Project Protocol

HS&DR Project: 15/145/04 – A realist evaluation of effectiveness, safety, patient experience and system implications of different models of using GPs in or alongside Emergency Departments

Summary of research

The emergency care system is in crisis and evidence is needed urgently to understand how best to manage workload and demand to safely achieve the highest standards of clinical and operational care, whilst ensuring that the experience of patients is acceptable and enhanced where possible. (1) A joint report by the Royal Colleges and NHS Confederation suggests that every Emergency Department (ED) should have a co-located primary care facility. (2) However, the evidence base to support different service models of General Practitioners (GPs) working within EDs (GP-ED models) is weak, (3-5) and may paradoxically increase overall attendances due to provider-induced demand, with only marginal savings per patient. (5) Previous work from the Primary Care Foundation has identified three main GP-ED models: GPs working geographically adjacent to EDs; GPs serving in a triage and screening capacity; and GPs fully integrated into ED service provision. (6) The effectiveness of each model is unclear in terms of its impact on service provision, patient experience and the effectiveness and safety of clinical care delivery.

We plan to undertake a **realist evaluation** to understand how the contextual differences between the three main GP-ED models (including patient, staff and organisational factors) influence how the services function in different settings (mechanisms) to generate variations in intended and unintended outcomes (effectiveness and safety of care provided; patient and staff experience; and wider system implications i.e. resource consequences, training needs, economic impact). (7) This analysis will be based around the ability of the 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. (8)

The project will include some preliminary work before funding (Phase 0), and then be conducted in three main Phases.

Phase 0: Preliminary work involving analysis of National Reporting and Learning System (NRLS) ED patient **safety incident reports** for the most frequent incidents and those that result in the most harmful patient outcomes, related to clinician type (GPs and ED clinicians). (9) We will also conduct a **scoping review** of ED relevant ambulatory care sensitive conditions to contribute to informing the choice of 'marker conditions'.

Phase 1: We will undertake a national **Survey** to characterise which GP-ED models are in use and to what extent in England and Wales, and the aims of the services they provide. To complement this, we will undertake a **rapid realist (literature) review** of the contexts in which and mechanisms by which different models achieve their outcomes. (10) We will then generate initial working theories on the **GP-ED models taxonomy**, to explore and clarify in a **Stakeholder conference**. The Stakeholder conference will also confirm a set of **'marker conditions'** (presenting conditions thought to be managed differently by GPs and ED clinicians i.e. investigation and admission rates) for subsequent in-depth analysis, including the effectiveness and safety of patient care provided, in Phase 2.

Phase 2: Using a mixed methods design, **twelve study sites** will be purposively sampled. Quantitative data analysis will consist of **Interrupted Time Series** analysis of NHS England / NWIS (Wales) and Emergency Care Dataset analysis, plus description of **case mix** and outcomes, and economic / **resource use evaluation**. This will be integrated with **qualitative data collection** ('marker conditions', field observations, key informant interviews, incident report analysis) using techniques such as pattern matching for a mixed methods synthesis. Three sites will be selected for each of the three main model types (GPs working geographically adjacent to EDs; GPs serving in a triage and screening capacity; and GPs fully integrated into ED service provision) and three that do not use GPs in or close to the service.

Phase 3: Segmented regression **analysis** of quantitative interrupted time series data, economic modelling of resource and outcome data, combined with field observation and interview data will inform the realist evaluation to compare how the different contexts and mechanisms lead to the intended and unintended outcomes across the different GP-ED models and identify what works for whom and in what circumstances. Findings will be provided to Survey participants and a **second Stakeholder conference** for feedback on credibility, transferability, and discussion.

The outcome of this work is to produce a **transferable evidence base for commissioning and delivery** concerning effective use of GP skills and resource in different ED settings in terms of: cost-effectiveness;

resource use; safety of care; patient and staff experience; capacity considerations and training; and sustainability and resilience, in the context of local systems. The **focus** is deliberately on the **ED sector** (not GP in-hours or out-of-hours or telephone advice services), aiming to address the key policy questions of where or how the greatest value can be delivered by using GPs in the ED setting, appropriately tailoring skill mix in context to achieve the best outcomes for patients, staff and the wider system. Even with this focus the research questions still require complex methodology and an extensive range of expertise. We have therefore assembled an experienced team of contributors covering service, policy, patient and research expertise, to deliver a high value-for-money project that answers the questions of importance to stakeholders.

Background, rationale and why this research is needed now

Increasing demand on the urgent and emergency services is overwhelming the capacity of the system and there are concerns about the consequent ability to deliver quality care. (11,12) 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 ED should have a co-located primary care out-of-hours facility. (2) The NHS England five year forward view also suggests redesigning urgent and emergency care services to integrate EDs with primary care. (13) However, we need to consider if GPs working in EDs are good value and how this is defined in terms of patient health outcomes, experience and safety versus the cost of delivering those outcomes such as resource use, admission rate and GPs' employment and training needs. (14,15) If GPs are found to add value, we need to establish in which urgent care model they provide the most effective and safe care for patients and what is the **optimum skill mix** required in different emergency care environments.

The evidence base to support service models of primary care services associated with EDs is weak and based on poor quality studies. (3-5) Work by the Primary Care Foundation identified three main GP-ED models: GPs working geographically adjacent to EDs; GPs serving in a triage and screening capacity; and GPs fully integrated into ED service provision. (6) The complexity of the situation is further illustrated by the two different financing models for supporting GPs in EDs, one where the GP provision is directly from GPs with an NHS contract, and another where the GP service is provided by a private enterprise (preliminary survey by co-applicants – see Plan, Phase 1b). The effectiveness of each model is unclear in terms of its impact on service provision, patient experience and the quality and safety of clinical care delivery. (6) The Foundation also concluded that the two main drivers behind initiatives to introduce primary care clinicians into the emergency care setting were cost reduction and to help achieve the four hour target, (6) despite the stated reason as meeting the needs of the patient to receive the right care, in the right place, at the right time. (16) Possible mechanisms for GPs to improve ED services include: timely consultations; lower resource use (investigation and admission rates); and effective triage or signposting to other agencies, but all are based on **weak evidence**. (3-5) The influence of the NHS versus private enterprise provider distinction on costs, effectiveness and experiences is also unknown.

The impact of any service change in this area is considerable and may lead to intended but also unintended outcomes e.g. a paradoxical increase in overall attendances due to provider-induced demand. (5) The impact on the wider health care system could also be significant. For example, if GPs are employed in EDs and fewer GPs are available to provide the 'core' in-hours or out-of-hours services, then this may exacerbate the problem further, with failure to secure in-hours appointments leading to unscheduled attendances at EDs. Also, if the ED is not functioning efficiently, the impact on secondary care services is potentially serious as people requiring urgent admission to specialist wards may not be effectively assessed, managed and efficiently referred onwards. Given the substantial cost of employing GPs, **cost-effectiveness of the different models is unknown**. Further implications on team-working, for continuing professional development and training of clinicians involved in unscheduled care provision are also largely unclear.

Recognising this lack of evidence, the HS&DR programme has issued a call for studies to evaluate the effectiveness, safety, patient experience and system implications of different models of using GPs in or alongside Emergency Departments. Timely, good quality research is required to investigate this. Ideally new service developments should be evaluated by randomised trials. However, the pressures are so intense in this domain that the services continually make changes to try to address the problems. This means it is practically impossible to control for other changes and biases in intervention or control arms across the timescales to conduct trials. However **well designed observational and quasi-experimental research** can still be useful to evaluate service developments, and conducted to provide meaningful evidence to inform policy within a shorter timescale than trials.

We propose a **realist evaluation** to address this knowledge gap. The realist evaluation process was designed to meet the challenges of evaluating complex interventions, recognising that the same intervention delivered in different settings will not always produce predictable results. (7) Realism is guided by an understanding that it is not the intervention itself that directly produces results, but that outcomes are generated through how the people exposed to the intervention react to it. A realist evaluation aims to understand how these reactions (known as mechanisms) generate outcomes, and how contextual factors influence how people react. The evaluation process produces a set of descriptions (termed 'theories') which describe **how interventions are observed to work in different settings**, and what outcomes are frequently produced. (17) For policy makers these theories provide an understanding of what works, for whom, in what setting and to what extent. This means that future **commissioning and delivery of interventions can be targeted** towards settings where they are likely to succeed and potential barriers to intervention success can be identified and addressed before implementation.

Aim & Research Questions

Aim: to determine clinical and cost effectiveness of GP-in-Emergency Department (GP-ED) models and to understand the ways in which service design and setting (context) influence how services function (mechanisms) to generate variations in outcomes.

In particular, we will answer the following **research questions**:

1. What models are in place? How are they staffed/funded/operationally managed/performance managed? On what scale are they delivered? (CONTEXT)
2. How do the models work (in comparison with standard practice)? Is the way they work in line with the intentions of those who set them up? (MECHANISM)
3. What are the outcomes of each model in terms of: percentages of ED attendances seen; admissions; re-attendance rates; waiting times; costs; patient safety; patient experience; team impact and sustainability? (OUTCOMES)
4. What are the relationships between context, mechanism and outcomes, and is the evidence base transferable to commissioning, service improvement and cost-effective delivery in other settings?

Overview of methods (numbers refer to Phases of Study to follow):

0. Preliminary analysis of National Reporting and Learning System (NRLS) patient safety incident data from EDs, to explore themes around safety incidents relating to type of clinician (GPs and ED clinicians) and case-mix. Also a scoping review of ED relevant ambulatory care sensitive conditions to contribute to informing the choice of 'marker conditions' for implicit exploration during qualitative inquiry (Phase 2c).

1a. **Rapid realist review** which we will register with the PROSPERO database to focus on the development of initial theories about the contexts within and mechanisms by which the different GP-ED models produce the intended and unintended outcomes, and initial consideration of economic implications.

1b. **Survey** all 200 Type 1 EDs in England and Wales for their current service model, use of GPs, aim of the service and targeted patient groups, perceived successes or failures – whether what is intended to work is achieved in practice, reasons for not having a GP component service where relevant.

1c. Follow up **key informant interviews** selected from the survey (GPs and ED clinicians) to describe apparent successes and failures of the models and contribute to informing the list of 'marker conditions'.

1d. Draft list of candidate '**marker conditions**' (conditions believed to be managed differently by GPs and ED clinicians i.e. investigations, admissions, observation times in the department, safety issues).

1e. Convene a **stakeholder conference** to discuss findings of Phases 1a+b+c+d, and to iterate the existing taxonomy of the three main models (GPs alongside EDs, used for screening and signposting or fully integrated in EDs). (6) This updated taxonomy will include contextual information about the different settings in which the GP-ED models operate, main resource drivers, the patterns of outcomes associated with the different models and working ideas about the mechanisms by which the outcomes are generated in certain contexts. The **taxonomy** will incorporate and be **structured around an effective practice framework** (i.e. caring for those with greatest health need first, doing only what is needed, reducing inappropriate variation and through co-production). Stakeholders will also participate in a consensus exercise to **select the 'marker conditions'** to be analysed in Phase 2.

2. **Case study design using 12 purposively sampled sites** for quantitative and qualitative data, which will be integrated to develop and test the initial working theories of how and why the different GP-ED models lead to their intended and unintended outcomes. Table 1, on the next page, outlines which data will be collected to address the different contexts, mechanisms and outcomes.

Quantitative data to include:

a. **Multiple interrupted time series** data over five years from NHSE Sitreps/ NWIS (Wales) for admission rates, re-attendance, investigations / treatments and waiting times, pre and post GP-ED model implementation. We recognise the limitations of the data based on what is entered into the system and from our piloting, investigations are likely to be classified as 'none', radiological and/or invasive blood tests and treatment as 'some treatment given' vs 'no treatment given'.
b. Cross-sectional data: Emergency Care Data Set (ECDS, post 2017) / HSCIC / NWIS datasets at a fixed point to compare: **case-mix** and patient demographics; **resource use** associated with waiting times, investigations and treatments used, discharge and admission rate measures.

Mixed Quantitative and Qualitative data to include:

c. **'Marker condition'** analysis to assess **differences in management** of five presenting conditions between GPs and ED clinicians, including patient experience (interviews), NHS resource and other service use for same episode, safety and the **reasons for such differences** if identified.

Qualitative data to include:

d. Field observation and key informant interviews (managers, GPs, ED clinicians and other staff) for experiences, perceived barriers, challenges, training / staffing implications, resource use review and other contextual issues.
e. NRLS/Datix data from case study sites examined inductively for themes about clinician groups (GPs and ED clinicians) and reported safety incidents.

3 **Integration of realist evaluation** - Data analysis

3a. Integration and interpretation of findings to produce refined **'middle range' theories**, which describe the strengths/weaknesses/ consequences (both effectiveness & resources) of each model, according to the effective practice framework.

3b. A follow-up national **survey** of the 200 Type 1 emergency department respondents (1b) to ascertain if our findings are credible and transferable.

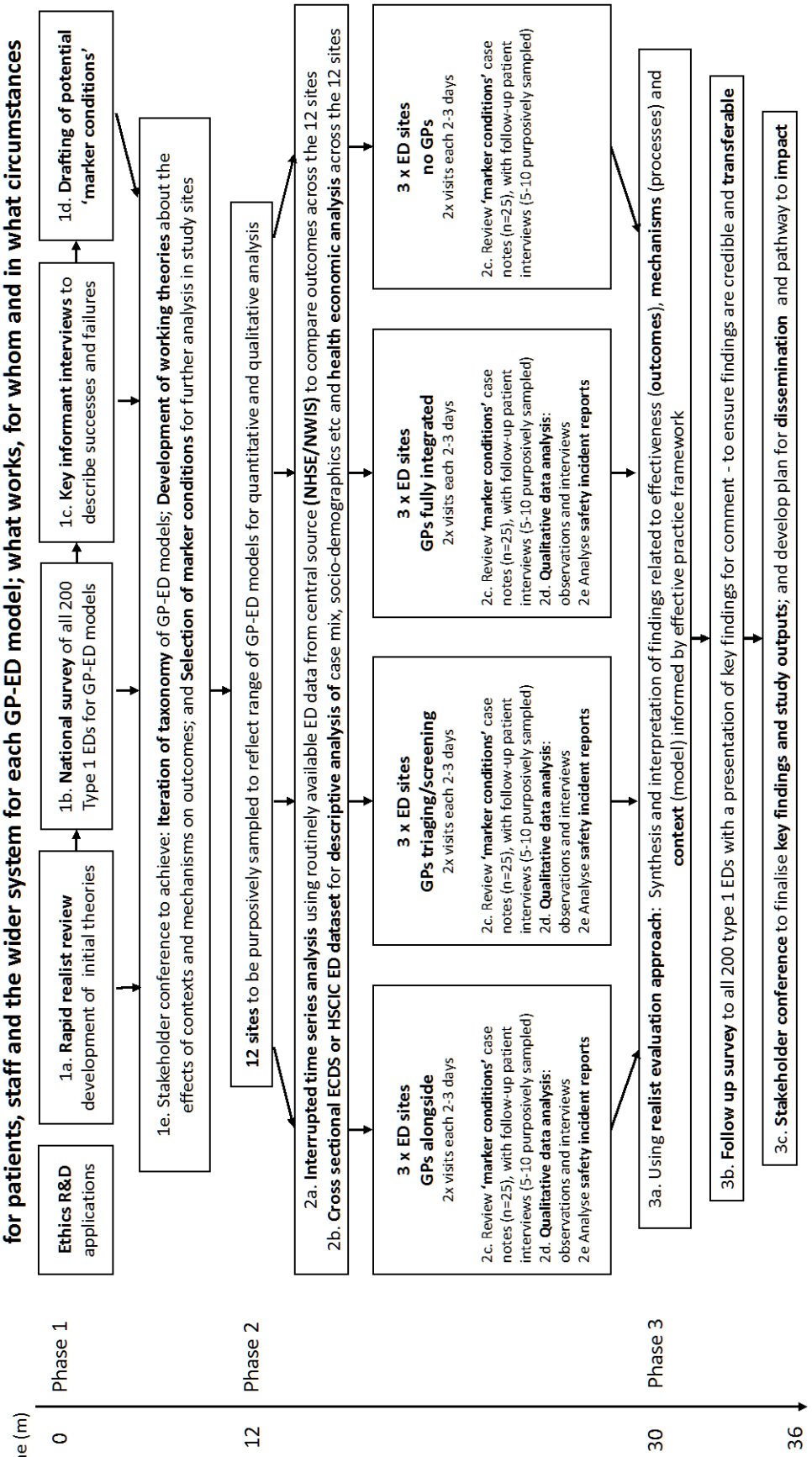
3c. Convene **stakeholder conference** to examine the evidence base and discuss how this may be **transferable to support commissioning and delivery** concerning effective use of GP skills and resource in different ED settings and implications for: cost effectiveness; resource use; safety of care; patient and staff experience; sustainability and training needs, in the context of local systems. Development of a **'toolkit'** for assessment of context, needs, local delivery and development.

Research Plan/Methods

The mixed methods design will use 'realist evaluation' to examine the effectiveness of the models in terms of what works, for whom and in what circumstances. (7) Through these methods, we will develop a detailed understanding of how the contextual differences between the three main GP-ED models (including patient, staff and organisational factors) influence how the services function in different settings (mechanisms) to generate variations in intended and unintended outcomes (effectiveness and safety of care provided, patient and staff experience and wider system implications i.e. resource consequences, training needs, economic impact). Table 1 (below) summarises our planned data collection methods focussing on each context, proposed mechanism (initial suggestions – subject to review and refinement) and outcome to test and refine our initial theories. The Flow chart, on the next page, illustrates progress and relationships between Phases.

Table 1: Framework for data collection to examine what works, for whom and in what circumstances for each GP-ED model

Context	**Proposed mechanisms (e.g.)**	**Outcomes**
Characteristics of the population served & locality including size, demography, perceptions of quality in ED and primary care 1b. Survey (to commissioners) 2a. NHSE/NWIS data 2c. Marker conditions with patient interviews 2d. Observations and key informant interviews **Characteristics of the patients** 1b. Survey (to commissioners) 2a. NHSE/NWIS data 2d. Observations and key informant interviews **Characteristics of the team** 1b. Survey (to commissioners) 2d. Observations and key informant interviews **Characteristics of the organization** 1b. Survey (to commissioners e.g. funding/contractual arrangements) 2d. Observations and key informant interviews	**Faster clinical decision making (less reliance on investigations)** 2a. NHSE/NWIS data 2b. ECDS/HSCIC +/-medical record data 2c. Marker conditions with patient interviews 2d. Observations and key informant interviews **Familiarity with appropriate filtering/triage or signposting (improve flow)** 2b. ECDS/HSCIC +/- medical record data 2c. Marker conditions with patient interviews 2d. Observations and key informant interviews **Dealing with uncertainty/ Safety netting (less likely to refer for admission)** 2a. NHSE/NWIS data 2b. ECDS/HSCIC +/-medical record data 2c. Marker conditions with patient interviews 2d. Observations and key informant interviews	**Patient experience** 2c. Marker conditions with patient interviews 2d. Observations and key informant interviews **Effectiveness** 2a. NHSE/NWIS data 2b. ECDS/HSCIC +/-medical record data 2c. Marker conditions with patient interviews 2d. Observations and key informant interviews **Safety** 2c. Marker conditions with patient interviews 2e. NRLS/Datix safety incident reports **System implications** 2a. NHSE/NWIS data (e.g.4 hour waiting targets) 2b. ECDS/HSCIC +/-medical record data (resource use: investigation, admissions) 2c. Marker conditions (resource use, including other services) 2d. Key informant interviews (e.g. training, staffing)


GPs in EDs Study: a realist evaluation to compare the contexts, mechanisms and outcomes for patients, staff and the wider system for each GP-ED model; what works, for whom and in what circumstances
Time (m)
0
Phase 1
12
Phase 2
30
Phase 3
36
Ethics R&D applications
1a. Rapid realist review development of initial theories
1b. National survey of all 200 Type 1 EDs for GP-ED models
1c. Key informant interviews to describe successes and failures
1d. Drafting of potential 'marker conditions'
1e. Stakeholder conference to achieve: Iteration of taxonomy of GP-ED models; Development of working theories about the effects of contexts and mechanisms on outcomes; and Selection of marker conditions for further analysis in study sites
12 sites to be purposively sampled to reflect range of GP-ED models for quantitative and qualitative analysis
2a. Interrupted time series analysis using routinely available ED data from central source (NHSE/NWIS) to compare outcomes across the 12 sites
2b. Cross sectional ECDS or HSCIC ED dataset for descriptive analysis of case mix, socio-demographics etc and health economic analysis across the 12 sites
3 x ED sites
GPs alongside
2x visits each 2-3 days
2c. Review 'marker conditions' case notes (n=25), with follow-up patient interviews (5-10 purposively sampled)
2d. Qualitative data analysis: observations and interviews
2e Analyse safety incident reports
3 x ED sites
GPs triaging/screening
2x visits each 2-3 days
2c. Review 'marker conditions' case notes (n=25), with follow-up patient interviews (5-10 purposively sampled)
2d. Qualitative data analysis: observations and interviews
2e Analyse safety incident reports
3 x ED sites
GPs fully integrated
2x visits each 2-3 days
2c. Review 'marker conditions' case notes (n=25), with follow-up patient interviews (5-10 purposively sampled)
2d. Qualitative data analysis: observations and interviews
2e Analyse safety incident reports
3 x ED sites
no GPs
2x visits each 2-3 days
2c. Review 'marker conditions' case notes (n=25), with follow-up patient interviews (5-10 purposively sampled)
3a. Using realist evaluation approach: Synthesis and interpretation of findings related to effectiveness (outcomes), mechanisms (processes) and context (model) informed by effective practice framework
3b. Follow up survey to all 200 type 1 EDs with a presentation of key findings for comment - to ensure findings are credible and transferable
3c. Stakeholder conference to finalise key findings and study outputs; and develop plan for dissemination and pathway to impact

Phase 0

- Preliminary work to contribute towards choice of 'marker conditions' to be undertaken before funded period by Cooper, Edwards, Carson-Stevens and 'PISA' research group, Cardiff University (January and February 2017) (https://www.cardiff.ac.uk/people/view/122861-carson-stevens-andrew).

0a National Reporting and Learning System (NRLS) analysis

NRLS data from 2003–15 are available to Cardiff University PISA group (Donaldson, Edwards, Cooper, Hibbert, Carson-Stevens) which has extensive experience of searching for and extracting safety incident reports for explicit criteria e.g. ED reports where clinician type (GP or ED) was deemed relevant and to analyse these incidents for severity of harm, and relationships of contributory and mitigating factors (9,18,19). Themes relating to case mix may emerge and contribute to the choice of 'marker conditions' (Phase 2c).

0b Scoping review

A scoping review (20) of ED relevant ambulatory care sensitive conditions (ACSC) (21) will also be performed to inform the choice of 'marker conditions' i.e. conditions that may be managed differently by GPs/ED staff.

Output: thematically analysed data on safety incidents arising with GPs working in EDs, and scoping review on ACSC, to contribute to generating list of 'marker conditions' (see 1d).

Phase 1 (0-12 months)

- To characterise which GP-ED models are in use and to what extent in England and Wales, the aims of the services they provide and the context and mechanisms by which they achieve their outcomes.
- To clarify the initial working theories of the GP-ED model taxonomy.
- To confirm a set of marker conditions for in-depth analysis in Phase 2.

1a Literature review

The previous HS&DR and Cochrane reviews of GP-ED models (3,4) and recent Ramlakhan review (5) will be used as a starting point for a **rapid realist review**, (10) with initial consideration of the possible economic implications. We will register with PROSPERO. We will replicate the search criteria used in earlier reviews to search the original databases for more recent articles. Databases: Medline, Embase, Cinahl, Cochrane DSR & CRCT, DARE, HTA Database, and NHS Evidence Specialist Collections. Searches will also be undertaken to identify additional relevant data which may come from a variety of sources (e.g. HS&DR Journals) including process evaluations, policy documents and opinion pieces. The co-applicants will act as an expert reference group and contribute papers for inclusion based on their expertise and access to grey literature. Bespoke data extraction forms will be designed to capture data relevant to the contexts within and mechanisms by which the different GP-ED models produce important outcomes. Outcomes data collection will be guided by a **framework of effective practice** and the degree to which the models appear to achieve the outcomes of:

- caring for those with greatest health needs first i.e. patients that need secondary care services are seen efficiently by clinicians with those skills;
- doing only what is needed, i.e. no more, no less and no harm;
- reducing inappropriate variation, e.g. investigation/admission rates;
- co-production, i.e. lay involvement in care decisions, service change and evaluation.(8)

We will identify, consolidate and express explanatory accounts. We will synthesise using Pawson's reasoning processes (juxtaposition, reconciliation, adjudication, consolidation, situating.) (7) This outcomes-focussed synthesis will be used to generate context-specific explanations for what works in the settings of interest. (10)

Output: A set of initial theories describing how different contexts and mechanisms relate to key outcomes, for further testing and refinement in subsequent study stages, and to contribute to choice of case study sites.

1b National Survey

Online/postal survey of all 200 Type 1 EDs in England & Wales for medical directors and commissioners to identify: the aims of employing GPs, service models in place (including non NHS GP providers), including date(s) of changes to models, and details such as access, patient volume, case mix and payment methods; governance and training processes for staff; views on whether the aims are achieved, and descriptions of apparent 'failures' for each model; and suggested 'marker conditions' believed by respondents to be managed differently by ED doctors and GPs e.g. febrile child, back pain. To increase response rates, follow up contacts

and telephone interviews will be made as necessary; consent for selected key informant interviews (1c) will be sought at this stage also.

Our **preliminary pilot survey** to ED providers in West Midlands achieved a good response rate (77%), with data from 17 departments. There was a range of models in place, varying also between in-hours and out-of-hours periods. Up to 20% of EDs employ GPs, and similar numbers use private companies or local GP groups to provide (up to 25% each). Other models also exist, including using the formal GP out-of-hours service. Approximately half of GPs so used are operating within the EDs, some 'adjacent' (up to 20%), and other models also exist (18%) or not applicable. Thus using our profile and contact networks, we feel confident that we can achieve a good response rate (which can be improved further with reminders and follow up to minimise response bias etc) and valuable data to understand the range of provision, models, and will also develop the survey to identify the intended aims of provision, and initial responses on the extent to which these are achieved, and possible reasons for this. This will provide the basis for selecting some key informants for further enquiry in 1c, and for purposive sampling of case study sites for Phase 2.

Output: identification of range of models of using GPs in EDs in current practice, for purposive sampling for case study sites (Phase 2); contribution to generating list of 'marker conditions' (see 1d).

1c Key informant interviews

Where particular contexts, mechanisms or outcomes are suggested by respondents in the survey, and thought to be of interest / importance to providing initial theory development for subsequent stages, commissioners or medical directors and frontline GPs and ED clinicians will be requested to be interviewed by telephone. Particular areas of interest may centre on descriptions of apparent 'successes' or 'failures' for each model to achieve their goals, with further discussions and interpretation of the reasons for these. Likely sample size 5-10, recruited via the survey (1b), for telephone interviews (audio-recorded, transcribed, for thematic analysis). (22) We will also explore suggested 'marker conditions' believed by respondents to be managed differently by ED doctors and GPs to supplement survey information.

Output: clarification of initial theory development concerning GP-ED contexts and mechanisms; and contribution to generating list of 'marker conditions' (see 1d).

1d Draft 'marker conditions'

Using findings from Phases 0, 1a+b+c, co-applicants (academic, clinical and public contributors) will draft a list of proposed 'marker conditions' for selection by stakeholder groups (see 1e). Conditions will be **chosen to test theories** about how the GP-ED model works. For example, a theory might be that GPs discharge more febrile children (O - Outcome) when they see children 'alongside' the ED setting (C - context) because this closely reflects their normal in-hours practice (limited access to investigation, 'discharging' with safety netting) and they are comfortable with uncertainty and safety netting (M - Mechanism). However, in an integrated model when investigation and referral of febrile children might be the expectation among colleagues and parents (C), do GPs reason that a new management style suits the setting (M) and order more tests and admit more patients (O)?

Co-applicants will select up to ten potential 'marker conditions', ranked in order of preference by (virtual) nominal group technique, to take forward to 1e.

Output: draft list of marker conditions for discussions in 1e.

1e Stakeholder conference

We will convene a group of major stakeholders to meet and discuss the findings of 1a+b+c+d, and through structured workshop discussion, **generate an updated taxonomy** which builds on the three Primary Care Foundation models (6) and is structured around the effective practice framework (8). This updated taxonomy will include contextual information about the different settings in which the different GP-ED models operate, the patterns of outcomes associated with the different models, and working ideas about the mechanisms by which the outcomes are generated in certain contexts. This is likely to include both when the models work well and also when they may not work so well. The context-mechanism-outcome configurations generated during this stage will be used to guide the choice of case study sites and the collection of data in Phase 2 which may act to confirm, refute, or elaborate upon the findings of Phase 1 of the study.

Stakeholders will review the draft '**marker conditions**' list (ten conditions from 1d), (21) and select five for in-depth study in Phase 2c via modified nominal group technique. (23) We will invite up to 40 people, to include clinical leads, commissioners, policy makers, GPs and ED clinicians, nurse practitioners, patients & public

contributors including parents of children that may use the service, in roughly equal proportions. We will recruit purposively via contacts (individual and organisational) of co-applicant group and from Survey (1b) responses. We will ensure the workshop format enables all attendees to contribute their different perspectives and experiences and for views to be heard and discussed. Our public contributor co-applicants will be actively involved in designing the workshop and will hold a pre-meeting for patient and public delegates to assist their participation in order to make effective contributions.

Output: updated GP-ED model taxonomy, informing selection of case study sites, and selected marker conditions.

Phase 2 Case Studies Data Collection (12-30 months)

- **12 Case Study Sites selected for data collection**

Case study sites will be **purposively sampled** from characteristics identified in the survey (1b), and according to the developing theories and taxonomy of model types (1a and 1e) about when the models work well or may not work so well. Three will be selected for each of the three main model types (GPs working geographically adjacent to EDs; GPs serving in a triage and screening capacity; and GPs fully integrated into ED service provision), implemented during the last five years for before-after data analysis, and three for sites who do not use GPs in or close to service. Other features of the purposive sampling frame will include:

- urban / rural; larger / smaller EDs (staff and catchment area);
- public / private providers of GP services in / alongside ED, where possible with ECDS data;
- regional variation, including England & Wales.

This sampling frame is intended to **ensure maximum transferability of findings** from the sites and methods chosen. The planned data collection is summarised in Table 2.

Table 2: Summary of planned data collection at the 12 case study sites. The three EDs not using GPs will be for quantitative analysis and 'marker condition' case note review only.

	GP-ED Models			
	Co-located (3 sites)	Triage (3 sites)	Integrated (3 sites)	No GPs (3 sites)
Quantitative data				
2a. NHSE/NWIS (patient demographics, waiting times, re-attendance, admissions, tests/ treatments, total numbers) Multiple interrupted time series data, *hypothesis testing*, pre and post GP-ED model implementation or at timely intervals if no GP-ED model in place	✓	✓	✓	✓
2b. ECDS (post 2017)/HSCIC/NWIS +/- medical record reviews Cross sectional data for *description* of case mix, patient demographics, rates of investigations, treatments, admissions, and as basis for *health economic evaluation*, for comparative data analysis between models	✓	✓	✓	✓
Quantitative & Qualitative data				
2c. 'Marker conditions' to *explore management differences* between GPs and ED clinicians (effectiveness, safety and patient experience; also subsequent unscheduled and service use for resource consequences)	✓	✓	✓	✓
Qualitative data				
2d. Key informant interviews / field observations	✓	✓	✓	X
2e. NRLS and local Datix patient safety incident report analysis for frequency, nature and severity of incidents related to GPs and ED clinicians	✓	✓	✓	X

2a Quantitative analysis of changes pre and post each GP-ED model implementation.

Data will be extracted and collated from NHS England Sitreps / NWIS (Wales) and local systems, such as Symphony, for each case study site for high level outcomes of:

- total numbers seen per quarter (to assess possibility of supply induced demand);
- admission rates (admission to hospital);
- re-attendance (seen again at same ED within 28 days);
- investigations (whether blood tests, xrays, microbiology tests undertaken);
- treatments (recorded interventions); and
- waiting times (time from presentation to completion of episode for individual patient).

Enquiries with NWIS (Wales) have confirmed no cost to the academic institutions for these data and that it is feasible to extract data on attendances, number of patients attending with non-trauma illness, waiting times, investigations, admission rates. Following Emergency Care Data Set (ECDS) piloting through 2016 (co-applicant Hughes leading implementation of ECDS), we also expect to be able to extract and utilise these outcomes from ECDS data in 2017 onwards in both England & Wales, and will use these data if more feasible. The focus is on ED management itself, not external / private providers of alternative services, so we will base extraction and analysis on ECDS data where possible.

Data will be captured per quarter for the five years prior to study, including implementation of a new GP-ED model (see purposive sample formation). These will be analysed as **multiple (one per site) interrupted time series data** for changes in the main quantitative data measures (admission rates, re-attendance, investigations / treatments, waiting times), analysing for changes from pre- to post introduction of relevant GP-ED models. The null hypothesis is that implementation of a GP-ED model does not lead to a change in outcome. We do not expect sufficient data quality to identify the split between patients seen by GP, ED physician or (e.g.) Nurse Practitioner, so data will be analysed at site and model levels only.

The Statistics RA will construct quarterly interrupted time series data on each case study site. For each site, the Statistics RA will fit a segmented regression model (c.f. model 1, (24)) to each of the main outcomes; for example, a Poisson model of number of admissions with log 'population at risk' as an offset, and a Poisson model of number of second and subsequent re-attendances with log number of first attendances as an offset. The Statistics RA will then analyse all case study sites simultaneously by fitting an extended segmented regression model (c.f. model 4, (25)) to each of the main outcomes; for example, a two-level or mixed Poisson model of number of admissions which incorporates a case study site-specific random effect. This random effects model will allow us to:

- Take into account heterogeneity between case study sites;
- Test for differences in the effect of model implementation between model types (and relative to No GPs);
- Control for case study site-specific factors such as urban/rural, larger/smaller EDs and region (e.g. England and Wales);
- Test for interactions between model type and these case study site-specific factors.

Output: apparent impacts on these outcomes pre and post the GP-ED model implementation, synthesised by ED model, and interpretation of whether there may be influences of regional / urban / rural / larger / smaller sized units.

2b Cross-sectional data from the Emergency Care Data Set or HSCIC ED dataset to compare: case-mix and patient demographics; process / outcomes (including resource use measures): waiting times; investigations and treatments used; discharge and admission rates.

Sample of 1000 patient attendances from each study site – random sample formation (unselected for urgency, symptom presentation or diagnosis, or clinician group, by random number generation from Trials Unit, applied to ID numbers), from 12 months period before study visit.

Descriptive analysis, synthesising by ED model (3 sites per model), reporting case mix and range of patients seen, and principal process / outcome measures (waiting times, investigations / treatments, admission / discharge rates).

Health economic analysis, taking the perspective of the UK NHS, we will examine the resource use associated with these principal process / outcome measures, for comparison between GP-ED model and 'no

GP' groups. This will use activity-based costing methods derived from best practice examples such as those used by Independent Hospital Pricing Authority (Australia; www.ihpa.gov.au) to identify resources used and related costs for typical episodes of care. Data regarding staff time and costs will be collected from study sites. Typical scenarios of care and estimates of the resource use and costs of delivering the differing GP-ED models compared with the 'no GP' model will be constructed. Unit costs data for resource use will be taken from NHS standard sources such as the Unit Costs of Health and Social Care, and economic analysis undertaken in order to estimate costs per 'treated patient', cost per 'averted admission' and cost per 'averted safety incident' from the NHS perspective.

The findings will be subjected to a series of sensitivity analyses to assess the impact of changes in the explanatory variables and understand the drivers of costs. The analysis will be *complemented by* contextualised data collection, based on the principles of *time-driven activity-based costing,* (26) with key informants in Phase 2d about resource use and potential resource release relating to provision and outcomes.

Output: description of case mix, and process measures for patients seen in different ED model groups, interpreted in light of regional / urban / rural / larger / smaller sized unit characteristics, and estimates of resource use and the consequences of care from different GP-models of ED provision, with initial interpretation of their relationships to outcomes achieved.

2c 'Marker condition' reviews

The conditions will be selected following: preliminary work on NRLS patient safety incident report analysis and a scoping review on ED relevant ACSC conditions (Phase 0); survey findings (1b) and key informant interviews (1c); and the consensus exercise at the stakeholder conference (1e). A sample of five patients will be identified for each of the five marker conditions in each case study site for detailed data collection and analysis regarding the effectiveness, safety, patient experience and resource use incurred in the illness episode. This analysis of marker conditions will be used to **test the working theories** (developing in the realist evaluation) that certain conditions are managed differently by GPs and ED clinicians resulting in differences in resource use, patient experience or quality and safety Outcomes, and to explore how the context or GP-ED model type appears to have influenced these differences.

