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

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Summary

Background

In the past ten years, the NHS policy focus has shifted towards a more integrated approach to patient care across primary, secondary and social care settings. The organisation and long-term sustainability of primary care in the UK has also been the subject of increasing debate and speculation. Pressures in the primary care setting arise from increased patient demand, a rise in the number of patients with multiple long-term conditions, higher costs, developments in the consulting technology and tightening workforce constraints as result of general practitioner (GP) recruitment and retention difficulties. This is set alongside a number of GP practice closures and reduced out of hours services, all of which is thought to be contributing to the rise in Accident and Emergency (A&E) pressures in terms of patient demand and waiting times.

The policy focus on care integration and primary care over recent years has led to the development of several recommendations including developing stronger integration between primary and secondary care. This was outlined in the NHS 'Five Year Forward View' in 2014. A further response, in the 2019 NHS Longer Term Plan, set out the intention that all

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GP practices in England should come together to deliver services as part of 'Primary Care Networks', a form of horizontal integration designed to cover populations of 30-50,000 patients.

Of particular recent policy and political interest is an innovative approach where primary care practices are integrated with acute hospital trusts, i.e. a form of vertical integration. This is where the coordination of functions, activities and organisation that provide different levels of patient care are under a single management. There are signs that vertical integration of primary care with secondary care may be adopted more widely in future. Consideration of such restructuring requires significant organisational change and to be informed by how the model will work and what the potential benefits to patients, staff and the health system as a whole, will be.

Relatively little is still known about this approach, although an initial, qualitative, rapid evaluation by BRACE showed that 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). It is anticipated that vertical integration may enable better management of patient demand on secondary care services. Vertical integration can lead to alterations in contractual arrangements and accountability, workforce recruitment, premises and care pathways, which in turn have the potential to create better care and outcomes for the patient. Interest in vertical integration is not limited to the UK NHS, other countries which have adopted this approach include the United States, Spain, Denmark and New Zealand.

Changes in the organisational structure of primary care may be expected to particularly impact on those patients presenting with more than one single chronic condition (multiple long-term conditions). In 2014, as many as eight in ten of all primary consultations involved patients with multiple long-term conditions and this number is continuing to rise. These patients are more complex in their needs and will often require access to many different health care providers not all from the same site. One of the postulated benefits of a change in the management of primary care to secondary care services is that it will enable closer working leading to more specialist engagement for patients in the community setting.

Aims

In 2020, the BRACE rapid evaluation of vertical integration investigated the implementation of acute hospitals managing general practices, as well as addressing questions relevant to scaling-up this model of integration in an English NHS setting. That qualitative phase 1 evaluation focussed on understanding the rationale for, and the implementation and early impact of, vertical integration. It included the development of a theory of change, identifying what outcomes this model of vertical integration is expected to achieve in the short-, medium- and long-terms, and under what circumstances.

Phase 2 of the study of vertical integration, described in the present protocol, will follow up and explore the outstanding issues identified in phase 1, including understanding the extent of vertical integration which has already taken place, the impact on secondary care service utilisation outcomes, how service delivery has changed (or is expected to change) and the patient experience of vertical integration, with a particular focus on whether patients with multiple long-term conditions are affected differently from other patients.

Evaluation questions

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

RQ1 How many GP practices have already vertically integrated with NHS organisations running acute hospitals in England; when did the integration between general practices and acute hospitals take place; and what are the characteristics (in terms of geographical location, patient demographics and practice size/workforce) of those practices where vertical integration has taken place?

RQ2: What impact is vertical integration having on secondary care utilisation (outpatient attendances, A&E attendances, all inpatient admissions, emergency inpatient admissions, inpatient admissions for ambulatory care sensitive conditions, bed days, readmission within 30 days of discharge)? Does this impact differ for people with multiple long-term conditions compared to other patients without long-term conditions, or living with a single condition?

RQ3: What impact is vertical integration having on the patient journey with regard to access to, and overall experience of, care? How does the experience differ for people with multiple long-term conditions compared to those living with no or one long-term condition?

Design and methods

We will take a mixed-methods approach to answering the research questions identified above. The work packages will overlap and thus inform each other to allow for both timely completion of the analysis and triangulation between the quantitative and qualitative data. The study will begin with a desk-based review of NHS trust annual reports, relevant literature and identified data sets, to understand the scale of vertical integration of primary care practices with acute NHS hospitals which has taken place across England. We will then complete a quantitative analysis of national secondary data to explore the impact of vertical integration on secondary care utilisation and the financial implications of that. The quantitative analysis will investigate if there is any differential impact on secondary care utilisation for people with multiple long-term conditions. Finally, we will carry out qualitative data collection and analysis with key stakeholders and patients across three case study sites to explore qualitatively the impact of vertical integration on patient experience of care, particularly focusing on patients with multiple long-term conditions. We propose to undertake four work packages:

WP1: Understanding the current scale of vertical integration in England: establishing the extent of vertical integration through a desk-based analysis of secondary care statutory financial reporting and primary care GP workforce data. Triangulation of practices where vertical integration has been identified though each approach will allow the robustness of the method of identifying practices to be assessed. Statistics that describe the characteristics of the vertically integrated practices will be provided: number of acute hospital trusts managing general practices; the number of general practices managed by the acute hospital trust; practice sizes in terms of patient population, patient demographics and workforce descriptives.

WP2: Development of the Statistical Approach. This will include identifying appropriate counterfactual or control sites as well as an appropriate approach to coding multiple long-term conditions. As part of this work package, we will develop a detailed Statistical Analysis Plan setting out our intended approaches. The Statistical Analysis Plan will be peer reviewed, pre-registered and published. There are several methodological questions that this work package will consider, for example how to deal analytically with GP practices which have merged during the study time frame, and how to consider and incorporate the impact of COVID-19 on our analyses of secondary care utilisation.

WP3: Quantitative analysis of the impact of vertical integration on secondary care utilisation: assessing the impact of vertical integration on our sample of practices for secondary care service utilisation both overall and more specifically for people with multiple long-term conditions. The initial stage of this work package will involve cleaning and preparation of the Hospital Episode Statistics (HES) data set. We will then examine the following outcomes: outpatient attendances, A&E attendances, all inpatient admissions, emergency inpatient admissions, inpatient admissions for ambulatory care sensitive conditions, bed days, readmission within 30 days of discharge; for the identified practices and their controls before and after the identified practices were vertically integrated. We will also report the financial implications in terms of an overall cost per secondary care utilisation for vertically integrated compared with non-vertically integrated practices.

