruitment.

Method of data collection	**Duration**	**Conducted by:**
An online survey (the exit survey) aims to research into PA students' experiences, work intention, challenges, and expectation	10 to 15 minutes	Online survey accessed through the link sent to the participants by their training programme
DCE questions at the end of the online survey explores PA students' preference for future positions	12 to 15 minutes	Online survey accessed through the link sent to the participants by their training programme

Exit Survey (Online Questionnaire)

The research will occur online where respondents can participate through a device of their choice, i.e. PC, tablet, or smartphone. Participants will answer survey questions before completing the Discrete Choice Experiment. The survey questions consist of demographic information (age group, gender and ethnic groups where participants can choose to answer 'prefer not to say'), training programme name, training experiences, work intentions, expectations, challenges encountered, workload, well-being, and longer-term career plans. To maximise response rates and avoid 'survey fatigue' from repeated questions with other existing surveys, we will engage with collaborators from PA training programmes through co-design

meetings to finalise the exit survey. We also aim to ensure that the survey including the DCE will be completed within 22-30 minutes.

Discrete Choice Experiment (DCE)

In the DCE, participants will be asked to complete 12 choice questions. For each choice question, they will be shown descriptions of two hypothetical PA posts, asked to select their preferred option and asked if they will consider taking that post after graduating. Each post will be described in terms of several attributes, which will be derived from a review of the literature, discussion with the PPI group, and co-design meeting(s) with stakeholders from PA training programmes and professional organisations. The combinations of the levels of these attributes will be different in each choice question.

The final DCE will be finalised after the co-designing process with the PPI group and stakeholders. Presentation of these scenarios will be preceded by explanatory screens to explain the task and the attributes, and a 'practice' scenario to help respondents become familiar with the choice task.

We plan to conduct a pilot study involving 30-40 participants, who are in their first year of their PA training, where some extra questions will be asked at the end of the survey to gauge participants' understanding and engagement with the process. In addition, an open-ended question at the end allows participants, amongst other things, to note anything that they found uncomfortable or upsetting, and we will be able to adjust the final survey if any such issues arise.

Establishing longitudinal database

In addition to our collaboration with stakeholders to recommend potential solution(s) to establish and mainstream long-term longitudinal database for PAs, we will also collect personal data from the participants in the exit survey for a possibility of conducting a follow-up survey in 2025/26. We plan to collect the participants' email address and phone number. These questions will be optional and asked as an opt in option 'to be contacted next year as part of the longitudinal surveys' at the end of the whole online questionnaire (after the DCE). This contact information will be kept in a separate file per Oxford University and GDPR data protection regulation and only newly assigned study ID will be attached to the main survey data.

Consent

As this is a simple online questionnaire, we will show a consent form where the participants can click on the "agree" or "disagree" button before beginning the survey. It will be made clear to them that this decision will have no impact at all on their studies. While participants are completing the survey, it will be straightforward that each participant can withdraw at any time by closing the browser window. Withdrawal during the study will result in the exclusion of the data for that participant from the analysis. We assume that completion and submission of the questionnaire imply that consent for the use of the questionnaire data has been given. Additionally, we will give participants an opt-in option to be contacted as part of the longitudinal surveys in the following year by providing their email address and phone number at the end of the survey.

- **<u>Data analysis</u>**

We will use statistical programmes such as STATA or R to produce descriptive statistics. Choice models will be estimated from the DCE and survey data. We will use the choice model to predict the probability that

each respondent will choose a particular job. The dependent variable is the respondents' job choices in the experiment. Independent variables are the jobs' attributes and participant characteristics from the questionnaire. Estimated coefficients in the model tell us how the probability of job choice varies with the attributes of the jobs and participant characteristics. To ensure rigour, transparency and reproducibility, we will follow guidance from the DCE literature on how to produce high-quality evidence (28,29). We will use a range of pilot studies, subject matter experts, literature reviews and data quality measures to "fine-tune" all aspects of our approach. We will employ extensive specification and statistical testing, including testing of internal validity (as detailed in (30,31)). We will also publish appendices providing in-depth details of our data and methods to ensure the reproducibility of our results in published articles.

Whenever the sample size is large enough to ensure the anonymity of each respondent, we will share summary statistics and findings from data analysis such as their experiences and expectations with the participating PA training programmes but no one outside the research team will have access to the survey and DCE data.

WP 1.3 PA workforce cohort data

- **Methodology overview**

For WP 1.3, our main objective is to identify improvements required for the routine administrative data and design the system for cohort studies of comparable quality to the UK Medical Education Database (UKMED). We will collaborate with PA training programmes, regulators, and professional bodies to lay out recommendations to establish and mainstream long-term longitudinal database strategies for PAs nationally (through administrative sources, longitudinal surveys or both).

