ISRCTN56909665 https://doi.org/10.1186/ISRCTN56909665

Realist evaluation: Paramedics in general practice (READY)

Submission date
23/02/2022

Recruitment status
No longer recruiting

Registration date
04/04/2022

Overall study status
Completed

Last Edited
03/03/2025

Condition category
Other

[_] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[X] Results
[_] 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 discus 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

Contact information

Type(s)
Principal investigator

Contact name
Prof Sarah Voss

ORCID ID
https://orcid.org/0000-0001-5044-5145

Contact details
Centre for Health and Clinical Research
University of the West of England Bristol
Glenside Campus (1H14)
Blackberry Hill
Bristol
United Kingdom
BS16 1DD
+44 117 328 8906
sarah.voss@uwe.ac.uk

Type(s)
Principal investigator

Contact name
Dr Matthew Booker

ORCID ID
https://orcid.org/0000-0002-6680-9887

Contact details
Centre for Academic Primary Care
Bristol Medical School
University of Bristol
39 Whatley Road
Bristol
United Kingdom
BS8 2PS
+44 117 928 7305
Matthew.Booker@Bristol.ac.uk

Additional identifiers

Integrated Research Application System (IRAS)
279490

Central Portfolio Management System (CPMS)
50839

National Institute for Health and Care Research (NIHR)
132736

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

Primary study design
Observational

Study design
Observational qualitative realist evaluation

Study type(s)
Other

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(s)
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

Key secondary outcome(s)
There are no secondary outcome measures

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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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
Blackberry Hill
Bristol
United Kingdom
BS16 1DD

Sponsor information

Organisation
University of the West of England

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 Programme, Health Services and Delivery Research, Health Services & Delivery Research, 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, The Health and Social Care Delivery Research (HSDR), Health and Social Care Delivery Research (HSDR), 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

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?
Results article		28/02/2025	03/03/2025	Yes	No
HRA research summary			28/06/2023	No	No
Protocol file	Paramedics WP2 version 5	21/11/2022	03/03/2023	No	No
Statistical Analysis Plan	Health Economics Analysis Plan version 1.0	28/02/2023	03/03/2023	No	No
Statistical Analysis Plan	Qualitative Data Analysis Plan version 1	28/02/2023	03/03/2023	No	No
Statistical Analysis Plan	Statistical Analysis Plan version 2	09/02/2023	03/03/2023	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes