Study Title: Service demand prediction based on information from connected devices

Internal Reference Number / Short title: Service demand prediction based on information from connected devices

Ethics Ref: TBC

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Statistician Signature: Not interventional – Not applicable

Declaration of Conflicts of Interest: None

Confidentiality Statement

This document contains confidential information that must not be disclosed to anyone other than the Sponsor, the Research Team, HRA, host organisation, and members of the Research Ethics Committee, unless authorised to do so.

TABLE OF CONTENTS

1. KEY CONTACTS

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Committees	West Essex Proof of Concept Project Board

2. LAY SUMMARY

The NHS faces an unprecedented demand for services. Contributing to this increasing demand is a population who are living longer but not necessarily in good health. There is a rise in patients with long-term conditions requiring regular care from the NHS. As part of the response to this, research is aimed at investigating possibilities for system-wide transformation. The research will focus on testing the theory that information about patient behaviour, conditions and events can be gleaned from wearables, monitors and other smart technologies. This information could enable a better understanding of drivers or triggers for the demand of services and therefore inform strategic health commissioning.

If information about patient behaviour, conditions and events, captured from wearables, monitors and other smart technologies can predict demand for services, then, providing these technologies to patients and using the data generated will enable providers to pre-empt and redirect demand or design new services. This hypothesis will be tested in a PoC trial.

3. SYNOPSIS

Study title	Service demand prediction based on information from connected devices		
Internal ref. no. / short title	Service demand prediction based on information from connected devices		
Study registration	IRAS Project ID 276149 17-11-2019		
Sponsor	NHS West Essex Clinical Commissioning Group, Building 4, Spencer Close, St Margaret's Hospital, The Plain, Epping, CM16 6TN.		
Funder	NHS England, Charter House, Parkway, Welwyn Garden City, AL8 6JL.		
Study Design	Clinical investigation or other study of a medical device		
Study Participants	Patients older than 65 years AND more than 2 comorbid conditions AND / OR more than one requirements for unscheduled urgent care in previous year AND / OR medium or high frailty score		
Sample Size	Phase 1: 100; Phase 2: 500		
Planned Study Period	Maximum project study period: 11 months Maximum patient participation period 24 weeks		
Planned Recruitment period	Phase 1: April/May 2020 Phase 2: July/August 2020		
	Objectives	Outcome Measures	Timepoint(s)
Primary	To test the hypothesis: If information about patient behaviour, conditions and events, captured from wearables, monitors and other smart technologies can predict demand for services, then, providing these technologies to patients and using the data generated will enable providers to pre-empt and redirect	Phase 1: 100 patients: Optimised models generate dynamic personalised monitoring plan for each participant. Phase 2: 500 patients: Model linking health outcomes to NHS activity will be developed and tested. Confidence of correlations between measured data and observed data from actual unscheduled care data during study period.	July 2020 October 2020

	demand or design new services.		
Secondary	Dropout Percentage: Number of readings taken by patients compared to their agreed plan.	Two percentages. Participants who can / want to receive automated compliance reminders. Participants who cannot / don't want to receive automated compliance reminders.	October 2020
	Correlation between adherence to agreed plan and the participant's frailty score.	Correlation	October 2020
	Number of visits required for each complication group by number of comorbid conditions to achieve best value	Table / charts / recommendations with confidence levels	October 2020
	Correlation of each type of device with each complication group as a predictor of exacerbation (i.e. determine which device(s) are most useful).	Table of devices / correlations / confidence levels.	October 2020
Intervention(s)	There are no clinical interventions in this study.		
Comparator	Comparison data will be obtained from GP surgeries participating in the study.		

4. ABBREVIATIONS

CI	Chief Investigator
CRF	Case Report Form
CTRG	Clinical Trials & Research Governance, University of Oxford

GCP	Good Clinical Practice
GP	General Practitioner
HRA	Health Research Authority
ICF	Informed Consent Form
NHS	National Health Service
RES	Research Ethics Service
PI	Principal Investigator
PIL	Participant/ Patient Information Leaflet
R&D	NHS Trust R&D Department
REC	Research Ethics Committee
SOP	Standard Operating Procedure

5. BACKGROUND AND RATIONALE

The study will focus on elderly people living both independently and in care homes, who experience regular health events which lead to NHS activity. To reach a statistically significant number of data points, whilst keeping cost and duration down, the study will target high risk patients who either have a history of repeat hospitalisations or have complex co-morbidities which results in frequent GP consultations and A&E visits.

This study focuses on the elderly for hypothesis testing. Our population is aging rapidly, driving changes in health and care needs in society. Between 2006 and 2016, the number of people over 65 years rose by 21% (1.7 million), with the 85's rising by more than 31% in England [1]. These demographic changes have been seen to have a significant impact on primary care - between 2011 and 2014, the number of annual GP appointments per person grew by 15.4%, mostly driven by growth among people over 65 years (growth among people under 65% was only 4% and population growth was 2%) [1]. Delays in accessing primary care have serious consequences for time-sensitive conditions such as ambulatory care sensitive conditions (ACSCs). Delayed interventions may result in avoidable ambulance and emergency department use, necessitate more intensive therapy and hospitalisation, or lead to increased morbidity or mortality. Hospital admissions for elderly with ACSCs have risen rapidly over the last decade and are currently estimated to account for 20-30% of hospitalisations [2,3]. Those suffering from multiple chronic conditions are most vulnerable [4-6]. Hospital admissions can be particularly disruptive to the elderly, exposing them to hospital acquired infections, functional decline and increasing dependency. With patients over 65 years accounting for 80% of the emergency admissions who stay for more than 2 weeks, these risks are very severe [7,8].

Studies have previously demonstrated the ability of telemedicine to decrease use of emergency departments and hospitalisations among vulnerable populations such as children and the elderly [9-12]. However, existing tools and guidelines were developed for the identification and management of individual health issues, verticalising problems. Yet, a complex patient suffers from multi-morbidity and polypharmacy. Consequently, they are often treated via a conglomeration of juxtaposed guidelines, taking more than 10 drugs a day with no certainty of efficacy [13]. Hence, the current disease-focused approach has been repeatedly subjected to scrutiny, calling instead for a patient-centred approach focused on

personalised appropriateness and adherence [13,14]. The impact of a high-intensity telemonitoring model for holistic geriatric health (identification of acute disease & chronic exacerbations) implemented in senior communities has been documented by Shah et al [15,16]. Building upon this preliminary evidence, the study will conduct a structured evaluation of the ability of a holistic data collection process in the community to enable early detection of unplanned health needs in complex patients such as the elderly. Moreover, as evident from data submitted by the Authority, in West Essex, people over 65 constitute the majority of patients with complex healthcare needs and lead to the majority of expenditure on hospital admissions (Figure 2).

5.1. Population to be Studied

Patients older than 65 years AND more than 2 comorbid conditions AND/OR more than two requirements for unscheduled urgent care in previous year AND/OR medium or high frailty score. The study participants will live in the South Uttlesford area of East Anglia, in the north of the West Essex CCG territory unless we are unable to recruit sufficient patients, in which case the study area may be extended.

5.2. Method

The study will use patient data held in care home and GP records to identify potential participants. Health professionals working for the participating care homes or GP surgeries will then use inclusion and exclusion criteria to select patients for invitation to join the study. In the care home phase (Phase 1), the care home manager will sign and hand an invitation letter and Patient Information Leaflet to the potential participants whom they have identified and ask them to sign an attached form giving consent to be approached by the research team for informed consent. In Phase 2, the primary care phase, GP surgery staff will send the invitation letter and Patient Information Leaflet to potential participant and process the returned forms, booking informed consent appointments. The research team is seeking the support of the North Thames Clinical Research Network in parallel with the application to the HRA/REC; if successful, staff from the CRN will support the recruitment and consenting process in Phase 2 only.

The study cohort will be taken from those who have needed most urgent care and who have the largest number of comorbidities, as defined by the inclusion and exclusion criteria above.

Phase 1 of the study will be conducted with up to 100 participants residing in care homes. Either Health Research Assistants employed by the research team or local care home employed professionals (the choice between these two to be at the care home's discretion) will use connected medical devices to collect data from the cohort at twice-weekly intervals for twelve weeks. In this phase **all devices will be used with all participants**.