- **Data sources and data management and data linkage**

We will explore two routes of establishing PA workforce cohort analyses using either routine administrative data or longitudinal surveys building up on the exit survey in WP1.2. Collaborating with the statistical agencies in WP 1.1, the FPA, the PA Schools Council representing Higher Education Institutions (HEIs) with PA programmes, and the General Medical Council (GMC), the expected licensing body for PAs, we aim to identify improvements required for the routine administrative data and design the system for cohort studies of comparable quality to the UK Medical Education Database (UKMED).

UKMED links education outcomes and the progression of cohorts of doctors from their application to medical school through the first few years of training and practice. Specifically, it consists of six stages of the doctor training and practice (31), i.e. (i) entry qualifications used to enter the medical schools including students' demographic data, (ii) aptitude test results used by medical schools in their selection processes, (iii) medical schools attended and exam outcomes, (iv) applications to foundation training and test scores, (v) doctors' experiences of training during the foundation years from the National Training Survey, (vi) data on postgraduate markers of trainees' progression including applications to some specialty training programmes and Royal College Membership exams, and (vii) fitness to practise data (held by GMC). The database contributed to an increase in scope and volume of research on medical education and workforce, and helped improve standards of training and workforce planning (32).

Another possible route is to access the NHS Electronic Staff Records (ESR). We will assess the potential of (and challenges with) using ESR as a backbone of the national longitudinal database. We also plan to explore the possibility of linking PAs' information (e.g. during their PA training) with the ESR in order to track their career movement and progression within the NHS over time. So far an attempt to track PA cohorts and study their career path has been limited to a cross-sectional survey from a single longest-running UK PA training programme (33). Our aim is to provide a recommended solution to key stakeholders for how to establish and mainstream long-term cohort studies on PAs nationally to inform NHS workforce planning.

WP2: Realist Review of global literature focused on the long-term integration of roles similar to PAs into the health workforce (Ethical review: not required)

We will use the literature to draw transferable lessons from successful and unsuccessful experiences with recruitment, retention and integration of roles like PAs into the healthcare workforce and labour market from countries with a longer history than the UK of utilising PAs to inform NHS workforce strategies. We will likely focus on high and upper-middle-income country literature as most relevant.

We will build on our previous systematic scoping review on UK PAs, and experiences using meta-ethnographic and realist reviews to do this and be supported by expert collaborators to conduct a Realist Review (34). The review will follow existing guidance on the conduct of realist reviews (35) and follow their quality and reporting standards (36). We will produce a programme theory that informs practical recommendations for the NHS on how to optimise the recruitment, retention and role satisfaction of PAs.

The realist review will have five-steps (37). The protocol will be registered on PROSPERO and published. The steps below are described linearly for sake of clarity, but in practice we will seamlessly and iteratively move between steps.

1) Developing the initial programme theory

We will develop an initial (candidate) programme theory which sets out how and why the introduction of PAs might impact the NHS workforce. A programme theory is defined as 'the description, in words or diagrams, of what is supposed to be done in a policy or programme (theory of action) and how and why that is expected to work (theory of change) (38).

It will be developed at an initial meeting of the project team and expert advisors. During this meeting, the project team will discuss and unpack the various intended and unintended outcomes that PAs might have in hospitals. As the project develops, the relevant context and mechanism for each outcome will be developed from data identified within the included documents.

2) Developing the search strategy

This initial theory will be refined as the synthesis progresses using secondary data drawn from the academic and grey literature. The search strategies employed to identify literature containing relevant data will be developed iteratively, and re-visited at predetermined milestones, using different permutations and additional concepts (39,40). Our information specialist from the Bodleian Health Care

Libraries, University of Oxford will help develop, refine and run the searches for this project, seeking input from the wider team.

Our search strategies will seek to retrieve relevant literature and be informed by our initial programme theory. We anticipate that they will include free text and subject heading terms to describe:

- Our population of interest: PAs and equivalent professions in other countries;
- Important outcomes for this review, including enablers and hindrances to the successful recruitment, retention and integration of PAs into the healthcare team.

Based on previous reviews in Embase, Medline, PubMed, CINAHL and Cochrane Database, we will subsequently use 'cluster searching' techniques to identify additional papers that might add to the conceptual richness and contextual thickness of studies initially identified within the sampling frame constructed through conventional topic-based searching. For example, we will aim to identify 'sibling' (i.e. directly linked outputs from a single study) and 'kinship' (i.e. associated papers with a shared contextual or conceptual pedigree) papers and reports (40). We will also conduct forward and backward citation searches using Google Scholar and Web of Science, to identify further related papers from the wider literature. Searching will continue until sufficient data is found to conclude that the refined programme theory is sufficiently coherent and plausible (39).

3) <u>Selection and appraisal</u>

Citations returned from the searches will be screened against our initial inclusion criteria (which may be refined if needed) set out below:

- Population groups: Physician Associates and equivalent professions in other countries
- Setting: In healthcare settings focusing mainly on secondary care
- Data: Recruitment, integration, retention and career development framework
- Countries: High-Income and Upper-Middle-Incomes countries (based on World Bank classification)
- Context: Licencing and regulatory framework for the professions, prescribing rights, etc.

Selection and appraisal are a two-step process:

1. Potentially relevant documents will initially be screened by title, abstract and keywords by a study team member, and any uncertainty will be resolved with the input of the CI.
2. The full texts of this set of documents will be obtained and screened. The study team member will read the full text of all the documents that have been included after screening based on title and abstract. Documents will be selected for inclusion when they contain data that is relevant to the realist analysis i.e., could inform some aspect of the programme theory.

At the point of inclusion, we will also assess the rigour of each piece of data – which will be done at the level of methods used to generate the data within the included document (where necessary) and also at the level of the programme theory (41). Documents may still be included even if judged to be of limited rigour, as we will also be making an overall assessment of rigour at the level of the programme theory. The study team member will also discuss decisions with the project team as appropriate.

4) <u>Data extraction</u>

Data will be uploaded into NVivo (a qualitative data analysis software tool) full texts of the included papers. Relevant sections of texts, which have been interpreted as relating to contexts, mechanisms and their relationships to outcomes, will be coded in NVivo. This coding will be inductive (codes created to categorise data reported in included studies), deductive (codes created in advance of data extraction and analysis as informed by the initial programme theory) and retroductive (codes created based on an interpretation of data to infer what the hidden causal forces might be for outcomes). The characteristics of the documents will be extracted separately into an Excel spreadsheet. Each new element of data will be used to refine the theory if appropriate, and as the theory is refined, included studies will be re-scrutinised to search for data relevant to the revised theory that may have been missed initially (39).

5) Data Analysis, Synthesis and Dissemination

Data analysis will use a realist logic of analysis to make sense of the initial programme theory. Data for analysis will be drawn from documents that have been included in the realist review after screening against inclusion criteria. The key researcher will undertake this step with support from CI and the Project Team. For example, we will have regular data analysis meetings, where the emerging findings and Context-mechanism-outcome configurations (CMOCs) (with supporting data) are presented to the team for discussion, debate and refinement. As part of our process of analysis and synthesis, a series of questions about the relevance and rigour of content within data sources will be asked (45):

• Relevance: Are sections of text within this document or transcript relevant to programme theory development?
• Rigour (judgements about trustworthiness): Are these data sufficiently trustworthy to warrant making changes to the programme theory?
• Interpretation of meaning: if relevant and trustworthy, do its contents provide data that may be interpreted as functioning as context, mechanism or outcome?
• Interpretations and judgements about CMOCs. For example, what is the CMOC (partial or complete) for the data that has been interpreted as functioning as context, mechanism or outcome?
• Interpretations and judgements about programme theory. For example, how does this particular (full or partial) CMOC relate to the programme theory? Within this same document or transcript, are there data, which informs how the CMOC relates to the programme theory?

Data to inform our interpretation of the relationships between contexts, mechanisms and outcomes will be sought across documents, because not all parts of the configurations will always be articulated in the same document. Interpretive cross-case comparison will be used to understand and explain how and why observed outcomes have occurred, for example, by comparing settings where PAs have had positive outcomes against those which have not; from this we will understand how context has influenced the results. When working through the questions set out above, where appropriate we will use the following forms of reasoning to make sense of the data: juxtaposition of data, reconciling of data, adjudication of data, and consolidation of data.

Ultimately, our analyses will be used to identify which practical intervention strategies might change existing contexts in such a way that 'key' mechanisms are triggered to produce desired outcomes.

Output or Deliverables: a more refined programme theory that articulates how, when, who, for whom and to what extent PAs can have positive outcomes when deployed in hospitals. This programme theory will

be used to inform the analytic phase of our case study in WP3 and provide a deeper understanding of how PAs might be able to help the NHS address hospital workforce challenges in the long-term.

WP3: Examining with selected NHS Hospital Trusts, Health Boards and diverse stakeholders on effective deployment of PAs in secondary care (Ethical review: in process)

WP 3.1: Qualitative interviews with health professionals, managers and patients

- **Methodology overview**

WP 3.1 will include interviews and focus group discussions of the roles and integration of PAs through case studies of eight NHS Health Boards/Trusts across the United Kingdom. The aim would be to explore (1) at the Trust and health board level, the range of roles and to what degree NHS Boards/Trusts employ PAs, AAs, SCPs, and ANPs and explore their employment intentions, as well as their current practice, appraisal, clinical governance, job description, scope of practice, line management structure, and (2) at the clinical team level, the integration of PAs into different hospital care teams. We would hope to understand the perspectives of key stakeholders involved in the recruitment, training and integration of PAs into secondary care in the NHS to inform practical recommendations on optimising recruitment, retention and role satisfaction of PAs, as well as an in-depth understanding of the scope of work of PAs across a range of secondary care contexts, in order to share learning & highlight successful and unsuccessful examples of PA deployment & integration across different NHS Trusts and Health Boards, as well as better ways of informing NHS patients of PA roles.

- **Sampling**

NHS Trusts will be purposively selected to include urban and rural areas of the UK, and both administrative and clinical leads at each Trust or Health Board will be approached for informed consent of the Trust/Health Board and its employees to participate in the qualitative study. Within each NHS study site, we will purposively sample key stakeholders including:

- Senior trust managers and divisional directors or associate directors.
- People in the clinical team including: PAs, consultants, nursing staff, junior doctors.
- Patients with experience of interaction with PAs after their discharge.

We will also use snowballing of key contacts to identify other relevant stakeholders within the NHS Trusts who are involved in the training, supervision or work with PAs. These stakeholders have been chosen as they have a direct relationship and impact on the work and future employment, training and regulation of PAs within the NHS. Stakeholders will be identified through consultation with locally-based collaborators at each participating NHS Trust/NHS Board. Stakeholders will be approached by a member of the research team for their informed consent to participate in either in-depth interviews or an FGD as part of the study.

Patients with lived experience with PAs will be sampled prospectively at the time of their service contact. Those who have been seen by PAs will be asked for their informed consent at the end of their inpatient stay or the end of their consultation with a PA, whether they would like to participate in the study. Patients will be recruited by a member of the research team (either the investigators or collaborating health professionals based within the participating NHS Trusts/NHS Boards) following their consultation or during their inpatient stay. Patients will be asked for their informed consent to participate in the study and for

their contact details to be shared with the research team. Interviews with patients will be conducted face-to-face following discharge from hospital either in a private room within the hospital site, or conducted online via Microsoft Teams or phone call if face-to-face interviews are not possible for NHS study site staff:

Participant Inclusion

- Participants is aged 18 years or above.
- Participant is willing and able to give informed consent for participation in the study AND is either a:
    - Senior Trust Manager OR divisional director or clinical lead within the participating hospital Trusts.
    - Part of the clinical team within the NHS Trust, including: PAs, Consultant medical staff, nursing staff, junior doctors, as well as non-clinical support staff across inpatient, outpatient and theatre settings whereas applicable.

Participant Exclusion

- Those who are not working within participating NHS Trusts.

For patients:

Participant Inclusion

- Participant is aged 18 years or above.
- Participants have lived experience interacting with PAs

Participant Exclusion

- Those unable or unwilling to give their informed consent for participation in the study.

- **<u>Data collection</u>**

We will conduct semi-structured, in-depth interviews (IDIs) and focus group discussions (FGDs) with key stakeholders meeting the inclusion criteria, who have given their written informed consent to participate in the study in each of the eight participating NHS Trusts. Senior trust managers, consultants will be interviewed at the time of their convenience, and PAs, junior doctors, nursing staff and other clinical and non-clinical team staff will be asked for their preference for taking part in in-depth interviews (IDIs) or focus group discussions (FGDs). Patients who have lived experience of PAs will also participate in the study. IDIs and FGDs will be audio recorded using an encrypted voice recorder and transcribed with Oxford University-approved professional transcriber or digital transcription services with participant consent.

Method of data collection	**Duration**	**Conducted by:**
Semi-structured, in-depth interviews (IDIs) with Senior Trust Managers and/or divisional directors, Consultants, patients seen by PAs.	30-60 minutes per interview.	Locally-based researcher and member of Oxford research team
Focus group discussions (FGDs) with i) PAs ii) nursing staff, iii) junior doctors, iv) patients.	60 to 90 minutes per FGD.	Locally-based researcher and member of Oxford research team

Population of interest	**Number across 8 sites and approach for data collection**	**Note**

Senior trust managers and/or divisional directors	We will purposively sample up to 20 senior managers across 8 sites or until data reach theoretical saturation, and conduct in-depth interviews	We will pay particular attention to sites with smaller number of PAs such as Oxford University Hospital NHS Foundation Trust. We will also capture the success and failures in integrating PAs.
Consultants	We will purposively sample up to 20 consultants across 8 sites or until data reach theoretical saturation, and conduct in-depth interviews	
PAs	We will purposively sample up to 40 PAs across 8 sites or until data reach theoretical saturation, and conduct in-depth interviews and / or focus group discussions	
Junior doctors, nursing staff, and other clinical and non-clinical team staff	We will purposively sample up to a total of 50 junior doctors, nursing staff, and other clinical and non-clinical team staff across 8 sites or until data reach theoretical saturation, and conduct in-depth interviews and / or focus group discussions	
Patient seen by PAs	We will purposively sample up to 20 patients in a range of clinical areas across 8 sites or until data reach theoretical saturation, and conduct in-depth interviews and / or focus group discussions	

In-depth interviews

Semi-structured in-depth interviews will be held face-to-face (where able) or online through Microsoft Teams with senior trust managers and/or divisional directors, Consultants, and patients seen by PAs. Participants will be invited to discuss their experiences of PAs, their knowledge of PA practice in healthcare delivery in their NHS Trusts, and their understanding of the long-term career prospects and roles of PAs within the NHS. Patients will be invited to discuss their experiences with PAs and their understanding of their role within the healthcare team (in the forms of either interviews or focus group discussions depending on availability). We do not anticipate that the questions will be difficult to answer or upsetting. We will continue the interviews until data reach theoretical saturation across sites, likely starting with a total of 15 interviews including with 5 senior managers, 5 consultants and 5 patients conducted at the first few study sites. We would then tailor recruitment as we progress across sites aiming to capture a variety of voices and fill potential gaps in our understanding. Together with the focus group discussion below, we imagine we would have up to a maximum total of 150 NHS Trust and Health Board staff (20 senior managers, 20 consultants, 40 PAs, 20 junior doctors, 20 nursing staff and 10 other clinical team staff, 20 patients) across eight sites or until data reach theoretical saturation. The interviews will last 30-60 minutes participants can ask for a break in between. The interviews will be audio-recorded and transcribed.

Focus / Small Group Discussions

Focus / small group discussions with between 4-8 participants depending on availability will be held face-to-face (where able) or online through online meeting platforms fully compliant with GDPR (such as MS teams) if any restrictions to meeting in person. FGDs will be conducted by a member of the research team, and last between 60-90 minutes. FGDs will be audio-recorded and transcribed as detailed above. Each FGD will start with an explanation of the purpose of the FGD and establish the ground rules of the focus group, including ensuring confidentiality of the discussion and respectful communication between members of the focus groups. FGDs will be conducted with i) PAs, ii) nursing staff, iii) junior doctors, and iv) patients. Group discussions with different staff and patient groups will be conducted separately due to the potential power dynamics and professional hierarchies, which may otherwise prevent participants from expressing their views freely. We do not anticipate that the questions will be difficult to answer or

upsetting. Similar to the interviews we will continue with group discussions until we seem to be learning little new but expect to conduct 5 focus groups with PAs, nursing staff, junior doctors and other clinical team members and 3 to 5 focus groups with patients across study sites. Together with the interviews described above, we aim to involve up to a maximum total of 150 NHS Trust and Health Board staff (20 senior managers, 20 consultants, 40 PAs, 20 junior doctors, 20 nursing staff and 10 other clinical team staff, 20 patients) across eight sites or until data reach theoretical saturation.

- **Data analysis**

Data collected through IDIs and FGDs will be transcribed by an Oxford-approved digital transcription software or service provider, saved with study identifiers instead of actual names, and analysed using thematic content analysis and whereas possible a realist logic, drawing upon existing theories and frameworks, including the health labour market framework. We will iteratively move between theory and empirical data to develop the best explanation of our empirical findings. These data will be curated using NVivo (software that aids qualitative data analysis) and summarised in a narrative and explanatory synthesis linked to a conceptual framework or programme theory. This will articulate how and why PAs are being introduced into hospital Trusts and Health Boards and contextual factors explaining, for example, why Trusts/Health Boards or hospital departments are early or late adopters of PAs within their workforce.

Using a multiple case study approach across several NHS Trusts and Health Boards, will enable both in-case and cross-case comparisons during the data analysis to address the intended outcome of sharing learning across NHS Trusts/Health Boards and practical guidance on the integration of PAs, with 'successful' and 'unsuccessful' exemplars across a variety of contexts, which will be co-selected with different stakeholders in the Trust.

WP 3.2: Participatory video making with physician associates

- **Methodology overview**

Participatory Video is a methodology used to enable individuals and groups to explore aspects of their lives and voice their experiences, perceptions, feelings and ideas by creating a short film which can be shown to different audiences (42). It has been used as a tool for community development (43–45), health promotion (46–48), programme evaluation and in conjunction with participant observation, as a research tool (48).

We plan to work with a group of 4-8 PAs in a 1-day collaborative film-making workshop. During this facilitated workshop, PAs will be encouraged to share and reflect on their roles, experiences, aspirations and issues which they prioritise as important to share and discuss with broader audiences. Working with a facilitator and a film-maker, the group will:

a) Prioritise content for the video through discussion
b) Storyboard ideas and discussion points/interview questions on flipcharts
c) Gather media interviews including film recording
d) Conduct a rough edit as a group

The participatory nature of the video-making process and the subsequent content of final video(s) produced, will largely be determined by the participants, however we anticipate that videos will help

express some of the key knowledge generated across all three research objectives: to explore PA roles; to learn about aspects of integration; and to highlight successful and unsuccessful examples of PAs work.

