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

HEALTH ECONOMICS ANALYSIS PLAN

VERSION 1 (28/02/2023)

Contents

Section 1: HEAP Administrative Information

Title	A Realist Evaluation of Paramedics Working in General Practice: Work Package 2: An assessment of clinical and cost effectiveness (READY Paramedics): Health Economics Analysis Plan (HEAP)
Study registration number; registry	IRAS Number: 279490 SPONSORS Number PIMS Project ID: 6424053
Source of funding	The National Institute for Health Research (NIHR) Health Service and Research Delivery Programme (NIHR132736).
Purpose of HEAP	The purpose of the HEAP is to describe the analysis and reporting procedure intended for the economic analyses to be undertaken. The analysis plan is designed to ensure that there is no conflict with the protocol and associated statistical analysis plan (SAP), and it should be read in conjunction with them.
Study protocol version; date	This document has been written based on information contained in the study protocol version 5.0, dated 21/11/2022. (WP2)
Study Statistical Analysis Plan (SAP) version, date	V2.0 9-2-23
Study HEAP version, date	V1.0 28/02/2023
HEAP revisions	Following approval of the HEAP, any changes to the HEAP will be recorded in Section 7.
Roles and responsibilities	The HEAP was prepared by Dr Nouf Jeynes (Senior Research Associate in Health Economics) and edited by Dr Kirsty Garfield (Research Fellow in Health Economic Evaluation) and Professor Will Hollingworth (Professor of Health Economics). The study health economists (Dr Nouf Jeynes, Dr Kirsty Garfield and Professor Will Hollingworth) are responsible for conducting and reporting the economic evaluation in accordance with the HEAP.

APPROVALS
The following people have reviewed this Health Economics Analysis Plan and agree with the contents.

Role	Name	Signature	Date
Health economist	Dr Nouf Jeynes		
Senior health economist	Dr Kirsty Garfield		
Lead health economist	Professor Will Hollingworth		
Chief investigator & Associate Professor in Emergency Care	Dr Sarah Voss		
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Section 2: Study Introduction & Background

2.1. Study Background and Rationale

General Practice (GP) services are under sustained pressure due to a growing and ageing population and increasing healthcare demand [1, 2] . There is also an expectation that GPs should increase urgent care access in order to reduce demand on Emergency Departments and other elements of the system[3]. GP services are increasingly turning to other staff to address medical shortages, and in line with this, The NHS England GP Forward View (GPFV) specifically highlights the skills of paramedics and suggests that GPs should look to make greater use of this professional group [4]. To support this, legislation for paramedic prescribing was enacted in April 2018. Examples of perceived benefits include the management of minor illnesses, 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 GPs.

READY is a Realist Evaluation (RE) study which will assess the clinical and cost-effectiveness of paramedics working in general practice. RE is a theory-driven approach to understanding complex interventions in complex environments [5]. 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 [6]. 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 practices, and the need to explain how key components (e.g., types of patients seen or mode of consultations) may work in a variety of ways in different contexts (practice sociodemographics).

2.2. Aim of the Study

The aims of the study are to evaluate the role of paramedics in GPs and to provide evidence about different service delivery models to determine their ability to:

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

In addition to the above, the study aims to examine the potential unintended consequences of deploying Paramedics in General Practices (PGP).

2.3. Objectives of the study

Through two Work Packages (WP), the objectives of the study will be measured either qualitatively or both qualitatively and quantitatively as follows:

- *WP1: Rapid realist review and consensus exercise*

A rapid realist review will be conducted to synthesise currently available information, classify models, and produce a set of realist programme theories about how different models work with which resources in different situations. The programme theories will be validated and refined through a series of consensus exercises. Health economic assessment is not part of WP1.

- *WP2: Realist evaluation and case studies*

A realist evaluation, including case studies (general practices), will test the programme theories in England by applying quantitative and qualitative methodologies. Qualitative data will be collected from patients, carers, and health professionals to understand the barriers and facilitators to PGP and the impact it has on access to general practice. Further to this, data will be collected to analyse the implications of different 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 of different models.

2.4. Research questions

This study will answer the following research questions:

1. What different models of PGP are in operation in England? (WP1)
2. What are the crucial mechanisms that underpin effective PGP in different contexts? (WP1)
3. How does PGP care impact on patient clinical outcomes (e.g. unplanned hospital admissions, prescriptions, referrals, tests and investigations)? (WP2)
4. 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? (WP2)
5. Does PGP result in patient reported safe management? (WP2)
6. What are the direct costs/savings associated with PGP care and does it provide good value for money? (WP2)
7. Does PGP lead to improved patient experience; how and for which patients? (WP2)

2.5. Study population

- Prospective study

At GP sites where PGP is used, adult patients using PGP care will be eligible to take part in the study. For each PGP model, in sites where PGP is not used, a control group will be formed, and adult participants will be eligible based upon frequency-matched characteristics (age, sex, presentation/symptoms).

- Retrospective study

Patients who have a first encounter with a GP or PGP at PGP sites and with a GP at non-PGP sites will be eligible for inclusion.

2.6. Intervention and comparators

- Intervention: PGP care models, including multiple configurations, which will be derived from the findings of WP1.
- Control: non-PGP care.

2.7. Study design

- Work package 1 (WP1): Rapid realist review and consensus exercise. Information on the study design of WP1 can be found in the READY protocol.
- Work package 2 (WP2): Realist evaluation and case studies

Programme theories devised in WP1 will be tested using a series of case studies with sites (general practices) in England. 24 case study sites (GPs) will be recruited as either 'core' or 'detailed' case study sites.

- Prospective study

  At core and detailed sites, patients will be recruited to the prospective study and participant-completed questionnaires will be completed at their baseline appointment (index visit) and at follow-up, 30 days later. The target sample size is 552 participants, recruited from 24 practices, with 23 participants per practice taking part.
- Retrospective study and qualitative interviews

  At detailed case study sites only including 8 PGP sites and 2 control sites, data collection, will include retrospective patients' Electronic Medical Record (EMR) data and qualitative interviews with participants and general practice staff. EMR data will be extracted at each of the 10 practices over a period of one year (to capture seasonal variation in demand).

Health economic analyses will be performed separately for patients participating in the prospective and retrospective studies. Conclusions will be made using all available data.

2.8. Study start and end dates

- WP1: 1 June 2021-31 Dec 2021.
- WP2: 1 September 2021-31 March 2023 (data collection is expected to be completed by January 2023 and data analysis by March 2023).

Section 3: Economic Approach

3.1. Aims of economic analyses

- Prospective study

  The primary aim of the economic analysis is to estimate the incremental costs (including NHS, patients/carers, and employers' costs) and differences in key outcomes of PGP care compared to non-PGP care and comparing the programme theories which were developed in the realist evaluation conducted in WP1.

- Retrospective study

  The primary aim is to conduct a cost analysis (including NHS costs) to describe the cost of care episodes in practices with and without PGP and their association with the programme theories developed from WP1.

3.2. Objective of the economic analyses

- Prospective study

  The primary objective is to conduct a cost-consequence study whereby incremental costs to the NHS, social services, patients/carers and employers are tabulated alongside differences in key outcomes such as the Primary Care Outcomes Questionnaire (PCOQ) domain scores [7] and the Patient Reported Experiences and Outcomes of Safety in Primary Care (PREOS) PC scores [8]. The secondary objective is to conduct a cost-utility analysis (cost per QALY) from the NHS perspective.

- Retrospective study

  The primary objective is to conduct a cost-analysis from the NHS perspective to describe the cost of care episodes in practices with and without PGP and their association with the programme theories developed from WP1. A further objective of the retrospective study is 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 (defined from WP1).

3.3. Overview of economic analysis

- Prospective study

  The primary analysis is a cost-consequence analysis 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, over 30 days following index appointment. A cost-consequence analysis is the primary analysis, as using the EQ-5D-5L in a cost-utility analysis may not be sensitive to important potential effects of PGP care on patient confidence in the health plan or ability to manage symptoms.

In a secondary analysis, a narrower cost-utility (cost per QALY) comparison from the NHS perspective will be reported, which is often used by NICE and others when comparing the cost-effectiveness of healthcare across different areas of the NHS. The cost per QALY gained of PGP care versus non-PGP care will be estimated over 30 days following index appointment. 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 EQ-5D-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 at a different willingness-to-pay thresholds.

- Retrospective study

  The analysis of routine GP practice 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, that is available from GP electronic medical records, from first presentation (index appointment) and any subsequent appointments during the following 30 days (inclusive of the index appointment). The 30 days will form the care episode. Appointments in EMIS are categorised based type (e.g., new, first, review, flare-up). For each patient, the first instance of a 'new' 'first' or 'review' appointment in the data extract will be considered their index appointment. Any care received during the care episode will be included, irrespective of type. Only one care episode will be included for each participant.

  Data may include PGP, GP and other primary health care practitioners; and mode of contact (e.g. telephone/video, home, clinic appointment); prescriptions; referrals; tests and investigations; and hospital admissions. We will conduct a cost analysis from the NHS perspective to describe the incremental costs/savings of care episodes in practices with and without PGP. Cost descriptions 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.

3.4. Jurisdiction:

The study will be conducted in the UK where the health system is publicly funded and is free at the point of access.

3.5. Perspectives

- Prospective study

  In the primary economic analysis a broad perspective will include the NHS, social services, patients/carers and employers. The secondary analysis will be conducted from the NHS perspective.

- Retrospective study

  The cost analysis will be conducted from the NHS perspective.

3.6. Time horizon

- Prospective study

  All analyses will compare costs and outcomes over 30 days after patient consent. For the retrospective data analysis, the cost analysis will be conducted over 30 days (a care episode) inclusive of an index visit.

Section 4: Economic Data Collection and Management

4.1. Statistical software use for health economic analysis

Stata version 17.0 or higher will be used for all health economic analyses.

4.2. Identification of resources

- Prospective study

  The following items of healthcare resource use that may differ between care configurations (i.e. model of PGP care) and the control group will be measured: primary care use, secondary care use, prescriptions, productivity and informal care.

- Retrospective study

  We aim to collect data from GP EMR on the following items of health care resource use that may differ between care configurations and the control group: primary healthcare use, unplanned hospital admissions, prescriptions, referrals and tests and investigations. Unplanned hospital admissions will be identified using a pre-defined list provided by the CI, to search free-text in primary care consultations data. Results regarding hospital admissions will include the caveat that it is likely to be an underestimate, given that not all hospital admissions that occur during the care episode may be entered in primary care data during the care episode.

4.3. Measurement of resource use data

- Prospective study

  Resource use data will be collected 30 days after the baseline visit using self-completed questionnaires. Questionnaires will be administered via post, online or by telephone with a member of the study team. The resource-use questionnaire will include the ModRUM core module to collect NHS resources [9]. ModRUM core module captures secondary care resources including A&E, outpatient, inpatient and day case admissions, whilst in primary care, it captures contact with clinicians either face to face or virtually – whether these consultations were with GPs or other NHS healthcare professionals. Home visits and community services are also captured in ModRUM. Productivity including time off work and usual activities is captured through a bespoke questions

whilst informal care is measured through an adapted version of the Informal Care Cost Assessment Questionnaire (CIIQ) [10].

- Retrospective study

  Information will be extracted by GP sites and shared with the research team. Information extracted from EMIS will include:

  - Patient characteristics: a bespoke data queries to extract age and gender.
  - Consultation mode: a bespoke data queries to extract if face-to-face consultation, telephone consultation, or online/video.
  - Clinician seen: a bespoke data queries will list if the appointment was with a GP, a nurse, or a paramedic.
  - Clinical codes for presentations
  - Type of consultation
    - First – The first occurrence of a clinical problem code or diagnosis code in the record.
    - New – A new occurrence of a clinical problem code or diagnosis code after a previously 'ended' problem/diagnosis.
    - Review – An activity in the clinical record pertaining to an existing/ongoing previously coded clinical problem code or diagnosis code that has not 'ended'. This includes (but is not limited to) chronic disease management.
    - Flare up – an activity in the clinical record pertaining to an acute exacerbation of an existing/ongoing previously coded clinical problem code or diagnosis that has not 'ended'.
    - End – Point at which a clinical problem or diagnosis code is specifically marked as no longer an active problem (e.g. condition is cured or permanently resolved).
    - None – Not associated with clinical problem or diagnosis code.
  - Medications: a list of medications will be identified and costed if they were prescribed in the same consultation.
  - Referrals including to secondary care will be based on searching EMR databases for pre-defined codes; they will be summarised in terms of the quantity of referrals but will not be costed.
  - Unplanned hospital admissions: a list of codes will be used to measure unplanned hospital admissions and will be analysed in a sensitivity analysis due to uncertainty in the quality of the data (i.e., not all hospital admissions will be captured within the GP data). These codes are: Emergency hospital admission", "Admission to A & E department", "Admission by GP", "Refer to casualty officer", and "Refer to hospital casualty". These will be distinguished from codes suggesting planned admissions such as "non-urgent hospital admission" or "Non-urgent gynaecological admission".

- Prescriptions: Name, Dosage and Quantity can be extracted from EMIS
- Tests and investigations: identified via clinical codes.

4.4. Valuation of resource use data

Health care resource use will be valued in monetary terms using the same cost year for all resources (2020/21). Primary healthcare resource use will be valued using the Unit Costs of Health and Social Care [11]. Prescribed medications will be valued using the Prescription Cost Analysis [12]. Secondary healthcare resource use will be valued using the National Schedule of NHS costs [13]. When a unit cost is not available for the year of analysis, it will be inflated to current prices using the NHS cost inflation index (NHSCII) [11]. Informal care and usual activities will be valued using the proxy good, using the Office for National Statistics Annual Survey of Hours and Earnings [14]

4.5. Identification of outcomes

- Prospective study

  Clinical effectiveness will be captured from patient experience, patient preferences and outcomes of care using self-report questionnaires. Quality of Life (QoL) will be measured at the time of collecting the patient experience, safety and other outcome measures.

4.6. Measurement of outcomes

- Prospective study

  Patient experience, safety and other primary care outcomes will be measured using PREOS and PCOQ at baseline and then at 30 days after baseline visit using a participant self-completed questionnaire. For the QoL, the EQ-5D-5L will be collected at the same time as clinical effectiveness measures.

4.7. Valuation of outcomes

- Prospective study

  Utility values will be estimated from EQ-5D-5L scores using the method recommended by NICE at the time of analysis. At the time of writing this HEAP, the recommended method will involve patients' EQ-5D-5L profiles being mapped to the EQ-5D-3L valuation set using a validated mapping function [15, 16]. The mapping function enables a utility score to be calculated for each patient based on published UK population utility values. The area-under-the-curve approach will be used to transform the utility scores into QALYs for the 30 days' time horizon.

Section 5: Economic Data Analysis

5.1. Analysis population

- Prospective study

  All patients who did not withdraw their consent will be included in the analyses.

- Retrospective study

  All patients with a 'first', 'new' or 'review' appointment with a GP or paramedic recorded in their EMR will be included.

5.2. Timing of analyses

The final analysis will be conducted at the end of the study. This is expected to be completed by May 2023.

5.3. Discount rates for costs and benefits

As costs and benefits will not be assessed beyond 12 months post index visit, discounting will not be required.

5.4. Cost-effectiveness threshold(s)

- Prospective study

  Adjusted mean costs and QALYs associated with each comparator group will be combined through the NB framework. Cost-effectiveness will be evaluated using the NB framework over a range of values for the QALY, including the UK NICE recommended cost-effectiveness thresholds of £20,000 and 30,000 per QALY.

5.5. Missing data

Handling missing data is relevant to the prospective data only. These will be reviewed and handled appropriately (e.g., by using multiple imputations).

5.6. Analysis of resource use and costs

- Prospective study

  Mean resource use will be estimated and presented by care configuration for each resource use category (e.g., outpatient visits, medication use, etc.). Standard deviations (SD) and the number of patients included in each configuration will also be presented. Appropriate regression techniques will be used to estimate adjusted mean costs and the difference in adjusted mean costs (and their associated 95% confidence intervals) between care configurations. Resource-use data from the ModRUM Core Module (use of primary and secondary care, and prescribed medications) and from items on 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, ethnicity new registrations, standard mortality weightings) and patient level factors (e.g., age, sex).

- Retrospective study

  Cost comparisons will use regression (e.g. GLM) techniques appropriate for non-negative potential skewed cost data with covariates indicating if an episode care is initiated by a paramedic

and other practice level variables (e.g. practice size, deprivation, urbanity, GP to paramedic ratio); variables indicating PGP implementation (paramedic integrations, patient complexity, ratio of paramedic to GP, and maturity of PGP) and patient level variables (e.g. age, sex,) registers the patient is on) to estimate incremental costs and associated 95% confidence intervals.

5.7. Analysis of outcomes

We will using a multi-faceted approach to quantitative analysis and triangulating 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 systemwide costs and outcomes.

- Prospective study.

QALYs will be estimated from EQ-5D-5L scores using the area under the curve approach [17]. Adjusted mean QALYs will be estimated using the appropriate regression technique, taking into account the multi-level structure and distribution of the data and adjusting for baseline EQ-5D-5L scores [17]. Separate multi-level models will be produced for each PGP model, which will compare outcomes with the control group.

5.8. Analysis of cost-effectiveness

- Prospective study.

In the primary cost-consequence analysis, incremental costs will be presented alongside incremental outcomes. In this analysis, costs and outcomes will not be combined and presented in an aggregated way. In the secondary economic analysis, the cost per QALY gained of PGP care at 30 days will be estimated. Based on the current NICE willingness to pay thresholds for a QALY of £20,000-£30,000 net benefit regressions will be used, adjusting for baseline EQ-5D-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.

5.9. Sampling uncertainty

- Prospective study.

Uncertainty will be addressed using cost-effectiveness acceptability curves for a range of willingness to-pay thresholds. This assesses the probability of the care configuration being the cost-effective option at a range of willingness-to-pay thresholds.

5.10. Sensitivity Analyses

Uncertainty in the methodological choices made for the present economic evaluation will be assessed through several sensitivity analyses. This will involve making plausible changes to key methodological assumptions to understand how changes in the methodological assumption impacts of the cost-effectiveness result. Examples include:

- If applicable, for the prospective analysis different approaches to the handling of missing data.
- For the retrospective data analysis, varying intervals (e.g., 60, 90 days) to test the robustness of our findings.
- Test the extent to which paramedic pay band effects cost-effectiveness.

Section 6: Reporting/Publishing

6.1. Reporting standards

The Consolidated Health Economic Evaluation Reporting Standards (CHEERS) guidelines will be followed when reporting the health economic evaluation, in a format appropriate to stakeholders and policy makers.

6.2. Reporting deviations from the HEAP

Any deviation from HEAP will be documented and justified in the final published report.

Section 7: Revisions to the HEAP post-approval

Date	HEAP version	Summary of revision

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