General Practitioners and Emergency Departments (GPED): Efficient Models of Care

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Glossary / abbreviations

A&E	Accident and Emergency Department (also known as Emergency Department)
APC	Admitted patient care
CCG	Clinical commissioning group
CQC	Care Quality Commission
DiD	Difference in difference
ED	Emergency Department (also known as Accident and Emergency Department)
ESR	Electronic staff record
GLM	Generalised linear model
GP	General Practitioner
GPED	General Practitioners working in or alongside the Emergency Department
HES	Hospital Episode Statistics
HRA	Health Research Authority
ICH-GCP	International conference for harmonisation of good clinical practice
LSOA	Lower super output area
MRC	Medical Research Council
NHS	National Health Service
NICE	National institute for Health and Care Excellence
NIHR	National Institute for Health Research
NoMAD	Implementation measure based on Normalization Process Theory
NPT	Normalization Process Theory
ONS	Office for National Statistics
POC	Publication Oversight Committee
PSSRU	Personal Social Service Research Unit
REC	Research ethics committee
SD	Standard deviation
SMG	Study management group
SOP	Standard operating procedure
SSC	Study steering committee
UK	United Kingdom
UWE	University of the West of England, Bristol
WP	Work package

1. Trial summary

Background
Pressure continues to grow on Emergency Departments (EDs) in the United Kingdom, with declining performance and adverse effects on patient outcome, safety and experience. One proposed solution is to locate GPs in or alongside the ED, with a number of models introduced. Currently, 40% of EDs report primary care co-location, however evidence of effectiveness is weak. There is no consensus regarding the most efficient model of care, or even whether GPs should be employed in this way.

Research question
What is the impact of GPs working in or alongside the ED (GPED) on patient care, the primary care and acute hospital team and the wider urgent care system? What is the differential impact of alternative service models of GPED?

Methods
Mixed-methods study, comprising three work packages.

Work Package A; Mapping, Taxonomy and Interviews
We will map, describe and classify current models of GPED in all EDs in England, building on previous work. This will include details of the service model, the extent of GP coverage within the model and the date of any service change. Through interviews with key informants we will examine the hypotheses that underpin GPED and its anticipated benefits. We will also undertake telephone interviews with an identified system leader in sites that we know either are or are not planning to implement GPED with capital funding provided by the Chancellor's Spring 2017 Budget announcement (capital bid sites) under the current policy initiative to incentivise the implementation of GPED in English EDs before winter 2017/18. All system leaders who received funding and complete a first interview will be invited to take part in a follow-up interview 12 months later to understand the extent to which the aims of the new GPED model were achieved. We will also send a brief electronic survey by email to a representative of each of the type 1 ED departments in England explore the extent of GP coverage within that model. This research activity is described in more detail in a related research protocol and has independent HRA approval (IRAS: 230848).

Work Package B; Quantitative Analysis of National Data
We will measure the impact of the models of GPED identified in WP-A, compared to a no-GPED model, using a retrospective analysis of routinely available Hospital Episode Statistics (HES) data alongside data collected directly from service providers. We will adopt three approaches; i) Cross sectional analysis – comparing EDs with and without GP cover; ii) Cross sectional analysis – including intensity of GP cover and iii) a quasi-experimental analysis and estimate difference-in-difference regression models with closely matched non-GPED sites as controls. Our primary outcome measure is the number of ED attendances, and we will also assess a wide range of secondary outcomes.

We will also calculate costs and consequences of the different GPED models on the basis of their estimated effects alongside estimated resource use, with the objective of identifying genuine changes in resource utilisation.

Work Package C; Case Studies
We will complete a detailed mixed-methods analysis in ten case study sites that are about to implement (six sites), or have already implemented (four sites) a GPED model of care. We will take advantage of the

current policy initiative described above by prospectively studying six sites before, and between 6 and 12 months after, they adopt GPED. These sites will be purposively selected to represent a range of geographical locations and 2 or 3 leading models of care based on the telephone interviews conducted in WP-A.

The six prospective case study sites will be complemented by a further four case study sites selected to include well-established GPED models, to understand how services mature and develop over time.

In each of the ten case study sites we will triangulate ED and HES data with local data sources and observable characteristics, focusing particularly on the wider local urgent care system, and combine this with a parallel qualitative study to ascertain the views and experiences of GPED from the staff working across the case study sites and from patients and carers using survey and interview techniques. There will be a two-way relationship between quantitative and qualitative data collection and analysis, and we will examine the effect of GPED on staff, patients, flow and resource use within the wider healthcare system.

Data collection in the case study sites will include:

• ED data, combined with local data sources relating to the wider urgent care system, including primary care data, where available
• Non-participant observation of clinical practice
• Patient and carer interviews

In the six prospective sites this will be combined with a longitudinal qualitative interview study collecting data from a wide range of staff, and staff surveys administered before and after GPED implementation.

Benefits
We will disseminate a comprehensive assessment of GPED from multiple perspectives to identify the most efficient model of care, maximise clinical and cost effectiveness, reduce staff pressure and improve patient outcome, safety and experience in the UK and internationally.

2. Background

Despite many initiatives to reduce demand, pressure continues to grow on the UK's Emergency Departments, with an associated decrease in performance.[1] This leads to Emergency Department (ED) crowding, associated with adverse outcomes and increased mortality.[2,3] There is a clear need to find a solution that reduces the burden on EDs and improves patient experience and safety.
The "Keogh Review" of urgent care aims to reduce pressure on EDs by treating more patients close to home in primary and community settings,[4] and is now being implemented in England. It includes a recommendation that co-located primary care models should be considered in every ED,[5] however, the optimal model to achieve this has not yet been identified, and evidence for the effectiveness of GPs in the ED is weak in both the UK and Europe.[6-9] A very recent review of primary care services located with EDs concluded that there is very little evidence to support this model of care, and that "a robust evaluation… is needed to inform future policy".[10]

Nevertheless, there is an increasing trend to include GPs at the hospital front door. A joint report from four Medical Royal Colleges recommended that every ED should have a co-located primary care

facility.[11] Estimates of the proportion of ED patients that could be managed by a GP vary widely between 15% and 40%.[12,13] There are a range of models of integration; most involve GP services alongside ED staff, with some operating a separate co-located service as a primary care "filter" in front of the ED, while others are more integrated with the ED team.[6] Current evidence suggests that some form of co-location exists in 43% of EDs,[14] but this is set to increase rapidly and co-location is a key aim of NHS England's urgent and emergency care "Vanguard sites".[15] In the Spring budget of 2017, delivered on 8th March, the Chancellor of the Exchequer announced the following:

Experience has shown that onsite GP triage in A&E departments, can have a significant and positive impact on A&E waiting times.
I am therefore making a further £100m of capital available immediately for up to 100 new triage projects at English hospitals in time for next winter.

As a direct result of this announcement, a significant number of EDs in England have bid for a share of this capital funding in order to implement GPED models of care before the winter of 2017/18, and are being supported by NHS England and NHS Improvement to make changes in the way their services are delivered. This provides an ideal research opportunity, since it is essential that these and all GPED initiatives are based on the best available evidence, and that where adopted they are used to generate reliable research that will guide future policy.

2.1 Why is this research important?

Effective evaluation of the different models of implementing a GP in or alongside the ED (GPED), including various approaches to patient triaging/streaming and integration with existing ED services, is essential to inform service development and meet the urgent heath needs of the population. As a result this issue will remain highly relevant and important to the future needs of the NHS.

This study uses a mixed-methods approach to evaluate the impact of GPs working in or alongside the ED on patients, healthcare professionals and the wider urgent care system, examining different models of service as well as comparing those EDs with and without collocated GPs. This builds on existing work to address uncertainty about the best way to implement GPED.

In order to evaluate GPED it is important to be clear about the intended benefits and mechanisms of action, but these have not been clearly articulated. There appear to be several implicit hypotheses that underpin GPED initiatives, including the following potential benefits:

A. Reduced pressure on the ED, freeing resource to concentrate on those most ill and injured.

B. Improved outcomes for patients, on the assumption that treatment of less seriously ill patients by GPs will be associated with better risk management, reduced resource use and a lower chance of unnecessary hospital admission.

C. Following on from the above, improved cost effectiveness.

D. Re-direction of patients into more appropriate services, providing education and reducing future ED attendances.

E. Reduced waiting time in the ED and improved performance against the "four hour standard", which

requires 95% of ED patients to be admitted, transferred or discharged within hour hours of arrival.

However, none of these hypotheses have been well tested, and we therefore aim to shed light on these issues. We will interview key policy and local system leaders to identify other hypotheses and potential mechanisms for benefit, some of which we will be able to examine through this research.

Whilst it is has been suggested that GPED may have some benefits for patients, the consequences for the NHS workforce, both GPs and hospital staff, have not been well considered, particularly when there is real uncertainty as to whether GPED reduces ED attendances,[16] and/or emergency admissions.[17] Some of the apparent impact of GPED on EDs may simply be re-labelling of the same work, with no real benefits for patients or the NHS. Co-located GP services may further increase demand at hospital sites, transferring the problem of over-crowding from EDs to GP urgent care centres. In particular, it is not clear what the impact is for GPs, who are already overstretched and in short supply, and GPED may not be the best use of their time and skills.[18]

Finally, the cost of implementing and running GPED is a legitimate concern in the current commissioning landscape. Budgets are adversely affected by unanticipated payment incentives, and this is a particular concern relating to the provision of walk in centres and other GP services in and alongside EDs.[19] Although GPs in the ED may be effective in reducing emergency admissions, they may not be cost effective.[9] We therefore intend to compare resource utilisation and costs of care at ED sites with and without GPED, and to compare the costs of different service models.

2.2 Why is this research needed now?

As the number of hospitals implementing GPED increases rapidly, with several competing models in use,[6] the need for definitive evidence regarding the most efficient model of care, and best use of scarce NHS resources, becomes increasingly urgent.

The research team has already produced both primary and secondary research relevant to the subject area. Salisbury et al completed an evaluation of walk in centres.[16] Findings indicated benefits for patients with good quality and safe care, but at additional cost,[20] and there are important lessons for this study. Purdy et al have reviewed the literature relating to avoidable emergency admissions,[9] with findings supporting continuity of care and access to records in general practice, but not GPED.

In light of our work to date we believe this research question is best addressed by a statistical examination of existing data combined with more detailed mixed-methods analysis in selected case study sites, using both retrospective and prospective approaches. We are particularly well placed to use routine data and case study methodology to evaluate the current initiative to increase the number of GPED sites in England announced by the Chancellor during the 2017 Spring budget.

For patients as service users, expectations and regard for their care and experience are important components of this evaluation. Research indicates that patients may attend the ED with non-urgent health problems because of the ease of access or a perceived need for diagnostic tests.[21] However, this can lead to increased re-attendance rates and patient follow-up visits. Total attendances at EDs are a small proportion of all consultations including those at GP surgeries in the surrounding area, so small shifts in patient behaviour could have major implications for the wider healthcare system.[22] We have therefore included consideration of these issues in this research.

3. Aims and objectives

Research questions

1. What is the impact of GPs working in or alongside the ED on patient care, the primary care and acute hospital team and the wider urgent care system?
2. What is the differential impact of different service models of GPs working in or alongside EDs?

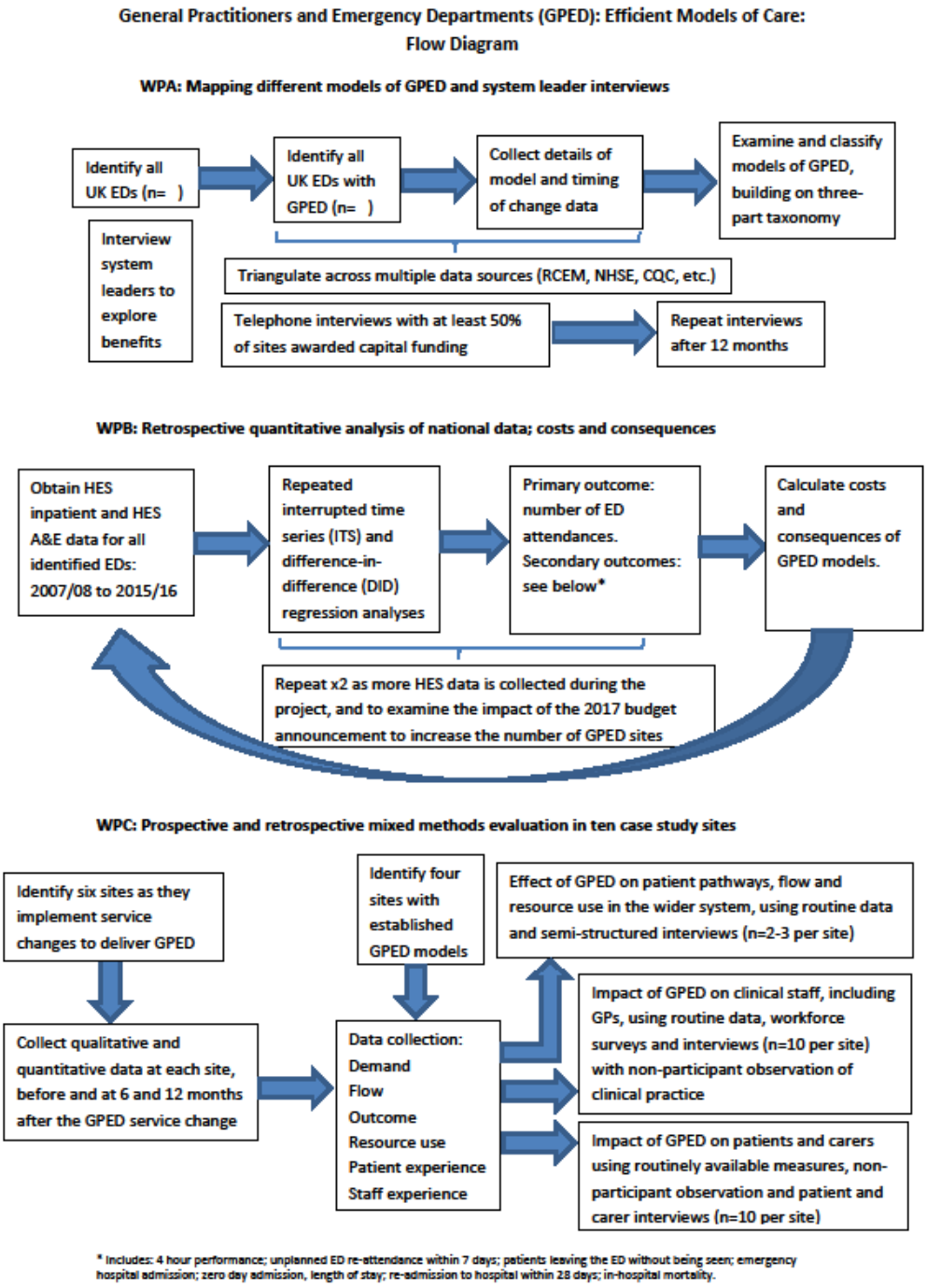
Objectives

1. To map and describe current models of GPED in England (drawing on multiple sources in WP-A).
2. To determine the impact of GPED on patient processes and outcomes including overall attendances, attendances in different components of the local urgent care system, waiting times, emergency admissions, re-attendances and mortality (from retrospective analysis of HES data in WP-B, collection of local data in WP-C, and non-participant observation in WP-C).
3. To assess the impact of GPED on the case-mix of admitted patients by exploring admission rates, including the number and proportion of short stay and zero day admissions, subject to an examination of coding behaviour by hospital Trusts, and any changes that may undermine the reliability of this measure (from retrospective analysis of HES data in WP-B).
4. To explore the impact of GPED on GPs, including turnover, absence, satisfaction, well-being and attitudes to and scope of practice (through a mixed-methods approach including workforce surveys and interviews in WP-C).
5. To explore the impact of GPED on the working patterns and roles of other health care professionals in the ED, including training, workload, skill-mix and expertise (through a mixed-methods approach including workforce surveys and interviews in WP-C).
6. To explore the impact of GPED on local urgent care services, on the wider system including primary care (e.g. demand for in-hours and out-of-hours GP appointments), and on the interface between services including patient flow (through a mixed-methods approach using secondary data analysis and qualitative techniques in WP-C).
7. To assess the impact of GPED on patients and carers (through interviews and non-participant observation in WP-C).
8. To compare resource utilisation and costs of care at ED sites with and without GPs in or alongside the ED, and to compare the costs of different service models (through economic analysis in WP-B).
9. To prospectively evaluate the current promotion of GPED models of care through collaboration with sites that have bid for capital funding to implement GPED, conducting interviews with identified system leaders and measuring changes in the above parameters over time and as implementation proceeds (through the baseline and 12 month interviews in WP-A, the analysis of HES data, where available, in WP-B, and a prospective mixed-methods case study approach in WP-C).

4. Plan of Investigation

4.1 Flow diagram

Figure 1: Flow diagram



4.2 Trial design

This is a mixed-methods study, divided into three Work Packages (WPs).

4.3 Work Package A: Mapping different models of GP working in and alongside Emergency Departments, and system leader interviews to understand the hypotheses that underpin GPED and the experience of implementing these models of care.

This Work Package will address objectives 1 and 9.

4.3.1 Work Package A1: Mapping different models of GPED.

We will work with the Royal College of Emergency Medicine (RCEM) and NHS England to identify, describe and classify current models of GP working in all EDs in England. In March 2015 RCEM published "Ignoring the Prescription" which indicated that 43% of EDs currently have a co-located primary care facility.[23] We will work collaboratively with the RCEM and NHS England to update this and explore in more detail the nature of these co-locations, current service configuration and the date of commencement of any service change(s).

A detailed survey of the Yorkshire and Humber region has been published more recently, showing a range of overlapping models in current use, and suggesting a relatively complex baseline position.[24]

We will triangulate these sources with CQC data, direct enquiry to individual sites and relevant data available from other researchers with an interest in this subject area to understand and classify current models of care, building on the four-part taxonomy proposed by Cooper et al 2019 (in press). This describes four main operational models:

- INSIDE: Integrated - Where the GP service is fully integrated with the Emergency Department service.
- INSIDE: Parallel - Where there is a separate GP service within the Emergency Department for patients with primary care type problems.
- OUTSIDE: Onsite – Where the GP service is on the hospital site but physically distinct from the Emergency Department.
- OUTSIDE: Offsite – Where the GP service is provided off the hospital site.

We will identify a date of commencement for every ED in which GPs work within or alongside the ED service (GPED). We will also map the local funding arrangements, to inform the cost and consequences work in WP-B. We will rank the identified models of care in order of frequency, and anticipate that two or three distinct model types are likely to emerge which we can then describe and examine in more detail through WP-B and WP-C.

4.3.2 Work Package A2: System leader interviews to understand the hypotheses that underpin GPED, and the experience of implementing a GPED model of care.

We will approach senior clinicians and managers in selected commissioner and provider organisations as well as NHS England and the Department of Health, inviting them to participate in a semi-structured interview that will explore their views on GPED, the potential advantages and disadvantages of this service configuration and the hypotheses that underpin it. An experienced

researcher will conduct 6-8 interviews that will be recorded digitally, transcribed verbatim and analysed thematically to identify anticipated benefits and impacts of the main GPED models.

Working with NHS England, we will identify a system leader in each of the sites that we know either are or are not planning to implement GPED with capital funding provided by the Chancellor's Spring 2017 Budget announcement, and invite them to participate in a telephone interview that will identify the local context, planned model, expected benefits and wider impacts. All those who received funding and are interviewed will be contacted again after 12 months to review progress against the originally stated objectives, and assess how successful the implementation of GPED has been and to understand the extent to which the aims of the new GPED model were achieved. We will also send a brief electronic survey by email to a representative of each of the type 1 ED departments in England explore the extent of GP coverage within that model.

We anticipate interviewing a system leader from at least 50% of EDs funded by the Spring 2017 initiative, and recruiting six of these as prospective case study sites in WP-C. Once again, the interviews will be recorded digitally and analysed thematically to identify anticipated benefits and impacts of the main GPED models.

This research activity is described in more detail in a related research protocol and has independent HRA approval (IRAS: 230848).

4.4 Work Package B: Retrospective analysis of routinely available national data and cost consequences analysis.

Through WP-A we will have created a typology of a number of models of GPED, and will have mapped which sites in England correspond with each of these main types (or are exceptions not fitting any of these models). We will also have clarified the underlying hypotheses and assumptions that have led to the growth of GPED, and will use these to inform and refine our subsequent analyses.

Building on this, in WP-B we will conduct a quantitative analysis of administrative data to measure the effectiveness, costs and consequences of the two or three most prevalent models of GPED currently implemented in the English NHS.

4.4.1 Work Package B1: Quantitative analysis of national data. This Work Package addresses objectives 2 and 3.

4.4.1.1 Statistical approach

Our analytical approach follows best practice recommendations for the analysis of observational data published by the UK Medical Research Council.[25]. We will adopt three approaches; i) Cross sectional analysis – comparing EDs with and without GP cover; ii) Cross sectional analysis – including intensity of GP cover and iii) where possible, a quasi-experimental analysis, using difference-in-difference (DID) regression models to identify the causal effect of each GPED model on the primary outcome (number of ED attendances) and on a number of secondary outcome measures (described below).

I. Cross sectional analysis – comparing EDs with and without GP cover

We have data from a survey our colleagues from Cardiff University collected, which we are currently supplementing and updating, on the times that any GPs work in hospital Trust EDs. This will be categorised into daytime and evening, and weekdays and weekends. Patterns of cover differ by Trust, and we will assume that over six months (three months either side of the date of questionnaire completion) this remained unchanged. Each patient record will be categorised by time (daytime / evening / weekday / weekend) and will therefore be flagged regarding whether or not they could in principle have been seen by a GP in the ED. Our first cross-sectional analysis will compare the outcome measures of patient cohorts who could have been seen by a GP with those who could not, accounting for casemix to the extent that is possible using routine data.

II. Cross sectional analysis – including intensity of GP cover

For a subset of Trusts, we have data on the number of GPs present in the ED. We can adjust this for size of the ED (using, for example, total number of ambulance arrivals). Times of day and days of the week (daytime / evening / weekday / weekend) will be attributed an 'intensity' variable – zero when no GP was present, and otherwise adjusted number of GPs present in principle. Our second cross-sectional analysis will be a 'dose-response' analysis, exploring whether more GPs present have a stronger effect on any of the outcome variables, accounting for casemix to the extent that is possible using routine data.

III. Quasi-experimental analysis

An additional survey of all hospital Trusts in spring 2019 will obtain (for a subset) the exact hours worked and FTE GPs in each ED. Analyses 1 and 2 above will be repeated with this improved data, using a regression discontinuity design and the cutoff time provided by each Trust to elicit the causal effect of the presence of one or more GPs. For the subset of Trusts where information is available in 2017 (Cardiff survey) and 2019 (UWE survey) we may additionally be able to use a before and after approach if we are confident that changes have occurred. We will use the ten case study sites, where we are confident of information about GPED models and timings, to pilot our regression discontinuity design. If feasible, we will use this approach more widely to replace the planned interrupted time series.

If feasible, we will also include a control group of non-GPED services in a difference–in-difference (DiD) approach. This mirrors the identification strategy of randomised controlled trials as closely as possible using observational, non-randomised data. The effect of an intervention (here adoption of a GPED model) is estimated by identifying the difference in outcomes between an intervention and a control group after the intervention was implemented. Both groups must share a common trend (but not necessarily level) in outcomes before the intervention, which suggests that they are equally affected by external factors. Any changes in the outcome for the control group that occur contemporaneously with the intervention can then be attributed to external factors, and changes in the intervention group over and above those in the control group are attributed to the intervention itself.

In our application, EDs that have implemented a GPED model form the intervention group while those operating a non-GPED model form the control group. Information on GPED model and start date for each ED site will be provided by WP-A. To reduce the risk of confounding, we will select control sites to mirror intervention sites with respect to the distribution of a number of observable pre-intervention structural characteristics, including, for example, volume of ED attendances, staffing levels, GP density in the local health economy, and average distance

travelled from patients' lower super output area (LSOA) of residence to the ED as an indication of accessibility of services. Furthermore, control sites will be selected that exhibit similar trends in ED attendances for at least three years prior to the intervention date to ensure that the identifying assumptions of the DID model are fulfilled.

All regression analyses will be conducted in a generalised linear model (GLM) framework to account for the non-normal distribution of outcome measures. All regression models will control for observed ED characteristics, patient case-mix, general time trends and seasonal effects. We will explore the possibility of a time-lag while GPs 'bed-in', and examine this using a variety of techniques, including statistical methods to reveal when any change occurs. We will also consider adding a 'during' phase to any 'before and after' analysis, to reflect implementation and bedding-in. We will conduct pooled analyses as well as analyses stratified by the two or three most common GPED models, and will adopt a Bonferroni-correction to ensure a family-wise error rate of 5%.

4.4.1.2 Data sources

We will analyse NHS England ED attendance data, and HES inpatient and HES A&E data for the period 2007/08 to 2015/16, subsequently extended to later periods as more data become available during the project lifetime, and with the long-term aim of assessing the impact of the Spring 2017 initiative to rapidly and substantially increase the number of EDs in England operating a GPED model, though given the time lag in obtaining routine data this may require an extension to the project. Data on monthly ED attendances by hospital is made publicly available by NHS England. This will be supplemented by the more detailed patient-level HES A&E dataset, which contains information on all ED contacts in England, including time of arrival and duration of wait in A&E. The HES inpatient (Admitted Patient Care; APC) dataset records detailed information on all admissions to inpatient care, including admission source (ED vs other), admission and discharge timings, primary and secondary diagnoses, treatments received, and discharge destination. HES APC can be linked to the A&E dataset through a unique patient ID. We have a long track record in successfully applying for, managing and analysing each of these substantial and complex datasets.

4.4.1.3 Primary and secondary outcomes

Our primary outcome measure is the number of ED attendances. This information is available from routine HES A&E data as well as public NHS England records since 2007/08, and is measured at ED level.

We will also assess a number of secondary outcomes:
1. 4 hour performance
2. Unplanned ED re-attendance within 7 days
3. Patients leaving the ED without being seen
4. Mortality within 28 days after attendance
5. Emergency hospital admission
6. Zero day admission (subject to an examination of coding behaviour by hospital Trusts)

These primary and secondary outcomes reflect the expectation that GPED affects both the volume and severity (i.e. case-mix) of patients requiring further attention by ED staff. We

recognise that some of these measures may represent changes in the care provided, while others will reflect changes in case mix, so will be interpreted with care. For example, if the number of cases managed in a site with GPs working within the ED remains the same, but 4 hour performance improves or the number of patents re-attending within 7 days goes down, this is likely to reflect improved performance. But if the number of cases in an ED site with a co-located primary care services goes down substantially but hospital admission rates (per 1000 patients) go up, this may reflect changes in case mix. Therefore, these measures will be used in an exploratory manner, to illustrate changes in volume and the process of care, and to generate propositions that can be explored further in WP-C.

All secondary outcomes are measured at patient level and will be adjusted for observed patient age, sex and case-mix where appropriate.

4.4.1.4 Sample size and power

Our analysis will use national data unless there are specific reasons to exclude individual hospitals. There is no sampling and therefore a sample size calculation is not appropriate. We have, however, estimated power as if it were a national one-off intervention using the following assumptions:

1. Hospital Trusts with type 1 emergency departments range between approximately 4,000 and 30,000 attendances per month. An estimated effect size within this range varies from 0.58 to 1.55; we have therefore assumed an effect size of 1.0.
2. Our time frame is 2007-8 to 2014-15 (at least) which is 96 months. We do not (yet) know when GPED services were introduced, so have assumed half way through this period on average.
3. Using a simulation-based power calculation method outlined by Zhang et al,[26] if we find levels of autocorrelation of 0.3, this results in 0.85 power to detect a 1 SD effect. Autocorrelation of 0.1 results in 0.96 power to detect a 1 SD effect. This effect size translates to around 65 attendances per month avoided from 4,000 in a small Emergency Department to 175 avoided from 30,000 in a large Emergency Department, or 2-6 patients each day.

This means that our study has the power to detect a much smaller effect size than is expected to occur clinically as a result of GPED initiatives. Furthermore, the analysis is very likely to deliver more power than this simple approximation, principally due to the large number of GPED services being introduced at varying time points. In addition, we have more time points than the Zhang simulation, although we are uncertain where in the time series the intervention will be. Overall, this power calculation is a low bound, which will be exceeded in the more sophisticated analysis planned.

4.4.2 Work Package B2: Costs and consequences.
This Work Package addresses objective 8.

We will calculate costs and consequences of the different GPED models based on their estimated effects alongside estimated resource use (e.g. GP salaries, incremental change in other staffing levels and costs), all derived from routine administrative datasets (WP-B1) and local datasets (WP-C) supplemented by information from WP-A. We will use Personal Social

Service Research Unit (PSSRU) unit cost estimates supplemented by local cost estimates to value changes in activity and resource inputs.

We will use information on the most common funding arrangements for GPED (from WP-A) to differentiate between costs that fall on hospital and primary care budgets, with the objective of identifying genuine changes in resource utilisation rather than cost shifting.

If the quantitative analyses in WP-B identify a significant impact of the different GPED models on patient health outcomes (e.g. mortality within 28 days after attendance), we will also calculate the cost-effectiveness of GPED and of the different models of GPED. To do so we will use health economic modelling techniques to translate patient health effects into quality-adjusted life years using published estimates of health-related quality of life by age and sex group and life expectancy data from the Office for National Statistics (ONS).[27] However, recent ED attendees are likely to have different long-term trajectories in life expectancy and quality of life compared with the general population, and we will therefore conduct a literature review to identify studies that have tried to quantify these differences, adapting our calculation accordingly. We will also conduct extensive sensitivity analyses around the assumed decrements in life expectancy and quality of life, and highlight any uncertainty that may change the conclusions of this analysis. We will inflate earlier costs (from the retrospective analysis in WP-B) to 2017 price levels using appropriate price indices, and we will discount any estimates of future costs and benefits using a 3.5% discount rate for costs and benefits (as recommended by NICE), with other options included in sensitivity analysis. Further sensitivity analyses will test the impact of underlying assumptions of the economic model.

4.5 Work Package C: Mixed-methods analysis in ten case study sites.

This Work Package addresses objectives 2, 4, 5, 6, 7 and 9.

4.5.1 Case studies

We recognise that there are limitations to the analyses that can be done with routine data. Therefore, to complement the national statistical analysis described above, we will conduct a more detailed mixed-methods analysis in ten case study sites that are about to implement (six sites), or have implemented (four sites) a GPED model of care, focussing on the main models identified in the early stages of the study.

The six prospective sites will be evaluated over time; both before, and 6 and 12 months after, the service change, through the collection and analysis of both quantitative and qualitative data as described below. The duration and structure of post implementation site visits will be revised if data saturation occurs, and in response to emerging themes in the data analysis.

The four established sites will be evaluated once, with a follow-up contact after 12 months.

4.5.2 Case study site selection

The case study sites will be selected purposively using a matrix approach that is based on the following factors:

- Established model – four sites, or prospective (newly introduced) model – six sites.

- Region of England (Northern, Southern or London). For practical reasons, we do not plan to recruit case study sites from the Midlands since another NIHR-funded study on the same topic will be recruiting case study sites from this region.

- Type of GPED model in place or planned (2 or 3 options depending on early results).

Given the range of factors involved, and the fact that the available resources will allow the completion of only 10 case studies, some cells of the case study selection matrix will be empty.

We will also seek to identify and select sites that can provide routine data about the number and characteristics (age, sex, deprivation) of patients who have consulted primary and other urgent care services outside the ED (e.g. type 3 and 4 A&E Departments (minor injury units and walk-in centres), where present) in the last 3 years or since they were established, if later. Most primary care services are highly computerised so we believe it will be possible to extract these data, although we anticipate using bespoke methods in each site.

We will also obtain routinely available information about other observable characteristics of the local health economy (e.g. overall demand, rurality, availability of primary care, quality indicators of local primary care e.g. from the GP Patient Survey) to provide contextual data that will help us to interpret findings from the case study sites, and to ensure valid comparisons.

Prospective (newly introduced) sites will be identified from the successful bids submitted to the capital fund established in Spring 2017 to support the rapid introduction of new GPED models of care in EDs in England, following the Chancellor's Budget announcement, and on the basis of the system leader interviews conducted in WP-A. We anticipate recruiting six prospective sites in WP-C.

Established sites will be identified during WP-A, and on the basis of local intelligence. We anticipate recruiting four established sites in WP-C.

4.5.3 Case study site data collection

Data collection from the case study sites will occur in one of two ways:

- Case study site visit. During a site visit a researcher will spend 1-3 weeks at a site collecting a wide range of quantitative and qualitative data, described in more detail in sections 4.5.1.4 to 4.5.1.9 below.

- Case study site contact. During a site contact a researcher may visit the site for a day, and/or speak to key informant(s) by telephone. Locally available routine data, identified during a previous case study site visit, will also be collected and analysed.

The overall data collection schedule is set out in Table 1

	Month 0	**Month 6**	**Month 12**

Prospective Case Study Site	Site Visit (Baseline: pre-implementation)	Site Contact	Site Visit
Established Case Study Site	Site Visit	-	Site Contact

Table 1: Data Collection Schedule

The first site visit will be to an established case study site. We will seek a well-established and recognised site and use this visit to inform subsequent baseline data collection in the six prospective case study sites. Once all the baseline (month 0) data has been collected from all the prospective case study sites we will then complete site visits in the three remaining established case study sites. Follow-up data collection will then proceed as described in Table 1. However, the post implementation visits to prospective sites will be revised in response to the ongoing analysis of study data, and if data saturation is apparent in order to reduce participation burden.

During a case study site visit a broad mixture of quantitative and qualitative data will be collected using the following methods:

4.5.4 Quantitative data collection: all sites

We do not anticipate using administrative national data (e.g. HES) in WP-C, as it is unlikely to be available in the study timescale. However, detailed data about activity and case-mix at each case study site will be combined with the data from WP-B1 to explore hypotheses about shifts in activity between the ED and co-located GPED services, and the impact on the health economy as a whole. We recognise that this will only be possible in the small number of case study sites, but it will enable us to explore whether the introduction of GPED appears to be associated with increases, decreases or no change in the number of people attending the hospital site (ED and GPED combined), and any effects on other local urgent care services.

We will collect quantitative data from the local healthcare community as outlined above, and where available additional routinely available local data relating to factors that include demand, flow, outcome, resource use, diagnostic testing, additional funding received to support the introduction of GPED (e.g. through the Chancellor's Spring 2017 initiative) and patient and staff experience from routinely administered surveys such as the Care Quality Commission (CQC) Accident and Emergency Survey and the annual NHS Staff Survey. We will also obtain routinely available workforce data, which includes measures of vacancy, sickness and turnover from the Electronic Staff Record (ESR).

To complement this quantitative analysis a parallel qualitative study (described below) will be conducted to ascertain the views and experiences of GPED from the staff and patients at each case study site. There will be a two-way relationship between the qualitative data collection and analysis and the quantitative analysis described above. Findings from the qualitative data on the experiences of the staff and patients will be explored further in the quantitative analysis of the additional data sources where available – for example, if it were the perception of staff that their model of GPED was resulting in fewer X-rays or lower admission rates for patients seeing a GP then this could be tested using the local quantitative data. Equally, any findings from the case study quantitative data analysis could be explored or explained further during qualitative

collection and analysis – for example, if the quantitative data suggested that the existence of a GPED model was leading to a large increase in the total number of patients attending the GP service with no corresponding reduction in the number attending ED, we could explore possible explanations for this within the qualitative study.

We will survey staff working in the case study ED sites, and in other local urgent care settings, to collate their perceptions of GPED using the NoMAD questionnaire; an implementation measure based on Normalization Process Theory (NPT).[28] NoMAD is a 23 item survey instrument for assessing implementation processes from the perspective of staff involved. It is a relatively new tool that has been developed to study implementation in a theoretically driven way. Whilst a pre-designed questionnaire is available for use, there is in-built flexibility to make the instrument more relevant to the study context. A slightly different version of NoMAD will be developed for each study site to allow a detailed examination of the model in each setting whilst facilitating comparison across sites. For example, whilst the same theoretically-driven questions will be used in all sites, they will be prefaced by detailed information about each context – this will take the form of a paragraph to describe the model of care in each site.

The NoMAD questionnaire will be complemented by a workforce survey that will include standardised and validated measures of work-related experiences and attitudes. The selection of constructs for measurement in this workforce survey will be informed by theoretical models of occupational strain and common workplace stressors, including the Job Demands-Resources Model,[29] and the Job Demands-Control Model.[30] Specific scales, including measures of job satisfaction, turnover intentions and psychological wellbeing will be obtained from prior organisational research,[31] and with reference to major data sources (such as the National GP Worklife Survey) that will enable comparison.[32]

4.5.5 Additional quantitative data collection: prospective sites only

In the six prospective case study sites the NoMAD questionnaire will be administered to all staff at two time points (0 and 12 months). The NoMAD is designed so that it can be used at different time points, to see if perceptions of a new service change over time. It will be used prior to implementation of GPED to examine staff expectations about whether it could become a routine part of their working practices and then again 12 months after implementation to describe participants' views about how GPED impacts on their work and to record any changes in attitudes towards GPED. Descriptive data from the questionnaire will be linked to data collection and analysis of the qualitative data. In keeping with current recommendations, a basic descriptive analysis of the questionnaire data will be produced to provide an overview of the perceptions of all staff within each case study site.

In the six prospective case study sites the workforce survey described above will also be administered prior to implementation of GPED, and again 12 months after implementation.

4.5.6 Quantitative data analysis

The analyses of routine quantitative data at the 'site' level will be characterised mainly by descriptive statistics that will complement the qualitative information collected, and which will take due account of any seasonal effects. This approach will enable us to look for potential differences and similarities in views within a case site as well as draw out meaningful

comparisons across case sites. Descriptive data from the NOMAD questionnaire will also be linked to the analysis of qualitative data, and will permit examination of changes over time in the prospective case study sites. The evaluation of data from the workforce survey will include descriptive analyses and examination of changes over time in a repeated measures framework. Multilevel regression analyses will also be considered to identify any worker-related characteristics or experiences that predict changes in job satisfaction or turnover intentions.

4.5.7 Qualitative data collection: all sites

We will select purposively approximately 10 staff at each of the sites to participate in qualitative semi-structured interviews regarding their experiences of working within their service model. We will capture, using a topic guide, information on: training/education needs; workload; skill-mix; professional boundaries; use of investigations and attitudes to risk; job satisfaction/stress; barriers and facilitators to service introduction; in addition to any topics arising from the local quantitative analysis. It is difficult to speculate on what these additional topics will be, as they are contingent on the outcomes of the quantitative analysis, but could include issues such as low staff morale, high staff turnover (if evident from the workforce surveys) or lack of communication (if highlighted from the NoMAD questionnaire). These may vary from site to site. The qualitative sample will include GPs, ED doctors and nurses of different grades. The sample will be selected to ensure a range of views regarding how the GPED model has been implemented in their context, based on responses given to the NoMAD questionnaire relating to: length of time working in the organisation, involvement in management/oversight of the GPED service and the participant's perceived value of GPED.

With the support of our PPI representatives, and to ensure a rounded perspective in each of the case sites, we will also gather information on the patient/carer experience of GPED. We will purposively select approximately 10-15 patients (and carers where appropriate) who have used the GPED service. Patients will be selected to obtain maximum variation based on gender, age and reason for consultation. Semi-structured interviews will be conducted with patients (and carers where appropriate) as soon after attendance as possible, to maximise recall relating to their experience. The interviews will explore: reasons for attending ED or GPED; the influence of GPED on their decision to attend; confidence in a GPED compared to ED doctor; impact of GPED on future ED/GP attendance. We will also ascertain their experiences of GPED in terms of: quality; advice; referrals and post-discharge care; satisfaction with the service. They will also be asked to explore which aspects of the service are most important to them and the barriers/facilitators to service use.

To supplement the interview data and to obtain a nuanced insight into how the GPED service model is working in practice we will also conduct non-participant observation of clinical practice within the study case sites. The observations will consist of 2 hour blocks covering different parts of the day/evening and different activities, e.g. clinical and non-clinical work, triage, informal interactions and clinical consultations. It is considered that a maximum of 12-16 hours of observations over a two-week period within each case site will provide sufficient information. Observations of consultations will be documented on a pro forma and will focus on how the clinicians present themselves during the consultation, as well as the response of patients and any interaction with colleagues during this time. Field notes will document everyday working practices, focusing specifically on the nature of the GPED service. These data will give greater

insight into workplace dynamics, relationships, decision-making and the distribution of tasks and responsibilities.

4.5.8 Additional qualitative data collection: prospective sites only

In the six prospective case study sites we will undertake a longitudinal interview study collecting data at baseline (prior to GPED introduction) and 12 months after introduction of the new service model. During the first interview we will capture, using a topic guide, information on: expectations of the new model of care; readiness to employ GPED; information on the appropriateness of the preparations made for the introduction of the new service. Following implementation, we will ascertain information on the experience of the new service and the impact on: training/education needs; workload; professional boundaries; job satisfaction/stress; clinical practice and risk management; barriers and facilitators to service introduction; in addition to any topics arising from the local quantitative analysis.

In the six prospective sites we will also conduct semi-structured interviews with key informants - commissioners and heads of service (2-3) before the GPED service goes live to gain insights into the reasons behind the choice of model, the expectations for the service, how staff have reacted to the plans and the preparatory processes that have taken place to implement the new service. Interviews will be repeated 6 and 12 months following full implementation of GPED. Topics will include: advantages and disadvantages of the new model of care; perceived effectiveness of the service model in terms of care provision; impact on staff; barriers and facilitators to successful roll out.

4.5.9 Qualitative data analysis

All interviews will be audio recorded digitally and transcribed verbatim. A computer package (NVivo) will be used to manage the data. Following transcription the interview material will be organised according to analytical headings using a constant comparison approach. To introduce transparency and a systematic approach we will engage in: detailed familiarisation; identification and indexing of key themes; contextualising these themes in relation to the broader dataset; and interpreting them, within the context of theoretical themes relevant to the interview material. We will use Normalisation Process Theory (NPT) to frame the analysis to understand how easy it was to implement the GPED interventions into routine practice.[33] NPT conceives making changes in established routines as a complex and dynamic enterprise, and proposes a model which explains the way in which new practices are adopted and absorbed by individuals into existing behavioural conventions and routines. During the analysis, regular meetings will be held between the research team to discuss the emergent themes from the fieldwork material to explore the potential to 'test' these in the local quantitative data. The analysis will allow us to gain in-depth insight into the 2 or 3 main models of GPED care. This approach will enable us to look for potential differences and similarities in views within a case site as well as draw out meaningful comparisons across case sites and for different models of GPED, to allow robust conclusions to be made.

The analysis and interpretation of WP-C, integrating both qualitative and quantitative information, is likely to include the following issues:

a) The effect of implementing GPED on patient pathways and flow within the local healthcare system, using non-participant observation and routinely available data.

b) The impact of GPED on patients and carers and on healthcare staff using interview data, workforce surveys and routinely available data.

c) Barriers and enablers to the implementation of a GPED model of care, and the development of recommendations to improve future implementation by identifying challenges and potential solutions.

4.6 Study duration

The study will commence on 1st June 2017 and end on 31st May 2020 (total duration 36 months). Data collection will occur between the 1st July 2017 and 31st December 2019.

4.7 Milestones

The key milestones are as follows:
Month 2: Key trial staff appointed; project governance and trial steering committee established.
Month 5: Regulatory and ethics approvals in place.
Month 9: All pre-implementation data from the prospective case study sites collected.
Month 12: Taxonomy completed.
Month 15: All six month follow-up data from prospective case study sites collected.
Month 21: All twelve month follow-up data from prospective case study sites collected.
Month 31: All study data collected and initial analysis complete.

4.8 Gantt chart

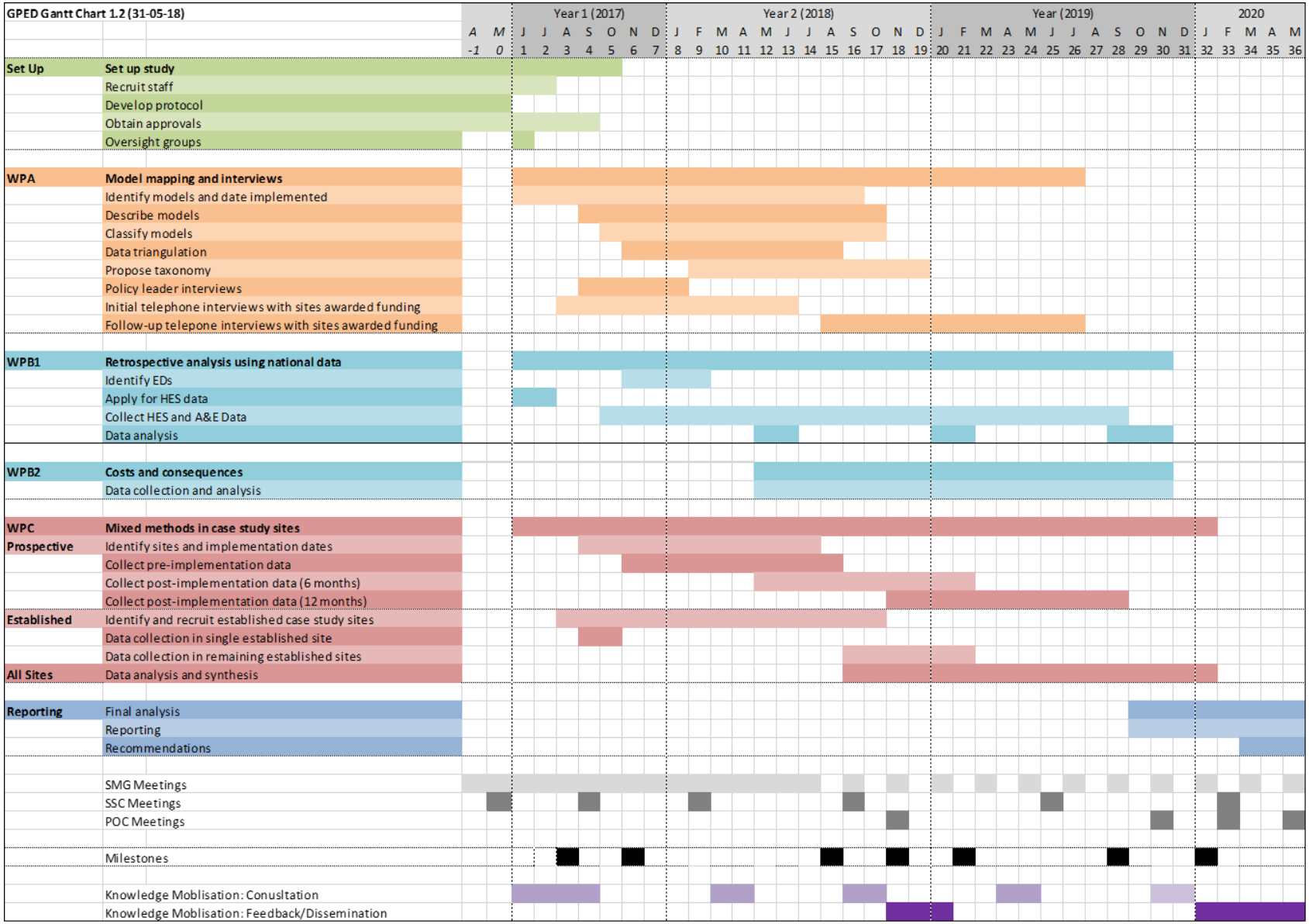


Figure 2: GPED Study Gantt Chart

5 Patient and public involvement

The aim of patient and public involvement within this study is to ensure that the perspective of patients and carers is considered fully as we study and compare the different models of GPED. It is important that the quality of patient care is not adversely affected by any proposed changes in service organisation. To help us ensure that the patient and carer perspective is central to our work we have formed a group of seven people with experience, either as carers or as patients, of using ED services. The members of this patient and carer group will be involved throughout all stages and work packages.

We will use a variety of methods to work with the group including face to face meetings, e-mail, telephone and video conferencing as appropriate and in keeping with the needs of group members. The work of the group will be supported by Dr Andy Gibson, Associate Professor in Patient and Public Involvement, who will also provide appropriate training and support to patients and carers and to the wider academic team to facilitate involvement.

The patient and carer advisory group will be involved in all stages of the research as follows:

5.1 Work Package A

The PPI group will help to write the schedules for the interviews with key informants to ensure we adequately address issues that are important from a patient perspective. This will highlight the degree to which potential patient benefits underpin the logic of these models of care alongside other issues.

5.2 Work Package B

We will review with our PPI group our plans for data collection. We will explore to what extent the data we propose to collect capture key issues from a patient and carer perspective, and if there are any data we should be collecting to better capture patient/carer concerns.

5.3 Work Package C

The PPI group will be involved in writing the ethics application and developing research instruments, e.g. interview and observation schedules. They will review our proposals for qualitative and quantitative data collection, to ensure these capture information relevant to patients and carers.

The PPI group will also be involved in the analysis of qualitative data produced by our research, to check the validity of our analysis from a patient and carer perspective.

The PPI group will contribute to our dissemination plans, helping to ensure that the findings are made available in an appropriate format to patients, carers and public groups. We aim to make our findings on the pros and cons of each model of care easily accessible and understandable to a lay audience.

We will hold four PPI workshops during the project, and the PPI group will select two of its members to attend the study steering committee.

6 Trial management

The trial will be hosted by NHS Bristol Clinical Commissioning Group (CCG) and sponsored and managed by the University of the West of England, Bristol (UWE). UWE will prepare study documentation and data collection forms, support participant recruitment, check data quality as the trial progresses and assist the research team in carrying out the study analyses, reporting and dissemination.

6.1 Day-to-day management

The trial will be managed by a study management group (SMG), which will meet in person or by teleconference every one to two months. The SMG will be chaired by the chief investigator and will include all members of the named research team (see Chief Investigator & Research Team Details).

A study coordinator will be employed at UWE and will be responsible for the day-to-day running of the study, obtaining approvals, reporting to Study Steering Committee (SSC), the Publication Oversight Committee (POC) and the Research Ethics Committee (REC), managing the budget, drafting reports and research papers. The study coordinator will report to the chief investigator regularly. They will liaise closely with the other trial staff and will ensure that all individual research components are undertaken in a timely manner and within budget.

The study coordinator will undertake monitoring procedures at a level appropriate to a risk assessment performed by the sponsor to ensure delivery of the study in accordance with the protocol.