We anticipate that the video(s) produced will be used in a range of ways including: to stimulate discussion in stakeholder and patient engagement (WP 3.3); raising public awareness through posting on a public-facing website; communicating study findings and issues to policy-makers; highlighting important issues in scientific presentations; and in educational settings.

Faces will not be blurred and voices will not be edited. We do not anticipate that the process will be difficult or upsetting. Participants do not need to discuss any information they feel uncomfortable sharing. However, participants would have the opportunity to review the edited videos before they are released. They will also sign a copyright consent form at the start of their participation.

- **Sampling**

Given the busy schedules of PAs, we will limit the duration of the video work to a one or two-day workshop. We will purposively sample 4-8 PAs from two sites to participate in the video work to reflect diversity in terms of gender and roles.

- **Data collection**

In spending a relatively long time with relatively few participants, this participatory approach takes a 'deep' as opposed to a broad qualitative exploration of views of participating PAs, together with findings from WP 3.1. Data for this component will comprise two types:

a) The film footage
b) Observation notes and digital voice recordings: discussions will be digitally recorded throughout the workshop and a research assistant will take detailed notes on the discussions taking place throughout the day. This is likely to include descriptions of how issues were prioritised, how disagreements were resolved and what decisions were made on what to omit from the final video.

Prior to sharing the final video, participants will be asked to approve the video, or decline the use of their contribution, and sign an Oxford University copyright form. When declining their footage will be removed from the video.

In addition to this data, the study team will take notes on specific meetings and events where the video was shown, any reactions and recommendations made in response to the video. Importantly the final video will be used during stakeholder and patient engagement (WP 3.3) and in PPI meetings for the purpose of eliciting responses from participants.

WP 3.3: Collective sensemaking workshops with stakeholders and patient groups

- **Methodology overview**

In addition to the negotiation of roles within Trusts/Health Boards, integration of PAs into the NHS workforce is also determined by regulators, professional associations and public perception of their competence and professional identity. We use the term "collective sensemaking" (49) in line with current discourses in participatory practices and research co-production as a guide to our work. In practice, this would take place in the format of stakeholder workshops and patient-focus group discussions.

- **Sampling**

For stakeholder workshops, we will purposively recruit stakeholders from the General Medical Council, the Faculty of Physician Associates, Health Education England (or its equivalent), the Royal Colleges of Physicians, General Practice, Nursing and the British Medical Association, alongside PA Schools Councils and individual training programmes, Trust/Health Board management and staff representatives. An estimated 8-10 stakeholders per Trusts and Health Boards, 5-6 PA training programme representatives with 10 national stakeholders will be invited.

For patient focus groups, we will leverage NHS Trusts' and Health Boards' patient and public involvement (PPI) structures and recruit participants through purposive and snowball sampling, with efforts to capture a diverse population. We will aim to conduct four focus groups, each containing 4-6 PPI participants. As they are part of existing PPI structures, we consider them as 'healthy' volunteers.

Participant Inclusion

- Participant is aged 18 to 65 years of age.
- Participants has experiences with PPI in one of the eight NHS Trusts' and Health Boards' PPI groups

Participant Exclusion

- Those unable or unwilling to give their informed consent for participation in the study.

- **Data collection**

During the stakeholder engagement workshops, we will deliberately convene regulators, leaders of professional associations, Trust/Health Board managers and staff using the visual material produced to promote reflective engagement with the topic of PAs and their work in secondary care. Our aim is to explore and where possible construct shared understandings on what works well (or does not), for whom, where and how in relation to the development of PA roles, and gain wider forms of feedback as a form of sense-making. This will help us understand and articulate the nature of or challenges with demand for PAs in the face of rapid growth in PA training (supply). We will keep notes during these meetings and may record these meetings to help with note-taking only if the participants consent to this. Recorded meetings will be deleted within 2 weeks of recording.

For collective-sensemaking with patient groups, we will share illustrative descriptions and videos of PA roles to focus group members, and then will gather patients' views and feedback on PAs noting whether they have previously engaged with PAs directly. We anticipate this to be 1-2 hours in total. Participants will be provided with information regarding the study and their participation will be voluntary, with no negative impact on those who choose not to participate or drop-out. Data collected from patient groups will be thematically analysed and fed into stakeholder workshops, which will be conducted separately, so there are "safe spaces" for patient engagement. Similarly, we will keep notes during these meetings and may record these meetings only if the participants consent to this. Recorded meetings will be deleted within 2 weeks of recording.

