Acute hospitals managing general practice services (vertical integration) - Study protocol

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SummaryBackground

Fostering greater integration and joint working across the primary/secondary care interface is an enduring health system priority, and carries the potential to deliver improvements for patients, clinical teams and local systems of care (including cost savings). There are innovative approaches to such integration emerging across a few places in the NHS and they have not yet been subject to independent evaluation. One such approach is acute hospitals taking over the running of general practices ('vertical integration'). In this approach, the acute hospital is contractually responsible for the delivery of core general medical services to patients in the practices concerned. There are several locations across the UK where acute trusts or health boards have taken over general practice contracts and are directly managing GP services, and are using this model of integration to redesign local services such as urgent care. Early impacts have been reported from one of these trusts, including a reduction in emergency hospital admissions and increasing access to GP appointments, but this has not been subject to independent evaluation. Beyond that, however, little is known about this model of integration: how it is being implemented; whether and how vertical integration might help or hinder the redesign of care pathways; whether and how services offered in primary care settings change as a result; the extent to which community and mental health services are included and/or affected; the impact on service utilisation, patient access, choice and experience; and the impact on the general practice, wider primary care and hospital workforces.

Aims

Our rapid evaluation will answer research questions concerned with the implementation of vertical integration as defined above. In particular, we will focus on understanding the early impacts of vertical integration: its objectives; how it is being implemented; whether and how vertical integration can underpin and drive the redesigning of care pathways; whether and how services offered in primary care settings change as a result; and the impact on the general practice and hospital workforces. The research will inform the development of a theory of change for vertical integration, describing its desired outcomes and the mechanisms by which these are expected to be achieved. The theory of change will guide and underpin a second phase evaluation to assess the impact of vertical integration, in particular on patients and on the efficiency and effectiveness of the health care system.

Evaluation questions

In order to address our aim, the study seeks to answer the following evaluation questions:

RQ1: What are the drivers and rationale for acute hospitals taking over the management and governance of general practices? What does this type of vertical integration aim to achieve?

RQ2: What models/arrangements exist for acute hospital organisations to manage general practices (including different contractual/legal/organisational arrangements across primary, secondary and community health services)?

RQ3: What is the experience of implementing this model of vertical integration, including barriers and enablers and lessons learnt?

RQ4: In what ways, if any, has this model of vertical integration influenced the extent and type of health service provision delivered in primary care?

RQ5: What are the views of the primary and secondary care workforces about working together in this way across the care interface?

RQ6: In what ways, if any, has this model of vertical integration had impact so far? What are the expected longer-term impacts? How is progress being measured?

Design and methods

Our evaluation comprises four distinct work packages (WP):

- WP1: Scoping: comprising a light touch, rapid review of the literature, supported by
 interviews with key informants and a project design workshop with policy makers and
 external researchers, to obtain an overview of any evidence already reported and to inform
 the development of propositions to be tested through comparative case studies.
- WP2: Comparative case studies of three vertical integration sites. The case studies will
 comprise: interviews with those involved in the conceptual design, implementation and
 analysis of this model of vertical integration at the respective sites; analysis of key
 documentation; observation of strategic meetings; and interpretation of existing metrics and
 cost information collected, and quantitative analyses undertaken, at case study sites.
- WP3: Qualitative analysis and development of a theory of change for each case study site as well as an overall theory of change for this type of vertical integration.
- WP4: Workshop to discuss the findings and their implications with academics, policy analysts and other experts.

Dissemination and outputs

We anticipate disseminating the findings of this evaluation project in a number of ways, including:

- 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 overall findings of the rapid evaluation, which may be of particular interest to the NHS community.
- An interim report to share preliminary evaluation findings with case study sites, NIHR HS&DR and the BRACE Steering Group and Health and Care Panel¹.

¹ The Health and Care Panel is made up of 50 members (diverse representation from system and organisational leaders; middle and operational clinical and general managers; frontline clinicians and other

- 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.
- Disseminating findings through BRACE networks, from using NHS channels such as lay networks of Non-Executive Directors and Primary Care Commissioning sub-committees, 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.

Study timeline

The study will take place over 14 months (January 2019 to March 2020), assuming access to case study sites and the timely securing of necessary ethical approvals.

Funding

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practitioner groups) who act as a source of advice from the health and care sector, and a sounding board in relation to the choice, design, delivery and dissemination.

Background and rationale

Background

There is growing interest in moving and extending the breadth of health care services delivered in primary care settings (NHS England 2017). However, the long term sustainability of primary care is a key issue within a climate of growing demand, rising multi-morbidity, increasing costs, new technology, and workforce constraints (Department of Health and Social Care 2019; Kumpunen et al. 2017; Smith et al. 2013). A recent survey led by Gibson et al. (2015) found that greater numbers of GPs were likely to quit direct patient care within the next five years due to 'increasing workloads, paperwork, and increased demand from patients'. There have been a number of GP practice closures across the UK (Dayan et al. 2014) and fewer GPs are providing out of hours services. Both factors are thought to be contributing to increased demand and waiting times for Accident and Emergency (A&E) services (Ham 2018; Ham et al. 2018).

The NHS across England and Wales is working towards a model of integrated systems of care, which are intended to create greater efficiencies and better co-ordinated working across the primary and secondary interface. Vertical integration may be one model (from many) that could support the foundations of greater care integration. The conceptualisation and movement towards integrated systems of care is not a recent phenomenon; for example, discussions around vertical integration and disintegration, whole systems working, increased inter-professional working and integrated care pathways across primary, community, mental and secondary care date back over decades (see for example: Croxson 1999; Shaw et al. 2011).

Stronger integration between primary and secondary care was outlined in the Five Year Forward View (FYFV) (NHS England 2014) and tested in NHS England's New Care Models Programmes through the Primary and Acute Care Systems (PACS) and Multispecialty Community Provider (MCP) vanguards (Checkland et al. 2017; National Audit Office 2018; NHS England 2016a, b, c). There is some learning from these with regard to service utilisation, changes to service provision, and methods to initiate and maintain integration across primary and secondary care (Naylor and Charles 2018). However, data and findings are limited across the vanguard sites, with questions over the reliability of outcomes data and uncertainty about the impact of PACs and MCPs on key dimensions of health service delivery (Tallack 2019).

An innovative approach to achieving stronger integration is the vertical integration of primary care organisations with secondary care organisations: the coordination within a single management entity of staff, infrastructure, functions and activities that contribute to different levels of patient care (primary, community and hospital services) (Gillies et al. 1993; Ramsay et al. 2009; Rumbold & Shaw 2010). Such organisational integration can range from virtual integration that entails the formation of relatively flexible alliance arrangements to a fully integrated organisational model in which a single body holds contracts to deliver both secondary and primary care services (Naylor & Charles 2018). In this evaluation, we are interested in the fully integrated model of vertical integration; specifically NHS acute hospitals taking over the management of GP practices.

There are a number of potential pragmatic reasons that might drive vertical integration between acute hospitals and GP practices. Vertical integration brings the opportunity to redesign services; address problems with governance, funding, differing objectives and drivers; enhance the ability to involve both primary care and secondary care clinicians in the design of effective and efficient clinical pathways; and, for patients, improve continuity of care and foster more seamless transitions between teams and services.. In particular, the vertical integration model might help to overcome

coordination challenges that result from the discrete financial 'silos' in which primary care and secondary care otherwise find themselves, e.g. where investment in one sector yields cost savings in the other. Vertical integration, entailing practice staff becoming salaried employees of an acute hospital NHS Trust (England) or Health Board (Wales), may particularly suit younger GPs, many of whom are showing reluctance to buy into the traditional 'partner-model' of general practice and a preference to be sessional or salaried (Sheaff et al. 2015; Ramsay et al. 2009; Steven et al. 2018).

Nevertheless, there are also concerns with the implementation of acute hospital and GP practice vertical integration. For example: fears among some GPs of reduced GP autonomy and of damage to the entrepreneurialism and innovation of general practice (GPonline 2014; Ramsay et al. 2009); mistrust from local primary care stakeholders (Round et al. 2018); doubts over how much of a reduction in health service utilisation is achievable through vertical integration (Wolfe et al. 2016), especially as compared with other models of integration (Steven et al. 2018).

Our initial scoping work identified five geographical locations where vertical integration between acute hospitals and GP practices is already taking place. Furthermore, our scoping work found that there is some interest among other acute hospitals in England and Wales to adopt this model of vertical integration. In particular, one of our case study sites has received a number of informal approaches about its model of vertical integration and is currently developing a guidance document to support other trusts to take over the management of local practices in their respective areas. The wider interest in adopting this model of vertical integration implies that rapid evaluation is needed.

Internationally, examples of similar vertical integration models have been identified in the US, where the Kaiser Permanente Community Health Initiative was set up to tackle poor health outcomes for low-income communities (Schwartz et al. 2018); in Spain, where the Alzira model of private providers managing hospital and primary care services has recently been reversed (Comendeiro-Maaløe et al. 2019); and in Denmark, where GP facilities have been located next to A&E departments to ensure the most suitable care is provided (Blom & von Bülow 2013).

Why is this research important/needed now?

Scoping work undertaken to inform the development of this protocol highlighted a paucity of evidence on fully integrated models of vertical integration, with some key gaps in the evidence base, namely:

- There is little systematic information on the rationale for vertical integration in a UK NHS setting, and on why it is developing in some places despite not being an explicit part of NHS policy in England or Wales.
- There is limited understanding about how to implement vertical integration in a UK NHS setting (e.g. contractual/governance and commissioning issues), as well as the working cultures in such models (e.g. between acute hospital and GP practice staff).
- There was no evidence identified on the core characteristics of acute hospital and GP practice integration and the enablers of such a model in a UK setting.
- There is very little information on the desired or achieved outcomes of vertical integration in a UK setting.

For Conrad & Dowling (1990) successful vertical integration demands a health care system that has capacity to plan, deliver, monitor and adjust the care of an individual over time. The NHS has, until recently and so far in only a few locations, traditionally separated primary care provision from acute hospital service provision. Key to achieving vertical integration is better clinical integration (coordination of treatment services for a patient) and functional integration (strengthening key

support functions, such as financial management, human resources, and strategic planning). Vertical integration may be one way of achieving better clinical and functional integration.

Vertical integration also leads to alterations in contractual arrangements and accountability, recruitment, premises and care pathways (Rittenhouse et al. 2011). Ultimately, the implementation of vertical integration of GP practices and acute hospitals has the potential to bring with it a significant change in the planning and delivery of primary and secondary care services. But little is known about this model of integration. A series of questions and knowledge gaps has been highlighted by our scoping research (which included a review of the literature, expert interviews and a design workshop):

- What are the drivers and incentives for acute hospital trusts to acquire GP practices why was vertical integration preferred to other models of integration, such as with non-acute trusts or horizontal integration with other primary care providers? How might these drivers and incentives change following the changes to the general practice contract in 2019/2020 (Department of Health and Social Care 2019; NHS England 2019b) and as a result of practices working as part of primary care networks (PCNs)?
- What is the theory of change (ToC) behind vertical integration? What are the intended outcomes of vertical integration, and by what mechanisms are these outcomes expected to be achieved?
- By what process is vertical integration implemented and achieved? Did areas encounter any resistance and, if so, was and how was this resistance overcome?
- Are acute hospitals attempting to grow the number of practices they are managing, and if so why? What is holding back more acute hospital GP practice mergers? Why do other practices in the areas where vertical integration is occurring not join the vertically integrated organisation? What is the nature of risk and accountability, including to commissioners of care, in a vertical integration model?
- What is the impact, if any, of vertical integration on the delivery of, and access to, primary and secondary care? Does vertical integration lead to a reconfiguration of patient care pathways?
- What impact does vertical integration have upon managing demand across primary and secondary care and does it impact upon the volume of referrals to acute hospital services and where patients are treated?
- How do community health and mental health services fit in with vertical integration? What is
 the incentive for community and mental health services to align and work with vertically
 integrated acute hospitals and GP practices?
- Has vertical integration affected the working of multi-disciplinary teams (MDTs)? Has it created barriers or does it act as an enabler?
- What are the costs and/or savings (expected and/or realised) that are associated with vertical integration?
- How does vertical integration affect recruitment and retention of primary care staff (of all kinds, including GPs)?
- What is the role of PCNs for those involved, or planning to be involved, with vertical integration? How will the drive for PCNs impact upon the operationalisation of vertical integration (NHS England 2019a; b)?
- Do patients' experiences of general practice care change, and if so how do they change, when the management of practices is taken on by an acute hospital trust?
- What is the extent of integration when acute hospitals take over GP practices?

How are such GP acquisitions regulated and by whom?

The potential impact of wider uptake of acute hospital and GP practice vertical integration, its relevance to policy around integration of care systems and creation of PCNs, and the lack of a relevant and robust evidence base, suggest this topic is highly appropriate for rapid evaluation. The development of collaborations between GP practices to enable them to operate at scale is of great interest in the NHS in England (NHS England 2019b). Direct management of GP practices by acute hospitals, in whatever precise form that takes, requires timely investigation. In the sections below, we detail how we will address gaps in current evidence, our methodological approach, and the outputs we expect to produce as result of this evaluation.

Project plan

Aims

The rapid evaluation will address two aims.

Aim 1 is to understand the early impacts of vertical integration: its objectives; how it is being implemented; whether and how vertical integration can underpin and drive the redesigning of care pathways; whether and how services offered in primary care settings change as a result; and the impact on the general practice and hospital workforces.

Aim 2 is to develop a theory of change (ToC) for vertical integration. At present, it is unclear what outcomes this model of vertical integration is expected to achieve in the short, medium and long terms, and under what circumstances. The ToC will clarify the desired outcomes of this model of vertical integration, how these outcomes are expected to be achieved, and what resources, approaches and activities are supporting the implementation of the model in practice.

We intend to test the ToC in a follow-up impact evaluation at a later date. The initial rapid evaluation proposed in the current protocol will inform the design of a protocol for the follow-up impact evaluation to examine outcomes and impacts, and explore the possibility of undertaking an economic evaluation.

There are synergies between this evaluation of acute hospitals managing GP services and the evaluation of large-scale GP collaborations that is also being undertaken by the BRACE Centre. We will bring together findings from across the two projects to better understand how two different models of primary care working impact of delivery and coordination of services, the drivers and benefits/challenges of working at scale, as well impact on staff well-being.

Research questions for the evaluation

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

RQ1: What are the drivers and rationale for acute hospitals taking over the management and governance of general practices? What does this type of vertical integration aim to achieve?

RQ2: What models/arrangements exist for acute hospital organisations to manage general practices (including different contractual/legal/organisational arrangements across primary, secondary and community health services)?

RQ3: What is the experience of implementing this model of vertical integration, including barriers and enablers and lessons learnt?

RQ4: In what ways, if any, has this model of vertical integration influenced the extent and type of health service provision delivered in primary care?

RQ5: What are the views of the primary and secondary care workforces about working together in this way across the care interface?

RQ6: In what ways, if any, has this model of vertical integration had impact so far? What are the expected longer-term impacts? How is progress being measured?

A formal evaluation of outcomes for patients will be a key focus for the follow-on impact evaluation; in this first phase of the project we will ask key groups whether they are starting to see any impact on patient care and experience across the primary-secondary care interface, in particular improving accessing to health care.

Research design and methodology

Design

We will undertake a cross-comparative case study qualitative evaluation comprised of: 1) a rapid review of the literature, stakeholder workshop and telephone scoping interviews; 2) interviews with key stakeholders across case study sites alongside observations of strategic meetings and analysis of key documents; 3) development of a theory of change for each case study site as well as an overall theory of change for this model of vertical integration; and 4) a workshop with policy experts, academics and other key stakeholder groups to share and discuss emerging findings. We will use a cross-comparative case study approach to address the research questions (De Silva et al. 2014).

Throughout the evaluation we will attempt to develop an understanding of the impact of VI on patient experience alongside our understanding of change at the provider and system level. In addition, we will pay particular attention to the local contexts in which VI is being developed and implemented, including cultures of working (which will have led to particular implementation strategies). This will enable us to explore the relationship between local contexts, processes and early outcomes (including patient experience) and support the identification of both generalisable and context-specific learning.

Our evaluation will be comprised of four distinct work packages (WP) detailed in Table 1.

Table 1. Summary of work packages and how research questions will be addressed

Work package (WP)	Description	Research questions
WP1: Rapid review of the	To obtain an overview of the	RQ1 and RQ2
literature, stakeholder	evidence already reported on	
workshop and telephone	vertical integration of secondary	
scoping interviews	and primary care services and to	
	inform the development of	
	propositions to be tested through	
	comparative case studies	
WP2: Comparative case	To undertake interviews with those	RQ1, RQ2, RQ3, RQ4, RQ5
studies of three vertical	involved in the conceptual design,	and RQ6
integration sites	implementation and analysis of this	
	model of vertical integration at	
	their respective sites; analysis of	
	key documentation (both internal	
	and publicly shared and that	
	related to patient experience);	
	non-participant observation of	
	strategic meetings; and	
	interpretation of existing metrics and cost information being	
	collected by, and any quantitative	
	analyses undertaken at, the case	
	study sites.	
WP3: Development of a	We will develop a theory of change	RQ1, RQ2, RQ3, RQ4, RQ5
theory of change (including	for each case study site as well as	and RQ6
a workshop with key case	an overall theory of change for this	
study site specific	model of vertical integration	
stakeholders)		
WP4: Workshop to share	Share and discuss findings	RQ1, RQ2, RQ3, RQ4, RQ5
key learning with academics,	generated from data collection	and RQ6
policy analysts, and other	from WP1 and WP2 and develop	
key experts and support the	recommendations for	
synthesis of findings	commissioners, providers and	
	policy makers	

Methodology

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

WP1: Rapid review of the literature, scoping interviews and stakeholder workshop

Rapid scoping review of literature

The first stage of the evaluation is a rapid scoping review of the literature to:

- Collate published, including grey, literature using a selective systematic approach to searching.
- Provide a descriptive summary of our findings.

Search strategy

The scope of the search is restricted to key search terms in Title and Abstract and published in English only, from 1990 onwards. We detail our search terms below:

"vertical" "structural" "integration" "integrate" "integrate" "integrated care" "model of care" models of care" AND "general practice" "gp" "primary care" "acute trust*" "NHS trust*" "NHS foundation trust*" "hospital" "secondary care"

We will seek to identify published literature in the following databases:

PubMed, Ovid MEDLINE, Journal of Integrated Care

We are aware that there may be a paucity of peer reviewed literature relevant to a UK NHS context. As a result, we will seek to identify unpublished and grey literature by requesting topic experts to inform us of any additional literature that we may have missed.

Inclusion criteria

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

- Published in the English language only
- Restricted by date i.e. 1990 to present
- Any of the following types of publication: journal articles and reviews; websites; publications from professional bodies, charities etc.; practice guidelines.

Data extraction and synthesis of findings

Titles and abstracts will be screened by two study team members against the inclusion criteria. The full text of all 'included' papers will then be obtained for further full-text screening. Disagreements will be resolved by a third reviewer.

The study team will take a descriptive thematic approach to synthesising findings drawn from the rapid scoping review guided by existing theory on vertical integration (Conrad et al. 1990). We will thematically categorise literature according to differing models of vertical integration to aid in the identification of core characteristics that act as enablers to successful implementation. We will then seek to draw connections between core characteristics and desired outcomes for vertical integration within a UK NHS context.

Telephone scoping interviews with key experts

Members of the study team will complete a number of telephone interviews (using a structured topic guide informed by the literature) and face-to-face meetings with academics, policy analysts and NHS staff involved with the implementation of vertical integration across different sites in the UK to: 1) gather their initial insights and views on why vertical integration was introduced in their area; and 2) seek their opinion with regard to which research questions a rapid evaluation should prioritise. In addition, scoping interviews will help the study team to build rapport and trust, identify a primary contact, and discuss the commitment required to mobilise data collection at potential case study sites.

Stakeholder workshop

We will hold a stakeholder project design workshop (Ørngreen and Levinsen 2017) which will include members of the project team, senior BRACE colleagues, and policy experts from the Kings Fund, Department of Health and Social Care and NHS England. The aim of the workshop will be to share

findings from the rapid review of the literature, scoping interviews with key experts, identify gaps in the literature, and help shape research questions as part of the evaluation.

A structured agenda will be prepared in advance of the workshop and will include time for presentations of findings from the rapid review of the literature and scoping interviews, and smaller group discussions. The project team will take detailed notes during the workshop, which will be used to further develop and refine the study design. A summary of the notes taken from group discussions and presentation slides will be shared with attendees for confirmation or correction following the workshop.

WP2: Comparative case studies of three vertical integration sites

A comparative case study approach will provide the opportunity to analyse and interpret variation in relation to the implementation of vertical integration at each site (Yin 2014). We will conduct comparative case studies of three vertical integration sites across England and Wales. We are aware from our scoping work that the sites vary in context and environment, and consequently implementation. This study design can help identify how such variation can lead to potential differences in outcomes.

The study team identified five sites where this model of vertical integration is already being delivered at scale. Three sites were selected and have agreed to participate in the study. The selection of case study sites was purposive, with the aim of ensuring variation across the three sites in terms of: 1) their rationale for implementing vertical integration and intentions for growth (i.e. management of more GP practices operating under this model in future); 2) geographical location and population served; 3) their legal and governance working frameworks; and 4) in the time since vertical integration was introduced

Table 2 provides a summary of our case study sites.

Table 2. Vertical integration case study sites

Case study site	Location	Date of commencement	No. of GP practices
Site A	England	July 2018	9
Site B	Wales	March 2016	16
Site C	England	April 2016	12

Data collection at three case study sites

The study team will develop a protocol to guide data collection at each case study site. Data collection will consist of three simultaneous stages: 1) stakeholder interviews; 2) analysis of key documentation (both internal and publicly shared information about monitoring the implementation of vertical integration, inclusive of quantitative data on utilisation and costs); and 3) non-participant observation of strategic meetings.

Stakeholder interviews

We plan to interview up to 20 key stakeholders at each case study site. The aim of completing interviews with stakeholders is to understand the rationale, drivers and challenges involved in the conceptualisation and implementation of vertical integration and interpret the experiences of primary and secondary care staff working together across the interface.

Potential participants for interview will be purposively sampled (Ritchie and Lewis 2003) and approached through each case study site's contact person. The case study contact person will be a senior manager involved in the integration of primary and secondary care service delivery. Their role will be to communicate with the project team, support the processing of local research/governance approvals, and facilitate data collection. We aim to interview key individuals involved in the design, implementation, governance and analysis of this model of vertical integration across primary and secondary care at the levels of strategic decision making and delivering patient care. Informants will include (but are not limited to): NHS health board/acute hospital chief executives, directors (clinical and non-clinical) and other NHS managerial level staff (related to integration and strategy, delivery of health care services, as well as financial and governance related management); board members from Clinical Commissioning Groups (CCGs); representatives from the Local Medical Committees (LMCs); GPs/GP practice cluster leads and primary care staff who have, and some who have not, implemented the vertical integration model in each area; and members of patient participant and/or Healthwatch groups who were involved in the conception and introduction of this model. We understand that some key individuals may have left case study sites since initial implementation. But the study team will still attempt to contact and interview them if appropriate.

We will invite individuals to participate in a semi-structured interview with one member of the study team completed at their place of employment or any other suitable location convenient to the interviewee. Each participant will be emailed a participant information sheet (PIS) prior to commencing the interview and will be given at least 48 hours to make a decision regarding whether they would like to participate or not. Prior to commencing the interview, interviewees will have the opportunity to ask questions about the study and/or wider BRACE related work. Participants will be required to sign a consent form prior to participating in the interview, including whether they consent to the recording of the interview. 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.

Where possible, interviews will be conducted face-to-face during field visits, although some telephone interviews may also be undertaken. A topic guide will be developed and used as an aide memoire during interviews. The main themes the topic guide will cover are: understanding the rationale behind the implementation of vertical integration; the clinical/legal/governance arrangements that have been set up (or will be) to facilitate this model, to understand the experiences of primary and secondary staff involved with the implementation of this model, and what are the outcomes this model is expected to deliver in the short, medium and long term.

Interviews will be audio-recorded (subject to consent being given) and transcribed verbatim by a professional transcription service, anonymised and kept in compliance with the General Data Protection Regulation (GDPR) 2018 and Data Protection Act 2018.

Thematic analysis of interview transcripts, observations and documents will be conducted for each case (Braun and Clarke 2006). We will iteratively develop a coding frame using findings from the rapid review, early interviews and discussion amongst the study team (Saldaña 2016). First, we will use an axial coding approach to code interview transcripts and notes from observations. Second,

codes will be organised into overarching themes, using NVivo 12 software. The study team will explore opportunities for data reduction and rapid data analysis to turn preliminary analyses around quickly (Miles and Huberman 1994). For example, creating template-based summaries of transcripts that are thematically aligned with our interview guide and creating matrices of data by site and stakeholder role. As a result, this approach to rapid data analysis can streamline the process of noting simultaneously and systematically similarities, differences, and trends in responses across groups of informants (Averill 2002, p. 856).

Non-participant observation of meetings

We will observe strategic meetings (at an executive and managerial level at the acute trust and/or meetings held amongst GPs at a practice level) between key stakeholders at case study sites across primary and secondary care. The aim of observation is to develop a better understanding of how decisions regarding implementation and delivery of vertical integration are made at local and executive board level. Furthermore, observations will provide the opportunity to gather data with regard to the ongoing challenges of implementing and sustaining the vertical integration model across a number of practices; with input from stakeholders ranging from those who are more concerned with strategic decision making, to GPs and other practice staff who are familiar with the everyday effects of vertical integration on their work. We plan to complete 6-8 observations at each case study site although the exact number will depend on scheduling and access.

Interactions will be recorded on an observation template which will be content-focused, based on the agenda for the meeting. We will use sociograms (visual representations of relationships between individuals in a given setting) to map the nature of interactions (Tubaro et al. 2016). Team members will also make reflexive notes post observation to detail how the meeting was chaired, contributions from attendees, the strategic direction of vertical integration at each site, and how challenges to delivering primary and secondary services are addressed as part of working within this model.

A member of the study team will provide a participant information sheet and written consent form one week in advance of the meeting to all attendees. Prior to the meeting commencing, a member of the study team will provide a verbal explanation of the project and its aims, and give everyone the opportunity to ask questions. Individuals who do not consent will be omitted from recorded observation notes. During meetings, team members will be seated appropriately to record observations but remaining non-obtrusive to discussion.

Document review

Members of the study team will request and review documents describing and containing data on the aims, drivers and challenges associated with the implementation of vertical integration. They may include documents containing information on any of the following (but not limited to): operational activities, changes to functional activity, changes to clinical activity, staff involvement and recruitment, patient involvement, data on health service utilisation and operating costs for GP practices and acute hospitals. The types of data and documents the project team may request include: original business cases, consultation documents with staff and/or patient participation groups prior to the introduction of the vertical integration model, on-going monitoring data (inclusive of quantitative data on utilisation and costs), minutes from meetings where the implementation of vertical integration is discussed, and any presentations developed to showcase progression of vertical integration at each site. Information will be extracted from source documents using a structured Excel extraction template.

WP3: Data analysis and development of a theory of change

Our aim is to develop a theory of change for this model of vertical integration specific to each case study site as well as a generic model for cross-case comparison. Theory of change is a comprehensive description and illustration of how and why a desired change is expected to happen in a particular context. It is focused in particular on mapping out or "filling in" what has been described as the "missing middle" between what a programme or change initiative does (its activities or interventions) and how these lead to desired goals being achieved (Taplin and Clark 2012). It does this by first identifying the desired long-term goals and then works back from these to identify all the conditions (outcomes) that must be in place (and how these related to one another causally) for the goals to occur (Taplin and Clark 2012). It also leads to better evaluation, as it is possible to measure progress towards the achievement of longer-term goals that goes beyond the identification of programme outputs (Taplin and Clark 2012). Hence, the theory of change will identify the outcomes that vertical integration is expected to achieve, which could then be measured in a follow-on project.

Hence, our data analysis of stakeholder interviews, observations and document reviews will be guided by the requirements of creating a theory of change. In order to develop a theory of change for each respective case study site, analysis will first be completed on an individual case study basis, before a combined analysis across all three case studies is undertaken. Once data collection is complete, we will deliver a workshop with each case study site, inviting those involved in the design and implementation of this model of vertical integration to share and discuss their views about what they expect vertical integration to achieve locally and the factors they feel will contribute to the model being successfully established and sustained. The workshops will be facilitated by two members of the project team using a structured agenda prepared in advance. Written notes will be taken to capture key points from discussions with a one page summary shared with attendees soon after the workshop is complete. These workshops will enable the project team to test emerging theories of change with local stakeholders before presenting them to external experts.

WP4 Workshop with policy experts, academics and other key expert

Emerging findings and theories of change will be discussed and tested in a half-day research workshop with the wider BRACE team and external experts (we will invite key staff from the Department of Health and Social Care and NHS England, and peer policy analysts active in the field of care integration e.g. from the King's Fund and Nuffield Trust) early in 2020. The evaluation team will produce case descriptions for each vertical integration site using a structured template to facilitate comparison.

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 theories of change 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 refine the theories of change and identify key messages emerging from the evaluation, and to help inform the approach to dissemination.

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

Follow-up impact evaluation

Having established theories of change for each of the three vertical integration case studies in this first evaluation, we envisage returning to the case study sites approximately 12 months after the initial evaluation has ended to complete a follow-up study to examine outcomes and impacts, and explore the possibility of undertaking an economic evaluation. Our first evaluation will produce evidence and insights (and theories of change) to inform the design of the protocol for the follow-up study. We have had preliminary discussions about this follow-up work with the case study sites and all are supportive of the idea in principle.

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 February 2020 and published in the NIHR Journals Library (HS&DR Programme), 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.
- An interim report to share preliminary evaluation findings with case study sites, NIHR HS&DR, the BRACE Steering Group and Health and Care Panel.
- A short summary report in digital format highlighting the overarching findings from the rapid literature review, 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.
- A short reporting document for each case study site, including the local theory of change, to share more widely with key local stakeholders.
- Web-based resources such as the summary report, link to full report, blogs to highlight key
 findings to non-expert as well as more expert audiences, 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. These resources 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 analyses of primary
 and integrated care developments, including: the BRACE evaluation of large scale GP
 collaborations, the new care models team (funded by the NIHR Policy Research Programme
 (PRP)), integrated care pioneers evaluation (funded by the PRP), research into GP
 federations (funded by HS&DR), and RCGP survey work with primary care networks.
 Dissemination with these other research teams 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 and the new GP contract in England, and of NHS developments in Wales.

• Disseminating findings through BRACE networks, from using NHS channels such as approaching lay networks of Non-Executive Directors and Primary Care Commissioning subcommittees, NHS England's CCG and any new primary care network newsletter, NHS Providers and NHS Confederation communication, National Association of Primary Care and RCGP statements, and the NHS Improvement Bulletin. We will draw on the expertise and assistance of our PPI collaborators, health and care panel (particularly members with communication/journalist expertise) and steering group members who are involved with the project and the BRACE Centre. We will also seek the guidance of Richard Kirby and Charlotte Augst (BRACE co-investigators) to understand how best to communicate preliminary findings with NHS staff and patients.

Project timetable

The study will take place over 14 months (January 2019 to March 2020), assuming timely access within our three case study sites, obtaining necessary ethical and governance approvals, as well as identifying and completing data collection with key stakeholders. Figure 2 shows the overall study timeline and the key milestones for the project.

Activity 2019 2020 lul Oct Feb Mar Mav lun Sep Nov Dec Feb Mar lan Apr Aug lan Rapid review of literature Telephone scoping interviews Project design workshop Confirmation/Access to case study sites Securing ethical/local management approvals Analysis of local documentation and data Primary qualitative research at each site Analysis and sysnthesis of findings Development of ToC workshops Workshop to share findings Reporting Dissemination

Figure 2. Study timeline and key milestones

Project management, governance and delivery

Project management and quality assurance

This proposal has been reviewed by the BRACE Director (Judith Smith), BRACE Deputy Director (Jo Ellins) and by three independent reviewers, two drawn from the BRACE Health and Care panel (including one patient panel member) and one of BRACE's academic critical friends. Further, input into the design and conduct of this evaluation has been commented upon by members of the BRACE Steering Group. The principal investigator, Jon Sussex (RAND Europe), will be responsible for the overall delivery and quality assurance of this project. The project manager, Manbinder Sidhu, will be responsible for the day to day management of inputs by University of Birmingham and RAND Europe team members towards this project. Jack Pollard (RAND Europe) will be responsible for supporting coordination of the evaluation and ensuring consistency between the individual researchers undertaking the three case studies. Manbinder Sidhu will complete fieldwork at two case study sites while Jack Pollard will complete fieldwork at a third site.

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 catchups; and use of project planning tools (such as 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, and to NIHR HS&DR as and when required. We describe potential risks and mitigation strategies in Table 3.

All reports and other deliverables will be peer reviewed by the BRACE Director (Judith Smith) and a minimum of three people, drawn from the following: BRACE's academic critical friends (Professors Mary Dixon-Woods (University of Cambridge) and Russell Mannion (University of Birmingham)), Health and Care Panel, and Steering Group.

Table 3. Potential risks and mitigation strategies

Risk	Impact	Likelihood	Mitigation
Loss of key staff	High	Low	Although the project team is small, in the event of one member leaving there is capacity and resources for this person to be replaced. Both principal investigators and project team member have extensive evaluation and research experience.
Non- engagement from case study sites	High	Medium	Success of this rapid evaluation will depend on the co-operation of case study sites support processes associated with appropriate governance approvals, participant recruitment, and data collection in a timely fashion. The project team has already built relationships with our case study sites and discussed with them the commitment required. Team members will continue to have on-going meetings with site delegation teams, to discuss the contribution required from each party for the duration of the evaluation.
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. The study team will ensure transfer of data from case study sites to RAND or University of

			Birmingham will be done according to GDPR guidelines.
Delays due to inability to recruit participants/ observations of meetings	High	Medium	There is a risk that we may be delayed in recruiting participants and completing observations in a timely manner, including if local research governance approvals prove to be slow. At each case study site, the project team will identify a key point of contact who will facilitate recruitment and data collection. The team will produce detailed, descriptive information sheets to inform potential participants the importance of the evaluation, why we have asked them to take part, their involvement, and associated risks and benefits. If participants are unable to complete face-to-face interviews they will have the option of completing their interview via telephone.
Changes to NHS primary and secondary care policy	High	Medium	There is a risk that changes to NHS primary and secondary care policy during the duration of the evaluation may influence the nature of the data we collect. Team members will remain aware of pending NHS policy changes and continue to communicate with policy experts during the evaluation.

Plans for service user and public involvement

This proposal has been peer reviewed by a PPI member of the BRACE health and care panel. Outputs from the project will be reviewed by at least one PPI 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

When appropriate, we will seek appropriate governance and research ethical approval from the University of Birmingham (as sponsor), NHS Health Research Authority, and local NHS Research and Development approval to recruit participants and collect data.

An application for ethical review by the University of Birmingham's Research Ethics Committee will be made at the earliest possible opportunity. The project team has received confirmation from the Health Research Authority (HRA) that this study is categorised as a service evaluation. Therefore, approval by the HRA or an NHS Research Ethics Committee is not required. We will contact the relevant local research and development (R&D) offices for the three case study sites 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 an email of invitation, information sheet, and will need to provide informed written consent.

Due to the sensitive content of discussion in stakeholder meetings at case study sites, 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 written consent for those who agree to be observed.

Confidentiality

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 filing 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.

Funding

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

Research team

Table 4 presents the team members and their corresponding roles and expertise.

Table 4. Study team members

Team member	Role and contribution	Relevant expertise
	in research team	
Jon Sussex, Senior	Principal investigator	Senior health economist with over 30 years'
Research Leader,	from RAND Europe,	experience of NHS research and consultancy using
RAND Europe	project conception	both quantitative and qualitative methodology.
	and scoping, data	Jon is also concurrently leading the RAND Europe
	collection, analysis,	contribution towards another BRACE evaluation
	facilitator of project	

	workshops, writing of reports/dissemination	titled "The evaluation of large-scale collaborations between primary care general practices".
Jack Pollard, Analyst, RAND Europe	Project conception, data collection, analysis, facilitator of project workshops, writing of reports/dissemination	Health economist with two years' experience of applied NHS research. Jack has strong quantitative (handling large and complicated datasets, analysing secondary data and applying econometric techniques) and qualitative (undertaking interviews, facilitating workshops and focus groups, and designing and programming surveys) skills.
Manbinder Sidhu, BRACE Research Fellow, University of Birmingham	Project manager from University of Birmingham, Health Service Management Centre, project conception and scoping, data collection, analysis, facilitator of project workshops, writing of reports/dissemination.	An applied social scientist with 10 years' experience of health research with the NHS and Third Sector organisations. Manbinder has extensive experiences using a range of qualitative methods and application of theory. He is a team member for another BRACE evaluation titled "The evaluation of large-scale collaborations between primary care general practices".

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