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Retrospective analysis of vital signs data from patients with COVID-19 using the 'virtual high dependency unit' monitoring system

Submission date
17/03/2022

Recruitment status
No longer recruiting

Registration date
22/03/2022

Overall study status
Completed

Last Edited
23/03/2022

Condition category
Infections and Infestations

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

Plain English summary of protocol

Background and study aims
Sometimes in hospital, patients are not detected quickly enough as becoming unwell. This may mean that they are less likely to survive than if the worsening of their illness had been picked up sooner, especially for patients with COVID-19. 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 breathing rate amongst other readings. Recent developments in technology mean it is now possible to monitor patients using small devices which attach to the wrist, finger or chest, enabling nursing staff to continually obtain data from these patients, whilst freeing them to continue to mobilise or perform certain activities. In the past years, researchers have tested these devices and developed a system to allow clinical staff to see the continuous vital signs. It became clear at the end of February 2020 that the technology and software developed could be adapted for the isolation ward for patients with COVID-19 at the John Radcliffe Hospital. This wearable system was particularly useful for patients with COVID-19 who did not need to be ventilated, as it is important for their recovery that they remain mobile. The aim of this study is to analyse anonymised data from patients wearing these devices to describe vital signs patterns over the course of COVID-19 infection while being monitored with this system, and to assess its impact on patient safety and care.

Who can participate?
This is a retrospective data study. Only patients aged 18 years or over who were monitored using the Virtual High Dependency Unit monitoring system as part of usual care during the COVID-19 pandemic are eligible.

What does the study involve?
This study involves analysing anonymised vital signs and other clinical data from eligible patients.

What are the possible benefits and risks of participating?
There are no risks to taking part in this study as the researchers are analysing anonymised data.

Where is the study run from?
University of Oxford (UK)

When is the study starting and how long is it expected to run for?
February 2021 to August 2022

Who is funding the study?
The Oxford NIHR Biomedical Research Centre (UK)

Who is the main contact?
Dr Sarah Vollam
sarah.vollam@ndcn.ox.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Sarah Vollam

ORCID ID
https://orcid.org/0000-0003-2835-6271

Contact details
Kadoorie Centre, Level 3
John Radcliffe Hospital
Oxford
United Kingdom
OX3 9DU
+44 (0)1865 223101
sarah.vollam@ndcn.ox.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
295599

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Version 2, IRAS 295599

Study information

Scientific Title
Trajectories of continuously monitored vital signs of patients with COVID-19: a retrospective data study

Study objectives
Despite acknowledgement of the physical effects of COVID-19, little is known about the trajectory of vital signs for patients with this new condition. The use of a unique ambulatory monitoring system in clinical practice offers an opportunity to examine the patterns of vital signs which have been collected continuously over several days as part of clinical care. This has the potential to inform future management of this illness and other similar viral respiratory infections. Furthermore, as intermittent measurements of vital signs were also taken by staff using standard hospital equipment and based on local early warning score protocols, these data offer the opportunity to compare the use of continuous versus intermittent vital signs measurements to detect deterioration.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 01/04/2021, Health Research Authority (2 Redman Place, Stratford, London, E20 1JQ, UK; +44 (0)207 104 8000; approvals@hra.nhs.uk), ref: 21/HRA/1234

Study design
Retrospective data study

Primary study design
Observational

Study type(s)
Other

Health condition(s) or problem(s) studied
COVID-19 (SARS-CoV-2 infection)

Interventions
An exploratory study investigating the trajectory of vital signs in hospitalised level one patients with COVID-19. This is a single-site hospital-based study using data collected as part of the usual care of patients admitted with COVID-19 through an ambulatory monitoring system deployed as part of the response to the COVID-19 pandemic. As this is a retrospective study there will be no participant recruitment or study visits.

Data will be requested for patients monitored using the AMS as part of usual hospital care between 23/03/2020 and 28/02/2021, consisting of a limited set of patient demographic and outcome data which will be linked with continuous vital signs data from the AMS and intermittent vital signs measurements, both collected as part of usual care. Once data have been linked, datasets will be anonymised by the Oxford University Hospitals NHS Foundation Trust and shared with the research group for the purposes of this study.

Intervention Type
Other

Primary outcome(s)
The physiological pattern of vital signs over the course of COVID-19 infection for hospitalised level 1 patients that used the vHDU system (ambulatory monitoring of vital signs), determined by measuring the frequency and duration of periods for which at least one vital sign (pulse rate, respiratory rate, blood oxygen saturation, blood pressure, Glasgow Coma Scale score and temperature) exceeds local Track and Trigger (Early Warning Score) thresholds, throughout the duration of each patient's monitored hospital admission.

Key secondary outcome(s))
1. The frequency and timing of deteriorations occurring during the monitored hospital admission for each patient (defined as periods for which at least one vital sign (pulse rate, respiratory rate, peripheral oxygen saturation, blood pressure, Glasgow Coma Scale score and temperature) exceeds local Track and Trigger thresholds) detected using continuous vital signs monitoring compared with those detected using intermittent vital signs measurements.
2. Number of adverse events in COVID-19 patients monitored via the ambulatory monitoring system: the number of in-hospital deaths, admissions to intensive care, escalation of care to NIV /HFNO and cardiac arrest calls documented in the care record as occurring during the monitored hospital admission for all patients
3. The number of deterioration events during the monitored hospitalisation period preceding an adverse event for those patients who experience an adverse event compared with the number of deterioration events in patients who did not experience an adverse event during their monitored hospital admission.
4. Escalation thresholds for both local Early Warning Scores and National Early Warning Score 2 will be applied to continuous vitals data throughout the monitored hospitalised period for each patient. Duration and frequency of continuous vital signs data meeting escalation thresholds will be compared between the two scoring systems.
5. Heart rate, respiratory rate and peripheral oxygen saturation measurements entered into the local electronic track and trigger system during each patient's monitored hospital admission will be compared with data recorded by the ambulatory monitoring system for the same parameter at the closest timepoint.
6. AMS system reliability measured using the number of hours of continuous vital-sign data acquired by the pulse oximeter and the chest patch during the time each patient was registered on the ambulatory monitoring system

Completion date
31/08/2022

Eligibility

Key inclusion criteria
1. Male or female, aged 18 years or above
2. Diagnosed with COVID-19
3. Admitted to a ward using the Virtual HDU monitoring system

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group

Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
Not monitored using the Virtual HDU system

Date of first enrolment
23/03/2022

Date of final enrolment
31/08/2022

Locations

Countries of recruitment
United Kingdom

England

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

Sponsor information

Organisation
University of Oxford

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Government

Funder Name
NIHR Oxford Biomedical Research Centre

Alternative Name(s)
NIHR Biomedical Research Centre, Oxford, OxfordBRC, OxBRC

Funding Body Type
Private sector organisation

Funding Body Subtype
Research institutes and centers

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
No data sharing is possible as the data is anonymised and retrieved for the purpose of this study only.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes