FULL/LONG TITLE OF THE STUDY

A Realist Evaluation of Paramedics Working in General Practice: Work Package 2: An assessment of clinical and cost effectiveness (READY Paramedics)

SHORT STUDY TITLE / ACRONYM

Realist Evaluation: Paramedics in general practice: (READY)

PROTOCOL VERSION NUMBER AND DATE

Protocol version tracker

V1.0 (20-09-2021)	Realist Evaluation: Paramedics in general practice: (READY) Work Package 2 Protocol
V2.0 (01-12-21)	Realist Evaluation: Paramedics in general practice: (READY) Work Package 2 Protocol Amended following REC Review 16-11-2021
V3.0 (01-03-22)	Participant 'thank you voucher' information added to sections: 7.3.1 and 7.3.2
V4.0 (27-09-22)	General Practice Staff and Commissioner Interview Participants 'thank you' voucher information added to sections: 7.3.1 and 7.3.2
V5.0 (21-11-22)	To add 12 additional case study sites to give a maximum of 36 To invite 8 core case study sites to conduct anonymised data extraction query To extend recruitment period from 31 December 2022 to 28 February 2023. Gantt chart revised accordingly. information added as Appendix 3 Updating named Research staff

RESEARCH REFERENCE NUMBERS

IRAS Number:	279490
SPONSORS Number	PIMS Project ID: 6424053
FUNDERS Number:	NIHR132736

SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor's SOPs, and other regulatory requirement.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor

I also confirm that I will make the findings of the study publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

For and on behalf of the Study Sponsor:

Signature: Date:

..../...../.....

Name (please print):

.....

Position:

.....

Chief Investigators:

Signature: Date:

..../...../.....

Name: (please print):

.....

Signature: Date:

..../...../.....

Name: (please print):

.....

LIST of CONTENTS

KEY STUDY CONTACTS

Chief Investigators	Dr Sarah Voss Associate Professor in Emergency Care Centre for Health and Clinical Research The University of the West of England Bristol Glenside Campus (1H14) Blackberry Hill, Bristol, BS16 1DD e. sarah.voss@uwe.ac.uk t. 0117 328 8906 Dr Matthew Booker GP & NIHR Clinical Lecturer in Primary Care (Urgent Care) Centre for Academic Primary Care University of Bristol Canynge Hall (1.07) 39 Whatley Road, Bristol, BS8 2PS e. matthew.booker@uhbristol.nhs.uk t. 0117 928 7305
Sponsor representative	Professor Olena Doran Associate Dean (Research) Faculty of Health and Applied Sciences University of the West of England Bristol Bristol, BS16 1QY e. olena.doran@uwe.ac.uk t. 0117 328 1670
Host representative	Mr Paul Roy Research, Innovation and Contracts Manager Bristol, North Somerset and South Gloucestershire CCG South Plaza, Marlborough Street, Bristol, BS1 3NX e. paul.roy@nhs.net t. 0117 984 1673
Funder representative	Alan Marshall Research Administrator Southampton NETSCC NIHR Evaluation, Trials and Studies Coordinating Centre (NETSCC) e. alan.marshall@nihr.ac.uk
Co-applicants	Professor Jonathan Benger Professor Sarah Purdy Professor Nicki Walsh Professor William Hollingworth

	Dr Justin Jagosh Hazel Taylor Dr Behnaz Schofield Dr Helen Baxter Dr Andy Gibson Alyesha Proctor
Collaborators	Kim Kirby Dave Coates Sarah Todd
Research staff	Trudy Goodenough Hannah Stott (1.6.21 to 30.09.22) Nicky Harris Grace Scrimgeour

STUDY SUMMARY

Study title	A Realist Evaluation of Paramedics Working in General Practice: An assessment of clinical and cost effectiveness (READY Paramedics)
Short title	Realist Evaluation: Paramedics in general practice: (READY)
Study design	Realist evaluation of the clinical and cost effectiveness of paramedics working in general practice
Study participants	Providers of paramedics working in general practice (PGP) service; key stakeholders who influence or are influenced by PGP, including providers, commissioners, patients, clinicians, practice staff.
Planned study period	2 years
Research questions/aims	To evaluate the role of paramedics in general practice (PGP) and provide evidence about different service delivery models to determine their ability to: • Achieve good clinical outcomes for patients • Provide safe patient care • Improve patient experience • Relieve GP workload pressure • Influence the workload of other general practice staff • Make efficient use of healthcare resources

FUNDING AND SUPPORT

Funder	This project is funded by the National Institute for Health Research (NIHR) Health Service and Research Delivery Programme (NIHR132736). The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.
Financial and non-financial support given	£597,737
Host	NHS Bristol North Somerset and South Gloucestershire (BNSSG) Clinical Commissioning Group (CCG)

STUDY STEERING COMMITTEE

Name	Role	Institution
Professor Katherine Checkland	Chair	The University of Manchester
Ms Sarah Blake	Public Contributor	Independent
Dr Joanna Charles	Health economics	Bangor University
Dr Rob Goodwin	Methodology	University of Nottingham
Dr Graham McClellend	Paramedic	North East Ambulance Service NHS Foundation Trust
Dr Kara Stevens	Medical statistics	University of Plymouth
Ms Adele Webb	Public Contributor	Independent

ROLE OF STUDY SPONSOR AND FUNDER

The sponsor takes primary responsibility for ensuring that the design of the study meets appropriate standards and that arrangements are in place to ensure appropriate conduct and reporting. The sponsor will ensure that: all necessary approvals from an NHS research ethics committee are obtained before undertaking or permitting another party to undertake any part of the project which requires ethics committee and/or R&D approval; each participating site obtains properly signed ethically approved informed consent and acknowledgement forms from any participants or their legal guardians who will be involved in the project or who will be suppliers of material used in the project; each participating site shall conduct the project in accordance with the approved protocol and all relevant laws.

The funder reserves the right to have access to and to use data compiled during the course of the Research and will respect existing guidance on confidentiality of any data which it obtains. The sponsor shall, at the request of the funder, deposit both qualitative and quantitative data in a relevant data archive subject to any reasonable delay necessary to enable the protection or exploitation of foreground IP.

ROLES AND RESPONSIBILITIES OF STUDY MANAGEMENT COMMITTEES/GROUPS & INDIVIDUALS

Study Management Group

The study will be managed by a study management group (SMG), which will meet, in person or by teleconference, approximately monthly. The SMG will be chaired by the chief investigators and will include all co-applicants, collaborators and research staff.

Study Steering Group

The Study Steering Committee will provide oversight of the entire study.. They will meet approximately every 6 months or more often if required.

KEY WORDS

primary health care; general practice; emergency medical services; health services; Allied Health Personnel

GANTT CHART

Updated 21.11.22

		Year 1												Year 2											
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24
		J-21	J-21	A-21	S-21	O-21	N-21	D-21	J-22	F-22	M-22	A-22	M-22	J-22	J-22	A-22	S-22	O-22	N-22	D-22	J-23	F-23	M-23	A-23	M-23
Set up	**4 Months (Feb 21 to May 21)**																								
	Staff recruitment																								
	Protocol development																								
	HRA & Ethics																								
	Convene SSC																								
WP1	**Rapid Realist Review**																								
	Searches																								
	Data extraction																								
	Interviews																								
	Data synthesis																								
	Consensus events																								
	Programme theories																								
WP2	**Realist evaluation of sites**																								
	Identify and approach sites																								
	Set up sites																								
	Data collection																								
	Data analysis																								
	Dissemination events																								
	Knowledge mobilisation																								
	Final analysis and reporting																								
	Project oversight																								
	SMG meetings (t/c)																								
	SMG meetings (f2f)																								
	SSC meetings																								
	PPI workshops																								
	RE project days																								
	Workshop (other research teams)																								

STUDY PROTOCOL

A Realist Evaluation of Paramedics Working in General Practice: WP2: An assessment of clinical and cost effectiveness (READY Paramedics)

1 BACKGROUND

General Practice (GP) services are under sustained pressure due to a growing and ageing population and increasing healthcare demand.[1,2] GP consultations are rising by up to 15% annually, and more than 340 million consultations now take place in England annually,[3] costing the NHS £9 billion.[4] There is also an expectation that general practice should increase urgent care access in order to reduce demand on Emergency Departments and other elements of the system.[5] Alongside this increasing workload, GP services face significant workforce pressures. Despite government ambitions to increase the overall number of GPs there has been a reduction in the past decade.[6] This means there is a shortage of GPs to meet rising demand; nearly 450 practices have closed in the last 5 years due to recruitment challenges and a lack of funding, affecting over a million patients.[7]

General practice is increasingly turning to other staff to address medical shortages. The NHS England GP Forward View (GPFV) proposes greater development of the multi-disciplinary, integrated workforce, capitalising upon the value that allied healthcare professionals (AHPs) can bring to support front-line service delivery.[5] Following this, the NHS Long Term plan announced funding for 20,000 more AHPs and clinical support staff over the next 5 years, with the intention that more patient care should be delivered by non-GPs.[8] The GPFV specifically highlights the skills of paramedics, and suggests that general practice should look to make greater use of this professional group. To support this, legislation for paramedic prescribing was enacted in April 2018. Examples of perceived benefit include the management of minor illness, home visits and the provision of same-day 'urgent' consultations. There is also a growing interest in rotational models of workforce development; paramedics move between different clinical settings in the ambulance service and general practice. These models are designed to address both the career aspirations of paramedics and workforce issues.[9] Various initiatives involving paramedics in general practice are being developed, yet there is a lack of research to guide implementation. Providing evidence on the safety and effectiveness of this model of service delivery is therefore of paramount importance.

Our research team has carried out a comprehensive review of the literature.[10] Currently available evidence advocates for paramedics working in primary care but fails to provide sufficient detail regarding their clinical contribution.[11] A small qualitative study carried out by one of our co-applicant team explored patients' views of paramedics carrying out home visits for older people. This found that views are generally positive but dependent on the reason for the visit.[12] To date, there is no systematic review on the safety, clinical or cost effectiveness of paramedics working in general practice and the evidence base is weak. Much of the literature focuses on which extended skills may be needed by paramedics to work autonomously or safely in general practice and other community settings.[13-16] This research is largely descriptive and there are many assumptions, such as paramedics reducing GP workload and costs, which have not been tested empirically.

Whilst not investigating paramedics specifically, a recent systematic review examined economic evaluations of nurses, pharmacists and other AHPs working as substitutes for GPs. The authors

emphasise the importance of measuring consultation length and accurately recording patients' subsequent healthcare use to improve the quality of future economic evaluations. Based on currently available evidence, they concluded that there is limited economic evidence for role substitution in general practice, and that more evaluations are needed.[17]

As a result of systematically searching the literature, trial registries and the NIHR portfolio during our preparatory work [10] and through our professional networks in the field, we have identified other planned and ongoing related work in this area. The ARRIVE study [18] will use a different methodology and is primarily concerned with comparing home visit outcomes between practice-employed and ambulance service employed paramedics in the Local Health Board footprint areas of Wales; it is likely to generate complementary findings but with a different focus. We propose to examine a variety of employment and working models, aiming to develop an evidence-base applicable to the evolving Primary Care Network (PCN) structure in England, including all consulting modalities (telephone/video consultations, clinic appointments and home visits). We have held several meetings with the ARRIVE team to identify areas where collaboration can be explored, particularly with respect to identifying the different employment arrangements in the present absence of a UK-wide dataset. Having agreed that the studies are mutually beneficial, the two research teams will maintain a constructive and collaborative dialogue and we have scheduled further meetings to ensure connection as our work progresses (including the potential for shared dissemination activities). We are also aware of several PhD projects in the UK and Ireland in related areas and have established constructive links with the students and their supervisory teams. We have had discussions with representatives from Health Education England about current workforce pilots of 'rotational models' and will remain closely connected with their service evaluations. In addition, a formal half day workshop will be held with these collaborators following completion of the realist review in month 7. This will facilitate the relevant research teams in sharing learning and working together with a focus on fair benefit and mutual consultation, with the ultimate aim of directing further research in this area.

2 RATIONALE

We have recently completed a national scoping survey of 165 general practices and paramedics.[10] Findings indicate that the tasks paramedics are undertaking are mostly same day home visits (92%), followed by same day clinics (75%), routine home visits (61%) and telephone triage (43%). A third of respondents also reported that paramedics carry out pre-booked clinics and same day telephone appointments. There is significant variation in reports on the types of condition and patient groups that paramedics are employed to see. This ranges from seeing all patients, to focusing on acute presentations, older patients, or housebound patients. The most common exclusions are infants, pregnant women and patients with mental health needs. Many models integrating paramedics into GP practices have developed in response to local circumstances. Our proposed study aims to capture these innovations and understand how they may inform national policies and guidelines.

This study will also examine the potential unintended consequences of deploying paramedics in general practice. Prior scoping work undertaken by our team included qualitative interviews with staff.[10] Analysis of these data suggests that a number of counter theories may exist alongside the drivers for this workforce initiative. For example, a perceived strength of paramedics is that they have been trained to see undifferentiated patients; on the other hand, some practices exclude specific

patient groups from seeing a paramedic. An additional argument in support of paramedics is that they will 'free up GP time'; however, in some cases the amount of training, supervision and support that is required may negate this advantage in the short term. A further assumption is that paramedics cost less to employ; however, they may need substantially more time than GPs to assess and treat patients and may make different and potentially more expensive management decisions. We will analyse data in the context of these complex and potentially contradictory circumstances using realist evaluation so the findings will inform decisions on the future organisation and delivery of services.

There is currently no reliable way to estimate the number of paramedics employed in general practice; workforce data sets do not capture staff employed in certain ways, for example by secondment or on rotations. However, the policy directive is very clear; in 2019 the NHS Long Term plan announced funding for 20,000 more AHPs and clinical support staff over the next 5 years, with the intention that more patient care should be delivered by non-GPs. In addition, General Practice Workforce data indicates that the number of paramedics working in general practice has more than doubled over the last two years[6], and an update to the GP contract in February 2020 means that community paramedics will be introduced to the 'Additional Roles Reimbursement Scheme' from April 2021.[19] We are therefore confident that this issue will be an area of growing importance for patients, carers and the future of the NHS. We will identify the most efficient ways of deploying paramedics in GP services to address the needs of the NHS and inform the planning and commissioning of future healthcare delivery.

3 THEORETICAL FRAMEWORK

Realist Evaluation (RE) is a theory-driven approach to understanding complex interventions in complex environments.[20] It draws on both constructivist (theory building) and positivist (theory testing) paradigms to offer causal explanations about generative forces that underpin intended and unintended outcomes in a process termed retroduction. RE seeks to understand what works, for whom, in what circumstances, how and why.[21,22] The approach is methodologically robust and systematic and facilitates a clear understanding of the interactions between context and mechanisms that influence the outcomes of interventions. RE has been adopted for this study due to the variation in the provision of paramedics in general practice, and the need to explain how key components (e.g. types of patient seen or mode of consultation) may work in a variety of ways in different contexts (practice sociodemographics).

Our use of realist methodology will allow us to develop and test theories related to the causal impact of contextual factors such as funding structure on PGP-related outcomes; therefore, outputs will be highly relevant to commissioning organisations. More generally, due to the COVID-19 pandemic, the landscape of general practice is changing and will continue to do so between now and the potential start date for this proposed research. This impact is likely to be seen in the NHS more generally, and in the ways that patients interact with general practice. As just one example of this, there has been a marked increase in remote and online consultations. Because the full impacts on patients and the NHS are yet to be understood, the context-sensitive analysis that we will undertake is ideally suited to these circumstances; we will capture and theorise on established as well as emerging PGP models of care in relation to current and future variations in context.

4 RESEARCH QUESTION/AIM(S)

4.1 Aim

To evaluate the role of paramedics in general practice (PGP) and provide evidence about different service delivery models to determine their ability to:

- Achieve good clinical outcomes for patients
- Provide safe patient care
- Improve patient experience
- Relieve GP workload pressure
- Influence the workload of other general practice staff
- Make efficient use of healthcare resources

4.2 Objectives

Work Package 2: Realist Evaluation and case studies
To test the programme theories developed and refined in WP1 (Rapid Realist Review of Paramedics Working in General Practice – separate protocol), using case studies of general practices in England. We will collect qualitative data from patient participants (or their adult carers (individuals) who accompanied the patient participant at their appointment) and general practice health professionals to understand the barriers and facilitators to PGP and the impact it has on access to general practice. We will analyse the implications of differing models of PGP compared to no PGP on healthcare resource utilisation, costs and patient reported outcomes and safety outcomes to assess clinical and cost effectiveness.

Inclusivity:
Throughout this work we will take steps to ensure that every person eligible to take part in this research will be offered the same opportunity regardless of demographics, social and economic factors and health status. We will use guidance from NIHR INCLUDE to identify underserved groups and address potential barriers to inclusion. Research staff will complete mandatory training on equality and diversity provided by UWE Bristol before commencing work on the project and we have commenced a project specific UWE Equality Analysis. We will also ask staff responsible for identifying participants at sites in WP2 to complete training as part of the site set-up. We will include monitoring for equality and diversity in the data collection and inclusivity will be a rolling item on the agenda for Study Management Group meetings.

4.3 Research questions

1. How does PGP care impact on patient clinical outcomes (e.g. unplanned hospital admissions, prescriptions, referrals, tests and investigations)?
2. How does PGP care impact on patient reported outcomes (e.g. concern, confidence in health plan, ability to manage symptoms, health related quality of life) compared to non-PGP care?
3. Does PGP result in patient reported safe management?
4. What are the direct costs/savings associated with PGP care and does it provide good value for money?
5. Does PGP lead to improved patient experience; how and for which patients?

5 STUDY DESIGN and METHODS of DATA COLLECTION AND DATA ANALYIS

5.1 Work Package 2: Mixed methods realist evaluation (case studies) (December 2021-May 2023)

5.1.1 Rationale and aims

A mixed methods, realist evaluation of PGP to identify which models of deployment work for whom, under what circumstances, how and with what resource implications.[21] Quantitative and qualitative data will be collected; quantitative data will focus on context and outcomes and qualitative data on the generative mechanisms. [25] The proposed programme theories will be tested through an iterative process of construction, exploration and refinement in relation to the data collected. Data analysis using CMO configuration will explain how PGP works in different circumstances, by considering: patient clinical outcomes and experience; staff experience; resource use; expenditure and savings; the wider impact on the general practice workforce.

5.1.2 Research questions:

- How does PGP care impact on patient clinical outcomes (e.g. unplanned hospital admissions, prescriptions, referrals, tests and investigations)?
- How does PGP care impact on patient reported outcomes (e.g. concern, confidence in health plan, ability to manage symptoms, health related quality of life) compared to non-PGP care?
- Does PGP result in patient reported safe management?
- What are the direct costs/savings associated with PGP care and does it provide good value for money?
- Does PGP lead to improved patient experience; how and for which patients?
- How and why does PGP affect the workload of GPs and other general practice staff?

5.1.3 Design

We will test the programme theories from WP1 using a series of case studies with sites (general practices) in England. We have opted to geographically contain the research within England due to variation in the organisation and delivery of general practice services across the UK. This will allow us to focus on a single policy environment to keep the range of contexts appropriate for the scope of the project.

General practices will be recruited as either ‘core’ or ‘detailed case study sites’. Data collection at core sites will only include participant completed questionnaires at the time of their baseline (index) appointment and at follow-up, 30 days later. At detailed case study sites, data collection will include, participant completed questionnaires at the time of their initial (index) appointment and at follow-up 30 days later, qualitative interviews with participants and general practice staff, and retrospective patient record data collection.

The PPI group will be involved in writing the ethics applications, refining research instruments, designing patient material and the interpretation of quantitative and qualitative data. This will help to ensure validity from a participant and carer perspective.

5.1.4 Quantitative methods

A full analysis plan will be developed and published prior to commencement. We propose a multi-faceted approach to the quantitative analysis including prospective data collected from individual participants eligible for PGP care and comparison of practice-level variables through retrospective individual patient data from the GP Electronic Health Record (EHR).

For the purposes of these analyses, the index visit is defined as the first eligible visit (e.g. first home visit when comparing PGP-led home visits versus GP-led home visits) during the study period. However, for many patients an individual general practice contact is part of a sustained relationship with a practitioner, and a management plan for long term conditions is built up over time. In the prospective study, we will collect data at baseline detailing the extent to which the relationship with the practitioner is already established and whether the visit is part of an ongoing episode of care. Similarly, in the retrospective analysis we will use routine data to track this. These will be important contextual variables; in our analysis we will assess whether they moderate any impact of PGP-led care on costs and outcomes.