WP4: A more detailed exploration of the impact on the patient journey with regard to access to and overall experience of care across three purposively case study sites: including a group 'familiarisation' interview across three case study sites with key service managers and clinicians from the acute hospital and GP practices; and primary qualitative research via interviews, capturing the views of patients from integrated and non-integrated GP practices, to understand their experiences of accessing services in areas where models of vertical integration are present.

Dissemination and outputs

We anticipate disseminating the findings of this evaluation project in a number of ways and to a wide audience including:

- A set of slides to share findings with a range of key audiences including primary care clinicians, commissioners, policymakers, patients/carers
- Web-based resources such as a webinar, a link to full report, blogs to highlight key findings to non-experts as well as more expert audiences and a video reflecting on the evaluation and its conclusions (made accessible to a range of audiences)

- Disseminating findings through BRACE networks, drawing on the expertise and assistance of our Patient Public Involvement (PPI) collaborators, National Voices, the BRACE Health and Care Panel[1] and BRACE Steering Group members
- 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
- Papers published in high quality, peer-reviewed, academic journals
- Publication of an article in primary care professional press such as Pulse, Health Services Journal, or GP Online, so as to reach practitioner and managerial audiences as well as policy makers
- Oral and/or poster presentations to primary care and policy focused conferences such as Health Services Research (HSR) UK conference
- Working with other research teams based in government related organisations, other NIHR funded research centres, and policy think tanks to connect our findings with their analyses of primary and integrated care developments.

Study timeline

The study will take place over 10 months (March 2022 to January 2023), assuming approval of the Statistical Analysis Plan, access to case study sites and the timely securing of necessary ethical approvals.

Funding

BRACE is funded by the NIHR Health and Social Care Delivery Research (HSDR) programme (HSDR16/138/31).

[1] The BRACE Health and Care Panel are a diverse group of people who support BRACE research. Their roles include commenting on protocols, attending dissemination events and workshops, and informing our prioritisation of research ideas and plans. They have varied backgrounds and include health professionals, members of charitable organisations, NHS managers, social care colleagues, and patients.

Background and rationale

In the past ten years, the NHS policy focus has shifted towards a more integrated approach to patient care across primary, secondary and social care settings. The organisation and long-term sustainability of primary care in the UK has also been the subject of increasing debate and speculation.

NHS England has a long-term commitment to primary care services, both regarding the role of general practice (GP) and its increased funding. However, the long-term sustainability of primary care has become a key issue for policy makers, growing in prominence given the increase in the complexity of care that patients managed in the primary care setting require (including those with multiple long-term conditions) and their associated demand for services. Alongside this, there has been an ever-increasing workload placed on primary care staff with associated work force shortages and Accident and Emergency pressures in secondary care. A recent survey, by Gibson and colleagues [1], 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 [2] and fewer GPs 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 [3, 4].

There are various responses to primary care sustainability and development, and better integration between primary and secondary care. Some of these responses are focussed around strengthening primary care itself. The 2019 NHS Long Term Plan announcing the intention that all GP practices in England should work together as part of 'Primary Care Networks' covering populations of 30,000–50,000. Since July 2019, all but a small number of practices have become horizontally integrated with neighbouring practices, while remaining separate legal entities, with separate contracts. A recent BRACE rapid evaluation of primary care networks found that there have been a number of facilitators and challenges to horizontal integration to achieve sustainable primary care, address growing workload issues, and improve the availability and coordination of local primary care services[5].

Alternative strategies have focussed on closer integration and working with other services and sectors, notably secondary care, as recommended in the NHS Five Year Forward View (FYFV) [6] and tested in the Primary and Acute Care Systems (PACS) and Multispecialty

Community Provider (MCP) vanguards [7-13]. 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. However, data and findings are limited across the vanguard sites (due to delays in synthesising and publishing data), with doubt over the reliability of outcomes data and impact on health service delivery [14].

More recently there has been considerable political and policy interest [15-17] in another approach, whereby acute hospitals manage general practice services [15, 18-21]. There may be expectations that such vertical integration leads to better management of the demand on secondary care services.

Vertical Integration of this sort coordinates the functions, activities and organisations that provide different levels of patient care (primary, community and hospital services) under a single management entity [22-24]. However, integration is better thought of as a continuum rather than a specific model, where the integration can be clinical or functional. It ranges from the formation of relatively loose alliance arrangements (e.g. the PACS model) to a fully integrated model in which a single body holds contracts to deliver acute and primary care services [25]. For Conrad and Dowling [26], successful vertical integration demands a health system that has capacity to plan, deliver, monitor and adjust the care of an individual over time.

This approach has already been trialled in other countries such as the United States [27], Spain [28], Denmark [29][26] and New Zealand [30]. In the UK setting, a study in Wolverhampton [31] examined the impact of vertical integration of an NHS acute hospital and ten general practices on unplanned hospital care. They found that rates of emergency department attendances didn't change after vertical integration, although they did find a slight, but statistically significant reduction in the rates of unplanned hospital admissions. They also highlighted that further work is required to check whether the findings are generalisable as well as to determine the impact on patient satisfaction, health outcomes and GP workload.

There is still very little known about how this model of vertical integration works and there are outstanding, critical questions which needed to be addressed. However, vertical integration models offer promising opportunities for 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). The

model has the potential to be particularly promising for the care and management of people with multiple long-term conditions who would potentially benefit from a more coordinated link between primary and secondary care services providing the specialist care they require.

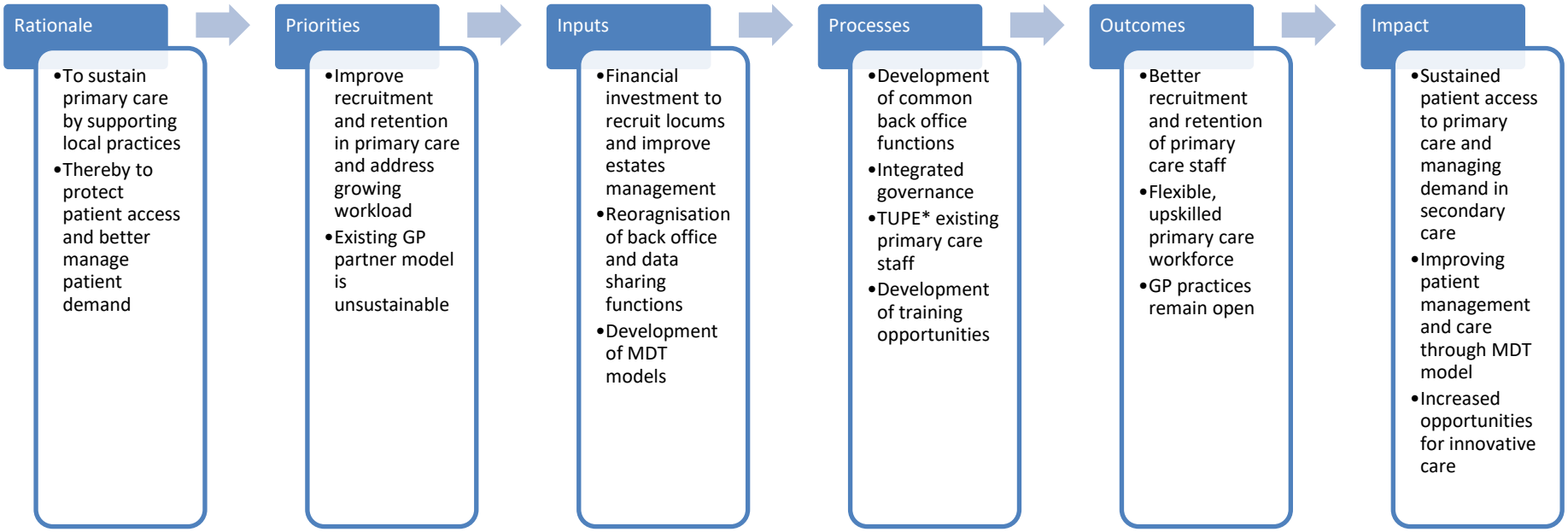
Learning from the BRACE Phase 1 evaluation of acute hospitals managing general practices

