The evaluation of large-scale collaborations between primary care general practices – Study protocol

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Summary

Background

The General Practitioner (GP) practice is one of the main first points of contact that patients have with the National Health Service (NHS) and acts as a gateway connecting people to specialist care at treatment centres, hospitals, mental health services and community health care. NHS general practice has high approval ratings among patients and the public (Robertson et al. 2018), and is considered important and cost-effective in that it enables health outcomes to be improved and health inequalities to be addressed, whilst containing costs in the wider health system (Kringos et al. 2013; Starfield 1998).

In its Five Year Forward View (FYFV) published in 2014, NHS England identified the need for GP practices to be more flexible and adaptable to deal with changing models of care that increasingly require collaboration across a range of health and social care services and providers, and that one way to do so was for practices to work together in a more systematic, sustained and organised manner. The NHS Long Term Plan (for England) published in January 2019 (NHS England 2019a) built on this by highlighting the potential to be gained by GP practices collaborating in formal primary care networks. The Long Term Plan states that spending on primary and community services will be at least £4.5 billion higher in five years' time to "*fund expanded community multidisciplinary teams aligned with new primary care networks based on neighbouring GP practices*". The new GP contract published by NHS England and the BMA in February 2019 (NHS England 2019b) mandates GP practices in England to join networks covering populations of 30,000-50,000 by July 2019, if they have not already done so through prior collaborative arrangements.

For over 30 years, some GP practices, but not all, have chosen to enter into many different forms of collaborative arrangements with other practices, and for various reasons. These reasons have included: to hold budgets and bid together for contracts; to undertake a planning or commissioning role in the local health system; to organise and provide out of hours primary care; to deliver a wider range of services within and across practices; to strengthen primary care management (including human resources and staffing); and to enable new forms of access to primary care 24 hours a day, seven days a week. The reasons for collaboration also evolve over time. In their 2017 survey (Kumpunen et al. 2017), the Nuffield Trust and the Royal College of General Practitioners (RCGP) reported that over three quarters of GP practices in England who responded to the survey indicated that they were collaborating with other practices in some way.

Collaborations between GP practices in England range from super-partnerships, which are structured through formal mergers of practices and share a board of directors and general medical services (GMS) contract, to networks which are more informal, and with numerous other specific forms in between, such as GP federations or multi-practice organisations (Smith et al. 2013). Practices can group together and form regional or national multi-practice organisations and do not have to be local to one other, although they often are. The way that practices work together varies in appearance and operation, and reflects differing aims and objectives for such collaboration (Pettigrew et al. 2019; Smith et al. 2013).

Scoping work conducted to inform the development of this protocol entailed a review of literature about GP collaborations in the United Kingdom (UK) and internationally; a set of interviews undertaken with key informants in the UK; and a stakeholder workshop held at NHS England in November 2018. This scoping work aimed to: identify key themes associated with GP collaborations; define relevant and timely research questions for this evaluation study that are able to inform the implementation of primary care networks in England; and develop a methodological design to address these questions within the scope of a time-limited rapid and rigorous evaluation.

The scoping exercise confirmed that there are many different ways in which GP practices collaborate, across multiple healthcare systems worldwide. Examples range from family medicine groups (FMGs) or local health networks (LHNs) in Canada to patient-centred medical homes in the United States of America (USA) and Australia, to primary healthcare homes and community owned organisations in New Zealand, to GP cooperatives in the Netherlands. Furthermore, the reasons for collaborating vary, ranging from aiming to improve local primary care-based services for patients; to enabling 'strength in numbers' for primary care when facing challenge from the wider health system; to having the critical mass to bid for service contracts; to meeting government requirements to reduce costs and/or be more cost-effective. The reported impacts of these collaborations in the research and policy literature tend to be largely qualitative and unquantified. Reasons for this are complex, including a tendency to commission descriptive studies at the time of initiating new collaborations and not then funding longer term tracking of outcomes, and the relative organisational weakness of primary care within health systems, which limits its access to research and evaluation (Bardsley et al. 2013).

Aims and evaluation questions

This rapid evaluation study seeks to provide clarity on the evidence available with respect to collaborations between GP practices, using robust methods to first review existing evidence and then, based on identified knowledge gaps, to evaluate the nature, functioning, potential and pitfalls of GP collaborations. We have a particular focus on understanding issues for rural as opposed to urban collaborations, and the motivations and experience of collaborations that have struggled to get going, stalled or failed. The findings from the rapid evaluation will help to inform NHS England's and the general practice community's future planning and guidance, particularly with reference to GP practices in England that are not yet collaborating actively. The findings will also be of relevance to primary care in the rest of the UK and in all health care systems with extensive primary care practice.

Specifically, the study seeks to identify:

1) the forms of collaboration used in primary care;

2) the rationales and incentives (both current and historical, financial or otherwise) for general practices to enter into collaborations or not;

3) evidence with respect to their positive and negative impacts, both intended and unintended; and

4) the facilitators of, and barriers to, effective and efficient collaboration.

Design and methods

This is a largely qualitative, multi-site evaluation study with four distinct elements, referred to as work packages (WP), comprising: a rapid evidence assessment (REA) and scoping interviews; methods development workshop; comparative case studies; and evidence synthesis workshop and reporting. These elements are summarised below and described in detail in the full body of this protocol. Our conceptual framework for the study is based on the model used by Smith and Mays (2007) to analyse the impacts of primary care organisations in New Zealand and England. It has the following elements: objectives underpinning collaboration; measures (or proxy measures) of impact of collaboration; degree of success in 'tipping the balance' of the wider health system towards primary care; and what role primary care collaborations play in strengthening primary care services and influence.

- **WP1 – Rapid evidence assessment and scoping interviews**: In work package 1, a review of the literature will draw systematically on the international body of evidence on GP collaborations in both the academic and grey literatures. This review will be informed by eight scoping interviews carried out with key primary care opinion formers at the national level, these being intended to identify the key issues, concerns and evidence gaps needing to be addressed in our evaluation study. The review will follow the principles of REA (Varker et al. 2015), this being consistent with the principles underlying systematic review methodology: clearly defined research questions; systematic and replicable search strategies; and explicit inclusion and exclusion criteria. The REA process consists of searches of academic and grey literature, the screening of the titles and abstracts of identified articles against inclusion and exclusion criteria, and full-text review and analysis of articles that meet the specified criteria. The results of the scoping interviews and the REA will be fed into WP2 and subsequently inform the focus of WP3.

- **WP2 – Stakeholder workshop**: Work package 2 consists of a research methodology and scoping workshop to discuss and build on the findings of the REA and initial scoping interviews with national informants. Participants in the workshop, in addition to the research team, include staff from NHS England and other academic and policy experts in the field. The aim is to consolidate the emerging learning from the REA and scoping interviews and assist the research team in: identifying key evidence gaps to be filled by this evaluation; finalising evaluation questions for the study; defining criteria for the selection of case studies to be conducted in WP3; and exploring appropriate methods to be used within the case studies.

- **WP3 – Case studies**: Work package 3 comprises comparative studies covering four cases. The unit of analysis will be 'collaborations' between GP practices. The four case studies will be purposively selected once we have developed a sampling frame which compares more

and less successful collaborations in urban and rural settings respectively. A comparative case study design will be employed to address evaluation questions 2-4 set out above, by testing a set of propositions regarding the functioning of GP collaborations. These propositions, based on the findings of the REA and scoping interviews (WP1), prior work conducted in the field by the authors and our understanding of the wider relevant literature and policy landscape, will guide the development of the case study protocol. A common protocol will guide the conduct of each case study, involving four main data collection components: stakeholder interviews (informed by a stakeholder mapping exercise in the local case study area and based on core criteria within our case study protocol); an online survey questionnaire to all practices within the collaboration being studied; non-participant observation of meetings at executive board level; and document review. We will also assess the extent to which case study sites have access to quantitative and cost data to monitor the running and impact of collaboration, and will review any such data. Initial orientation site visits will be made in relation to each case, to introduce the project, establish points of contact between the evaluators and the local leads of the GP collaboration, collect relevant documentation, determine the approach to be taken to stakeholder mapping, and explore local research governance framework. Following collection of data via each of the four approaches outlined above, each case study will first be analysed separately. Detailed case descriptions will be developed in order to describe the history, context and organisation of the collaboration. Thematic analysis of interview transcripts and observations will be conducted for each case (based on principles outlined by Braun and Clarke's six step approach (2006). A coding frame will be developed for the first case (based on the interview guides and an initial reading of interview transcripts and field notes) and applied in the analysis of the remaining cases, adapted as necessary for application to all four cases if new dimensions emerge in the other sites. This will be followed by cross-case analysis, whereby cases will be systematically compared and contrasted according to the major themes identified, with an emphasis on context in order to understand similarities and differences between the cases.

- **WP4 – Workshop, synthesis and reporting**: The fourth work package is the process of synthesis of research findings across work packages, and in relation to each of the four evaluation questions. As part of this process, our draft synthesis will be tested out in a second workshop with as far as possible the same stakeholders as WP2, to present, challenge and refine the findings emerging from the case studies in WP3. These findings will be reviewed in the light of the findings that emerged from WP1 and were discussed in WP2. Discussions about these final emerging findings will inform key messages and recommendations in the final report, all set out in relation to the four evaluation questions, and highlighting those findings which are considered to be of most significance, and serve to fill prior evidence gaps.

Dissemination and outputs

We anticipate disseminating the findings of this evaluation project in a number of ways, both written and verbal. Potential outputs include:

- A final report submitted to the National Institute for Health Research, Health Services and Delivery Research stream (NIHR HS&DR) to be published in the NIHR Journals Library.
- A short summary report in digital format highlighting the overarching findings from the REA, scoping interviews, case studies and synthesis work, focused on shared learnings for the future implementation and development of primary care networks, which may be of particular interest to NHS England, the general practice and primary care community in the NHS and more widely.
- Web-based resources such as the summary report, link to full report, blogs to highlight key findings, and videos of research team members and others (e.g. BRACE PPI and health and care panel members) reflecting on the evaluation and its conclusions. Such resources can, and will, be tailored to the specific groups that are identified through the evaluation as being key to the development of collaborations between GP practices.
- Papers published in high quality, peer-reviewed, academic journals.
- Oral and/or poster conference presentations such as at the British Journal of General Practice (BJGP) conference, the Society for Academic Primary Care (SAPC) conference and Health Services Research UK.
- Working with other research teams to connect our findings with their analysis of primary and integrated care developments, including the new care models team (funded by PRP), integrated care pioneers evaluation (funded by PRP), research into GP federations (funded by HSDR), and RCGP survey work with primary care networks. This will likely include joint workshops and events, drawing together a wider body of learning about GP collaborations in the context of the NHS Long Term Plan.
- Disseminating findings through BRACE networks, from using NHS channels such as NHS England's CCG Bulletin, NHS Providers and NHS Confederation bulletins, and the NHS Improvement Bulletin through to utilising the assistance of PPI collaborators, health and care panel and steering groups members who are involved with the project and the BRACE Centre.

We anticipate that by bringing together the findings from the international REA and the insights from the NHS case studies, we will be able to provide recommendations for future implementation and development of primary care networks and other collaborations in the NHS.

Study timeline

The study will take place over 13 months (September 2018 to September 2019), assuming access to relevant data and the four GP collaboration case studies, and the timely securing of necessary ethical approvals.

Funding

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Background and rationale

Background

Collaborative working across GP practices is becoming increasingly common in the NHS in England, and in the wider UK and international context. This is reflected in the governmental push for practices to collaborate and form 'primary care networks', thereby seeking to embed what many regard as a substantial change in the organisation, identity and culture of general practice. In January 2019, NHS England published the NHS Long Term Plan (for England), in which it set out a medium-term vision for all general practices to work together with other local practices within extant or new primary care networks. The NHS Long Term Plan set out that an additional £4.5 billion will be invested over the next five years to "fund expanded community multidisciplinary teams aligned with new primary care networks based on neighbouring GP practices" (NHS England 2019b).

The NHS Long Term Plan builds on the new models of care (many of which were focused on primary and community health services) advocated in the 2014 NHS England Five Year Forward View (FYFV) (NHS England 2014). The 2016 General Practice Forward View (NHS England 2016) described how the NHS needed to change to make sure that sufficient primary health care can be provided, and noted that GP practices must stay flexible and adaptable to cope with change, including health needs and new technology. The new GP contract published in February 2019 will require all GPs in England to join primary care networks covering populations of 30,000-50,000 by July 2019, if they have not already done so (NHS England 2019a). It remains to be seen how far such networks build on existing collaborations such as GP federations, super-partnerships and locality groups, or alternatively are required by NHS England to assume a certain form and functions according to a nationally specified template.

For over 30 years, GP practices in England have entered into various collaborative arrangements, citing different reasons for doing so. These reasons include: to hold budgets and bid together for contracts (Elvey et al. 2018; Smith et al. 2013), to commission services for a local population as part of national policy on primary care led commissioning (Smith et al. 2004; Checkland et al. 2013; Pettigrew et al. 2018); to deliver a wider range of services for patients (Pawa, Robson, and Hull 2017; Rosen et al. 2016); to strengthen practices' resilience by providing better primary care management and better staffing resources (Erler et al. 2011); and to enable better access to care for patients through longer opening hours (Baird et al. 2018; Rosen 2016); amongst others (Pettigrew 2016). Unsurprisingly, these collaborations vary in form, functions, staffing, and culture and it is often difficult to divorce the commissioning aspect of a GP collaboration from its role in developing service provision, given that many commissioning collaborations move to focus on the provision of care within primary and community services (Smith and Mays 2007). It is striking that some GP practices have chosen not to enter into any collaborative model to date. Reasons for this also appear to vary and may include factors such as a fear of loss of professional dominance or autonomy, albeit that little research has been undertaken into the nature of and reasons for non-collaborative working across GP practices in the NHS or overseas.

In 2017, the Nuffield Trust and the Royal College of General Practitioners (RCGP) undertook a survey of all GP practices across England, seeking to establish the pattern and frequency of collaborative working across practices (Kumpunen et al. 2017). Of all respondents to the survey, over three quarters reported that their practice was already working in collaboration with other local GP

practices. Their reasons for working in such a way included to share costs, and to diversify or extend services for patients (Kumpunen et al. 2017). The survey emphasised that there are many forms of GP collaboration across the NHS which vary in how the practices work together, and in the reasons for having decided to do so (Rosen et al. 2016). For example, survey respondents in England and also overseas reported various pressures experienced by GP practices that had prompted them to form collaborations, including workforce shortages, growing workload, financial and administrative pressures (Baird et al. 2018; Barnett et al. 2012; Elvey et al. 2018).

