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Safer and more efficient vital signs monitoring: an observational study

Submission date
19/11/2018

Recruitment status
No longer recruiting

Registration date
01/02/2019

Overall study status
Completed

Last Edited
02/04/2024

Condition category
Signs and Symptoms

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Background and study aims
Taking measurements of heart rate, blood pressure, temperature and other "vital signs" is an important part of care for nearly all patients in hospital. Staff and patients often refer to this as taking observations. Changes in observations are used to track recovery and can show when someone's condition is getting worse and needs urgent attention. When changes are spotted early, medical staff can often prevent serious deterioration, provide early treatment and avoid serious consequences including death. However, taking observations can be burdensome to patients, interfering with rest and sleep, which are also important to recovery. Frequent observations also cause more work for nursing staff. At the moment, there is little evidence to guide hospital staff on how frequently to take observations. Therefore, it is important to find out how often patients need to be monitored.

This study aims to address this by developing an evidence-based protocol for how frequently observations should be made that will be both safe and achievable across all acute NHS hospitals.

Who can participate?
Data from the records of all adult patients who have been admitted to the Oxford University Hospitals NHS Foundation Trust and Portsmouth Hospitals NHS Trust will be used. No personal information that identifies individual patients will be used.

A random sample of staff members from both Trusts as well as University Hospitals Southampton NHS Foundation Trust will be recruited to be observed taking vital signs observations.

What does the study involve?
Records from two hospitals where vital signs are recorded in electronic systems will be used. In total, 6 million measurements from over 200,000 hospital admissions are available. Using information from one hospital, early warning scores can be calculated and tracked for changes over time, the aim of identifying the earliest point possible where deterioration can be detected. By linking these measurements to other information (such as diagnoses, cardiac arrests, intensive care admissions), the extent to which changes in vital signs affect patients' risk of poor

outcomes can be determined. The results of these analyses will be used to set monitoring schedules, which will then be tested on the patient data from the second hospital.

Additionally, ward staff taking observations will be watched and timed., enabling an estimation of how much work will be generated by each monitoring schedule and estimate the expected staff requirements.

What are the possible benefits and risks from participating?
There is no benefit to participants but future patients and staff may benefit from the evidenced-based protocol for patient monitoring once complete. There are no known risks to participants taking part in this study.

Where is the study run from?
The study is being run by the University of Portsmouth in collaboration with the University of Oxford and the University of Southampton. Patient vital signs observations data will be taken from the Oxford University Hospitals NHS Foundation Trust and Portsmouth Hospitals NHS Trust. Ward staff taking observations at Oxford University Hospitals NHS Foundation Trust, Portsmouth Hospitals NHS Trust and University Hospital Southampton NHS Foundation Trust will be studied.

When is the study starting and how long is it expected to run for?
October 2018 to September 2021

Who is funding the study?
National Institute of Health Research (NIHR) (UK)

Who is the main contact?
Rachel Henning
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Contact information

Type(s)
Public

Contact name
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Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
17/05/03

Study information

Scientific Title
Safer and more efficient vital signs monitoring to identify the deteriorating patient: an observational study towards deriving evidence-based protocols for patient surveillance on the general hospital ward

Acronym
FOBS

Study objectives
This study aims to recommend an externally validated vital signs monitoring protocol for patients on general medical and surgical wards which maximises the detection of patient deterioration without increasing current nursing workload.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Current ethics approval information as of 27/01/2020:
Approved 26/06/2019, South Central – Berkshire REC (Bristol REC Centre, Whitefriars, Bristol, BS1 2NT; 02071048224; nrescommittee.southcentral-berkshire@nhs.net), ref: 19/SC/0190, 19/CAG/0132

Previous ethics approval information as of 29/07/2019:
Approved 26/06/2019, South Central – Berkshire REC (Bristol REC Centre, Whitefriars, Bristol, BS1 2NT; 02071048224; nrescommittee.southcentral-berkshire@nhs.net), ref: 19/SC/0190

Previous ethics approval information:
Not provided at time of registration – submission pending

Study design
Observational mixed methods study

Primary study design
Observational

Secondary study design
Mixed methods

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Patients at risk of deterioration in the hospital

Interventions
Current interventions as of 27/01/2020:
This study involves retrospective analysis of vital signs data from Portsmouth and Oxford hospitals. These data will be used to model the rate of change of vital signs over time using continuous-time state-space models and their relationship with adverse outcomes. Vital signs will be converted to different scoring schemes (such as NEWS or CEWS). Alongside quantifying the future risk of adverse outcomes given a patient's current vital signs, the use of such scoring systems allows prediction of the likelihood of clinically significant changes to a patient's condition, by using established thresholds. The results of these probability models will enable the design of monitoring protocols, where vital signs are measured at the earliest future time points where deterioration is most likely to be detected.
Vital signs monitoring will also be observed in a sample of four wards in four different hospitals. Staff workload (time, grade) involved in taking and responding to vital signs in different patient groups will be estimated. In addition, potential reductions in mortality and changes in ICU use associated with improved detection will be modelled. These estimates will be used to model the incremental costs for all protocols whose performance is equivalent to or exceeds that of the current early warning score protocols for detecting deterioration. We will engage with key clinical stakeholder groups (nurses, doctors, healthcare assistants) to identify additional factors to be considered in designing monitoring protocols. We will collect views from these key professional groups though focus groups, interviews, ad-hoc discussion, and facilitated /mediated Twitter Chat sessions.

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Intervention Type
Mixed

Primary outcome measure
1. The future risk of adverse outcomes will be determined by the change in vital signs vs the risk of adverse outcomes over time.
1.1. Adverse outcomes will be defined as mortality, unplanned admission to ICU and cardiac arrest.
2. Staff workload will be measured using the time taken to obtain and record vital signs observations and the factors that affect the time taken.
3. The cost for all protocols will be measured using estimates of the cost associated with changes in frequency and type of vital signs observations.

Secondary outcome measures
N/A

Overall study start date
01/10/2018

Completion date
30/09/2021

Eligibility

Key inclusion criteria
Current inclusion criteria as of 27/01/2020:
For the database study:
1. Aged 16 years and over
2. Admitted to any hospital from Portsmouth Hospitals NHS Trust since 1st January 2010 or Oxford University Hospitals NHS Foundation Trust since 1st January 2017

For the observational study:
1. At each site, we will randomly select 4 wards on which to conduct observations

Previous inclusion criteria:
For the database study:
1. Aged 16 years and over
2. Admitted to any hospital from Portsmouth Hospitals NHS Trust or Oxford University Hospitals NHS Foundation Trust since 1st January 2014

For the observational study:
1. At each site we will randomly select 4 wards on which to conduct observations

Participant type(s)
Patient

Age group
Adult

Lower age limit
16 Years

Sex
Both

Target number of participants
In the database, we aim to include over 200,000 patient admissions. In the ward based study, we aim to capture at least 640 sets of observations.

Key exclusion criteria
1. Patients whose data are not entered into local electronic patient records
2. Patients who request that their details are not used for research
3. Patients on maternity wards

Date of first enrolment
01/01/2014

Date of final enrolment
31/03/2020

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Oxford NHS Foundation Trust
John Radcliffe Hospital
Headley Way
Oxford

United Kingdom
OX3 9DU

Study participating centre
Portsmouth Hospitals NHS Trust
Queen Alexandra Hospital
Portsmouth
United Kingdom
PO6 3LY

Sponsor information

Organisation
University of Portsmouth

Sponsor details
Finance Office
University House
Winston Churchill Avenue
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United Kingdom
PO1 2UP

Sponsor type
University/education

ROR
https://ror.org/03ykbk197

Funder(s)

Funder type
Government

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

Results and Publications

Publication and dissemination plan
1. The project aim is to produce an evidence-based protocol for patient surveillance on general hospital wards.
2. There will be a final report within 12 months of the end of the project.
3. One or more papers will describe the protocol and the process by which it was developed. These will be published in the latter stages of the project or after project completion.
4. Further interim papers are likely and will be confirmed at a later date.

Intention to publish date
30/06/2022

Individual participant data (IPD) sharing plan
Patient level data will be collected without specific, individual, informed consent. An application for a waiver of consent will be made to the HRA Confidentiality Advisory Board as part of the ethical review process.

No patient level data will be collected/recorded as part of the qualitative research work. Consent will be 'assumed' to collect summary level data where this is relevant to the wider task under observation (the task of taking vital signs observations).

The qualitative research datasets generated during and/or analysed during the current may be available after study closure upon request from the Chief Investigator, Professor Jim Briggs (jim.briggs@port.ac.uk). Applications to access the dataset/s for secondary data analysis will be reviewed by the Frequency of Observations management committee and Project Oversight Group and approval will be determined by the extent to which plans improve quality of care and patient outcomes, support research in 'recognising the deteriorating patient', and support the training, education, or continuing professional development of clinical professionals.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/06/2021	25/03/2021	Yes	No
Protocol file	version 1.2	20/03/2019	10/08/2022	No	No
HRA research summary			28/06/2023	No	No
Results article		01/03/2024	02/04/2024	Yes	No