In 2019/20, BRACE carried out a phase 1 rapid evaluation of arrangements in three case study areas where the NHS organisations operating acute hospitals had additionally taken over the running of general (medical) practitioner (GP) practices at scale in England and Wales – i.e. a fully integrated model of vertical integration[32]. The aims of the evaluation were to understand the early impact of vertical integration, namely: 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 study team also developed a theory of change for vertical integration, identifying what outcomes it is expected to achieve in the short-, medium- and long-terms, and under what circumstances (see Figure 1).

After interviewing 52 stakeholders, observing meetings and reviewing documents, the authors found the single most important driver of vertical integration to be the maintenance of primary care local to where patients live. Vertical integration of GP practices with organisations running acute hospitals has been adopted in some locations in England and Wales to address the staffing, workload and financial difficulties faced by some GP practices. This phase 1 study answered some of the pertinent questions about the introduction of vertical integration. However, it did not go so far as to investigate the impact of on secondary care utilisation and patient experiences of vertical integration. This is largely because the arrangements we evaluated had only been in place for a relatively short amount of time, perhaps not sufficient time to expect some key outcomes to appear. This follow-up study will evaluate the outcomes and develop some of the key issues identified in the initial study (and validate a theory of change). These interests are reflected in the research questions for the currently proposed project.

Findings from the phase 1 evaluation were published as an NIHR HS&DR Rapid Evaluation Centre Topic Report [33] and were also more recently published in a peer-reviewed journal [32].

Figure 1. Overall vertical integration theory of change developed from the BRACE phase 1 rapid evaluation



* TUPE-Transfer of Undertakings (Protection of Employment) - A 'TUPE transfer' happens when an organisation, or part of it, is transferred from one employer to another; a service is transferred to a new provider, for example when another company takes over the contract

Why is this research important/needed now?

The implementation of vertical integration of GP practices and acute hospitals continues to be of high policy interest and has the potential to bring with it a significant change in the planning and delivery of primary and secondary services. Phase 1 of our rapid evaluation found that vertical integration was enabling primary care to continue to be provided for patients in areas where GP practices have faced particular difficulty. We also found that vertical integration was further developed where there were good pre-existing relationships between primary and secondary care.

Despite the recent political interest about management of primary care as illustrated by the publication of the article in the Times and the response provided in the BMJ and Pulse [15, 16, 32] still very little is known about this model of integration in terms of how effective it is nationally. Our previous report from 2020 [32, 34] outlined several areas warranting further investigation which this phase 2 evaluation will seek to answer. These areas include identifying to what extent there has been service redesign as a result of the vertical integration arrangement, as distinct from being a result of horizontal integration via Primary Care Networks. We will look at service utilisation (Accident and Emergency attendances, emergency admissions and re-admissions, length of stay in bed-days) in secondary care as a way of exploring the impact of the redesign of primary care management. We will also assess whether this impact is different for patients with multiple long-term conditions, who might be expected to be affected more than other patients by better integration between primary and secondary care. The phase 2 evaluation will build on the previous work by exploring the views of patients whose practices have vertically integrated in relation to their experience of accessing primary care services. Within this, we will also assess whether these views are different for those patients with multiple long-term conditions.

Who is the research aimed at?

The evaluation findings will be of interest to an international audience as vertical integration is not limited to the UK NHS. At a national and local level, the findings will be of particular interest to NHS policy and decision makers including trusts, Integrated Care Systems (ICSs), Primary Care Networks (PCNs) and general practices, across England, who are considering whether and how to integrate services across the primary and secondary care interface. They

will also be of interest to patients and the public, both those whose practices have already integrated with hospital trusts and those whose practices may consider doing so in the future.

Anticipated outputs (see section 'expected outputs and plans for dissemination') include reports, articles, slide decks and presentations plus briefings tailored for distribution to NHS, policy maker and wider patient and public audiences.

Project plan

Aims

In 2020, the BRACE rapid evaluation of vertical integration investigated the implementation of acute hospitals managing general practices, as well as addressing questions relevant to scaling-up this model of integration in an English NHS setting. That qualitative phase 1 evaluation focussed on understanding the rationale for, implementation and early impact of vertical integration. It included the development of a theory of change, identifying what outcomes this model of vertical integration is expected to achieve in the short-, medium- and long-terms, and under what circumstances.

Phase 2 of the study of vertical integration, described in the present protocol, will follow up and explore the outstanding issues identified in phase 1, including understanding the extent of vertical integration which has already taken place, the impact on secondary care service utilisation outcomes, how service delivery has changed (or is expected to change) and the patient experience of vertical integration, with a particular focus on whether patients with multiple long-term conditions are affected differently from other patients.

Research questions for the evaluation

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

RQ1: How many GP practices have already vertically integrated with NHS organisations running acute hospitals in England; when did the integration between general practice and the acute hospitals take place; and what are the characteristics of those practices where vertical integration has taken place?

RQ2: What impact is vertical integration having on secondary care utilisation (outpatient attendances, A&E attendances, all inpatient admissions, emergency inpatient admissions, inpatient admissions for ambulatory care sensitive conditions, bed days, readmission within

30 days of discharge)? Does this impact differ for people with multiple long-term conditions compared to other patients without long-term conditions, or living with a single condition?

RQ3: What impact is vertical integration having on the patient journey with regard to access to and overall experience of care? How do models of vertical integration support patient transitions from primary care to acute care? How do patients experience services, more commonly found in secondary care, within a vertically integrated general practice setting? How does the experience differ for people with multiple long-term conditions compared to other patients?

Research Design and Methodology

Design

We will take a mixed-methods approach to answering the research questions identified above. The work packages will overlap and we will set up a process to allow for both timely completion of the analysis and triangulation between the quantitative and qualitative data. The study will begin with a desk-based review of NHS trust annual reports, relevant literature and identified data sets, to understand the scale of vertical integration of primary care practices with acute NHS hospitals which has taken place across England. We will then complete a quantitative analysis of national routine data to explore the impact of vertical integration on secondary care utilisation and the financial implications of that as detailed in work package 3. The quantitative analysis will investigate if there is any differential impact on secondary care utilisation for people with multiple long-term conditions. Finally, we will carry out qualitative data collection and analysis with key stakeholders and patients across three case study sites to explore qualitatively the impact of vertical integration on patient experience of care, particularly focusing on patients with multiple long-term conditions.

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	Outputs	Research questions
WP1: Understanding the current scale of vertical integration	We will establish the extent of vertical integration through a desk-based analysis of: secondary care statutory financial reporting and primary care GP workforce data. Triangulation of practices where vertical integration identified though each approach will allow the robustness of these approaches to be assessed.	A short summary report will be provided along with descriptive statistics relating to practice characteristics, geographical location and practice workforce.	RQ1
WP2: Development of the statistical analysis approach	Identifying the appropriate counterfactual or control sites and the appropriate approach to coding multiple long-term conditions.	Development of a Statistical Analysis Plan for peer review, pre registration and publication.	RQ1, RQ2

Work package (WP)	Description	Outputs	Research questions
WP3: The impact of vertical integration on secondary care utilisation	The first stage in this WP is to clean the HES record level data ready for analysis with the required outcomes and controls. We will then assess the impact of vertical integration in our sample of practices overall and for patients with long-term multiple conditions for secondary care service utilisation for the identified outcomes, for the identified vertically integrated and control practices before and after the vertical integration was introduced. Preliminary work has identified that about 20 acute NHS Trusts have some form of vertical integration of GP practices. This work suggests that the majority have between 1-4 practices, although a couple of Trusts have more (up to 20). We will include ALL GP practices in England which we have identified run as part of a vertical integration model in WP1, accounting for variation between the Acute Trusts with which they are integrated as part of the analysis. In addition about 12 Community or Mental Health Trusts own GP practices, and we will include these as a	A clean and analysis ready data set. Results on secondary service utilisation before and after vertical integration for control and intervention practices. An overview of the financial implications in terms of any cost saving or increase from a Health Service perspective.	RQ2

Work package (WP)	Description	Outputs	Research questions
	supplementary or sensitivity analysis, or as part of a control group. Because we hold data from 2012/3 under our current Data Sharing Agreement we are confident that we will have a large enough sample size for the practices *before* they became integrated with acute hospitals; we will include data from up to 2020/2021 in our analysis; allowing for follow up until the end of March 2021. We will also report the financial implications based on the secondary care resource use data for vertical integrated and non-vertically integrated practices.		

Work package (WP)	Description	Outputs	Research questions
WP4: Impact on the patient journey with regard to access to and overall experience of care	One group interview in each case study site, to which we invite key service managers and clinicians from the acute hospital and GP practices. Primary qualitative research via interviews, capturing the views of patients from integrated and non-integrated GP practices, to understand their experiences of the following where vertical integration models are present: What impact is vertical integration having on the patient journey with regard to access to and overall experience of care? How do models of vertical integration support patient transitions from primary care to acute care? How do patients experience services, more commonly found in secondary care, within a vertically integrated general practice setting? How does the experience differ for people with multiple long-term conditions compared to other patients?	A detailed qualitative analysis and reporting of the results of this work package integrated into the final report. Further validation or revision of the theory of changes as proposed in the Phase 1 evaluation.	RQ3

Methodology

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

WP1: Understanding the current scale of vertical integration in England

Context

WP1 is important in describing the scale and scope of vertical integration and also in identifying potential intervention and control areas for the subsequent analysis. Despite recent interest in this area, work to date has focussed only on individual case study sites [31, 32] and to our knowledge there has been no national review of where and how vertical integration has taken place.

As our phase 1 work demonstrated [32], the nature of GP contracts is not a reliable method of identifying vertical integration practices and there is currently no clear way of doing so. The contractual form of vertical integration varies nationally, with many GP practices continuing with their GMS contract [35-38] even after vertical integration has taken place.

As part of our preliminary scoping work for this rapid evaluation, we have contacted a variety of relevant primary care representatives to enquire about data which can help us understand which practices and trusts are vertically integrated. These included representatives of the British Medical Association (BMA), the Royal College of GPs (RCGP) and NHS England and NHS Improvement. However, none of these organisations held such information systematically. Nonetheless, the reorganisation of the administration of primary care associated with a practice changing to a vertically integrated model represents a substantive change in the financial relationships between primary and secondary care. Therefore, this work package will seek to establish the extent of vertical integration through a desk-based analysis of secondary care statutory financial reporting [39, 40]. We will continue to seek the advice of expert opinion about how to identify vertically integrated practices.

Approach to identifying vertical integration

Our approach to WP1 will triangulate data from both primary and secondary care to allow for possible incompleteness of either approach to identifying vertically integrated practices. We will cross check our findings by revisiting the results established during the first phase of this work and our existing knowledge of where vertical integration is occurring. We will try to identify vertical integration from secondary and primary care perspectives as outlined below. We will perform a cross-check between the search approaches used in both the primary and secondary care perspectives to see if we identify the same practices.

We will first identify and draw up a list of all NHS and foundation trusts in England.[2] Although this evaluation is only focused on vertical integration in acute trusts, we will include all 220 trusts in this review. This is because the information on integration of GP practices in community trusts may also provide useful information for any counterfactual. We will then retrieve the 'annual report and accounts' for each of the identified NHS trusts for the financial year ending March 2021.

A key finding from the phase one evaluation was that vertical integration was a way of sustaining local primary care, and one form of vertical integration was for a trust to employ GP practice staff. We will triangulate the information from secondary care annual reports and accounts and the data on the workforce in each practice to identify practices where GPs are not employed as partners, locums or salaried GPs [41]. This should enable us to build on our earlier work to identify further sites where vertical integration is occurring.

The next stage will be to the use annual reports for each of the identified NHS trusts (described above) to find information on primary care organisational involvement. Each NHS foundation and non-foundation trust must publish annual reports and accounts to allow scrutiny of the year's operations and outcomes [39, 40]. Every trust annual report typically takes a PDF format which is located on the trust website. We will select only the reports from 2020-2021. This will enable us to use the 'find and retrieve' search option for the terms 'general practitioner' and 'GP' within the report. For trusts which have vertically integrated general practices during financial year 2020-2021, this will identify that the hospital has a financial relationship with a provider of primary care. For trusts with no vertically integrated practices, we expect a few uses of the term 'general practitioner' in the report (in scoping work this is typically around pension reporting), but these will clearly not be related to vertical integration. We will flag these trusts as those where vertical integration is not occurring.

In order to avoid the identification only of areas where we already know that vertical integration is occurring, we will employ a blinded approach to searching for the vertically integrated practices. The researcher will be independent of the study to date and will have no prior knowledge of vertically integrated practices. We will also carry out a cross-check with an additional blinded researcher who will carry out a second review of a sample of annual reports and expect 100% concordance in the trusts identified by both researchers. This is a

[2] A- Z List of All NHS Acute (Hospital) Trusts in England (www.nhs.uk)

novel method which has not previously been implemented and so it is important to ensure the analysis is appropriate and accurate. We will additionally cross check the findings of the blinded reviews against study team knowledge of areas where vertical integration is occurring. Again we expect 100% concordance, but are mindful of the importance of being able to demonstrate confidence in the approach.

We are identifying vertical integration in two ways, at the hospital level through trust annual reports and also from a GP perspective through workforce data. From a primary care perspective, we propose to identify practices where GPs are not employed as a salaried partner, trainee or locum, by using the NHS workforce data from the 31st of March, 2021[3]. The data will be accessed via the GP workforce data set which reports all types of GP contracts. Our focus for searching will be on GPs funded by 'other', i.e. not salaried, partners or locum practitioners (preliminary review of these data identified 243 practices, of which several were clearly vertically integrated). We will review GP practice websites for further details about the possible vertical integration through targeted internet searches of practice names, and will cross check these practices against those identified through the review of hospital trust annual reports.

Where there is potential uncertainty about whether a GP practice is managed by a hospital or not, we will use the hospital annual report data as the deciding source of evidence; these reporting processes are statutory and completeness is mandated.

We will then construct a spreadsheet to detail all relevant information of the practices identified, this will include: date of vertical integration (which we will identify from the annual report of the hospital trust), name of practices, practice codes and type of ownership (for example whether the GP practice is wholly owned by the trust or whether the trust has a wholly owned subsidiary company which then owns the practice).

Describing vertically integrated practices

The final stage of WP1 will be to use the public health profiles 'Fingertips'[4] to retrieve data (such as practice population list size, geographical location, deprivation decile and ethnic mix) on the vertically integrated practices. At this scoping stage we think that practices will be relatively straightforward to classify as vertically integrated or not, although we expect there may be some further decisions needed about classification as the work progresses. We will

[3] General Practice Workforce, 30 November 2021 - NHS Digital
[4] Public health profiles - OHID (phe.org.uk)

produce descriptive statistics for each of the sets of practices in summary text and tabular form, including whether the vertical integration is with an acute or community trust, and whether the hospital is an NHS trust or an NHS foundation trust.

WP2: Development of approaches to defining a counterfactual or control group and identifying multiple long-term conditions in administrative healthcare data

Context

This project presents two important methodological challenges: identifying appropriate counterfactual or control sites for vertically integrated practices, and defining an approach to the identification of multiple long-term conditions in Hospital Episode Statistics (HES) data. The clustered nature of the data is a third issue, both practice mergers occurring over time, and also the clustering of vertically integrated practices around a small number of hospitals. While solving these challenges is core to this project, these challenges are not unique to health services research and our work in these areas will make an important contribution to research in this area. In the sections below we describe our proposed approaches to these challenges. As part of developing these approaches we will also consider how to incorporate the impact of COVID-19. We do not expect COVID-19 to have had a differential impact in vertically integrated practices compared with other practices. However, it had a profound impact on secondary care utilisation within the evaluation time frame and so it is an area where we will need to consider specifically how to incorporate this impact into our analysis framework – particularly for practices that became vertically integrated during or after April 2020. Our findings and resulting approach for this project will be summarised in a full statistical analysis plan which will undergo external peer review and will be published on the project NIHR website.

Identifying counterfactual or control sites for vertically integrated practices

Identification of the appropriate counterfactual or control sites will commence once work package 1 is complete as this will have enabled the study team to understand the nature and extent of vertical integration that has taken place across England. In preliminary work during the development of this protocol, we have identified the following potential counterfactual/control groups and we expect the final decision about this to follow one of these methods. We will consider using two different approaches (with one as a sensitivity analysis, as carried out in a recent paper by Sutton et al [42]) to ensure the robustness of the analysis approach selected. The decision about which approach/es to use will be made

following further consultation with relevant experts, the development process of the statistical analysis and consultation with the research team:

- GP practices which have not vertically integrated, but which are in the same geographical area as those practices which have vertically integrated.
- A national comparator practice which has not vertically integrated, but which has been matched through propensity score matching for a suitable comparison. We expect this to be a two stage matching process whereby we match first on area possibly using the 'Rightcare' tool [43], and then find controls at the practice level.
- Synthetic and Generalised synthetic controls following the approach for an analysis of a vertical integration in Wolverhampton undertaken by a team of researchers at the Strategy Unit (NHS Midlands and Lancashire Commissioning support Unit) [31].

Identifying multiple long-term conditions in HES data

Using HES data to identify patients with multiple long-term conditions is anticipated to be a complex process, which will require detailed data management and coding. We will consider the approach set out by Tonelli et al [34], which identified validated algorithms for ICD-10 coding of 30 morbidities in administrative data [35]. Simultaneously, we will be coding ambulatory care sensitive conditions (ACSC) according to the approach outlined by the Nuffield Trust [44]. We will explore how this intersects with our coding of multiple long-term conditions, and will also consider the public multimorbidity code developed by the Health Foundation and available via GitHub[5]. We will review the strengths and weaknesses of each approach and clarify the final analysis approach in the Statistical Analysis Plan. We have sought, and will continue to seek, expert opinion and advice on our methods from professionals with experience in this area; these include statisticians from the Health Foundation, the Strategy Unit at the NHS Midlands and Lancashire Commissioning Support Unit and colleagues in RAND.

Testing coding approaches for multiple long-term conditions will be an iterative process, where final decisions about the data format will be informed by cleaning and preparing the Hospital Episode Statistics data (see Appendix 1). We will clean the HES data informed by the approach outlined by the University of York in 'Analysing Patient level Data using Hospital

[5] GitHub: Where the world builds software · GitHub is a repository hosting service online.

Episode Statistics' [33] and will also consider the use of the Health Foundation HES Pipeline code [45].

We will additionally consider how to incorporate the impact of COVID-19 into the final analysis framework. We know that secondary care utilisation during 2020-2021 was profoundly different from the preceding years. We will initially split the analyses into pre-COVID-19 and post-COVID-19 timeframes to look descriptively at what impact this may have on the evaluation. It is possible that we will continue with this stratified analysis, however the approach will be clarified as part of this work package.

This work package will include a presentation of our proposed methods at the NIHR statistics workshop in June 2022 and publication of our final statistical analysis plan.

WP3: Analysis of the impact of vertical integration on secondary care utilisation including consideration for people with multiple long-term conditions

We will assess the impact of vertical integration on our sample of vertically integrated practices for secondary care service utilisation (of HES data) by reporting the unadjusted figure for: outpatient attendances, A&E attendances, all inpatient admissions, emergency inpatient admissions, inpatient admissions for ambulatory care sensitive conditions, bed days, readmission within 30 days of discharge, for the identified practices and controls before and after the vertical integration took place.

The approach for the counterfactual/control groups is expected to be the most important determinant in the selection of the final analysis framework. For example, if we use control practices we will use a difference in difference (DID) framework [46]. For analysis using synthetic controls, formal statistical inference is more complicated [31, 47]. For each approach, graphs will be constructed to allow for visualisation of all outcomes to describe the different time points before and after each practice becomes vertically integrated. In the next phase of the analysis we will consider the impact of vertical integration overall and then more specifically for people with multiple long-term conditions.

Finally, we will report the impact of vertical integration on use of secondary care in financial terms. This will be based on the secondary care resource use data to which we will apply the average NHS costs for admitted patient care, outpatient appointments and A&E attendances. The National schedule of NHS costs for the most recent publicly available year will be applied to each outcome measure in order to provide an aggregate overall cost per secondary care

utilisation to compare vertically integrated practices with our control, non-vertically integrated practices.

We will use both Stata version 15 and R for the data cleaning and statistical analyses.

WP4: Qualitative Comparative case studies of three vertical integration sites

A comparative case study approach will provide the opportunity to analyse and interpret the views of patients and thus understand their experiences of accessing services across primary and secondary care in areas where vertical integration set-ups are present [48]. We will conduct comparative case studies of three vertical integration sites across England. We are restricting the qualitative analysis to England so that we focus on locations for which we also have the data readily available for the quantitative analysis part of this rapid evaluation. BRACE already has access to the requisite NHS activity data for England. It would not be possible within the timescale of the rapid evaluation to obtain corresponding data for Wales, Scotland or Northern Ireland. We propose to return to the two Phase 1 case study sites in England, and one additional vertical integration site in England, to undertake further qualitative data collection and analysis. (The third case study from our Phase 1 study was in Wales and hence, due to our Phase 2 being focused on models of vertical in England only, for the reason just explained, this site will be omitted.

As part of earlier work packages, the study team will have identified a number of sites where this model of vertical integration is already being delivered at scale. We will take a purposive approach to selecting our third site, with the aim of ensuring variation in our sample in terms of: 1) geographical location and population served; 2) their legal and governance working frameworks; and 3) the time since vertical integration was introduced.

Table 2 provides a summary of the two case study sites that took part in our Phase 1 evaluation. For more information about these sites please refer to our NIHR report[6].

[6] https://njl-admin.nihr.ac.uk/document/download/2033189

Table 2. Vertical integration case study sites from Phase 1

Case study site	Location	Date of commencement	No. of GP practices
Urbanville	England	July 2018	9
Greenvale	England	April 2016	12

Data collection at three case study sites

Data collection will consist of two stages: 1) familiarisation interviews with each case study site; and 2) interviews with patients, particularly those living with multiple long-term conditions, from integrated and non-integrated GP practices, to understand their experiences of accessing services and coordination of care.

We plan to complete a single group 'familiarisation' interview, at each case study site, inviting key strategic and service level managers and clinicians from both primary and secondary care. The aim of completing such an interview with these stakeholders is to understand: the model in operation and how it has evolved since it was first established and subsequently implemented, and what (if any) elements of the current model are expected or indeed have been designed to improve the care and support of people with multiple long-term conditions (which may also be relevant to testing the theory of change model developed from Phase 1). Such interviews will also help the study team identify practices to approach and ascertain if we may expect to see any impacts (positive or negative) for people with multiple long-term conditions.

Potential participants for the familiarisation interview will be purposively sampled [49] and approached through each case study site's contact person. This will be a senior manager involved in the integration of primary and secondary care service delivery, whose 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 management, governance and analysis of this model of vertical integration across primary and secondary care at the levels of strategic decision making and those delivering patient care. Informants may include: NHS managerial level staff (related to integration and strategy,

delivery of health care services); secondary care clinicians; and senior GPs who have been involved with the implementation of a vertical integration model in their area. We will invite individuals to participate in an online (Zoom/MS Teams) structured group interview with one member of the evaluation team leading the interview and a second team member supporting and note taking. Group interviews will consist of no more than four participants; if more potential interviewees are identified then a second group interview at each case study site will be considered.

We plan to complete between 6-8 interviews with patients living with multiple long-term conditions at each case study sites (N=24). Our analysis will also form part of the BRACE overarching analysis of service innovations and how they are experienced by and impact on people living with multiple long-term conditions. We use the definition from the National Institute for Health and Care Excellence (NICE) which defines multimorbidity as "the presence of two or more long-term health conditions, which NICE states can include:

- Defined physical and mental health conditions such as diabetes or schizophrenia
- Ongoing conditions such as learning disability
- Symptom complexes such as frailty or chronic pain
- Sensory impairment such as sight or hearing loss
- Alcohol and substance misuse (NICE, 2016)".

To identify patients with multiple long-term conditions, we will ask each case study site contact person to facilitate communication between study team members and Primary Care Networks (PCNs) which their respective integrated practices are part of. The rationale for working with PCNs is to work with a group of practices that may include those that are integrated and not integrated as part of local vertical integrated arrangements, and hence may expedite access for researchers into case study sites. Where PCNs are entirely (or in the majority) created from integrated practices, then the study team with ask the case study site contact person to facilitate communication with local neighbouring PCNs to identify suitable patients for interview. Study team members will work with senior GP leads and practice managers to identify suitable patients for interview, using the following inclusion criteria:

- Aged 18 years and over;
- Living with at least two long-term health conditions (in accordance with NICE guidance); and
- Have accessed primary and/or secondary care services within the past 12 months.