Table 3: 'Marker condition' data collection

Marker Condition *To be confirmed by Phase 1*	**Proposed mechanisms**	**Outcomes data**			
		Resource use (cost)	**Effectiveness (patient health outcomes)**	**Safety**	**Patient Experience**
E.g. Febrile child <5 years old E.g. Cough and breathlessness E.g. Increased confusion in elderly E.g. Low back pain E.g. *to be confirmed*	**Faster clinical decision making** (less reliance on investigations) **Familiarity with appropriate filtering/triage or signposting** (improve flow/ waiting times) **Dealing with uncertainty/ safety netting** (less likely to refer for admission)	2b. Staff contacts, number and rate of investigations/ admissions/ treatment (ECDS) 2c. Patient interviews about subsequent re-presentation to in-hours GP or other unscheduled care 2d. Key informant interviews	2c. Medical record reviews for: **Explicit review** - evidence based appropriate care for the condition **Implicit review** describing what took place, was documented, impact of staffing, wider system.	2c. Patient Interviews 2e. NRLS/ Datix incident reports for specific marker conditions	2c. Patient Interviews

The five selected 'marker conditions' will be identified from Phases 0 and 1 as those likely to show differences in management between GPs and ED clinicians. They will be based on symptoms or nature of presentation rather than diagnosis.We will recruit a purposive sample of five patients for each condition (**n=25 cases per site, 300 total**); they will be patients who attended in the previous month; we will also include approximately half for patients seen by ED doctors, and half by GPs in those services. Patients will be selected by the

research team during site visits (see 2d). We will seek patient consent for record review and (sub-sample 60+, see below) to be interviewed by telephone, aiming to do the latter between 28-56 days after index consultation to allow for follow up of subsequent help-seeking in relation to this episode, but not too distant to raise recall bias problems.

Record review – effectiveness and safety

We will examine the medical record with an approach based on the principles of Structured Judgment (27,28) to examine Explicit criteria (based on DUQUA approach (29) which has been used for e.g. chest pain management). Using our clinical expertise, and knowledge of standard guidelines (NICE etc) available to generalists, the co-applicant group will draft **criteria for each of the five chosen 'marker conditions'**, and these will be reviewed by the Stakeholder group as an expert / scientific reference group. Adherence to **Explicit criteria** will be summarised quantitatively across conditions, and models. The research team will also examine records according to '**Implicit criteria**' to describe what was documented, what took place, the pathway followed at this attendance and subsequent attendances elsewhere and resources (especially investigations, treatment, admissions) used. These data will be analysed qualitatively, through thematic analysis of these notes and descriptions, exploring potential differences between GP-model groups (more/ lower costs, likelihood of involving further specialist / clinician groups, subsequent re-attendances), the risks / mitigating factors identified, learning points for training, etc. There will be opportunity also to address issues emerging alongside the developing theories from earlier Phases of the research, not yet identified and mapped out here. Any identified safety incidents, though likely to be uncommon in this small sample, will be assessed by the PISA classification method to describe the incident's nature, characteristics, harm level, and contributory and potential mitigating factors.(9)

Patient interviews – patient experience and outcomes, resource use

We anticipate interviewing **5-10 participants per study site** (total sample 60+ from the 300 total in Phase 2c), depending on data saturation as analysis indicates. (30) We will conduct these one-to-one interviews with selected patients over the telephone, purposively sampled from these patients attending with the marker conditions. The sampling frame will ensure that we have participants across the case study sites; also range of age, gender, urgency of presentation, and those seen by ED / GP / Nurse practitioner staff groups. The interviews will be semi-structured, audio-recorded for transcription, and subsequent thematic analysis **exploring the main effectiveness, safety, experience and perceived benefit for the patient**. (22) This will include areas that correspond to the effective practice framework domains (see Phases 1a, 3a) (8). We will also ask patients to report which further services were used in relation to this index episode (e.g. subsequent re-attendances at ED, use of in-hours or out-of-hours GP or telephone advice lines).

As above, we will undertake thematic analysis, structured also around the effective practice framework Outcomes, including co-production and impact on patient experience. We will also examine for the apparent or perceived impact for the patient and the wider system, and the potential reasons or Mechanisms for differences in Outcomes identified. We will summarise the current episode (investigations, treatments, admissions etc) and subsequent **use of services** (re-consultations, up to 28 days post index consultation) from this purposive sample, including resource use and related costs, summarised quantitatively across the 300 patient cases. We will interpret these data for potential differences in Outcomes by GP model, regional / urban / rural / larger / smaller sized ED unit and other emergent characteristics. As the sample is purposive, this part of the analysis is in essence inductive for differences and further understanding gained, and we recognise that findings (including the quantitative summary data) would require further testing in subsequent more representative samples, but they will inform the developing theories of this realist evaluation.

Output: indication of whether management differences appear to exist across GP-ED model types, and other influences on these differences and their Outcomes for patients including effectiveness, safety, and experiences. We will estimate resource use, NHS costs, capacity utilisation from the detailed analysis of these selected cases and potential for resource release for each model regarding the key elements of provision (senior review, investigations, treatment, admissions) and outcomes (re-consultation, length of stay, safety, patient experience outcomes).

2d Further qualitative data capture and analysis

The primary aim of the realist method is to **generate theories** about how the interventions work. These theories describe how the introduction of resources into a context triggers a process of reasoning which leads to the outcomes observed. (31) Qualitative methods are well suited to exploring this reasoning process, to develop our understanding of how the intervention (GPs in ED) creates its effect, and why it might function

differently in different settings. In addition to the qualitative data in Phase 2c, we will collect further data from those nine sites implementing one of the models of using GPs (not the comparison three sites without GPs).

We will undertake site visits to each case study site where a GP-ED model is being implemented. These will be for 2-3 days, on two occasions to each site (i.e. 5 days for 9 sites = 45 days).

Observation

We will observe the process of presentation, triage, waiting times, assessment, investigation / treatment / referral processes, discharge and review plans in the case study sites. Observations may help to uncover key influences on staff and patient behaviour which might not be clearly visible or accessible during the other data collection Phases (e.g. the influence of workplace culture). (32) We will carry out some observation shifts in the public/waiting area where patients present and are triaged; with permission of patients, we will also carry out observation shifts in the consulting room where the patient interacts with the GP; clinicians will be able to ask the researcher to leave the room at any time if they decide that it would be inappropriate to observe the consultation. To record observations, we will use a structured observation framework, with prompts including the time and duration of the contact, interaction between patients and clinicians, and details of process as listed above. We will pilot our observation framework and may refine it. Between patient contacts, the field researcher may discuss previous patient contacts with the clinician, asking clinicians to describe their process of reasoning and decision making in the handling of the contact. These conversations will be recorded (with permission) on a digital recorder and later transcribed. The researchers will not have direct contact with the patients, will record no patient identifiable information and no interactions with the patient will be audio-recorded. The observations will provide data to develop the theories about **how the models operate and why they may work differently** in different settings. In addition, the insights from the observations may also help to inform the direction of the staff interviews in which impressions formed by the observer can be explored and elaborated upon by the interviewees. The researchers performing observations will be aware of the working theories about how the models operate which will allow the data gathered during this Phase to be targeted towards further theory refinement, or the development of any new theories which emerge from the data.

Key informant interviews

We will select and recruit a purposive sample of managers and clinicians (ED, GP, nurse practitioner groups; senior and junior) at each site. We will undertake face-to-face semi-structured interviews, audio-recorded for transcription and thematic analysis. (22) We anticipate **4-6 interviews per study site**, depending on data saturation as analysis indicates, (30) likely 35+ in total. A realist interviewing approach will be used during which the researchers' working theories will be explained to the interviewees for discussion and refinement based on the participants' experiences. (7,33) The interviews will **explore mechanisms for the perceived 'success' or 'failure' of each model** in achieving the effectiveness, safety and organisational aims, including staff experiences, perceived barriers and challenges, and the wider impact. The latter will include experiences or perceptions about staff recruitment, retention, continuity, capacity gains and losses, training needs and delivery, team-working and team climate.

Using the emerging analysis of the 'marker conditions' (2c), the interviews will also explore the theories around **why the marker conditions may be managed differently by different clinicians** or within different GP-ED models. The perceived impacts, including benefits for patients, use of further services for same or subsequent episodes; meeting goals of care/model (identified in Survey 1b), resource redeployment barriers and opportunities will also be discussed as part of the time-driven activity based costing and health economic evaluation. (26)

Data from observations and interviews will be analysed collectively and interpreted for differences between GP-ED models, along with contextual factors including: regional / urban / rural / larger / smaller sized unit and other emergent characteristics, and in order to further develop and refine the theories from earlier Phases. The influencers and drivers of resource use and costs will be identified and characterised.

Output: Detailed data to contribute to the understanding of the mechanisms of 'why and how' the three GP-models operate differently in different settings (and why marker conditions may be managed differently) and how the models impact on resources and factors associated with those differences.

2e NRLS & local patient safety incident report analyses

We will analyse data of incidents reported, for example via Datix and local Trust / Board level to the National (NRLS) dataset or direct to NRLS, from each of the nine case study sites with a GP-ED model, in the

preceding one year, if they relate to aspects concerning the type of clinician involved (e.g. GP or ED clinician) and specifically searching for the 'marker conditions'.

We will classify the incidents for type, level of patient harm and contributory and mitigating factors using our own validated classification method (9), seeking to test our working theories on differences in management between GPs and ED clinicians through different GP-ED models and whether this has any safety implications for patients or provides understanding about resilience in these different models of GP-ED.

Output: inductive analysis of NRLS data from case study sites for themes about roles, outcomes, service development, resilience and safety implications of different clinician groups and models of care operating in this context.

Phase 3 Integration of realist evaluation (30-36 months)

- Data analysis

3a. Integration and interpretation of findings, to produce a set of **refined middle range theories**

- "Which Contexts, Mechanisms, and Outcomes are associated with successful GP-ED models, barriers, unintended consequences?"

This stage will integrate the realist review (1a), quantitative analyses from the survey (1b), interrupted time series data (2a), cross sectional data (2b, including health economic) with the mainly qualitative (also summary) data and analyses from marker conditions (2c), field observation and interviews (2d), and NRLS datasets (2e). This **mixed-methods synthesis** will analyse the strengths and weaknesses of the proposed Mechanisms that lead to the intended and unintended Outcomes (effectiveness, safety & resources) of each model, (7,34,35) in achieving the goals of effective practice:

- caring for those with greatest health needs first;
- doing only what is needed (no more, no less and no harm);
- reducing inappropriate variation; and
- co-production.(8)

We will also interpret the influences of the setting or Contexts (including regional / urban / rural / larger / smaller units, staff mix) and the Mechanisms explored on those Outcome domains, including also impact on resources and the wider system, and the implications for service development, human resource, training and sustainability / adaptability of the service model. The qualitative data (principally Phases 2c, 2d, 2e) will help us to understand the detail of the types of models (taxonomy, 1e) and how they are implemented (1b, 1c, 1e), where there has been any change in this from the original intention (1b), and the understandings/beliefs of those involved (clinicians and managers) of the Mechanisms by which they might work (1b, 1c, 2d). Integrating the empirical data (quantitative and qualitative) from our case study sites with the developing theories from the earlier review (1a), we will generate **'middle range theory'** that seeks to utilise all aspects of data to address the research aims about understanding what works, for whom, in what circumstances and contexts for the ED setting. (36) The goal is also to orientate this understanding gained towards **application in practice, ensuring that findings assist policy-makers, commissioners and providers** to know where or how the greatest value can be delivered by using GPs in the ED setting, appropriately tailoring skill mix in context, to achieve the best outcomes for patients, staff and the wider system.

Output: integrated quantitative and qualitative analyses, focusing on patient, staff and service outcomes, building middle-range theories of effective, efficient use of GPs in EDs.

3b. Follow up Survey

We will send a follow up survey to all respondents from the 200 Type 1 emergency centres in 1b. Recommended by our PPI co-applicants, the focus of Phase 3b will be to ascertain if our findings are felt to be **credible and transferable**. Postal, email and telephone reminders will be used to maximise response rate, and participants will be made aware of the value of responses in informing the output of the study and the stakeholder conference to follow (3c).

Output: Confirm if findings are credible and transferable, identifying for the policy-maker and provider intended audiences of our findings which of the theories resonate most strongly and widely.

3c. Stakeholder conference

We will convene a second stakeholder conference to examine the integrated evidence base (3a, the 'theories'), and the implications for effectiveness, safety, resources, sustainability, resilience and training needs, and to generate **transferable, actionable findings** about cost-effective practice and service development / improvement, in the context of local systems and changing needs and priorities. As part of the output we aim to produce a **'toolkit'** for assessment of context, needs, aims, capacity, resources, sustainability, delivery and development. This may be useful to policy-makers at macro level, but will be particularly directed towards the needs of commissioners and providers at service / site levels.

Where possible, we will re-convene the same participants as in Phase 1e – up to 40 individuals to include clinical leads, commissioners, policy makers, GP and ED Clinicians, nurse practitioners, patients & public members including parents of children that may use the service, in roughly equal proportions. We will fill any spaces through purposive recruitment via contacts (individual and organisational) of the co-applicant group. As before, our format will provide opportunities for active participation of all attendees to ensure the range of perspectives and experiences is voiced and considered. Discussion will use mixed stakeholder small groups to review findings, consider credibility and transferability, and discuss how these map to organisational and sectoral needs. From this analysis, we will identify where there is consensus and/or a range of needs / views, to distil as the 'toolkit' of assessment steps as above. Our public contributors will co-plan the workshop and convene a pre-meeting for patient and public members to support their effective participation.

Output: consensus on transferable findings about cost-effective practice and service development, in the context of local systems that can achieve multi-faceted outcomes of 'effective practice' and value-for-money; and a commissioners' and providers' toolkit to inform review, design and context-specific implementation of models of using GPs in the ED setting.

Dissemination and Projected Outputs

We will disseminate our transferable evidence base on the effective use of GP skills and resource in the different GP-ED models to inform policy-makers, commissioners and providers in making decisions about cost-effective practice and service improvement, applicable in the context of local systems. These will be disseminated to governments, commissioning groups, Royal Colleges, health boards and providers as soon as practicable. Where possible the co-applicants will consider where **actionable interim findings** are evident during the project (see Timetable) and plan for their dissemination. Co-applicants are well positioned within their policy, clinical and patient networks to identify the most effective means of dissemination to colleagues, providers and policy-makers. Our public contributors will play a leading role in ensuring dissemination to the wider public in the interests of accountability and in keeping with the principles of co-production. This will raise knowledge of findings and awareness of potential applicability, to increase support and influence on the implementation and uptake of our findings. The dissemination strategy includes the following elements:

1. **Communication with reporting health organisations**: We will summarise our findings for dissemination to NHS organisations. We anticipate our study will provide the evidence base for unscheduled care delivery in Emergency Departments in England and Wales, evaluating different models of GPs in or alongside EDs for their effectiveness and safety, good use of resources and sustainability, suitable for local contexts. We will explore strategies for dissemination with the Stakeholder group and other senior advisors, consisting of senior policy and operational representatives of both nations and from Royal Colleges (Emergency Medicine, General Practitioners). It is likely that this will involve presentations at leading national conferences, as well as securing invitations to smaller seminars and local meetings to a variety of professional and lay audiences.

2. **Media**: Our public contributors will lead this dissemination theme. All co-applicants will draw on their networks (e.g. Involving People, PRIME Centre Wales and others), and communication teams at our Universities, NHS Trusts and government connections to publicise findings and implications for practice for a public audience. We will identify messages suitable for national and local television, radio and press coverage and for dissemination using social media. In addition to media outlets, we will publicise our findings to interested members of the public, for example through the existing participants ("cohort") in Health Wise Wales, National Voices, Health & Social Care Alliance of Alliances.

3. **Peer-reviewed publications**: Our team has demonstrable success for producing high-profile academic outputs including journal publications with major impact relating to emergency medicine, patient safety, health policy, public health, and primary care. The rapid realist review protocol will be available on PROSPERO and a final NIHR report will be written giving a full account of the methodology and its findings

4. **Education and training:** We will plan educational events in collaboration with the Royal Colleges of Emergency Medicine, General Practitioners and Institute of Healthcare Management. We will develop, for example, the model from our PISA patient safety work in primary care, which is now being disseminated via an RCGP Spotlight Award, with support for meetings, events, and educational or other personal / practice development programmes.

5. **Conferences**: The final stage of the research is to convene a key stakeholder conference (Phase 3c) to examine the evidence, its implications for effectiveness, safety, resources, sustainability and training needs, to inform policy-makers, commissioners and providers. This will also provide a network of stakeholders for cascade of the evidence base and 'toolkit' to other groups, including further meetings / conferences when available. Although some aspects of this research are context specific (NHS setting etc), our approach is to seek transferable findings, both across NHS and potentially of international significance. Our co-applicants include several high profile members experienced in health policy or service delivery, and who are often invited to present at international conferences, and these will also be a valuable vehicle for dissemination of our findings.

Expertise in the Team & Project management

The co-applicant group includes **specific sub-groups** with individual activities and expertise:

- NRLS/patient safety analysis (PISA group: Carson-Stevens (lead), Donaldson, Edwards, Cooper, Hibbert);
- Methodological support (Swansea-based; statistics: Berridge; economics: Anderson; trials and mixed methods: Snooks; qualitative methods: Porter; Realist methodology: Davies, Cardiff);
- PPI contribution (Evans (lead), Harrington, Hepburn); and
- Policy / service experts (Cooke (lead), Dale, Siriwardena, Donaldson, Rainer, Hughes).

The study will last 36 months and be conducted in three main Phases following preliminary work, with specific team members responsible for certain areas as outlined in Table 4 (on the next page). Phase 1 will be conducted over 12 months with the rapid realist review and survey being coordinated from Cardiff. Cooper (an academic GP) and an appointed research associate (RA) will attend the case study sites for quantitative and qualitative data collection in Phase 2 (months 12-30). Analysis of the data will start in Phase 2 and continue into the last 6 months of Phase 3. The uploaded Gantt chart illustrates the study timetable in detail.

The full Study Management Group of co-applicants will have eleven face to face meetings (month 0, 4, 6, 9, 12, 16, 20, 24, 28, 32, 36 to review progress strategically, interpret data to contribute to theory development, and consider throughout the implications for policy, education and service delivery for clinicians, and for patients. Where possible the co-applicants will consider where **actionable interim findings** are evident, and **plan for their dissemination**. In addition, we will convene the stakeholder conferences at 11 and 34 months for additional external input (Phases 1e, 3c). All meetings are costed, including for meaningful PPI attendance and contribution. The **in-house (mainly Cardiff) Operational Group** will meet every 2 weeks (or more if needed), with links to **methodological co-applicants / staff (mainly Swansea)** and **public contributors** by audio-call as appropriate to study needs, for example to discuss arising themes and if additional data are required during follow up site visits or from other sources, and certain team members will meet in person to coordinate activities. A **Steering Committee** including a scientific, PPI and provider expert will also be invited and convened to meet annually to review progress against objectives and timescale.

Ethics and governance

Research Ethics and R&D approval will be required for Phases 1b, 1c, 2c and 2d, and will be sought through the Health Research Agency system and local Trusts / Boards.

In addition, there will be an application for an NHS England Information Governance toolkit, submitted before the funded period. Cardiff University Information Security Framework (ISF) guidelines will be followed and we will adhere to informatics governance requirements, concordant with NWIS, HSCIC as appropriate.

Table 4. Responsibilities

Phase	Description	Team members responsible
0	Preliminary NRLS work and ACSC scoping review	Cooper, supported by Edwards, Carson-Stevens & PISA group
1a	Rapid realist review	Edwards & Cooper with expertise from Davies, consulting with the policy / service experts sub-group for interpretation and generation of theory
1b	Design and coordinate the online survey utilising contacts and profile to maximise reach and response rates	Cooper, the appointed RA and administrator, supported by Edwards, with expertise from Cooke and service experts sub-group
1c	Key informant interviews to follow up the survey	Cooper and the appointed RA, with analysis supported by Edwards, Porter, Snooks
1d	Draft the list of marker conditions	The Cardiff team (Edwards, Carson-Stevens, Cooper, Davies, Rainer) and Swansea team (Anderson, Berridge, Porter and Snooks) including PPI representatives (Evans, Harrington, Hepburn)
1e	Achieve full representation of commissioners, medical directors, ED clinicians and GPs and PPI at the stakeholder meeting	Edwards, Cooke, Dale, Donaldson, Hughes, Rainer, Siriwardena, Snooks and the PPI team contacts/networks
2a	Quantitative data collection NHSE Sitreps / NWIS	Cooper and the appointed RA will assist the Swansea team (Berridge, with appointed statistician) with the data extraction
2b	Quantitative data collection ECDS/HSCIC data +/- medical record reviews	Cooper and the appointed RA will assist the data extraction for Anderson for health economic analysis, with appointed health economist. Hughes has expertise in ECDS data to advise on this stage.
2c,d,e	Qualitative interviews and observations, marker condition analysis and patient safety incident reports	Cooper and the appointed RA, supported by Edwards, Davies, Porter, Snooks, Evans; Carson-Stevens re safety reports.
3a	Multiple interrupted time series data analysis (from 2a) from NHSE Sitreps/ NWIS (Wales) for admissions, re-attendance, investigations and treatments, and waiting times pre & post GP-ED model implementation and quantitative ECDS/HSCIC data for health economic evaluation (from 2b) Analysis of the qualitative data, including marker conditions (2c), observations (2d) and key informant interviews (2d) Safety incidents (2e)	Swansea team (Berridge, with appointed statistician for 2a, Anderson, with appointed health economist for 2b) Cooper and the appointed RA, supported by Edwards, Davies, Porter, Snooks, Evans Edwards, Cooper with support from Carson-Stevens, Donaldson, Hibbert
3b	Follow up survey	Cooper with support from Edwards and Davies and policy/service/PPI subgroups
3c	Stakeholder conference	Edwards, Cooper supported by the Cardiff team with expertise from Cooke, Dale, Donaldson, Hughes, Rainer, Siriwardena, Snooks and the PPI team contacts/networks

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