- **Data analysis**

All meeting recordings will be transcribed and meeting notes will be entered into NVivo. A framework approach will be used to analyse the data (50,51). This will involve: familiarisation with the data through repeated reading of the transcripts; generating codes; and sorting the codes into overarching themes, with the aim of further contributing to a conceptual framework.

8. INFORMED CONSENT

Consent will be sought to participate in the study by researchers with Good Clinical Practice and Good Research Practice training and qualified to conduct informed consent. Each participant must personally sign and date the latest approved version of the Informed Consent Form (ICF) or provide recorded verbal consent before any study-specific procedures are performed. There will be a specific Participant Information Sheet (PIS) and consent form for each participant type.

Printed or online versions of the PIS and ICF will be presented to the participants detailing the exact nature of the study; what it will involve for the participant; and any risks involved in taking part. It will be clearly stated that the participant is free to withdraw from the study at any time for any reason without prejudice to future care, and with no obligation to give the reason for withdrawal.

The participant will be allowed time to consider the information, provided both verbally and within the PIS, and will be given the opportunity to question the Investigator or other independent parties to decide whether they wish to participate in the study. For printed Informed Consent will then be obtained by means of participant dated signature and dated signature of the person who presented and received the Informed Consent in a face-to-face setting, and by the participant clicking the 'agree' button in an online-setting. Verbal consent will be recorded if telephone or online interviews are being conducted. The person who received the consent (a representative from the study research team) will be suitably qualified and experienced, and have been authorised to do so by the Chief Investigator. A copy of the signed ICF will be given to the participant. The original signed form will be retained at the University of Oxford.

Each participant has the right to withdraw from the study at any time. Those who have taken part in individual IDIs may withdraw their consent for their data to be used with regards to the interviews. Due to the dynamic and interactive nature of focus / small group discussions (FGDs), participants who withdraw from the study who have participated in FGDs, will still have their anonymised data used within the analysis. Participants who withdraw from the study will not be replaced due to the dynamic nature of the interviews and FGDs.

9. DATA MANAGEMENT

9.1 Access to Data

Direct access will be granted to authorised representatives from the Sponsor or host institution for monitoring and/or audit of the study to ensure compliance with regulations.

9.2 Data Storage and Management

For WP 1.1, the secondary data will be stored securely on a university server accessible only by the research team.

A database capturing data from WP 1.2 (self-administered questionnaires and DCE) will be developed in Oxford-approved survey software such as REDCap or JISC. The online questionnaire will directly be captured in REDCap or JISC and the participants can opt-in to participate in the study after reading the participant information sheet and consent explanation sheet on the first page of the online survey. Data from these questionnaires will be collated on a central server maintained by the University of Oxford after being de-identified and encrypted for transmission over the Internet. The information generated from the questionnaire survey that includes personal identifying data (PID) will be kept confidential. No record which contains personal identifying information will be shared or published. The questionnaires will only be identifiable through unique Study Identification Numbers (SID) which will be linked with participants' phone numbers and email addresses (only if the participants agree to provide these information). SIDs will be stored separately from the research data in an encrypted password-protected laptop and a university server accessible only by the research team.

Qualitative data from WP 3 will be collected in the form of audio files from interviews, group discussions and workshops. Audio files will be transcribed verbatim. These files will then be kept securely on a university server accessible only by the research team. All transcriptions will be de-identified by removing any details or names or addresses and given pseudonyms so that they can easily be discussed between specified team members whilst protecting participants' identities. Recordings will be encrypted using 7-zip and safely transferred via approved university file-sharing services like Filr, Onedrive or Teams to be transcribed by Oxford-approved professional transcribers on the InfoSec third-party register and with whom we have a consultancy contract and confidentiality agreement in place, or Oxford-approved digital transcribing software, are University approved and fully compliant with GDPR.

Once the transcription has been received by the research team, and checked against the audio recording, this recording will be permanently deleted from the secure server. Transcripts of interview data (saved with a SID) will be kept for five years from publication or public release of the work. We will use Nvivo to organise the data. Underlying data will be stored in password-protected files with strong participant identifiers kept separately from the rest of the data.

Similarly for WP 3.2, the footage for participatory videos will be stored securely on a university server accessible only by the research team. The final video approved by study participants will be released publicly.

10. QUALITY ASSURANCE PROCEDURES

The study may be monitored, or audited in accordance with the current approved protocol, relevant regulations and standard operating procedures.

11. ETHICAL AND REGULATORY CONSIDERATIONS

There will be no physical risk to the participants. In order to fully appreciate the experiences of PAs and/or working with PAs, it will be necessary to explore their views, thoughts and feelings. There is a

potential for the participants to disclose information that they may find upsetting or distressing, perhaps most likely in interviews or focus groups. The research team will be fully trained in how to address this should it happen and offer to terminate discussions if the participant prefers. The other burden to the participants is time. All interviews and focus group discussions will be scheduled at a convenient time for participants.

