# Study protocol

**Full title:** The MEASURE study: Mixed Methods EvaluAtion of the high-volume low-complexity Surgical hUb pRogrammeE
**Short title: MEASURE**

**Sponsor:** University of York

**Funder:** NIHR Health Services and Delivery Research Programme

**Funders Reference:** NIHR153387

**IRAS Reference:**32816

**Protocol Version Number:** 1.2 dated: 18/07/2023



FUNDED BY
NIHR | National Institute for Health and Care Research

## 1.1. Signature page

The undersigned confirm that the following protocol has been agreed and accepted and that the Co-Chief Investigators agree to conduct the study in compliance with the approved protocol.

| | | |
|---|---|---|
| **For and on behalf of the Study Sponsor:** | | |
| Signature:  | | Date: 12 June 2023 |
| Name: Michael Barber | | |
| Position: Sponsor Representative | | |
| Co-Chief investigators: | | |
| Signature: | | Date: |
| Name: | | |
| Signature: | | Date: |
| Name: | | |



FUNDED BY NIHR | National Institute for Health and Care Research

## 1.2. Key study contacts

| | |
|---|---|
| Co-Chief Investigators | Professor Joy Adamson, York Trials Unit, University of York<br>Email. Joy.adamson@york.ac.uk Phone: 01904325881<br><br>Dr Peter Sivey, Centre for Health Economics, University of York<br>Email. Peter.Sivey@york.ac.uk Phone: 01904321465 |
| Project Manager | Dr Arabella Scantlebury, York Trials Unit.<br>Email: Arabella.scantlebury@york.ac.uk Phone: 01904 321105 |
| Sponsor Representative | Michael Barber,<br>University of York<br>Email: michael.barber@york.ac.uk |
| Funder(s) | National Institute for Health Research (NIHR) Health Health and Social Care Delivery Research<br>Email: monitoring@nihr.ac.uk |
| Study Steering Committee | *Study Steering Group Chair:*<br>Professor Matt Sutton (Chair in Health Economics)<br>*Members:*<br>Professor Peter Hutchinson (Director of Research, Royal College of Surgeons)<br>Professor Mike Grocott (Professor of Anaesthesia, University of Southampton)<br>Dr Andrew Moore (Senior Lecturer in Musculoskeletal Health Services Research, University of Bristol)<br>Emily Lam (Lay representative) |
| Co-applicants | Professor Karen Bloor, University of York (Professor of Health Economics and Health Policy, Work Package 5 lead)<br><br>Professor Nils Gutacker, University of York (Professor of Health Economics)<br><br>Professor Amar Rangan, University of York (Professor of orthopedic surgery)<br><br>Dr Simon Davies, University of York (Consultant Anesthetist)<br><br>Dr Adriana Castelli, University of York (Senior Research Fellow, Work Package 4 lead)<br><br>Professor Andrew Street, London School of Economics and Political Science (Professor of Health Economics) |



FUNDED BY NIHR | National Institute for Health and Care Research

| | |
|---|---|
| | Professor Caroline Moore, University College London (Professor of Urology)<br><br>Mr Ahmed Saad, South Tees Hospitals NHS Foundation Trust (Consultant Opthamologist)<br><br>Mrs Karen Glerum-Brooks, University of York (PPI and Engagement manager) |



FUNDED BY
NIHR | National Institute for Health and Care Research

## 1.3. Amendment History/Changes from previous version

| Amendment Number | Revised Protocol Version Number and date | Details of key changes made (including justification if required) |
|---|---|---|
| 1 | 1.1 27.06.2023 | Changes requested by funder:<br>Amend capitalisation in title; add date next to version number in the header, amend sentence on title page to state this is a draft, add a sentence to section 7.1 to note that amendments to the protocol need review and approval by the funder prior to REC submission. |
| 2 | 1.2 18.07.2023 | Changes requested by funder:<br>Change funder email address to monitoring@nihr.ac.uk |



FUNDED BY
NIHR | National Institute for Health and Care Research

# Contents





FUNDED BY NIHR | National Institute for Health and Care Research

FUNDED BY
NIHR | National Institute for Health and Care Research

## 1.4. Study summary

| | |
|---|---|
| TITLE | The MEASURE study: Mixed Methods Evaluation of the high-volume low-complexity surgical hUb pRogrammeE |
| ACRONYM | MEASURE |
| Methodology | Mixed methods study comprising six integrated work packages |
| Study Duration | 48 months |
| Study Centres | NHS High Volume Low Complexity Surgical Hubs in England. |
| Objective | What is the impact of the HVLC hubs on productivity, patient care and the workforce and what is the differential impact of different service models of HVLC hubs? |
| Aims and objectives | 1. To characterise the implementation timing, scale, scope and staffing of HVLC hubs currently working/being set up in England (WP 1).<br>2. To determine the impact of HVLC hubs on equity of access, uptake, and indicators including volume of activity, patients' length of stay, waiting times, productivity across different patient populations (WP2, WP3, WP4, WP6).<br>3. To explore the impact of HVLC models on professionals working in the hubs (including training, workload, skill-mix, turnover, absence, satisfaction, well-being and attitudes to and scope of practice) (WP3, WP5).<br>4. To explore the impact of HVLC hubs on the wider local NHS including spillovers in other areas of the NHS (e.g. emergency care); workforce issues across the wider trust(s) including workload, satisfaction, attitudes to and scope of practice (WP2, WP3, WP4, WP5).<br>5. To assess the impact of HVLC hubs on patients and carers (including views on travel/transport, nature/suitability, accessibility of premises, and satisfaction, patient reported outcome measures (PROMS) where available). The impact of hubs on the patient pathway, continuity of pre- and post-surgical care, and outpatient appointments will also be considered<br>(WP2, WP3).<br>6. To explore the implementation of HVLC hubs – how have changes been enacted and experienced and what are the barriers and facilitators to implementation (WP1, WP3).<br>7. To compare resource utilisation and costs of care across different service models and typologies of HVLC hubs (WP1, WP2). |
| Methods | Work package 1: Describe and classify current and planned models of HVLC hubs in England<br>Work package 2: Quantitative empirical evaluation of the effects of HVLC surgical hubs<br>Work package 3: In-depth qualitative case studies of purposively selected HVLC hubs<br>Work package 4: Productivity of HVLC hubs |



FUNDED BY
NIHR | National Institute for Health and Care Research

| | |
|---|---|
| | Work package 5: Mixed methods workforce appraisal<br>Work package 6: Overall cost impact in relation to outcomes and effectiveness |
| Study steering committee | Provide oversight of all aspects of the study on behalf of the sponsor and the funder. |
| Virtual Study Advisory Group | Provide advice on individual work packages and assist with dissemination. |
| Patient and Public Involvement: | Main study PPI group: 4-6 individuals who are on HVLC surgical waiting lists or have had one of the target surgeries.<br>Additional PPI recruitment from hospitals selected from case sites (WP3) to inform local site based communication and advice on patient recruitment. |

## 2. Background and rationale

The COVID-19 pandemic resulted in cancellation of a substantial amount of elective surgery, leading to lengthening waiting times, and exacerbating a backlog of patients awaiting treatment.[1] Existing models of elective care often involve patients being treated in acute hospitals, where surgeons, anaesthetists, nursing and diagnostic staff, have competing demands from more complex, urgent and emergency care. This can lead to inefficiencies in care provision, patient dissatisfaction, and adverse health consequences from long waits. To tackle the backlog, NHS England's elective recovery plan[2] aims to increase elective care throughput of the NHS to 130% of pre-pandemic "business as usual" volume by 2024/25. The high-volume low-complexity (HVLC) surgical hubs model has been proposed to achieve this aim, improving efficiency and productivity by ring-fencing staff and facilities in particular locations to drive efficiencies in the elective care pathway and treat low complexity elective patients more quickly. Existing HVLC approaches have been pioneered within the Getting it Right First Time (GIRFT) programme[3], and GIRFT are supporting the rollout of this concept of regional HVLC hubs throughout the NHS.

In August 2022, the government provided more details on the HVLC surgical hubs policy, announcing the development of 50 new surgical hubs[4], providing locations for 20 of the new hubs, and also clarifying the 91 surgical hubs "currently operational" in the NHS. Throughout 2022, GIRFT have also released more documentation on guidance for the design and layout of hubs[5] as well as the management of workforce for successful surgical hubs.[6] More recently, the Royal College of Surgeons, with support from the Royal College of Anaesthetists have developed a non-mandatory accreditation scheme, which aims to ensure national standards for the HVLC hubs. Currently, eight HVLC surgical hubs have been awarded accreditation as part of a pilot scheme.[7]

Previous literature in health economics and health services research has sought to document the drivers of hospital-level efficiency and outcomes. Research has often focused on the effects of high-



FUNDED BY NIHR | National Institute for Health and Care Research

volumes of particular procedures being associated with better outcomes,[8] lower costs,[9] and the potential for these economies of scale to be realised in specialty hospitals. [10]

The aims and objectives of the HVLC hubs have been clearly set out.[3] It is important to understand if HVLC surgical hubs can achieve their objectives, therefore rigorous independent evaluation is required to complement the extensive internal monitoring and evaluation.

There are very few examples of national surgical policy initiatives in England and as a result there are a distinct lack of surgical policy evaluations on which to build evidence-based practice. To date, there have been no independent evaluations of the HVLC surgical hubs policy published in peer-reviewed journals. However, a recent publication by Barratt and colleagues (2022) presents findings from an independent evaluation of the GIRFT programme in elective orthopaedic surgery,[11] funded by NIHR ARC North Thames. This mixed method evaluation (using National Joint Registry Data, Hospital Episode Statistics and qualitative case studies) found that whilst substantial improvements in several outcomes were noted, these started before GIRFT and were likely to be attributable to both GIRFT and other concurrent initiatives. Additionally, Briggs et al., (2022) describe four current HVLC surgical hubs in a case report, to illustrate how for staff, HVLC surgical hubs may improve training, retention and overall staff experience.[12] These evaluations provide a good starting point to the evidence base relevant to HVLC surgical hubs, however, it is important to build and expand on this evidence alongside the proposed expansion of the hubs programme over the coming years. Whilst we propose similar methods to Barratt et al, in our evaluation we will be able to consider longer follow-up periods, a greater number of sites, a broader range of surgical specialities and a greater number of quantitative outcome measures (in particular, on productivity). The case-study findings from Barrat et al.,[11] will usefully inform our qualitative work which we can apply to a greater number of sites selected on the basis of our quantitative analysis and informed by key stakeholder priorities.

The duration of our proposed evaluation allows for an iterative approach over three time points, therefore, we will be more able to take a longitudinal approach than has been previously possible and will allow for interim findings to be incorporated into the development of the hubs implementation programme across the duration of the study.

## 3. Aims and objectives

The objectives of the proposed research are:

1. To characterise the implementation timing, scale, scope and staffing of HVLC hubs currently working/being set up in England (WP 1).



FUNDED BY NIHR | National Institute for Health and Care Research

2. To determine the impact of HVLC hubs on equity of access, uptake, and indicators including volume of activity, patients' length of stay, waiting times, productivity across different patient populations (WP2, WP3, WP4, WP6).

3. To explore the impact of HVLC models on professionals working in the hubs (including training, workload, skill-mix, turnover, absence, satisfaction, well-being and attitudes to and scope of practice) (WP3, WP5).

4. To explore the impact of HVLC hubs on the wider local NHS including spillovers in other

areas of the NHS (e.g. emergency care); workforce issues across the wider trust(s) including workload, satisfaction, attitudes to and scope of practice (WP2, WP3, WP4, WP5).

5. To assess the impact of HVLC hubs on patients and carers (including views on travel/transport, nature/suitability, accessibility of premises, and satisfaction, patient reported outcome measures (PROMS) where available). The impact of hubs on the patient pathway, continuity of pre- and post-surgical care, and outpatient appointments will also be considered (WP2, WP3).

6. To explore the implementation of HVLC hubs – how have changes been enacted and experienced and what are the barriers and facilitators to implementation (WP1, WP3).

7. To compare resource utilisation and costs of care across different service models and typologies of HVLC hubs (WP1, WP2).

# 4. Methods

## 4.1. Design

A mixed methods evaluation consisting of six integrated work packages including a quasi-experimental evaluation using routine data sources and qualitative case studies (figure 1). This approach is similar to other recent large-scale evaluations of national health policies e.g. incorporating General Practitioners into Emergency Departments,[13] reconfiguration of acute stroke services[14] and GIRFT for orthopaedic surgery.[11]

## 4.2. Secondary Data Sources for Quantitative Analysis

Our analyses will combine routinely collected NHS England Hospital Episode Statistics (HES) data with additional data sources including information from the National Joint Registry (NJR), Civil Registration Secondary Cut data (out of hospitals deaths), Patient Reported Outcome Measures (PROMs), National Cost Collection, NHS workforce statistics, including the Electronic Staff Record (ESR), data from Trust annual financial accounts (TACs), and ONS National Life Tables.



FUNDED BY
NIHR | National Institute for Health and Care Research

Our access to HES data will be through a Programme Level Agreement, which is currently under review with NHS England. HES data from NHS England have been received with a lag of approximately six months. This will allow our empirical analysis to keep pace with developments on-the-ground in the NHS.

We have obtained a letter of support from the Deputy Director of the NJR confirming support in principle for data access for this project. CI Rangan will facilitate access to the NJR as a surgeon member of the NJR research committee. The NJR provides additional information on top of what is available in HES including the American Society of Anaesthesiologists (ASA) classification,[15] clinical outcomes such as revisions and mortality, and PROMs with a long term follow-up. The ASA classification, widely used by surgical teams to classify the complexity of patients, especially by the number and severity of their comorbidities, is important for this project to accurately identify high-complexity and low-complexity patients in the data. For other non-orthopaedic specialties covered by this project, there are no comprehensive registry-type datasets covering HVLC procedures, for these specialties, we rely on information from HES and from the code recipes provided for the majority of high-volume and low-complexiy specialties, including orthopaedic surgery, on the High Volume Low Complexity (HVLC) programme website to capture patient complexity.

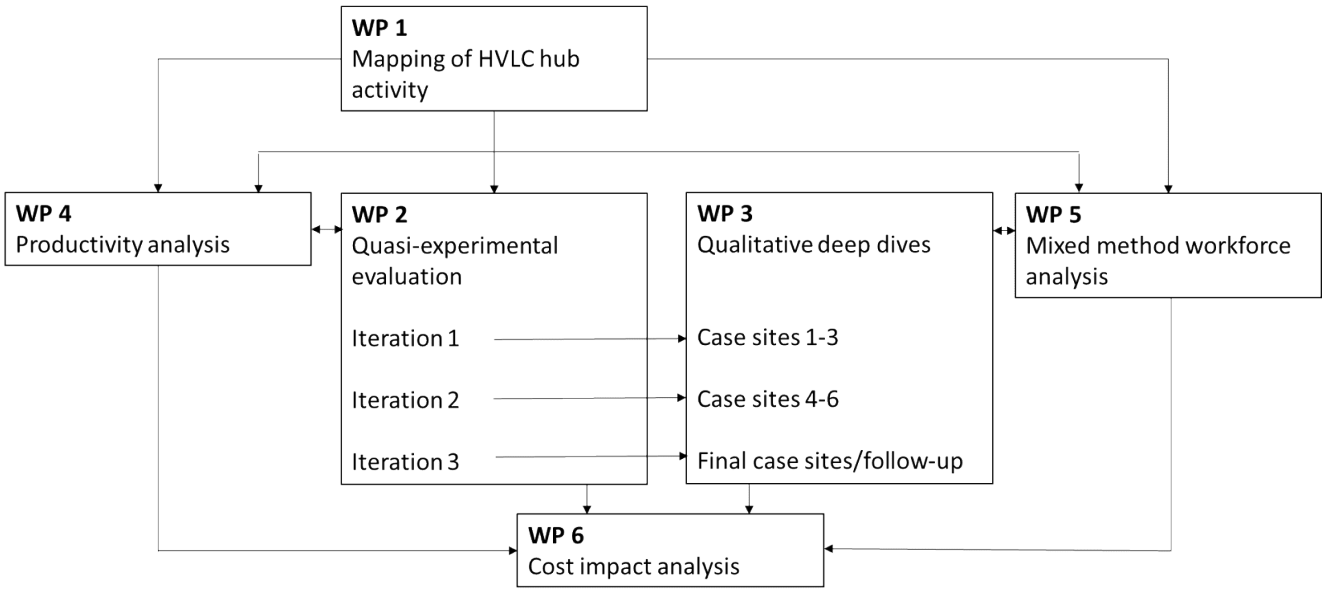
We will engage with NHS England to discuss access to the “Model Health System'' dataset, which provides hospital provider-level performance information which can be used to compare hospitals over time. The above dataset includes additional information metrics, such as the GIRFT gateway metrics,[16] which will be important additional measures to evaluate HVLC surgical hubs’ performance.

All patient data to be analysed are pseudonymised (by NHS England or the NJR) with no patient-identifiable information. All published outputs will include only aggregated statistics, such as those at the level of national averages, for providers or commissioners, by geographical areas or by subgroups defined by patient characteristics. No information will be published about individual patients or clinicians.

For work package 5 (mixed methods workforce analysis) we will apply to NHS England for an extract of the National Workforce Dataset (NWD), which incorporates the Electronic Staff Record, and collates workforce information consistently from all providers of NHS care.



FUNDED BY
NIHR | National Institute for Health and Care Research




## 4.3. Theoretical framework

We will use the Consolidated Framework for Implementation Research (CFIR) [17] to inform our research. We have selected this framework as it provides a comprehensive taxonomy of influencing factors that can be used to examine what works, where and why, across multiple contexts - which we envisage, based on similar evaluations of national health policy[13] will be the core components of our analysis. The CFIR comprises five major domains: intervention characteristics, outer setting (wider context), inner setting (local context), characteristics of the individuals involved, and the process of implementation. Of particular relevance to our study is the recent CFIR Outcomes Addendum [18]which has increased the reach of the CFIR to include innovation outcomes - i.e. the 'success or failure of the innovation' (HVLC hubs), as relevant to innovation recipients, innovation deliverers and key decision makers. This framework is particularly well suited to the evaluation of care model redesigns, [19] can be successfully applied in mixed methods studies[19] and is an appropriate framework for economic evaluations.[20] In addition, the available tool kits help to ensure mechanisms for efficient feedback of findings at appropriate stages throughout the programme of work.[21]

## 4.4. Work Package 1: Describe and classify current and planned models of HVLC hubs in England (Leads: JA/PS)

This WP involves two integrated phases of work that will run in parallel to provide an up-to-date description of the hubs programme - in order to understand the nature of existing/planned HVLCs



FUNDED BY
NIHR | National Institute for Health and Care Research

including: current service configuration (e.g. standalone, integrated, ring-fenced), funding, workforce, and the date of commencement of any service change.

### Part 1: Identifying intervention characteristics

We will conduct a desktop review of documentary evidence of the current state of the HVLC surgical hub programme - including NHS/government publications and where available board papers from NHS Trusts and Integrated Care Systems (ICSs) and successful applications to the NHS Capital Settlement scheme.[22] In addition we will draw upon our expert network - in particular the support provided by direct links with the HVLC team at the Department of Health and Social Care, and NHSE in order to generate a 'live' database of current hub activity. We aim to understand and classify current models of HVLC and map the local funding and staffing arrangements, to inform WPs 2, 4 and 5. As per current GIRFT guidance[5] we anticipate that three distinct model types (stand-alone/integrated/ring-fenced hubs) are likely to emerge which we can then analyse in more detail through WP2, WP3 and WP4.

### Part 2: Data verification

We will begin to analyse the quantitative datasets (HES, NJR and Model Health System if appropriate), to explore and verify information about identification of low-complexity patients and location of surgical hub sites in the data. For example, we will check for which surgical hubs mentioned in government announcements[4], or identified in Part 1 or Part 3 of this work package, we can identify via site codes in the HES APC data, and how this has changed over time. This is likely to be easier for standalone hubs which are separate NHS facilities than for ring-fenced or integrated hubs which are units of existing NHS hospitals or facilities.[5] We will check for appropriate definitions of high/low complexity patients and how they can be identified in alternative datasets. For example, the NJR will allow us to use ASA codes to identify low-complexity patients, but HES only contains primary and secondary diagnosis codes which can approximate complexity.

### *Part 3: Qualitative key informant interviews*

In order to obtain an overview of the HVLC hub programme we will invite senior key informants (n=10-15 including for example policy commissioners, those responsible for national delivery) in selected organisations to participate in qualitative interviews to explore their views on HVLC hubs: to understand the development of the hubs programme, its evolution over time, the mechanisms that underpin the programme, and their expectations for HVLC hubs as part of the wider elective recovery plans. In our preparatory work, we have already identified a number of key stakeholders (from NHS England, Department of Health and Social Care, GIRFT). We will draw on these contacts and other key stakeholders in our VSAG in order to recruit the most appropriate individuals into our interview study.



FUNDED BY
NIHR | National Institute for Health and Care Research

Topic guides will be informed by the CFIR framework,[23] with input from our VSAG and PPI group. Interviews will be transcribed verbatim and an initial qualitative analysis using the CFIR framework will summarise key findings from this research that will inform the remaining work packages - for example, we will generate hypotheses/research questions to be tested in the quantitative analysis and inform qualitative data collection within the case-sites.[24] Following this descriptive analysis this data will then be included as part of the interpretive analysis described in WP3.

This work will take place at the start of the project and will provide the necessary information required to proceed with the subsequent work packages. At this stage, the outputs from this work will facilitate the generation of initial research questions/hypotheses that will inform the first iterations of our quantitative and qualitative work (see below). Given the expected continued development of the hubs programme, our 'live' database will be continuously updated over the course of the project, so further iterations of both the quantitative and qualitative work will be based on the most current information regarding hub implementation.

## 4.5. Work Package 2: Quantitative empirical evaluation of the effects of HVLC surgical hubs (Lead: PS)

### Study Design

We will perform a quasi-experimental evaluation of the HVLC hubs programme building on the MRC guidance on methods for the evaluation of complex interventions using observational data.[25] Our empirical approach will take into account the inherent complexities in the quantitative evaluation of surgical hubs. Many currently operational surgical hubs (e.g. the South West London Elective Orthopaedic Centre) are long-standing specialist elective facilities which may have transitioned to HVLC hub status without any formal accreditation from GIRFT. In such cases it may be hard to identify a clear and meaningful "start date" for HVLC hub status, and therefore we will adjust our methods accordingly.

In other cases, such as the 20 named new hubs mentioned in the government press release in August[4] and from named recipients of targeted investment funds (TIF) to develop hubs[22, 26] we will have more certainty about when trusts developed sites into surgical hubs and when they became operational. We will use information from the preliminary work and data verification in WP1 to clarify when changes to using a surgical hub model have occurred, and if the sites can be captured in our datasets. Throughout we will consult with our VSAG and through regular feedback opportunities with the GIRFT HVLC team at NHSE to check how we are classifying the trusts, sites and timing of the use of surgical hubs.



FUNDED BY NIHR | National Institute for Health and Care Research

We will use the variation in timing of implementation of HVLC hubs across England using a staggered difference-in-difference methodology.[27] By measuring the change in outcomes in areas when the HVLC hub model is adopted, and comparing these to the change in outcomes in (yet) unaffected areas, we will be able to estimate the intended and unintended effects of the HVLC hub model of care.

In instances where we cannot be sure of the timing of surgical hubs or we cannot be sure that any 'control' areas are unaffected by the reform, we will explore other flexible empirical approaches such as cross-sectional analyses [28] (which do not require variation over time), and event studies[29] (which do not require unaffected control groups). We will also follow the approach of our previous NIHR project 15/145/06 ('General Practitioners and Emergency Departments (GPED): Efficient Models of Care') to test whether different types of hubs, including stand-alone, integrated or ring-fenced hubs achieve different outcomes.[5] A flexible empirical approach emphasising heterogeneity and evaluation of alternative models will align the quantitative approach with the qualitative case studies in WP3 and the five domains of the CFIR framework. For example the type of hub (stand-alone/ring-fenced/integrated) is an intervention characteristic, whereas the geographical context of a hub (e.g. Bridlington Hospital vs South-West London Elective Orthopaedic Centre) is part of the "outer setting" affecting implementation.

### Data and Outcomes

We will use NHS England data from the HES admitted patient care (APC) dataset, HES outpatient care dataset, the Emergency Care Services dataset, NJR and other sources detailed in section 4.2. from financial years 2010/11 through to the latest data available. We will analyse a range of outcomes that capture the main intended effects of the HVLC hubs model using the volume of low-complexity patients treated as the primary outcome. Several secondary outcomes will also be examined including waiting times and length of stay (LOS) for low-complexity patients, additional hospital-level productivity measures, volume, waiting times and length of stay for high-complexity patients, health outcomes and further spillover effects on emergency and acute care.

The additional hospital-level productivity measures will come from the Model Health System dataset, including operating theatre usage time. These productivity/volume/capacity usage measures are intrinsically linked because the HVLC model aims to treat low-complexity patients more quickly, reducing LOS, which in turn allows greater overall volume of patients to have surgery and shorter waiting times.

Many of the secondary outcome variables aim to capture spill-over effects of the HVLC hubs programme. Our analysis will aim to capture within, between and diagonal spillover effects.[30] Within spillovers are unintended effects on the targeted units, including (positive or negative) effects



FUNDED BY
NIHR | National Institute for Health and Care Research

on health outcomes of high-volume low-complexity patients. We will test for any impacts on health outcomes including readmission and mortality rates, revision rates and PROMs where they are available (e.g. for joint replacements).

Between spillovers include intended outcomes on non-targeted units. This would include effects on the volume, length of stay and waiting time for high-complexity patients (not targeted by the programme). Diagonal spillovers would include unintended effects on non-targeted units, this would include effects on health outcomes for high-complexity patients, effects on emergency and acute care through four-hour target performance in A&E and delayed transfers of care from inpatient wards.

We will use input from the VSAG and PPI group to interpret and prioritise the outcome variables in our analysis. For example, we will seek their views on the relative importance of waiting times compared to health outcomes and the relative priority of treatment for low-complexity vs high-complexity patients.

Throughout our analysis we will explore the consequences of the HVLC hubs programme for health inequalities by socio-economic position and across protected characteristics [31] where data allows. We will present all results with impacts summarised by IMD quintile (linked to HES through patients' lower super output area, LSOA, of residence), by age, sex, and across the major groups of ethnic origin. It will not be feasible to account for inequalities by other protected characteristics such as disability, religion or sexual orientation as we cannot measure them in the secondary datasets we plan to use. However, our qualitative work will collect data pertaining to perceived inequalities experienced by underserved populations from both staff and patient interviews.

Our quantitative analysis will align with the in-depth qualitative case studies described in WP3 as outlined in the attached Gantt chart with three main iterations (beginning in months 7, 15, and 23 of the project). In each iteration we will analyse a different specialty and identify trusts where the HVLC hub model has had the largest impacts. The first iteration of the quantitative analysis will focus on data on orthopaedic procedures, making use of the expertise in our project team (CIs Rangan and Davies) and making use of the existing surgical hubs in this area (e.g. South West London, Bridlington). In following iterations we will cover urology and ophthalmology (CIs Moore and Saad), followed by the remaining HVLC specialties (general surgery, ENT, obstetrics/gynaecology), as well as updating our existing analyses with updated data and comparing results across specialties.

### 4.6. Work Package 3: In-depth case studies of purposively selected HVLC hubs (Leads: JA/ASc)



FUNDED BY
NIHR | National Institute for Health and Care Research

We plan to integrate our qualitative work with the quantitative analysis described in WP2, 4 and 5 - and have proposed three iterations of the main quantitative analysis. Following charting of the quantitative findings at each time point (with input from our VSAG and PPI groups) we will purposively sample up to nine sites for 'deep-dives', that is, qualitative in-depth case studies of selected hubs. Similar methods have been used successfully to examine variation across health care settings in order to understand how clinical teams and organisations achieve success according to a range of outcomes. [11, 13, 32]

## Purposive selection of qualitative case sites

Following each iteration of quantitative analysis we expect to identify a number of key findings relating to various aspects of the HVLC programme development. We will construct a sampling matrix based on key quantitative outcomes alongside site contextual factors (see table 1 for dummy matrix). We will draw on the opinions of our VSAG and PPI groups to help us select the key outcomes to focus on in the selection of sites for our qualitative case sites. Once we have populated the matrix with findings from each iteration of the analysis, the study team will highlight (up to ten per iteration) potential sites of interest (for example, showing positive deviance for a particular outcome, such as increased volume or reduced waiting times, and having particular hub characteristics). These options will be presented electronically to our VSAG for feedback, after which three sites will be selected for participation in a qualitative 'deep dive'. This process will be repeated for the first two iterations of the quantitative analysis. Therefore, following the second phase of quantitative analysis we will have purposively selected six in-depth qualitative case sites. We see stakeholder buy-in (via the VSAG and PPI group) to the selection of sites as crucial to ensure this work is prioritised according to the ongoing developments within the hub programme and shifting research priorities of key stakeholders for relevant and timely feedback for further hub development/ implementation.

Table 1: Dummy table for qualitative sampling frame

| | Specific criteria stemming from quantitative analysis to be finalised by study team, VSAG and PPI | | | | | |
|---|---|---|---|---|---|---|
| | Outcome 1 e.g. waiting times | Outcome 2 e.g. productivity | Intervention characteristic 1 e.g. Hub configuration | Intervention characteristic2 e.g. Workforce model | Local context 1 e.g. population density | Local context 2 e.g. population deprivation |
| Site 1 | | | | | | |



FUNDED BY NIHR | National Institute for Health and Care Research

| | | | | | | |
|---|---|---|---|---|---|---|
| Site 2 | | | | | | |
| Site 3 … | | | | | | |

Following the third iteration of the quantitative analysis, we propose to take a flexible approach - rather than specifying in advance the number of deep dives, we will base decision making regarding further data collection on the findings already obtained. It is important to note that the list of hubs included in the analysis will change over time, as an increasing number of hubs come onstream. Whilst some hubs will feature in the analysis only once, others may appear in all three iterations. We will take this into account in phase three of the qualitative research. For example, it may be most appropriate to select only one new deep dive site in addition to returning to previous sites in order to explain a change that has been observed in the quantitative analysis. For this longitudinal approach it may be more appropriate to conduct a smaller amount of targeted data collection, for example, purposive key informant interviews based on our prior knowledge of the site. Data collection will be adaptive and responsive.

### Data collection at the qualitative case-sites

Data collection at sites will consist of a combination of non-participant observational data, semi-structured qualitative interviews and documentary data.[13, 32] The researcher(s) will spend approximately 5-7 days at the purposively selected hub over a two-month period. Prior experience[13] tells us that the amount of data that is required and the characteristics of the key stakeholders that should be included in our sampling is likely to vary greatly across location. Therefore, data collection at each site will start with a familiarisation visit, followed by qualitative observations to gain an understanding of the case site in order to purposively select the key individuals at the site to approach for interview and further observation. At each site approximately 12-15 hours of observation will take place over the duration of the visit, recorded in field notes. This may include for example, team meetings etc. We estimate that approximately 10-15 interviews will be required per site and will include purposively sampled stakeholder groups: staff (anaesthetists, surgeons, nurses, hub administrators, local GIRFT co-ordinator(s) and relevant service leaders e.g. operational managers and regional elective recovery leads as appropriate); and patients and/or their carers. Patient interviews will include participants with a broad range of characteristics following INCLUDE principles. [33, 34] Relevant policy and procedural documents relating to each case site will also be collated.



FUNDED BY NIHR | National Institute for Health and Care Research

All qualitative data collection will be informed by the tools available as part of the CFIR suite of resources, [23] including topic guides and observation templates which will be adapted for our specific purposes. Topic guides for staff will explore the implementation and impact of the HVLC hubs programme from the perspectives of the various participants, as well as the policy's background and the prior expectations relating to any changes in service provision. The interviews will also capture how the hub provision fits within the wider local surgical provision. The interviews will also cover workforce issues (providing the qualitative data for WP5) and will include experiences of staffing models, training requirements, communication, staff well-being, staff recruitment and sustainability. Patient interviews will capture their experience of being referred to the hub, the treatment within the hub and follow-up care, general views on service configuration and elective recovery. Patients will be provided with study materials whilst at the hub, but given the short stay many patients will experience it is anticipated that arrangements will be made to interview patients once they are at home and well enough to participate.

### Recruitment at sites

Within site recruitment of staff and patient participants will be discussed at the site initiation visit and will subsequently be facilitated by the site chief investigator (CI). The site CI will help to identify appropriate key informants to approach in the first instance and will disseminate study information to potential participants on site. This will be supplemented by opportunistic recruitment by researchers at site visits. Patient recruitment will be informed by local PPI representation (see PPI plans).

### Qualitative data analysis

All qualitative interviews across WP1 and WP3 will be audio recorded digitally and transcribed verbatim, other qualitative data will be in the form of field notes and documentation. Our analytic approach is based on our experience of analysing large quantities of qualitative data on the GPED project (involving data from non-participant observation of 142 individual clinical encounters and 467 semi-structured interviews across ten case-study sites).[13, 24, 35] Designed to deal with large quantities of multi-dimensional qualitative data, we will utilise the pen-portrait approach.[36] Drawing on all of the data collection methods used, we will document a holistic descriptive account of each of the sites - a 'pen-portrait'. This narrative description of each hub will be presented under the broad domains of the CFIR (hub characteristics, outer setting (wider context), inner setting (local context), characteristics of the individuals involved, and the process of implementation). As each pen portrait becomes available, we will offer to feedback this analysis to each of the case-sites.

At the end of the first iteration of the qualitative work - when three pen-portraits are available - the qualitative study team will discuss these early findings with our VSAG and PPI groups and together we



FUNDED BY
NIHR | National Institute for Health and Care Research

will identify either hypothesis or 'domains of influence'[24] that we will explore in more detail in further qualitative data collection/analysis and quantitative data analysis. Here we will compare and contrast each of the pen-portraits in order to map key features from the descriptive accounts across and between case-sites. This will use an interpretive approach [37] using principles derived from Braun and Clarke's reflexive thematic analysis (TA) [38] and will also incorporate the qualitative data produced in WP1. This will allow for us to explore key findings for the purposes of the main report according to the CFIR; and undertake more thorough in-depth analysis of pertinent issues that have been identified as important from the initial qualitative analysis and input from stakeholders. Whilst it is not possible to state in advance all of the themes will be developed, this will include an in-depth analysis of workforce issues (linked to WP5).

## 4.7. Work Package 4: Productivity of HVLC hubs (Lead: AC)

We propose to measure the productivity of the HVLC surgery hubs by means of two well-established measures: (i) the NHS productivity measure developed by the Centre for Health Economics [39] and (ii) the operational productivity measure developed by Lord Carter [40] and used by NHS England in their Model Health System.

We will analyse productivity at the level of each hub and within each clinical specialty, data permitting, therefore analysing productivity levels both within and between specialties. Similar to WP2, we will start our productivity analyses with orthopaedics, making use of the expertise in our project team in orthopaedic surgery. We will consult with the PPI group early in the project to inform the refinement of productivity measures for hubs.

Finally, the research team will investigate the potential impact of the establishment of HVLC surgery hubs on the wider system, flagging up any potential (unintended) effects on the productivity of non-HVLC activity by NHS Trusts.

### Methods

The CHE NHS productivity measure relates changes in outputs relative to changes in inputs used. Outputs are adjusted for changes in measures of quality (e.g. survival, waiting time). Inputs include the number of doctors, nurses and support staff providing care, the equipment and clinical supplies used, and the facilities where care is provided. Further, in recent research in English NHS Trusts, we have developed metrics to apportion input use to single specialties which may be useful when apportioning inputs use, especially labour input, to HVLC hubs.

The operational productivity measure divides total costs of an organisation by the Weighted Activity Unit (WAU), a 'common currency' to describe an amount of clinical activity, with a weighting applied



FUNDED BY NIHR | National Institute for Health and Care Research

that takes account of case-mix and complexity. The value of a WAU is £3,500.[40] A unit is said to be "operationally productive" if their cost per WAU is less than the value of a WAU.

With the CHE approach, we propose to measure labour productivity, and if possible, total factor productivity of the hubs. Productivity is calculated by comparing the total amount of healthcare output to input(s) for each HVCL hub. The objectives of this WP are:

1. to produce measures of productivity, standardised to the national average, for the six specialties identified for the initial roll-out of the HVLC surgical hubs, differentiating wherever possible between types of surgical hub (stand-alone/ring-fenced/integrated)

2. In order to gain a better understanding of the relative performance of the HVLC surgical hubs compared to NHS Trusts without such hubs, we will also calculate productivity measures for NHS Trusts without HVLC surgical hubs, also standardised to the national average, limited to the six specialties.

3. to compare the measures of productivity within and between specialty, both for NHS Trusts with and without a HVLC hub.

The operational productivity measure (Carter) will provide an alternative measure, widely used by NHS Trusts to compare performance and productivity, and it will be used to sense-check findings of the CHE measure of productivity.

### Data and Outcomes

Our productivity measures will use several different data sources including several of the same comprehensive datasets used in WP2 and described in section 4.2. Our study period will start from the introduction of the HVLC hubs programme in 2021 to the latest year available.

To measure NHS outputs, we will use: Hospital Episode Statistics (HES) Admitted Patient Care, HES Outpatient, Patient Reported Outcome Measures, and Civil Registration Secondary Cut data (Source: NHS England). To measure NHS inputs, we will use: NHS Electronic Staff Record (ESR), including payroll data (Source: NHS England); and Trust annual financial accounts (TACs) for Foundation and non-Foundation Trusts (Source: NHS England). Finally, unit cost information for outputs will be derived from the National Cost Collection data and, if possible, PLICS data (Source: NHS England).

As discussed in the "Secondary Data Sources"section (4.2), we plan to negotiate access to the "Model Health System'' dataset, which provides hospital-level performance information which will also be used to assess surgical hubs' productivity using the GIRFT gateway metrics. We will discuss with relevant stakeholders whether any further data are being collected on HVLC surgical hubs, and request



FUNDED BY
NIHR | National Institute for Health and Care Research

access to these data, in order to support the analyses of both the HVLC surgical hubs productivity and of drivers of productivity variations of HVLC hubs.

We will pursue input from the PPI group and the VSAG to reach an agreement on proposed process and health outcome quality indicators to use in our analysis to adjust the measures of NHS output. For example, we will seek PPI views on the relative importance of process measures, such as waiting times, compared to health outcomes, such as survival, emergency readmissions, PROMs.

Finally, we expect the productivity measures developed to evaluate HVLC surgical hubs to vary

- within and between HVLC hubs specialties,
- within and between different types/models of surgical hubs,
- between NHS Trusts with HVLC hubs and NHS Trusts without hubs

Therefore, we propose to investigate the potential drivers of such variations, following some of our previous work.[41, 42] The selection of determinants will be based on past literature, and the GIRFT 'gateway frameworks' metrics included in the Model Health System. Further determinants will be selected based on the specific set-ups of the surgical hubs, as informed by findings from WPs 1, 3, and 5, and as set out in the five domains of the CFIR. The five domains of the CFIR will also be used to help explain findings of the analyses

## 4.8. Work Package 5: Mixed methods workforce appraisal (lead: KB)

The staffing of HVLC hubs, and the implications of changes in staffing for care delivered in wider Trusts, are crucial contributors to the success of this policy. We will therefore seek to: map the teams in place within Trusts with longstanding and newly implemented HVLC hubs; identify wherever possible the staff working in the hubs and any changes in wider service staffing resulting from the introduction of newer hubs; and explore associations between different staffing models and the effectiveness of the HVLC hubs (as measured in WP2 and WP4).

Initially we will explore existing data sources, including NHS England's workforce statistics, the NHS Electronic Staff Record (ESR) and data reflecting local labour markets, such as the wages component of the NHS market forces factor.[43] We will examine workforce drivers of successful HVLC models by comparing hubs of different scale, team composition and staffing models on the basis of outcome measures derived from WP2 and 4, taking account of the hierarchical nature of the data. We will monitor indicators of workforce wellbeing and sustainability such as rates of recruitment, retention, turnover, vacancies and use of bank and agency staff. Routinely collected staffing data may, however, be limited in detailing the exact size, composition and working practices of teams working across the



FUNDED BY
NIHR | National Institute for Health and Care Research

hubs and wider NHS organisations. Therefore, we will build on WP1 to describe staffing models in place in the hubs, creating a taxonomy of these if there is variation in approaches between Trusts and over time.

This will be coordinated with the primary qualitative data collection in WP3 where we will investigate staffing models in detail, taking into account the local context and the advice of our PPI panel and VSAG. Data collection from the case sites, descriptively summarised in the pen portraits will include workforce information, which will be explored in more depth. We will, for example, examine rotas, how teams in the HLVC hubs work, whether staff work across hubs and other NHS or private sector organisations and where health professionals moved from when the hubs were created. Within the qualitative case-studies we will also gather data on broader labour market forces and the local contextual factors that impact on workforce for each particular site, in order to explore how these external factors have influenced the nature and functioning of the hubs. We will use CFIR to integrate and interpret the quantitative and qualitative data in a mixed method analysis (see section below on work package integration for more detail).

## 4.9. Work Package 6: Overall cost impact in relation to outcomes and effectiveness (Lead: PS)

We will conduct a cost-consequence analysis of the different HVLC models based on their estimated effects alongside estimated resource use (e.g. salaries, capital investment). The estimated effects of HVLC models will follow from the data analysis on patient volumes, health outcomes and spillover effects estimated in WP2. Resource use will be derived from the documentation relating to capital investment applications[16, 22] summarised in WP1, alongside routine administrative datasets on throughput (HES and tariff data), staffing (workforce minimum datasets, and ESR), and any available local datasets, and by collating information across all WPs 1-5. We will use Personal Social Service Research Unit (PSSRU) unit cost estimates supplemented by local cost estimates to value changes in resource inputs. We will use information on the most common funding arrangements to identify genuine changes in resource utilisation rather than cost shifting.

We anticipate taking a 'non-inferiority' approach to analysis of health outcomes, but if the quantitative analyses in WP2 identify a significant impact of the different HVLC models on patient health outcomes (e.g. mortality, readmissions, PROMS), we will explore the feasibility of calculating the cost-effectiveness of the HVLC system using health economic modelling techniques to translate patient health effects into quality-adjusted life years (using published estimates of health-related quality of life by age and sex group and life expectancy data from the Office for National Statistics).



FUNDED BY NIHR | National Institute for Health and Care Research

## 4.10. Work package integration

### Mixed method analysis to integrate qualitative and quantitative findings

In addition to the separate quantitative and qualitative analyses, we will conduct higher-level synthesis to integrate the study findings using a triangulation protocol - in order to combine different methods to gain a more complete picture[44] relating to the overall objectives of the study. Both qualitative and quantitative findings will be jointly displayed in a mixed method matrix according to the relevant domains of CFIR in order to draw meta-inferences from both sources of data.[45] This process of using implementation models to integrate large, complex quantitative and qualitative data sets has been successfully achieved in other large scale policy evaluations.[13, 14]

## 4.11. Summary of patients/service users/carers/public as research participants

Whilst the mainstay of the data relating to patients will be based on routinely collected information which is available for the whole surgical population e.g. HES (see WP2), surgical patients will be included as research participants in our qualitative work (WP1, WP2 and WP5). As we have outlined, we will sample patients attending hubs in order to gain an in-depth understanding of their journey and their experience of treatment within and outside of the surgical hub. As outlined above, **all** patients would potentially be eligible for participation in the qualitative study. We will be using maximum variation sampling in order to ensure that patients with wide ranging socio-demographic and health characteristics are included in our sample.

Participants will be identified at each site and whilst there will be generic procedures for recruitment of participants for the study as a whole, site specific context will be taken into consideration for recruitment at each location supported by the local PPI recruitment at each site. For example, at the site initiation visit (using NIHR INCLUDE guidelines[33, 34]), we will ascertain from staff information relating to the local population and how under-served populations at each site might be optimally recruited and consented. At site initiation visit we will also enlist the support of the site PI to identify up to two local PPI representatives. We will meet these representatives in order to inform local site based communication (e.g. how hubs are referred to locally, names of other local units etc.) and also advice on patient recruitment in that locality. Following this information seeking, the appropriate study materials will be selected. This might include selection of specific language based materials/use of interpreters/sound recorded study information/infographics - to optimise recruitment from a broad range of potential participants. We have costed for the provision of these resources. Each participant recruited into the qualitative study will be interviewed once, at the setting of their choice, either face-to-face or via zoom/telephone. Each participant will be offered compensation for travel costs/time



FUNDED BY
NIHR | National Institute for Health and Care Research

spent on the project. All respondents will be given the opportunity to receive feedback on the study findings.

## 5. Stakeholder engagement

Figure 2 illustrates how key stakeholders will feed into all stages of the research process

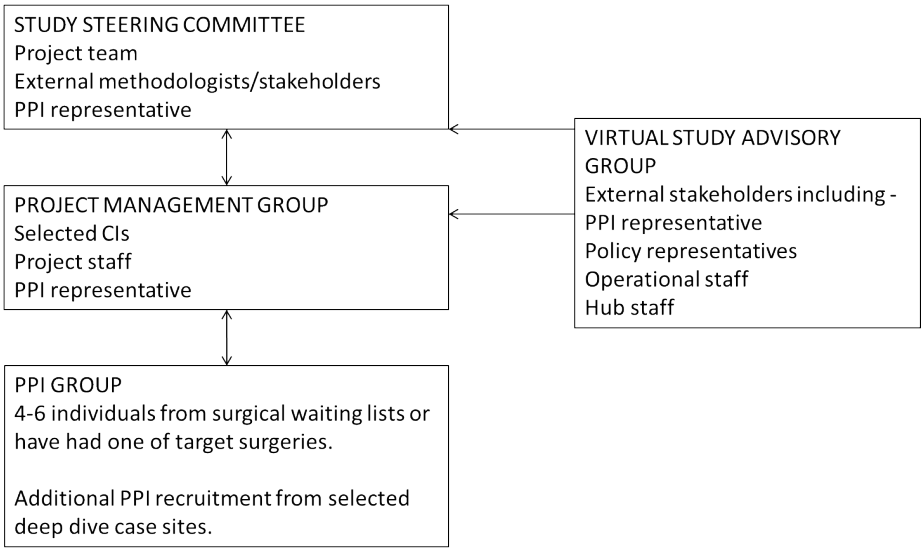



*Figure 2: Stakeholder engagement in the research*

## 5.2. Patient and public involvement

The patient's voice will be heard loud and clear throughout our project. Figure 1 in our proposal outlines show how we will strongly integrate PPI into our project management. PPI contributors will be members of:

### 1) Study Steering Committee

The study steering committee supervises the project on behalf of the sponsor and funder. We will recruit a PPI contributor to join this committee. We will aim to find a person who has considerable experience as a PPI contributor in various roles, including on a steering committee.

### 2) Virtual Study Advisory Group

A strong feature of our study management strategy is the development of a Virtual Study Advisory Group (VSAG). Feedback from this group will inform the study steering committee and the project management group. This group has strong stakeholder representation including patient representation, clinical staff and NHS policy membership. The VSAG will help us with all aspects of the project including the prioritisation of quantitative outcomes, selection of case-study sites and dissemination activities. For this group we intend to recruit a public contributor from a patient



FUNDED BY NIHR | National Institute for Health and Care Research

advocacy charity to represent the interests of all patients and their families (e.g. The Patients Association or POhWER). We will invite this public contributor to attend the project management meetings as and when desired, keeping the burden on this person in mind.

### 3) Study-wide PPI Group

We will set up a PPI group made up of individuals who have either had one of the surgical procedures targeted at HVLC hubs, or are on the waiting list and/or carers. This group will have input on the day-today management of the project. For example, members will help us prepare study materials, topic guides for qualitative work and help us to develop patient recruitment strategies. In addition, the PPI group will provide feedback on study findings as they emerge and will have input into the prioritisation of quantitative outcomes and selection of case-study sites and will be consulted on dissemination strategies.

### 4) Site-specific PPI

We also intend to recruit one or two PPI members for each case-study site, facilitated by the site PI. This consultation will inform local site patient recruitment, facilitate the equitable recruitment of under-served populations, and help ensure that all study materials are appropriate to the local context (e.g. using local terms to describe HVLC hubs/local hospitals etc). It is anticipated this will only require one meeting per site.

### PPI Lead

Our PPI Lead Karen Glerum-Brooks is a co-applicant on this study. She will coordinate all PPI activities. Karen is a specialist PPI and Stakeholder Engagement Manager who will manage the collection of PPI input and provision of feedback through group meetings and individual calls or visits. She will recruit PPI representatives and seek to build strong relationships with them.

### EDI in PPI

Karen takes a personalised, flexible approach to PPI to ensure that people with a wide range of backgrounds can become involved. She assesses contributors' needs for support during the informal recruitment calls. Each PPI contributor will receive a Welcome Pack that explains the study and the role of PPI in it. It also informs PPI contributors about practical issues such as payment procedures. The content of the Welcome Pack will be discussed during the first meeting. Further training and support will be provided according to individual needs.

## 5.3. Virtual Stakeholder Advisory Group

We have determined the time-frame of our project based on the current proposed timetable of HVLC hub implementation; being mindful of this rapidly changing landscape we have put in place several measures to maximise practice/policy relevant outputs in a timely fashion across the duration of the



FUNDED BY NIHR | National Institute for Health and Care Research

project. Crucial to achieving our objectives is substantive stakeholder involvement incorporated into all stages of our research. To this end, in the preparation of this application we have directed significant efforts towards wide-ranging stakeholder engagement, which has informed our evaluation design, and we have created a Virtual Stakeholder Advisory Group (VSAG). It has been noted that broad stakeholder engagement integrated throughout the research process can increase the relevance of the research as well as facilitating study procedures[46] (for example, up-to-date intelligence relating to hub implementation and accessing qualitative case-study sites) and provide a mechanism to share emerging findings with the most relevant individuals in order to inform refinements to the developing hubs programme or further implementation strategies. Our VSAG includes representation from NHS England, Department of Health and Social Care, GIRFT, surgical leadership within NHS Trusts, NHS Trust operations directorship, clinical hub leadership as well as hub staff (at Bridlington Hospital, the existing HVLC hub in York and Scarborough Teaching Hospitals Foundation Trust). The VSAG incorporates PPI representation (patient advocacy member), however, does not replace the role of the PPI group (see figure 2). We will draw on the advice and input from the VSAG membership across all work packages, in addition to our dissemination strategy.

# 6. Data handling, storage and record keeping

Data will be collected and retained in accordance with the UK Data Protection Act 2018.

## 6.1. Data storage, security and archiving

All data will be collected and retained in accordance with the General Data Protection Regulation (May 2018). All study documentation will be retained in a secure location (secure password-protected server located at the University of York) during the conduct of the study and for 5 years after the end of the study, when all patient identifiable paper records (qualitative data) and NJR (quantitative) data will be destroyed by confidential means. Other quantitative data will be stored as per the data agreement in place through the Centre for Health Economics (see below).

The sponsor will permit monitoring and audits by the relevant authorities, including the HRA. The Chief Investigators will also allow monitoring and audits by these bodies and the sponsor, providing direct access to source data and documents, including the database.

***Qualitative data:***

Identifiable consenting participant details for the qualitative study will be collected and entered on a database (on a secure password-protected server located at the University of York) but access to these personal details will be restricted to delegated users only. All information collected during the course



FUNDED BY
NIHR | National Institute for Health and Care Research

of the study will be kept strictly confidential. Data from qualitative interviews and observations will be transferred onto the secure server as soon as possible and data removed from the portable recording device as soon as possible and stored on University computers.

***Quantitative data:***

The Centre for Health Economics (including CIs Castelli, Gutacker and co-PI Sivey) have developed data security, handling sensitive data and overall privacy policies, as well as extensive guidance for members of staff. Data are stored on the University of York Data Safe Haven (DSH), an ISO 27001 certified Information Security Management System.

These processes provide guarantees on data use and security, necessary for gaining access to NHS England data. CI Castelli is the lead applicant to NHS England for all data applications within CHE and has built strong working relationships with NHS England data account managers. Our access to HES data will be through a new Programme Level Agreement with NHS England, which is currently under review.t The PLA will allow broad access to NHS England data such HES Admitted Patient Care, HES Outpatient care, etc .

## 6.2. Data sharing

Quantitative datasets will not be made available for sharing outside the Centre for Health Economics. Qualitative data will not be made available for sharing until after publication of the main results of the study. Thereafter, anonymised individual patient qualitative data will be made available for secondary research, conditional on assurance from the secondary researcher that the proposed use of the data is compliant with the MRC Policy on Data Preservation and Sharing regarding scientific quality, ethical requirements and value for money.

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

# 7. Ethics and regulatory approvals

The proposed study will be conducted in accordance with ICH Good Clinical Practice guidelines.

The quantitative work in this research uses observational secondary data and a quasi-experimental research design. Data will be obtained from routinely collected datasets (NHS England, Hospital Episode Statistics) with additional data sources potentially including information from the National Joint Registry, Civil Registration Secondary Cut data (out of hospitals deaths), Patient Reported Outcome Measures (PROMs), National Cost Collection , NHS workforce statistics, including the



FUNDED BY
NIHR | National Institute for Health and Care Research

Electronic Staff Record (ESR), data from Trust annual financial accounts (TACs), and ONS National Life Tables.

Routine care is not altered by the study and it therefore does not raise significant ethical issues. As these data sets are routinely available with data sharing agreements already in place through the Centre for Health Economics, (University of York) we are not seeking NHS Ethical approval for quantitative components of the study.

NHS ethics committee approval will be required for the qualitative work in WP 1 and 3 (which also provides data for WP5). WP 1 includes a small number of interviews with NHS staff; NHS ethics committee approval is not required for this, but the research will need a process of informed consent and approval from the participating NHS sites and will require HRA approval. WP 3 requires NHS ethics committee approval since it involves observation of practice, access to local documents and interviews with staff and patients. Appropriate consent mechanisms will be instituted for NHS staff and patient participants, based on previous similar studies. No individuals lacking capacity will be recruited, and no major barriers are anticipated.

The study protocol will be registered with the research registry.

### 7.1. Sponsor approval

Any amendments to study documents must be reviewed and approved by the sponsor and funder prior to submission to the REC.

## 8. Safety

### 8.1. Assessment and management of risk

We do not anticipate that qualitative study participants will be subject to any substantial risks during the study and the nature of interviews are not anticipated to involve discussions of sensitive and/or distressing topics for participants. However, patients may find discussion of recent illness/injury/or experiences of treatment upsetting. Equally, we will be mindful that in some circumstances patients will either be preparing for, or recently received surgical treatment. We will, therefore, be led by staff and patients as to an appropriate time to approach patients for and conduct interviews during case site visits. We will offer the opportunity for interviews to be conducted either during our case site visits or at a later date (e.g. via telephone or video conferencing) following a patient's discharge from hospital. For patients who may lack capacity or feel unable to participate we will, where appropriate, seek opportunities to conduct interviews with carers. The qualitative researchers conducting this



FUNDED BY NIHR | National Institute for Health and Care Research

aspect of the study are experienced in dealing with interviewing sensitively and will offer the participants opportunity to pause or stop the interview process, or to move onto another question. Hospital staff are unlikely to find interviews upsetting but will also have the opportunity to pause or stop the interview process, or to move onto another question.

A risk assessment will be carried out before any data collection commences in a healthcare setting. The qualitative researcher will adhere to the University's Lone Working policy, and policy for The Safety of Social Researchers when conducting data collection at case study sites.

The qualitative researchers will receive managerial support from the research team, and should they be exposed to any upsetting or harmful interactions will receive appropriate follow-up. The University has a free staff counselling service, should the researchers wish to seek support external to the study team.

### 8.2. Safeguarding

In the very rare circumstance that a safeguarding issue is suspected, for example during data collection during qualitative case site visits (WP 3), a Study Specific Procedure will be followed. Here the research staff member should immediately inform the Designated Safeguarding Lead at the study site, which in this case would be the site PI or most senior member of setting staff available, and complete any paperwork required by the setting. The chief investigators (CI's) should be informed, however as the external organisation (i.e. NHS hospital) holds primary safeguarding responsibility, research staff should facilitate reporting the incident through the setting's process. The CI's will inform the Sponsor that an issue was reported to the setting with primary safeguarding responsibility and whether or not further action was taken (if known). The CI's *will not* disclose personal information or details of the event/concern, only that a concern was identified and reported.

## 9. Monitoring, Audit and Inspection

The project will be sponsored by the University of York and monitored in accordance with the Sponsors policy. All study related documents will be made available on request for monitoring and audit by the sponsor, the relevant REC, the Health Research Authority (HRA). Significant study findings will be presented to the appropriate oversight committee.

Two committees will be established to govern the conduct of this study:

A Study Steering Committee (SSC).

A Project Management Group (PMG).



FUNDED BY NIHR | National Institute for Health and Care Research

### 9.1. Study Steering Committee

The SSC will meet biannually and will consist of an independent chair, an independent subject specialist, an independent clinical academic, an independent qualitative methodologist, an independent health economist and a Patient and Public Involvement (PPI) representative. The committee will oversee all aspects of the research on behalf of the sponsor and funder. We have anticipated at least one meeting per year for the SSC to be face-to-face to optimise team coherence, the other following a virtual or hybrid model. All project activities will be supported and informed by the VSAG and the PPI group facilitated by the PPI co-applicant (KGB).

### 9.2. Day-to-day management

The study will be managed by The Project Management Group (PMG). The PMG will comprise the co-applicants, members of the study team and PPI representatives. The PMG will meet monthly for the first year and then quarterly thereafter, and will be chaired alternatively by PS/JA and will involve all of the co-applicants, the researchers working on the project and PPI representation. This committee will have responsibility for the delivery of the project.

Each work package has identified co-leads, who will have overall responsibility for the delivery of the proposed work. A 40% fte study coordinator (ASc) will be responsible for the day-to-day running of the study, obtaining approvals, reporting to committees, managing the budget, drafting reports and research papers. The study coordinator will report to the chief investigators every week to ensure delivery of the research in accordance with the protocol, liaising closely with other study staff and researchers to ensure that all individual research components and milestones are achieved according to the study timetable and within budget.

### 9.3. Success criteria and barriers to proposed work

We have identified three possible barriers to the proposed work and mitigation against delays include:

1.) Delays in receiving NHS England data

We will mitigate this risk by building on our strong track record and working relationships with data authorities NHS England. CI Castelli is the lead applicant to the NHS England for all data applications within CHE and good links with key account managers. We have all the processes in place to make an application for an additional three years of data. This should allow us to carry out the quantitative analyses described in WPs 2 and 4. Currently we receive NHS England data with a lag of approximately six months which will allow our empirical analysis to keep pace with developments on-the-ground in the NHS.

2.) Breaches in data governance, data security



FUNDED BY NIHR | National Institute for Health and Care Research

We will mitigate this risk by building on our experience of dealing with sensitive data and will ensure all parties maintain the highest standards of data governance and security. For WP2 and WP4, data will be stored in the University of York Data Safe Haven, which is operated under an ISO 27001 certified Information Security Management System, and accessed only by authorised University of York staff. Staff access is monitored by the CHE Data Governance Group, following the strict processes of CHE and the Data Safe Haven. The names of individuals with access to specific datasets will be recorded in the CHE Information Asset Register. Guidance on confidentiality, data protection and data breaches is provided to staff from University of York Information Security and Data Protection policies, Data Safe Haven policies, CHE policies, CHE induction, as well as through University mandatory online training.

3.) Difficulties in recruiting sites for qualitative deep dives

We have designed our qualitative case studies to be responsive to emerging quantitative findings and the developing priorities of key stakeholders which means that we are unable to identify particular sites for recruitment at the proposal stage. Therefore, we are unable to secure sites in advance of the start of the project. However, we do not anticipate it will be problematic to recruit case sites as the team has extensive experience of this type of activity and we anticipate we will have several sites to select from at each iteration using our sampling matrix. For example, we have already visited one HVLC hub site (Bridlington Hospital) and obtained a letter of support in developing this proposal. In addition, we will have the support of the VSAG and other key stakeholders that will help us to facilitate site recruitment.

## 10. Definition of End of Study

End of study will be defined as the date at which the last participant has completed the study processes, which for this study will be completion of qualitative data collection (WP3).

## 11. Indemnity

This study will be sponsored by the University of York. For the qualitative components of this research, study participants and NHS professionals will be covered by the setting's indemnity insurance. To meet the potential legal liability for harm to participants arising from the design, conduct and management of the research, NHS employees involved in the study will be covered by NHS indemnity and university employees will be covered by their institution's insurance.

## 12. Financial and Competing Interests

Competing interests that might influence study design, conduct or reporting will be declared. There are currently no competing interests.

## 13. Complaint handling

The PIS (WP3) will provide participants with contact details of the Sponsor and CIs in case of complaint.



FUNDED BY NIHR | National Institute for Health and Care Research

## 14. Amendments

All amendments will be approved by the co-CI's and all substantial amendments will be approved by the co-CI's, the Sponsor and the TMG prior to submission for ethical approval.

## 15. Dissemination

We have a range of dissemination/output activities planned to ensure our dissemination strategy provides timely feedback to the relevant stakeholders.

### Continuous knowledge mobilisation to policy relevant stakeholders:

Following conversations with HVLC programme leads at NHS England, we intend to foster a process of 'live' feedback of study findings in order to influence future policy developments. We plan to have frequent and regular flexible feedback opportunities timetabled with NHS England. These could take the form of virtual or in-person meetings, or asynchronous written updates (e.g. an email of bullet points). This arrangement will be a two-way information stream, whereby key stakeholders at policy level receive up-to-date feedback from the study team as well as the study team receiving the necessary intelligence relating to the GIRFT/surgical hubs programme to inform our iterative quantitative and qualitative analysis. We consider this feedback mechanism to be our most direct route to impact, as we can communicate the up-to-date interim findings from our evaluation directly to those responsible for the continued design and implementation of the HVLC hubs programme.

These discussions will be in addition to having relevant stakeholder representation on our study steering group (see figure 1). This involvement of stakeholders is designed to ensure the research questions are in line with the experiences of patients, clinicians and commissioners and to promote collaboration and wider learning. This will enable us to design a tailored dissemination strategy to ensure we communicate our findings with all interested parties. We will take advantage of all opportunities to present our findings to non-academic groups.

### Dissemination to non-academic audiences:

This includes service users, clinicians and service providers and will be facilitated through the use of existing networks including those from the Virtual Study Advisory Group and social media (research team and Department of Health Sciences/Centre for Health Economics twitter accounts). These networks will be utilised to drive traffic to a study website which will act as a repository of materials designed to increase the accessibility of research and to maximise impact. All outputs, both academic and non- academic, will be made publicly available via the study website. Peer reviewed academic outputs and research reports together with associated summaries and key findings will be produced for funders, policy makers and NHS audiences and held on the website. We will use email lists and twitter to publicise and encourage active commentary on our outputs. We will seek opportunities for press releases and media interviews, and explore the use of blog posts by staff members and other



FUNDED BY
NIHR | National Institute for Health and Care Research

user-friendly ways of packaging and disseminating findings will be investigated such as animations and video presentations.

### Academic outputs:

This will include several papers, submitted to high impact peer-reviewed journals throughout the duration of the project, in addition to appropriate conference presentations or workshops. Through these mechanisms we will reach many of the clinical, academic and lay audiences who have an interest in the subject area. This will provide an early stage in the pathway to generating future impact.

### Impact on health inequalities:

Throughout our dissemination activities we will have an active focus on reporting results of the study with respect to the impact on health inequalities. All three dissemination mechanisms detailed above, continuous knowledge mobilisation to policymakers, dissemination to non-academic audiences and academic outputs, will report results and findings disaggregated by deprivation quintiles, age, sex, and other protected characteristics where possible. For example in WP2 where we assess the main quantitative impact of the surgical hub programme, we will use the data available in HES and the NJR (and Model Hospital if appropriate) to gauge the impacts of surgical hubs on waiting times for patients in high deprivation vs low deprivation areas, for women and men, and for different ethnic groups. This information can be used to target interventions within the hubs accordingly.

