A realist evaluation of effectiveness, safety, patient experience, and system implications of different models of using General Practitioners in or alongside Emergency Departments

Outline Statistical and Health Economics Analysis Plan

Short title: GPs-in-EDs

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Abbreviations and Definitions

ALF	Anonymous Linkage Field
A&E	Accident and Emergency Data in HES
ECDS	Emergency Care Data Set
EDDS	Emergency Departments Data Set
GPs	General Practitioners
HES	Hospital Episode Statistics
ICER	Incremental Cost-Effectiveness Ratio
IGRP	Information Governance Review Panel
ITS	Interrupted Time Series
MITS	Multiple Interrupted Time Series
NHS Digital	NHS Digital is the national information and technology partner to the health and care system
PEDW	Patient Episode Database for Wales
SAIL	Secure Anonymised Information Linkage
SHEAP	Statistical and Health Economics Analysis Plan
SNOMED-CT	Systematized Nomenclature of Medicine – Clinical Terms
SOPs	Standard Operating Procedures
SPSS	Name of a Statistical package
STATA	Name of a Statistical package
STU	Swansea Trials Unit

1 Synopsis of Project Protocol

1.1 Background

Increasing demand on the United Kingdom (UK) National Health Service, urgent and emergency services is testing the capacity of the system and there are concerns about the consequent ability to deliver good quality care [1]. One of the recommendations in a joint report by the Royal Colleges of Emergency Medicine, Paediatrics and Child Health, Physicians and Surgeons to address these pressures is that every Emergency Department (ED) should have a co-located primary care facility [1].

The evidence base to support different service models of General Practitioners (GPs) working within EDs (Gps-in-Eds models[1]) is weak [1]. Understanding the impact of such a service on patient health outcomes, experience and safety and the health services resource use and related cost of delivering these outcomes is important. This research and the analyses described here are intended to evaluate the ability of GPs in the ED setting and different GP models to achieve the key outcome domains described in an effective practice framework: i.e. addressing greatest health needs first; only doing what is needed; reducing inappropriate variation; and co-production [1] and the resources needed to deliver these outcomes.

1.2 Aim and Objectives

The overall aim of the study is to determine the clinical effectiveness and the resources, costs, and consequences of General Practitioners (GPs) working in Emergency Department (GPs-in-EDs) models and to understand the ways in which service design and setting (context) generate variations in outcomes.

This document outlines the principles underpinning the Quantitative and Economic evaluation of different GPs-in-EDs models. Updated versions of this SHEAP will contain further details as study sites are confirmed, data sources are specified, and outcomes of interest are agreed and precisely defined.

This document should be read in conjunction with the current version of the study protocol [1], summarised by the study schematic in the Appendix 1. The study is based on 12 purposively selected sites representing a range of GPs-in-EDs models, including Control (no GPs-in-EDs) (Table 1). The specific aim of the quantitative analysis is to evaluate how different GPs-in-EDs models perform compared to others (including the control) with respect to any outcomes. The health economics analysis will evaluate the impact and

[1] We refer to this as 'GPs-in-EDs' in this document

relative differences of GPs-in-EDs compared with no GP in terms of the use of health care resource utilisation, costs and consequences for patients attending the ED.

2 Study Setting

2.1 Study period and population

The study period for statistical analysis is an eight year period from 1.10.2010 to 01.10.2018 for the analyses. We will consider episodes of emergency attendances from all study sites for the eight-year period. This study window was selected to allow acquisition of data covering at least 1 year before and after the GPs-in-EDs model was implemented at a study site. Two economic analyses are planned the first of which has the same study period. The second - an analysis of GPs-in-EDs compared with ED doctors' management of marker conditions - takes differing time periods, determined as when the GPs-in-EDs service was deemed to be in 'steady state.'

The different GPs-in-EDs models and their respective time-period of model implementation can be found in Table 1 and Table 2.

2.2 Different GPs-in-EDs Models

Phase 1 of this study included a national survey to characterise existing GPs-in-EDs models in England and Wales. Following this, three main GPs-in-EDs models were characterised. In control sites, there are no GP service models (Table 1, Table 2).

GPs-in-EDs Model	Formats of GPs in ED Model	Characteristics of GPs working within thein EDs Model
Model A	**INSIDE** the emergency department: ***Integrated***	The primary care service is fully integrated with the emergency medicine service within the emergency department
Model B	**INSIDE** the emergency department: ***Parallel***	There is a separate primary care service within the emergency department for patients with primary care type problems
Model C	**OUTSIDE** the emergency department: ***On site***	Patients access a primary care service separate to the emergency department, elsewhere on the hospital site
Null Model	**No GPs** in the EDs: ***Control site***	Typical ED service without any presence of GPs in any format

Table 1: GPs-in-EDs Models

2.3 Study sites

During the site recruitment the study researchers aimed to have full representation of all 'GPs-in-EDs' models (including null model), and seek to have a balanced coverage of administrative information for the sites. Besides the type of model (Table 1), they also collected site specific information on whether sites are (or can be defined as):

- Urban/Rural
- Larger/Smaller EDs (in terms of staff and catchment area)
- Public/Private providers of GP services
- Located in England or Wales

For the quantitative analysis, we aimed to purposively selected 12 sites, all level 1 A&E services [2] with the GPs-in-EDs model introduced within the study period. We are considering the control (absence of GPs) as one of the categories of the 'GPs-in-EDs model' as the null model (Table 2) in statistical analysis.

Table 2: List of Study sites and date of introduction of GPs-in-EDs

	Site name	Date model introduced	GPs-in-EDs model(s)
1	Musgrove Park Hospital, Taunton	01/01/2017	INSIDE: Integrated (Model A)
2	Friarage Hospital, North Allerton	28/03/2016	INSIDE: Integrated (Model A)
3	Chichester Hospital, Chichester	01/10/2010	INSIDE: Integrated (Model A)
4	Airedale General Hospital Keighley	01/10/2015	INSIDE: Parallel (Model B)
5	Queen Elizabeth Hospital, Gateshead	04/02/2015	INSIDE: Parallel (Model B)
6	Royal United Hospital, Bath	01/04/2018	INSIDE: Parallel (Model B)
7	St Georges Hospital, London	01/09/2012	INSIDE: Parallel (Model B)
8	University Hospital of North Tees, Stock on Tees	01/04/2017	OUTSIDE:on site (Model C)
9	Countess of Chester Hospital, Chester	01/10/2017	OUTSIDE:on site (Model C)
10	Warwick Hospital, Warwick	Not Applicable	Control (Null Model)
11	Royal Gwent Hospital, Newport	Not Applicable	Control (Null Model)
12	Southport and Formby District General Hospital, Southport	Not Applicable	Control (Null Model)

Manchester Royal Infirmary also took part in the national survey for their model and was initially selected for inclusion in the quantitative analysis. However, the GPs-in-EDs service was implemented on 1st of January 2005. Since its inception falls earlier than the data coverage (starting from October 2010) and almost all the other models falls around the years of 2015-2017, it was not included in the quantitative analysis. Data: Sources, Acquisition, and Management.

2.4 Level of Data

We are planning to obtain data at the level of a patient attendance at an ED. This will enable us to aggregate the data by patient; by any time-period; and by site, as required for the analysis. For the quantitative analysis, we are planning to arrange the data by fortnightly time units.

2.5 Data Sources

The primary data sources for the statistical analyses will be HES (Hospital Episode Statistics) A&E data from NHS Digital for the sites in England, and the Emergency Department Data Set (EDDS) from the SAIL Databank for the single site in Wales.

2.6 Data Acquisition & Management

The source of the Welsh site (Royal Gwent Hospital) was EDDS data from SAIL. We have already received the Royal Gwent Data for the study period. Data acquisition from SAIL needed completing the scoping for SAIL data followed by the submission of IGRP application (Information Governance Review Panel). The IGRP application includes our proposed use of the SAIL gateway (an NHS Digital trusted third party) as a 'safe haven' repository for NHS Digital data.

The English sites require HES A&E data from NHS Digital is ongoing. The application process has undertaken via NHS Digital DARS (Data Access Request Service) which involves: (i) initial scoping enquiry; (ii) review, clarification, and discussion; (iii) detailed application, including dates, fields/variables/outcomes; etc.; (iv) approval, conditions, costings. We are benefitting from expertise within SAIL to assist with Information Governance & Data Security elements within the application. We have already explored the study sites codes needed for the DARS application. The site codes are useful to select the data for any specific site. Both SAIL and HES, we are acquiring the data for the financial year 2010/11 to 2018/19 to cover the study period.

2.7 Data items

We have applied for patient level data, including ALF (a unique anonymised ID) and information on admission date and time, gender, age, health event date and time, visit status (first attendance or re-attendance), attendance category, diagnosis, investigations, and treatment and disposition codes. The list of patient-level data items from SAIL EDD is given in the Appendix (Table 4). We will update this appendix once we acquire the HES A&E data.

2.8 Data Quality Assessment

We are aware that various factors are likely to affect the quality of the requested routine data from both SAIL and NHS Digital, with variations from site to site (even within the same GPs-in-EDs model) and over time. These include, but are not limited to, site-specific factors such as staffing levels, bed occupancy rates, and local practices, all of which may then influence one or more outcome measures. We will therefore undertake, for each study site, an assessment of the data quality for that site, - essentially, sense checking for the completeness of outcomes, and the presence of unexpected features (e.g.: "spikes") or trends. These explorations will be presented and interpreted in the context of the sites' known history over the study window. As far as possible, we will seek reasons for such data "spikes," omissions, or unexpected variations over time which may reasonably be attributed to local circumstances or complexities. We have already started this assessment of SAIL data from the single Welsh control site and will extend this to NHS Digital data for all English sites.

3 Outcome measure

We will calculate various site-specific estimates from patient level data which will be used as outcome measure to summarise and compare the sites and respective models. These incudes the total number and rate of ED attendances, admissions, proportion of re-attendances, and the proportion admitted as an inpatient to the same hospital. We will also calculate the average patient age and the gender split. The current, provisional, list of estimates can be found in the Appendix (Table 5) which will be further updated once we acquire the HES data.

For each site we, will also calculate the number of the unique new ED attendance and number of repeated attendance or follow ups. For the repeaters, the length of consecutive visits (in days) will be explored too. Diagnoses are reported using ICD10 (International Classification of Diseases 10) codes. For each site, diagnosis of the attendance will be explored for modal causes of new attendance and repeaters. The diagnosis of the ED attendances will be also explored with respect to the Marker Conditions listed in table 7.

4 Descriptive Statistics

Descriptive statistics will be used to summarise and compare the outcome measures (as outlined above and in Table 5) between site specific comparison and various 'GPs-in-EDs model'. For continuous variables (e.g., number of fortnightly ED admission, number of ED discharge, duration in ED), we will be using summary statistics like mean, standard deviation, median, inter quartile range, minimum and maximum. For categorical outcome measures (e.g. ED attendance category, re-attendance, discharge to other health care, discharge destination, proportion seen by GP), we will be using frequencies and percentages. Besides the site by site and model comparison, we will also provide the

summary statistics of the outcome before and after the implementation of GPs-in-EDs model. This will provide us crude estimate to explore the effect of models by time and by site. For adjusted analysis, we will use statistical modelling to compare the outcome by site and time. Description of the statistical evaluation can be found in section 6.

5 Statistical Evaluation

The effectiveness of GPs-in-EDs models will be measured and compared using the outcome measures (as outlined above), aggregated by site and per fortnight [1]. For each outcome measure, the comparison will be made between the null model (control) and the composite model (i.e. composite of model A, B, and C) and comparison of the null model with the each of models A, B and C separately. We are considering the comparison of the null and the composite mode as the primary outcome to evaluate the key objective of the study. The will assess the effect of any sort of effect of the GPs-in- EDs.

5.1 Statistical Model Hypotheses

To evaluate the clinical effectiveness of GPs-in-EDs models, we formulate the following specific null hypotheses:

Null Hypothesis 1 The proportion of 'new attendances' per fortnight does not vary with respect to the presence of a GP service compared with no GP nor with the type of GPs-in-EDs model.

Null Hypothesis 2 The proportion of 're-attendances' per fortnight does not vary with respect to the presence of a GP service compared with no GP nor with the type of GPs-in-EDs model.

Null Hypothesis 3 The mean ED time does not vary with respect to the presence of a GP service compared with no GP nor with the type of GPs-in-EDs model.

Null Hypothesis 4 The proportion of the patients admitted as an inpatient to the same hospital does not vary with respect to the presence of a GP service compared with no GP nor with the type of GPs-in-EDs model.

The null hypothesis 1 means that there is no difference in 'new ED attendance' between any intervention (any of A, B and C or their composite models) and control models, indicating that the rate ratio between two models would be 1. All hypotheses will be assessed using two-tailed tests and 5% significance.

5.2 Multiple Interrupted Time Series

We will consider how the presence of a GP service *per se* the type of GPs-in-EDs model might affect each outcome. If any of the GPs-in-EDs models (i.e. any of A, B and C or their composite models) is more effective than control, we expect there to be a gradual change in the slope (gradient) of the outcome measure (e.g. proportion of new attendances) [3]. Specifically, we assume that all GPs-in-EDs models would reduce the slope related to some or all outcome measures (including proportion re-attending, mean ED times, rate of inpatient admissions), but expect that the opposite effect on the slope for the outcome on new attendances. We assume GPs-in-EDs to have an impact of the implementation period due to the intervention and therefore will consider a lag period before the changes in slopes occur [4]. Since the dataset time unit is fortnightly, we will consider two- time units (i.e. roughly one month) of lag in general. Before deciding the lag period, we will adopt a data driven approach and explore the shift of slope change(s) following two lags for each intervention site [3].

We will use exploratory time series methods using the fortnightly site-specific estimates to assess trends in each outcome measure before and after the implementation of GPs-in-EDs, and support these by appropriate numerical summaries before and after implementation of the model. This will also help us to identify underlying trends, seasonal patterns, and outliers. To control the seasonality and long-term trends, we will adopt complex functions like Fourier terms (i.e. pairs of sine and cosine functions); or splines) [3, 5]. This will enable us to control both short and long term trends.

We will use Multiple Interrupted Time Series (MITS) models to test the null hypotheses. For each GPs-in-EDs model, we will develop an Interrupted Time Series (ITS) model comparing that specific model to Control. For any outcome measure, the null model (control), will be compared separately for each of case model(s) (i.e. Models A to C in Table 1 and 2). Thus, we will have several ITS models comparing GPs-in-EDs models (i.e. any of A, B and C or their composite models) with the control model. The comparison will be based on any specific outcome measure (e.g. rate of new attendances) and will measure the changes in the outcome before and after the introduction of that GPs-in-EDs model (defined as the interruption).

In technical terms, the goal of such segmented regression analysis is to estimate the interaction terms between implementation of the GPs-in-EDs model and time as well as estimating the effects relative to the control population [4]. The data elements underpinning this regression model can be presented in a tabular format similar to that shown in Table 3. Tables 3 was developed based on the site: Royal United Hospital where Model B (intervention) was implemented on 1st April 2014 (Table 2).

Table 3: Format of the data tables for segmented regression analysis

Fortnight (1)	**R_{GP_ED} (2)**	**$R_{control}$ (3)**	**$R_{Difference}$ (4)**	**Implementation (5)**	**Time (6)**	**Time-After (7)**
1/10/10 – 15/10/10				0	1	0
15/10/10 – 29/10/10				0	2	0
29/10/10 – 12/11/10				0	3	0
12/11/10 – 26/11/10				0	4	0
26/11/10 – 10/12/10				0	5	0
…….	…….	…….	…….	…….	…….	…….
…….	…….	…….	…….	…….	…….	…….
…….	…….	…….	…….	…….	…….	…….
…….	…….	…….	…….	…….	…….	…….
13/07/18 – 27/07/18				1	204	113
27/07/18 – 10/08/18				1	205	114
10/08/18 – 24/08/18				1	206	115
24/08/18 – 07/09/18				1	207	116
07/09/18 – 21/09/18				1	208	117

Notes:

- *This table is based on Model B site (Royal United Hospital Bath) where intervention started 1st April 2014*
- *2 lag periods are considered (so expect to slope change from 29th April 2014)*

For each model evaluation (i.e. any of A, B and C or their composite models) compared with control, we use estimates of the outcome measures in the 8 years period centred around the implementation of 'GPs-in-EDs' (model A, B or C and their composite). Aggregating data on a fortnightly basis, there will be approximately 208 values for each outcome measure. Column 2 contains the rates of outcome for sites with GPs-in-EDs, while column 3 has rates for control sites (null model). Column 4 is the difference of the two rates, and column 5 contains values of a binary variable, with 0 and 1 indicating, respectively, times before and after implementation of GPs-in-EDs. Column 6 indicates time for the 208 fortnightly periods over 8 years study period. Column 7 contains 0 for periods before the GPs-in-EDs implementation, and a sequential number denoting the period post-implementation. Since we have different models implemented at various point of time, column will 7 vary with respect to any specific Model. For example, let us we consider the Model B (INSIDE: Parallel) for the site: Royal United Hospital, Bath where the intervention was implemented on 1st April 2014. Given 2 lag periods (i.e. 2 fortnight time units), we should expect the change of slope from 29th April 2014. Therefore, the time-after (column 7) should start counting from this date. Thus for the Model B and for this site, we will have approximately 94 units of outcome measure before the intervention and 117 units of outcome measure after the intervention.

The structural equation of the segmented regression model may then be expressed as:

$$\text{Rate}_{\text{difference}} = \beta_0 + \beta_1 \text{time}_t + \beta_2 \text{Implementation}_t + \beta_3 \text{time\_after}_t + e_t,$$

in which $\text{Rate}_{\text{difference}}$ is the difference between the rates of new attendance for case and control sites; β_1 is the coefficient of time; β_2 is the coefficient of the model implementation

before and after; β_3 is the coefficient of the difference between the rates from the case and control sites.

The estimate of β_2 indicates the effect of implementing the GPs-in-EDs model; while the estimate of β_3 measures any slope in successive time-periods post-implementation, and therefore represents the continuing effect of the model. These are the two main coefficients of interest summarising the statistical significance of the effect of the GPs-in-EDs model compared with data the control sites.

We will adopt similar separate segmented regression models for each GPs-in-EDs model (i.e. any of A, B and C or their composite models) for each of outcome measure of interest. Using combined results from all segmented regression models, we will be able to assess the statistical significance for each of GPs-in-EDs model. We can also assess the most influential GPs-in-EDs model through values of the estimated coefficients.

5.3 Health Economics Evaluation

5.3.1 Cost Consequences Analysis

For both the economic analyses described below, a cost-consequences analysis (CCA) framework will be employed. CCA is a form of economic evaluation where disaggregated resources, their costs and a range of outcomes are presented to allow readers to form their own opinion on their relevance and relative importance to their decision-making context [7]. This is typically presented using a descriptive table to present the results of outcomes in a disaggregated format, together with the resources, estimates of mean costs with appropriate measures of dispersion.

The advantage of using a CCA approach rather than cost effectiveness analysis is that the outcomes are not restricted to health outcomes and can include other measures, in this case those pertinent to ED performance and optimisation of resources e.g. changes in ED times These non-health considerations are becoming increasingly relevant to NHS decision makers and provide the opportunity to measure economic consequences without the complexity that a full comparative analysis would require, especially given the competing models and multiple sites detailed in Table 2.

The CCA in each of these cases below will examine the healthcare resources, costs and outcomes utilised in the GPs-in EDs models, with GPs-in EDs, whatever the model of service and no GPs (control).

The two health economic analyses investigating the comparison in management between an ED doctor or GP in ED are described below.

5.3.2 Health Economic Evaluation 1: CCA GPs-in-EDs compared with control

The first CCA is aligned with the quantitative evaluation described in section 6.2. The change in outcomes (consequences) from implementing a GP-in ED service are derived from the statistical analysis. The main outcomes are:

- Number of ED attendances per fortnight;
- Number of ED discharges;
- Number of admissions from ED to in-patient care;
- Duration in ED;
- Number of Investigations;
- Number of Treatments;
- Re-attendance at ED with the same condition within 28 days;
- Discharge disposition (i.e. destination of discharge);

A full list of data items for the analyses is detailed in Appendix 2 Table 5

The comparison of interest for the analysis is 'control' prior to the 'interruption' in the time series before a GP-in-ED service was fully implemented and after the 'interruption' when the GP-in- ED service was fully implemented.

The way in which the estimates of the resources and costs for the health economic analyses is described in section 5.3.4 below.

Time horizon:

The time horizon exceeds a 12 month period so in line with good practice for analysis of periods exceeding one-year, a discount rate of 3.5% per annum is applied as recommended by the National Institute for Health and Care Excellence (NICE) [6].

5.3.3 HE Evaluation 2: CCA of GPs-in-EDs compared with ED doctor care of patients with Marker Conditions

The second CCA considers the resources, costs and outcomes of the management of selected marker conditions (see Appendix 2 Table 7), managed by ED doctors compared with management by the GPs-in-EDs.

The marker conditions for these analyses were selected for the qualitative analysis as well as the current analysis and undertaken by a separate group from the health economics team. The marker conditions were identified as those likely to show differences in management between GPs and ED clinicians. They are based on symptoms, or nature of presentation, chief/presenting complaint as well as diagnoses. The methods are reported elsewhere.

The economic analyses will estimate the change in resources, their costs, and the consequences of management by a trained GP (i.e., a primary care-based approach) and management by an ED doctor.

The consequences for the patients seen by GP compared with an ED doctor with the ED include:

- Proportion of admissions from the ED to in-patient care;
- Proportion of ED discharges;
- Overall duration in ED;
- Duration in ED from initiation of treatment to discharge[2];
- Investigations;
- Treatments;
- Diagnosis;
- Re-attendance at ED with the same condition within 30 days;
- Discharge destination (e.g. admission to in patent care, other setting, or home);
- Discharge destination including number of admissions from ED to in-patient care;

These will be summarised irrespective of the GPs-in-EDs service model and setting and where possible also by model and setting.

To undertake this analysis, we intend to utilise anonymised patient level data extracts from the study site local ED databases. The software that supports the database available in each ED vary but all data systems consistently collect and include information on chief complaint, final diagnosis diagnostic tests and treatments, the health care staff responsible for management of the patients and resources used (e.g. diagnostic tests), the timings of the patient's progress from first contact along that pathway of care to discharge or admission. Appendix 2, Table 8 has a 'sample' data set for a patient with the back pain marker condition used to facilitate specification of the data extracts.

Should these local data not be available the analysis will be undertaken with the same (e.g. HES) data used for the statistical analysis. The local data are preferred as the presenting/chief complaint is recorded allowing the evaluation of patient management based on the information the treating clinician has, initially, prior to final diagnosis. The ED the data received thus far suggest that the level of detail and quality of the data are better, plus the insights and knowledge of the local data analysts and clinical staff enable better understanding and interpretation of the data.

The CCA will compare the outcomes (consequences) of GP care of patients presenting with marker condition compared with ED clinician care over a 12-month period following the introduction and 'stabilisation' of the GP-in-ED model. The latter will be advised by the clinical director in each study centre. The analyses will be undertaken for the 12-month time period in a 'window' between Jan 2017 and December 2019. All patients within that period with the marker condition as the Presenting/Chief Complaint will be included in the dataset, irrespective of the diagnosis.

[2] This is the time that management by the ED doctor or GP will take place, albeit that investigations and treatments may be given by others, it has been agreed that this is the best proxy for time taken for patient management.

Tables will be prepared to summarise the data and allow inspection of the data for completeness and quality. The summary tables will also allow adjusting of the data to take account of variables that may cause bias or confounding. For each marker condition two separate analyses will be undertaken:

1. *'Intention to Treat'*: that is including all patients who attended during the 12-month period with the marker conditions as the presenting complaint;
2. *'Per Protocol'* : that is with all diagnoses that are not musculo-skeletal related back pain or other similar back pain conditions that are appropriate for management by a GP working in an ED excluded (e.g. excluding patients with a back pain chief complaint with a subsequent diagnosis of kidney stones) the goal is for the diagnosis to match the marker condition.

Analysis 1 represents the 'real world' where the GP-in ED and the ED doctor may see patients that may not have a diagnosis that relates to the presenting/chief complaint representing the marker condition because of workload pressures or poor streaming. The consequences being that the level of severity or presentation are not entirely suited to the managing clinician's skill set. Analysis 2 allows investigation of any difference between a GP in ED managing a marker condition and management of the same condition (confirmed by diagnosis) by an ED doctor. Both analyses have value for informing patient management and service configuration.

Summary statistics including mean, standard deviation and/or 95% confidence intervals or non-parametric equivalents (e.g. median and interquartile range) will be presented.

In addition to the economic analysis, the descriptive statistics will be used to test the working theories (developed in the realist evaluation) that certain conditions are managed differently by GPs and ED clinicians. Any resulting differences in resource use may also facilitate exploration of how the context of the services or GPs-in-ED model type appears to have influenced these differences.

Time Horizon

As this CCA takes a one-year time horizon no discount rate will be used.

5.3.4 Identification and Measurement of Costs for CCA

Each of the study sites has its own unique context and access to resources. Funding arrangements for the ED and GPs-in ED services are often complex and can be from multiple internal (e.g. Hospital Trust) and external (e.g. CCG) sources. In addition, the mechanisms for employing the GPs in EDs can vary. Identifying the cost of provision of the GPs-in-ED service may be unique to the study site. We will identify as far as possible these local site-specific costs but also plan to estimate a generalisable cost of GP-in-ED provision of care compared with an ED doctor driven service.

The costs for the implementation of the GPs-in-EDs model where it has been set up de-novo within the study time period will be identified where possible. Business cases and information held by local study site finance teams are the likely sources of this information.

EDs operate within Hospital Trusts and will have defined budgets. Disaggregated data on the budget for GPs in EDs Service will be requested.

Guided by clinical co-investigators the emphasis of our analyses are to investigate any changes in resources (rather than costs) used in managing marker condition patients that a GPs-in-EDs service (whatever the model) delivers. However, of importance to EDs with a constrained budget we will identify and summarise the differing approaches to staffing and mechanisms for paying the costs of the GP service and indicative costs (e.g. block contracts, specified services, GPs in ED as Trust staff, GPs in ED provided by Locum agencies or other service providers such as local GP consortia).

Where possible we will also take account of any management costs that relate to the differing services. We will also - as far as is possible - respect the principle of opportunity costs and consider the cost of the GPs-in EDs provision within the context of a limited budget and the alternative uses of that budget within the ED when interpreting our analyses.

We will also identify the payment by results (PbR) tariffs under which the marker conditions fall. (i.e., the payments that are made to the Trust for each healthcare resource group (HRG)[3] and provide summaries of these.

We plan to estimate if data allow;

1. Incremental cost of provision GPs in EDs per year compared with the absence of such a service;
2. Comparative cost of GPs-in-EDs and ED doctors per patient for each marker condition;
3. Average cost of GPs-in-EDs per year for different provider models.

Tariffs and National costs of the healthcare resources will be obtained from NHS reference costs [7] and the most up to date version of the costs of health and social care costs published by PSSRU [8] will be used.

Sensitivity Analysis

[3] PbR is the payment system in NHS England. Commissioners pay healthcare providers for each patient seen or treated, taking into account the complexity of the patient's healthcare needs. The unit of healthcare for which a payment is made, can take a number of forms covering different time periods from an outpatient attendance or a stay in hospital, to a year of care for a long-term condition. Tariffs are the set prices paid for the unit of healthcare. PbR currently covers the majority of acute healthcare in hospitals, with national tariffs for admitted patient care, outpatient attendances, ED, and some outpatient procedures. Admitted patient care and ED healthcare resource group (HRGs) are clinically meaningful groups of diagnoses and interventions that consume similar levels of NHS resources.

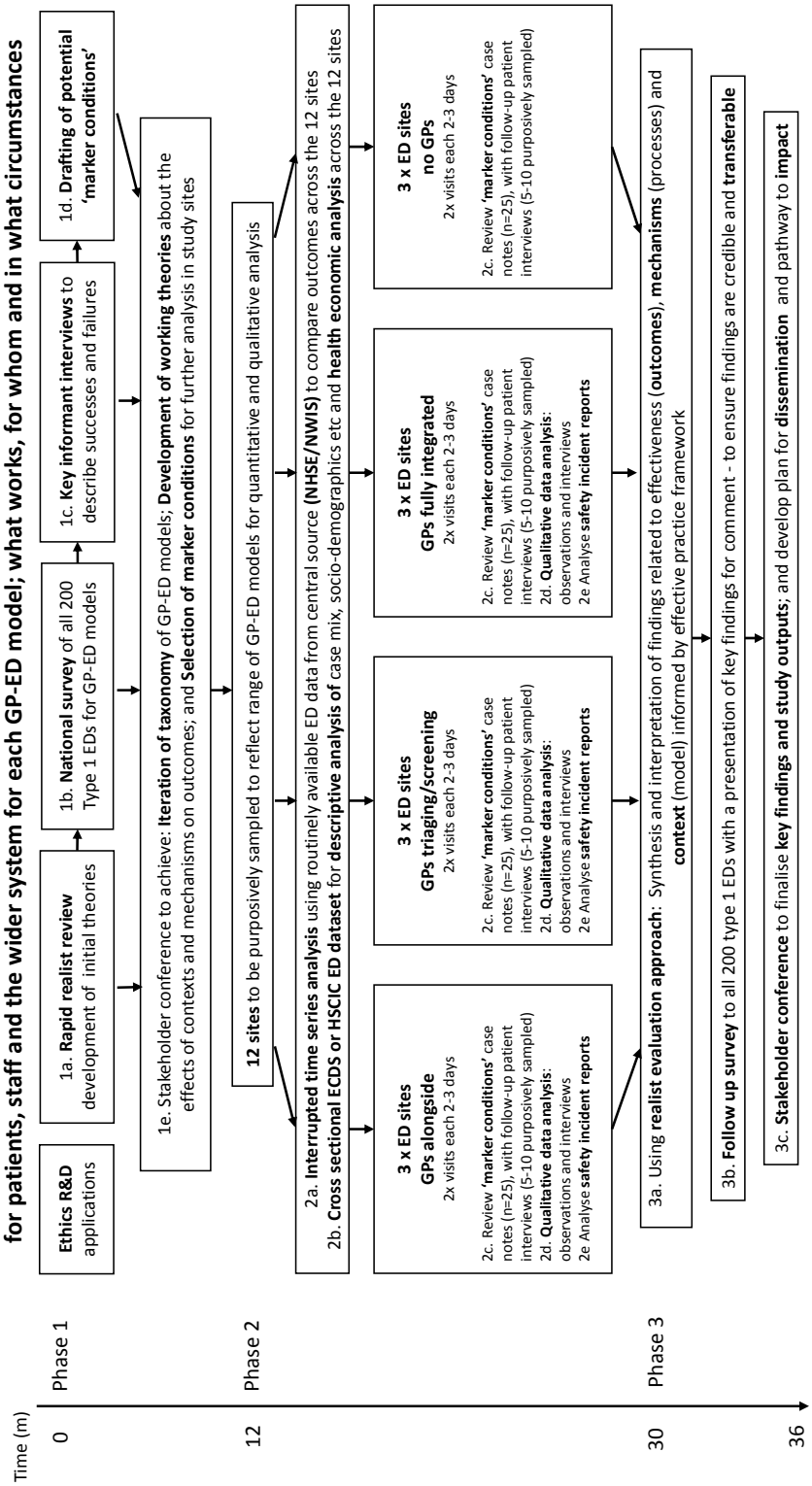
Sensitivity analysis will be undertaken to account for the uncertainty in the parameters used in the CCAs. Deterministic one-way sensitivity analysis will be undertaken to examine the impact of changes in key parameters by modifying the value within a plausible range (e.g. upper/lower 95% confidence intervals, +/-30% to key parameters advised by clinical co-investigators). Results will be tabulated for comparison between GPs-in EDs and ED doctors.

Statistical Software

Data processing, statistical analysis and Health Economics evaluations will be carried out using SPSS (version 23) and STATA (version 15).

6 Appendices

6.1 Appendix 1: Study Diagram



Note: *The Models names here is as per the latest protocol which will be updated in near future.*

6.2 Appendix 2: Data Items for the Quantitative Evaluation

Table 4: Patient level data items to be acquired HES, EDDS

Name of data items	Source: HES/EDDS/PEDW	Code of data item
Arrival date		
Arrival Time		
Gender		
Age		
Health Event Date		
Health Event Time		
Re-attendance		
Attendance Category		
Treatment		
Investigations		
Diagnosis		
Discharge Destination Code		
Hospital Admission Date		
Hospital admission Time		

Table 5: Site level measures estimated from aggregated patient level data

Data Items Name	Data Source
Site ID	List of sites
Type of GP services	List of sites
GPs-in-EDs model	List of sites
Size of the ED	List of sites
Region (England/Wales)	List of sites
Total Number of patients arrived	Derived data
Mean and Median age of the patient	Derived data
Mean and Median age per different age categories	Derived data
Mean and Median of the duration from event to arrival	Derived data
Total Number of re-attendance	Derived data
Proportion of re-attendance	Derived data
Total Number of patients under each attendance category	Derived data
Total number of patients under each treatment code	Derived data
Total number of patients under each Investigations code	Derived data
Total number of patients under each Diagnosis code	Derived data
Mean Duration at the A & E	Derived data
Total number of Discharge to any healthcare facilities	Derived data
Proportion of patients discharged to other healthcare facilities	Derived data
Proportion of patients admitted to same hospital	Derived data

Table 6: Provisional list of data Items specific to Economic Evaluation

Data Items Name	Data Source
Chief Complaint	
A&E Staff Member Code	
Number of Investigations (by type)	
Number of Treatments (by type)	
Duration of Treatment to discharge from RD	
Duration of Wait (Time of attendance to treatment)	
Diagnosis	

Table 7: List of Marker Conditions

Marker condition	Time period	ECDS Acuity	Chief complaint	Patient age	Exemplar diagnoses	Seen by
Child <10 with a fever	Last 3 months	3,4,5	Fever Unwell child	Less than 10	Infectious disease Respiratory Upper respiratory tract infection Surgical ENT Otitis media / ear infection Surgical ENT Tonsillitis	5-10GPs 5-10 ED staff
Cough and breathlessness	Last 3 months	3,4,5	Short of breath Difficulty breathing Noisy breathing Coughing up blood	Any	Infectious disease Respiratory Lower respiratory tract infection Infectious disease Respiratory Bronchopneumonia Infectious disease Respiratory Lobar pneumonia	5-10 GPs 5-10 ED staff
Abdominal pain	Last 3 months	3,4,5	Abdominal pain	Any	Infectious disease GU / GI Infectious gastroenteritis Infectious disease GU / GI Urinary tract infection	5-10GPs 5-10 ED staff
Back pain	Last 3 months	3,4,5	Pain in back / trunk (no injury)	Any	Soft tissue injury / wound Muscle injury Lower back Soft tissue injury / wound Sprain / ligament injury Lumbar spine Musculoskeletal Orthopaedics Sciatica	5-10 GPs 5 ED staff
Chest pain	Last 3 months	3,4,5	Chest pain	Any	Medical Gastroenterology Oesophageal spasm Medical Gastroenterology Gastro-oesophageal reflux Medical Gastroenterology Gastritis Musculoskeletal Rheumatology Costochondritis Medical Respiratory Pulmonary embolism	5-10 GPs 5 ED staff

Table 8: Sample Marker condition back pain data

TRIAGE_SCORE	Age at attendance	Sex_Description	Attend_Cat_Code (1= unplanned, 2 planned)	Referral_Source_Description	Arrival_Mode_Description	HRG code	SNOMED acuity code	SNOMED acuity	PreviousAEVisitDate	AAndEAttendanceDisposalCodeText	clinician
4	68	FEMALE	1	SELF REFERRAL	Ambulance			non urgent level emergency care		Discharge To Primary Care Service	
3	71	FEMALE	1	NULL	Other			standard level emergency care		Discharged No Follow Up	
4	29	FEMALE	1	SELF REFERRAL	Other			urgent level emergency care		Discharge For GP F/U - To Check Progress	
3	27	FEMALE	1	SELF REFERRAL	Ambulance					Discharged To Other OP Same Trust	
2	27	FEMALE	1	GENERAL MEDICAL PRACTITIONER	Ambulance					Admissions	
3	25	MALE	1	SELF REFERRAL	Other					NULL	
4	13	FEMALE	1	SELF REFERRAL	Other					Discharged To Fracture Clinic Same Trust	
4	83	FEMALE	1	SELF REFERRAL	Other						
4	72	FEMALE	1	SELF REFERRAL	Other						

3	25	MALE	1	SELF REFERRAL	Other											
3	35	FEMALE	1	SELF REFERRAL	Other											
3	38	FEMALE	1	HEALTH CARE PROVIDER	Ambulance											

Present_Complaint	chief_complaint_description	chief_complaint	Arrival_Date_Time	LEFT_DEPT_DT_TM	snomed_diagnosis_desc	snomed_diagnosis_code	AE_DIAG1	AE_DIAG2	Investigation_Code1	Investigation_Description1	Investigation_Code2	Investigation_Description2	Treatment_Code1	Treatment_Description1	Treatment_Date1
Back Pain	Pain in hip / leg / knee / ankle / foot	10601006	21/02/2019 13:37	21/02/2019 17:02	NULL	10601006			1	X-RAY PLAIN FILM	1	X-RAY PLAIN FILM	NULL	NULL	NULL
Back Pain	Pain in hip / leg / knee / ankle / foot	10601006	19/02/2019 13:48	19/02/2019 17:30	NULL	10601006			3	HAEMATOLOGY	5	BIOCHEMISTRY	NULL	NULL	NULL
Back Pain	Pain in hip / leg / knee / ankle / foot	10601006	16/03/2019 08:39	16/03/2019 12:14	NULL	10601006			1	X-RAY PLAIN FILM	3	HAEMATOLOGY	NULL	NULL	NULL
Back Pain	Pain in hip / leg / knee / ankle / foot	10601006	18/03/2019 22:24	19/03/2019 02:45	NULL	10601006			NULL	NULL	NULL	NULL	NULL	NULL	NULL
Back Pain	Constipation	14760008	21/01/2019 10:48	21/01/2019 15:39	Constipation (finding)	14760008			1	X-RAY PLAIN FILM	3	HAEMATOLOGY	NULL	NULL	NULL

Back Pain	Pain in hip / leg / knee / ankle / foot	10601006	04/02/2019 21:08	05/02/2019 01:06	Sprain of hip (disorder)	17883008			1	X-RAY PLAIN FILM	NULL	NULL	NULL	NULL	NULL
Back Pain	Generalised weakness	13791008	31/01/2019 15:01	31/01/2019 21:37	NULL	21522001			3	HAEMATOLOGY	6	URINALYSIS	NULL	NULL	NULL
Back pain post fall	Pain in hip / leg / knee / ankle / foot	10601006	18/03/2019 13:46	20/03/2019 19:27	NULL	22253000	Pain		12	COMPUTERISED TOMOGRAPHY (EXCLUDES GENITOURINARY CONTRAST EXAMINATION/TOMOGRAPHY)	3	HAEMATOLOGY	NULL	NULL	NULL
Back Pain	Pain in hip / leg / knee / ankle / foot	10601006	09/01/2019 14:10	09/01/2019 17:11	Sciatica (disorder)	23056005			NULL	NULL	NULL	NULL	NULL	NULL	NULL
Back Pain	Pain in hip / leg / knee / ankle / foot	10601006	07/03/2019 11:51	07/03/2019 15:42	Sciatica (disorder)	23056005			NULL	NULL	NULL	NULL	NULL	NULL	NULL
Back Pain	Pain in hip / leg / knee / ankle / foot	10601006	18/03/2019 09:59	18/03/2019 13:57	Sciatica (disorder)	23056005			1	X-RAY PLAIN FILM	1	X-RAY PLAIN FILM	NULL	NULL	NULL
Back Pain	Generalised weakness	13791008	04/02/2019 13:37	04/02/2019 17:12	Sciatica (disorder)	23056005			21	PREGNANCY TEST	6	URINALYSIS	NULL	NULL	NULL

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