ISRCTN23769228 https://doi.org/10.1186/ISRCTN23769228

# Can we understand and identify factors contributing to the successful detection of deteriorating patients and rescuing them within the hospital ward?

**Submission date**
02/10/2020

**Recruitment status**
No longer recruiting

**Registration date**
26/04/2021

**Overall study status**
Completed

**Last Edited**
19/01/2024

**Condition category**
Other

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

**Plain English summary of protocol**
Background and study aims
Every year up to 20,000 hospital patients suffer a preventable death because staff inadequately recognise patient illness or there are delays in a medical review and escalation of care where necessary. Further reductions to patient deaths are possible, by examining the care of unwell hospital patients who are successfully treated.

The aim of the study is to develop a framework of success factors that can inform refinements to the escalation of care (rescue) processes resulting in improved deteriorating patient outcomes.

Who can participate?
Staff working in the hospital can participate in phases 1 and 3. In phase 2, patient records will be used.

What does the study involve?
Phase 1: Staff observations during escalation events
Observation of around between 200-400 care escalation events detailing staff interactions for ward patients. Escalation of care defined as any communication relating to the recognition of patient deterioration.

Phase 2: Care record reviews
Review of between 200-400 patient care records (nursing and medical documentation) from patients who deteriorated, improved, and were not admitted to ICU.

Phase 3: Staff interviews
Interviews with 30 expert doctors and nurses to identify: escalation success factors, how these could be applied effectively, and the impact of pandemic care models

Phase 4: Data analysis and integration
This final stage involves looking at all the data together. This knowledge will be used to develop an intervention to help staff identify and communicate that a patient is becoming more unwell. This intervention will be tested in a future research study.

What are the possible benefits and risks of participating?
There are no direct benefits or risks. The output of this study may reduce hospital mortality, morbidity, unnecessary ICU admissions or facilitate timely ICU admission.

Where is the study run from?
Oxford University Hospital NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
April 2020 to April 2023

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

Who is the main contact?
Jody Ede
jody.ede@ouh.nhs.uk

# Contact information

### Type(s)
Scientific

### Contact name
Mrs Jody Ede

### ORCID ID
https://orcid.org/0000-0001-7289-6991

### Contact details
Adult Intensive Care Unit
John Radcliffe Hospital
Oxford
United Kingdom
OX3 9DU
+44 (0)7710169303
jody.ede@ouh.nhs.uk

# Additional identifiers

### Clinical Trials Information System (CTIS)
Nil known

### Integrated Research Application System (IRAS)
283418

### ClinicalTrials.gov (NCT)
Nil known

### Protocol serial number
IRAS 283418

# Study information

### Scientific Title
SUccess Factors Facilitating Care during Escalation (SUFFICE)

### Acronym
SUFFICE

### Study objectives
To understand and identify success factors contributing to patients being detected as deteriorating and rescued within the clinical ward area

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Approval pending, London Confidentiality Advisory Group 20CAG0106
Queen Square Ethics committee, ref: 20/HRA/3828

### Study design
Multicentre mixed-methods exploratory sequential study

### Primary study design
Observational

### Study type(s)
Prevention

### Health condition(s) or problem(s) studied
Escalation of care for deteriorating ward patients

### Interventions
Phase 1: Two groups of participants are recruited and consented in this phase of data collection. The first participant group are those medical staff that are directly observed and shadowed during observations of escalation events. These participants are required to sign a consent form prior to the observation sessions giving their informed consent to being observed by a researcher. Staff will be shadowed for no longer than 4 hours at a time, but may be shadowed on multiple occasions. The second participant group are those clinical staff members that are indirectly observed but are integral to an escalation event. It is not feasible to obtain prior written consent from this group, so verbal consent will be collected in the first instance. Once the escalation event is completed (and it is safe to do so) indirectly observed staff will sign a retrospective consent form.

Between 200-400 (COVID positive and negative) escalation events will be observed to develop a theoretical understanding of the process of rescue. Informal interviews will supplement observations, probing events, staffing levels, or actions. Data collected will include patient factors (age, admission type), escalation factors (escalation triggers, EWS), and contextual ward factors (staffing levels). Shelford Safer Care Nursing Tool (SNCT) data, giving an indication of ward staffing levels and ward acuity or dependency will be collected for wards where an escalation event is witnessed.

Phase 2: Involves a review of between 200-400 patient care records (nursing and medical documentation) from patients who deteriorated, improved, and were not admitted to ICU.

We will review 350 care records to understand why some patients deteriorate to the point where their condition would trigger an intensive care review (a trigger event) but avoid and ICU admission. A further 50 notes (giving a total of up to 400 care records) will be reviewed from participants who became unwell on the ward, were admitted to ICU and died. The review process is conducted in three stages; Level 1 reviews, Level 2 (in-depth) reviews and validation:
1. Level 1 reviews: care records are given quality of care scores before, during, and after the trigger event. Quality of care is graded by the reviewer, from 1-5 (1- very poor care, 2- poor care, 3- adequate care, 4 good care, and 5- excellent care) in each care period. A vignette will be documented consisting of explicit judgements justifying the rationale of each quality of care grade. A modified Case Report Form (CRF) tool will be used to collect the data based on the Structure Judgment Tool utilised within NHS mortality reviews. Data collected will include patient factors; age, length of hospital stay, Clinical Frailty Score, and Charlson Co-morbidity scores, Safer Nursing Care Tool (SNCT) data.
2. Level 2 reviews will be conducted on care records that have been graded scores of 4-5 (indicating Good to Excellent care). From these records, a rich qualitative narrative of care factors will be extracted giving a chronology of care pre and post-trigger event. Themes from care reviews may also be explored in Phase 3.
3. Validation- A random proportion of Level 1 (10%) and Level 2 (n=5) care record reviews will be conducted by a second researcher to assess care judgements scores (1-5) and a Kappa Coefficient (for interrater reliability) calculated. The second researcher is likely to be one of the research team (list as contributors) or a clinical/research colleague with suitable expertise, training and trust clearances. Significant agreement will be assumed with a result of >0.64 based on a previous notes review study.

Phase 3: Staff participants are recruited and consented prior to the interviews. These will be held face to face of via the telephone and should last no longer than 90 minutes. Interviews will be digitally recorded.

We will interview up to 30 nursing and medical experts with greater than 4 years' clinical experience, to understand factors affecting successful care escalation and identify how these could be applied effectively across healthcare settings. This may be staff who also participated in Phase 1. Interviews will be guided by a piloted interview topic guide exploring how staff manage the task of escalation, decisions made, and why.

Phase 4: This final stage involves looking at all the data to develop an intervention for use in a future research study to help staff identify and communicate that a patient is becoming more unwell. We will perform a framework analysis on study data to identify care escalation success factors, that if effectively applied, may afford improvements to the process of care escalation. It is likely that this framework will be multi-faceted and may include (SOCK-B):
1. Success factor (description of the factor)
2. Outcome (what outcome that factor facilitates)

3. Context (what is the context to that factor such as ward, patient)
4. Knowledge base (what is understood about that factor in the literature)
5. Balancing measure (identify negative system outcomes if that factor)

### Intervention Type
Procedure/Surgery

### Primary outcome(s)
2. Framework development of care escalation success factors to inform refinements to the escalation process, resulting in improved deteriorating patient outcomes developed from observations, care record reviews, and staff interviews

### Key secondary outcome(s))
1. Identification of success factors to generate a report detailing how care escalation success factors can be applied more effectively and an analysis report describing patients who are successfully escalated and care escalations in both COVID-19 and non-COVID-19 patients through observations, care record reviews, and staff interviews detailing successful care escalation in ward patients

### Completion date
01/04/2023

## Eligibility

### Key inclusion criteria
1. Phase 1: Staff participants should be over the age of 18 and be willing to give informed consent.
2. Phase 2: Retrospective Care Records Review (RCRR):
2.1. Record reviews survivors:
2.1.1. Patients have had an EWS 7 or greater
2.1.2. Have not been admitted to ICU
2.1.3. Survived their hospital admission (discharged home or to another care facility)
2.1.4. Have Covid-19 and non-Covid-19 infections
2.2. Record reviews deceased:
2.2.1. Patients have triggered a 7 or greater NEWS score
2.2.2. Have been admitted to ICU and died
2.2.3. Have Covid-19 and non-Covid-19 infections
3. Phase 3: Staff Applied Cognitive Task Analysis (ACTA) interviews: Any staff member who has experience of escalating or receiving a care escalation, and has 4 years or greater clinical experience

### Participant type(s)
Mixed

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 years

### Sex
All

### Key exclusion criteria
1. Phase 1: Events that do not meet the escalation of care definition
2. Phase 2: Patients not for cardiopulmonary resuscitation or receiving palliative care
3. Phase 3: Participant not able to give informed consent

### Date of first enrolment
01/11/2020

### Date of final enrolment
01/11/2021

## Locations

### Countries of recruitment
United Kingdom

England

### Study participating centre
**John Radcliffe Hospital**
Oxford University Hospital NHS Foundation Trust
Oxford
United Kingdom
OX3 9DU

### Study participating centre
**Churchill Hospital**
Oxford University Hospitals NHS Foundation Trust
Old Road
Headington
Oxford
United Kingdom
OX3 7LE

## Sponsor information

### Organisation

Oxford University Hospitals NHS Trust

**ROR**
https://ror.org/03h2bh287

# 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

**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? |
|---|---|---|---|---|---|
| Results article | | 10/12/2023 | 19/01/2024 | Yes | No |
| HRA research summary | | | 28/06/2023 | No | No |
| Protocol (preprint) | non-peer-reviewed protocol in preprint | 16/11/2021 | 19/11/2021 | No | No |