PCN clinical directors and managers will be asked to identify and contact (using letter/email/phone call) up to 20 eligible patients to contact from each case study site. Up to 8 interviews will be completed per site comprised of patients from integrated and non-integrated general practices, high and low users of primary and secondary care, and vary by gender, ethnicity and age (if possible). Hence, in total, 24 interviews with patients will be completed. PCN clinical directors and managers will be responsible for excluding any patients who should not take part in the study based on medical and/or well-being concerns. The following exclusion criteria will be applied:

- Patients under 18 years;
- Patients on palliative care pathways; and
- Patients who lack mental capacity or who are unable to take part in an interview due to their ill-health.

Once identified, patients will be invited to participate in a semi-structured interview with one member of the study team completed online (Zoom, MS Teams, Skype) or by telephone. It is anticipated that interviews will be 30 – 60 minutes in length

Each patient will be emailed/posted 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 what taking part would involve. Participants will be required to sign a consent form (written or electronic via email) or provide verbal consent 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 without having to offer a reason for doing so, and will also be given

information about how to find out more about the study, or to raise concerns about its conduct.

A topic guide will be developed and used as an aide memoire during interviews, it will be reviewed by members of the BRACE Health and Care Panel[7] and PPI reviewers for this project. The main themes the topic guide for the familiarisation interviews are likely to include: understanding the rationale behind the implementation of vertical integration (or if the drivers have changed since we last collected data in the two areas involved in the phase 1 study); understanding the experiences of primary and secondary staff involved with the delivery of this model; and what outcomes this model is expected to deliver in the short, medium and long-term and what data is currently collected to address this. The main themes the topic guide for the patient interviews will likely cover are: discussions about recent experiences of accessing care as part of their local health care system including both primary and second care, co-ordination of care, communication and care planning between clinicians and the patient, speed of access and range of clinicians/allied health professionals patients had access to along with barriers and facilitators (accounting for the COVID-19 pandemic), perceived quality of care, decision making, and perceptions regarding patient confidence about achieving their goals and outcomes when managing their long-term health conditions.

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.

Data analysis and write up

We will adopt a pragmatic approach to qualitative thematic analysis [50] which will enable comprehensive analysis of the data but with a more rapid timescale than traditional qualitative analysis. Members of the study team will participate in two half-day interpretation and analysis workshops during analysis and write up of qualitative findings, which will also draw in contributions from policy, theoretical and methodological experts from across BRACE networks and the health and care sector (e.g. we may invite experts from the Department of

[7] Diverse representation from system and organisational leaders; middle and operational clinical and general managers; frontline clinicians and other 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.

Health and Social Care, NHS England & Improvement, policy analysts active in the field of care integration, as well as service users from the BRACE PPI panel and National Voices – which is a partner in the BRACE Centre). Contributions from key experts will help shape interpretation, relate on-going learning to what might be happening in real-time with regard to policy, and how best to disseminate findings to a range of interested audiences.

Conducting interviews with patients during the COVID-19 pandemic

Despite the easing of COVID-19 restrictions the study team remain careful to reduce the risk of transmission, therefore interviews will be conducted by telephone or via video; however, face-to-face interviews will be arranged for those who prefer this method and/or lack access to a telephone/video platforms. Although telephone and online video interviews cannot completely replace face-to-face interaction due to challenges in rapport and trust-building, understanding non-verbal cues, and variation in presentation of one's self, they work as a viable alternative [51]. Before and during the COVID-19 pandemic, the research team has developed extensive experience in conducting online qualitative data collection, including interviews and focus groups with healthcare professionals and patients. Some of the challenges and our proposed mitigation strategies are:

- Challenges building rapport and trust with the interviewee[52]: The researchers will ensure to spend a few minutes at the start of each interview asking the interviewee more informal questions to ensure that they feel comfortable. In addition, a lay information sheet outlining the project and the topics of discussion will be sent to the interviewee ahead of time[53].
- Understanding non-verbal cues[51]: Where possible, the interviews will be conducted via video to support the reading of non-verbal cues. If interviews need to be conducted by phone, at the interviewee's request, the researchers will ensure extra effort is placed on active listening and speaking to the interviewee instead of using body language.
- Technology challenges (e.g. poor internet connection, poor image quality): The interviewers will test their internet connection and video quality ahead of conducting interviews. If the interviewee is facing technical difficulties, the interview could be switched to telephone (a back-up phone number will be provided to all interviewees).

If interviewees are not experienced in the video platform, the researchers will offer a 10-minute walk-through ahead of the interview.

- Security and confidentiality: Only BRACE-approved video platforms will be used to conduct interviews to ensure IT security. Participant confidentiality will be ensured by the researcher conducting the interview in a private location and taking time at the start of an interview to ensure interviewees are comfortable and are in a suitable location[54].

Synthesis and cross-analysis of findings

The study team will thematically synthesise findings across quantitative and qualitative work packages guided by a framework proposed by Colombani et al. (2022) [55]. We will also adopt a "following a thread" approach put forward by O'Cathain [56] and colleagues (2008) whereby synthesis of data takes place at the data analysis stage to identify key themes and data that warrants further analysis. Hence, following the identification of key themes within each data set, researchers will use over-arching domains suggested by Colombani et al. (2022) [55] to create a 'thread' to organise our findings.

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 January 2023 and published in the NIHR Journals Library (HS&DR Programme), as well as other high-quality, peer-reviewed academic journals. Alongside this, other main routes for dissemination will be:

- A short summary slide deck highlighting key learning 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 a 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.
- Papers published in high quality, peer-reviewed, academic journals
- Publication of an article in primary care professional press such as Pulse, Health Services Journal, or GP Online.

- A series of workshops highlighting the key findings and methodology, intended for NHS primary and secondary care organisations such as the Royal College of General Practitioners, NHS England and Improvement, the NHS Confederation, the British Medical Association and Clinical Commissioning Groups.
- Working with other research teams to connect our findings with their analyses of primary and integrated care developments (NHS England and Improvement, Department of Health and Social Care, Nuffield Trust, and King's Fund). Dissemination with these other research teams will likely include joint workshops and events, drawing together a wider body of learning about primary and secondary care reorganisation in the context of the NHS Long Term Plan and the new GP contract in England.
- 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 approaching lay networks of Non-Executive Directors and Primary Care Commissioning sub-committees, 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 10 months (March 2022 to January 2023), assuming approval of the Statistical Analysis Plan by the NIHR, timely data cleaning and coding and access to case study sites, obtaining necessary ethical and governance approvals, as well as identifying and completing data collection with key stakeholders. Table 3 shows the overall study timeline and the key milestones for the project.

Table 3. Study timeline and key milestones

Activity	2022 March	April	May	June	July	August	September	October	November	December	2023 January
Understanding the scale of vertical integration											
Development of SAP											
Data cleaning and preparation											
Quantitative analysis of the impact of vertical integration on secondary care utilisation											
Qualitative 'familiarisation' interviews											
Qualitative interviews of patients and GP practices – patient experience											
Reporting											
Dissemination											

Project management and quality assurance

This proposal has been reviewed by: the acting BRACE Director (Jo Ellins), an independent reviewer with quantitative skills (Kate Morley), a reviewer drawn from the BRACE Health and Care Panel (Richard Allen) and one of BRACE's academic critical friends (Russell Mannion). 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 (University of Birmingham), will be responsible for the day-to-day management of inputs by University of Birmingham and RAND Europe team members towards this project. RAND Europe will be responsible for supporting coordination of the evaluation and ensuring consistency between the individual researchers undertaking the quantitative work packages. Manbinder Sidhu will complete qualitative fieldwork across all three case study sites with support from team members when necessary. Catherine Saunders (University of Cambridge) will lead all quantitative work packages as well as providing data to day input on these work packages. Charlotte Davies (RAND Europe) will also carry out the day-to-day input for the quantitative work packages under the guidance of Catherine Saunders. Charlotte will also be responsible for the data management of the HES data at RAND Europe.

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 (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.

Regular meetings will be held to update on progress to date and address any arising issues promptly. The project team will report to the BRACE Executive team, BRACE Steering Group, and to NIHR HSDR as and when required. We describe potential risks and mitigation strategies in Table 4.

All reports and other deliverables will be peer reviewed by the BRACE Director (Jo Ellins/Judith Smith) and input 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 4. Potential risks and mitigation strategies

Risk	Impact	Likelihood	Mitigation
Increased demand on NHS workforce as a result of the COVID-19 pandemic	High	High	The project team will be prepared for the potential likelihood that NHS staff could suspend participation in this evaluation if the transmission of the virus increases either locally and/or nationally. The principal investigator for the project will communicate with senior members of the BRACE Executive team and seek guidance from NIHR HS&DR if such a situation occurs and will act accordingly.
Loss of key staff	High	Low	Although the project team is small, in the event of one member leaving there is some but limited capacity and resources for this person to be replaced. Both principal investigators and project team members 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. Given the previous good relationships established with case study sites in Phase 1, we envisage quicker than usual to access there to participants for interview. But this will not apply to the additional case study site, that was not involved in the phase one study. The project team will arrange site initiation meetings at each site, as well as on-going meetings with site delegation teams, to discuss the commitment and 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. Work with HES data will following guidelines and principles set out NHS Digital as per the agreement with BRACE, and specifically working arrangements at RAND.
Delays due to inability to recruit	High	Medium	There is a small, but not insignificant, risk that we may be delayed in recruiting participants, in a timely manner, including if local research governance approvals prove to be slow.

Risk	Impact	Likelihood	Mitigation
participants for interview			We will ensure that we have on-going open lines of communication with those involved in making governance decisions and key stakeholders for data collection.

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. Topic guides for interviews will be reviewed by members of the BRACE PPI group. We will have regular meetings during the evaluation to seek advice on our proposed methods and share learning and emerging findings with the BRACE PPI group, which includes eight patient and public members. Outputs from the project will be reviewed by at least one patient panel member. 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.

Funding

BRACE, including this evaluation, is funded by the NIHR Health and Social Care Delivery Research (HSDR) programme (HSDR16/138/31).

Research Team

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

Table 5. Study team members

Team member	Role and contribution in research team	Relevant expertise
Jon Sussex, Senior Research Leader, RAND Europe	Principal investigator from RAND Europe, project conception and scoping, data collection, analysis, facilitator of project workshops, writing of reports/dissemination	Senior health economist with over 30 years' experience of NHS research and consultancy using both qualitative and quantitative methodologies. Jon was principal investigator for the phase 1 BRACE evaluation of vertical integration.

Team member	Role and contribution in research team	Relevant expertise
Catherine Saunders, Senior Research Associate, University of Cambridge	Project conception, quantitative data cleaning, collection and analysis. Writing of reports/dissemination	Applied statistician working at the University of Cambridge and as part of the BRACE rapid evaluation centre.
Charlotte Davies, Senior Analyst, RAND Europe	Project conception, quantitative data cleaning, collection and analysis. Writing of reports/dissemination	Health economist with 10 years' experience of applied NHS research. She has experience in handling large and complicated datasets, analysing secondary data and applying econometric techniques.
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 was the lead researcher for the BRACE phase one evaluation of vertical integration.

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 and we will seek clarification from the University of Birmingham Head of Research Governance to ascertain whether our study should be categorised as 'research' or evaluation with regard to seeking necessary ethical approvals. We will seek approval by the Health Research Authority (HRA) or an NHS Research Ethics Committee as necessary and in the first instance 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 an invitation and information sheet via email (or by post if email is inconvenient) and will need to provide informed written consent.

Confidentiality

If required by local R&D governance processes, team members visiting NHS sites, if that is ever necessary, will secure NIHR research passports. Interview data collected will be anonymised and immediately stored 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. See Appendix 1 for further details regarding the Hospital Episode Statistics data set.

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 academic 'critical friends' – Professors Mary Dixon-Woods and Russell Mannion. The study protocol has been independently reviewed by a patient experience representative on the

BRACE Health and Care Panel and by one of our academic critical friends. The protocol has also been internally reviewed by the acting director of BRACE and a senior statistician at RAND Europe.

Appendix 1: Data-set

Hospital Episode Statistics (HES) - The data relate to individual patient use of NHS services. This includes health related data, but with very limited personal identifiers. Raw data sheets provided by NHS Digital to RAND Europe Community Interest Company are stored in the secure data server and uploaded into a SQL database. The relevant data will be extracted from the data sets by calling the SQL database using Stata 15.0, which is installed in the secure area.

Data covering the period 2013-2021 will be used: the fields are limited to those that we might reasonably expect to be required within the evaluation.

All data processing will also be carried out on site at RAND Europe. Data will only be shared off-site with University of Birmingham or University of Cambridge colleagues or any other third-parties in aggregated form with small numbers suppressed in line with the HES Analysis Guide. University of Cambridge and University of Birmingham colleagues may access the data on site at RAND Europe offices in Cambridge.

The record level data will be processed into a cleaned analysis data set with the required outcomes as follows:

- Outpatient appointments
- A&E attendances
- Inpatient admitted care
- Ambulatory sensitive care admissions
- Readmissions
- Bed days
- Multiple long-term conditions.

There will be no requirement nor attempt to identify individuals from the data. There may be a requirement to link publicly available data, using the GP-practice identifier (within HES and considered non-sensitive and publicly available), to identify vertically integrated practices and control groups. No linkage will be done at the record-level; linkage will only be carried out using aggregate data with small numbers suppressed in line with the HES analysis.

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