

# Realist evaluation: Paramedics in general practice (READY)

<b>Submission date</b> 23/02/2022	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 04/04/2022	<b>Overall study status</b> Completed	<input checked="" type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 03/03/2025	<b>Condition category</b> Other	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

General practices are under increasing pressure. There is a shortage of doctors to meet demand so general practices are using other health professionals to undertake some tasks. Paramedics (people trained to give emergency care outside of hospital) are one of the professions being used alongside doctors in general practice. However, we do not know if this is safe for patients or cost effective for the NHS. Research is needed urgently to inform national policy.

The role of paramedics in general practice varies greatly across England. For example, in many cases paramedics are employed to carry out home visits. However, some practices use paramedics for same day clinics or telephone appointments. Some paramedics do not see certain groups of patients (such as babies or pregnant women) whereas in other cases paramedics do see these patients. Due to these differences, it is impossible to simply compare practices that employ paramedics with those that do not to see which patients get a better service and how much it costs.

We are therefore using an approach called 'Realist Evaluation' to look at what works best in different circumstances. Different practices have different problems to solve; one way of using paramedics may work well for one practice but not another. We will look at the effect this variation has on factors such as patient care, safety and experience, staff workload and costs to the NHS.

### Who can participate?

Participants will be general practice managers, people who make funding decisions, doctors, paramedics and patients, or their carers, to ensure that we fully understand the important issues.

### What does the study involve?

Initially we will look at previous research on using paramedics in general practice. We will investigate issues that might be important in understanding what works for patients and staff and how it affects resources like time and money. We will talk to key people such as general practice managers, people who make funding decisions, doctors, paramedics and patients to ensure that we fully understand the important issues. This information will be used to guide a detailed investigation of general practices.

The next stage of the investigation will focus on 24 different practices across England. Practices that represent the different ways that paramedics are being used, and those that do not have

paramedics, will be included. We will include practices that vary in size, geography and other characteristics. In all 24 practices, a sample of patients who have and haven't seen a paramedic will be invited to participate in the study to provide additional detail about their appointment, how they felt about it and what happened after it. In 12 of these practices, patients, doctors, nurses, managers and reception staff will be interviewed. We want to understand why certain models may work better in different situations and for different people. We will also collect information about patients who have seen a paramedic instead of a doctor. We can then investigate any differences in outcomes for patients or in costs to the NHS.

What are the possible benefits and risks of participating?

**Benefits:** There are no direct benefits to participation in the study. The patient questionnaires and our interviews with patients and general practice staff will help us to understand the different ways in which paramedics work in general practice.

**Risks:** Taking part in the evaluation may raise questions for participants (patients, carers and practice staff) about the care provided by their general practice. Opportunities to discuss any matters or issues raised will be made available to patients and practice staff.

Where is the study run from?

University of the West of England (UK)

When is the study starting and how long is it expected to run for?

June 2021 to May 2023

Who is funding the study?

National Institute for Health Research (NIHR) Health Services and Delivery Research (HS&DR) funding programme (UK).

Who is the main contact?

Prof. Sarah Voss, sarah.voss@uwe.ac.uk

### **Study website**

<https://www.bristolhealthpartners.org.uk/reach/current-projects/research-and-service-delivery/realist-evaluation-paramedics-in-general-practice-ready-paramedics/>

## **Contact information**

### **Type(s)**

Principal Investigator

### **Contact name**

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**Type(s)**

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## Additional identifiers

**EudraCT/CTIS number**

Nil known

**IRAS number**

279490

**ClinicalTrials.gov number**

Nil known

**Secondary identifying numbers**

CPMS 50839, NIHR132736, IRAS 279490

## Study information

**Scientific Title**

A realist evaluation of paramedics working in general practice: An assessment of clinical and cost effectiveness

**Acronym**

READY Paramedics

**Study objectives**

The overall aim of this study is to evaluate, using realist evaluation methodology, 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

Realist evaluation is a theory-driven approach to understanding complex interventions in complex environments, seeking to understand what works, for whom, in what circumstances, how and why. 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. Realist evaluation 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).

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Approved 30/12/2021, Yorkshire & The Humber - Bradford Leeds Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ, UK; +44 2071048083; bradfordleeds.rec@hra.nhs.uk), ref: 21/YH/0275

### **Study design**

Observational qualitative realist evaluation

### **Primary study design**

Observational

### **Secondary study design**

Cohort study

### **Study setting(s)**

Community

### **Study type(s)**

Other

### **Participant information sheet**

Not available in web format, please use the contact details to request a patient information sheet.

### **Health condition(s) or problem(s) studied**

Paramedics working in general practice in England

### **Interventions**

This evaluation study is in 2 parts: Work Package 1 and Work Package 2.

Work Package 1 will review previous research on using paramedics in general practice. We will

investigate issues that might be important in understanding what works for patients and staff and how it affects resources like time and money. We will talk to key people such as general practice managers, people who make funding decisions, doctors, paramedics and patients to ensure that we fully understand the important issues. This information will be used to guide a detailed investigation of general practices in Work Package 2.

Work Package 2 will focus on 24 different practices across England. Practices that represent the different ways that paramedics are being used, and those that do not have paramedics, will be included. We will include practices that vary in size, geography and other characteristics. In all the case study sites, we will collect information about patients who have seen a paramedic instead of a doctor so that we can investigate any differences in outcomes for patients or in costs to the NHS. 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 interview patients, doctors, nurses, managers, and reception staff. We want to understand why certain models may work better in different situations and for different people. A sample of patients who have and haven't seen a paramedic will be invited to complete some questionnaires that will provide additional detail about their appointment, how they felt about it and what happened after it.

## **Intervention Type**

Other

## **Primary outcome measure**

1. Patient reported health outcomes are measured using the Primary Care Outcomes Questionnaire (PQOC) at index appointment and 30 days
2. Patient reported experience and safety are measured using the Patient Reported Experiences and Outcomes of Safety in Primary Care (PREOS-PC) compact version at index appointment and 30 days
3. Patient general health-related quality of life is measured using the EQ5D-5L at index appointment and 30 days
4. Patient health resource use is measured using the ModRUM Core Module (WPAI:GH V2.0) and the Caregiver Indirect and Informal Care Cost Assessment Questionnaire (CIIQ) at 30 days
5. Patient and carer experience measured using qualitative interviews at the end of the study
6. Staff experience measured using qualitative interviews at the end of the study

## **Secondary outcome measures**

There are no secondary outcome measures

## **Overall study start date**

01/06/2021

## **Completion date**

31/05/2023

# **Eligibility**

## **Key inclusion criteria**

Work Package 1:

Consensus event (one):

1. Representatives from the Patient and Public Involvement (PPI) group
2. Paramedics
3. GPs

4. Practice managers
5. Other staff involved with PGP
6. Commissioners

#### Work Package 2:

##### Qualitative Interviews:

1. Patient/carers
2. General Practice staff
3. Local clinical commissioners

##### Questionnaires

4. Patient participants (and carers if required) from each case study site

##### Consensus event (two):

5. Representatives from the Patient and Public Involvement (PPI) group
6. Paramedics
7. GPs
8. Practice managers
9. Other staff involved with PGP
10. Commissioners

#### **Participant type(s)**

Mixed

#### **Age group**

Adult

#### **Sex**

Both

#### **Target number of participants**

Planned Sample Size: 732; UK Sample Size: 732

#### **Total final enrolment**

489

#### **Key exclusion criteria**

Quantitative prospective data collection (questionnaires) and qualitative interviews:

1. Participants aged under 16 years.
2. Participants unable to provide informed consent
3. Difficulties with spoken/written English such that participants would be unable to complete questionnaires by phone, email or post, even with support.

#### **Date of first enrolment**

01/01/2022

#### **Date of final enrolment**

28/02/2023

## **Locations**

#### **Countries of recruitment**

United Kingdom

**Study participating centre**

**University of the West of England**

School of Health and Social Wellbeing

Faculty of Health and Applied Sciences

Glenside Campus

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## **Sponsor information**

**Organisation**

University of the West of England

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**Sponsor type**

University/education

**Website**

<http://www.uwe.ac.uk/>

**ROR**

<https://ror.org/02nwg5t34>

## **Funder(s)**

**Funder type**

Government

**Funder Name**

Health Services and Delivery Research Programme

**Alternative Name(s)**

Health Services and Delivery Research (HS&DR) Programme, NIHR Health Services and Delivery Research (HS&DR) Programme, NIHR Health Services and Delivery Research Programme, HS&DR Programme, HS&DR

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

United Kingdom

**Funder Name**

National Institute for Health Research

**Alternative Name(s)**

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

United Kingdom

## Results and Publications

**Publication and dissemination plan**

For patients and members of the public

A wide-reaching approach will be used for the general public including tailored materials on a user-friendly website that will be co-produced with the study PPI group. It is 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. We will also seek opportunities to present our work at relevant commissioning events, including national conferences and through existing links with NHS England.

For general practice teams

Early engagement with general practice teams as stakeholders 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.

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, conference presentations or workshops are planned at the following conferences: Society for Academic Primary Care, Royal College of General Practitioners, Royal College of Emergency Medicine and the College of Paramedics.

Intention to publish date

02/12/2024

Individual participant data (IPD) sharing plan

The current data sharing plans for this study are unknown and will be available at a later date

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol file</a>	Paramedics WP2 version 5	21/11/2022	03/03/2023	No	No
<a href="#">Statistical Analysis Plan</a>	Health Economics Analysis Plan version 1.0	28/02/2023	03/03/2023	No	No
<a href="#">Statistical Analysis Plan</a>	Qualitative Data Analysis Plan version 1	28/02/2023	03/03/2023	No	No
<a href="#">Statistical Analysis Plan</a>	Statistical Analysis Plan version 2	09/02/2023	03/03/2023	No	No
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Results article</a>		28/02/2025	03/03/2025	Yes	No