NHS activity data will be obtained from the records held in GPs' clinical systems at the end of Phase 1 to enable models to be constructed that will test the study hypothesis and allow the mapping of chronic conditions to device types to be optimised. This will mean that in **Phase 2**, participants will only be asked to use devices that have been proved in **Phase 1** to be effective at collecting useful data relevant to their specific set of co-morbidities.

In **Phase 2**, a total of 500 participants will be enrolled who meet the study inclusion criteria. Any participants from **Phase 1** who want to continue to have their health measurements taken will be permitted to proceed to **Phase 2** and the remained, up to a total of 500, will be recruited from their GP surgeries and asked to participate from their own homes. Continuing care home residents will continue to receive twice-weekly visits from the project's Health Research Assistants (or care home employed

professionals, as appropriate); those participating in the study from their own homes will do so autonomously using the smartphone, the Reassure OneApp application loaded onto the smartphone, and a set of devices appropriate to their co-morbidities. They will be shown how to take their health measurements during an initial visit from one of the project's Health Research Assistants, and the Reassure OneApp application will also display reminders of how to do this. In addition to this, Health Research Assistants will be available to make visits to the participant's home to support them in collecting their health measurements at the request of the participant.

The medical devices will send back data to central server facilities in Cambridge, UK to L2S2's patient management system that will automatically adjust the visit frequency for each patient and prompt compliance to minimise dropout.

At the end of **Phase 2**, NHS activity data will be obtained from the participants' GP to allow correlation between the actual recorded instances of requirement for unscheduled care and the data collected in the trial from the medical devices.

Machine learning and statistical analysis will be used to determine the validity of using home collected and care home collected data from smart medical devices to predict future likelihood of requirements for unscheduled urgent care.

5.3. Summary of findings from previous studies

Studies have previously demonstrated the ability of telemedicine to decrease use of emergency departments and hospitalisations among vulnerable populations such as children and the elderly [9-12]. However, existing tools and guidelines were developed for the identification and management of individual health issues, verticalising problems. Yet, a complex patient suffers from multi-morbidity and polypharmacy. Consequently, they are often treated via a conglomeration of juxtaposed guidelines, taking more than 10 drugs a day with no certainty of efficacy [13]. Hence, the current disease-focused approach has been repeatedly subjected to scrutiny, calling instead for a patient-centred approach focused on personalised appropriateness and adherence [13,14]. The impact of a high-intensity telemonitoring model for holistic geriatric health (identification of acute disease & chronic exacerbations) implemented in senior communities has been documented by Shah et al [15,16]. Building upon this preliminary evidence, the study will conduct a structured evaluation of the ability of a holistic data collection process in the community to enable early detection of unplanned health needs in complex patients such as the elderly. Moreover, as evident from data submitted by the Authority, in West Essex, people over 65 constitute the majority of patients with complex healthcare needs and lead to the majority of expenditure on hospital admissions (Figure 2).

Figure 1 Analysis of complex patients in West Essex CCG

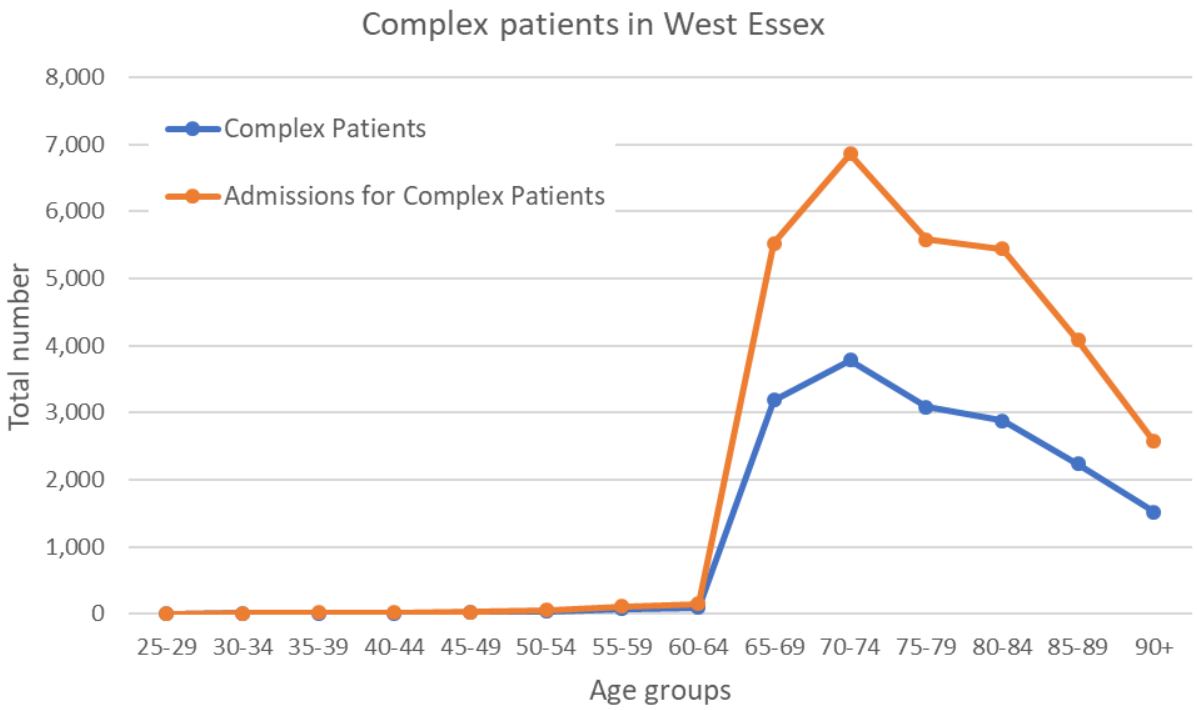
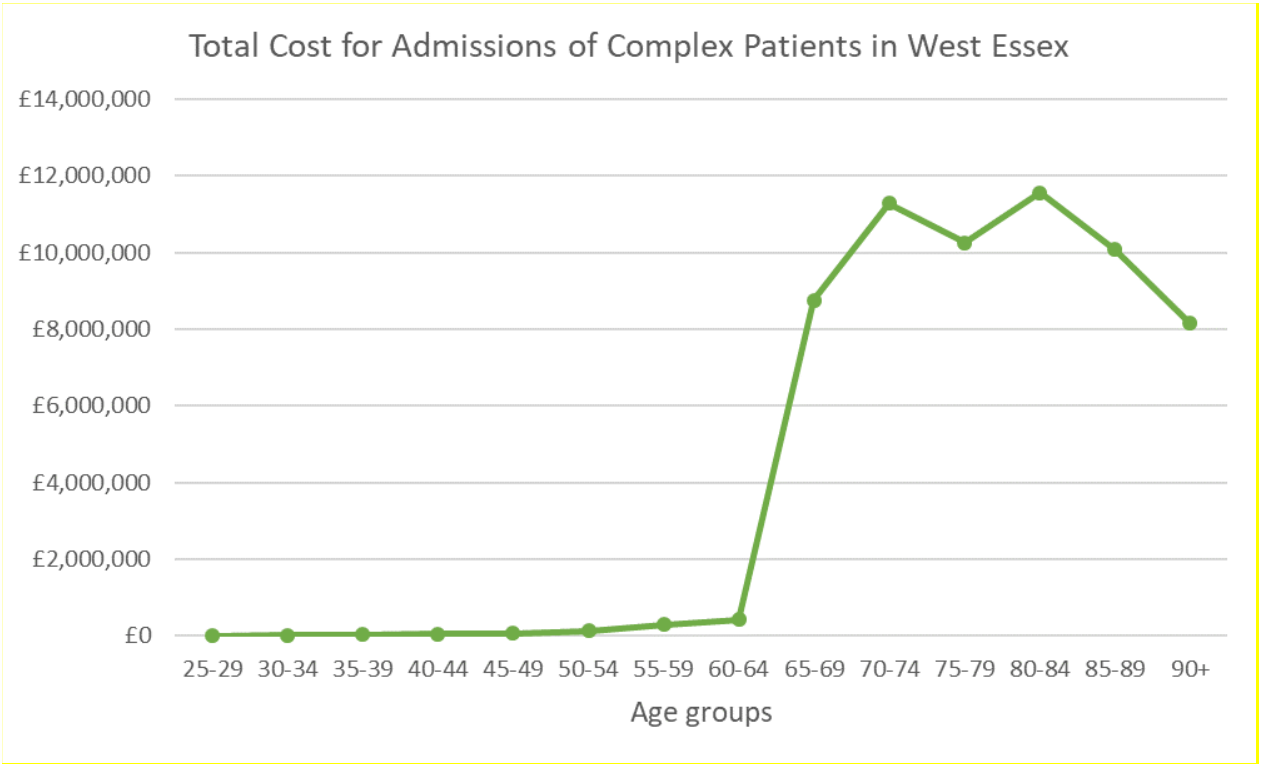


Figure 2



5.4. Risks

L2S2 perform risk analyses to ISO 14971 as part of the company ISO 13485 Quality Management System (QMS). Risks for this project are listed below:

001 Risk: Cross Infection between patients

Hazard: Bacteria, spores and viruses could be transferred by a device if reused

Hazardous Situation: Inadequate cleaning / disinfection / sterilization

Harm: Pathogens could be transferred between patients

Likelihood: Frequent

Severity: Serious

Risk Assessment: Serious

Mitigation: All devices will have a record entry in the master device database that will show cleaning status and allow cleaning process to be tracked.

Cleaning / Disinfection / Sterilisation will be performed to formal procedures and tracked

Devices that enter or contact mucous membranes will either be single use or will be returned to the company for formal cleaning between each reuse.

Cleaning processes will be audited once per month.

Residual Risk: Acceptable

002 Risk: Contact Dermatitis

Hazard: Patient's skin reacts with surfaces of any of the medical devices

Hazardous Situation: Allergic or rash reaction happens after wearing / touching the devices

Harm: Discomfort, rash or swelling requiring intervention

Likelihood: Rare

Severity: Minor

Risk Assessment: Reasonable

Mitigation: Patients will be asked if they have a history of adverse effects from any contact materials as part of the study inclusion criteria and throughout the study. The HCAs will check the patients at each visit, and to minimise any effects, the device will be withdrawn from the patient if any adverse effects are detected.

Residual Risk: Acceptable

5.5. Rationale for undertaking the study

In 2019 there has been a step change in the costs of personal medical devices, ease of use, cost of connectivity and machine learning capabilities. These changes render the technology more affordable by the NHS and more usable by elderly people. In 2018, the Emergency Care Data Set (ECDS) was introduced to all A&E departments in England and for the first time comprehensive outcomes based data on

attendance at A&E departments is available. Together the changes in technology and availability of high-quality reference data make this study possible.

Participants will be selected who are likely to exacerbate during the trial period and therefore the size and duration of the study are considered adequate to test the hypothesis thoroughly.

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6. OBJECTIVES AND OUTCOME MEASURES

Objectives	**Outcome Measures**	**Timepoint(s) of evaluation of this outcome measure (if applicable)**
Primary Objective The purpose of the study is to find out the confidence of correlation and its statistical significance	The correlation confidence level for exacerbation prediction from data collected from medical devices in the particpant's home or care home with actual attendance data obtained from GP surgeries. .	End of study (study is non-interventional)
Secondary Objectives 1. Determine drop out percentage 2. Determine relationship between frailty and ability to adhere to plan 3. Determine relationship between number of co-morbidities and resource required.	1. Dropout Percentage: Number of readings taken by patients compared to their agreed plan. 2. Correlation between adherence to agreed plan and the participant's frailty score.	End of study

4. Determine effectiveness of different devices as predictors of exacerbation by complication group.	3. Number of visits required for each complication group by number of comorbidities 4. Correlation of each type of device for each complication group as a predictor of exacerbation (i.e determine which device(s) are most useful).	

7. STUDY DESIGN

The study type will be observational, collecting data from wearables and remote monitoring medical devices to determine correlations with primary data collected from GP surgeries attended by the participants in the course of the study.

Participants will be recruited by West Essex CCG from patients in their region who meet the study inclusion criteria.

The first phase of research with up to 100 participants will be conducted in care homes with twice-weekly visits from Health Research Assistant's (HRA) employed by the research team, equipped with a standard kit of medical devices who will ensure the devices are used appropriately to maintain data quality and who will monitor the effectiveness of the electronic devices. If care homes would rather be trained to undertake these duties using their own staff, the research team will train them and remunerate the care home for these staff costs.

The second phase of 500 participants will be conducted in participants' homes and care homes with visits from a research team HRA to ensure safe and effective use of condition specific wearable and monitoring devices when this is requested. Visit frequency will be automatically adjusted by feedback from the monitoring systems. (Typically once per week.)

The electronic devices will provide primary medical data as well as metadata regarding battery charging behaviour, adherence to study procedures, effect of active compliance management and direct feedback from the participants. The visit frequency will be adjusted to ensure maximum effectiveness of the equipment and to maximise economic benefit to allow a 'best practice' baseline to be established.

The medical devices issued to each patient will be determined by observations and data collected by the HRAs in conjunction with baseline data derived from GP data.

In **Phase 1**, all devices will be used to take measurements from all participants. Devices will be issued to HRAs who will use them to ensure correct use and valid data.

In **Phase 2**, devices will be allocated to participants based on data gathered in **Phase 1**. It is anticipated that this will demonstrate the best combinations of devices for recording health measurements for different sets of co-morbidities, and prove or disprove the following assumptions:

Heart failure 0.44%
Weight, heart rate, BP, spO2, CO2 (using N-Tidal device if CE approved in time)

COPD / Asthma 0.96+0.94 = 1.9%
Peak flow, spO2, respiration rate, thermometer, CO2 (using N-Tidal device if CE approved in time)

Frailty / Falls / possible Syncope 1.35 + 0.33%
Heart rate, ECG, BP, spO2, CO2 (using N-Tidal device if CE approved in time)

High frailty bedbound (3%)
Heart rate, spO2, thermometer, respiration rate, CO2 (using N-Tidal device if CE approved in time), BP

Blood disorders / immune suppression / post chemotherapy (less than 0.1%)
Temperature, spO2, respiration rate, CO2 (using N-Tidal device if CE approved in time)

Diabetes 3%
Blood sugar, weight, temperature

Renal failure / Liver failure (less than 0.1%)
Weight, blood pressure, temperature, blood sugar

% based on figures from

https://digital.nhs.uk/data-and-information/data-tools-and-services/data-services/emergency-care-data-set-ecds-data-quality#ecds-data-quality-summary-report-from-april-2018

ECDS is the new national emergency care dataset introduced into all type 1 and type 2 A&E departments in 2018 in England by Dr Hughes, the Chief Investigator for this study.

7.1. Visit Plan

Phase One

1. Meeting with the participant to explain the purpose and form of the study and gain consent, conducted by a member of the project team. Average meeting time 30 minutes.
2. Research team will talk to care home professionals to gain participant's medical history, current medication and urgent care attendance history from locally-held record.
3. Initial meeting between the research team Health Research Assistant (HRA) and participant (or care home employed professional and participant). The timetable for the study will be discussed and dates for routine visits will be agreed as far as is possible. The HCA will conduct risk assessments to ensure that the patient can be tested safely. The HCA will use medical devices appropriate to the participant's medical condition determined by the HCA and historical data if available. Average meeting time 30 minutes.
4. Follow up visits by the HCA twice weekly to take measurements from the participant using all devices. This is expected to last for approximately 12 weeks per participant, but will end when either the participant exacerbates, elects to drop out of the study or the study ends.

5. A final visit will be conducted at the end of the study to ensure patients understand their rights with respect to data processing and retention. Average meeting time 30 minutes.

Phase Two

1. Meeting with the participant to explain the purpose and form of the study and gain consent, conducted by an appropriately trained professional at the GP surgery. Average meeting time 30 minutes.
2. Research team will access the participant's record in the GP's clinical system to gain participant's medical history, current medication and urgent care attendance history.
3. Initial meeting between the Health Research Assistant (HRA) and participant in their place of residence. The timetable for the study will be discussed and dates for routine visits will be agreed as far as is possible. The HRA will conduct risk assessments to ensure that the patient can be tested safely. The HRA will allocate medical devices appropriate to their medical condition as determined by the HRA and historical data if available. They will then explain how to use them. Average meeting time 60 minutes.
4. If requested by the participant, follow up visits by the HRAs will be carried out at approximately one week intervals for the remainder of the study to collect data and confirm that the participant is coping with the technology and not suffering physical or mental adverse effects. At each visit the HRA will use appropriate connected medical devices assigned to the participant to monitor both the effectiveness of equipping community staff with technology and to collect data professionally to contrast with self-measurements later in the study. Average meeting time 20 minutes.
5. Participants will be expected to participate for 12 weeks.
6. Visits from HRAs may be offered proactively to participants by phone if they appear to be experiencing problems with using the devices, e.g. failure to charge the devices, improper use and sporadic use.
7. A final visit will be conducted at the end of the study to recover the equipment and ensure patients understand their rights with respect to data processing and retention. Average meeting time 30 minutes.

Participants will be encouraged to collect their own estimations of their frailty and condition (NICE guideline 56) throughout the trial for correlation against the measured data. (Participants will be asked to record data about their mood and how well they are feeling.)

7.2. Process for Self-Collecting Data

For participants judged to be able to self-monitor, each participant will be issued with appropriate medical devices and a single-purpose Android mobile phone that will automatically run the Reassure OneApp data collection application whenever restarted. The phone will be fitted with a data SIM provisioned with a data allowance sufficient to span the study period. The phone will not be usable for any other purpose than its use as the data collector in this study. The patient will not have to use their own mobile phone or WiFi network.

According to participants' capabilities, some will enter data from simple medical devices manually, as this is the lowest cost way of providing remote technology. Others will be issued medical devices that will connect to the phone over Bluetooth i.e. that will require no participant intervention. This will allow the effectiveness of these approaches to be evaluated across a broad cohort of participants.

The Reassure OneApp application will support simple, user friendly self-assessment questionnaires, which will be securely passed back along with the electronically collected data.

The smartphone will pass back information about the current charge of the battery to enable the HRA to swap the phone with a charged phone if the participant is confused by the charging process.

Devices will be cleaned, disinfected or sterilised as appropriate before being given to another participant.

7.3. Study flowchart

See Appendix A

8. PARTICIPANT IDENTIFICATION

8.1. Inclusion Criteria

Patients older than 65 years AND

more than 2 comorbid conditions AND/OR

more than one unscheduled urgent care attendances in previous year AND/OR

medium or high frailty score.

The study participants will primarily live in the South Uttlesford area of East Anglia, in the north of the West Essex CCG territory.

8.2. Exclusion Criteria

The participant may not enter the study if ANY of the following apply:

- Children
- Individuals for whom consent cannot be obtained (i.e. individuals with mental impairments)
- Individuals who have rare chronic conditions which cannot be monitored with the devices used in the study (e.g. complex musculoskeletal conditions like ankylosing spondylitis, liver failure patients)
- Patients on palliative care
- Individuals whose wellbeing might be compromised through the measurements, such as an individual with bullous skin disease or osteogenesis, imperfect with a blood pressure cuff
- Individuals with mental health conditions whose wellbeing and care could be compromised by the introduction of measurements
- Individuals living in locations significantly far away geographically from other prospective participants (e.g. in locations where domiciliary carers might not be able to cost-effectively reach to collect measurements)
- Individuals who lose mental capacity during the study period will be removed from the study.

9. PROTOCOL PROCEDURES

9.1. Recruitment

Participants will be selected who have a high likelihood of exacerbating during the study period, as specified in the inclusion criteria. In **Phase 1**, the potential participants will be identified by the care homes and selected participants will also be recruited by the care homes. Once the participant has agreed to take part, the research team will visit to gain informed consent.

In **Phase 2**, identification of patients will be undertaken by GP surgeries and once the participant has agreed to join the study, GP surgery staff or staff from the local Clinical Research Network (subject to confirmation) will gain informed consent.

9.2. Screening and Eligibility Assessment

The inclusion and exclusion criteria above will be used to identify eligible participants to approach.

9.3. Informed Consent

The participant must personally sign and date the latest approved version of the Informed Consent form before any study specific procedures are performed. Where participants are unable to give consent, their legal guardian will be approached and asked if they will agree to the person taking part in the study.

Written and verbal versions of the Participant Information and Informed Consent will be presented to the participants (or legal guardians) detailing no less than: the exact nature of the study; what it will involve for the participant; the implications and constraints of the protocol; the known side effects and any risks involved in taking part. It will be clearly stated that the participant is free to withdraw from the study at any time for any reason without prejudice to future care, without affecting their legal rights, and with no obligation to give the reason for withdrawal.

The participant will be allowed as much time as wished to consider the information, and the opportunity to question the Investigator, their GP or other independent parties to decide whether they will participate in the study. Written Informed Consent will then be obtained by means of participant dated signature and dated signature of the person who presented and obtained the Informed Consent. The person who obtained the consent must be suitably qualified and experienced and have been authorised to do so by the Chief/Principal Investigator. A copy of the signed Informed Consent will be given to the participant. The original signed form will be retained at the study site.

A copy of the Informed Consent is uploaded to the IRAS site.

9.4. Blinding

This is a non-interventional study and is blinded only with respect to the data analysts. The care workers need access to participant names and demographic data to support their visits. To enable participant collected data to be correlated with hospital and GP records collected during the study period, it will be necessary to use identifiable data. This is explained in clear language in the Participant Information Sheet.

10. DESCRIPTION OF STUDY INTERVENTION(S), COMPARATORS AND STUDY PROCEDURES (CLINICAL)

This project is observational only. It is not interventional.

10.1. Description of study intervention(s)

Not applicable

10.2. Description of comparator(s)

Not applicable

10.3. Description of study procedure(s)

Not applicable

10.4. Device safety

All devices used to collect clinical data are CE marked medical devices used within the scope for the device registered by its manufacturer. All devices and the procedures have been risk assessed and have been determined to present extremely low risk to the participants.

No NHS affordable smart watches are available with CE medical device approval at this time. Smart watches will not be used to return medical data in this trial but non-medical device watches will be issued to patients who have no history of allergies or dermatitis, to provide trend data to drive the compliance processing. The device used will be a mainstream product built in ISO13485 accredited facilities to medical quality control.

In **Phase** 1, participants will be checked by the Health Research Assistant at each visit for any sign of minor skin reaction; in **Phase 2**, participants will be advised in the initial home visit to report any skin reaction or other problem to the research team. If there are any issues, the device will be taken back from the participant.

10.5. Maintenance and storage of devices

L2S2 opens, tests and charges all purchased devices on arrival in a sterile facility in its premises in Cambridge. The devices are then turned off and stored in labelled plastic bags. When devices are to be despatched to participants their charge state is checked again and software is put on the device. The sealed devices are sent by courier to the HRAs (or care homes) who will assign each device to a participant. This is done with the device in the sealed bag which is not opened until the device is first used by the participant.

When the device needs to be taken back, the patient, HRA or care home employed professional will place the device(s) in biological control bags and return them to the Cambridge site either for cleaning, disinfecting or sterilising according to approved procedures set out in ISO13485, or for safe disposal if the device is not to be reused. Devices that can be cleaned in the field like the blood pressure meter are assessed to be low risk and may be cleaned with DiffX wipes or spray. The HRA will use a cleaning protocol wizard on a section of the Reassure OneApp application only visible to research team staff to provide a complete, auditable trail of cleaning / sterilisation procedures.

The HRA will record the condition of the devices at each visit and will clean them / remove them as appropriate to ensure safety is not compromised.

10.6. Device ownership

It is made clear to the participants at the start that the devices issued to them are loaned and that they will be collected at the last study visit by the HRA.

10.7. Baseline Assessments (Visit 1)

This is an observational study using devices that give accurate measurements. As soon as a participant is measured, the research team's software will start to establish the participant's norms to allow the analytics processing to take into account natural variation. The purpose of the first meeting is (for participants who self-monitor) to train the participant and issue equipment so that the HRA can confirm that the participant knows how to use the devices safely and effectively to collect a first set of data.

Each participant will have a schedule for taking health measurements that will be accessible on their loaned smartphone via the Reassure OneApp application.

10.8. Subsequent Visits

In **Phase 1,** visits will be made in the participants' care homes twice-weekly and will take approximately 20 minutes. These will be undertaken either by HRAs from the research team or by care home employed professional, depending on the preference of the care home. They will continue for the 12 week duration of the study.

In **Phase 2**, these visits may also be performed at the participant's request in their own home and will take approximately 20 minutes.

10.9. Final Visit

A final meeting with the participant will be held approximately one week after the last measurement visit. The HRA will pick up all of the issued equipment and return to L2S2 for cleaning.

A final report will be issued to all participants within three months of the end of **Phase 2**.

The exact interval between measurements will be data driven, set by monitoring the returned data.

10.10. Common to all Visits

The following procedures will be checked at the start of each visit by the HCA:

- eligibility check – confirm nothing has changed e.g. mental capacity
- assessment of outcome measures
- assessments of safety
- assessments of compliance with the study protocol
- general health and wellbeing of the patient

10.11. Sample Handling

No samples will be taken from participants in this study.

Self-entered data or data collected by Bluetooth connected devices is described separately.

10.12. Early Discontinuation/Withdrawal of Participants

During the course of the study a participant may choose to withdraw early from the study treatment at any time. This may happen for several reasons, including but not limited to:

- The occurrence of what the participant perceives as an intolerable adverse event
- Inability to comply with study procedures
- Participant decision

Participants may choose to stop the study assessments.

Participants may also withdraw their consent, meaning that they wish to withdraw from the study completely.

1) Participants may withdraw from active participation but allow the study team to continue to access their medical records and any relevant hospital data that is recorded as part of routine standard of care.

2) Participants can withdraw from the study but permit data and samples obtained up until the point of withdrawal to be retained for use in the study analysis. No further data would be collected after withdrawal.

In addition, the Investigator may discontinue a participant from the study treatment at any time if the Investigator considers it necessary for any reason including, but not limited to:

- Ineligibility (either arising during the study or retrospectively having been overlooked at screening)
- Significant protocol deviation
- Admission to hospital care
- Clinical decision

Following a complete withdrawal, confirmation will be sent to the participant confirming destruction of all personal data.

All data obtained from registered/enrolled participants will be analysed. Withdrawal from the study may result in exclusion of the data for that participant from certain analyses.

If participants leave the study for any reason a substitute will be sought to maintain study numbers to provide as high a volume of data as possible to train the machine learning.

The type of withdrawal and reason for withdrawal will be recorded in the Case Report Form (CRF).

If the participant is withdrawn due to an adverse event, the Investigator will arrange for follow-up visits or telephone calls until the adverse event has resolved or stabilised.

10.13. Definition of End of Study

The end of the study will be when the final report and recommendations are presented to the CCG in October/November 2020. The data governance, quality management, and archiving will continue for three further years when the data will be destroyed.

11. SAFETY REPORTING

This is a non-interventional study. It uses CE approved medical devices together with mobile phone technology and a digital watch. No serious adverse events are predicted; therefore, safety reporting is not applicable.

12. STATISTICS AND ANALYSIS

12.1. Statistical Analysis

Studies to measure interventions are designed using power calculations that minimise the risk of not finding a difference between treatments if one exists (a type II error).

In a purely observational study, such calculations are less relevant, but the study design still needs to provide assurance that sufficient data will be collected to but for this study.

This is mainly achieved by ensuring that the target population has a high event frequency of the index condition – in this case deterioration of healthcare such that hospital admission would be necessary. The mean time of residence for a patient in nursing home care is approximately 15 months, but with half the residents dying in the first six months of residence.

https://www.geripal.org/2010/08/length-of-stay-in-nursing-homes-at-end.html?m=1

Following the protocol described below, a cohort of elderly people (>65 years) living independently and in care/nursing homes, with

- a moderate or high degree of frailty,
- comorbidities as defined in the appendix using standardised NHS list
- a history of regular NHS activity will be identified.

Stage 1 of data collection will feature a universal monitoring plan across for nursing home residents and, following analysis, Stage 2 of data collection will ensure measurements are collected with frequency and using devices appropriate to the needs of different participants by tailoring the frequency and type of monitoring to the needs of the condition and patient.

To provide assurance that the sample size is likely to provide sufficient event frequency, a power calculation was performed (Jones et al. 2003).

Data provided by the West Essex CCG was used to explore different incidence rates of index episodes of health deterioration requiring NHS treatment in the target population as defined above.

As 50% of the nursing home population is likely to die within six months of admission, the recruitment of existing nursing home patients means event prevalence rates of 55% is a conservative estimate.

The lowest acceptable sensitivity of the algorithm was assumed to be 85% (SN) and the lowest acceptable specificity – 80% (SP). A confidence interval of 5% (W) was selected. The required sample size can be determined via the sensitivity or the specificity limit, depending on priorities:

$$\mathbf{N(SN)} = \frac{\mathbf{TP + FN}}{\mathbf{P}} = \mathbf{1.96^2} * \frac{\mathbf{(SN(1-SN))}}{\mathbf{W^2}}$$

$$\mathbf{N(SP)} = \frac{\mathbf{FP + TN}}{\mathbf{(1-P)}} = \mathbf{1.96^2} * \frac{\mathbf{(SP(1-SP))}}{\mathbf{W^2}}$$

Incidence of health issue						
	0.3	*0.35*	*0.4*	*0.45*	*0.5*	*0.55*
N(SN)	**653**	**560**	**490**	**435**	**392**	**356**
N(SP)	**280**	**301**	**327**	**356**	**392**	**435**

Stage I		# unique patients							# unique patient non-episode		# unique patient episode	
		nursing/ care		indep. living								
incidence of an episode	month	new	old	new	old	total	dropout	cumulative patients	month	cum	month	cum
35%	1	100				**100**	7	100	65	65	35	35
35%	2	42	58			**100**	7	142	65	130	35	70
35%	3	42	58			**100**	7	184	65	195	35	105

Stage II		# unique patients							# unique patient non-episode		# unique patient episode	
		nursing/ care		indep. living								
incidence of an episode	month	new	old	new	old	total	dropout rate	cumulative patients	month	cum	month	cum
35%	1	400		100		**500**	36	500	325	325	175	175
35%	2		371		93	**464**	33	500	302	627	162	337
35%	3		344		86	**430**	31	500	280	907	151	488

Therefore for this observational / exploratory study, the study design and numbers proposed (100 for the first stage and 400 for the main stage) provide reasonable assurance that a sufficient number of index events will occur in the target population.

12.2. Decision points

An interim report will be presented to the CCG based on the data collected from the first 100 patients in the care homes in the middle of May 2020. This will include outcome performance measures on the device / condition groupings, the confidence of correlation between the measurements and the actual data from the A&E departments and the GPs. The decision when to proceed to phase 2 will be made jointly by L2S2 and the CCG.

12.3. Stopping rules

The CCG has the final decision to end the trial. This is a non-interventional, observational study and the data will not be analysed until the study is complete, and therefore other than the CCG deciding that the study is not being managed correctly, the study will proceed to the planned end.

12.4. Procedure for Accounting for Missing, Unused, and Spurious Data.

All data collected will be validated to ensure values are in bounds before inclusion in aggregated datasets. Otherwise all data collected will be included.

12.5. Service transformation recommendations

Phases 1 and 2 of this study are focused on establishing whether reliable predictions of future health exacerbations that would result in the requirement for urgent unscheduled care can be correlated to measurements derived from medical devices used by patients at home. Whilst a full health economics analysis is not a requirement of this investigation, accurate cost data will be measured and passed through to the CCG for further analysis after the study is complete. The CCG will have access to detailed historical cost data.

A final output of this study will be service transformation suggestions. These will be prepared by L2S2 with assistance from the CCG. L2S2 will seek advice from contracted A&E specialists and GPs.

13. DATA MANAGEMENT

All data on L2S2's servers are encrypted AES 256 and are only available in the physically secure server room.

13.1. Source Data

Participants' NHS activity data and relevant data related to their health condition(s) will be collected with their consent from their GPs' clinical systems and direct from participants using a personal app – Reassure OneApp – installed on the smartphone loaned to them for the duration of the study. Data gathered by the carers will be entered and stored in an L2S2 electronic system (in wide use within the NHS – ISO 27001 / ISO 13485 accredited / DS&P Toolkit accredited / Cyber Essentials) whilst in the presence of the participants. All documents will be stored safely in confidential conditions. On all study-specific documents containing data, other than the signed consent, the participant will be referred to by the study participant number/code, not by name.

13.2. Access to Data

Direct access to anonymous data will be granted to authorised representatives from the Sponsor and host institution for monitoring and/or audit of the study to ensure compliance with regulations.

13.3. Data Recording and Record Keeping

All trial data will be entered directly into the L2S2 record system. This system is validated and is used in accordance with the company's ISO 27001 and ISO 13485 procedures.

The participants will be identified by a unique trial specific number and/or code in any database. The name and any other identifying detail will NOT be included in any trial data electronic file.

The study data will be stored in L2S2 servers at 2b Oakington Business Park, Cambridge and encrypted backups will be stored at L2S2's approved secondary site in Cambridge. Both sites are approved for the storage of identifiable data (NHS Digital) and are accredited to ISO 27001 and Cyber Essentials.

The identifiable data will be destroyed when the final outcome reports are created. The consent form will be retained while ever data is held.

14. QUALITY ASSURANCE PROCEDURES

The L2S2 Reassure system enforces procedures and maintains a full audit of all activity. The study will be managed to ISO 9001 and ISO 13485 procedures. Standard operating procedures will be created for all aspects of the study. L2S2 will be audited for compliance to both standards by BSI during the study period.

In addition, the quality assurance procedures will include a risk adaptive approach based on a formal risk assessment, planned monitoring activities and the involvement of a number of study oversight personnel.

15. RISK ASSESSMENT

A risk assessment and monitoring plan will be prepared before the study opens and will be reviewed as necessary over the course of the study to reflect significant changes to the protocol or outcomes of monitoring activities.

16. STUDY MONITORING

Regular monitoring will be performed according to the study specific Monitoring Plan. Data will be evaluated for compliance with the protocol and accuracy in relation to source documents as these are defined in the study specific Monitoring Plan. Following written standard operating procedures, the monitors will verify that the clinical study is conducted and data are generated, documented and reported in compliance with the protocol, GCP and the applicable regulatory requirements.

17. PROTOCOL DEVIATIONS

A study related deviation is a departure from the ethically approved study protocol or other study document or process (e.g. consent process or administration of study intervention) or from Good Clinical Practice (GCP) or any applicable regulatory requirements. Any deviations from the protocol will be documented in a protocol deviation form and filed in the study master file.

A standard operating procedure is in place that describes the procedure for identifying non-compliances, escalation to the central team and assessment of whether a non-compliance /deviation may be a potential Serious Breach.

18. SERIOUS BREACHES

A “serious breach” is a breach of the protocol or of the conditions or principles of Good Clinical Practice which is likely to affect to a significant degree –

(a) the safety or physical or mental integrity of the trial subjects; or

(b) the scientific value of the research.

In the event that a serious breach is suspected the Sponsor must be contacted within 1 working day. In collaboration with the clinical investigator, the serious breach will be reviewed by the Sponsor and, if appropriate, the Sponsor will report it to the approving REC committee and the relevant NHS host organisation within seven calendar days.

19. ETHICAL AND REGULATORY CONSIDERATIONS

19.1. Declaration of Helsinki

The Investigator will ensure that this study is conducted in accordance with the principles of the Declaration of Helsinki.

19.2. Guidelines for Good Clinical Practice

The Investigator will ensure that this study is conducted in accordance with relevant regulations and with Good Clinical Practice.

19.3. Approvals

Following Sponsor approval, the protocol, informed consent form and participant information sheet will be submitted to an appropriate Research Ethics Committee (REC), and HRAand host institutions for written approval.

The Investigator will submit and, where necessary, obtain approval from the above parties for all substantial amendments to the original approved documents.

19.4. Other Ethical Considerations

No children will be included in this study. This study is non-interventional and data will not be analysed until the interim report and final report stages.

In the unlikely event that one of the study professional HCAs observes a severe worsening of condition in a participant that is not known to the participant's medical team and such 10that the abnormality was medically important, they will discuss the implications with the participant's care team. Participants will not be informed. It is important to note that remote monitoring data are not collected for diagnostic purposes, and therefore the monitoring is not a substitute for a clinical appointment. Rather, the monitoring is intended for research purposes only.

19.5. Reporting

The CI shall submit once a year throughout the study, or on request, an Annual Progress report to the REC Committee, HRA (where required) host organisation, Sponsor and funder (where required). In addition, an End of Study notification and final report will be submitted to the same parties.

19.6. Participant Confidentiality

The study will comply with the General Data Protection Regulation (GDPR) and Data Protection Act 2018, which require data to be de-identified as soon as it is practical to do so. The processing of the personal data of participants will be minimised by making use of a unique participant study number only on all data collected in study databases. Personal identifiable data will be kept separate from the study data and only used by the carers who attend the participants and for keys to correlate with hospital and GP databases. All documents will be stored securely and only accessible by study staff and authorised personnel. The study staff will safeguard the privacy of participants' personal data.

19.7. Expenses and Benefits

No payments will be made to study participants.

20. FINANCE AND INSURANCE

20.1. Funding

This trial is funded by NHS England, though funding has been disbursed to NHS West Essex Clinical Commissioning Group who have contracted the running of the trial to L2S2 Ltd and act as the Commissioning Authority.

20.2. Insurance

This is an NHS sponsored project so the NHS Indemnity Scheme shall apply.

L2S2 carries professional indemnity insurance (£10 million) and public liability insurance (£5 million).

20.3. Contractual arrangements

Appropriate contractual arrangements will be put in place with all third parties, including but not limited to: hospitals providing baseline and monthly data, GP surgeries providing baseline and monthly data, contract care organisations, any subcontractors.

21. PUBLICATION POLICY

The Investigators will be involved in reviewing drafts of the manuscripts, abstracts, press releases and any other publications arising from the study. Authors will acknowledge that the study was funded by West Essex CCG. The West Essex CCG will own study data and will control press releases. Authorship will be determined in accordance with the ICMJE guidelines and other contributors will be acknowledged.

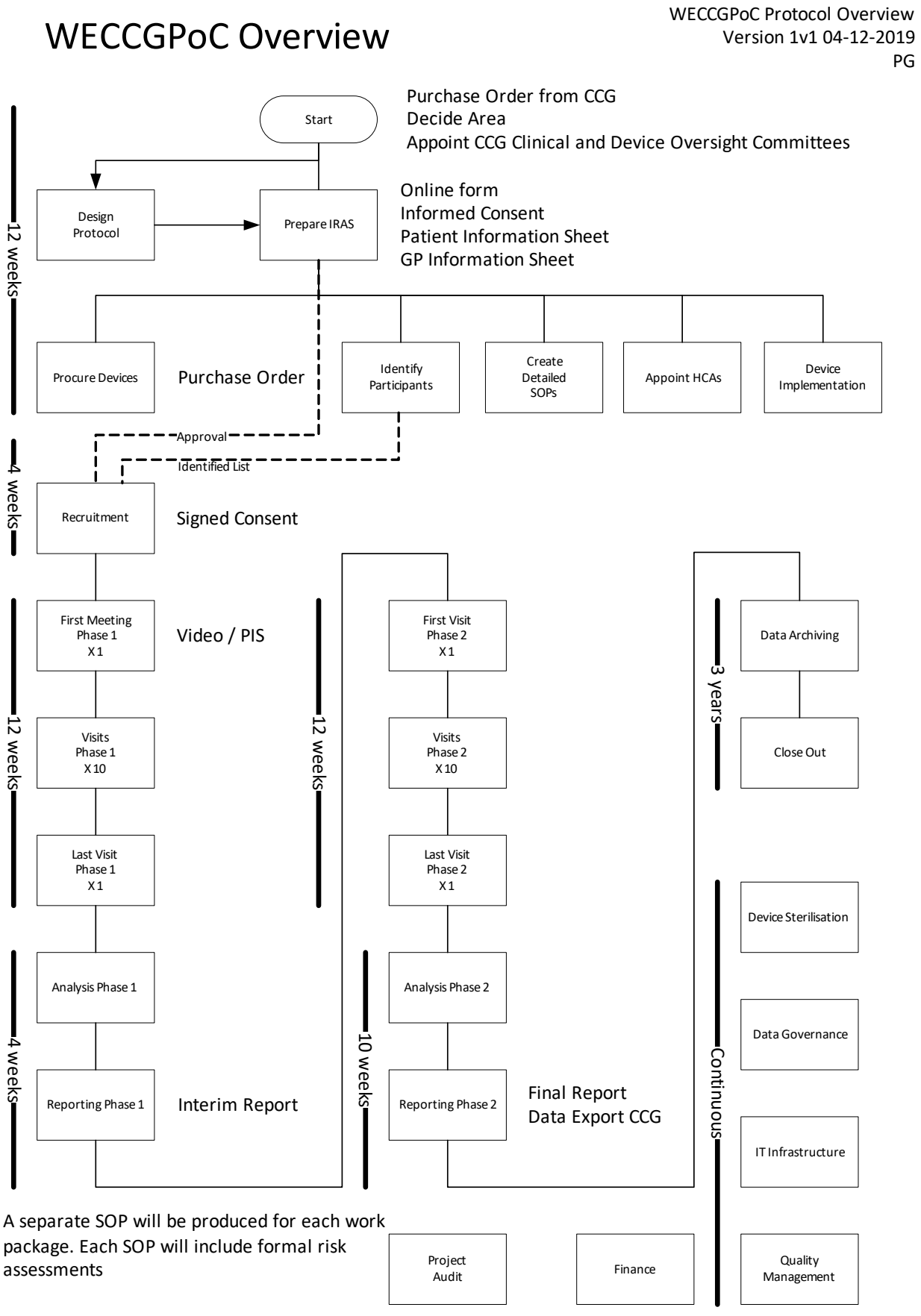
22. DEVELOPMENT OF A NEW PRODUCT/ PROCESS OR THE GENERATION OF INTELLECTUAL PROPERTY

Analyses and conclusions of study data and proposals of redesign of NHS services based on them ('foreground intellectual property') will be the intellectual property of West Essex CCG, as will the right to exploit analysis derived from the study data. Intellectual property related to use of the devices used from recording health measurements ('background intellectual property') vests in L2S2 Ltd. Ownership of IP generated by employees of L2S2 vests in L2S2 Ltd and exploitation is managed by L2S2 Ltd.

23. ARCHIVING

Copies of all reports and analytics will be copied to the West Essex CCG at the end of the study. L2S2 will hold the anonymised data for three years and copies of all study materials for seven years after the closure of the project in the company's secure storage facilities in Cambridge UK as described in the participants' brochure.

24. APPENDIX A: STUDY FLOW CHART



25. APPENDIX B: AMENDMENT HISTORY

Amendment No.	Protocol Version No.	Date issued	Author(s) of changes	Details of Changes made
1	2.0	09/03/2020	Steve Curd	Numerous revisions to align RP to new processes
2	2.1	03/06/2020	Philip Gaffney	COVID thresholds
3	2.2	11/06/2020	Philip Gaffney	Aligned with latest government COVID guidelines

List details of all protocol amendments here whenever a new version of the protocol is produced. Protocol amendments must be submitted to the Sponsor for approval prior to submission to the REC committee and HRA (where required).

26. Appendix D NHSD_comorbid_conditions

The attached spreadsheet lists the Snomed codes for comorbid conditions that will be extracted from Accident and Emergency Department ECDS data. This data together with GP data and the collected data from wearables and appropriate medical devices will be used to build models to test the study hypothesis.

Dr Hughes, the Chief Investigator for this study was responsible for the design and deployment of the ECDS to all Accident and Emergency Departments in England in 2018 as the national database for emergency medicine.

27. Appendix E COVID-19 Procedures

Specific COVID-19 procedures have been added to the monitoring app and the care home staff research assistant's SOP.

Phase 1 of the trial was suspended because of the onset of COVID-19 in the UK. It was clear in February 2020 that visiting care homes would be unsafe and the UK was put into lockdown by the government on 23 March to attempt to limit the spread of coronavirus.

It appears that the government will gradually lift lockdown rules from June 2020 but it will be necessary to continue shielding of vulnerable participants for the foreseeable future. The study cohort is focussed on the over 65s with multiple co-morbidities and this group will be particularly susceptible to harm by COVID-19. It would not be possible to visit care homes under the government guidelines that state that care homes should restrict all non-essential healthcare visits.

The trial protocol has been revised to avoid the need for physical contact with the care homes and participants.

The Reassure app used to collect data in this trial has been updated to include secure video conferencing and safety features that make it possible to conduct the trial remotely and yet still obtain reliable data. The app is already in use in NHS hospitals to allow remote monitoring of participants at home during COVID-19.

Before COVID-19 it was intended that staff in some care homes would collect the participant data. Now only care homes that will allow their staff to collect data will be included in the trial. It is proposed that the care home staff will receive training via the app video link to enable them to use the devices safely and achieve good data quality.

The video will not be used for or with participants, only for staff assistance and training.

Each time it is used, the opening screen of the app will assess whether the participant is displaying the symptoms of COVID-19 infection.

It does this by requiring the staff member to follow an on-screen protocol as follows:

1. At the start of each shift the staff member shall record their own temperature and answer COVID symptoms questions. If COVID is suspected, the app will prevent further use by that staff member until a negative result from a formal COVID-19 test is entered or until seven days have passed from the last symptoms. If the staff member is not suspected of having COVID0-19 the app continues as before.
2. Take the participant's temperature using the provided digital thermometer in forehead temperature mode to avoid physical contact with the participant.
3. Answer the question does the participant have a new, continuous cough.
4. Answer the question has the participant reported a loss or change to their sense of smell or taste.
5. Answer the question does the participant have diarrhoea or vomiting.

If the measured temperature is 38.0^{O}C (was 38.2^{O}C but GP advice has caused us to change the threshold temperature to 38.0^{O}C or greater or (previously AND) the answer is yes to any of the questions 1 - 3, the app will indicate to the staff member through a screen message that the participant may have COVID-19. In this case, the participant shall be temporarily excluded from the trial and will have no further involvement until they have been formally tested for COVID-19.

If the test returns negative, the participant shall continue to be included in the trial.

If the participant's test returns positive and the participant is well enough in the view of their doctor and the member of staff to allow re-inclusion in the trial, the trial shall continue with a completely separate set of devices reserved for use on participants with confirmed infection. The original devices and monitoring equipment that first recorded the suspected infection for a participant will not work for that participant unless a negative test result is entered or until seven days after confirmed infection and the symptoms have passed. The digital thermometer that was used to measure the participant's temperature is easily cleanable and will be made safe by the care home's enhanced hygiene procedures. The participant shall be considered clear of risk of passing infection seven days after being tested positive for COVID-19 and the symptoms have passed and monitoring shall continue with the original set of devices.

If the participant's test returns unclear, void, borderline or inconclusive, the participant shall be temporarily excluded from the trial until a further test with a positive or negative outcome is available.

If the participant has a negative result but has diarrhoea or vomiting, the participant shall be temporarily excluded from the trial until 48 hours after the symptoms have stopped.

The app records a full time and date stamped audit log of all actions.

28. Appendix F Informing the Care Home Staff to take Action Based on Device Readings

Readings from medical devices recording vital signs can be used together with a clinical knowledge of a patient's conditions to provide an informed view of whether a patient is suffering an exacerbation that should be investigated. An individual reading from a vital signs monitoring device may cause unnecessary worry and not indicate a serious condition for a particular patient. Care home staff are not medically qualified and will not in general be able to interpret occasional out of bounds readings.

However, values from some devices that give a reliable indication irrespective of the patient's specific condition may be used to aid common sense judgment that action should be taken. The medical device monitoring phone is programmed to show vital signs according to the NEWS2 scoring system used in hospitals to give an 'at a glance' display of a patient's overall status. The SpO_2 alerts and colour scheme used is that of Scale 1 in the NEWS2 scoring system. SpO_2 on its own is not considered to be a safe warning sign as medical knowledge of the patient's condition is needed to decide on a suitable alert threshold.

