ISRCTN51530527 https://doi.org/10.1186/ISRCTN51530527

Can the use of wrist or chest-worn wearable devices that measure heart rate, oxygen levels and breathing rate improve the detection of in-hospital patient deterioration-the Virtual High Dependency Unit Study?

Submission date 13/06/2019	**Recruitment status** Suspended	[X] Prospectively registered [ ] Protocol
Registration date 26/07/2019	**Overall study status** Completed	[ ] Statistical analysis plan [ ] Results
Last Edited 04/08/2020	**Condition category** Signs and Symptoms	[ ] Individual participant data [ ] Record updated in last year

Plain English summary of protocol

Current plain English summary 19/09/2019:

Background and study aims

Sometimes in hospital, patients are not detected as becoming unwell quickly enough. This may mean that they are less likely to survive than if the worsening of their illness been picked up sooner. One reason for this may be that hospital staff are unable to monitor patients' vital signs frequently enough to help them decide if a patient is becoming more unwell. Currently, for nurses to monitor patients, they are either attached to a static machine by the patient's bedside or staff have to visit the patient every few hours to manually measure blood pressure, heart rate and respiratory rate amongst other readings. It is now possible that we can monitor patients using small devices which attach to the wrist, finger or chest. This means that nursing staff can continually obtain data from these patients even if the patients wish to mobilise or perform certain activities.

Who can participate?

NHS patients and NHS staff.

What does the study involve?

We are trying to test some of these systems on patients within the clinical area. This will allow us to understand how well these systems work in the clinical environment and how wearable these devices are from the patient perspective. At this stage of the study, none of the data from these devices will be available to clinical staff given that we need to test their reliability within the clinical setting first. We will also develop a computer system which allows staff to document and reviews these observations, which supports their clinical workflows. To develop this system, we will be using feedback at the beginning and the end of the study from users to help us make the most suitable design which will work within their clinical environments.

What are the possible benefits and risks of participating?
No benefits or risks to participating.

Where is the study run from?
The study will be run by the Critical Care Research Group at the Kadoorie Centre for Critical Care Research and Education.

When is the study starting and how long is it expected to run for?
01/05/2018 to 02/03/2022

Who is funding the study?
This study is funded by the NIHR Oxford Biomedical Research Centre.

Who is the main contact?
Carlos Areia
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Previous plain English summary:
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Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
14142

Study information

Scientific Title
Virtual HDU Phase 4: Ambulatory monitoring system user interface integration and development.

Acronym

VHDU

Study objectives
This proposed work aims to develop an electronic system for capturing vital signs in post-operative surgical patients. This will comprise of a fully integrated Ambulatory Monitoring System (AMS) and User Interface (UI). The devices within the AMS will be selected from a number of potential devices and will be refined for use in this patient cohort. The UI will be developed and tested in the clinical environment. We will conduct this work in three potentially overlapping phases. The outcomes of the study will be evaluated by assessing data capture and quality; wearability of monitors; and usability of the system.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 24/06/2019, South Central - Hampshire A Research Ethics Committee (Holiday Inn Southampton, Herbert Walker Ave, Southampton SO15 1HJ; nrescommittee.southcentral-hampshirea@nhs.net; 0207 104 8033), ref: 19/SC/0181.

Study design
This is a longitudinal observational study made up of 3 key stages:
Stage A: Focus Groups
Stage B: Locational testing of AMS
Stage C: User Interface design and Usability Testing

Primary study design
Observational

Study type(s)
Other

Health condition(s) or problem(s) studied
Clinical deterioration of vital sign parameters such as blood pressure, oxygen levels. heart rate or respiratory rate.

Interventions
The first stage of this study aims to understand the clinical user requirements for an AMS-SEND interface. This interface will allow clinical staff to capture and review clinical data from the AMS. A core group of staff participants will be invited to attend a focus group during the early stages of the research. It is anticipated that this group of 5-8 clinical staff members purposively selected from the surgical emergency unit (where all other VHDU research phases have been conducted) and be asked to provide feedback on current UI designs and discuss system functionality). Staff will be approached face to face or by email and have been previously identified from other vHDU studies.

Currently within the Oxford University Hospital (OUH) NHS Foundation Trust, staff input physiological vital sign data into the System for Electronic Notification and Documentation (SEND). This system then displays an aggregate score. Depending on the score generated, the system mandates a course of action according to the escalation of care protocol (i.e. increase observation frequency or refer to a senior colleague for review). If patients were monitored within the clinical area with an AMS, clinical workflows may alter. Observations could be

automatically displayed in the SEND system from the AMS devices without nurse involvement. These observations would then need accepting or rejecting by the clinical staff. With this in mind, it is important that these observations are displayed in such a way that they are clearly distinguishable from observations which were manually inputted. Their aggregate score would also need distinguishing as this would only be made up of three variables (respiratory rate, heart rate and oxygen saturations), rather than the standard number of variables. This initial focus group will explore these issues to provide a baseline for the UI development. During these groups, they will discuss the clinical tasks surrounding the care of patients on continuous monitoring, so that the task of understanding and interacting with the data within the AMS-SEND interface is developed, and can therefore be used for testing in Stage C. It is important that when assessing effectiveness and efficiency, these are assessed against realistic tasks taken from the clinical workflow to truly evaluate the usability of the system.

Stage B – Locational testing of AMS
Locational testing of AMS will be conducted on surgical patients on the target ward. We will conduct several rounds of testing in Stage B.

Patients will be recruited in cohorts of up to 10 per testing cycle. Each AMS will be worn for up to 5 days, during which vital signs and connectivity data will be collected. Patients will be free to remove the monitoring devices at any time.
Each AMS will comprise of up to two devices included in appendix 1. This is likely to be a combination of one chest-worn patch (collecting respiratory rate and heart rate) and one wrist-worn device (collecting peripheral oxygen saturations and heart rate). These devices will be connected via secure Bluetooth to an Embedded Computer (EC, such as Tablets, Smartphones or Single Board Computers). The ECs are small and can be mounted easily to any surface using adequate fixtures. They can be powered either by conventional power socket or internal batteries. The data derived from the monitors will be pushed by the ECs to an OUHFT NHS server managed by the IBME. Both the software running on the ECs and the server will be developed by members of the research team based at the IBME. The ECs software will not store any data locally, except for temporary buffers.
At the end of the testing period (either following 5 days of wear or participant request to remove equipment), each participant will complete a wearability questionnaire. Demographic data will also be collected, such as age, sex and Body Mass Index (BMI). Details regarding informed consent, device removal and study visits are included below in the relevant sections.

Stage C – User Interface design and Usability Testing
Stage C will run concurrently with stage B. The planned cycles of patient testing in stage B will allow several iterations of the UI to be developed and optimised for functionality and suitability for the clinical area. The UI is likely to have fictitious data initially for preliminary testing and towards the end of the study will use de-identified, real patient data (available only to research staff).

*user feedback will be continuous throughout the iterations and it may involve up to 5 key users from the focus group
Human factors methods including observation, process mapping and task analysis.

For the UI to be optimised we need to understand the environment into which this technology is being placed. We will process map the workflows of managerial and clinical teams, incorporating human factors methodologies such as hierarchical task analysis and cognitive task analysis, to inform how the system should be implemented and will be used. This process gives a detailed systematic description of clinical tasks. We will want to understand (but not limited to) the process of vital signs monitoring.

We will develop stakeholder groups from participants who participated in the initial focus group, for each clinical area which will form the basis of engagement for this project. It is likely that interest will be generated through word of mouth. Volunteers will come forward and be included for the development/testing phase. Questionnaires specific to the situation will be developed during the project for use with staff participants during interface usability testing. Interface usability testing.

We will undertake formal usability testing on a feature-complete version of the AMS-SEND system to assess the interface according to the three dimensions outlined in ISO 9421 – effectiveness, efficiency and user satisfaction. This will be undertaken using a combination of methodologies such as heuristic analysis, think aloud, user questionnaires and scenario testing (cognitive walkthrough). We will seek to benchmark the usability data against pre-existing ward monitoring systems to provide a comparative dataset. Our previous experience indicates mixed fidelity usability testing delivers the best results, whilst retaining the opportunity for speed of iteration – that is that the clinical data and environment are tested in high fidelity (real life) situations, which allows the interface to be at a lower fidelity developmental stage, whist delivering the most information to the design team.

Intervention Type
Device

Phase
Not Applicable

Primary outcome(s)
1. The functionality of the interface is determined using the following measures at the end of the study.
1.1. Completed AMS and SEND integration with user interface.
1.2. Real-time AMS data.
1.3. Completed user interface.

Key secondary outcome(s))
1. End-user requirements for the AMS-SEND linked system is determined using collated end-user requirements at the end of stage A.
2. The reliability of data recording in a clinical setting is determined using the proportion of time windows each vital sign (heart rate, SPO2 and breathing rate) is recorded versus time the device is worn at the end of stage B.
3. The reliability and wearability in a clinical setting is determined using the following measures throughout the study:
3.1. Frequency and duration of data drop-out for each vital sign parameter.
3.2. Waveform quality of each vital sign parameter.
3.3. Wearability questionnaire.
4. User interface design optimisation is determined using the following measures throughout the study:
4.1. Satisfaction - System Usability Scale.
4.2. Effectiveness – >80% correctness of specific tasks.
4.3. Efficiency – time to complete task better than currently.
4.4. Workload – NASA TLX ensuring workload to interpret data is not too high.

Completion date

02/03/2022

Eligibility

Key inclusion criteria
Stage A: Staff Focus Group/Interviews
1. Any clinical staff member who uses SEND or measures patient vital signs

Study B: Locational testing of AMS
1. Willing and able to give informed consent for participation in the study.
2. Aged 18 years or above.
3. Admitted to a surgical emergency unit (including post-ICU patients) and not currently monitored with continuous monitoring

Study C: Usability Testing
1. Any clinical staff member who uses SEND and measures patient vital signs
2. Any staff member who may be an end user of a AMS-SEND system

Participant type(s)
All

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
Stage A: Staff Focus Group/Interviews
1. Any staff member who cannot give informed consent

Stage B: Locational testing of AMS
1. Allergies to nickel.
2. Intra-cardiac device
3. Already on continuous monitoring
4. Diagnosed dementia

Stage C: Usability testing
1. Any staff member who cannot give informed consent

Date of first enrolment
01/08/2019

Date of final enrolment

01/03/2022

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Oxford University Hospital Foundation NHS Trust,
John Radcliffe Hospital, Headley Way,
Oxford
United Kingdom
OX3 9DU

Sponsor information

Organisation
University of Oxford

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
University/education

Funder Name
NIHR Oxford Biomedical Research Center

Results and Publications

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			26/07/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes