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

STUDY PROTOCOL (v2.8 14th August 2020)

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BACKGROUND

Delays in the escalation 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. 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).

In the UK, at least 10 remote home monitoring models have been documented with the aim outlined above (this does not include models operating as a step-down service following hospital inpatient stay). These models have mainly involved the following processes: 1) patient triage through 111, GP practice, hot hub (or ED for those pilots 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 pilot). 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.

Despite previous research on the use of remote home monitoring models for other conditions, there is a lack of studies on the implementation of these models for remote home monitoring during the COVID-19 pandemic. This mixed-methods evaluation of remote home monitoring models in the UK will seek to address this gap in two phases: (i) by capturing the lessons learnt during the implementation of these models during wave 1 of the pandemic and (ii) evaluating the implementation of the models during wave 2.

This protocol has been developed during a four-week scoping exercise which has included initial scope of the literature (see appendix 2), discussions with each of the proposed sites (n=11), documentary analysis, and discussions with colleagues at PHE and NHSE. From discussions with a team from Imperial, our understanding is that they will be analysing retrospective data from sites operating during wave 1 of the pandemic provided to them by NHS Digital; therefore we are not proposing a quantitative analysis of outcomes in phase 1.

PHASE ONE

STUDY AIMS AND CONCEPTUAL FRAMEWORK

The aims of this study will be to: develop a conceptual map of remote home monitoring models (including their key characteristics), explore the experiences of staff implementing these models during the COVID-19 pandemic, understand the use of data for monitoring progress against outcomes, and document variability in staffing and resource allocation. We will focus on models with the following characteristics:

- Implemented during the COVID-19 pandemic (retrospective in the case of sites implemented during wave 1 of the pandemic)

- Focused on monitoring patients prior to hospital admission (although including one site using step-down ward)
- Delivered from primary and secondary settings
- Include some element of patient recording of oxygen saturation using pulse oximetry

The overall study will be guided by a conceptual lens that takes into consideration the sociopolitics of health technologies (Blume 1992; Leheoux and Blume 2000). 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).

RESEARCH QUESTIONS FOR PHASE 1

1. What are the conceptual models guiding the implementation of remote home monitoring models during the COVID-19 pandemic?
2. What are the processes that acted as barriers and facilitators in the design and implementation of pilots of these models during wave 1 of the pandemic?
3. What were the expected outcomes of the virtual wards implemented during wave 1 of the pandemic?
4. What data were collected by pilot sites and how has it helped them monitor progress against their expected outcomes?
5. What quantitative evidence have the sites used from national and international experiences of these models to help inform clinical management decisions?
6. How were resources allocated (including staffing models) to implement the remote home monitoring pilots during wave 1 of the pandemic?
7. What are the lessons learnt from implementing remote home monitoring models during wave 1 of the pandemic? Can some of these lessons be used for planning care delivery during the winter months?

DESIGN FOR PHASE 1

This is a multi-site study that will combine qualitative and quantitative approaches to analyse the implementation and impact of remote home monitoring models implemented during the COVID-19 pandemic. Phase 1 will involve a rapid qualitative study to retrospectively capture the lessons learnt during the implementation of remote home monitoring models during wave 1 of the pandemic.

Methods for phase 1

Phase 1 will be divided in two main workstreams: a systematic review of the literature and a rapid qualitative study to capture the lessons learnt during wave 1 of the pandemic.

Systematic review

We will conduct a rapid literature review of the use of remote home monitoring during the COVID-19 pandemic following the rapid review method proposed by Tricco et al. (Tricco et al. 2017). The rapid review method follows a systematic review approach, but proposes adaptations to some of the steps to reduce the amount of time required to carry out the review (i.e., the use of large teams to review abstracts and full texts, and extract data; in lieu of dual screening and selection, a percentage of excluded articles is reviewed by a second reviewer, and software is used for data extraction and synthesis, as appropriate (Tricco et al. 2017)).

The review will be divided into two parts: 1) an evidence mapping exercise to rapidly map the landscape on this topic, develop a draft conceptual map of remote home monitoring models, capture lessons learnt during implementation and develop a formal search strategy to be used in the systematic review, 2) a systematic review of the literature on remote home monitoring during COVID-19, including grey literature and peer-reviewed articles.

We will use the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) statement (Moher et al. 2009) to guide the reporting of the methods and findings. The review protocol will be registered with PROSPERO.

Review research questions

The review will seek to answer the following questions:

Evidence mapping

1. What are the key terms used to define remote home monitoring models?
2. What are the main characteristics of the current evidence base on remote home monitoring models? (i.e. type of publication, country, patient population)
3. What are the main types of remote home monitoring reported in the literature? (app-based, paper-based, primary-are-led, secondary care-led, etc.)
4. What are the lessons learnt from implementing remote home monitoring models during the COVID-19 pandemic?

Systematic review

1. What are the aims of remote home monitoring models?
2. What are the main components of these models?
3. What are the patient populations considered appropriate for remote monitoring?
4. How is patient deterioration determined and flagged?
5. What are the expected outcomes of implementing remote home monitoring?
6. How have these models been evaluated?
7. What are the benefits and limitations of implementing these models?

The systematic review protocol has been registered in PROSPERO and can be found here: https://www.crd.york.ac.uk/prospero/display_record.php?RecordID=202888

Rapid qualitative study of first wave

Qualitative fieldwork will be based on telephone semi-structured interviews with a purposive sample of staff from the eight pilot sites implemented during wave 1 of the pandemic and documentary analysis of internal documents developed by these sites (Table 1). Data collection will follow a rapid qualitative research design involving teams of field researchers, participatory approaches, and iterative data collection and analysis (McNall and Foster-Fishman 2007). The interviews will focus on capturing the theories of change and logic models guiding the design and implementation of the remote home monitoring models, staff experiences of implementing the models during wave 1 of the pandemic, and processes used to implement the models (including factors that acted as barriers and enablers). In order to start this study rapidly, we are not including patient experiences directly so that the study could be classed as a service evaluation. We will however ask staff about their perceptions of patient experience and include any data they have on this.

As part of the fieldwork, we will obtain information on the data collected during wave 1 (including the data fields, numbers of patients covered and their outcomes, and the extent to which the sites used both bespoke and standard data collection). We will also collect data on the staffing models used during wave 1 and different approaches for the allocation of resources. We will gather information on whether they have used other available quantitative

evidence to help inform clinical decisions. We will use this information to assess the value of the data in helping the sites monitor progress against outcomes as well as identify the resources used in the implementation of each of the sites. This will lead to recommendations about data collection, methodology, resource allocation, staffing models and evidence sourcing to assist with wave 2.

Documentary analysis will be used to develop the theories of change and logic models guiding the pilot 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 pilot sites.

Documentary analysis and interviews will be used to understand key broad contextual factors such as population served, geography and availability of other services.

Table 1. Sample of remote home monitoring pilot sites included in the rapid qualitative study

	Pilot site name	**Location**	**Setting**	**Implementation stage**	**Main outcomes of interest**	**Patient-reported data**
1.	Royal Free	Royal Free London Hospital	Secondary care (ED)	Started 23 March	Reattendance ED Admission 30 day mortality Patient satisfaction	Paper-based
2.	Winchester City	Winchester City PCN.	Primary care	Started 6 April	O2 saturation Use of antibiotics Admission hospital ICU admission 30 day mortality	Paper-based
3.	Winchester SDEC Covid Virtual Ward pilot - Same Day Emergency Care COVID Virtual Ward	Royal Hampshire County Hospital (RHCH)	Secondary care (ED)	Implementation (started 14 May)	Ventilation Mortality Reattendance to ED Admission ICU admission 999 call	Paper-based
4.	Royal Berkshire Hospital (TICC-19)	Reading	Secondary care (ED)	2 April	Re-admission rate Patient experience	Paper-based
5.	West Hertfordshire (Watford)	Hertfordshire	Secondary care (ED)	14 March	Readmission ICU admission Mortality	App (Medopad) and paper-based
6.	Manchester Royal Infirmary	Manchester	Secondary care (step down model)	19 March	Mortality Re-attendance Avoid unnecessary admissions	Paper-based
7	NHS Tees Valley CCG COVID-19 Virtual Ward Vanguard Bid	Tees Valley	Secondary care (step-down model), planning primary care model	Early implementation (started 8 June only for secondary care) Primary care to start early July.	Unplanned admissions Mortality Protected hospital capacity	App (My M Health)
8.	NWL	(Central London and Hillingdon CCGs)	Primary care model	?	Admission ICU admission Mortality	App + telephone

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 2 and will grow throughout the study due to snowball sampling. We will aim to carry out interviews with 3-5 participants at each pilot site for a total sample of 24-32 telephone interviews. The documentary analysis will include all documents on the remote home monitoring models developed by pilot sites.

Table 2. Sampling framework for interviews with pilot site participants

Participant category	**Number of interviews**
Pilot site lead	8 (1 per site)
Staff in charge of monitoring	8-16 (1-2 per site)
Staff with knowledge of data collection/use	8 (1 per site)
Total	24-32 interviews

Recruitment
An informed consent process using participant information sheets and written consent will be used for recruitment to ensure informed and voluntary participation. 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.

ETHICS AND DISSEMINATION

The study protocol and materials for phase 1 of the evaluation will be reviewed by the UCL/UCLH Joint Research Office. This phase 1 was classified as a service evaluation based on the HRA decision tool, thus not requiring research ethics committee approval (although protocol and materials are being reviewed by University of Birmingham Humanities and Social Sciences ethics committee). 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.

We will regularly share feedback with stakeholders on: (1) the conceptual models guiding the design and implementation of remote home monitoring models; (2) lessons learnt during the implementation of the models during wave 1 of the pandemic; and (3) data collection by pilot sites and their use, and (4) staff views and experiences with processes of implementation. We also aim to publish the findings from the systematic review and the empirical research conducted in phase 1 in peer-reviewed journals.

OUTPUTS OF PHASE 1 OF THE EVALUATION

During phase 1 of the evaluation we will generate the following outputs:

1. A conceptual map of remote home monitoring models implemented around the world (based on the evidence map and early findings from the systematic review).
2. A synthesis of main lessons learnt during the implementation of remote home monitoring models during wave 1 of the pandemic (including use of data and staffing models).

TIMELINE FOR PHASE 1
Evidence mapping exercise: complete
Systematic review: July-October 2020 (sharing emerging findings in September 2020)
Data collection complete: 28 August 2020
Data analysis complete: 4 September 2020
Report complete: 11 September 2020
Sharing of findings from phase 1 with stakeholders and discussion about phase 2 design: 17 September 2020

PHASE 2

In phase 2, we will seek to evaluate the models implemented during wave 2 of the pandemic using a mixed-methods study design. The final research questions and design of phase 2 of the evaluation will be informed by the findings from phase 1 and discussions with colleagues at PHE and NHSE, and with colleagues at Imperial in relation to their proposed study.

RESEARCH QUESTIONS FOR PHASE 2

1. Have the conceptual models guiding the implementation of remote home monitoring models during the COVID-19 pandemic changed during wave 2 of the pandemic?
2. What are the processes that acted as barriers and facilitators in the design and implementation of pilots of these models during wave 2 of the pandemic?
3. Are the benefits of the home monitoring approach being realised during a second wave?
4. How were resources allocated (including staffing models) to implement the remote home monitoring pilots during wave 2 of the pandemic?
5. What are the lessons learnt from implementing remote home monitoring models during wave 2 of the pandemic? What are the potential lessons for other conditions that may be amenable to remote monitoring at home?

METHODS FOR PHASE 2
The findings from phase 1 will be used to design a mixed-methods evaluation capturing the processes of implementation and impact of remote home monitoring models that are in operation during wave 2 of the pandemic.

Qualitative study of implementation during wave 2 of the pandemic
Qualitative fieldwork will be based on telephone semi-structured interviews with a purposive sample of staff from the 12 pilot sites implemented during wave 2 of the pandemic and documentary analysis of internal documents developed by these sites (Table 3). The interviews will focus on capturing the theories of change and logic models guiding the design and implementation of remote home monitoring models, staff experiences of implementing the models during wave 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.

The documentary analysis will be used to develop the theories of change and logic models guiding the pilot 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 pilot sites.

Documentary analysis and interviews will be used to understand key broad contextual factors such as population served, geography and availability of other services.

Table 3. Sample of remote home monitoring pilot sites included in the rapid qualitative study

	Pilot site name	**Location**	**Setting**	**Implementation stage**	**Main outcomes of interest**	**Patient-reported data**
1.	Royal Free	Royal Free London Hospital	Secondary care (ED)	Started 23 March	Reattendance ED Admission 30 day mortality Patient satisfaction	Paper-based
2.	Winchester City	Winchester City PCN.	Primary care	Started 6 April	O2 saturation Use of antibiotics Admission hospital ICU admission 30 day mortality	Paper-based
3.	Basingstoke	Hampshire – 11 GP practices	Primary care	Remote monitoring without pulse oximetry implemented since 6 April (will be shut down 17 July). Might implement a later model with PO if numbers increase.	TBD	AccuRx: Electronic system based (SMS, online questionnaires)
4.	Winchester SDEC Covid Virtual Ward pilot - Same Day Emergency Care COVID Virtual Ward	Royal Hampshire County Hospital (RHCH)	Secondary care (ED)	Implementation (started 14 May)	Ventilation Mortality Reattendance to ED Admission ICU admission 999 call	Paper-based
5.	Slough covid-19 BAME pilot project*	Slough - The Frimley Health & Care ICS	Primary care	Planning (implementation planned for second week July)	Mortality Morbidity Ventilation ICU admission	Paper-based but might use an app in the future
6.	NHS Tees Valley CCG COVID-19 Virtual Ward Vanguard Bid*	Tees Valley	Primary and secondary care	Early implementation (started 8 June only for secondary care) Primary care to start early July.	Unplanned admissions Mortality Protected hospital capacity	App (My M Health)
7.	Dorset Pilot – Pulse Oximetry and Digital Remote Monitoring	Dorset	Primary care	Early scoping (to start in 6 weeks)	Length of stay Admission	App (My M Health)
8.	Covid-19 Virtual Ward – Remote monitoring with pulse oximetry in patients with suspected COVID-19	One Gloucestershire-Churchdown Surgery	Primary care with support from secondary care	Early testing (planned rollout in late August)	TBD	Paper-based
9.	Royal Berkshire Hospital (TICC-19)	Reading	Secondary care (ED)	2 April	Re-admission rate Patient	Paper-based

					experience	
10.	West Hertfordshire (Watford)	Hertfordshire	Secondary care (ED)	Mid-March	Readmission Admission to ICU Mortality	App (Medopad) and paper-based
11.	NWL	(Central London and Hillingdon CCGs)	Primary care model	?	Admission ICU admission Mortality	App + telephone
12.	Manchester Royal Infirmary	Manchester	Secondary care (step down model)	19 March	Mortality Re-attendance Avoid unnecessary admissions	Paper-based

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 4 and will grow throughout the study due to snowball sampling. We will aim to carry out interviews with 3-5 participants at each pilot site for a total sample of 36-48 telephone interviews. The documentary analysis will include all documents on the models developed by pilot sites.

Table 4. Sampling framework for interviews with pilot site participants

Participant category	**Number of interviews**
Pilot site lead	12 (1 per site)
Staff in charge of monitoring	12-24 (1-2 per site)
Staff with knowledge of data collection/use	12 (1 per site)
Total	**36-48 interviews**

Recruitment
An informed consent process using participant information sheets and written consent will be used for recruitment to ensure informed and voluntary participation. 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.

Economic analysis
The aim of the economic analysis is to quantify the costs of different pilot sites from an NHS perspective, using a cost analysis (CA) approach. The cost analysis will be focused on the costs of implementing remote home monitoring models without looking at the ultimate outcomes. This approach is an important first step to determine the feasibility of implementing these models at a larger scale. The CA will be conducted separately for each of the pilot sites and we will potentially compare the cost categories between sites. This approach will form a basis for any future analyses and will be an effective tool to identify the most significant cost categories and gaps as well as any initial improvements in terms of resource allocation.

The CA will consist in a retrospective analysis that will consider all the resources (including staff's costs) that all sites have engaged in implementing remote home monitoring models. All the sites will be able to bid for potential funding from NHS. In this respect, the CA will also be able to help identify the potential cost categories that are more in need for funding (or

where funding could be extended further) therefore help in the future implementation of the remote home monitoring models.

Measuring Costs
Each of the sites will be costed using data on resource use during the first and second waves. We will calculate the costs of all the used or planned resources, medical equipment (e.g. number of pulse oximeters) and appointed or internal medical staff (e.g. hours spent by each staff's categories). The costing will be based on staff's unit costs and the costs of other resources employed, accounting for whether and how these costs may be shared across different sites. For each site, we will also identify where these costs are utilised. In addition, we will also try to include possible costs that could be attributed exclusively to remote home monitoring models (e.g. misdiagnosis due to remote assessing of patients materialised by double referrals or patients getting back to the services after an initial referral is made). This will be done by identifying such possible uses of resources through the telephone interviews mentioned above. Total costs will be compared in terms of average costs per patient using the throughput number of patients for each site during the duration of the pilots.

Quantitative analysis
The aims and design of the quantitative analysis will be informed by the findings from phase 1 of the evaluation. This may include collection and analysis data collected prospectively from the sites to inform analysis of the potential benefits of the home monitoring approach and how they compare against what would have been expected.

ETHICS AND DISSEMINATION FOR PHASE 2
Requirements for the ethical review of phase 2 of the evaluation will depend on the research questions and study design (to be determined after phase 1).

TIMELINE FOR PHASE 2
Study design: September/October 2020

REFERENCES

Blume, S. S. 1992. Insight and Industry: On the Dynamics of Technological Change in Medicine. Cambridge: MIT Press.

Gale N, Health G, Cameron E, Rashid S, Redwood S. Using the framework method for the analysis of qualitative data in multi-disciplinary health research. BMC Medical Research Methodology 2013; 13:117.

Greenhalgh, T., Procter, R., Wherton, J. et al. What is quality in assisted living technology? The ARCHIE framework for effective telehealth and telecare services. BMC Med 13, 91 (2015). https://doi.org/10.1186/s12916-015-0279-6

Greenhalgh, T., A'Court, C. & Shaw, S. Understanding heart failure; explaining telehealth – a hermeneutic systematic review. BMC Cardiovasc Disord 17, 156 (2017). https://doi.org/10.1186/s12872-017-0594-2

Karampela, I. et al. Remote Monitoring of Patients in Quarantine in the Era of SARS-CoV-2 Pandemic. 2020 doi:10.3233/SHTI200486

Lehoux, P., & Blume, S. (2000). Technology assessment and the sociopolitics of health technologies. Journal of health politics, policy and law, 25(6), 1083-1120.

Margolius D., et al. On the Front (Phone) Lines: Results of a COVID-19 Hotline in Northeast Ohio. Preprint 2020. https://doi.org/10.1101/2020.05.08.20095745

Moher D, Liberati A, Tetzlaff J, Altman DG. Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement. BMJ 2009; 339: 332-336.

Powell, J., Gunn, L. E. E., Lowe, P. A. M., Sheehan, B., Griffiths, F., & Clarke, A. (2010). New networked technologies and carers of people with dementia: An interview study. Ageing and Society, 30(6), 1073.

Thornton, J. The "virtual wards" supporting patients with covid-19 in the community. BMJ 2020;369:m2119 doi: 10.1136/bmj.m2119

Tricco A., et al. Rapid reviews to strengthen health policy and systems: A Practical Guide. World Health Organization; 201