The quantitative component of the study will address, amongst other things, the clinical effectiveness of PGP. Clinical effectiveness will be derived from patient experience, patient preferences and outcomes of care. These domains will be assessed using a combination of patient reported data and data extracted from health care records. This will enable us to provide a detailed account of clinical effectiveness; drawing on information about unplanned hospital admissions, prescriptions, referrals, tests and investigations from medical records and combining it with patient reported outcomes, safety and experience. The evidence produced from the synthesis of this with the cost effectiveness data will provide a comprehensive account of the effectiveness of PGP to inform commissioning decisions.

5.1.4.1 Prospective collection of data

We aim to obtain complete data from 23 adult participants receiving PGP care at each of the case study sites using PGP models. This will provide a sample of approximately 138 participants receiving care from each PGP model (assuming 3 PGP models each used in 6 practices). For each PGP model, we will identify a frequency matched (age, sex, presentation/symptoms) control group from the 6 selected practices that do not offer that model of PGP care.

Eligible participants will be identified and approached by practice staff at each site. We will ensure inclusivity as outlined in section 4.2. We will assess participant experience and outcome of the consultation using the *Primary Care Outcomes Questionnaire (PCOQ[26]), the Patient Reported Experiences and Outcomes of Safety in Primary Care (PREOS-PC[27]), compact version[28] and the EQ5D-5L.[29,30]* Questionnaires will be administered by post, telephone or email (secure data transfer), depending on participant preference; housebound participants will be included where this is a component of a particular PGP model.

The PCOQ measures common outcomes, such as reduction in pain or depression and broader outcomes, such as reduction in concern and a sense of confidence in health plan or an understanding of illnesses/problems and an ability to manage symptoms. It is scored in four domains: Health and wellbeing; health knowledge and self-care; confidence in health provision; confidence in health plan. PCOQ data will be collected on, or immediately after, the day of the index appointment and again 30 days later.

The PREOS-PC has been designed as a tool to comprehensively collect information about patient experience and patient reported safety problems in general practice. It independently assesses five domains of patient safety: practice activation; patient activation; patients' experiences of safety problems; patient safety outcomes (harm); general perceptions of safety. It provides discrimination between different levels of patient-reported safety between practices and is sensitive to change. PREOS-PC data will be collected on, or immediately after, the day of the index appointment and again 30 days later. We have opted to use the compact version after feedback from our public involvement group.

The EQ5D-5L provides a brief measure of general health-related quality of life.[29] The EQ5D-5L descriptive system comprises five dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Responses are mapped to an index score (anchored at 0 [dead] and 1 [full health]) using a valuation set reflecting the preferences of the general population. These index scores are used to calculate *Quality Adjusted Life Years (QALYs)* to compare the effectiveness of PGP care with other healthcare interventions. EQ5D-5L data will be collected on, or immediately after, the day of the index appointment and again 30 days later.

We will also use a customised resource use questionnaire, based on the *ModRUM Core Module* [31], WPAI:GH V2.0 [32] and the Caregiver Indirect and Informal Care Cost Assessment Questionnaire (CIIQ) [33]) sent by email, link to a secure online platform or by post 30 days after the index consultation to assess the use of NHS and social services, time off work/usual activities and informal care. This will be combined with data extracted from the primary care EHR (see below) to identify and measure resources used in the NHS and other sectors.

Sample Size:
Sample sizes of 138 in each of the PGP models and control groups will be obtained by sampling in 6 practices with an average of 23 participants in each practice. This will achieve 90% power to detect a difference between the group means of 0.5 of a standard deviation of the change in PCOQ scores.[34] This assumes an estimated intracluster correlation coefficient (ICC) of 0.02, a coefficient of variation of cluster sizes of 0.65 with a significance level of 0.050 with a two-sided test. To achieve 138 complete datasets per group, assuming a conservative 50% follow-up rate, 276 participants (46 per practice) will be recruited.

5.1.4.2 Retrospective routine data extraction
In preparation for this proposal we have designed, piloted and extracted datasets suitable for our intended analysis, using EMIS Web systems. We have demonstrated that we can use bespoke data queries to rapidly extract information, at individual patient level, on specific events (e.g. patient characteristics, type of consultation, clinician seen, clinical codes for presentation) and outcomes (e.g. length of consultation, medications, referrals, further contacts) that can be compared across PGP models. Practices will be offered the option of using their own staff to run the data query or to request that a member of the research team visits the practice and conducts the query. Only de-identified patient data will be accessed by research team members.
Data will be de-identified at source and transferred to the central research team using secure file transfer. These data queries will be supported by standard operating procedures applied at each case study site. We have included adequate resources for data extraction, cleaning and standardisation,

and members of the study team (MB, WH, SP) have experience of mapping these data extraction protocols across the other primary care Electronic Health Records systems in England [37-39].

We will extract data from the GP EHR at each of the 12 practices for patients eligible for PGP over a period of one year (to capture seasonal variations in demand). The exact eligibility criteria will depend on the models of PGP identified in WP1. For example, in practices that use PGP for home visits, we will identify all home visits during the study period (whether or not the visit was made by a PGP) and a control group of patients with home visits from practices that do not have PGP. We will then extract information on all general practice contacts (including consultation length), tests, medications and referrals during a 30 day (care episode) after the initial home visit (index visit). A 30-day interval has been selected to provide sufficient time to evaluate outcomes directly related to the care received at the index visit. We will use sensitivity analysis with varying intervals (e.g. 60, 90 days) to test the robustness of our findings.

5.1.4.3 Quantitative data analysis

How does PGP care impact on patient clinical outcomes?

We will use descriptive analyses to characterise the workload and type of PGP care provided in each model (e.g. number of episodes; demographics; patients seen). Clinical outcomes from the GP EHR (unplanned hospital admissions, prescriptions, referrals, tests and investigations) and the customised *ModRUM Core Module* (use of primary and secondary care, social services, time off work/usual activities and informal care) will be compared between each PGP model and GP led care using multilevel models which take account of practice level factors (such as practice size, deprivation, urbanity, new registrations, standard mortality weightings) and patient level factors (age, sex, ethnicity, medical acuity, recent attendances, multimorbidity, complexity).

How does PGP care impact on patient reported outcomes compared to non-PGP care?

The PCOQ (patient reported outcomes, concern, confidence in plan, symptom management), PREOS PC (patient reported safety) and EQ5L-5D (health related quality of life) data will be analysed using multi-level models which allow for practice level and patient level factors (as above). Separate multi-level models will be produced for each PGP model, which will compare outcomes with the control group.

What are the direct costs/savings associated with PGP care?

We will value resource use using national unit costs[35] and information on paramedic salaries to estimate the NHS costs of the care episode.

Prospective data analysis: The primary economic analysis will be a broad perspective cost-consequence study [36] whereby incremental costs to the NHS, social services, patients/carers and employers are tabulated alongside differences in key outcomes such as PCOQ domain scores and PREOS PC scores.

In secondary analysis we will also report a narrower cost-utility (cost per QALY) comparison from the NHS perspective which is often used by NICE and others when comparing the cost-effectiveness of healthcare across different areas of the NHS. We have chosen a cost consequence analysis as our primary analysis as the EQ5D-5L may not be sensitive to important potential effects of PGP care on patient confidence in the health plan or ability to manage symptoms. Cost comparisons will use regression (e.g. GLM) techniques appropriate for non-negative potential skewed cost data with

covariates indicating PGP practice (Y/N); other practice level variables (e.g. practice size, deprivation, rurality, practice staff composition); and patient level variables (e.g. age, sex, presentation, number and type of comorbidities, number of current medications, number of QoF (Quality and outcomes Framework) registers the patient is on) to estimate incremental costs and associated 95% confidence intervals. In the secondary economic analysis, we will estimate the cost per QALY gained of PGP care at 30 days. Based on the current NICE willingness to pay thresholds for a QALY of £20,000-£30,000 we will use net benefit regressions, adjusting for baseline EQ5D-5L scores and baseline practice and patient characteristics to estimate the incremental net benefit (and 95% CIs) and determine whether PGP care is cost-effective. Uncertainty will be explored using cost effectiveness acceptability curves to estimate the probability that PGP care is cost-effective. Separate analyses will be performed for each model of PGP care compared to no PGP care.

Retrospective data analysis: The analysis of routine data will provide detailed information on the process of care for a large cohort of patients who received or were potentially eligible to receive PGP care at a relatively low research cost. It will allow us to assess the wider impact of PGP care on GP workload and provide richer information on exactly how PGP care is being used between and within each model. We will record resource use during the care episode including: PGP, GP and other primary care contacts; duration and mode of contact (e.g. telephone, home, surgery); prescriptions; referrals; tests and investigations; and hospital admissions. We will conduct a cost analysis from the NHS perspective to compare the incremental costs/savings of care episodes in practices with and without PGP home visits.[37] Cost comparisons will use regression (e.g. GLM) techniques appropriate for non-negative potential skewed cost data with covariates indicating PGP model; other practice level variables; and patient level variables to estimate incremental costs and associated 95% confidence intervals.

Using this multi-faceted approach to quantitative analysis and triangulating these findings with the qualitative findings on (for example) the need for GPs to supervise PGP work, we will construct a comprehensive evaluation of the impact of different models of PGP care on individual and system-wide costs and outcomes.

5.1.5 Realist qualitative enquiry

Semi-structured realist interviews will be conducted with patient participants (or their adult carers (individuals) who accompanied the patient participant at their appointment), paramedics, general practice staff and commissioners. Topic guides will be based on the research questions and the CMO programme theories and developed with PPI input. They will be designed to elicit information about how PGP and non-PGP models work, for whom and under which circumstances. The focus of the interview data is to understand the mechanisms through which the intervention, in a given context, results in intended and unintended outcomes.

5.1.5.1 Qualitative sampling

We will conduct 12-15 interviews at each detailed case study site: Patient Participant/carer (n=4-6); GP (n=2); paramedic (n=1-2); practice nurse (n=1-2); reception staff (n=1); practice manager (n=1); local commissioner (n=1). We will ensure inclusivity as outlined in section 4.2.

The sample selection for the qualitative (interview) component has been determined following a careful consideration of the potential qualitative information power available from realist interviews. Whilst this may seem like a large number of qualitative interviews, the variety of perspectives is a key

element of the realist design and is necessary to robustly test the study's programme theories. One of the benefits of the realist approach is that it does not seek thematic saturation, and interviews can be scaled or focussed around quite specific areas as theories evolve. The sample size (and composition) has been refined by detailed review of feedback from realist evaluation experts, the NIHR HS&DR panel who have funded this evaluation, and our study steering committee. Our analysis plan ensures that a meaningful analysis of these interviews is both feasible within the allotted time and necessary to the study aims and objectives.

5.1.5.2 Qualitative methods

Realist qualitative interview techniques will be used [23,24] to test and refine the programme theories with key stakeholders. Members of the study team have established a process for conducting interviews remotely; this approach will be adopted if government restrictions on social contact are in place. Topic guides will be customised according to the specific PGP model being investigated; for example, in sites where paramedics undertake telephone triage, interviews will include questions about this process. Given the consultation restrictions resulting from COVID-19, we anticipate that remote consultations will impact on service delivery and will include this in our investigation. We will also consider issues such as supervision time which cannot be assessed using routinely collected data. Interviews will investigate the acceptability of the substitution of GP with a paramedic. All interviews will be audio-recorded and transcribed verbatim.

5.1.5.3 Qualitative analysis

Interview transcripts will be imported into NVivo 12 for analysis. Two researchers will independently review transcripts, and a sample (20%) will be double coded to ensure consistency in interpretation and coding allocation. Data will be analysed in relation to programme theories, and evidence gathered that either confirms or refutes these statements. Analysis may identify new and emerging theories that were not explicit in the realist synthesis and consensus exercise (WP1); these theories will be reported. We will run a PPI workshop to involve contributors in this analysis.

5.1.6 Data synthesis:

Qualitative and quantitative findings will be triangulated to produce a comprehensive evaluation of the impact of different models of PGP care on individual and system wide costs and outcomes. We have included study sites that do not have PGP, as well as different models of PGP. This will allow us to test the programme theories that will be developed during WP2 against negative case examples. We will be able to investigate if differences in effectiveness can be attributed to PGP or whether they can be accounted for by other factors. PPI members will be fully involved in synthesising the quantitative and qualitative data and in developing our participant facing dissemination strategy.

6 STUDY SETTING

Study Setting

We will recruit a total of 24 general practice case study sites in England. Up to 12 sites will be detailed case study sites where we will collect qualitative data and both retrospective and prospective quantitative data. We will approach and interview a key informant from each site about the main features of the model that has been implemented. We will use this data to determine, in consultation with the Study Steering Committee, a subset of sites that reflect the maximum variation in each

model identified. We will also develop a sampling strategy for each site, based on our experience from previous work. The remaining 12 (or more) sites will be core case study sites where we will collect prospective quantitative data only. The sites for each PGP/no PGP model will be recruited according to a sampling frame which will be confirmed during WP1.

We will recruit case study sites, according to the taxonomy developed during WP1 using a sampling frame to account for practice demographics (further details below).

We will use data collected during preparatory work and WP1 to ensure we sample case study sites that are representative of service models in England and have a geographical spread. We will select sites that do and do not have PGP in operation, and we will also study different models of PGP. Of the 24 sites, we anticipate that 6 sites will have no PGP and a further 18 will cover three common models.[10] This will be confirmed during WP1, however the three models are likely to be based on the types of consultation undertaken by paramedics, e.g., home visits only, clinic based same-day/urgent care only or fully embedded in routine practice.

We will work closely with CRNs to identify and approach suitable sites. Sites approached by the CRN will be offered the opportunity to register interest in participating in a detailed or core case study. Data (geography and socio-demographics) from sites who register will be mapped to the appropriate sampling frame and suitable sites will be contacted and invited to participate. The proposed number of sites has been determined to allow investigation of a sufficient range of case study sites, whilst being feasible within the study timeframe and resources.

The scope and design of the detailed case studies in WP2 will be built in a way that is responsive to the outputs that emerge through WP1. This will be an iterative process and the nature and number of case studies will be adapted accordingly (see table below for an illustrative example). The sampling frame is likely to include components of practice demographics, such as size, urbanity and deprivation index and will be used to ensure variation in the types of practices selected for case studies. It will be applied in a flexible manner depending on the types of model observed. For example, if we find low numbers of a particular model in small sites located in areas with a low deprivation index we will adjust our sampling frame accordingly.

Number of case study sites per model (illustrative for 2, 3 and 5 models)

	Two PGP models			**Three PGP models**			**Five PGP models**		
	Detailed	Core	**Total**	Detailed	Core	**Total**	Detailed	Core	**Total**
No PGP	4	4	**8**	3	3	**6**	2	2	**4**
PGP Model 1	4	4	**8**	3	3	**6**	2	2	**4**
PGP Model 2	4	4	**8**	3	3	**6**	2	2	**4**
PGP Model 3				3	3	**6**	2	2	**4**
PGP Model 4							2	2	**4**
PGP Model 5							2	2	**4**
Total	***12***	***12***	**24**	***12***	***12***	**24**	***12***	***12***	**24**

7 SAMPLE AND RECRUITMENT

7.1 Selection and recruitment of sites

We will recruit general practice case study sites, according to the taxonomy developed during WP1 using a sampling frame to account for practice demographics as described above in Section 6.

We will use data collected during preparatory work and WP1 to ensure we sample case study sites that are representative of service models in England and have a geographical spread. We will select sites that do and do not have PGP in operation, and we will also study different models of PGP. Of the 24 sites, we anticipate that 6 sites will have no PGP and a further 18 will cover three common models.[10] This will be confirmed during WP1, however the three models are likely to be based on the types of consultation undertaken by paramedics, e.g., home visits only, clinic based same-day/urgent care only or fully embedded in routine practice.

We will work closely with CRNs to identify and approach suitable sites. Sites approached by the CRN will be offered the opportunity to register interest in participating in a detailed or core case study. Data (geography and socio-demographics) from sites who register will be mapped to the appropriate sampling frame and suitable sites will be contacted and invited to participate. The proposed number of sites has been determined to allow investigation of a sufficient range of case study sites, whilst being feasible within the study timeframe and resources.

7.1.1 Eligibility Criteria

Case study sites

Twenty-four general practice case study sites will be recruited in total.

Up to 12 sites will be detailed case study sites where we will collect qualitative data from participants and both retrospective and prospective quantitative data. We will approach and interview a key informant from each site about the main features of the model that has been implemented. We will use this data to determine, in consultation with the Study Steering Committee, a subset of sites that reflect the maximum variation in each model identified. We will also develop a sampling strategy for each site, based on our experience from previous work.

The remaining 12 (or more) sites will be core case study sites where we will collect prospective quantitative data only.

The sites for each PGP/no PGP model will be recruited according to a sampling frame which will be confirmed during WP1.

Detailed case study sites (n= up to 12)

Prospective quantitative data

We aim to obtain complete data from 23 adult participants receiving PGP care at each of the case study sites using PGP models. This will provide a sample of approximately 138 participants receiving care from each PGP model (assuming 3 PGP models each used in 6 practices). For each PGP model, we will identify a frequency matched (age, sex, presentation/symptoms) control group from the 6 selected practices that do not offer that model of PGP care.

Eligible participants will be identified and approached by practice reception or administrative staff at each site. We will ensure inclusivity as outlined in section 4.2. We will assess participant experience and outcome of the paramedic consultation using the *Primary Care Outcomes Questionnaire (PCOQ[26]), the Patient Reported Experiences and Outcomes of Safety in Primary Care (PREOS-PC[27]), compact version[28] and the EQ5D-5L.[29,30].*

Questionnaires will be administered by post, telephone, email (secure data transfer) or via a secure online platform, depending on participant preference; housebound participants will be included where this is a component of a particular PGP model.

Retrospective data collection
We will extract data from the GP EHR at each of the 12 practices for patients eligible for PGP over a period of one year (to capture seasonal variations in demand). The exact eligibility criteria will depend on the models of PGP identified in WP1. For example, in practices that use PGP for home visits, we will identify all home visits during the study period (whether or not the visit was made by a PGP) and a control group of patients with home visits from practices that do not have PGP. We will then extract information on all general practice contacts (including consultation length), tests, medications and referrals during a 30 day (care episode) after the initial home visit (index visit). A 30-day interval has been selected to provide sufficient time to evaluate outcomes directly related to the care received at the index visit.

Patient participant qualitative interviews
Between 4-6 patient participants (or their adult carers (individuals) who accompanied the patient participant at their appointment) from each case study site will be invited to take part in a qualitative interview .

General practice staff and commissioner participant qualitative interviews
We will conduct 7-9 interviews at each detailed case study site with the following staff groups: GP (n=2); paramedic (n=1-2); practice nurse (n=1-2); reception staff (n=1); practice manager (n=1); local commissioner (n=1). 1 commissioner from each general practice locality will also be invited to take participate in the qualitative interviews. We will ensure inclusivity as outlined in section 4.2.

Core case study sites

Prospective quantitative data
Eligible participants will be identified and approached by practice staff at each site. We will ensure inclusivity as outlined in section 4.2. We will assess participant experience and outcome of the paramedic consultation using the *Primary Care Outcomes Questionnaire (PCOQ[26]), the Patient Reported Experiences and Outcomes of Safety in Primary Care (PREOS-PC[27]), compact version[28] and the EQ5D-5L.[29].*

We will also use a customised resource use questionnaire, based on the *ModRUM Core Module [31]* sent by email, link to secure online platform or by post 30 days, after the participant's index consultation to assess the use of NHS and social services, time off work/usual activities and informal care.

Questionnaires may be given to participants in person at the time of their appointment by reception/administrative staff at the case study site, sent by post, or via in online secure platform or by email (secure data transfer), depending on participant preference. Questionnaires may be completed by telephone with a member of the study team if requested by the participant or their carer. Housebound participants will be included where this is a component of a particular PGP model.

7.1.2 Inclusion criteria

Participants

- All adults, 16 years and over, with capacity to give informed consent. (Carer support if required)
- Understanding of English language sufficient to take part in an interview or complete a standardised questionnaire with an interpreter or carer if required. Where necessary, translated versions of questionnaires will be available.
- Registered with a general practice in England.

General practice staff participants

- All adults, 18 years and over.
- Staff member within a general practice in England

Commissioners

- Adults, 18 years of age and over
- Commissioner with responsibilities for primary care workforce or urgent care

7.1.3 Exclusion criteria

Participants

- Less than 16 years of age
- Does not have with capacity to give informed consent
- Understanding of English language is insufficient to take part in an interview or complete a standardised questionnaire even with an interpreter/translated version if required.
- Not registered with a general practice in England.

General practice staff participants

- Less than 18 years of age.
- Not a general practice member of staff in England

Commissioners

- Commissioner without relevant experience or responsibilities

7.2 Sampling

7.2.1 Sample Size:

Sample sizes of 138 in each of the PGP models and control groups will be obtained by sampling in 6 practices with an average of 23 participants in each practice. This will achieve 90% power to detect a difference between the group means of 0.5 of a standard deviation of the change in PCOQ scores.[36] This assumes an estimated intracluster correlation coefficient (ICC) of 0.02, a coefficient of variation of cluster sizes of 0.65 with a significance level of 0.050 with a two-sided test. To achieve 138

complete datasets per group, assuming a conservative 50% follow-up rate, 276 participants (46 per practice) will be recruited.

7.2.1.1 Detailed case study sites

Prospective quantitative data

We aim to obtain complete data from 23 adult participants receiving PGP care at each of the case study sites using PGP models. This will provide a sample of approximately 138 participants. For each PGP model, we will identify a frequency matched (age, sex, presentation/symptoms) control group from the 6 selected practices that do not offer that model of PGP care.

Qualitative interviews

The sample selection for the qualitative (interview) component has been determined following a careful consideration of the potential qualitative information power available from realist interviews. Whilst this may seem like a large number of qualitative interviews, the variety of perspectives is a key element of the realist design and is necessary to robustly test the study's programme theories. One of the benefits of the realist approach is that it does not seek thematic saturation, and interviews can be scaled or focussed around quite specific areas as theories evolve. The sample size (and composition) has been refined by detailed review of feedback from realist evaluation experts, the NIHR HS&DR panel who have funded this evaluation, and our study steering committee. Our analysis plan ensures that a meaningful analysis of these interviews is both feasible within the allotted time and necessary to the study aims and objectives.

Participant qualitative interviews

Between 4-6 patient participants (or their adult carers (individuals) who accompanied the patient participant at their appointment) from each detailed case study site will be invited to take part in a qualitative interview.

General practice staff participant qualitative Interviews

We will conduct 7-9 interviews at each detailed case study site: GP (n=2); paramedic (n=1-2); practice nurse (n=1-2); reception staff (n=1); practice manager (n=1); local commissioner (n=1).

Retrospective data collection

We will extract data from the GP EHR at each of the 12 practices for patients eligible for PGP over a period of one year (to capture seasonal variations in demand). The exact eligibility criteria will depend on the models of PGP identified in WP1. For example, in practices that use PGP for home visits, we will identify all home visits during the study period (whether or not the visit was made by a PGP) and a control group of patients with home visits from practices that do not have PGP. We will then extract information on all general practice contacts (including consultation length), tests, medications and referrals during a 30 day (care episode) after the initial home visit (index visit). A 30-day interval has been selected to provide sufficient time to evaluate outcomes directly related to the care received at the index visit.

7.2.1.2 Core Case study sites

Prospective quantitative data
At least 12 sites will be identified as core case study sites where we will collect prospective quantitative data only.

7.3 Recruitment

Detailed case study sites

7.3.1 Sample identification

We will work closely with CRNs to identify and approach suitable general practice sites. Sites approached by the CRN will be offered the opportunity to register interest in participating in a detailed or core case study.

Data (geography and socio-demographics) from sites who register will be mapped to the appropriate sampling frame and suitable sites will be contacted and invited to participate. The proposed number of sites (24) has been determined to allow investigation of a sufficient range of case study sites, whilst being feasible within the study timeframe and resources.

Patient participants: Prospective questionnaire data collection
Eligible participants will be approached and provided with written and verbal information about the study by case study site practice reception staff at the time of their initial appointment.
Reception staff will be provided with information to support their role and identification of eligible participants. When a participant is interested in taking part, the reception staff will provide them with a 'Study Pack' containing the Participant Information Sheet, Questionnaire booklet and Consent Form. Also included in the detailed case study site Study Pack will be brief information about the qualitative interviews and study team contact details for further information.
As a thank you for the time spent completing both Questionnaire booklets, we will offer each participant a £10 voucher. This will be sent to each participant once we receive their completed second questionnaire booklet.

Qualitative interviews.
Information about the Interview study will be available to all participants (or their adult carers (individuals) who accompanied the patient participant at their appointment) in the detailed case study sites. For participants who receive the prospective questionnaire data Study Pack, information about the interview will be included in the Study Pack. If the participant or their adult carer (or individual) who accompanied the patient participant to their appointment) is interested in interested in taking part in an interview, they will be directed to contact the study team directly for further information.
To ensure that the interviews are available to all eligible participants, posters and flyers will publicize the interviews at each detailed case study site. Contact details of the study team will be included so that participants who are interested in taking part can easily contact the study team for further information.
As a thank you for the time spent on the interview, we will offer each participant a £10 voucher for taking part.

General practice staff participants
General practice staff participants (GPs, practice nurses, reception staff and paramedics) within detailed case study sites will be invited to take part in the study. In each case study site, we will aim to interview 2 GPs; 1-2 paramedics; 1-2 practice nurses; 1 member of reception staff; 1 practice manager.
As a 'thank you' for the time spent on the interview, we will offer each general practice staff participant a £10 voucher for their participation.

Commissioner interviews
For each GP practice detailed case study site, we will identify and invite the local commissioners with responsibility for managing the primary care workforce to take part in a qualitative interview.
As a 'thank you' for the time spent on the interview, we will offer each commissioner participant a £10 voucher for their participation.

7.3.2 Consent

Quantitative data
Patient participants
Prospective questionnaire data collection
Participants will be approached and provided with written information about the study by case study site practice reception/administrative staff at the time of their initial appointment. Reception staff will be provided with information to support their role and aid identification of eligible participants. If reception team staff are concerned about whether it is appropriate to provide the initial study information to participants, the local site lead (a clinician, the study champion) will be able provide any support required.

Patient participants who indicate that they are interested in taking part, will be provided with a Study Pack containing the Participant Information Sheet, Consent Form and Questionnaire booklet and SAE.

If participants decide to take part, they will have the option of completing and returning the Questionnaire Booklet and Consent Form by post or online. Should participants wish to complete the questionnaires by telephone with a member of the study team, the study team will request that the consent form is returned by email or post prior to telephone questionnaire completion.
As a thank you for the time spent completing both Questionnaire booklets, we will offer each participant a £10 voucher. This will be sent to each participant once we receive their completed second questionnaire booklet.

If participants would like more information about any aspect of the study at any time, they will be able to ask for further information by contacting the study team. Contact details for the study team will be provided in the Participant Information Sheet.

Participants will be provided with a copy of their consent form to keep for their records, copies will also be stored with study documentation at University of the West of England.

Participants will be allocated a study ID; personal identifiable information will be minimized to include only data required for the study. Including contact details as necessary for participants require support to complete the questionnaire by telephone and the administration of the follow up questionnaire booklet (30 days after the participant's initial appointment).

Completed questionnaires will be identified by study ID, and returned to the research team by email, online or by post. Contact information required for administering the second questionnaire booklet will be stored securely until required and then removed.

Retrospective data collection
The retrospective data extraction will involve routinely collected, anonymised patient data. Data will be de-identified at source and transferred to the central research team using secure file transfer. We will not seek consent from participants for this.

Qualitative interviews.
Patient participants
Information about the Interview study will be available to all participants in the detailed case study sites. For participants who receive the prospective questionnaire data Study Pack, information about the interview will be included in the Study Pack. If participants are interested in interested in taking part in an interview, they will be directed to contact the study team for further information.

To ensure that the interviews are available to all eligible participants, posters and flyers will be used to publicise the interviews at each detailed case study site. Contact details of the study team will be included so that participants who are interested in taking part can easily contact the study team for further information.

Once a participant has agreed to take part in an interview, a date, time, and preferred location for the interview will be arranged with a researcher from the study team. Interviews may take place face to face, by telephone or via a secure online platform, depending on the participant's preference and any COVID restrictions in force at the time of the interview. Consent will be obtained before the digital recording of the interview begins. Researchers will sign and date participant Consent Forms and return them to participants for their records.
As a thank you for the time spent on the interview, we will offer each participant a £10 voucher for taking part.

General practice staff and commissioner participant qualitative interviews
Participant Information Sheets will be provided at case study sites for all staff eligible to take part in the qualitative interview: GPs, paramedics; practice nurses and reception staff. There will be the opportunity to speak with the members of the study team to ask questions about the interview before agreeing to take part. Those interested in participating may return a completed 'consent to contact form' direct to the study team online or by post or contact the study team by telephone/email directly to register their interest. Informed consent will be obtained before the interview and confirmed before digital recording of the interview begins. Researchers will sign and date participant Consent Forms and return them to staff participants for their records.
As a thank you for the time spent on the interview, we will offer each general practice staff participant a £10 voucher for their participation.

Commissioners with responsibility for managing the primary care workforce will be approached directly by the study team. Participant Information Sheets will be provided to those interested in taking part in an interview. Commissioners who express an interest in participating will be followed up by the study team, and if they agree to participate, informed consent will be obtained before the interview and confirmed before digital recording of the interview begins. Researchers will sign and date participant Consent Forms and return them to participants for their records.
As a 'thank you' for the time spent on the interview, we will offer each commissioner participant a £10 voucher for their participation.

8 ETHICAL AND REGULATORY CONSIDERATIONS

8.1 Assessment and management of risk

The study involves collecting data from participants through interviews, a consensus meeting and self-completion questionnaires. Data collection will not be undertaken face to face if social distancing measures are in place at the time. All data can be collected remotely if necessary. It is not anticipated that the data collection will pose any risks to the participants. However, if they feel they are in any way unable or unwilling to continue with the interviews, a consensus meeting or self-completion questionnaires and would like their data to be excluded from the study, they are able to stop participation at any time without the need to offer an explanation.

8.2 Research Ethics Committee (REC) and other Regulatory review & reports

All appropriate ethics and governance requirements will be in place in advance of recruiting study sites or participant. All participants will be volunteers and will provide informed consent. Participants will have the right to withdraw at any time until their data is analysed.

Participants will include NHS staff and patient participants and an HRA application to obtain NHS ethics approval will be made. No research activities will begin until all research approvals are obtained.

Regulatory Review & Compliance

Before any site can enrol participants into the study, the Chief Investigators will ensure that appropriate approvals from participating organisations are in place. Specific arrangements on how to gain approval from participating organisations will be obtained and comply with the relevant guidance.

For any amendment to the study, the Chief Investigators, in agreement with the sponsor, will submit information to the appropriate body in order for them to issue approval for the amendment. The Chief Investigator or designee will work with sites (R&D departments at NHS sites as well as the study delivery team) so they can put the necessary arrangements in place to implement the amendment and confirm their support for the study as amended.

Amendments
If the sponsor wishes to make a substantial amendment to the REC application or the supporting documents, the sponsor will submit a valid notice of amendment to the REC for consideration. The REC will provide a response regarding the amendment within 35 days of receipt of the notice. It is the sponsor's responsibility to decide whether an amendment is substantial or non-substantial for the purposes of submission to the REC.

Amendments will also be notified to the national coordinating function of the UK country where the lead NHS R&D office is based and communicated to the participating organisations (R&D office and local research team) departments of participating sites to assess whether the amendment affects the NHS permission for that site. Note that some amendments that may be considered to be non-substantial for the purposes of REC still need to be notified to NHS R&D (e.g. a change to the funding arrangements).

8.3 Peer review
Independent peer review: The protocol has been peer reviewed by the funder (NIHR HS&DR)

8.4 Patient & Public Involvement
Details on how public contributors will be involved in carrying out this research can be found throughout this protocol. A comprehensive public involvement plan for the project is outlined below. We have scheduled five workshops over the duration of the project. In addition, two public contributors will join the Study Steering Committee and participate in meetings.

Public contributors will be involved in writing the ethics applications and refining data collection tools, particularly the interview schedules. Public contributors will also be involved in designing information sheets, consent forms and other participant facing materials. We will run workshops to support public contributor involvement in quantitative and qualitative data interpretation and in the synthesis of the qualitative and quantitative data. We have opted to collect patient data using the Patient Reported Experiences and Outcomes of Safety in Primary Care, compact version after feedback from our public contributors expressed concern about the length of the comprehensive version. We will also follow advice from our public contributors on the most secure ways to collect and store this data. This will help ensure that participants are happy to fill in the questionnaires.

Dissemination
The participant education component of the dissemination strategy will be designed and developed with our public contributors and facilitated by Baxter and Gibson. The group will also be involved in developing the materials for presentation of the research and findings to non-academic audiences and developing appropriate public dissemination strategies.

Support
We believe that effective public involvement needs to be well supported and resourced. Our public involvement work will be supported by staff from both Universities involved in this bid. Our public involvement lead (Gibson) has a wide breadth of experience in public involvement, working with a range of research methodologies and public groups. He is conversant with realist evaluation and involving public contributors in both quantitative and qualitative data interpretation. He will ensure that our public contributors receive appropriate support and training to enable them to fully understand and participate in meaningful discussions about our research methodology and its outcomes. In particular, he will ensure that our public contributors are familiar with the realist

evaluation and data interpretation. To do this he will draw on the resources developed by our local public involvement partnership, People in Health West of England (www.phwe.org.uk), which Gibson leads.

8.5 Protocol compliance

Accidental protocol deviations can happen at any time. They must be adequately documented on the relevant forms and reported to the Chief Investigator and Sponsor immediately.

Deviations from the protocol which are found to frequently recur are not acceptable, will require immediate action and could potentially be classified as a serious breach.

8.6 Data protection and participant confidentiality

The University of the West of England, Bristol (UWE) is the sponsor for this study based in the United Kingdom. UWE will use information from participants in order to undertake this study and will act as the data controller for this study. This means that UWE is responsible for looking after participants' information and using it properly. The University of the West of England, Bristol, will securely erase identifiable information about participants at the conclusion of the study once the final report has been accepted by the funder.

Participants' rights to access, change or move information are limited, as we need to manage their information in specific ways in order for the research to be reliable and accurate. Participants will have the right to withdraw their data up until the point of their data being analysed; this will be made clear on the Participant Information Sheets. To safeguard their rights, we will use the minimum personally-identifiable information possible.

Data storage and access

Data management:

All data will be retained in accordance with University (UWE), University of Bristol (UoB) and Funder (NIHR) policies. In all outputs, reports, publications and other available documents details will be provided of methodology used, analytical and procedural information, definitions of variables, vocabularies, units of measurement, etc so that users are able to make sense of available data. This will be included within above documents, as supplementary data, on our study website, or by other means. Where relevant and permissible, data will be added to the University Research Data Repository.

Data storage and back-up:

Data storage and back up procedures follow University (UWE and UoB) recommended guidance and procedures. All electronic data generated as part of the project will be stored on UWE or UoB OneDrive using password protected, encrypted university computers. All of the immediate study team are University staff and therefore have access to 1TB of OneDrive storage which provides sufficient storage space for study data. OneDrive data can be accessed online through password protected mobile apps and on University issued PCs and/or Laptops. In the event of off-site working or data collection, as per university recommendations, data may be temporarily held on external devices such as pen-drives (USB sticks) and encrypted audio recorders. For safety and security, it will be common practice of the study team that data are uploaded to university systems using a university laptop as soon as possible after collection.

In the case of collection of identifiable research data (e.g. research interviews), audio-recordings will be uploaded to OneDrive immediately and the original recording deleted, before the researcher leaves the external site. If upload is not possible, all files are encrypted, and upload will be undertaken at the earliest possible convenience. The UK Data Service Guidance on data storage will also be consulted for other best practice. Interviews will be recorded on an encrypted device, anonymised and transcribed verbatim. The data will be anonymised using a PIN (Participant Identification Number) generated specifically for this study by the study coordinator.

Hard-copy data will be stored at the University of the West of England in a fireproof, lockable filing cabinet. Consent forms and identifiable information will be stored separately from study data. Hard copies of identifiable information will be destroyed when no longer required by the research team.

In relation to back up and recovery of data in the event of an incident, OneDrive is not backed up as such but it is resilient as it is cloud based, with the basic protection offered by the "restore previous version" functionality.

Study database and data use
The database will be developed by the study team. No confidential personal data that identifies individual participants will be included in this database apart from the unique participant study ID. This will be linked to a separate database, containing data linking the participant study ID, to the relevant confidential personal data which will be held securely by the immediate study team. All qualitative data will be analysed by the immediate study team. All identifying information will be removed from transcripts and replaced with PIN (Participant Identification Number). No confidential personal data that identifies individual participants will be included in any of the qualitative analyses (including analysis performed in databases/Excel/NVivo) apart from the PIN. This will be linked to a separate database containing data linking the PIN to the relevant confidential personal data.

Archiving
Personally identifiable information will be securely erased on completion of the study. De-identified study data will be stored for 5 years after the end of the study. Hard-copy data will be stored at the University of the West of England in a fireproof, lockable filing cabinet. Electronic participant data will be stored in OneDrive on password protected, encrypted university computers.

8.7 Indemnity

This is to clarify the University of the West of England, Bristol (UWE) insurance arrangement for employees and for students working under the supervision of a UWE employee and where the project is included on an authorised UWE research register.

For research which is not deemed a clinical trial (i.e., not on UWE's clinical trials register) UWE's Professional Indemnity policy provides insurance cover for indemnity against legal liability for damages and claimant's costs and expenses arising out of any act, neglect, error or omission (i.e. wrongful advice given in good faith).

UWE's Employers Liability Insurance is in place to protect UWE's employees if they are harmed whilst engaged on UWE business, should UWE be held legally liable.

UWE's Public Liability insurance policy covers legal liability for third party personal injury, death, disease or illness to any person or loss or damage to third party property. Details of the Employers / Public and Professional Indemnity policy covers are attached.

8.8 Access to the final study dataset

The immediate study team (named protocol contributors) will have access to the final study data set. Additionally, de-identified data may be shared as per license agreements and regulations for relevant study outcome measures.

9 DISSEMINATION POLICY

9.1 Dissemination policy

Knowledge mobilisation

Knowledge mobilisation (KM) is the process of sharing knowledge between groups, individuals and organisations and is the key element of preparing a pathway to meaningful impact. The team has a dedicated knowledge mobilisation practitioner (Baxter), with long standing local and national networks and established relationships with clinicians and local and national commissioners. Our preliminary work has allowed a thorough analysis of stakeholders (patients, clinicians, commissioners and service providers) and the mechanisms to engage them in this project. A multi-layered combined KM plan is proposed to overcome the potential barriers to knowledge translation at the individual, organisational and systems levels, with the aim of supporting sustainable change. Three key KM interventions will be implemented from the outset of the study: patient education/use of nudge theory, knowledge brokering within commissioning organisations and a mid-way stakeholder dissemination meeting. Nudge theory will be explored with the PPI group to understand in what ways a 'nudge' might make information more salient or accessible to target audiences at an individual level. For example, the use of certain words, phrases or pictures. The patient education component of the KM strategy will be co-designed and co-developed with the PPI group and facilitated by Baxter and Gibson.

Outputs and dissemination

Target audiences for dissemination, the outputs tailored for each audience and the mechanisms for mobilising knowledge are listed below. However, it is anticipated that knowledge products will be relevant for multiple audiences and knowledge cross transference will be maximised. To evaluate the effectiveness of the knowledge mobilisation strategy, feedback will be sought from stakeholders throughout, and dissemination events will include an evaluation component. Alternative metrics will be explored to capture/evaluate impact.

For study participants

At the end of the study, a summary of the study findings will be sent to each participating general practice, and to individual participants if requested, via post, or email as preferred. The summary and more detailed findings will also be available on the study website. The details of which will be circulated to all of the study participants.

For patients and members of the public

A wide-reaching approach will be used for the general public, using inclusive communication strategies. Knowledge products will be initially developed through the KM patient education work, based on early findings from the study. It is anticipated that this will take the form of tailored materials on a user-friendly website that will be co-produced with the study PPI group. Email lists and Twitter will be used to publicise and encourage active commentary, with the use of existing social media networks to drive traffic to the website. Opportunities will be sought for press releases and guest blogs to established blogs. It will be important to disseminate the findings to communities with lower levels of health literacy, therefore digital stories and animations, video presentations and graphics will be explored with the study PPI group, with a focus on inclusivity.

For commissioners and service providers

We will collaborate with local primary care commissioners and attend commissioning meetings using the mechanisms of knowledge brokering and relationship building. We will also seek opportunities to present our work at relevant commissioning events, including national conferences and through existing links with NHS England. We anticipate that the main knowledge products of most interest to commissioners and service providers will be the taxonomy, which will be communicated via the midway workshop/dissemination meeting. Structured guidance for commissioning will be published from the main study findings and we envisage this will provide a framework for commissioners to identify which features of their local health contexts match most closely to patient and service level outcomes from the various PGP models. The guidance will be co-developed and discussed with local and national commissioners via knowledge brokering and at the final stage dissemination meeting. All developed materials will be made available via the main study website. The barriers to working with commissioners and other policy makers of time, language and differing priorities are well documented in the literature.[40-42] The knowledge mobilisation practitioner is experienced in work in this area and will seek to minimise potential barriers through established relationships and networks.

For general practice teams

Through early engagement with general practice teams as stakeholders we will create opportunities to influence practice at an early stage. We will also present at general practice educational events to share learning and to maximise opportunities to influence decision making. The knowledge products likely to be of most value to general practice teams are the taxonomy which will be shared midway through the study, the website of materials and the structured guidelines. We anticipate similar barriers to knowledge mobilisation as those for policy makers and we will utilise existing relationships and networks to address these.

For academics

Academic outputs will include papers covering the methodological approach, main findings and evaluation, submitted to high impact peer-reviewed journals, such as the BMJ, the British Journal of General Practice and the Emergency Medicine Journal. In addition, we plan to give conference presentations or workshops at the following conferences: Society for Academic Primary Care, Royal College of General Practitioners, Royal College of Emergency Medicine and the College of Paramedics.

Impact

Short term impacts will be achieved through the production of the taxonomy and the early dissemination phase. This is likely to be of greater benefit to commissioners and clinicians who work to shorter timescales. Investment in patient education will facilitate patient involvement and influence from the outset of the study. By demonstrating how different models are more cost effective and safe in different circumstances (for example, depending on the size, rurality or case mix of the GP practice), our outputs will help inform how paramedics' differing levels of training and experience might be suited to different models of working in general practice. The involvement of stakeholders in the conception and throughout the study is intended to facilitate a pathway to impact at an earlier stage with the potential to improve patient safety, patient experience and to inform the local and national commissioning of NHS services. It is anticipated that this will lead to a reduction in demand on the GP workforce and improved workforce configuration in general practice and urgent care services.

9.2 Authorship eligibility guidelines and any intended use of professional writers

Authorship criteria

Authorship credit will be based only on substantial contribution to all the following criteria:

- Conception and design; or the acquisition, analysis or interpretation of data
- Drafting or critically revising the article for important intellectual content
- Final approval of the version to be published
    - Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

The level and order of authorship is the responsibility of the CIs.

10 PROJECT MANAGEMENT

10.1 Day to day management

The project will be managed and co-ordinated across UWE and Bristol University. Qualitative data will be held at UWE while quantitative data will be held and analysed at Bristol University. Shared OneDrive will be used to enable careful monitoring of timelines and returns. The joint CIs (Voss and Booker), Project Manager, Research Fellow and Project Administrator will review progress and address concerns on a weekly basis. Minutes will be maintained to ensure action points are reviewed and addressed regularly. The Project Manager will oversee the process of obtaining research approvals, maintain study documentation and liaise with all recruiting sites. The Project Administrator will send questionnaires and deal with all administrative tasks, with supervision from the Study Manager and CIs as appropriate. The CIs will meet every three months with the host organisation (BNSSG CCG) lead finance officer to review budgets.

10.2 Study Management Group (SMG)

The SMG will consist of the co-applicant team and the project research staff. The SMG will meet monthly by teleconference, or face to face if required. SMG meetings will be chaired by one of the joint CIs who will alternate this responsibility. Agendas and relevant meeting documents will be sent to the SMG for review one week before each meeting. Minutes will be taken and actions documented and completed. The SMG will monitor progress in relation to the project Gantt chart, the study objectives and project

milestones. Any matters arising that are challenging to resolve will be referred to the Study Steering Committee (see below).

10.3 Study Steering Committee (SCC)

We will convene an SSC during the study set-up. This will include an independent Chair, an expert in evaluation, an independent statistician, a health economist, a GP, a paramedic and two PPI representatives. The committee will agree Terms of Reference prior to the initial meeting. They will meet 4-6 times during the study to advise the team, oversee adherence to research governance, and review progress, patient safety and any proposed protocol or ethics amendments. Additional meetings will be arranged should progress issues arise that require wider consultation. Meetings will be preceded by a written report from the CIs on study progress (e.g. milestones reached, recruitment completed).

10.4 Contracting organisation

The joint lead applicants have honorary contracts with NHS Bristol, North Somerset and South Gloucestershire CCG (BNSSG CCG) who will host this research. BNSSG CCG and UWE have a Partnership approach to developing and managing health research, with jointly funded academic and support posts, which are intended to deliver the BNSSG CCG Knowledge Mobilisation Strategy. The Knowledge Mobilisation strategy is a collaborative venture, a partnership between BNSSG CCG with the Centre for Academic Primary Care (CAPC) in the University of Bristol, and the Centre for Health and Clinical Research (CHCR) at the University of the West of England (UWE). The Knowledge Mobilisation strategy is designed to increase both evidence-informed practice and practice-informed research. BNSSG CCG and UWE co-fund a Professor of Knowledge Mobilisation leading this work (Walsh), who is also a co-applicant in this project.

BNSSG CCG have expertise in hosting NIHR grants which are focused on primary care, community care and public health. As a host of NIHR awards, BNSSG CCG is established as the most research active CCG in England. Health research hosted by BNSSG CCG has benefitted study delivery across the country, especially in relation to securing Excess Treatment Costs and coordinated Research Governance support.

BNSSG CCG's membership of Bristol Health Partners (a formal partnership of the local CCG, two universities, the Community Providers, Local Authorities and NHS Trusts), ensures they are well placed to ensure the resulting Intellectual Property is coproduced and disseminated to the consumers (Health Commissioners) effectively to maximise impact and patient benefit. BNSSG CCG will act as the contract holder on behalf of a collaboration of the member practices of the CCG, as well as the Local Authorities and Community Providers within this geographical area.

11 REFERENCES

1. Hobbs FR, Bankhead C, Mukhtar T, Stevens S, Perera-Salazar R, Holt T, et al. Clinical workload in UK primary care: a retrospective analysis of 100 million consultations in England, 2007–14. The Lancet 2016;387(10035):2323-2330.
2. Baird B, Charles A, Honeyman M, Maguire D, Das P. Understanding pressures in general practice. : King's Fund London; 2016.
3. NHS Digital. Appointments in General Practice, October 2018. https://digital.nhs.uk/data-and-information/publications/statistical/appointments-in-general-practice/oct-2018 [Accessed 06-09-2020]
4. NHS Digital. NHS Payments to General Practice - England, 2017/18. 2018; Available at: https://digital.nhs.uk/data-and-information/publications/statistical/nhs-payments-to-general-practice/england-2017-18 [Accessed 04-09-2020].
5. NHS England. General practice forward view. 2016. https://www.england.nhs.uk/wp-content/uploads/2016/04/gpfv.pdf [Accessed 04-09-2020].
6. NHS Digital. General Practice Workforce 30 June 2020. Available at: https://digital.nhs.uk/data-and-information/publications/statistical/general-and-personal-medical-services/30-june-2020 [Accessed 06-09-2020]
7. PULSE. Revealed: 450 GP surgeries have closed in the last five years. 2019; Available at: http://www.pulsetoday.co.uk/news/hot-topics/stop-practice-closures/revealed-450-gp-surgeries-have-closed-in-the-last-five-years/20036793.article [Accessed 04-09-2020].
8. NHS. The NHS long term plan. 2019; Available at: www.longtermplan.nhs.uk [Accessed 04-09-2020].
9. Turner J, Williams J. An Evaluation of early stage development of rotating paramedic model pilot sites. 2018; Available at: https://www.hee.nhs.uk/sites/default/files/documents/Feasability%20Study%20of%20the%20Rotating%20Paramedics%20Pilot%20-%20Final.pdf [Accessed 04-09-2020].
10. Schofield B, Voss S, Proctor A, Benger J, Coates D, Kirby K, et al. Exploring how paramedics are deployed in general practice and the perceived benefits and drawbacks: a mixed-methods scoping study. BJGP open 2020.
11. Eaton G, Wong G, Williams V, Roberts N, Mahtani KR. Contribution of paramedics in primary and urgent care: a systematic review. Br J Gen Pract 2020 May 28;70(695):e421-e426.
12. Proctor A. Home visits from paramedic practitioners in general practice: patient perceptions. Journal of Paramedic Practice 2019;11(3):115-121.
13. Moule P, Clompus S, Lockyer L, Coates D, Ryan K. Preparing non-medical clinicians to deliver GP out-of-hours services: lessons learned from an innovative approach. Education for Primary Care 2018;29(6):376-380.
14. Woollard M. The role of the paramedic practitioner in the UK. Australasian Journal of Paramedicine 2015;4(1).
15. Rasku T, Kaunonen M, Thyer E, Paavilainen E, Joronen K. The core components of Community Paramedicine–integrated care in primary care setting: a scoping review. Scand J Caring Sci 2019.
16. Ball L. Setting the scene for the paramedic in primary care: a review of the literature. Emerg Med J 2005 Dec;22(12):896-900.

17. Anthony BF, Surgey A, Hiscock J, Williams NH, Charles JM. General medical services by non-medical health professionals: a systematic quantitative review of economic evaluations in primary care. Br J Gen Pract 2019 May;69(682):e304-e313.
18. Jones J, Kingston M, Driscoll T, Edwards A, Evans B, Hussain A, et al. ARRIVE: Ambulance paramedics Responding to urgent patient Requests In general practice for home Visits—Evaluation development. British Journal of General Practice 2019;69(suppl 1):bjgp19X702845.
19. British Medical Association. GP Contract Agreement England 2020/21 https://www.bma.org.uk/collective-voice/committees/general-practitioners-committee/gpc-england/gp-contract-agreement-england-2020-2021 [Accessed 06-09-2020].
20. Pawson R, Tilley N. Realist evaluation.[Online] Available at: http://www.communitymatters.com.au/RE_chapter.pdf [Accessed 06-09-2020].
21. Pawson R. Evidence-based policy: a realist perspective. : Sage; 2006.
22. Pawson R, Tilley N, Tilley N. Realistic evaluation: Sage; 1997.
23. Manzano A. The craft of interviewing in realist evaluation. Evaluation 2016;22(3):342-360.
24. Mukumbang FC, Marchal B, Van Belle S, van Wyk B. Using the realist interview approach to maintain theoretical awareness in realist studies. Qualitative Research 2019:1468794119881985.
25. Marchal B, Van Belle S, Van Olmen J, Hoerée T, Kegels G. Is realist evaluation keeping its promise? A literature review of methodological practice in health systems research. Evaluation 2012;18(2):192-212.
26. Murphy M, Hollinghurst S, Cowlishaw S, Salisbury C. Primary Care Outcomes Questionnaire: psychometric testing of a new instrument. Br J Gen Pract 2018 Jun;68(671):e433-e440.
27. Ricci-Cabello I, Avery AJ, Reeves D, Kadam UT, Valderas JM. Measuring Patient Safety in Primary Care: The Development and Validation of the "Patient Reported Experiences and Outcomes of Safety in Primary Care" (PREOS-PC). Ann Fam Med 2016 May;14(3):253-261.
28. Oxford University Innovation Limited. PREOS-PC Compact (2018) https://innovation.ox.ac.uk/wp-content/uploads/2018/07/PREOS-PC-27-item-version-SAMPLE.pdf [Accessed 06-09-2020]
29. Herdman M, Gudex C, Lloyd A, Janssen M, Kind P, Parkin D, et al. Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L). Quality of life research 2011;20(10):1727-1736.
30. EuroQol. https://euroqol.org/eq-5d-instruments/eq-5d-5l-about/ [Accessed 06-09-2020]
31. Garfield, K., Husbands, S., Thorn, J.C. *et al.* Development of a brief, generic, modular resource-use measure (ModRUM): cognitive interviews with patients. *BMC Health Serv Res* **21,** 371 (2021). https://doi.org/10.1186/s12913-021-06364-w
32. Home (reillyassociates.net) (last accessed 13SEPT21)
33. Landfeldt E, Zethraeus N, Lindgren P. Standardized Questionnaire for the Measurement, Valuation, and Estimation of Costs of Informal Care Based on the Opportunity Cost and Proxy Good Method. Appl Health Econ Health Policy. 2019 Feb;17(1):15-24. doi: 10.1007/s40258-018-0418-2. PMID: 30105745; PMCID: PMC6346077.
34. Primary Outcomes Questionnaire (PCOQ) User Guide. http://www.bristol.ac.uk/media-library/sites/primaryhealthcare/documents/PCOQShortUserGuide_Oct2016.pdf [Accessed 06-09-2020]

35. Personal Social Services Unit (PSSRU). Unit costs of Health and Social care 2019: https://www.pssru.ac.uk/project-pages/unit-costs/unit-costs-2019/ [Accessed 06-09-2020]
36. Coast J. Is economic evaluation in touch with society's health values? BMJ 2004 Nov 20;329(7476):1233-1236.
37. Busby J, Schroeder K, Woltersdorf W, Sterne JA, Ben-Shlomo Y, Hay A, et al. Temporal growth and geographic variation in the use of laboratory tests by NHS general practices: using routine data to identify research priorities. Br J Gen Pract 2013 Apr;63(609):e256-66.
38. Hollingworth W, Biswas M, Maishman RL, Dayer MJ, McDonagh T, Purdy S, et al. The healthcare costs of heart failure during the last five years of life: a retrospective cohort study. Int J Cardiol 2016;224:132-138.
39. Ozawa M, Brennan PM, Zienius K, Kurian KM, Hollingworth W, Weller D, et al. The usefulness of symptoms alone or combined for general practitioners in considering the diagnosis of a brain tumour: a case-control study using the clinical practice research database (CPRD) (2000-2014). BMJ Open 2019 Aug 30;9(8):e029686-2019-029686.
40. Checkland K, Harrison S, Snow S, Coleman A, McDermott I. Understanding the work done by NHS commissioning managers. Journal of health organization and management 2013.
41. Oliver K, Innvar S, Lorenc T, Woodman J, Thomas J. A systematic review of barriers to and facilitators of the use of evidence by policymakers. BMC health services research 2014;14(1):2.
42. Wye L, Brangan E, Cameron A, Gabbay J, Klein JH, Anthwal R, et al. What do external consultants from private and not-for-profit companies offer healthcare commissioners? A qualitative study of knowledge exchange. BMJ Open 2015 Feb 25;5(2):e006558-2014-006558.

12 APPENDICES

12.1 Appendix 1- Required documentation

List here all the local documentation you require prior to initiating a participating site (e.g. CVs of the research team, Patient Information Sheet (PIS) on headed paper etc.).

12.2 Appendix 2 – Amendment History

Amendment No.	Protocol version no.	Date issued	Author(s) of changes	Details of changes made
ONE	V.2	01-12-21	Sarah Voss Trudy Goodenough	Amendments made in response to REC committee review 16 November 2021. Rewording of references to patient or staff to participant. Clarification of participant recruitment and study participation pathway. Justification for qualitative interviews sample size.
Two	V3.0	01-03-22	Sarah Voss Trudy Goodenough	Addition of information for 'thank you vouchers' offered to patient participants who complete both questionnaires and/or participate in qualitative interviews.
Three	V4.0	27.09.22	Sarah Voss Trudy Goodenough	Addition of information for 'thank you vouchers' offered to GP staff and commissioner participants who participate in qualitative interviews.
Four	V5.0	21.11.22	Sarah Voss Matthew Booker Trudy Goodenough	To add 12 additional case study sites to give a maximum of 36 To invite 8 core case study sites to conduct anonymised data extraction query To extend recruitment period from 31 December 2022 to 28 February

				2023. Gantt chart revised accordingly. information added as Appendix 3 Updating named Research staff Detailed in Appendix 3, page 32

List details of all protocol amendments here whenever a new version of the protocol is produced.

Protocol amendments must be submitted to the Sponsor for approval prior to submission to the REC.

12.3-Appendix 3: Amendment 21.11.22

This Protocol amendment has 3 sections:

1. **Additional sites**

   This section of the protocol amendment applies to the following sections of the Study Protocol:

   SECTION 5: STUDY DESIGN and METHODS of DATA COLLECTION AND DATA ANALYIS

   5.1 Work Package 2: Mixed methods realist evaluation (case studies) (December 2021-May 2023)

   5.1.4 Quantitative methods

   5.1.4.1 Prospective collection of data

   5.1.4.3 Quantitative data analysis

   SECTION 6: STUDY SETTING

   SECTION 7: SAMPLE AND RECRUITMENT

   7.1 Selection and recruitment of sites

   7.1.1 Eligibility Criteria

   7.2.1 Sample size

   7.2.1.1 Detailed case study sites

   7.2.1.2 Core Case study sites

   Amendment summary: To Recruit up to an additional 12 case study sites (general practices), further to the original intended recruitment of 24 general practices in England, bringing the total maximum number of general practices involved to 36.

   Justification: The additional sites are necessary to attain the study recruitment target of 552 patient participants (23 patients per case study site) who complete questionnaire data at baseline and follow up. The recruitment target of 552 participants has been specified by the study statisticians as required for the statistical and health economic analysis of the participant provided quantitative data. We have recently reviewed recruitment across our 24 case study sites and, despite providing a range of support measures to sites, it is unlikely that this recruitment target will be met. Some sites have been recruiting well and could potentially over recruit. However, in discussion with the study statisticians, a more robust analysis would be achieved by opening to more sites rather than over-recruiting at existing sites. We have received many more expressions of interest from general practices than we have been able to accommodate within the 24 site limit, and so this approach will also enable more interested sites to participate, whilst ensuring robustness of our intended analysis.

   What this means for patients and sites: We will recruit up to 12 further general practices as core or detailed sites as defined in our protocol. Core sites are asked to identify 23 patient participants who complete a baseline and 30-day follow-up questionnaire, following an appointment with a practice clinician. Core sites do not include interviews or routine data queries. Detailed sites are asked to identify 23 patient participants as for core sites and additionally include undertaking a routine data query (provided and supported by the research team) and interviews with general practice staff and patients.

2. Addition of patient level 'data query' for core sites.

This section of the protocol amendment applies to the following sections of the Study Protocol:

SECTION 5: STUDY DESIGN and METHODS of DATA COLLECTION AND DATA ANALYIS
5.1 Work Package 2: Mixed methods realist evaluation (case studies) (December 2021-May 2023)

5.1.4 Quantitative methods
5.1.4.2 Retrospective routine data extraction
5.1.4.3 Quantitative data analysis

SECTION 6: STUDY SETTING

SECTION 7: SAMPLE AND RECRUITMENT
7.1 Selection and recruitment of sites
7.1.1 Eligibility Criteria
7.2.1 Sample size
7.2.1.1 Detailed case study sites
7.2.1.2 Core Case study sites

Amendment summary: To invite 8 'core' case study general practice sites to run the same electronic health records data query as is being run at our 12 'detailed' study sites.

Justification: Part of the study protocol includes our 12 'detailed' case study general practice sites running an anonymised data query on the electronic health records system (both EMIS Web or SystmOne systems), to identify consulting patterns and inform the economic analysis between sites with a paramedic and without. This forms the retrospective analysis component of the study. Searches were developed and tested for both EMIS and SystmOne platforms. The extraction of data using EMIS has been completed as planned, but it has not proved possible to capture the same data from SystmOne practices due to the differences in the software architecture, despite significant efforts in search development. Thus, to provide sufficient data for all aspect of the planned statistical analysis of the anonymised patient level data, we would like to invite our 8 EMIS core case study sites (GP practices) to undertake the data extraction in addition to their original research activities.

What this means for patients and sites: Sites currently taking part as 'core' sites will be invited to undertake this additional activity that is taking place at 'detailed' sites. Running the data query at site level has taken 15-30 minutes at each detailed site. This additional data query would be funded within the costings of the study. Each core case study site would be issued with an amended OID outlining the additional research costs that would be payable to them for this work.

3. **Extension of Work Package 2 (WP2) patient completed quantitative data collection period. This change applies to the study flow chart. Gantt Chart Page ix, updated to reflect this change.**

   To provide sufficient time for our additional case study sites to reach their recruitment targets for baseline and follow-up questionnaires as outlined in above, we will extend the data collection period from 31 December 2022 (Study Protocol Vs4 Gantt chart) to 28 February 2023. The resources for this extension for the additional sites will be covered by the existing study service support costs and research costs and agreed with sites when they are recruited into the study.