## References

1. Burn, S., Propper, C., Stoye, G., Warner, M., Aylin, P., Bottle., A., *What happened to English NHS hospital activity during the COVID-19 pandemic?* . IFS Briefing Note BN328, 2021.
2. NHS England. *Delivery plan for tackling the covid-19 backlog of elective care.* 2022a; Available from: https://www.england.nhs.uk/coronavirus/publication/delivery-plan-for-tackling-the-covid-19-backlog-of-elective-care/.
3. Getting it Right First Time (GIRFT). *"High Volume Low Complexity Guide for Systems"*. 2021; Available from: https://www.gettingitrightfirsttime.co.uk/wp-content/uploads/2021/12/GIRFT_HVLC_Guide_Edition_2_FINAL.pdf.
4. Department of Health and Social Care. *Press release: Over 50 new surgical hubs set to open across England to help bust the COVID-19 backlogs.* 2022; Available from: https://www.gov.uk/government/news/over-50-new-surgical-hubs-set-to-open-across-england-to-help-bust-the-covid-backlogs.
5. Getting it Right First Time (GIRFT). *"Design and Layout of Elective Surgical Hubs"* 2022; Available from: https://www.gettingitrightfirsttime.co.uk/wp-content/uploads/2022/04/HVLC_2022-04-05_Guide_Design-and-layout-of-elective-surgical-hubs.pdf.
6. Getting it Right First Time (GIRFT). *"Establishing an Effective and Resilient Workforce for Elective Surgical Hubs"*. 2022; Available from: https://www.gettingitrightfirsttime.co.uk/wp-content/uploads/2022/08/Workforce-guidance-for-surgical-hubs-Aug22h.pdf.
7. Getting it Right First Time (GIRFT). *Eight surgical hubs win recognition for meeting top clinical and operational standards* 2023; Available from: https://gettingitrightfirsttime.co.uk/eight-surgical-hubs-win-recognition-for-meeting-top-clinical-and-operational-standards/.



FUNDED BY NIHR | National Institute for Health and Care Research

8. Judge, A., Chard, J., Learmonth, I., Dieppe, P., *The effects of surgical volumes and training centre status on outcomes following total joint replacement: analysis of the Hospital Episode Statistics for England.* Journal of Public Health, 2006. **28**(2): p. 116-124.
9. Freeman, M., N. Savva, and S. Scholtes, *Economies of scale and scope in hospitals: An empirical study of volume spillovers.* Management Science, 2021. **67**(2): p. 673-697.
10. Schneider, J.E., et al., *The economics of specialty hospitals.* Medical Care Research and Review, 2008. **65**(5): p. 531-553.
11. Barratt, H., et al., *Mixed methods evaluation of the Getting it Right First Time programme in elective orthopaedic surgery in England: an analysis from the National Joint Registry and Hospital Episode Statistics.* BMJ open, 2022. **12**(6): p. e058316.
12. Briggs, T., et al., *Optimising surgical hubs for staff: case studies on training, wellbeing and retention.* British Journal of Healthcare Management, 2022. **28**(12): p. 1-9.
13. Scantlebury, A., et al., *Do general practitioners working in or alongside the emergency department improve clinical outcomes or experience? A mixed-methods study.* BMJ open, 2022. **12**(9): p. e063495.
14. Fulop, N., et al., *Evaluation of reconfigurations of acute stroke services in different regions of England and lessons for implementation: a mixed-methods study.* Health services and delivery research, 2019.
15. Doyle, D.J., et al., *American society of anesthesiologists classification*, in *Statpearls [internet]*. 2021, StatPearls Publishing.
16. Getting it Right First Time (GIRFT). *GIRFT Methodology*. 2022; Available from: https://gettingitrightfirsttime.co.uk/girft-methodology/.
17. Damschroder, L.J., et al., *Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science.* Implementation science, 2009. **4**(1): p. 1-15.
18. Damschroder, L.J., et al., *Conceptualizing outcomes for use with the Consolidated Framework for Implementation Research (CFIR): the CFIR Outcomes Addendum.* Implementation Science, 2022. **17**(1): p. 1-10.
19. Kirk, M.A., et al., *A systematic review of the use of the Consolidated Framework for Implementation Research.* Implementation Science, 2015. **11**(1): p. 1-13.
20. Merlo, G., et al., *Applying an implementation framework to the use of evidence from economic evaluations in making healthcare decisions.* Applied Health Economics and Health Policy, 2019. **17**: p. 533-543.
21. Keith, R.E., et al., *Using the Consolidated Framework for Implementation Research (CFIR) to produce actionable findings: a rapid-cycle evaluation approach to improving implementation.* Implementation Science, 2017. **12**(1): p. 1-12.
22. NHS England. *Capital Guidance 2022 to 2025*. 2022b; Available from: https://www.england.nhs.uk/wp-content/uploads/2021/12/B1256-capital-guidance-for-2022-25.pdf.
23. Research., C.F.f.I. *Qualitative Data*. 2022; Available from: https://cfirguide.org/evaluation-design/qualitative-data/,.
24. Scantlebury, A., et al., *Potential impacts of general practitioners working in or alongside emergency departments in England: initial qualitative findings from a national mixed-methods evaluation.* BMJ open, 2021. **11**(5): p. e045453.
25. Craig, P., et al., *Using natural experiments to evaluate population health interventions: new Medical Research Council guidance.* J Epidemiol Community Health, 2012. **66**(12): p. 1182-1186.
26. Department of Health and Social Care. *"£700 million to support the NHS this winter"*. 2021; Available from: [URL:https://www.gov.uk/government/news/700-million-to-support-nhs-this-winter].



FUNDED BY NIHR | National Institute for Health and Care Research

27. Callaway, B. and P.H. Sant'Anna, *Difference-in-differences with multiple time periods.* Journal of Econometrics, 2021. **225**(2): p. 200-230.
28. Siciliani, L., P. Sivey, and A. Street, *Differences in length of stay for hip replacement between public hospitals, specialised treatment centres and private providers: selection or efficiency?* Health economics, 2013. **22**(2): p. 234-242.
29. Dobkin, C., et al., *The economic consequences of hospital admissions.* American Economic Review, 2018. **108**(2): p. 308-352.
30. Francetic, I., et al., *Framework for identification and measurement of spillover effects in policy implementation: intended non-intended targeted non-targeted spillovers (INTENTS).* Implementation science communications, 2022. **3**(1): p. 1-15.
31. UK Government. *Types of Discrimination (protected characteristics)*. 2020; Available from: https://www.gov.uk/discrimination-your-rights.
32. Hughes, L., et al., *Excellence in elective hip and knee surgery: what does it look like? A positive deviance approach.* Journal of Health Services Research & Policy, 2020. **25**(1): p. 5-12.
33. NIHR. *Improving inclusion of under-served groups in clinical research: Guidance from the NIHR-INCLUDE project. UK: NIHR.* 2020; Available from: https://www.nihr.ac.uk/documents/improving-inclusion-of-under-served-groups-in-clinical-research-guidance-from-include-project/25435.
34. Treweek, S., et al., *Developing the INCLUDE Ethnicity Framework—a tool to help trialists design trials that better reflect the communities they serve.* Trials, 2021. **22**(1): p. 337.
35. Scantlebury, A. and J. Adamson, *Conducting a large, longitudinal, multi-site qualitative study within a mixed methods evaluation of a UK national health policy: reflections from the GPED study.* International Journal of Qualitative Methods, 2022. **21**: p. 16094069221140873.
36. Sheard, L. and C. Marsh, *How to analyse longitudinal data from multiple sources in qualitative health research: the pen portrait analytic technique.* BMC Medical Research Methodology, 2019. **19**(1): p. 1-10.
37. Sheard, L., *Telling a story or reporting the facts? Interpretation and description in the qualitative analysis of applied health research data: A documentary analysis of peer review reports.* SSM-Qualitative Research in Health, 2022. **2**: p. 100166.
38. Braun, V. and V. Clarke, *Reflecting on reflexive thematic analysis.* Qualitative research in sport, exercise and health, 2019. **11**(4): p. 589-597.
39. Castelli, A., et al., *Productivity of the English National Health Service: 2017/18 update.* 2020.
40. Carter, P. *Productivity in NHS Hospitals. Independent report for Department of Health and Social Care.* . 2015; Available from: https://www.gov.uk/government/publications/productivity-in-nhs-hospitals.
41. Castelli, A., et al., *Examining variations in hospital productivity in the English NHS.* The European Journal of Health Economics, 2015. **16**: p. 243-254.
42. Aragon Aragon, M.J., A. Castelli, and J. Gaughan, *Hospital Trusts productivity in the English NHS: Uncovering possible drivers of productivity variations.* PloS one, 2017. **12**(8): p. e0182253.
43. NHS England. *A guide to the market forces factor.* 2021; Available from: https://www.england.nhs.uk/wp-content/uploads/2021/12/22-23NT_Dt-Guide-to-the-market-forces-factor.pdf.
44. O'Cathain, A., E. Murphy, and J. Nicholl, *Three techniques for integrating data in mixed methods studies.* Bmj, 2010. **341**.
45. Guetterman, T.C., M.D. Fetters, and J.W. Creswell, *Integrating quantitative and qualitative results in health science mixed methods research through joint displays.* The Annals of Family Medicine, 2015. **13**(6): p. 554-561.
46. Riley, W.T., et al., *Rapid, responsive, relevant (R3) research: a call for a rapid learning health research enterprise.* Clinical and translational medicine, 2013. **2**(1): p. 1-6.



FUNDED BY NIHR | National Institute for Health and Care Research