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The measurement of vital signs by Lifelight® software in comparison to the standard of care

Submission date
27/05/2022

Recruitment status
No longer recruiting

Registration date
18/08/2022

Overall study status
Completed

Last Edited
02/10/2023

Condition category
Other

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Vital signs provide important information about an individual's health. This includes their blood pressure, how fast their heart is beating, how much oxygen is in their blood and how fast they are breathing. They are usually measured during a medical assessment and are important markers of how a patient's illness may be affecting them. Measurements of vital signs can also be used by people at home to help monitor their conditions and help them to recognise when they need to seek medical help.
The standard clinical equipment currently used involves lots of different pieces of equipment. It can be uncomfortable for patients and can sometimes take a long time to get the necessary measurements. This can lead to vital signs not always being done when they are required, or taking up a lot of healthcare staff time, meaning there is less time available for other caring activities. The equipment becomes less accurate over time and must be regularly calibrated to retain adequate accuracy. Some patients are asked to monitor their medical conditions at home using this equipment, but the time and effort required may mean that they are less likely to do this. In addition, there may be patients who might benefit from self-monitoring, but the equipment is too cumbersome or expensive to be available for everyone who needs it, when they need it.
The COVID-19 pandemic has led to many changes in the way hospitals now work. The rigorous infection control measures and the need to eliminate any potential risk of infection spread are vital but can be time-consuming. Equipment needs to be disinfected between patients to prevent the transfer of infection. This means there is an urgent need to develop contactless technology to measure vital signs. This innovative approach will enable the continued provision of high-level patient care at the same time as reducing pressure on nursing and equipment resources. The aim of this study is to advance the development and accuracy of the Lifelight® app for the measurement of vital signs, therefore developing a non-invasive and easy-to-perform means of measuring vital signs which can be implemented across a wide range of settings, both within hospitals and out in the community.

Who can participate?
Anyone over the age of 16 can take part but particularly people who have blood pressure or oxygen saturation readings outside of the normal ranges. This includes people admitted to hospital, those attending outpatient clinic appointments and members of staff.

What does the study involve?
Lifelight® is a computer program ("app") for measuring vital signs which can be used on smart devices that contain a camera. It is able to measure all of the vital signs by measuring very small changes in skin colour that occur each time the heart beats. This means that it does not need to touch the patient. This could be an effective way of measuring vital signs, especially during the COVID-19 pandemic when prevention of cross-contamination between patients is essential. Patients are also likely to be reassured by a contactless approach. The app uses data from looking at a person's face to calculate the vital signs. This is possible because there are tiny changes in facial skin that occur each time the heart beats.
The researchers will recruit people who are attending one of two hospitals, either as an inpatient, an outpatient, a friend/relative of a patient, or a member of hospital staff. The exact number will depend on how quickly the app "learns" and how many of the vital signs are outside of the normal range. The researchers will take the participant's vital signs using standard clinical equipment while they record a video of their face. They will use most of these measurements and video to teach the app how to become more accurate at measuring vital signs. They will keep the remaining data separate and use it to test how accurate the app is. All of the data will be kept securely. The researchers will also collect feedback from participants and healthcare staff on their experiences using the app and information to assess whether there are any savings to the healthcare economy through the use of this technology.

What are the possible benefits and risks of participating?
There is no immediate benefit to participants in this study. Should the technology prove sufficiently accurate, it has the potential to significantly improve the recording of vital signs in all settings by minimizing equipment, time and staffing requirements. It could also allow much more accurate research on blood pressure, cardiac and respiratory problems by allowing much more frequent assessment of vital signs with minimal disturbance to the participant.
It may be possible to identify participants from the video footage collected in this study. Full-face, full-resolution video data are necessary to develop Lifelight® into a clinically useful device. The necessary information required to perform the analysis cannot be obtained from blurred videos. The risk of participants being identified however is minimised by the video files only being labelled with a Xim ID number (this is linked to the study ID number but the link to this number will be kept within the hospital study site and will only be accessible by the research team within that site). Moreover, in most cases, these videos will not be seen by anyone, as the initial analysis of these videos will be conducted computationally only. However, some videos may be viewed by Xim's science team, for example in the case where the algorithm is not performing as expected on that video.

Where is the study run from?
1. Queen Alexandra Hospital (UK)
2. The Royal London Hospital (UK)

When is the study starting and how long is it expected to run for?
October 2020 to April 2022

Who is funding the study?
1. National Institute for Health Research (UK)
2. NHSX (UK)
3. NHS England (UK)

Who is the main contact?
Prof. Anoop Chauhan
anoop.chauhan@porthosp.nhs.uk

Contact information

Type(s)
Scientific

Contact name
Prof Anoop Chauhan

Contact details
Research Department, 1st Floor
Lancaster House
Queen Alexandra Hospital
Southwick Hill Road
Cosham
United Kingdom
PO6 3LY
+44 (0)2392286000
anoop.chauhan@porthosp.nhs.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
289242

ClinicalTrials.gov number
NCT04763746

Secondary identifying numbers
CPMS 47654, IRAS 289242

Study information

Scientific Title
The measurement of VItal SIgns by Lifelight® software in comparisON to the standard of care – Multi-site Development (the VISION-MD study)

Acronym
VISION-MD

Study objectives

To further develop the Lifelight® blood pressure, heart rate, respiratory rate and SpO_2 algorithms across more extensive clinical ranges.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 24/11/2020, South Central - Berkshire Research Ethics Committee (Bristol REC Centre, Whitefriars, Level 3, Block B, Lewins Mead, Bristol, BS1 2NT, UK; +44 (0)20 7104 8057; berkshire.rec@hra.nhs.uk), ref: 20/SC/0432

Study design
Non-randomized; Both; Design type: Screening, Device, Cross-sectional

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Measurement of vital signs

Interventions
Following informed consent, the study staff member will complete a very brief set of demographic and medical history questions, limited to the presence or absence of medical problems and treatment for them. Participants with the capacity to consent will be recruited into either sub-protocol 1, 2 or 3, depending on their previous clinical observations assessed during screening. Participants who lack the capacity to consent to take part in the study will be recruited into sub-protocol 4.

Sub-protocol 1 participants will have blood pressure, oxygen saturation and heart rate measured.
Sub-protocol 2 participants will have respiratory rate and oxygen saturation measured.
Sub-protocol 3 participants will have oxygen saturation measured.
Sub-protocol 4 participants will have blood pressure, heart rate, respiratory rate and oxygen saturation measured.

Participants may also be recruited to a sub-protocol on the basis of their skin tone. This is because there are targets within Sub-protocols 1, 2 and 3 related to skin tone.

Not all vital signs are collected in all participants to focus the study nurse's attention on fewer tasks and to avoid the collection of data that is not subsequently used to meet the study objectives. This approach should help to keep all aspects of data collection as high quality as possible and is consistent with the GDPR requirement of data minimisation. For all sub-protocol 1, 2, 3 and 4 participants, the study team will complete a set of pre-measurement observation questions. Background luminosity will be measured using a handheld lux meter. The staff member will then prepare for and take the participant's routine observations using standard clinical equipment during the same 60-second period that video is captured of the participant's face using the Data Collect app. Best efforts will be made to adhere to the Lifelight® measurement conditions listed in Appendix B. These measurements and video capture will be repeated once more in the case of Sub-protocols 2 and 3, and twice more in the case of sub-protocols 1 and 4. Once measurements are concluded, the study staff member will complete the post-measurement observation questions. In all cases, the cleaning protocol outlined in Appendix D will be adhered to after each study session.

