A mixed methods evaluation of remote home monitoring models during the COVID-19 pandemic in England

STUDY PROTOCOL (v1.6 12th May 2021)

EVALUATION PHASE 2

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SCIENTIFIC ABSTRACT

Background: Delays in escalating patients' care to hospital in the COVID-19 pandemic have resulted in patients being admitted to hospital with advanced COVID-19, thus requiring invasive treatment and potential admission to intensive care. Remote home monitoring (also known as 'virtual wards') may help to reduce delays and identify at risk patients earlier. Remote home monitoring models are currently being developed and used all over the world. Services providing remote home monitoring using pulse oximetry for COVID-19 patients were developed in some areas in England during the first wave of the pandemic and subsequently. These models mainly involve patient triage, providing patients with monitoring equipment, asking the patients to record their observations, monitoring calls from staff and follow-up once patients have been discharged from the service. In November 2020, NHS England launched a national roll-out of this model of care called COVID Oximetry @ home. In addition, in January 2021, NHS England launched a national roll out of early discharge models, referred to as 'virtual wards'. Within this study we are studying both pre-hospital and early discharge models. Previous research has explored remote home monitoring for other conditions, but there is a lack of research on the effectiveness and implementation of remote home monitoring models for COVID-19. Social, political and socio-technical theoretical lenses will be used to inform this research project.

Aims and objectives:
This evaluation aims to:

1) Explore the effectiveness of COVID Oximetry @home (e.g. in relation to mortality and use of hospital services)
2) Assess the cost-effectiveness of implementing COVID Oximetry @home
3) Analyse processes of implementation of the COVID Oximetry @home service
4) Analyse patients' experiences of, and engagement with the COVID Oximetry @home service
5) Analyse staff' experiences of delivering and implementing COVID Oximetry @home

Methods:
This study will use mixed-methods.

To explore the effectiveness of COVID Oximetry @home, we will use routinely available data, management information summaries produced by the programme and hospital administrative data to estimate the impact of COVID Oximetry@home on hospitalisations and mortality, including the impact of tech-enabled oximetry. We will seek to identify variations within and between local areas implementing COVID Oximetry @home.

To identify the costs of implementing COVID Oximetry @home, we will conduct a cost analysis of implementing and running the service, and following up those who require treatment followed by a cost-effectiveness analysis to estimate the incremental cost per life saved and the incremental cost per quality-adjusted life year from using COVID Oximetry @home. We will compare costs and outcomes of digital and analogue models.

To explore processes of implementation and patient and staff experiences of receiving and delivering the COVID Oximetry @home service, we will undertake: a) a national study and b) in-depth case studies.

a) We will conduct a national survey with patients and carers, and a national survey of staff in approximately 25 NHS sites. The national survey with patients and carers will explore their experiences of receiving COVID Oximetry @home and their engagement with the service. The national survey with staff will explore their experiences delivering COVID Oximetry @home. We will also seek to explore different experiences of both

patients and staff with analogue vs digital models. Survey data will be analysed using descriptive statistics and univariate analyses.

b) For the in-depth case studies, we will conduct one-to-one interviews with a purposive sample of patients and staff from 14 selected sites. The patient interviews will include patients' experiences of receiving COVID oximetry @home and the barriers and facilitators to engagement, or will explore reasons for withdrawal or declining COVID oximetry @home. In four sites, we will also ask some of the patients and staff who have used digital solutions to narrate the process of using the technology (think aloud methodology). The staff interviews will include providers' experiences of implementing and/or delivering COVID oximetry @home and the barriers and facilitators to delivery. We will rapidly analyse the data using Rapid Assessment Procedure (RAP) sheets.

This is a collaborative project between BRACE and RSET (two NIHR HS&DR programme rapid evaluation teams) with input from our clinical advisory group (colleagues at Public Health England (PHE), NHS England (NHSE)) NHS Digital and NHSX, and with other research teams working in this area.

Patients/service user, carer and public involvement
We will involve patients, carers and public involvement throughout the project. For example: PPI members have provided input into the project and the development of the data collection tools. We will also ask for PPI input on the findings.

Timelines for delivery: We aim to obtain the necessary approvals between November 2020 and January 2021. We will aim to complete data collection and analysis for the effectiveness and cost studies between January 2021-May 2021, the national study in January 2021-April 2021 and in-depth case studies in February 2021-May 2021. We will share interim findings throughout the project. We will submit the final report in June 2021.

Anticipated impact and dissemination: We will regularly share feedback with stakeholders throughout the project on lessons learned, data collected, and patient and staff views on COVID Oximetry @home. We anticipate that this study will inform clinical practice for the current COVID-19 pandemic, but also will inform the use of remote monitoring models in other conditions and areas of the NHS. Dissemination will be facilitated through existing and new networks. We will also publish the findings in peer-reviewed journals and submit a report to the NIHR.

PLAIN ENGLISH SUMMARY

Background to the research

- During the first wave of the COVID-19 pandemic, some patients were not admitted to hospital until they were displaying advanced symptoms of COVID-19.
- These patients may then have received invasive treatments and/or been admitted to intensive care.
- Monitoring patients at home may help to reduce these delays and identify patients earlier.
- In England during the first wave of the pandemic, a number of areas established remote monitoring for COVID-19 patients. In November 2020 a healthcare service called COVID Oximetry @home was launched by NHS England for national roll out. In January 2021, NHS England launched a national roll out of early discharge models, referred to as 'virtual wards'. Within this study we are studying both pre-hospital and early discharge models.
- In COVID Oximetry @home, patients receive COVID care at home. As part of this service, patients are given an oximeter and asked to record their oxygen levels regularly. Patients are monitored and sent for further care if problems arise.
- Previous research has looked at home monitoring for other conditions, but no research has looked at whether COVID care at home is effective, how patients experience and engage with COVID care at home and how staff find delivering COVID care at home.
- To understand our findings, we will use social, political and technical frameworks.

Aim of the research

This research aims to evaluate the COVID care at home service, including its effectiveness, cost-effectiveness, whether it can be implemented successfully in practice, and patient and staff experiences of engagement and delivery.

Design and methods used

This research will use a range of different methods to answer specific questions:

To find out whether COVID care at home reduces COVID related deaths and ensures appropriate use of hospital services, we will analyse evidence and information that is already available together with information provided by the service and the data hospitals collect for their administration systems. We will look at differences across different areas offering COVID care at home.

To find out how much it costs to provide COVID care at home, we will ask those delivering and implementing the service to provide information on how long it takes to offer certain aspects of the service. We will then use this information to work out the cost of providing COVID care at home.

To find out about implementation of, as well as how patients and staff have experienced COVID care at home, we will do two things.

a) First, we will conduct a national survey with a) patients and carers and b) staff in as many NHS trusts across the country as possible. The surveys will explore patient experiences of receiving COVID care at home and staff experiences of delivering COVID care at home. We will analyse this data using descriptive statistics (e.g. percentages).
b) Secondly, we will carry out case studies in 14 selected NHS sites. We will speak with patients who have received COVID care at home, or who have withdrew from receiving care or declined care. We will also speak with staff who have set up or

delivered COVID care at home. These interviews will help us to find out more about how people experienced receiving or delivering COVID care at home and the things that help or get in the way. In four sites, we will also ask some of the patients and staff who have used digital solutions to talk us through using the technology.

This is a collaborative project between BRACE and RSET (two NIHR HS&DR programme rapid evaluation teams) with input from colleagues at Public Health England (PHE), NHS England (NHSE), NHS Digital and NHSX, and with other research teams working in this area.

The project started in November 2020 and will finish in June 2021.

Patients/service user, carer and public involvement
We will involve patients, carers and public involvement throughout the project. For example, we have already spoken with some patient representatives and healthcare professionals to find out their views on the project and the types of questions that we will ask during the surveys and interviews. We will also be piloting the survey and interview questions with patients who have received COVID care at home, and staff who have delivered COVID care at home. Later on in the project, we will also ask for patient and healthcare professionals' views on our findings.

Dissemination
Throughout the project, we will regularly share feedback on findings. We will share this information through our networks and findings will be available on our website. We aim to publish our findings in academic journals and submit a final report to our funder, the National Institute for Health Research.

Why is this research important to patients/the NHS?
This research is important to patients and the NHS, as it will help us to find out if healthcare services that require patients to monitor at home are effective, affordable and suitable and practical for both patients and healthcare professionals. Our learning from this research may also help us to consider whether and how home monitoring models should be used moving forward in the COVID-19 pandemic but also for other conditions.

BACKGROUND

Delays in the escalation and admission of patient cases during the COVID-19 pandemic has led to the admittance of patients with advanced course of the disease, requiring invasive treatment and potential admission to ICU. Research suggests that delays in admission increases patient mortality (Alaa et al, 2020). Remote home monitoring models (sometimes referred to as 'virtual wards') seek to remotely monitor patients considered high-risk of deterioration at home to: 1) avoid unnecessary hospital admissions (appropriate care at the appropriate place), and 2) escalate cases of deterioration at an earlier stage to avoid invasive ventilation and ICU admission. Remote home monitoring models have been implemented in the US, Australia, Greece and UK, with some variation in the frequency of patient monitoring, modality (telephone or video calls and use of applications or online portals), patient criteria and use of pulse oximetry (Margolius et al. 2020; Karampela et al. 2020; Thornton 2020; Hutchings et al. 2020; Kricke et al. 2020; Annis et al. 2020; O'Keefe et al. 2020; Ford et al. 2020; Nunan et al, 2020). There is emerging evidence that community oxygen saturation predicts outcomes, including mortality and ICU admission (Inada-Kim et al, 2020).

In the UK, several remote home monitoring models have been documented with the aim outlined above (this does not include models operating as an early discharge service following hospital inpatient stay). These models have mainly involved the following processes: 1) patient triage through 111, GP practice, hot hub (or emergency department (ED) for those in secondary care), 2) patient provided with pulse oximeter, patient information (including escalation warning signs and what to do) and mechanism for recording observations regularly (app or paper diary) (potential observations being symptoms, pulse, heart rate, temperature, O2), 3) patient receives regular monitoring calls from staff (either primary or secondary care depending on model). Symptoms and trends of O2 saturations are monitored. Modality/frequency of surveillance at clinician discretion. Calls are used to identify cases of deterioration and inform patient of next steps, and 4) Patients expected to 'check out' around 14 days mark (when recovery expected) - follow up to check symptoms and have oximeter and diary returned.

The national roll out of remote home monitoring models was launched by NHS England in November 2020 to support the development and implementation of these models of care, including the purchase and distribution of pulse oximeters which clinical commissioning groups across England will be able to access. To date, sites have been set up across England across primary and secondary care (for pre-hospital models). In addition, in January 2021, NHS England launched a national roll out of early discharge models, referred to as 'virtual wards'. Within this study we are studying both pre-hospital and early discharge models. Despite previous research on the use of remote home monitoring models for other conditions, there is a lack of studies on the impact (effectiveness) and implementation of remote home monitoring models for COVID-19 patients, including in-depth analyses of patients' and staff's experiences of receiving and delivering care. This mixed-methods evaluation of remote home monitoring models in England will seek to address this gap by exploring the impact of the implementation of remote home monitoring models for COVID-19 patients (referred to as the CO@H programme), the costs of implementing these models, the experiences of patients with remote home monitoring, staff experiences of delivering care and the processes used to implement these models at national and local levels. The study will have a particular focus on inclusivity of these services and potential impact on inequalities.

DESIGN

This is a multi-site study that will combine qualitative and quantitative approaches to analyse the implementation and impact of CO@H. The design of this evaluation was informed by the findings from phase 1 (evaluation of remote home monitoring for Covid-19 patients during the first wave of the pandemic in England (Vindrola-Padros et al. 2020a) a systematic review (Vindrola-Padros et al. 2020b, discussions with colleagues at PHE and NHSE, sites running

or planning to implement remote monitoring, and with evaluation partners in relation to their proposed studies.

THEORETICAL LENS

We will analyse remote home monitoring models in the social and political context where these are designed and implemented (including the clinic and home), the multiple realities, assumptions and values that play a role in their implementation, the organisational structures that shape experiences of receiving and delivering care and the sociopolitical issues that frame the development, diffusion and use of technology (Leheoux and Blume 2000). This lens goes beyond an analysis of remote home monitoring solely as a technological innovation to consider dimensions such as: self-management, accountability and clinical responsibility, 'personalised care', inequalities in access to care and 'caring at a distance' (Greenhalgh et al. 2015, 2017; Powell et al. 2010).

Furthermore, Greenhalgh et al. (2017) provide an example of a suitable framework with a socio-technical lens that incorporates non-adoption, abandonment, and challenges to the scale-up, spread, and sustainability (NASSS) of technologies for health and social care. This includes expected and necessary changes/adaptation to staff working practices and the context for widespread use of the technology. This framework (informed by theory and evidence) describes the barriers to successful uptake of innovations and provides a guide to the type of issues that should be considered by evaluators (Greenhalgh et al., 2017).
We will use these frameworks as a sensitising device, to inform the development of questions in the surveys and interviews, and to help in the interpretation of findings.

RESEARCH QUESTIONS

***Workstream 1*:** Is CO@H associated with mortality and use of hospital services?
Workstream 2: What are the costs of CO@H and is it good value for money?
Workstream 3 and 4:

- What are the factors influencing delivery of CO@H? Do these vary by type of model, geography, mode of remote monitoring approach (digital or paper/phone)?
- What are the experiences and behaviours (i.e. engagement with CO@H, use of other services) of patients in CO@H? Do these vary by type of model, patient characteristics, mode of remote monitoring?
- Are there potential impacts on inequalities?
- What are the experiences of staff delivering CO@H?

METHODS

The evaluation comprises the four workstreams outlined below.

WORKSTREAM 1: THE IMPACT OF CO@H

The aim of workstream 1 is to use routinely available data and hospital administrative data to both describe and estimate the impact of the roll out of remote home monitoring models under the CO@H programme.

We will investigate four separate questions:

1. How do hospitalisations and mortality due to COVID-19 compare before, during and after implementation within each implementing area and between areas?

   We will use routine data reported at (or mapped to) area level and, subject to the completeness of the data, use a modelling approach that accounts for population characteristics, dates of implementation and levels of uptake. The proposed outcomes will be mortality and hospitalisations due to COVID-19. We will explore the use of time

series regression models, such as interrupted time series, to account for varying dates of implementation and the development of implementation plans over time,. If uptake is variable between sites, we will also investigate dose-response models during the implementation period.

2. How do virtual ward (early discharge from hospital) models impact the frequency and characteristics of people readmitted for COVID 19?

   We propose an analysis focussing on patients admitted with COVID-19 which compares COVID-19 readmissions between areas before and after implementation. This will be analysed at an individual patient level relating the occurrence of a readmission to patient characteristics, characteristics of the previous hospital stay, and features of the local area such as use of oximetry and case volumes.

3. Is there evidence of a change in the characteristics (and experiences) of people admitted to hospital with COVID-19 that may be related to implementation of remote monitoring?

   We propose to compare the characteristics of patients admitted with COVID-19 to those admitted before CO@H is implemented within the local area, and with patients admitted during Wave 1. With this analysis we will identify variations within local areas implementing CO@H and between areas. This analysis will allow us to describe the effect of CO@H on admission characteristics and hospital experiences, such as lengths of stay and use of mechanical ventilation. We will also investigate issues around equity of access: for example, by analysing any influences on admissons of different ethnic groups.

   4.Does the use of tech-enabled oximetry have a measureable effect on mortality and hospitaliations?

   We propose to enhance the models we will be creating as part of the main study with the inclusion of information on the extent to which different CCGs onboard patients with tech-enabled oximetry. Our rationale is that if it does affect outcomes in a different way to the analogue model, then it might explain some of the differences we observe between CCGs. We have negotiated the receipt of aggregated data by CCG from the national programme. Since patient age might be a confounding factor, given that younger patients among the over 65's may be more likely to use the tech-enabled approach, we are also planning to receive data further disaggregated by broad age bands (e.g. <50, 50-64, 65-79, 80+). As wider context, we will also report on the ratio of tech-enabled to analogue approaches across CCGs and over time, and report on the variety of tech-enabled products being adopted by different CCGs.

We will also carry out analysis of the impact on non-COVID patients (e.g. mortality, and hospitalisations) to investigate any impacts on the availability and access of health services as a whole during the pandemic.

Much of the data required to undertake these analyses are already available. We will require dates of implementation of home monitoring models and data on uptake to be provided by Kent, Surrey and Sussex AHSN and NHS Digital. Monitoring uptake would require regular feeds of information about the number of people using pulse oximetry which can then be compared against the number of positive tests in the area for the eligible population. Incidences of infection are being sought from Public Health England.

Patient level analyses of COVID-19 admissions and readmissions will be undertaken with inpatient Hospital Episode Statistics (HES) data. HES data will be analysed on a secure server

based at the Nuffield Trust, which acts as the data processor for these data, with University College London and the Nuffield Trust acting as joint data controllers. The access and use of HES data for this project is governed by a data sharing agreement with NHS Digital covering NIHR RSET work DARS-NIC-194629-S4F9X.

Mortality data are readily available from ONS by local authority, but not further subdivided by age. We are sourcing this further level of detail from Public Health England (PHE). Changes in local implementation plans will be identified in the data collected by Kent, Surrey and Sussex AHSN and by discontinuities in the data.

Table 1. Data requirements and availability

Item	**Source**	**Period of reporting**	**Available granularity**
Mortality from COVID-19	PHE	Weekly (week of occurrence)	By age and CCG
Mortality from other causes	ONS (deduced by subtracting COVID mortality from all-cause mortality)	Weekly (week of occurrence)	By local authority
Hospital admissions, readmissions and inpatient experiences	HES	Daily (from patient-level episode data)	Whatever is available in HES: includes age, LSOA of residence, gender, ethnicity etc.
Positive test results/cases	Test and Trace (gov.uk) /PHE	Weekly	Age and LA
Incidence of COVID-19	PHE	Weekly	Age and CCG
Use of mechanical ventilation	NHSE	Daily	Hospital
Dates CO@H implemented	NHS Digital/ Kent, Surrey and Sussex AHSN	Weekly	CCG, hospital trust and sites of implementation
Uptake of oximetry by area among those who are eligible	NHS Digital via Imperial team		Age, CCG, technology
Uptake of vaccinations among eligible, and wider population	NHSE/PHE (TBC)		Not yet available
Local population characteristics	ONS	Generally annual	Age and LSOA

WORKSTREAM 2: ECONOMIC ANALYSIS

The aim of workstream 2 is to conduct an economic analysis of remote home monitoring models within the CO@H programme. This will comprise: (A) a cost analysis of (1) implementing and (2) running the CO@H sites in the programme plus (3) treating patients whose health deteriorates and who are, as a consequence, followed up in the ED, and/or outpatient and inpatient settings including the ICU; and (B) a cost-effectiveness analysis combining the results from (A) with data of the impact of remote home monitoring on survival to estimate the incremental cost per life saved and the incremental cost per quality-adjusted life year (QALY) gained of remote home monitoring models under the CO@H programme. In addition we will run this analysis to compare the digital and analogue models.

Implementing and running costs for remote home monitoring models under the CO@H programme

Remote home monitoring models at each of the study sites will be costed using data on staffing (paid staff and volunteers) and non-staff resource use during the second wave. The cost analysis will be conducted separately for all the sites in the CO@H programme using a similar data collection form to Phase 1. We will also explore how the costs of CO@H vary when comparing digital and analogue models. Contacts at each site will be asked to complete the form using Microsoft word, and to electronically return the form to the research team. Data will be checked and cleaned before analysis. We will calculate the costs of staff and non-staff inputs (e.g. number of pulse oximeters) and divide this by the total number of patients to calculate the mean cost per monitored patient.

Costs of treating patients whose health deteriorates

We will include the costs of ED and outpatient visits, and inpatient stays including in the ICU and days on mechanical ventilation. Resource use data will be obtained from the Proposed National Dataset for the CO@H evaluation (we have agreed to work with Imperial on this analysis), plus the planned analyses for workstream 1, and costed using national tariffs. Regression analyses will be used to calculate mean costs per patient undergoing remote home monitoring and in the comparator group. Our central estimates will be based on analyses of the Proposed National Dataset for the CO@H evaluation, assuming an appropriate comparator can be found; workstream 1 data will be used in sensitivity analyses.

Measuring outcomes

We will account for the impact of the remote home monitoring models on mortality based on the outcomes from the Imperial and IAU evaluations and workstream 1. Combining data on the age of patients with residual life expectancy data from actuarial life tables will allow us to produce estimates of the differences in residual years life lost between remote home monitoring and the control. These residual years of life lost will be discounted and quality-of-life-adjusted using EQ-5D age-related population norms and published utility estimates from the CEA Registry at Tufts Medical Center (https://cevr.tuftsmedicalcenter.org/databases/cea-registry). We will also account for reductions in quality of life among patients whose health deteriorated but who did not die based on published data on the duration of COVID-19 infection and published utility estimates from the above source. Both elements combined will allow us to estimate the QALY differences associated with remote home monitoring. These differences will be combined with the calculated cost differences described above to calculate the incremental cost-effectiveness of remote home monitoring models.

Budget impact

We will combine the incremental costs described above with data on projected numbers of patients per site and nationally to estimate the local and national impact of the rollout of CO@H.

Digital vs analogue models

We will conduct the same economic analysis to compare the costs and benefits of digital and analogue models using data from the main study supplemented with new patient level data. The analyses will include (A) implementing and running costs for different remote home monitoring models, (B) the cost of treating patients whose health deteriorates, and (C) measuring outcomes. For (A), implementation costs will be collected at the site level as part of the main evaluation. To calculate running costs we will collect new data from 4 sites which will be studied in-depth (see WS4 below), where we will collect data on the time spent per patient on different activities (e.g., patient triage/risk stratification, patient information and training, patient monitoring, patient data reporting, tools for flagging deterioration, escalation processes, patient discharge from ward) depending on the technology used. For (B) we will use the data collected for the main evaluation including the costs of ED and outpatient visits, and inpatient stays including in the ICU and days on mechanical ventilation. Regression

analyses will be used to calculate mean costs per patient using different digital versus analogue models. For (C) we will investigate the impact of digital and analogue models on mortality based on the outcomes from the Imperial evaluation and Workstream 1. Combining data on the age of patients with residual life expectancy data from actuarial life tables will allow us to produce estimates of the differences in residual years life lost between remote home monitoring and the control. These residual years life lost will be discounted and quality-of-life-adjusted using EQ-5D age-related population norms and published utility estimates from the CEA Registry at Tufts Medical Center (https://cevr.tuftsmedicalcenter.org/databases/cea-registry), allowing us to estimate the QALY differences associated with digital and analogue models. These differences will be combined with the calculated cost differences described above to calculate the incremental cost-effectiveness of digital and analogue models remote home monitoring models under the CO@H programme.

WORKSTREAM 3: NATIONAL STUDY OF IMPLEMENTATION, PATIENT AND STAFF EXPERIENCE

The aim of this workstream is to a) understand the development of the national CO@H programme and b) analyse the implementation of CO@H, and patient and staff experiences of care in sites across the country.

Understanding the national CO@H programme

In order to develop the theories of change guiding the development of the national programme, as well as capture changes in design and implementation over time, we will conduct a small number of interviews with national leaders and analysis of key documents.

Interviews with national leaders

National leaders working on the development and supporting the implementation of CO@H at will be sampled purposively, capturing the views of key leaders with different roles across organisations (i.e.NHSE/I, NHS Digital, NHSX, etc.). We aim to carry out 4-5 interviews at national level.

Documentary analysis of national CO@H programme

This analysis will include documents developed at a national scale, including standard operating procedures (SOPs) and other guidance for sites.

Staff survey

Survey design and data collection

We will carry out a national survey capturing staff experiences of CO@H – the survey will be conducted in approximately 25 sites on a range of criteria (see table 2 below). The survey will be targeted at staff setting up, managing and delivering the service, including any volunteers. Different sets of questions will be developed for these groups of staff (i.e. one for service leads and one for staff delivering the service). The main purpose of the survey will be to gather information on the staff involved in delivering CO@H, different set-up processes and models implemented, staff experiences of implementing these models, and factors influencing delivery. As part of the survey we will also seek to explore different experiences of analogue vs digital models. The survey will include a number of closed questions focused on documenting staff experiences of setting up, managing and delivering the service. These questions will be followed by a single, open text question at the end to give participants the opportunity to share any wider thoughts. To reduce burden and maximise response rates, the online survey will take no longer than 15-20 minutes to complete. It will be delivered using an online platform (REDCap). The survey will be piloted with a small number of sites to determine whether questions are appropriate and relevant to research questions and their role, while identifying areas for further refinement prior to circulation nationally.

Recruitment

Staff will receive an email from their practice/hospital or other relevant networks with a link to fill out an online survey (see also Table 2). If they follow the link, they will reach an information page which provides background to the study, potential risks and a description of how the data will be used to ensure informed and voluntary participation. It will be made clear that individual responses will be treated confidentially and reported anonymously. Case study sites will be asked to keep a record of the number of surveys they have sent out to determine staff response rates. This page also includes a box staff can tick to indicate their consent to take part in the study. NHS case study sites will circulate the survey to staff completed surveys will be returned directly to the study team, through the online survey platform (REDCap), for analysis.

Data analysis
The quantitative data will be analysed using statistical software. Descriptive statistics will be used and depending on the number of responses received, we will use univariate analyses to compare staff experiences of delivering the service across staff groups and service models. Interviews with national leaders will be despectively interpretated using RAP sheets (Vindrola-Padros et al. 2020c).

Patient/carer survey

Design, data collection and sampling
The aim of the survey will be to capture the experiences of patients who received CO@H, and their engagement with the CO@H service. If patients are not able/willing to take part in the survey, they will be able to allow their carer to complete the survey on their behalf, reflecting on the patient's experience with the service. The survey will be sent to patients who have received care at participating sites by NHS staff . The survey will include a number of closed questions focused on: socio-demographic characteristics, the service that patients have received, their experience with the service and their engagement with the service. As part of the survey we will also seek to explore differences between analogue vs digital models. These questions will be followed by a single open text question at the end to give participants the opportunity to share any wider thoughts. To reduce burden and maximise response rates, the online survey will take between 15 and 30 minutes to complete. Case study sites will be asked to keep record of the number of surveys they have sent out to determine patient response rates. It will be delivered using the online platform REDCap. We will aim to pilot the survey via a small number of sites with some patients/carers who have received CO@H to determine whether questions are appropriate and relevant, while identifying areas for further refinement prior to circulation nationally. Study sites will circulate the surveys to patients, patients will then return completed surveys directly to the study team for analysis, either electronically through REDCap or via post using pre-paid envelopes.

In addition to English, we will also offer the information sheets for the patient survey and the survey itself in six other languages (Polish, Bengali, Urdu, Punjabi, French and Portuguese).

Recruitment, consent and administration of the survey
When a patient is discharged from the remote home monitoring service in any of the sites that have decided to take part in the national-level study, they will be approached by NHS staff to take part in a survey in one of two different ways: 1) if the patient was monitored through the use of an app, they will receive a SMS with a link to the online survey, 2) if the patient was monitored through regular phone calls and a paper-based recording method, they will receive the survey in the post (with a pre-paid addressed envelope). NHS staff will distribute the online and paper version of the survey so the research team will have no access to patient information. Both survey options (online and paper) will include prefacing information with a background to the study, potential risks, indicating voluntary participation, anonymity and a

description of how the data will be used. This page also includes a box patients can tick to indicate their consent to take part in the study.

The method of administering the suvey i.e. NHS staff sending to patients means that there will be no reminders. Due to capacity, we are unable to conduct the survey with patients over the phone. NHS staff will be asked to record the number of surveys that they have distributed allowing us to determine response rate.

Data analysis
The quantitative survey data will be analysed using statistical software. Descriptive statistics will be used and depending on the number of responses received, we will use univariate analyses to compare patient experiences of the service across patient groups and service models (as reported by patients and carers). We will offer to carry out site-specific analyses of patient experience data for sites that request this information.

WORKSTREAM 4: IN-DEPTH CASE STUDIES OF IMPLEMENTATION, PATIENT AND STAFF EXPERIENCE
The aim of this workstream will be to document the implementation of CO@H (including the identification of factors acting as barriers and enablers in implementation), staff experiences of delivering the service and patient experiences of care in a sample of 14 sites. This workstream will provide a more in-depth exploration of staff and patient experience, capturing the experiences and behaviours (i.e. engagement with CO@H, use of other services, knowledge of escalation processes, safety-netting, etc.) of patients who received the CO@H service, and where possible, include those who withdrew from the service and those who were offered the service, but declined participation. In four of these sites, we will conduct an in-depth comparison of digital vs analogue models. This workstream will draw out potential implications for these models of care for patients with conditions other than COVID-19.

Both staff and patient interview guides will be piloted with a small number of sites to determine whether questions are appropriate and relevant to research questions and their experience of engaging with patients while delivering CO@H, and identifying areas for further refinement prior to circulation nationally. The interviews will be semi-structured, audio recorded (subject to consent being given), 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.

Staff interviews

Data collection
We will undertake semi-structured interviews with a purposive sample of staff from 14 selected sites implemented during waves 1 and/or 2 of the pandemic and NHS clinical/strategic leads working on the implementation of CO@H at a national level. Sites will be selected based on characteristics such as geographic location (with regard to socio-economic deprivation), healthcare sector (primary care, secondary care or both), type of model (pre-hospital, early discharge or both), mechanism for patient observation reporting (app, paper-based or both) and stage of implementation (implemented in wave 1, wave 2 or both) (see Table 2). We will carry out interviews by telephone or using an online platform such as Zoom or MS Teams to help build rapport with participants. An analysis of internal documents developed by these sites will also be conducted. The interviews will focus on capturing data relevant to theories of change (Weiss, 1995) guiding the design and implementation of remote home monitoring models, staff experiences of implementing the models during waves 1 and/or 2 of the pandemic, processes used to implement the models (including factors that acted as barriers and enablers), the allocation of resources during implementation and decisions made in relation to the collection of patient data and expected outcomes (at local and national levels), and potential implications of this model of care for conditions other than COVID-19. In addition,

in four sites, we will also ask some of the staff who have used digital solutions to narrate the process of using the technology (think aloud methodology) (Eccles & Arsal, 2017).

Table 2. Sampling characteristics for study sites

Variables	Description
Setting	Secondary care Primary care
Type	Pre-hospital Early discharge Both
Mechanism for patient monitoring	Paper-based App (different types of digital platform) Both
Geographic location	Different areas of the country
Timing of implementation	Implemented since wave 1 of the pandemic Recently implemented (from wave 2 onward)
Involvement in evaluation with Imperial and IAU	

Interview sampling

The interviews will be carried out with a purposive sample of study participants that will be designed in relation to the sampling framework outlined in Table 3 and will grow throughout the study due to snowball sampling. We will aim to carry out interviews with 3-4 staff members at each site (including lead, staff delivering the service and staff with data knowledge) for a total sample of 42-56 staff interviews.

Table 3. Sampling framework for interviews with staff members

Participant category	**Number of interviews**
Site lead	14 (1 per site)
Staff delivering the service	14-28 (1-2 per site)
Staff with knowledge of data collection/use	14 (1 per site)
Total	**42-56 interviews**

Recruitment and consent processes for staff interviews

In the case of staff interviews, the researcher will contact potential participants via email and will send them a participant information sheet. Participants will then be given 48 hours to review the information and ask questions about the study. If the participant agrees to take part in the study, they will be asked to sign the consent form. The researcher will then arrange a time to carry out the interview over the phone or an online platform (Zoom or MS Teams). Staff will be also be offered the alternative to take part in a group interview (where feasible) if completing an individual interview is not possible. An informed consent process using participant information sheets and written consent (scanned forms or typewritten/electronic signature) will be used for recruitment to ensure informed and voluntary participation.

Data analysis

Data collection and analysis will be carried out in parallel and facilitated through the use of RAP sheets as explained in Vindrola-Padros et al. (2020c). RAP sheets will be developed per site to facilitate cross-case comparisons and per population (to make comparisons between sub-groups). The categories used in the RAP sheets will be based on the questions included in the interview topic guide, maintaining flexibility to add categories as the study is ongoing.

Patient/carer and Carer Interviews

Data collection
The interviews with patients and carers will focus on documenting their journeys of remote home monitoring, their experiences of being ill and monitored at home, experiences with escalation and discharge, their engagement with the service, and recommendations for improving these models.

Patient information sheets and consent forms for the interviews will also be translated and offered in six other languages (Polish, Bengali, Urdu, Punjabi, French and Portuguese). The study team can provide a telephone based interpretation service to help them to complete the interview. Interpretation services are available for speakers of the following languages: Polish, Bengali, Urdu, Punjabi, French, and Portuguese.

If patients are not able/willing to take part in the interview, we will ask patients if we can approach their carer (if they have one) to capture their perceptions of the patient's journey and overall experience with the service. During the interview, we will ask patients/carers some brief questions relating to socio-demographic characteristics including whether they are a patient or carer, age, gender, ethnicity, how many people they live with, education and qualifications, employment status, English as a first language, disability and postcode (the latter to be used as indicator of social deprivation). We will emphasise that as with all parts of the interview, these questions are optional. In addition, in four sites we will also ask some of the patients who have used digital solutions to narrate the process of using the technology (think aloud methodology) (Eccles & Arsal, 2017).

Interview sampling
The semi-structured interviews with patients will also follow a purposive sampling approach. Patients will be sampled in relation to their age, gender, ethnicity, deprivation score (by postcode), employment status, comorbidities, mechanism for onboarding, type of monitoring approach, remote length of stay, and outcome (including those who withdrew from the 'virtual ward' and those who were escalated) in order to be inclusive and capture as wide a range of responses as possible. These same patient characteristics will be taken into consideration when developing the sampling for the carers. If possible, we will also seek to include patients who refused to receive care through a virtual ward and patients who dropped out (and their carers if patients are not able/willing to take part). We will aim to recruit 6 patients and/or per study site.

Recruitment and consent processes for patient and carer interviews
Staff leads will first contact potential patients to see if they are happy to be approached by a researcher. This will include patients who have received the CO@H service, those who have withdrawn and those who have declined the service. If they agree, the researcher will then contact the patient/carer via telephone or email to discuss the study. If the patient/carer is contacted via phone, they will be asked if a participant information sheet and consent form can be sent via email. If they prefer post and are unable to send the consent form electronically, both of these documents will be sent via post with a pre-paid addressed envelope so they can return the signed consent form to the team. Due to COVID-19 and current lockdown restrictions, we are currently unable to access our office premises to retrieve signed consent forms. Therefore, in addition to asking patients and carers to post their consent forms back to us, we will also take verbal consent (audio-recorded) at the start of the interviews from patients/carers who choose to send their consent form via post. The researcher will then contact them to arrange a time to carry out the interview. Interviews will be carried out via telephone or an online platform (e.g. Zoom or MS Teams) as preferred by the patient. If patients are not able/willing to take part in the interview, we will ask patients if we can approach their carer (if they have one) to capture their perceptions of the patient's journey and overall experience with the service.

If the patient is contacted via email, the participant information sheet and consent form will be sent in a subsequent email and the patient will be given the option to schedule a call with the researcher to discuss the study. The participant information sheet will contain information on the study, potential risks and a description of how the data will be used to ensure informed and voluntary participation. If the patient/carer agrees to take part in the study, they will be instructed to email back the signed consent form (scanned forms or typewritten/electronic signature). Interviews will be carried out via telephone or an online platform (e.g. Zoom or MS Teams) as preferred by the patient. If patients are not able/willing to take part in the interview, we will ask patients if we can interview their carer alone..

Data analysis for the interviews
Data collection and analysis will be carried out in parallel and facilitated through the use of RAP sheets as explained in Vindrola-Padros et al. (2020c). RAP sheets will be developed per site to facilitate cross-case comparisons and per population (to make comparisons between sub-groups). The categories used in the RAP sheets will be based on the questions included in the interview topic guide, maintaining flexibility to add categories as the study is ongoing.

Documentary analysis
This analysis will include documents on the models developed by the 14 selected sites (including standard operating procedures, information developed for patients and carers). The documentary analysis will be used to develop the theories of change and logic models guiding the sites as well as capture changes in design and implementation over time. The documentary analysis will also allow us to identify if there were instances of cross-fertilisation or sharing of information across sites. Documentary analysis and interviews will be used to understand key broad contextual factors such as population served, geography and availability of other services.

INTEGRATION OF FINDINGS ACROSS ALL WORKSTREAMS
The RAP sheets mentioned above will be developed at site level (1 per research site) and at population level (including sub-groups of staff and patients) for the 12 sites involved in workstream 4. Data from all four workstreams will be added to these to facilitate processes of triangulation. Findings on local barriers and facilitators to implementation and patient and staff experiences will aid the interpretation of findings on outcomes, service use and costs. Quantitative data on resource allocation will be understood in relation to qualitative data on staff experiences of planning and delivering services. Data from the case studies will be used to explain the survey findings (representing experiences and trends at a national scale). In addition, emerging findings from this study will be discussed in relation to those from the two other evaluation partners (Imperial and IAU).

PPI
Members of the study team met with service user and public members of the BRACE Health and Care Panel and patient representatives from RSET to discuss the study, what research with patients might explore, and methods of patient recruitment to ensure inclusivity. Patient facing documents, such as the consent form, topic guides, patient survey and patient information sheet will also be reviewed by this group. We will incorporate their feedback into the study documents prior to data collection, while interpreting findings, and throughout the study. We might also engage in conversations with existing patient groups and organisations to request feedback on the study, collect additional data and/or cross-check our interpretations.

ETHICS
The study protocol will be divided into two separate protocols. (1) A protocol covering Workstreams 1 and 2 and the staff elements of Workstreams 3 and 4 will be reviewed by the University of Birmingham Humanities and Social Sciences ethics committee and the UCL/UCLH JRO as a service evaluation. (2) A protocol and materials for the patient survey

and interviews (WS3 and 4) will be submitted to the UCL/UCLH JRO for sponsorship review and to the HRA for review and approval. We are aware of the sensitive nature of this research for organisations and individuals. The research team has experience in conducting research on similar sensitive topics. We will maintain the independence of the research, follow an informed consent process, and maintain the anonymity of participants and organisations.

GOVERNANCE

This study is part of a wider evaluation of three teams: this one, The Institute of Global Health Innovation at Imperial College London & Imperial College Healthcare and The Improvement Analytics Unit at the Health Foundation. We will meet weekly with the NHS Digital CO@h Evaluation Workstream Group chaired by Professor Jonathan Benger and work in close partnership with the other evaluation teams. As a shared governance structure, we will ensure the work of the three evaluations remains joined up to garner learning as the evaluation progress. In addition, we will operate a policy of ensuring stakeholders are aware of developments of the research as it progresses through weekly stand-up meeting and have early sight of outputs for comment and agreement of publication strategy.

We will continue to work closely with the NIHR 70@70 Senior Nurse Research Leaders and our Clinical Advisory Group throughout the project to ensure the evaluation is relevant and conducted in a way that involves expert clinical input as required. The Clinical Advisory Group will be led by Dr Karen Kirkham (Integrated Care System Clinical Lead, NHSE/I Senior Medical Advisor Primary Care Transformation, Senior Medical Advisor to the Primary Care Provider Transformation team), Dr Matt Inada-Kim (Clinical Lead Deterioration & National Specialist Advisor Sepsis, National Clinical Lead - Deterioration & Specialist Advisor Deterioration, NHS England & Improvement) and Allison Streetly (Deputy National Lead, Healthcare Senior Public Health Advisor, Public Health England). The team will work with research nurse leaders from the NIHR 70@70 programme to seek advice on data collection and recruitment in relation to staff and patient survey and interviews.

The team will meet weekly throughout the duration of the evaluation. The evaluation will be discussed as a standing item at monthly NIHR RSET and NIHR BRACE meetings, in terms of progress against project milestones and to address any practical or methodological issues, and to help maintain the independence of the evaluation.

INSURANCE

University College London holds insurance against claims from participants for harm caused by their participation in this evaluation. Participants may be able to claim compensation if they can prove that UCL has been negligent. However, if this evaluation is being carried out in a hospital, the hospital continues to have a duty of care to the participant of the evaluation. University College London does not accept liability for any breach in the hospital's duty of care, or any negligence on the part of hospital employees. This applies whether the hospital is a NHS Trust or otherwise.

QUALITY ASSURANCE

This protocol has been externally peer-reviewed and reviewed by our clinical advisory group. and the NHS Digital CO@h Evaluation Workstream Group.

OUTPUTS AND DISSEMINATION

Outputs will include:

1. An assessment of the impact of remote monitoring on mortality, hospital admission, length of stay and readmission with COVID-19.
2. An assessment of the impact on the characteristics of patients admitted to hospital with COVID-19, including information that could reflect equality of access.

3. A cost-effectiveness analysis to estimate the incremental cost per life saved and the incremental cost per quality-adjusted life year gained of remote home monitoring models under the CO@H programme.
4. An analysis of patients' and staff experiences of these models, including findings in relation to inclusivity of these services.
5. An analysis of the main lessons learned during the implementation of remote home monitoring models and their effectiveness during waves 1 and 2 of the pandemic (including use of data and staffing models). This will include implications for the development and improvement of these services for COVID-19 patients (including those diasadvantaged communities) and other conditions.

We will regularly share feedback with stakeholders on: (1) lessons learned during the implementation of the models during wave 2 of the pandemic; and (2) data collection by sites and their use, and (3) patient and staff views and experiences of CO@H. We will offer to carry out site-specific analyses of patient experience data for sites that request this information. Dissemination to sites will be facilitated through existing and new national and regional networks (e.g. the Communities of Practice group, COVID Oximetry@ Home Learning Network).

We aim to present findiings are relevant conferences and publish findings in peer reviewed journals. We will submit a final report to the National Institute for Health Research, Health Services and Delivery Research programme (NIHR HS&DR)

In addition, we plan a range of dissemination methods to reach different audiences. These will be developed with input from the Nuffield Trust communications team and National Voices to disseminate to orgamisations that represent NHS staff as well as patients and carers. These may include:

- a range of slide packs to share findings with a range of key audiences including primary and secondary care clinicians, commissioners, policymakers and patients/carers facilitated through existing (the NHS Communities of Practice group, COVID Oximetry@ Home Learning Network) and new networks
- Appropriate non-expert forms of dissemination e.g. videos, blogs, podcasts.

DATA MANAGEMENT

Data will be managed in line with legal and regulatory requirements, including the General Data Protection Regulation (GDPR) and the Data Protection Act (2018), and necessary research approvals.

Professor Naomi Fulop will act as the data controller for this study. She will process, store and dispose of all data in accordance with all applicable legal and regulatory requirements, including the General Data Protection Regulation (GDPR) and the Data Protection Act (2018) and any amendments thereto. Data will not be transferred to any party not identified in this protocol and are not to be processed and/or transferred other than in accordance with the patients' consent.

Workstream 1

Much of the organisational-level data required to undertake these analyses are already publicly available. Other data, at an organisation level, will come from management information systems provided by Kent, Surrey and Sussex AHSN and NHS Digital, that are supporting the implementation programme. We are sourcing data on incidence of Covid and mortality from Public Health Engand via secure data transfer.

HES data will be analysed on a secure server based at the Nuffield Trust, which acts as the data processor for these data, with University College London and the Nuffield Trust acting as joint data controllers. The access and use of HES data for this project is governed by a data sharing agreement with NHS Digital covering NIHR RSET work DARS-NIC-194629-S4F9X.

Workstream 2
The research team will distribute a copy of the data collection tool to contacts at participating sites. Participants will complete the form using Microsoft Word and will be asked to return it to the research team via email. Data from the completed data collection tool will be stored securely using password protected spreadsheets to which only the research will have access to.

Workstream 3
The research team will develop the surveys using an online platform (Opinio and/or REDCap). A paper copy of the patient survey will also be available. Surveys will be sent to patients and staff by the individual NHS sites. NHS sites will be asked to circulate the survey using their individual site ID. Therefore, researchers will not have access to any patient or staff contact details. Surveys will be returned to the research team, either electronically through Opinio/REDCap, or by posting completed surveys in pre-paid envelopes to our RSET team members at the Nuffield Trust or UCL. Surveys received via post will be stored securely in locked filing cabinets within secure Nuffield Trust or UCL offices. Data from patient surveys sent via post will be either inputted into REDCap by members of the research team or securely transferred into the Data Safe Haven (using the Data safe haven file transfer portal). Data from the patient surveys will be directly stored in the UCL Data Safe Haven via REDCap, as this will include identifiable information (postcode data). Data from the completed surveys will be stored securely using password protected spreadsheets to which only the RSET and BRACE researchers will have access to.

Workstream 4
Patient and staff interviews (qualitative data) will be recorded on an encrypted, password-protected digital recorder (only the researcher will know the password). Data will be collected by a team of qualitative researchers from RSET (University College London and Nuffield Trust) and BRACE (University of Birmingham and RAND Europe).

Patient consent forms and audio-recordings of interviews will be securely transferred using the Data Transfer portal onto the UCL Data safe Haven (a secure electronic environment, certified to ISO27001 information security standard and conforms to the NHS Information Governance Toolkit). Once transferred onto the Data Safe haven, the data will be cleared from the Dictaphone. Patient consent forms received via post will be posted to our RSET team members at the Nuffield Trust. Patient consent forms received via post will be stored securely in locked filing cabinets within the secure Nuffield Trust office.

Digital audio-recordings of patient and staff interviews will be sent to a UCL-approved contractor for transcription (TP transcription limited). Transcripts will be fully anonymised (names and places) and organised by participant codes. Anonymised transcripts and other relevant data will be stored in a secure folder to which only the named researchers (RSET and BRACE qualitative team) have access. Only the research team will have access to participants' personal data (i.e. name and contact details). A password protected spreadsheet of interviewees and their contact details will also be held on the Data Safe Haven. Participant identifier codes will be stored in the DSH and kept separate from study data. Data will be shared between UCL and University of Birmingham researchers using the DSH.

TIMELINE * (see Figure 1)

- *Study design*: September/November 2020
- *Data collection and analysis for quantitative impact study begins:* February 2021
- *Data collection for economic analysis study begins:* February 2021
- *Data collection for national study of implementation, patient and staff experience begins*: February 2021
- *Sharing descriptive quantitative analyses of areas*: March 2021
- *Data collection for in-depth case studies of implementation, patient and staff experience begins*: February 2021
- *Sharing emerging findings, including interim quantitative findings*: May/June 2021
- *Data collection for qualitative implementation study ends*: May 2021
- *Data collection and analysis for quantitative impact study ends:* May 2021
- *Data collection for economic analysis study ends:* May 2021
- *Data collection for patient experience study ends*: May 2021
- *Submission of final report*: July 2021

Figure 1. Gannt Chart

	2020				2021						
	Sept	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	July
Study design											
Data Collection & analysis											
Quantitative impact study											
Economic analysis											
National study of implementation, patient and staff experience											
In-depth case studies											
Sharing descriptive quantitative analyses of areas											
Sharing emerging findings (incl. quant findings)											
Submission of final report											

*these dates are dependent on HRA approvals of patient experience elements, gaining access to sites and response rates. The timeline could vary due to engagement with the study and barriers created by COVID-19, including delivery of vaccination programme.
We describe potential risks and mitigation strategies, relevant to each of our workstreams in Table 4 below.

Table 4: Potential risks and mitigation strategies

	Risk	Impact	Likelihood	Mitigation
WS 2, 3, & 4	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 general practice and acute trust staff could suspend participation in this evaluation if the transmission of the virus increases either locally and/or nationally and/or need to focus their attention predominantly on the national vaccination programme. The principal investigator for the project will communicate with senior NHS leads, and seek guidance from NHS Digital and NIHR HS&DR if such a situation occurs and will act accordingly.
WS1, 2, 3, & 4	Loss of key staff	High	Low	There is a large project team, in the event of one member leaving there is capacity and resources for this person to be replaced from the wider team or to bring other researchers in.
WS 2, 3, & 4	Non-engagement from sites	High	Medium	The research team has built relationships with the national NHS COVID Oximetry@ Home Learning Network and other regional networks, and already received a number of expressions of interest from sites to take part in the evaluation. Team members will have on-going meetings with site delegation teams/gatekeepers, to discuss the contribution required from each party for the duration of the evaluation.
WS3	Low response rates from patient and staff surveys	High	Medium	Given our proposed method of administering the surveys (distributed by sites not the research team) means that we will not be able to send reminders, there is a risk that the study team encounters a low response rate from staff and patients completing surveys. In addition, staff and patients may only return partially completed surveys. At each participating site staff leads will be asked to encourage staff to complete surveys and remind staff to ask patients to complete surveys at discharge. The team will have designated team members to communicate with each case study site to maintain engagement with site leads.
WS4	Inability to recruit participants for interview	High	Medium	There is a risk the study may be delayed in recruiting participants because it will be the responsibility of case study sites to identify staff and patients to interview on behalf of the evaluation team At each case study site, the team will identify a key point of contact regarding participation and will be in regular contact with them. The team will produce detailed, descriptive information sheets to inform potential participants of the importance of the evaluation, why we have asked them to take part, their involvement, and associated risks and benefits.

WS1	Data is not available at a useful level of granularity	High	Medium	We are exploring different possible avenues for extracting the data we need, including offering data processing agreements between parties where necessary (e.g. with PHE). In some ways the level of granularity that is available determines the style of analysis we do. HES is patient-level data, so there is no risk there.
WS1	There is too long a lag between some of the data and the present	High	medium	Many of the data currently available is recent. With HES we would expect a lag of 6-8 weeks.
WS1	Some of the data reported from the sites are not complete	High	Medium	Strong efforts are being made by NHS Digital to improve completeness of data, but it is not guaranteed, particularly in obtaining retrospective data for the earlier periods of collection. We have different options for analysing the data depending on what becomes available.
WS3/WS4	Delays to ethical and governance approvals for patient experience aspects	High	High	Our study has been badged as an Urgent Public Health Study and we will have support from CRNs to ensure that this risk is mitigated.
WS3	Delays to accessing paper surveys	High	High	Due to being in lockdown, there may be some delays in accessing the patient surveys returned to Nuffield Trust offices. This may delay our ability to analyse this data.

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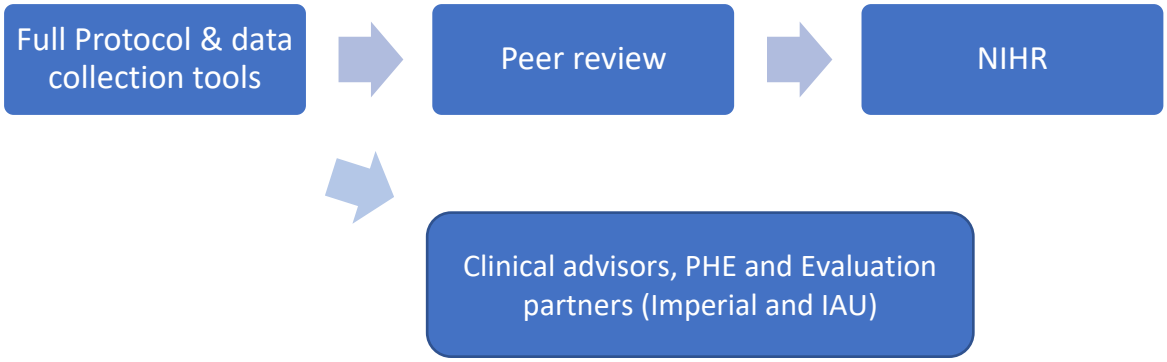
PROTOCOL APPENDICES

***Appendix 1*. Flowchart of study review processes**

1. **Full protocol**



2. **Service Evaluation Protocol**: Workstream 1, 2, 3 (staff survey) and 4 (staff interviews)

3. **Research Protocol:** Workstream 3 (patient survey) and workstream 4 (patient interviews)