The priorities of distinct GP collaborations often differ and can also evolve over time (NHS England 2014). For example, some collaborations tend to focus on increasing patient access to care, enhancing staff experience, and becoming more sustainable from an economic perspective; while other collaborations may instead focus on delivering more services to patients locally rather than in hospitals (Kumpunen et al. 2017).

International literature gives insight into the diverse models that GP practices adopt in order to collaborate with one another. For example, in the Canadian province of Québec, family medicine groups (FMGs) are one common model of collaboration, while in Ontario, family health teams are more common (Breton et al. 2011). The USA and Australia have tended recently to develop pilots of adopting the patient-centred medical home (PCMH) model (Agency for Clinical Innovation n.d.; U.S. Department of Health & Human Services n.d.), while GP cooperatives have been developed in the Netherlands (Wensing n.d.).

Table 1, building on the work of Rosen et al. (2016a), sets out some of the main examples of GP practice collaboration in England. For example, super-partnerships represent a formal merger of practices and their GMS contracts, and have a board of directors to oversee the collaboration, together with a shared contract which binds all practices together. Federations can either be informal or formal in the way they are set up and work together (Pettigrew 2016; Smith et al. 2013), and take a variety of legal and contractual forms. Networks are typically informal in nature, coming together around a set of specific issues, or to inform the planning of local services. Furthermore, while GP practices can group together based on geographical proximity, some collaborations are not geographically contiguous; rather, they are regional or national multi-practice organisations that are spread across a region or the country as a whole, and are often run by GP-owned or corporate organisations (Smith et al. 2013). Notably, some types of collaborations may go by more than one name but may share common characteristics in terms of functions performed (British Medical Association 2018b).

Table 1. Overview of primary care collaboration models in England (adapted from Rosen et al. (2016))

Collaboration model	Key characteristics
Informal network	Networks (described as 'informal networks' here in order to distinguish between them and 'primary care networks' as set out in the Long Term Plan) are one way in which GP practices can collaborate. There are no formal ties between the practices, instead relying on informal discussions, meetings and cooperation. All practices in such a network would keep their own contracts and funding sources and no particularly tangible objectives are

	expected to be set (British Medical Association 2018c; Rosen et al. 2016).
Multi-site practice organisation	These organisations are very formal in nature, where there is one core company or other group of directors, which holds one GP contract for all practices under that management framework. The goals of each practice, therefore, should be in alignment with those of the organisation as a whole. Funds are held in the central hub of the organisation and disseminated to practices for specific purposes (Rosen et al. 2016).
Super-partnership	Similar to multi-site practice organisations, the super-partnership represents the merger of previously independent GP practices into a single new organisation. The governance for super-partnerships is complex. Practices may either choose to manage each of their contracts separately, although activities and goals are shared and aligned across all participating practices, or they may choose to redraw a new GMS contract with an executive board to oversee the work of all participating practices. In the latter case, funds will be redistributed according to any new processes in place (Rosen et al. 2016; British Medical Association 2018e).
Federation	Federations are more formal than networks but less formal than multi-site practice organisations and super-partnerships. In federations, participating GP practices maintain responsibility for their own contracts; however some additional legal agreements might be pursued and put into place in order to carry out joint activities. An executive board function typically exists to oversee the federation, however, each practice may set its own goals and objectives and not necessarily have each of these align with the organisation as a whole (Rosen et al. 2016; British Medical Association 2018a).
Primary care home (PCH)	The PCH model was created by the National Association of Primary Care (NAPC). An integrated care model, it has four key characteristics that need to be met in order for a collaboration to be categorised as a PCH: 1) the partnership must span across primary, secondary, and social care; 2) there is a strong element of personalised care with the aim of improving the health of the population as a whole; 3) all funding is channelled through one central budgetary system between all stakeholders in the collaboration; and 4) it covers a population of 30,000-50,000 registered patients across collaborators. There is no specific requirement for collaborators to be geographically contiguous (National Association of Primary Care n.d.).
Hubs	Hubs often emerge as part of existing collaborative relationships amongst different GP practices that are already in place, and are usually focused on delivering extended access general practice care. Their aims and objectives can differ depending on local population needs; however, a core feature is that they provide same-day urgent appointments to registered patients, and this can be done for example, by having a shared triage system to point patients to the most appropriate route of care. Additionally, they may offer out-of-hours care, for example during evenings or weekends (British Medical Association 2018d).

Why is this research important/needed now?

Scoping work conducted to inform the development of this protocol highlighted some key gaps in the evidence base about GP collaborations, namely:

- There is little quantified evidence of the benefits of collaboration across practices, beyond those reported in qualitative studies, and often about 'enthusiast' sites.
- There is very little quantified evidence about costs and savings associated with GP collaborations and, where such analysis has been undertaken, the results are typically equivocal.
- There has been very little study of why some GP practices and localities do not engage in collaborations, and whether or not this matters in relation to the care and services that they provide.
- There has been little research into why and how some GP collaborations struggle or fail, and the consequences of this.
- There is a lack of studies of the specific issues associated with GP collaborations in rural as opposed to urban settings.

A further point to emerge from the scoping work was that GP practices may be part of more than one collaboration of varying sizes in order to fulfil different aims and objectives. Topic experts emphasised the importance of not narrowing the scope of this rapid evaluation to one particular patient group (e.g. services for people with diabetes) as this would omit the possibility of building a wider picture of the range of collaborations in primary care. Additionally, they advised that the focus should be on the role of collaborations to provide care rather than to commission it, as the latter has been extensively researched previously.

In light of rapidly developing policies on primary care networks and the declared intention to implement them across the NHS in England (NHS England 2019b), this evaluation responds to the need identified by NHS England for better understanding of the likely development, operation and trajectory of such networks. This study will build on the existing work that has already been undertaken by the Nuffield Trust, the RCGP, the London School of Hygiene and Tropical Medicine (LSHTM) and others. To this end, the following questions have been raised by our scoping work:

- What are the benefits, if any, of collaboration: i) for patients; ii) for staff; iii) for the local health system? How might we quantify these?
- What are the costs, if any, of collaboration (financial costs, opportunity costs and other kinds of cost)?
- What are the challenges to successful collaboration and to what extent are the enablers/facilitators for successful collaboration in place within local systems of care?
- What further kinds of support and/or investment are most needed to create an environment for effective collaboration, and what role, if any, is there for financial incentives?
- Why do some practices choose not to collaborate? What happens in areas where practices choose not to collaborate? Does this affect care outcomes in any way, and if so how? Does this affect staff experience in any way?
- Do general practices need to collaborate to achieve key outcomes (e.g. improving access, achieving sustainability)?

- What are the advantages and disadvantages of having a single approach to primary care collaborations? Could there be a set of core aims/desired outcomes for a collaboration/network?

In the project plan below, we set out how this rapid evaluation study can respond to some of these questions, and seek to fill specific evidence gaps related to urban as opposed to rural GP collaborations, the reasons why some practices do not collaborate in a meaningful manner, and how and why some collaborations struggle, stall or fail. This focus has been determined through our scoping and review work, and in discussion with NHS England and other workshop participants, and on the basis that we wish to avoid replicating the extensive body of research on GP collaborations, adding instead to those areas that have been previously ignored or under-researched.

As this is one of the first of a new, more rapid, approach to evaluations, the research team will remain alive to the possibility of adjustments being required to the approach as the evaluation progresses.

Project plan

Aims

This evaluation sets out to identify the forms of GP collaboration used in primary care in England, the rationales and incentives (both current and historical, financial or otherwise) for general practice to enter (or not) into collaborations, highlighting evidence with respect to their positive and negative impacts, and any barriers or facilitators to effective collaboration and achieving impacts. There will be a particular focus on seeking to understand why some practices do not enter into collaborations, why some collaborations stall or fail, and whether and how the experience of rural collaborations may differ from that of urban examples. The findings from the evaluation will feed into NHS England's planning and implementation guidance for primary care networks and will inform proposals for longer term study of primary care networks.

Evaluation questions

In order to address these aims, the study seeks to answer the following evaluation questions:

1. What are the different forms of GP collaboration in primary care in England and how have they been implemented in a sample of urban and rural settings?
2. What are the rationales and incentives for general practices to enter into different forms of collaboration, and what are the reasons for and consequences of not doing so? In particular, what role do financial incentives play in facilitating or inhibiting collaboration? What are the expected outcomes of GP collaborations?
3. What evidence exists about the positive or negative impacts associated with different experiences of establishing (or not) GP collaborations?
4. What are the barriers to and facilitators of effective collaboration across GP practices, both with respect to successful and unsuccessful collaboration, and achieving impact or not?

Research design and methodology

Design

We have adopted a multi-method evaluation approach, drawing on a rapid review of the literature, scoping interviews, two stakeholder workshops, and comparative case studies. This approach was selected to answer the evaluation questions set out above, and to develop and investigate propositions about the rationales underlying GP practice collaboration, the barriers and facilitators to effective collaboration and achieving impact, the experiences of rural as opposed to urban collaborations, and the lessons to be gained from understanding why some collaborations stall or fail. This approach ensures that our efforts to evaluate GP collaborations in practice are informed by existing evidence, and focused on identified knowledge gaps. A case study approach is appropriate in order to generate an in-depth and context-specific understanding of the factors of interest. The case study approach is widely used in healthcare research, for case studies can provide richness and detail that may be difficult to obtain through other methods (Abercrombie, Hill, and Turner 1998).

A comparative case study design (Stake 2006; Yin 2009) was selected to allow us to explore whether the implementation, progress (or otherwise) and impact of GP collaborations are affected by common or specific factors across cases.

The evaluation comprises four distinct work packages (WPs):

- *WP1*: A Rapid Evidence Assessment (REA) to obtain a comprehensive overview of the evidence already reported and to inform the development of propositions to be tested through comparative case studies (WP3).
- *WP2*: A workshop led by members of the study team for NHS England and other relevant stakeholders (e.g. academic and policy experts in the field, PPI representatives), where initial findings from the REA are shared. The aim of this workshop is to further clarify evidence gaps and evaluation questions and thus inform next steps for WP3.
- *WP3*: Comparative cases studies of four GP collaborations to explore how these collaborations have been established and work in practice. We propose four such case studies in order to achieve a balance between the degree of detailed analysis possible and the limited budget and timescale available for this rapid evaluation. We anticipate that at least one of the case studies will be an area which started collaborating but struggled to continue after a period of time, in order to understand the reasons for this. We also intend that at least two of the case studies will be in a rural setting.
- *WP4*: A second workshop in which experts and other stakeholders in the field come together to review the key results emerging from WP1-3. This will assist in the final synthesis and reporting of the findings from WP1-3 and the development of recommendations, and will feed into the final report and other methods of dissemination of evaluation project findings.

Figure 1 depicts the project design through a flow chart.

Figure 1. Flow diagram of study design

The four WPs will each aim to address one or more evaluation questions (EQs) and this is summarised in Table 2.

Table 2. Summary of each evaluation question against the four work packages

	WP1: REA	WP2: Workshop	WP3: Case studies	WP4: Workshop
EQ1: What are the different forms of collaboration in primary care in England and how have they been implemented in a sample of rural and urban settings?	●	●	●	
EQ2: What are the rationales and incentives for general practices to enter into different forms of collaboration, and what are the reasons for and consequences of not doing so? In particular, what role do financial incentives play in facilitating or inhibiting collaboration? What are the expected outcomes of GP collaborations?	●	●	●	●
EQ3: What evidence exists about the positive or negative impacts associated with these different experiences of establishing (or not) GP collaborations?	●		●	●
EQ4: What are the barriers and facilitators to effective collaboration across GP practices, both with respect to successful and unsuccessful collaboration and achieving impact or not?	●		●	●

Methodology

The methods used in each of the evaluation work packages are described below.

WP1: Rapid Evidence Assessment (REA)

This WP aims to address all four evaluation questions set out above.

The REA includes both scholarly (academic) literature and grey literature (i.e. reports and articles not submitted to a traditional academic journal). The REA aims to:

- Identify effective collaborations of general practices established for planning, commissioning, and service provision purposes
- Explore the impact of such collaborations on costs in the health and care system.
- Identify the barriers and facilitators to ensuring successful outcomes when bringing multiple GP practices together in a collaboration, including the role played (if any) by financial incentives.
- Examine why certain GP collaborations may be more effective than others, and what reasons affect this.

Search strategy

Similar to a systematic review, an REA follows a systematic approach – in line with guidance on literature reviews in health care (Centre for Reviews Dissemination 2009; Higgins 2011; Varker et al. 2015) – but the scope of the search is restricted to key search terms and review criteria to allow for a focused review within a limited timeframe (Barends, Rousseau, and (Eds.). 2017). Examples of search terms to be used are listed in Table 3.

Table 3. Example search terms

Search Terms
"collaboration"[Title/Abstract] OR "collaborat*"[Title/Abstract]" OR "partnership"[Title/Abstract] OR "cooperation"[Title/Abstract] OR "co-operation"[Title/Abstract] OR "cooperat*"[Title/Abstract] OR "co-operat*"[Title/Abstract] OR "network"[Title/Abstract] OR "federation"[Title/Abstract] OR "alliance"[Title/Abstract] OR "super-partnership"[Title/Abstract] or "superpartnership"[Title/Abstract]
AND
"primary care" OR "general practice"

Grey literature is obtained via two means: 1) by searching websites of institutions most relevant to this topic area (the Nuffield Trust, King's Fund, RCGP, etc.); and 2) by requesting topic experts to inform us of any additional literature that we may have missed.

Study selection

The study team will search PubMed, Ovid MEDLINE, Web of Science, and Scopus for literature published in the English language in the last twenty years. The first 15 years of the search will be limited to reviews only as it is anticipated that the majority of the literature will be captured through reviews in this time period. More recent literature will not necessarily be captured through a review study so all methodologies will be included for the final five years. Selected search terms as well as

forward citation searching will be used to identify relevant literature. The search will be limited to titles and abstracts.

Inclusion criteria

Publications are eligible for inclusion if they meet the following criteria:

- Published in the English language only
- Focussed on High-income OECD countries (i.e. excluding Chile, Greece and Mexico)
- Restricted by data as follows:
    - 1998 to 2012 inclusive – reviews only
    - 2013 to September 2018 – all publications

Particular focus is placed on studies of primary care in England as well as countries with health care systems comparable to that of England, to allow for identifying key examples of GP collaborations applicable and relevant to the NHS and general practice in England.

Data extraction

Identified literature will be downloaded, stored and processed using EndNote X8 citation manager software. Titles and abstracts are screened by two study team members against the inclusion criteria (with 10% random sample subject to review by both reviewers). The full text of all 'included' papers is then obtained for further full-text screening. Any discrepancies are reviewed by a third study team member.

Data such as types of GP collaborative models, demographics of collaborations, impacts of collaboration, and any reported barriers and facilitators, are extracted using a using a pre-piloted Microsoft Excel spreadsheet.

Synthesis and reporting

A narrative approach will be taken to synthesise the findings. The Preferred Report Items for Systematic Reviews and Meta-Analysis (PRISMA) (Moher et al. 2009) statement will be used to guide the reporting of the methods and findings.

The review protocol will be registered with PROSPERO.

WP2: Stakeholder workshop

The half-day research methodology workshop (Ørngreen and Levinsen 2017) will involve, in addition to the research team, eight to twelve participants drawn from NHS England, as well as a patient representative (from the BRACE health and care panel) and academic and policy experts in the field. The aim of the workshop is to discuss the findings of the REA (WP1) with a sample of likely evidence users, and to help identify gaps in the literature, and thereby identify and agree the appropriate focus of and specific evaluation questions for the GP collaboration case studies in WP3. Furthermore, the results of the REA will be consolidated at this stage, helping to shape the data collection strategy for the case studies.

A structured agenda will be prepared in advance of the workshop and will include time for plenary discussions, presentations of findings from the rapid evidence assessment and scoping interviews, and smaller group discussions. The agenda and a slide-deck of the REA findings will be shared with the participants in advance of the workshop to allow for a structured and productive discussion.

Members of the study team will take detailed notes during the workshop, which will be used to further develop and refine the case study design (WP3). Notes of the workshop, including proposed detailed evaluation questions, and confirmed evidence gaps, will be shared with all participants following the workshop.

WP3: Case studies

We will conduct comparative case studies of four primary care collaborations in England. This work package will comprise three phases: 1) case study selection and site recruitment; 2) data collection at four case study collaboration sites; and 3) analysis and write-up. These phases will be undertaken between March and August 2019. The unit of analysis will be 'collaborations' between GP practices (e.g. network, federation, primary care home, hub or super-partnership). A comparative case study design will be employed to address evaluation questions 2-4 as set out above, by testing a set of propositions regarding the underlying rationale for GP collaboration, the positive and negative impacts associated with such collaborations and the barriers to, and facilitators of, their effective functioning. These propositions (developed based on the findings of the REA and scoping interviews (WP1), the stakeholder workshop, prior work conducted in this field by members of the BRACE team and our understanding of the wider relevant literature and policy landscape) will guide both the selection of the cases and the development and use of the case study protocol.

The propositions to be explored in the case studies will include the following:

- Collaborations permit the exploitation of economies of scale and scope in the provision of primary care services within and across practices.
- Collaborations enable greater provision of specialist health services in primary care settings.
- Collaborations enhance opportunities for multidisciplinary team working within local primary and community health services.
- Collaborations provide the opportunity for workforce innovations including greater use of non-GP health care professionals in delivering direct patient care in GP practice settings.
- Collaborations between general practices in rural settings will differ with respect to their underlying rationale and the factors influencing their effectiveness and impact compared to those in urban settings (Source: Stakeholder workshop; Literature review).
- Factors relating to professional (and in particular medical) dominance and autonomy in general practice and primary care pose a challenge to the functioning of GP collaborations as expected for primary care networks (Freidson 1985, 1970).
- Financial incentives may stimulate or accelerate collaborations or they may crowd out intrinsic motivations to collaborate (Frey and Jegen 2001).
- A proportion of collaborations will prove unsuccessful and cease, for a variety of reasons.
- Some GP practices will resist joining, or being active participants in, GP collaborations, and this may or may not matter for their patients and practices.
- Collaborations will struggle to secure sufficient management and leadership resource to enable them to maximise desired benefits.
- Collaborations will assume differing forms and functions, despite potential policy pressure towards uniformity, and this will present a challenge to NHS England and clinical commissioning groups (CCGs).

Phase 1: Case study selection and site recruitment

Sampling strategy

In order to select case studies that will enable us to test the propositions set out about above, we will undertake a multi-stage sampling process to select four collaborations not hitherto evaluated that vary with respect to the following sampling criteria:

- Rural or urban setting.
- Collaborations which are facing significant challenges or ceased operation or those who are operating smoothly.

In order to reduce variability in the context within which the collaborations operate, we will seek to select two pairs of collaborations, one identified as experiencing challenges and one that is functioning well - within each of two selected CCG regions (i.e. one pair in a CCG with practices serving a primarily urban catchment and one pair in a CCG with practices serving a rural catchment). Specifically, we will endeavour to focus one of the four case studies on a collaboration which is no longer operating or has stalled.

In the first stage of the sampling process we will seek to develop a long list of GP collaborations in operation in England. The evaluation team will make every effort to obtain a list of all existing collaborations in England, by contacting multiple organisations including the RCGP, the Nuffield Trust, and NHS England. In order to ensure that this list includes those collaborations that may have experienced challenges as well as those that are operating effectively, we will supplement lists of collaborations known to expert contacts with those identified through a targeted search of the GP and health policy press (for example, Pulse, Health Service Journal or GP Online).

The inclusion and exclusion criteria set out below will then be applied to this long list of collaborations:

- **Inclusion criterion:** Collaborations between GP practices in England (including those that are currently active and those that have ceased operation with the last two years).
- **Exclusion criterion:** Collaborations that have already been the focus of research or evaluation within the last two years.

The decision to exclude those collaborations that have already been well studied is based on expert advice given in interviews and a workshop when scoping the evaluation and a desire to ensure new learning that fills known evidence gaps. An indication of whether a GP collaboration has already been the focus of prior research or evaluation will be determined based on the study team's knowledge of the wider body of literature, and a search undertaken by HSMC Library and Information service, building on the REA with additional targeted desk-based research and input from expert advisors on our health and care panel, and at HSDR as required.

We will conduct desk research in order to: 1) apply the study inclusion/exclusion criteria; and 2) categorise the collaborations based on the sampling criteria (rural urban setting; degree to which they are operating successfully/experiencing challenges). Rurality of the setting of the collaboration will be determined based on the Office for National Statistics 2011 rural urban classification by CCG (Office for National Statistics 2019). The second criterion will be determined based on information included in the source lists, supplemented by 1) a further targeted search of online magazines Pulse

(PULSE n.d.), Health Service Journal and GPonline (Haymarket Media Group Ltd.), and 2) discussions with key stakeholders in the field (from our Health and Care Panel, and WP2 workshop attendees), to identify collaborations which may no longer be operating.

Case selection and site recruitment

Beginning with those cases that meet study inclusion criteria, we will identify those that are highlighted as experiencing challenges, making little progress or that have ceased operation, in both an urban and rural setting. For each setting we will approach up to five collaborations by writing to the identified primary contact/senior leader for the collaboration. In the case that greater than five collaborations are identified, the selection decision will be made by having discussions amongst the research team, based and using criteria such as longevity of the collaboration, size of the collaboration, and degree of distinctiveness of the particular network and its focus. The letter sent to a GP collaboration to invite them to participate in the evaluation project will be accompanied by an information sheet outlining the purpose of the evaluation and detailing what would be involved for the participating organization, both in respect of their contribution, and also what they will receive in terms of feedback and insights from the evaluation team. The contacted individuals will be invited to express interest in participating in the case study element of the evaluation and to complete a brief online survey (using the SmartSurvey platform) seeking details on the nature and maturity of the collaboration, an indication of whether it is still operating, a rating of the degree to which the collaboration is achieving expected outcomes and details of other collaborations operating locally. Respondents will be informed that they may be then be selected to take part.

For those collaborations expressing an interest in participating, we will then seek to identify other collaborations operating within the same CCG region that have not been identified as facing particular challenges through the method of snowballing. This identification process will be informed by the longlist of collaborations described above and any responses to the brief survey sent to potential case study sites.

Given the rapid nature of the evaluation, we will proceed with the first pair of collaborations within a CCG, for which both express interest in participating.

We will follow up with the primary contact by email and arrange a prompt telephone conversation and subsequent initial orientation site visit to answer any questions about the evaluation, build trust, and discuss how best to mobilise the case study work, including undertaking a stakeholder mapping exercise (see below). Once we have identified our case study sites, we will seek appropriate governance and research ethical approval from the University of Birmingham (as sponsor), NHS Health Research Authority (if required), and local NHS Research and Development approval to recruit participants and collect data.

Phase 2: Data collection at four case study sites

A common protocol will guide the conduct of each case study, involving three main data collection components: non-participant observation of meetings at executive board level; stakeholder interviews (informed by a local stakeholder mapping exercise); and document review including review of any quantitative data and metrics available to the collaboration for monitoring its costs or impacts. Site visits will be organised in such a way that we can co-ordinate attendance and observation of key meetings and face-to-face interviews.

Stakeholder interviews

Potential participants for interviews will be identified via a stakeholder mapping exercise. This process will be initiated through discussion with the collaboration lead contact for our evaluation and supplemented by attendance at a meeting of the collaboration's executive board or equivalent (at which non-participant observations will be undertaken, in addition to seeking agreement from board members to participate in an interview and asking them to identify other key individuals as potential interviewees). Individuals will be sampled purposively in order to focus on those most likely to have knowledge of impacts, barriers, and enablers in order to address the evaluation questions set out above. We will seek the support of a local administrator contact within the collaboration, who is willing to forward information related to the evaluation and help with arranging interviews and securing documents for analysis.

In the case of a collaboration that is no longer in operation (it is hoped that one such case will be included), it will not be possible to attend a meeting of the executive board. Instead, the identification of potential interviewees will be undertaken based on a process of snowballing from our initial contact in the case study site. We realise that some of these interviewees will likely have moved to other jobs and locations, and we will interview them in person or by phone as appropriate, and will give particular thought to how best to approach such individuals in what may be sensitive situations.

All individuals approached to participate in the case studies (WP3) will receive an information sheet (by email or in person) and will be given at least 48 hours to make a decision regarding whether they would like to participate or not. They will be given the opportunity to ask questions about the evaluation and their potential role in it, and to have these answered satisfactorily. Participants will be required to sign a consent form prior to participating in the interview, including as to whether they consent to the recording of the interview or not. Participants will be allowed to withdraw from the study at any time, and will also be given information about how to find out more about the study, or to raise concerns about its conduct.

Semi-structured interviews will be conducted with stakeholders associated with each case study collaboration. It is anticipated that those interviewed will include individuals in a wide range of roles across a number of member practices in the collaboration (e.g. those leading the collaboration, different staff types whose role is dependent on the collaboration, GPs and practice managers at practices who are highly engaged with the collaboration or who may work at the periphery of it, and at least one CCG representative). We also anticipate interviewing in each case study a member of the local Healthwatch organisation. We plan to interview up to 15 individuals in each case study or until the point of reaching saturation in relation to the data gathered in each GP collaboration (thus up to 30 interviews per CCG region), although the exact number will vary dependent on the size and nature of the collaboration.

Where possible, interviews will be conducted face to face during field visits, although some telephone interviews may also be undertaken. Interviews are expected to last between 30-60 minutes. Written consent will be obtained for participation. Interviews will follow a common interview guide, developed to test the propositions relating to the functioning of GP collaborations set out above. The interview guide will also align with the evaluation questions, but will allow for flexibility in direction should interesting or relevant issues arise during the interview. The interview

guide will include general questions relating to collaboration and more tailored questions related to the specific role of the interviewee. Questions will include those seeking to understand the reasons why collaborations stall or fail to take off, as well as what happens and why when they are more successful. Participants will be encouraged to talk from their own perspective. With permission, interviews will be audio-recorded and transcribed verbatim by a professional transcription service. Transcripts and notes will be anonymised.

All interview recordings and transcripts will be kept in compliance with the General Data Protection Regulation (GDPR) 2018 and Data Protection Act 2018. As interviews will be conducted by both RAND Europe and University of Birmingham researchers, the data will be recorded and stored on password-protected computers in accordance with their procedures in restricted folders that only study team members can access. Interviewees will have the opportunity to request further information about the data security practices, should they wish to do so.

Non-participant observation of meetings

In addition to conducting interviews, we will observe key meetings of each case study GP collaboration in order to gain a deeper understanding of how the collaboration operates and what priorities and challenges it is currently addressing. Observations will be conducted at executive board level, or equivalent, meetings for each of the collaborations and will be recorded by means of notes using a semi-structured observation framework and mapping of interactions within the meeting.

Permission for observations to be undertaken during meetings will be obtained from the person chairing the meeting prior to the start of the meeting. Information sheets will be circulated by the relevant researcher to all attendees before the meeting. At the start of each meeting, the researcher will give a brief description of the evaluation aims, what is involved in participation, and will highlight that it is possible for any individual to be excluded from the observations. Verbal consent of the participants will be noted by the researcher. If any individual does not agree to participate, any contributions they make to the meeting will be excluded from the field notes, or the observations will not take place.

Document review

Finally, we will conduct a review of documents describing, and containing data on, the case study collaborations, their mission, priorities and aims, challenges and objectives, status (i.e. operational or no longer operating), activities, set-up, operation, staff involvement, costs and outcomes of collaboration, to contextualise the development and functioning of the collaboration and to provide a historical perspective. Documents will be sourced through internet search and signposting by stakeholders and are likely to include: records related to the structure, infrastructure and governance; setting within wider health system; agendas and minutes of board and other meetings; and communications materials. In addition, we will profile the population served, using routinely collected anonymised data. Information will be extracted from source documents using a structured Excel template.

The information gathered will complement the findings from the interviews enabling us to develop a rich description of the collaborative effort and to triangulate information gathered from the interviews.

Phase 3: Analysis and write-up

Between June and August 2019, the insights gained through the site visits, as well as any further information obtained from documentary reviews, will be analysed for each case study site and written up using a structured template covering the key characteristics of the explored site. We will take a content analysis approach to documentary reviews and observations; hence, an iterative process of reading appropriate literature and engaging in interpretation whilst organising information into categories related to: the type of collaboration and how it developed over time, insights into how the collaboration works in practice, insights into the impacts of the collaboration, facilitators and barriers to the collaboration, and any gaps and issues identified (Bowen 2009). We will be mindful that documents will not necessarily be an accurate or complete recordings of events but we will assess their contribution to the issues being explored.

The triangulation process will systematically compare the findings from the different sources to the evaluation questions and will highlight consistencies or any inconsistencies between the different sources as described in phase 2 of the case studies. A more granular breakdown of the analysis is given in the 'Data analysis and synthesis' section below.

WP4: Review workshop, synthesis and reporting

A second half-day to a day workshop will be held in late summer of 2019. Attendees will likely include participants of the first workshop in WP2, as well as any other key experts or stakeholders identified in WP3. The aim of this second workshop will be to test out emerging analysis and conclusions, and help develop and frame the key messages and recommendations emerging from case studies, building on the results of the scoping interviews and REA.

As with the WP2 workshop, a structured agenda will be prepared in advance of the workshop and will include time for plenary discussions, presentations of findings and analysis and smaller group discussions to reflect on the evaluation material and debate implications. The agenda and a slide-deck of the emerging findings will be shared with the participants in advance of the workshop to allow for a structured and productive discussion. Members of the study team will take detailed notes during the workshop, which will be used to identify key messages and recommendations emerging from the results of the evaluation, and to help inform the approach to dissemination.

Data analysis and synthesis

Our approach to the analysis of the data within WPs 1 and 3 will be guided by theory as a result of our engagement with the literature on collaborations of general practices, and in particular the framework developed by Smith and Mays (2007) with the following elements: objectives underpinning collaboration; measures (or proxy measures) of impact of collaboration; degree of success in 'tipping the balance' of the wider health system towards primary care (in this case the local primary care network area, and overarching CCG); and the role played by primary care collaborations in strengthening primary care services and influence. We will also draw on the work of Checkland and her team about the use of programme theory in assessing the development and effectiveness of primary care commissioning groups (Checkland et al. 2013).

Our narrative approach to synthesising the findings of the REA will be guided by existing theory relating to large scale collaboration in general practice. Both the development of the case study protocol and thematic and comparative analysis of the data gathered within case studies will seek to test specific propositions relating to the underlying motivations for and operation of GP

collaborations, together with the factors impacting on their success, developed based on our own REA, knowledge of the wider literature, and relevant theory (Smith and Mays 2007; McDermott et al. 2017).

Synthesis of findings across work packages 1-3 will be further guided by input from expert advisors, through two workshops conducted following the REA and following preliminary analysis of the case studies. The first will draw on the findings of the REA to guide development of the case study approach and case selection and the second will contextualise our findings and inform our final presentation of findings and conclusions.

Narrative synthesis of findings of the REA

We will take a narrative approach (Ryan 2013) to synthesising the findings of the REA, guided by existing theory regarding how large-scale collaboration in general practice works (Smith and Mays 2007; McDermott et al. 2017). We will first develop a preliminary descriptive synthesis of the findings of the studies included in the evidence review, based on a systematic examination of the results, using methods such as grouping studies according to form of collaboration and tabulating findings to aid in the identification of important characteristics across the studies. We will then seek to explore relationships within and between studies and identify reasons for any differences. We will use insights from theory to explore why and under what circumstances specific aspects and mechanisms of GP collaboration appear to deliver (or not) expected benefits promised within the objectives set for the specific network or group. In this, we will draw on Pawson and Tilley's realist evaluation approach (Pawson and Tilly 1997).

Case study analysis

The four cases will be treated as separate studies and analysed independently in the first instance. Thematic analysis of interview transcripts, observations and survey responses will be conducted for each case (Braun and Clarke 2006). A coding frame will be developed for the first case (based on the interview guides and an initial reading of interview transcripts and field notes and guided by the propositions that we are seeking to test, these having been developed via our REA and scoping work). The coding frame (Saldaña 2016) will be developed iteratively as analysis progresses, with regular meetings between members of the evaluation team to discuss meaningful themes and to make refinements. The analysis of subsequent cases will use the coding frame developed for the first case, with further refinements where necessary.

Transcripts and observation notes will be read and re-read and codes applied to meaningful sections of text. As analysis progresses, codes will be organised into overarching or organising themes, using NVivo 12 software. Particular attention will be paid to examples which do not fit into the identified themes. Emerging findings will be discussed initially in a research workshop of the evaluation team (those working on this study) and then with the wider BRACE team and external experts at the second workshop in WP4 to guide analysis. Sourced documents, observations, and field-notes will be used to triangulate interview findings.

The evaluation team will construct detailed case descriptions for each of the four cases. These will be written up using a structured template to facilitate comparison. The template will cover the key characteristics of the explored site, the type of collaboration and how it developed over time, and findings in relation to key themes (based on thematic analysis)

This will be followed by cross-case analysis, whereby cases will be systematically compared and contrasted according the major themes identified, with an emphasis on context in order to understand similarities and differences between the cases. Specifically, the propositions identified earlier will be tested against the case study evidence, and alternatives theories developed where appropriate.

All individuals and organisations involved in the study will be anonymised for all reporting.

Expected outputs and plans for dissemination

Results from this evaluation project will be written up and shared widely in a number of forms, both written and verbal. The final report to NIHR will be submitted in late September 2019. This will include insights for future implementation, operation and development of primary care collaborations and will be published in the NIHR Journals Library (HS&DR stream), as well as other high-quality, peer-reviewed academic journals. The main routes for dissemination will be:

- A final report submitted to the National Institute for Health Research, Health Services and Delivery Research stream (NIHR HS&DR) to be published in the NIHR Journals Library.
- A short summary report in digital format highlighting the overarching findings from the REA, scoping interviews, case studies and synthesis work, focused on shared learnings for the future implementation and development of primary care networks, which may be of particular interest to NHS England and the general practice and primary care community in the NHS and more widely.
- Web-based resources such as the summary report, link to full report, blogs to highlight key findings, and videos of research team members and others (e.g. members of the BRACE PPI and health and care panels) reflecting on the evaluation and its conclusions. Such resources can, and will, be tailored to the specific groups that are identified through the evaluation as being key to the development of collaborations between GP practices.
- Papers published in high quality, peer-reviewed, academic journals
- Oral and/or poster conference presentations such as at the British Journal of General Practice (BJGP) conference, the Society for Academic Primary Care (SAPC) conference and Health Services Research UK.
- Working with other research teams to connect our findings with their analysis of primary and integrated care developments, including the new care models team (funded by PRP), integrated care pioneers evaluation (funded by PRP), research into GP federations (funded by HS&DR), and RCGP survey work with primary care networks. This will likely include joint workshops and events, drawing together a wider body of learning about GP collaborations in the context of the NHS Long Term Plan.
- Disseminating findings through BRACE networks, from using NHS channels such as NHS England's CCG Bulletin, NHS Providers and NHS Confederation bulletins, and the NHS Improvement Bulletin through to utilising the assistance of PPI collaborators, health and care panel and steering groups members who are involved with the project and the BRACE Centre.

We anticipate that by bringing together the findings from the international REA and the insights from the NHS case studies, we will be able to provide recommendations for future implementation and development of primary care networks and other collaborations in the NHS.

Project timetable

The study will take place over 13 months (September 2018 to September 2019), assuming timely access to relevant data and the four GP Practice case studies and prompt securing of necessary ethical approvals. Figure 2 shows the overall study timeline and the key milestones for the project.

Figure 2. Study timeline and key milestones

Activity	2018				2019								
	Sept	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sept
REA													
Workshop													
Preparation for ethical/gove[illegible] approval													
Case study: phase 1													
Case study: phase 2													
Case study: phase 3													
Analysis and synthesis													
Reporting													
Dissemination													

Project management, governance and delivery

Project management and quality assurance

This proposal has been reviewed by the project leads and by three peers, two drawn from our BRACE health and care panel (including one patient panel member) and one from our BRACE steering group. The principal investigator, Professor Judith Smith, is responsible for the overall delivery and quality assurance of this project, and for day to day management of inputs by University of Birmingham team members to this project. Jon Sussex is responsible for the overall management of the inputs provided to this project by RAND Europe. Amelia Harshfield (RAND Europe) will be responsible for day-to-day project management and coordination of the evaluation study and fieldwork, ensuring consistency between the individual researchers undertaking the four case studies.

We will apply the following project management principles and processes: ensuring clarity of team members' roles, and the delegation of tasks and reporting duties; internal team meetings and catch-ups; and use of project planning tools (Gantt chart, timesheets, internal monitoring reports). RAND Europe's approach to project management is guided by its ISO 9001:2015 certification and is seen as fundamental to the successful and timely delivery of the evaluation.

For this particular project, weekly team teleconferences/meetings will be held in order to update progress and address any arising issues promptly. The project team will report to the BRACE Executive team, Steering Group, Patient and Public Involvement (PPI) panel members and NIHR as and when required. Potential risks to the project and their associated mitigation strategies have been highlighted in Table 4.

Table 4. Potential risks and mitigation strategies

Risk	Impact	Likelihood	Mitigation
Loss of key staff	High	Low	Leaders of this project have a shared approach to the evaluation. In the unlikely circumstance of the unavailability of one, the other could deliver. The project manager brings substantive evaluation expertise and management skills. Any challenges following her unlikely departure would be mitigated by RAND Europe's high standards of project management support, record keeping, and the availability of other staff relevant expertise.
Non-engagement from GPs in collaborations	High	Medium	Lack of GP engagement in research is well-documented. However, as this is an evaluation with a formative aspect where we will work closely with case study sites and offer timely feedback, and we are reliably informed by the RCGP that this work will likely be considered a significant benefit to GP collaborations, we do not foresee this being a major risk. When recruiting case studies, we will ask local PCN leads to commit to helping us access GPs for interviews and any survey work. Should we face non-engagement based on our proposed strategy, we will consider alternative ways to engage GPs.
Loss of data	High	Low	Although unlikely that data loss would occur, the University of Birmingham and RAND Europe have resilient, well-tested IT systems with data from all computers backed up in multiple locations which would enable the recovery of any lost data on local servers.
Timelines slipping or inability to access certain data in the proposed timeline due to factors outside our control (e.g. bad weather)	High	Medium	There is a small, but not insignificant, risk that we may be delayed in accessing the resources we need in a timely manner, including if local research governance approvals prove to be slow. Additionally, access to items for the documentary review may be delayed if the documents are not readily available online, and it may prove challenging to arrange interviews when clinicians and others are very busy with their NHS work. In the case of the timeline slipping, we will ensure to keep the NIHR and any other relevant stakeholders informed of progress and when the new completion date of the project is.

Plans for service user and public involvement

There will be a number of opportunities for patient and public involvement within this project. This proposal has been peer reviewed by a patient member of the BRACE health and care panel, who will also be invited to attend the stakeholder workshop (WP2). Outputs from the project will be reviewed by at least one patient panel member. Project findings will be shared and discussed at

meetings of the full BRACE health and care panel, which includes eight patient and public members. We will also seek the advice of those members in terms of the best ways to communicate findings to patient and public audiences, helping to ensure that dissemination activities have a wide reach and impact.

Ethical issues and approvals required

An application for ethical review by the University of Birmingham's Research Ethics Committee will be made at the earliest possible opportunity. As this project is a service evaluation, approval by the Health Research Authority (HRA) or an NHS Research Ethics Committee will not be required. However, we will write and submit a short one-page summary to the HRA to confirm that this is indeed the case. We will contact the relevant local research and development (R&D) offices for advice regarding the local requirements for approval and/or registration of service evaluations.

Participant consent

We will provide information sheets to all participants taking part in our evaluation which we detail its aim, study design, risks, benefits and who they may contact if they have further questions, and their right to withdraw from the study at any point. Participants taking part in interviews will receive a letter/email of invitation, information sheet, and will need to provide informed written consent.

Due to the sensitive content of discussion in stakeholder meetings, some NHS staff members may feel uncomfortable being observed. Along with explaining the purpose of the study and rationale for completing observations, NHS staff members in attendance will be given the opportunity to state if they would like to be omitted from the recording of observations. We will obtain verbal consent for those who agree to be observed.

Confidentiality

If required by local R&D governance processes, team members visiting NHS sites will secure NIHR research passports. Interview and observation data collected on NHS sites will be anonymised before leaving the premises and data will be brought back to RAND Europe or University of Birmingham in a secure and encrypted format. Data stored on research team laptops will be both password and bit locker protected. Electronic data will be held securely on a restricted access network and any paper-based data will be stored in a locked filling cabinet. Participant identifier codes will be stored separately from the anonymised interview transcripts.

Indemnity and insurance

The University of Birmingham holds the relevant insurance cover for this study, as confirmed via our BRACE contract with NIHR.

Sponsor

The University of Birmingham will act as the main sponsor and guarantor for this study.

Data storage

The project team will store data at the University of Birmingham for up to five years after data collection is complete (or until it is no longer necessary). Data will then be archived in accordance to University of Birmingham research governance processes.

Quality assurance

All reports and other deliverables will be peer reviewed by a minimum of three people: two members of our health and care panel (including one patient member) and one of our critical friends – Professors Mary Dixon-Woods and Russell Mannion. The study protocol has been independently reviewed by two members of the BRACE Health and Care Panel (patient experience representative, and current NHS Primary care employee) and by one of our academic critical friends. The protocol has also been internally reviewed by members of the BRACE Executive Committee. Further, input into the design and conduct of this evaluation has been commented upon by senior NHS England colleagues and members of the BRACE Steering Group.

Funding

BRACE, including this evaluation, is funded by the NIHR Health Services and Delivery Research (HS&DR) programme (HSDR16/138/31).

Research team

Table 5 presents the team members and their corresponding roles and expertise.

Table 5. Team members

Team member	Role and contribution in research team	Relevant expertise
Judith Smith, Director of BRACE, University of Birmingham	Overall project lead for this study, project conception and scoping, data collection, analysis, facilitator of project workshops, dissemination	Health services research and healthcare management specialist with over 30 years' experience of NHS organisation and management. Particular research expertise in the organisation, governance and management of primary care, and the development of primary care networks and organisations in the UK and overseas.
Jon Sussex, Senior Research Leader, RAND Europe	Project lead from RAND Europe, project conception, project management	Health economist with 30 years' experience of NHS research and consultancy
Sarah Ball, Senior Analyst, RAND Europe	Project conception, analysis, dissemination	Experienced health services researcher and psychologist, with a focus on primary care transformation
Amelia Harshfield, Analyst, RAND Europe	Day-to-day project manager, conception, data collection, analysis, dissemination	Background in public health and primary care research, specialising in health services research. Project manager to multiple projects, rapid evidence assessment experience from multiple projects, an extensive understanding and experience of quantitative data analysis.
Natasha Elmore, Analyst, RAND Europe	Project conception, data collection, analysis, dissemination	Qualitative methods and analysis; documentary review; systematic and REA experience; extensive experience in primary care research

Manbinder Sidhu, BRACE Research Fellow, University of Birmingham	Project conception, data collection, analysis, dissemination	An applied social scientist with 10 years' experience of health research with the NHS and Third Sector organisations.

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