A selection of sub-protocol 1, 2 and 3 participants will be asked to complete a questionnaire related to vital sign monitoring and their preference for Lifelight® or other technologies for measuring vital signs.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Lifelight®

Primary outcome measure
1. Blood pressure (systolic and diastolic) is measured using an automatic sphygmomanometer at baseline and at each subsequent study visit if undertaken (maximum of 10 study sessions)
2. Heart rate is measured using a portable SpO_2 pulse oximetry patient monitoring system at baseline and at each subsequent study visit if undertaken (maximum of 10 study sessions)
3. SpO2 is measured using a portable SpO_2 pulse oximetry patient monitoring system at baseline and at each subsequent study visit if undertaken (maximum of 10 study sessions)
4. Respiratory rate calculated by an appropriately trained healthcare professional at baseline and at each subsequent study visit if undertaken (maximum of 10 study sessions)

Secondary outcome measures
1. The potential clinical efficacy of Lifelight's estimates for blood pressure as well as heart rate, respiratory rate and SpO_2 in multiple clinical settings, e.g. ICU, outpatient clinics and general hospital wards, measured using the Lifelight Data Collect app at baseline and at each subsequent study visit if undertaken (maximum of 10 study sessions)
2. The impact of variables other than vital signs on the accuracies of the Lifelight® vital signs estimates, e.g.:
2.1. Age measured in years at baseline
2.2. Gender measured as Male or Female at baseline
2.3. Temperature measured using a standard-of-care temperature probe at baseline and at each subsequent study visit if undertaken (maximum of 10 study sessions)
2.4. Health condition recorded from electronic patient record at baseline
2.5. Medication recorded from electronic prescription record at baseline

2.6. Cosmetics measured by the presence or absence of visible foundation/concealer (determined by the HCP undertaking the study procedures) at baseline and at each subsequent study visit if undertaken (maximum of 10 study sessions)
2.7. Facial hair measured by the presence or absence of facial hair covering the participant's cheeks (determined by the HCP undertaking the study procedures) at baseline and at each subsequent study visit if undertaken (maximum of 10 study sessions)
2.8. Skin tone measured using the Fitzpatrick scale at baseline and at each subsequent study visit if undertaken (maximum of 10 study sessions)
2.9. Ambient lighting measured using a hand-held lux meter at baseline and at each subsequent study visit if undertaken (maximum of 10 study sessions)
3. The health economic potential of Lifelight® compared to usual practice measured using the length of time it takes to measure vital signs using standard-of-care equipment vs Lifelight® (from the time that the clinician decides to conduct a vitals check, incorporating the time it takes to find the vital signs)
4. Patient and healthcare professional (HCP) experience with existing, contact-based methods that measure vital signs compared to Lifelight measured using a participant or HCP feedback questionnaire following completion of the participant's last study session (for participants) or end of the study for HCPs

Overall study start date
27/10/2020

Completion date
22/04/2022

Eligibility

Key inclusion criteria
16 years old or above

Participant type(s)
Mixed

Age group
Mixed

Lower age limit
16 Years

Sex
Both

Target number of participants
Planned Sample Size: 9500; UK Sample Size: 9500

Key exclusion criteria
Does not meet the inclusion criteria

Date of first enrolment
27/07/2021

Date of final enrolment
01/04/2022

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Queen Alexandra Hospital
Southwick Hill Road
Cosham
Portsmouth
United Kingdom
PO6 3LY

Study participating centre
Royal London Hospital
Whitechapel
London
United Kingdom
E1 1BB

Sponsor information

Organisation
Xim (United Kingdom)

Sponsor details
Chase Green House
42 Chase Side
Enfield
Romsey
England
United Kingdom
EN2 6NF
+44 (0)7803950356
laurence@xim.ai

Sponsor type
Industry

Website
https://www.ximxim.com/

ROR
https://ror.org/04yewpw08

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
NHS England; Grant Codes: AI_AWARD02031

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
NHSX

Results and Publications

Publication and dissemination plan
1. The protocol manuscript has been drafted
2. Planned publication in a high-impact peer-reviewed journal

Intention to publish date
01/03/2023

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available due to protected intellectual property (IP). The sponsors of the study are a small-to-medium enterprise and the data collected in this study will be used to generate further future IP. The availability of publicly accessible data will affect the commercial competitiveness of the company.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Protocol article		11/01/2023	02/10/2023	Yes	No