All data recorded will be held in the strictest confidence and any output will be anonymised, with the exception of participatory video which will be publicly facing and discussed below under 10.4.

If the researchers observe, or are told about any practice that they may be concerned about this would be raised immediately with the lead investigator. Where necessary the External Advisory Committee will be consulted to seek guidance on how to proceed. If the information is considered to be concerning, then this would be addressed by contacting a relevant contact (Principal Investigator) at the relevant Trust or Health Board and discussing it with them. In the unlikely event of situations that may be of a more serious nature, then the relevant authorities would be notified, e.g. the GMC, police or social services. Participants can also contact the University of Oxford Research Governance, Ethics & Assurance Team (RGEA) office on 01865 616480 or the director of RGEA at RGEA.complaints@admin.ox.ac.uk.

11.1 Declaration of Helsinki

The Investigator will ensure that this study is conducted in accordance with the principles of the Declaration of Helsinki.

11.2 Approvals

Following Sponsor approval, the protocol, informed consent form, Participant Information Sheets will be submitted to an appropriate Research Ethics Committee (REC), HRA, and each of the host institutions for written approval. The Investigator will submit and, where necessary, obtain approval from the above parties for all substantial amendments to the original approved documents.

11.3 Other Ethical Considerations

Ethical considerations for participatory videos

Appearing in a public-facing video can have risks as well as benefits. On one hand, video presents a powerful means of sharing experiences and views to a range of groups, whilst on the other, expressing sensitive views can have consequences for future participant working relationships. Care will be taken to ensure that risks are minimized by protecting the identity of participants where deemed important. After being explained the scope, purpose and potential risks and benefits of the video work, participants will be invited to sign a consent form. To a large extent the content of the video will be regulated by the participants through the 'group edit,' for example if participants are uncomfortable with a clip, they can suggest edits. Prior to sharing the final video, participants will be asked to approve the video, or decline use of their contribution, and sign an Oxford University copyright form.

11.4 Reporting

The CI shall submit once a year throughout the study, or on request, an Annual Progress report to the REC Committee, HRA (where required), host organisation and Sponsor. In addition, an End-of-Study notification and final report will be submitted to the same parties.

11.5 Participant Confidentiality

The study will comply with the UK General Data Protection Regulation (GDPR) and Data Protection Act 2018, which require data to be de-identified as soon as it is practical to do so. The processing of the personal data of participants will be minimised by making use of a unique participant study number only on all study documents and any electronic database(s). All documents will be stored securely and only accessible by study staff and authorised personnel. The study staff will safeguard the privacy of participants' personal data.

11.6 Expenses and Benefits

Participation in WP 1.2 survey, longitudinal cohort and discrete choice experiment participants is completely voluntary and will not lead to direct benefits to the individuals.

For WP 3.1 to 3.3, i.e. semi-structured interviews, focus group discussions, participatory videos and stakeholder and patient collective-sensemaking participants, reasonable travel expenses for any visits will be reimbursed on production of receipts, or a mileage allowance provided as appropriate.

12. FINANCE AND INSURANCE

12.1 Funding

This study is funded by the National Institute for Health and Care Research (NIHR), Health and Social Care Delivery Research (HSDR) Programme (NIHR153324). The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.

12.2 Insurance

The University has a specialist insurance policy in place which would operate in the event of any participant suffering harm as a result of their involvement in the research (Newline Underwriting Management Ltd, at Lloyd's of London).

12.3 Contractual arrangements

Appropriate contractual arrangements will be put in place with all third parties.

13. PUBLICATION POLICY

The Investigators will be involved in reviewing drafts of the manuscripts, abstracts, press releases and any other publications arising from the study. Authors will acknowledge that the study was funded by National Institute for Health and Care Research Health and Social Care Delivery Research (HSDR) Programme. Authorship will be determined in accordance with the ICMJE guidelines and other contributors will be acknowledged.

14. ARCHIVING

Data from the study will be collated on a central server maintained by the University of Oxford after being de-identified and encrypted for transmission over the internet. The information that includes

personal identifying data (PID) will be kept confidential. No record which contains personal identifying information will be shared or published. We will keep identifiable information for 3 years after the study has finished, and we will keep other data for five years from publication or public release of the work. Other research documents with personal information, such as consent forms, which will be held securely at the University of Oxford for 5 years after the end of the study. If consent forms or other personal details will be archived at each host institution, this may be as per 5 years or as per the organisation's policy.

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APPENDIX A: AMENDMENT HISTORY

Amendment No.	Protocol Version No.	Date issued	Author(s) of changes	Details of Changes made

List details of all protocol amendments here whenever a new version of the protocol is produced. This is not necessary prior to initial REC submission.

Protocol amendments must be submitted to the Sponsor for approval prior to submission to the REC committee, and HRA (where required).