In Reassure, values that will cause a red alert to be triggered to help the care home worker decide if a patient's condition might require attention are as follows:

Respiration	<= 8 or >= 25 BPM
Temperature	>= 38.0^{O}C (COVID-19 threshold)
Systolic Blood Pressure	<= 90 or >220 mmHg
Pulse	<= 40 or >= 131 bpm (at rest)

ECDS_UniqueID	Sort1	Sort2	ECDS_Group	ECDS_Description	SNOMED_Code	SNOMED_Description	Notes
2018111100	11	11	Circulation / blood	Hypertension	38341003	Hypertensive disorder, systemic arterial (disorder)	
2018111500	11	15	Circulation / blood	History of anticoagulant therapy	161647008	History of anticoagulant therapy (situation)	
2018112100	11	21	Circulation / blood	Ischaemic heart disease	414545008	Ischemic heart disease (disorder)	
2018113100	11	31	Circulation / blood	Cardiac pacemaker in situ	441509002	Cardiac pacemaker in situ (finding)	
2018114300	11	43	Circulation / blood	Congestive heart failure	42343007	Congestive heart failure (disorder)	
2018114500	11	45	Circulation / blood	Left heart failure	85232009	Left heart failure (disorder)	
2018114900	11	49	Circulation / blood	Heart failure	84114007	Heart failure (disorder)	
2018115100	11	51	Circulation / blood	Mitral valve disorder	11851006	Mitral valve disorder (disorder)	
2018118100	11	81	Circulation / blood	Congenital cardiac failure	206586007	Congenital cardiac failure (disorder)	
2018211100	21	11	Respiratory	Asthma	195967001	Asthma (disorder)	
2018212100	21	21	Respiratory	Chronic obstructive lung disease	13645005	Chronic obstructive lung disease (disorder)	
2018212300	21	23	Respiratory	Chronic bronchitis	63480004	Chronic bronchitis (disorder)	
2018214100	21	41	Respiratory	Pulmonary emphysema	87433001	Pulmonary emphysema (disorder)	
2018215100	21	51	Respiratory	Respiratory failure	409622000	Respiratory failure (disorder)	
2018311100	31	11	Gastrointestinal	Dysphagia	40739000	Dysphagia (disorder)	
2018312100	31	21	Gastrointestinal	Jaundice	18165001	Jaundice (finding)	
2018312500	31	25	Gastrointestinal	Liver function tests abnormal	166603001	Liver function tests abnormal (finding)	
2018511100	51	11	Endocrine / Rheumatology	Diabetes mellitus	73211009	Diabetes mellitus (disorder)	
2018515100	51	51	Endocrine / Rheumatology	Rheumatoid arthritis	69896004	Rheumatoid arthritis (disorder)	
2018551100	55	11	Renal / urology	Retention of urine	267064002	Retention of urine (disorder)	
2018552100	55	21	Renal / urology	Renal impairment	236423003	Renal impairment (disorder)	
2018553100	55	31	Renal / urology	Chronic kidney disease	709044004	Chronic kidney disease (disorder)	

2018555100	55	51	Renal / urology	Chronic interstitial nephritis	60926001	Chronic interstitial nephritis (disorder)	
2018555500	55	55	Renal / urology	Small kidney	236448000	Small kidney (disorder)	
2018556100	55	61	Renal / urology	Multiple renal cysts	253883006	Multiple renal cysts (disorder)	
2018556300	55	63	Renal / urology	Congenital cystic kidney disease	82525005	Congenital cystic kidney disease (disorder)	
2018556900	55	69	Renal / urology	Polycycstic kidney disease	765330003	Autosomal dominant polycystic kidney disease (disorder)	New term Oct 2018
2018611100	61	11	Neurology	Epilepsy	84757009	Epilepsy (disorder)	
2018612100	61	21	Neurology	Multiple sclerosis	24700007	Multiple sclerosis (disorder)	
2018613100	61	31	Neurology	Cerebral infarction	432504007	Cerebral infarction (disorder)	
2018613300	61	33	Neurology	Cerebrovascular accident	230690007	Cerebrovascular accident (disorder)	
2018613700	61	37	Neurology	Cerebrovascular disease	62914000	Cerebrovascular disease (disorder)	
2018615100	61	51	Neurology	Subarachnoid haemorrhage	21454007	Subarachnoid intracranial hemorrhage (disorder)	
2018615500	61	55	Neurology	Cerebral haemorrhage	274100004	Cerebral hemorrhage (disorder)	
2018618100	61	81	Neurology	Aphasia	87486003	Aphasia (finding)	
2018618500	61	85	Neurology	Hemiplegia	50582007	Hemiplegia (disorder)	ECDS uniqueID modified April 2018
2018711100	71	11	Psychiatry / psychology	Anxiety disorder	197480006	Anxiety disorder (disorder)	
2018712100	71	21	Psychiatry / psychology	Depressive disorder	35489007	Depressive disorder (disorder)	
2018712500	71	25	Psychiatry / psychology	History of deliberate self harm	314550003	History of deliberate self harm (situation)	
2018712900	71	29	Psychiatry / psychology	Bipolar disorder	13746004	Bipolar disorder (disorder)	
2018716500	71	65	Psychiatry / psychology	Eating disorder	72366004	Eating disorder (disorder)	
2018716700	71	67	Psychiatry / psychology	Schizotypal personality disorder	31027006	Schizotypal personality disorder (disorder)	
2018717100	71	71	Psychiatry / psychology	Schizophrenia	58214004	Schizophrenia (disorder)	
2018717500	71	75	Psychiatry / psychology	Psychotic disorder	69322001	Psychotic disorder (disorder)	
2018717700	71	77	Psychiatry / psychology	Delusional disorder	48500005	Delusional disorder (disorder)	

2018751100	75	11	Developmental	Developmental delay	248290002	Developmental delay (disorder)	
2018752100	75	21	Developmental	Autistic disorder	408856003	Autistic disorder (disorder)	
2018753100	75	31	Developmental	Learning difficulties	161129001	Learning difficulties (finding)	
2018754100	75	41	Developmental	Developmental academic disorder	1855002	Developmental academic disorder (disorder)	
2018811100	81	11	Sensory / age related	Dementia	52448006	Dementia (disorder)	
2018811500	81	15	Sensory / age related	Alzheimer's disease	26929004	Alzheimer's disease (disorder)	
2018812100	81	21	Sensory / age related	Elderly fall	298344006	Elderly fall (finding)	
2018814100	81	41	Sensory / age related	Blindness - both eyes	193699007	Blindness - both eyes (disorder)	
2018814500	81	45	Sensory / age related	Blindness of one eye	22950006	Blindness of one eye (disorder)	
2018814900	81	49	Sensory / age related	Registered blind	170727003	Registered blind (finding)	
2018815100	81	51	Sensory / age related	Complete deafness	8531006	Complete deafness (disorder)	
2018815200	81	52	Sensory / age related	Bilateral deafness	162344009	Bilateral deafness (disorder)	
2018815300	81	53	Sensory / age related	Profound acquired hearing loss	737050003	Profound acquired hearing loss (disorder)	SNOMED definition and or code amended April 2018
2018815400	81	54	Sensory / age related	Profound sensorineural hearing loss	700454004	Profound sensorineural hearing loss (disorder)	
2018815500	81	55	Sensory / age related	Severe hearing loss	3561000119106	Severe hearing loss (disorder)	
2018911100	91	11	Social / drug / alcohol	Smoker	77176002	Smoker (finding)	
2018912100	91	21	Social / drug / alcohol	Lives alone	105529008	Lives alone (finding)	
2018915100	91	51	Social / drug / alcohol	Alcohol abuse	15167005	Alcohol abuse (disorder)	
2018916100	91	61	Social / drug / alcohol	Recreational drug use	26416006	Drug abuse (disorder)	
2018916200	91	62	Social / drug / alcohol	Misuses drugs	361055000	Misuses drugs (finding)	
					28728008		Code Deprecated 31.03.2019
					525791000000105		Code Deprecated 31.03.2019