6.2 Study Steering Committee and Publication Oversight Committee

Two committees will be established to govern the conduct and reporting of the research:

A. Study Steering Committee (SSC), meeting six times during the project lifetime, with an independent chair, appropriate clinical and investigator expertise and two patient representatives. The SSC will oversee all aspects of the research and its component work packages;

B. A Publication Oversight Committee (POC) will oversee and assure all study outputs, ensuring absolute independence in the interpretation and communication of all research findings. This additional committee has been established to ensure that a critical distance is maintained between the Chief Investigator (Professor Benger, who is also the National Clinical Director for Urgent Care at NHS England) and the study findings and outputs.

7 Ethical considerations

This research uses an observational and quasi-experimental design. Routine care is not altered by the study, and it therefore does not raise significant ethical issues. Nevertheless, NHS ethics committee approval will be required for WP-C.

For WP-A and WP-B no patient identifiable data will be accessed, and as a result the governance and approvals process is anticipated to be straightforward.

WP-C requires NHS ethics committee approval since it involves access to patient identifiable data, observation of practice, staff surveys and interviews with staff and patients. Appropriate mechanisms to provide written information and informed consent will be instituted for all NHS staff and patient participants.

8 Research governance

This study will be conducted in accordance with:

- International Conference for Harmonisation of Good Clinical Practice (ICH GCP) guidelines
- Research Governance Framework for Health and Social Care

8.1 Sponsor approval

Any amendments to the trial documents must be approved by the sponsor prior to submission to the REC.

8.2 NHS approval

Approval from the local NHS Trust (s) is required prior to the start of the trial.

Any amendments to the trial documents approved by the REC will be submitted to the Trust for information or approval as required.

8.3 Monitoring by sponsor

The study will be monitored and audited in accordance with the Sponsor's policy. All study related documents will be made available on request for monitoring and audit by the sponsor, the relevant REC, the Health Research Authority (HRA) and for inspection by other licensing bodies.

9 Data protection and participant confidentiality

9.1 Data protection

Data will be collected and retained in accordance with the UK Data Protection Act 1998.

9.2 Data storage and sharing

9.2.1 Data storage

All study documentation will be retained in a secure location during the conduct of the study and for 5 years after the end of the study, when all patient identifiable paper records will be destroyed by confidential means.

Where trial related information is documented in the medical records – those records will be identified by a 'Do not destroy before dd/mm/yyyy' label where the date is five years after the last patient last visit.

Access to stored information will be restricted to authorised personnel. Data forms will be stored in a lockable filing cabinet in a secure room, to which access is restricted to authorised personnel. Electronic data will be stored in a secure area of an NHS hospital server.

Any data that are transferred out of the secure environment (for example for statistical analysis) will be anonymised and individual participants identified by study number only.

In compliance with the Medical Research Policy (MRC) on Data Preservation, relevant 'meta'-data about the trial and the full dataset, but without any participant identifiers other than the unique participant identifier, will be held indefinitely.

9.2.2 Data sharing

Data will not be made available for sharing until after publication of the main results of the study. Thereafter, anonymised individual patient data will be made available for secondary research, conditional on assurance from the secondary researcher that the proposed use of the data is compliant with the MRC Policy on Data Preservation and Sharing regarding scientific quality, ethical requirements and value for money. A minimum requirement with respect to scientific quality will be a publicly available pre-specified protocol describing the purpose, methods and analysis of the secondary research, e.g. a protocol for a Cochrane systematic review.

10 Knowledge mobilisation and dissemination of findings

10.1 Knowledge Mobilisation

During the initial and final stages of Work Package A stakeholder meetings will be held to feedback findings and discuss the implications and challenges of the identified GPED models. This involvement of stakeholders is designed to ensure the research questions are in line with the experiences of patients, clinicians and commissioners and to promote collaboration and wider learning. Existing local and national relationships and networks will be utilised to promote attendance and involvement at these meetings. During Work Package C case study sites will be invited to a tailored dissemination meeting of the research findings from the other work packages which will facilitate learning between the stakeholders and the research team, enhance good collaborative relationships and increase the opportunity for the research findings to have maximum impact on effective practice in the sites implementing GPED.

10.2 Dissemination

This study will be disseminated through the Knowledge Mobilisation Team based at the Centre for Academic Primary Care in Bristol; Dr Helen Baxter will lead on this work. This innovative team is the only one of its kind in the country and includes a communications officer. The team works between Bristol, South Gloucestershire, North Somerset CCGs and the University of Bristol with a research focus in the areas of urgent care and long term conditions. The close links with commissioning organisations that the team has developed will ensure that an awareness of commissioning priorities and knowledge informs the research throughout.

We will take advantage of all opportunities to present our findings and outputs to non-academic groups. Dissemination to non-academic audiences including service users, commissioners, clinicians and service providers will be facilitated using existing networks such as email lists held by the knowledge mobilisation team and social media (research team, centre and Network twitter accounts). These networks will be utilised to drive traffic to a study website which will act as a repository of materials designed to increase the accessibility of research and to maximise impact.

All outputs, both academic and non- academic, will be made publicly available via the study website. Peer reviewed academic outputs and research reports together with associated summaries and key findings will be produced for funders, policy makers and NHS audiences and held on the website. We will use email lists and twitter to publicise and encourage active commentary on our outputs and to generate debate within the academic field. We will seek opportunities for press releases and media interviews and explore the use of digital stories, blog posts by staff members (we will also submit guest blog posts to established blogs) and Academic Health Science Network (AHSN) dissemination (via Network of Networks). Other user friendly, innovative ways of packaging and disseminating findings will be investigated such as animations and video presentations. We will seek to evaluate impact throughout the knowledge mobilisation phase using alternative metric tools.

10.3 Academic Outputs

Academic outputs will include a minimum of three papers, submitted to high impact peer-reviewed journals, and at least four conference presentations or workshops. Potential suitable conferences are the Society for Academic Primary Care and the Royal College of Emergency Medicine. Through these mechanisms we will reach many of the clinical, academic and lay audiences who have an interest in the subject area. This will provide an early stage in the pathway to generating impact.

10.4 Commissioning Outputs

Our approach to generating impact will include formal collaboration with urgent care commissioners and attendance at commissioning steering groups for urgent care and presentations at relevant events, including national commissioning conferences and through the chief investigator's links with NHS England. We will utilise our existing relationships with clinical commissioning groups and the networks built during the study with other clinical commissioning groups nationally. This will maximise opportunities to influence future commissioning decisions in relation to the study findings.

10.5 National and International Outputs

We will disseminate our findings nationally and internationally through conferences, meetings and workshops, and through peer-reviewed publications as described above. We have strong links with both the Collaboration for Leadership in Applied Health Research and Care (CLAHRC) West and the West of England Academic Health Science Network (AHSN) through our university partnerships, which will extend our direct reach. Members of the research team have established national and international contacts within primary care and emergency medicine, and the Chief Investigator has a policy role at NHS England that will assist further with dissemination and implementation.

11 Amendments to protocol

Amendment number (i.e. REC and/or MHRA amendment number)	Previous version	Previous date	New version	New date	Brief summary of change	Date of ethical approval (or NA if non-substantial)
15	1.0	06/06/17	1.1	02/07/19	We have revised the study protocol to reflect an update to the plan of investigation with some minor changes to the data collection in WP-C and the analysis in WP-B.	

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