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BMJ Open

How human factors affect escalation of care: a protocol for a systematic review and thematic synthesis of qualitative studies

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Keywords:	Failure to rescue, Escalation of care, Human factors, Qualitative, Thematic synthesis, Systematic Review

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Manuscripts

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4 1 Title Page5
6 2 **How human factors affect escalation of care: a**
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8 3 **protocol for a systematic review and thematic**
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10 4 **synthesis of qualitative studies**
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26 14 **Oxford and the Wellcome Trust through the Health Innovation Challenge Fund. The views**
27 15 **expressed are those of the author(s) and not necessarily those of the NHS, the NIHR or the**
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1 ABSTRACT

2 Introduction

3 Failure to rescue (FTR) is defined as mortality after complications during an in-hospital admission.
4 Incidence of FTR varies between hospitals but has been estimated as 10.9% in high-volume hospitals
5 and 13.3% in low-volume hospitals. Several national reports such as National Confidential Enquiry
6 into Patient Outcomes and Death (NCEPOD) and NICE CG 50 emphasise this theme

7 For FTR to be avoided, there must be a successful escalation of care (EOC) initiated by bedside staff.
8 Studies have found that Human Factors such as situational awareness, team working,
9 communication and safety culture contribute to FTR. Understanding these human factors is essential
10 to developing working systems that mitigate barriers and encourage facilitation of EOC. This
11 qualitative systematic review is the first synthesis of what is known about the human factors that
12 affect EOC.

13 Methods and Analysis

14 We will search MEDLINE (Ovid) and EMBASE (Ovid) for studies describing human factors that affect
15 FTR and EOC. A search strategy was developed by two researchers assisted by a medical librarian.
16 Only studies exploring EOC in hospital ward populations using qualitative data collection methods
17 will be included. Screening will be conducted by two researchers from different professional
18 backgrounds. Selected studies will be assessed for quality, rigor and limitations. Two researchers will
19 extract and thematically synthesise codes using a piloted data extraction tool to develop analytical
20 themes.

21 Ethics and dissemination

22 This systematic review will use available published literature and therefore no ethical approval is
23 required. This systematic review will be limited by the quality of studies available and the rigor and
24 reproducibility of study findings. This review will synthesise what is known about human factors and
25 escalation of care, highlighting gaps within the literature. Results of this review will be published in
26 peer reviewed journal, presented at conferences and publicised on social media.

27 TRIAL REGISTRATION

28 PROSPERO: (CRD42018104745)

29 ARTICLE SUMMARY

30 Strengths and Limitations of this study

- 31 • FTR is a common and significant problem in healthcare which affects patient mortality
- 32 • For FTR to be avoided, an escalation of care needs to occur. This efficacy of this can be
33 positively or negatively affected by human factors
- 34 • This protocol ensures a comprehensive and unbiased search and analysis of qualitative
35 studies exploring this phenomenon using best practice guidelines
- 36 • The results of this review will identify strengths and weaknesses of the literature in this
37 area
- 38 • This review will highlight future research direction and address some of the identified
39 weaknesses

40

1 INTRODUCTION

2 FTR is defined as the mortality rate of patients who suffer complications in hospital (1) . The
3 incidence of FTR varies between hospitals but has been estimated as 10.9% in high-volume hospitals
4 and 13.3% in low-volume hospitals. A proportion of patient deaths (32%) reported to the National
5 Patient Safety Agency (NSPA) had failures surrounding diagnostic errors and deteriorations which
6 were not adequately recognised (5). This theme is present in several national reports such as
7 National Confidential Enquiry into Patient Outcomes and Death (NCEPOD) (3,6–8) and NICE CG 50
8 (4).

9 For FTR to be avoided, bedside clinical staff must usually initiate successful escalation of care (EOC)
10 (9). This staged process requires detection of deterioration, communication about deterioration, and
11 medical actions following a senior review (3). Many factors affect this process such as situational
12 awareness, team working, communication, safety culture and leadership (3,10–14). Understanding
13 these human factors is essential to developing working systems that mitigate barriers and encourage
14 facilitation.

15 As a primary outcome, this qualitative systematic review will identify the human factors which affect
16 EOC in the acute hospital setting. It will summarise what is currently understood about the
17 involvement of human factors and their implications for practice. As a secondary outcome, it will
18 identify any gaps in the current literature and establish strengths and weaknesses of the research.
19 This will identify potential areas for further research in human factors and EOC.

21 Methods and Analysis

22 Registration

23 This protocol adheres to the requirements of Preferred Reporting Items for Systematic Review and
24 Meta-analysis Protocols (PRISMA-P). The protocol was registered with PROSPERO
25 (CRD42018104745)

26 Information sources

27 Literature search strategies will be developed using Medical Subject Headings (MeSH) and text
28 words related to the human factors involved in the escalation of care for deteriorating patients.

29 The following databases will be searched: MEDLINE (Ovid), EMBASE (Ovid).

30 Reference lists of eligible studies and relevant reviews will be explored to identify further eligible
31 studies.

32 Search strategy

33 A draft of the search strategy was developed by three of the authors (JE, VW and TP - a medical
34 librarian). The proposed search strategy is shown in the online Supplementary File 1.

35 Inclusion Criteria

36 *Types of studies*

37 This systematic review will include qualitative studies which report primary data. Qualitative studies
38 are defined as those studies which use qualitative data collection and analysis methods. These can

1 include but are not limited to: ethnography, interviews, focus groups and human factors methods.
2 Data analysis is likely to be but not limited to: thematic analysis, grounded theory and discourse
3 analysis.

4 *Phenomenon of interest*

5 Studies must report primary data and describe the human factors which affect FTR and EOC. FTR is
6 defined as patient mortality following complications (1) and EOC is a staged process where patients
7 are detected as deteriorating and that deterioration is communicated followed by a senior review
8 (3). We will include any qualitative study which explores the perspective of patients or clinical staff
9 (adults or paediatric) and the human factors which affect the EOC process. We are defining human
10 factors as any barrier or facilitator that affects teamwork, tasks, equipment, workspace, culture and
11 organisation (15).

12 *Setting*

13 The study setting is in-hospital, ward care.

14 **Exclusion criteria**

15 *Types of studies*

16 We will exclude systematic reviews, grey-literature, editorials, letters, practice guidelines and
17 abstract-only reports. We will also exclude protocols without study data.

19 *Phenomenon of interest*

20 We are only interested in real-life scenarios where human factors effects can be studied in the
21 patient environment. Simulation based studies will be excluded.

22 *Setting*

23 We will exclude studies carried out in the Emergency Department, Critical Care (including the
24 Intensive Care Unit and Coronary care) or Maternity. These are specialised areas which makes
25 generalisability of EOC themes to the ward environment challenging. We will also exclude studies
26 set in palliative care.

27 *Time-frame*

28 No time limitations will be applied

29 *Language*

30 Non-English papers will be excluded.

31 **Study selection**

32 Reference lists from both databases will be entered into Covidence software (Covidence systematic
33 review software, Veritas Health Innovation, Melbourne, Australia. Available at www.covidence.org).
34 Papers will be de-duplicated. Two authors will independently screen titles and abstracts of identified
35 papers against the inclusion and exclusion criteria. They will not be blinded to journal titles, study
36 authors or institutions. If there is disagreement or uncertainty regarding eligibility, the full-text will
37 be reviewed. We will retrieve full-text for all articles not excluded by the initial screening. Two
38 authors will independently assess these papers against the inclusion and exclusion criteria outlined
39 above. We will resolve disagreements about eligibility by discussion between the screening
40 researchers or a third party. We will record the reason for excluding studies.

41 **Data extraction**

1 Data extraction tools will be developed and piloted before the review takes place. Extracted data will
 2 be entered into an Excel spreadsheet. Initial codes from studies will be documented with NVivo
 3 [NVivo qualitative data analysis Software; QSR International Pty Ltd. Version 10, 2014]. Two
 4 reviewers will independently extract a selection data from the texts to ensure validity of results. Any
 5 discrepancies within the data collection phase will be resolved by discussion between reviewers.

6 *Data items extracted*

7 We will extract the following data from each included publication. The data extraction method has
 8 been piloted with a sample selection of papers and valid data has been obtained.

9 *Table 1- Anticipated data to be extracted*

Study Characteristics	Patient/Participant demographics	Study setting	Themes	Rigor
<ul style="list-style-type: none"> • Author • Date of study • Study Type • Methodology • Country of study • Data collection methods • Journal • Data analyses 	<ul style="list-style-type: none"> • Age • Patient group • In-patient characterisation 	<ul style="list-style-type: none"> • Level of care • Hospital Type • Education 	<ul style="list-style-type: none"> • Codes 	<ul style="list-style-type: none"> • Strengths • Weaknesses • Reporting guidelines used

10

11 **Quality Assessment**

12 The CASP qualitative checklist (Critical Appraisal Skills Programme) will be used to assess credibility,
 13 transferability, dependability and confirmability. This checklist is an extensive and comprehensive
 14 tool commonly used in qualitative study assessment (16,17). Two researchers will discuss quality
 15 findings for each study and a consensus will be reached as to the studies' inclusion or exclusion
 16 within the systematic review. As part of the CASP assessment the authors will explore the potential
 17 for reporting bias within the studies and biases will be reported in studies' limitations.

18 **Data Analysis**

19 We will undertake a thematic synthesis (17) using the Thomas and Harden (18) framework. The
 20 three stages of the framework are: coding of the findings of studies, categorisation of codes into
 21 descriptive themes, and categorisation of descriptive themes into analytical themes (19). NVivo
 22 software will be used to facilitate the analysis and record decisions (audit trail) of coding by the
 23 researchers. Codes relating to human factors and EOC will be identified in the text, and tables will be
 24 used to create descriptive and analytical themes. Key codes, descriptive themes and analytical
 25 themes will be presented in the results.

26 **Ethics and dissemination**

27 The proposed systematic review will use available published literature and therefore no ethical
 28 approval is required. This systematic review will be limited by the quality of studies available and the
 29 rigor and reproducibility of study findings. Original studies included in the review could themselves
 30 be limited and it may be difficult to assess the researcher involvement and their individual bias. The

1 two researchers carrying out screening for this review come from different professional
2 backgrounds; this limits interpretation bias when assessing the studies to include. A recognised
3 assessment tool will be used to determine study quality. Using NVivo to code studies will aid
4 transparency in and demonstrate a clear strategy for identifying themes. An audit trail will be kept
5 throughout the systematic review detailing research decisions made and methodological steps
6 taken.

7 The results from this review will be published and made publically available. A number of social
8 media techniques (Twitter, Facebook) will be used to promote the protocol, final systematic review
9 paper and results. We will also aim to attend at least one conference to present findings from this
10 work.

11
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For peer review only

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3 1 S0964339709001074-main.pdf?_tid=42ebcfc6-34aa-11e7-a31b-
4 2 00000aacb362&acdnat=1494329333_5d17d9cc08ce503e7b37debb709eaa99
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1 Contributions

2 PW is the guarantor. JE was responsible for the overall design of the systematic review. JE and VW
3 drafted the manuscript. TP and JE developed the search strategy. PW and JD provided systematic
4 review and qualitative expertise. All authors read, provided feedback and approved the final
5 manuscript.

6 Declarations

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15 by the NIHR Biomedical Research Centre, Oxford.

16 *Availability of data and materials*

17 Not applicable

18 *Consent for publication*

19 Not applicable

20 *Ethics approval and consent to participate*

21 Not applicable

22 *Competing interests*

23 The authors declare that they have no competing interests.

24

Supplementary File 1 (Draft Search Strategy for MEDLINE)

1. HOSPITALIZATION/
2. TERTIARY CARE CENTERS/
3. (ward or wards).ab,ti.
4. (inhospital or inpatient* or "in hospital").ab,ti.
5. (hospitalised or hospitalized).ab,ti.
6. "general hospital".ab,ti.
7. "nurs* staff* ".ab,ti.
8. "in patient".ab,ti.
9. bedside.ab,ti.
10. outreach.ab,ti.
11. 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10
12. FAILURE TO RESCUE,HEALTH CARE/
13. "fail* to rescue ".ab,ti.
14. VITAL SIGNS/
15. MONITORING,PHYSIOLOGIC/
16. "vital sign* ".ab,ti.
17. (track and trigger).ab,ti.
- 18."early warning".ab,ti.
19. "warning score* ".ab,ti.
20. "early sign* ".ab,ti.
21. "warning system* ".ab,ti.
22. (deteriorat* or escalat*).ab,ti.
23. triggering.ab,ti.
24. HOSPITAL RAPID RESPONSE TEAM/
25. "rapid response".ab,ti.
26. "critical care outreach".ab,ti.
27. 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26
28. MEDICAL ERROR/
29. DELAYED DIAGNOSIS/
30. COMMUNICATION/
31. PATIENT CARE TEAMS/

1
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3 32. PATIENT SAFETY/
4

5 33. ORGANIZATIONAL CULTURE/
6

7 34. LEADERSHIP/
8

9 35. "human factor* ".af.
10

11 36. "human error* ".af.
12

13 37. "clinical error* ".af.
14

15 38. "medical error* ".af.
16

17 39. "protocol adherence".af.
18

19 40. "protocol compliance".af.
20

21 41. "teamwork* ".af.
22

23 42. communication.af.
24

25 43. ("socio cultural" or sociocultural).af.
26

27 44. "situation awareness".af.
28

29 45. "organisational culture".af.
30

31 46. "organizational culture".af.
32

33 47. "safety culture".af.
34

35 48. "patient safety".af.
36

37 49. leadership.af.
38

39 50. "root cause analysis".af.
40

41 51. 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36 or 37 or 38 or 39 or 40 or 41 or 42 or 43 or 44
42 or 45 or 46 or 47 or 48 or 49 or 50
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PRISMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols) 2015 checklist: recommended items to address in a systematic review protocol*

Section and topic	Item No	Checklist item	Page No
ADMINISTRATIVE INFORMATION			
Title:			
Identification	1a	Identify the report as a protocol of a systematic review	Pg 1 Line 3
Update	1b	If the protocol is for an update of a previous systematic review, identify as such	n/a
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number	Pg 2 Line 28 Pg 3 Lines 22-25
Authors:			
Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	Pg 1 Lines 6-10
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review	Pg 9 Lines 1-5
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments	n/a
Support:			
Sources	5a	Indicate sources of financial or other support for the review	Pg 1 Lines 13-16 Pg 9 Lines 6-10
Sponsor	5b	Provide name for the review funder and/or sponsor	Pg 1 Lines 13-16 Pg 9 Lines 6-10
Role of sponsor or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	n/a
INTRODUCTION			
Rationale	6	Describe the rationale for the review in the context of what is already known	Pg 2 Lines 2-12 Pg 3 Lines 9-14
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	Pg 3 Lines 15-19
METHODS			
Eligibility criteria	8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review	Pg 3 Lines 35-38 Pg 4 Lines 1-13

Information sources	9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage	Pg 3 Lines 26-31
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated	Supplementary File 1
Study records:			
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	Pg 4 Lines 30-32 Pg 4 Lines 41-42 Pg 5 Line 1
Selection process	11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)	Pg 4 Lines 30-39
Data collection process	11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	Pg 4 Lines 40-42 Pg 5 Lines 1-2
Data items	12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications	Pg 5 Lines 4-8 (inc table)
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	Pg 3 Lines 15-19
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis	Pg 5 Lines 9-15
Data synthesis	15a	Describe criteria under which study data will be quantitatively synthesised	n/a
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I^2 , Kendall's τ)	n/a
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)	n/a
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned	n/a
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)	Pg 5 Lines 14-15
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (such as GRADE)	Pg 5 Lines 9-15

*** It is strongly recommended that this checklist be read in conjunction with the PRISMA-P Explanation and Elaboration (cite when available) for important clarification on the items. Amendments to a review protocol should be tracked and dated. The copyright for PRISMA-P (including checklist) is held by the PRISMA-P Group and is distributed under a Creative Commons Attribution Licence 4.0.**

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BMJ Open

How human factors affect escalation of care: a protocol for a qualitative evidence synthesis of studies

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Date Submitted by the Author:	09-Jan-2019
Complete List of Authors:	Ede, Jody; John Radcliffe Hospital, University of Oxford Westgate, Verity ; University of Oxford, Nuffield Department of Clinical Neurosciences Petricin, Tatjana; University of Oxford Health Care Libraries, Cairns Library Darbyshire, Julie; University of Oxford, NDCN Watkinson, Peter; Oxford University Hospitals NHS Trust, Kadoorie Centre for Critical Care research and Education
Primary Subject Heading:	Qualitative research
Secondary Subject Heading:	Evidence based practice, Nursing, Intensive care, Research methods
Keywords:	Failure to rescue, Escalation of care, Human factors, Qualitative, Thematic synthesis, QUALITATIVE RESEARCH

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7 2 **How human factors affect escalation of care: a**
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9 3 **protocol for a qualitative evidence synthesis of**
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26 13 **“Supported by the NIHR Biomedical Research Centre, based at Oxford University Hospitals Trust,**
27 14 **Oxford and the Wellcome Trust through the Health Innovation Challenge Fund. The views**
28 15 **expressed are those of the author(s) and not necessarily those of the NHS, the NIHR or the**
29 16 **Department of Health”**
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32 17
33 18 Word count: 126434
35 19 Keywords: Failure to rescue, escalation of care, human factors, qualitative, thematic, systematic
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1 ABSTRACT (300)

2 Introduction

3 Failure to rescue is defined as mortality after complications during hospital care. Incidence ranges
4 10.9% - 13.3% and several national reports such as National Confidential Enquiry into Patient
5 Outcomes and Death and National Institute of Clinical Excellence CG 50 highlight failure to rescue as
6 a significant problem for safe patient care.

7 To avoid failure to rescue events, there must be successful escalation of care. Studies indicate that
8 human factors such as situational awareness, team working, communication, and a culture
9 promoting safety contribute to avoidance of failure to rescue events. Understanding human factors
10 is essential to developing working-systems that mitigate barriers and facilitate prompt escalation of
11 care. This qualitative evidence synthesis will identify and synthesise what is known about the human
12 factors that affect escalation of care.

13 Methods and Analysis

14 We will search MEDLINE (Ovid), EMBASE (Ovid), and CINAHL for studies describing human factors
15 affecting both failure to rescue and/or care escalation. A search strategy was developed by two
16 researchers and a medical librarian. Only studies exploring in-hospital (ward) populations using
17 qualitative data collection methods will be included. Screening will be conducted by two researchers
18 from different professional backgrounds. We are likely to undertake a thematic synthesis, using the
19 Thomas and Harden framework. Selected studies will be assessed for quality, rigor and limitations.
20 Two researchers will extract and thematically synthesise codes using a piloted data extraction tool to
21 develop analytical themes.

22 Ethics and dissemination

23 The qualitative evidence synthesis will use available published literature and no ethical approval is
24 required. This synthesis will be limited by the quality of studies, rigor and reproducibility of study
25 findings. This publication will synthesise what is known about human factors and escalation of care,
26 highlighting gaps within the literature. Results will be published in a peer-reviewed journal,
27 publicised at conferences and on social media.

28 TRIAL REGISTRATION

29 PROSPERO: (CRD42018104745)

30 ARTICLE SUMMARY

31 Strengths and limitations of this study

- 32 • Failure to rescue is a common problem in healthcare with significant effects on patient
33 mortality
- 34 • For failure to rescue to be avoided, an escalation of care needs to occur. The efficacy of
35 this can be positively or negatively affected by human factors
- 36 • This protocol ensures a comprehensive and unbiased search and analysis of qualitative
37 studies exploring this phenomenon using best practice guidelines
- 38 • The results of this review will identify strengths and weaknesses of the literature in this
39 area
- 40 • This review will highlight potential research direction for future studies and will address
41 some of the weaknesses identified in published research projects

1 INTRODUCTION

2 Failure to rescue is defined as the mortality rate of patients who suffer complications in hospital (1).
3 The incidence of failure to rescue events varies between hospitals but has been estimated as 10.9%
4 in high-volume hospitals and 13.3% in low-volume hospitals (2). A proportion of patient deaths
5 (32%) reported to the National Patient Safety Agency (NSPA) had failures surrounding diagnostic
6 errors and deteriorations which were not adequately recognised (3). Failure to recognise the need to
7 rescue patients by providing timely escalation of care is a finding in several national reports such as
8 National Confidential Enquiry into Patient Outcomes and Death (NCEPOD) (4–7) and NICE CG 50 (8).

9 For ‘failure to rescue’ to be avoided, bedside clinical staff must usually initiate successful escalation
10 of care (9). This staged process requires detection of deterioration, communication about
11 deterioration, and medical actions following senior review (4). Many factors affect this process such
12 as situational awareness, team working, communication, safety culture and leadership (4,10–14).
13 Understanding these human factors is essential to developing working systems that mitigate barriers
14 and facilitate prompt escalation of care.

15 The aim of this qualitative evidence synthesis is to map the human factors which affect escalation of
16 care in the acute hospital setting. It will summarise what is currently understood about the role
17 human factors play in the delivery of good clinical care. Secondly, it will identify gaps in the current
18 literature and establish strengths and weaknesses of research conducted to date. This will produce
19 an evidence base from which escalation of care theory could be developed. We will also identify
20 potential areas for further research in human factors and the escalation of care process.

22 Methods and Analysis

23 Registration

24 This protocol adheres to the requirements of Preferred reporting items for systematic review and
25 meta-analysis protocols (PRISMA-P). The protocol was registered with PROSPERO (ref:
26 CRD42018104745)

27 Information sources

28 Literature search strategies will be developed using Medical Subject Headings (MeSH) and text
29 words related to the human factors involved in the escalation of care for deteriorating patients.

30 The following databases will be searched: MEDLINE (Ovid), EMBASE (Ovid), and CINAHL.

31 Reference lists of eligible studies and relevant reviews will be explored to identify further eligible
32 studies.

33 Search strategy

34 A draft of the search strategy was developed by three of the authors (JE, VW and TP). The proposed
35 search strategy is shown in the online Supplementary File 1.

36 Inclusion Criteria

1 *Types of studies*

2 This qualitative evidence synthesis will include qualitative studies which report primary data.
3 Qualitative studies are defined as those using qualitative data collection and analysis methods.
4 These can include, but are not limited to, ethnography, interviews, focus groups and human factors
5 methods. Data analysis is likely (but not limited) to include thematic analysis, grounded theory,
6 and/or discourse analysis. We will also include grey literature. All studies meeting inclusion criteria
7 will be included and reviewed.

8 *Study focus*

9 Studies must report primary data and describe human factors affecting failure to rescue and
10 escalation of care. Failure to rescue is defined as patient mortality following complications (1) and
11 escalation of care is a staged process where patients are identified as 'deteriorating', and that
12 deterioration is then communicated followed by senior review and medical intervention where
13 necessary (4). We will include any qualitative study which explores the perspective of patients or
14 clinical staff (adults or paediatric) and the human factors which affect the escalation of care process.
15 We are defining human factors as any barrier or facilitator that affects teamwork, tasks, equipment,
16 workspace, culture, or organisation (15).

17 *Setting*

18 The study setting is in-hospital, ward care.

19 **Exclusion criteria**

20 *Types of studies*

21 We will exclude systematic reviews, editorials, letters, practice guidelines and abstract-only reports.
22 We will also exclude protocols without study data.

23 *Phenomenon of interest*

24 We are only interested in real-life scenarios where human factors effects can be studied in the
25 patient environment. Simulation based studies will be excluded.

26 *Setting*

27 We will exclude studies carried out in the Emergency Department, Critical Care (including the
28 Intensive Care Unit and Coronary care) or Maternity. These are specialised areas which makes it
29 challenging to generalise to the ward environment any 'escalation of care' practices identified in
30 these areas. We will also exclude studies set in palliative care.

31 *Time-frame*

32 No time limitations will be applied

33 *Language*

34 Non-English papers will be excluded.

35 **Study selection**

36 Reference lists from all databases will be entered into Covidence software (Covidence systematic
37 review software, Veritas Health Innovation, Melbourne, Australia. Available at www.covidence.org).
38 Papers will be de-duplicated. Two authors will independently screen titles and abstracts of identified
39 papers against the inclusion and exclusion criteria. They will not be blinded to journal titles, study
40 authors or institutions. If there is disagreement or uncertainty regarding eligibility, the full-text will
41 be reviewed. We will retrieve full-text for all articles not excluded by the initial screening. Two
42 authors will independently assess these papers against the inclusion and exclusion criteria outlined
43 above. We will resolve disagreements about eligibility by discussion between the screening
44 researchers or a third party. We will record the reason for excluding studies.

1 Data extraction

2 Data extraction tools will be developed and piloted before the review takes place. Extracted data will
 3 be entered into Excel (Microsoft Office 2016). Initial coding will be documented with NVivo [NVivo
 4 qualitative data analysis Software; QSR International Pty Ltd. Version 10, 2014]. Two reviewers will
 5 independently extract a selection data from the texts to ensure validity of results. Any discrepancies
 6 within the data collection phase will be resolved by discussion between reviewers or a third party.

7 *Data items extracted*

8 We will extract the following data from each included publication (refer to Table. 1 for full data
 9 details). The data extraction method has been piloted with a sample selection of papers and valid
 10 data have been obtained.

11 *Table 1- Anticipated data to be extracted*

Study Characteristics	Patient/Participant demographics	Study setting	Themes	Rigor
<ul style="list-style-type: none"> • Author • Date of study • Study Type • Methodology • Country of study • Data collection methods • Journal • Data analyses 	<ul style="list-style-type: none"> • Age • Patient group • In-patient characterisation 	<ul style="list-style-type: none"> • Level of care • Hospital Type • Education 	<ul style="list-style-type: none"> • Codes 	<ul style="list-style-type: none"> • Strengths • Weaknesses • Reporting guidelines used

13 Quality Assessment

14 The CASP qualitative checklist (Critical Appraisal Skills Programme) will be used to assess credibility,
 15 transferability, dependability and confirmability. This checklist is an extensive and comprehensive
 16 tool commonly used in qualitative study assessment (16,17). As part of the CASP assessment the
 17 authors will explore the potential for reporting bias within the studies and biases will be reported in
 18 studies' limitations. We will also apply the Confidence in the Evidence from Reviews of Qualitative
 19 research (GRADE-CERQual) criteria to judge studies (18). Two researchers will discuss each study and
 20 a consensus will be reached to include or exclude.

21 Data Analysis

22 This review aims to explore relevant theory and map barriers and facilitators to escalation of care for
 23 which thematic synthesis is well suited (17). We are likely to undertake a thematic synthesis, using
 24 the Thomas and Harden framework (19). This framework supports data extraction from anywhere
 25 within the paper, and is not confined to the results alone. The three stages of the framework are:
 26 coding findings from included studies, categorisation of codes into descriptive themes, and
 27 categorisation of descriptive themes into analytical themes (19). Stage one involves line by line
 28 coding of data, where each sentence is allocated a code. Stage two involves categorising each coded
 29 sentence into descriptive, broader themes. The final stage involves generating analytical themes, or
 30 'going beyond' the findings of the initial study, which relate to the fixed or emerging research
 31 question. Whilst we have been explicit at this point as to the anticipated framework, it is also

1 justifiable for this to change once the search has been conducted (20). NVivo software will be used
2 to code the original text from the papers. Using this software will facilitate analysis for this evidence
3 synthesis and will be used to record decisions (by audit trail) of coding. Codes relating to human
4 factors and escalation of care will be identified from anywhere within the papers, and tables will be
5 used to record descriptive and analytical themes. Key codes, descriptive themes and analytical
6 themes will be presented in the results. We will use the enhancing transparency in reporting the
7 synthesis of qualitative research (ENTREQ) guidelines to report findings (21).

8 **Patient and Public Involvement (PPI)**

9 A patient representative has read and provided feedback on the protocol. As a result, some points
10 have been clarified and medical “jargon” removed.

12 **Ethics and dissemination**

13 The proposed evidence synthesis will use published literature and therefore no ethical approval is
14 required. This publication will be limited by the quality of studies available and the rigor and
15 reproducibility of study findings. Original studies included in the review could themselves be limited
16 and it may be difficult to assess the researcher involvement and their individual bias. The two
17 researchers carrying out screening for this review come from different professional backgrounds,
18 limiting interpretation bias when assessing the studies for inclusion. A recognised assessment tool
19 will be used to determine study quality. Using NVivo to code studies will aid transparency and
20 demonstrate a clear strategy for theme identification. An audit trail kept throughout the process,
21 will detail decisions made and methodological steps taken.

22 The results from this review will be published and made freely available. A number of social media
23 techniques (including Twitter, Facebook, and our research group website) will be used to promote
24 the protocol, final paper and results. We will also aim to attend at least one conference to present
25 findings from this work.

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50 21 [00000aacb362&acdnat=1494329333_5d17d9cc08ce503e7b37debb709eaa99](http://ac.els-cdn.com/S0964339709001074/1-s2.0-S0964339709001074-main.pdf?_tid=42ebcfc6-34aa-11e7-a31b-00000aacb362&acdnat=1494329333_5d17d9cc08ce503e7b37debb709eaa99)
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For peer review only

1 **Contributions**

2 PW is the guarantor. JE was responsible for the overall design of the QES. JE and VW drafted the
3 manuscript. TP and JE developed the search strategy. PW and JD provided QES and qualitative
4 expertise. All authors read, provided feedback and approved the final manuscript. We would like to
5 thank patient representative, TD for his contribution to this work.

6 **Declarations**

7 *Funding*

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15 by the NIHR Biomedical Research Centre, Oxford.

16 *Availability of data and materials*

17 Not applicable

18 *Consent for publication*

19 Not applicable

20 *Ethics approval and consent to participate*

21 Not applicable

22 *Competing interests*

23 The authors declare that they have no competing interests.

24

Supplementary File 1 (Draft Search Strategy for MEDLINE)

1. HOSPITALIZATION/
2. TERTIARY CARE CENTERS/
3. (ward or wards).ab,ti.
4. (inhospital or inpatient* or "in hospital").ab,ti.
5. (hospitalised or hospitalized).ab,ti.
6. "general hospital".ab,ti.
7. "nurs* staff* ".ab,ti.
8. "in patient".ab,ti.
9. bedside.ab,ti.
10. outreach.ab,ti.
11. 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10
12. FAILURE TO RESCUE,HEALTH CARE/
13. "fail* to rescue ".ab,ti.
14. VITAL SIGNS/
15. MONITORING,PHYSIOLOGIC/
16. "vital sign* ".ab,ti.
17. (track and trigger).ab,ti.
18. "early warning".ab,ti.
19. "warning score* ".ab,ti.
20. "early sign* ".ab,ti.
21. "warning system* ".ab,ti.
22. (deteriorat* or escalat*).ab,ti.
23. triggering.ab,ti.
24. HOSPITAL RAPID RESPONSE TEAM/
25. "rapid response".ab,ti.
26. "critical care outreach".ab,ti.
27. 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26
28. MEDICAL ERROR/
29. DELAYED DIAGNOSIS/
30. COMMUNICATION/
31. PATIENT CARE TEAMS/

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3 32. PATIENT SAFETY/
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5 33. ORGANIZATIONAL CULTURE/
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7 34. LEADERSHIP/
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9 35. "human factor* ".af.
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11 36. "human error* ".af.
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13 37. "clinical error* ".af.
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15 38. "medical error* ".af.
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17 39. "protocol adherence".af.
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19 40. "protocol compliance".af.
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21 41. "teamwork* ".af.
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23 42. communication.af.
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25 43. ("socio cultural" or sociocultural).af.
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27 44. "situation awareness".af.
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29 45. "organisational culture".af.
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31 46. "organizational culture".af.
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33 47. "safety culture".af.
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35 48. "patient safety".af.
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37 49. leadership.af.
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39 50. "root cause analysis".af.
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PRISMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols) 2015 checklist: recommended items to address in a systematic review protocol*

Section and topic	Item No	Checklist item	Page No
ADMINISTRATIVE INFORMATION			
Title:			
Identification	1a	Identify the report as a protocol of a systematic review	Pg 1 Line 3
Update	1b	If the protocol is for an update of a previous systematic review, identify as such	n/a
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number	Pg 2 Line 29 Pg 3 Lines 25-26
Authors:			
Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	Pg 1 Lines 6-10
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review	Pg 10 Lines 1-4
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments	n/a
Support:			
Sources	5a	Indicate sources of financial or other support for the review	Pg 1 Lines 13-16 Pg 9 Lines 6-14
Sponsor	5b	Provide name for the review funder and/or sponsor	Pg 1 Lines 13-16 Pg 9 Lines 6-10
Role of sponsor or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	n/a
INTRODUCTION			
Rationale	6	Describe the rationale for the review in the context of what is already known	Pg 2 Lines 2-12 Pg 3 Lines 1-14
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	Pg 3 Lines 15-20
METHODS			
Eligibility criteria	8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review	Pg 3 Lines 34-36 Pg 4 Lines 1-18

Information sources	9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage	Pg 3 Lines 27-32
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated	Supplementary File 1
Study records:			
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	Pg 4 Lines 36-38 Pg 5 Lines 2-6
Selection process	11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)	Pg 4 Lines 38-44
Data collection process	11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	Pg 5 Lines 2-6
Data items	12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications	Pg 4 Lines 7-10(in table)
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	Pg 4 Lines 9-10
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis	Pg 5 Lines 13-20
Data synthesis	15a	Describe criteria under which study data will be quantitatively synthesised	n/a
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I^2 , Kendall's τ)	n/a
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)	n/a
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned	n/a
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)	Pg 5 Lines 13-20
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (such as GRADE)	Pg 5 Lines 19-20

*** It is strongly recommended that this checklist be read in conjunction with the PRISMA-P Explanation and Elaboration (cite when available) for important clarification on the items. Amendments to a review protocol should be tracked and dated. The copyright for PRISMA-P (including checklist) is held by the PRISMA-P Group and is distributed under a Creative Commons Attribution Licence 4.0.**

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BMJ Open

How human factors affect escalation of care: a protocol for a qualitative evidence synthesis of studies

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Keywords:	Failure to rescue, Escalation of care, Human factors, Qualitative, Thematic synthesis, QUALITATIVE RESEARCH

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Manuscripts

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4 1 Title Page5
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7 2 **How human factors affect escalation of care: a**
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9 3 **protocol for a qualitative evidence synthesis of**
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11 4 **studies**
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25 12
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27 14 **Oxford and the Wellcome Trust through the Health Innovation Challenge Fund. The views**
28 15 **expressed are those of the author(s) and not necessarily those of the NHS, the NIHR or the**
29 16 **Department of Health”**30
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35 19 Keywords: Failure to rescue, escalation of care, human factors, qualitative, thematic, systematic
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1 ABSTRACT

2 Introduction

3 Failure to rescue is defined as mortality after complications during hospital care. Incidence ranges
4 10.9% - 13.3% and several national reports such as National Confidential Enquiry into Patient
5 Outcomes and Death and National Institute of Clinical Excellence CG 50 highlight failure to rescue as
6 a significant problem for safe patient care.

7 To avoid failure to rescue events, there must be successful escalation of care. Studies indicate that
8 human factors such as situational awareness, team working, communication, and a culture
9 promoting safety contribute to avoidance of failure to rescue events. Understanding human factors
10 is essential to developing work-systems that mitigate barriers and facilitate prompt escalation of
11 care. This qualitative evidence synthesis will identify and synthesise what is known about the human
12 factors that affect escalation of care.

13 Methods and Analysis

14 We will search MEDLINE (Ovid), EMBASE (Ovid), and CINAHL, between database inception and 2018,
15 for studies describing human factors affecting failure to rescue and/or care escalation. A search
16 strategy was developed by two researchers and a medical librarian. Only studies exploring in-
17 hospital (ward) populations using qualitative data collection methods will be included. Screening will
18 be conducted by two researchers. We are likely to undertake a thematic synthesis, using the Thomas
19 and Harden framework. Selected studies will be assessed for quality, rigor and limitations. Two
20 researchers will extract and thematically synthesise codes using a piloted data extraction tool to
21 develop analytical themes.

22 Ethics and dissemination

23 The qualitative evidence synthesis will use available published literature and no ethical approval is
24 required. This synthesis will be limited by the quality of studies, rigor and reproducibility of study
25 findings. Results will be published in a peer-reviewed journal, publicised at conferences and on social
26 media.

27 TRIAL REGISTRATION

28 PROSPERO: (CRD42018104745)

29 ARTICLE SUMMARY

30 Strengths and limitations of this study

- 31 • Failure to rescue is a common problem in healthcare with significant effects on patient
32 mortality
- 33 • For failure to rescue to be avoided, an escalation of care needs to occur. The efficacy of
34 this can be positively or negatively affected by human factors
- 35 • This protocol ensures a comprehensive and unbiased search and analysis of qualitative
36 studies exploring this phenomenon using best practice guidelines
- 37 • The results of this review will identify strengths and weaknesses of the literature in this
38 area
- 39 • This review will highlight potential research direction for future studies and will address
40 some of the weaknesses identified in published research projects

1 INTRODUCTION

2 Failure to rescue is defined as the mortality rate of patients who suffer complications in hospital (1).
3 The incidence of failure to rescue events varies between hospitals but has been estimated as 10.9%
4 in high-volume hospitals and 13.3% in low-volume hospitals (2). A proportion of patient deaths
5 (32%) reported to the National Patient Safety Agency (NSPA) had failures surrounding diagnostic
6 errors and deteriorations which were not adequately recognised (3). Failure to recognise the need to
7 rescue patients by providing timely escalation of care is a finding in several national reports such as
8 National Confidential Enquiry into Patient Outcomes and Death (NCEPOD) (4–7) and NICE CG 50 (8).

9 For ‘failure to rescue’ to be avoided, bedside clinical staff must usually initiate successful escalation
10 of care (9). This staged process requires detection of deterioration, communication about
11 deterioration, and medical actions following senior review (4). Many factors affect this process such
12 as situational awareness, team working, communication, safety culture and leadership (4,10–14).
13 Understanding these human factors is essential to developing working systems that mitigate barriers
14 and facilitate prompt escalation of care.

15 The aim of this qualitative evidence synthesis is to map the human factors which affect escalation of
16 care in the acute hospital setting. It will summarise what is currently understood about the role
17 human factors play in the delivery of clinical care. Secondly, it will identify gaps in the current
18 literature and establish strengths and weaknesses of research conducted to date. This will produce
19 an evidence base from which escalation of care theory could be developed. We will also identify
20 potential areas for further research in human factors and the escalation of care process.

22 Methods and Analysis

23 Registration

24 This protocol adheres to the requirements of Preferred reporting items for systematic review and
25 meta-analysis protocols (PRISMA-P). The protocol was registered with PROSPERO (ref:
26 CRD42018104745)

27 Information sources

28 Literature search strategies will be developed using Medical Subject Headings (MeSH) and text
29 words related to the human factors involved in the escalation of care for deteriorating patients.

30 The following databases will be searched: MEDLINE (Ovid), EMBASE (Ovid), and CINAHL. Dates
31 searched will be from database inception to January 2018.

32 Reference lists of eligible studies and relevant reviews will be explored to identify further eligible
33 studies.

34 Search strategy

35 A draft of the search strategy was developed by three of the authors (JE, VW and TP). The proposed
36 search strategy is shown in the online Supplementary File 1.

37 Inclusion Criteria

1 *Types of studies*

2 This qualitative evidence synthesis will include qualitative studies which report primary data.
3 Qualitative studies are defined as those using qualitative data collection and analysis methods.
4 These can include, but are not limited to, ethnography, interviews, focus groups and human factors
5 methods. Data analysis is likely (but not limited) to include thematic analysis, grounded theory,
6 and/or discourse analysis. We will also include grey literature. All studies meeting inclusion criteria
7 will be included and reviewed.

8 *Study focus*

9 Studies must report primary data and describe human factors affecting failure to rescue and
10 escalation of care. Failure to rescue is defined as patient mortality following complications (1) and
11 escalation of care is a staged process where patients are identified as 'deteriorating', and that
12 deterioration is then communicated followed by senior review and medical intervention where
13 necessary (4). We will include any qualitative study which explores the perspective of patients or
14 clinical staff (adults or paediatric) and the human factors which affect the escalation of care process.
15 We are defining human factors as any barrier or facilitator that affects teamwork, tasks, equipment,
16 workspace, culture, or organisation (15).

17 *Setting*

18 The study setting is in-hospital, ward care.

19 **Exclusion criteria**

20 *Types of studies*

21 We will exclude systematic reviews, editorials, letters, practice guidelines and abstract-only reports.
22 We will also exclude protocols without study data.

23 *Phenomenon of interest*

24 We are only interested in real-life scenarios where human factors effects can be studied in the
25 patient environment. Simulation based studies will be excluded.

26 *Setting*

27 We will exclude studies carried out in the Emergency Department, Critical Care (including the
28 Intensive Care Unit and Coronary care) or Maternity. These are specialised areas which makes it
29 challenging to generalise to the ward environment any 'escalation of care' practices identified in
30 these areas. We will also exclude studies set in palliative care.

31 *Time-frame*

32 No time limitations will be applied

33 *Language*

34 Non-English papers will be excluded.

35 **Study selection**

36 Reference lists from all databases will be entered into Covidence software (Covidence systematic
37 review software, Veritas Health Innovation, Melbourne, Australia. Available at www.covidence.org).
38 Papers will be de-duplicated. Two authors will independently screen titles and abstracts of identified
39 papers against the inclusion and exclusion criteria. They will not be blinded to journal titles, study
40 authors or institutions. If there is disagreement or uncertainty regarding eligibility, the full-text will
41 be reviewed. We will retrieve full-text for all articles not excluded by the initial screening. Two
42 authors will independently assess these papers against the inclusion and exclusion criteria outlined
43 above. Papers which inclusion is uncertain, will be fully reviewed for synthesis suitability. We will

1 resolve disagreements about eligibility by discussion between the screening researchers or a third
2 party. We will record the reason for excluding studies.

3 **Data extraction**

4 Data extraction tools will be developed and piloted before the review takes place. Extracted data will
5 be entered into Excel (Microsoft Office 2016). Initial coding will be documented with NVivo [NVivo
6 qualitative data analysis Software; QSR International Pty Ltd. Version 10, 2014]. Two reviewers will
7 independently extract a selection data from the texts to ensure validity of results. Any discrepancies
8 within the data collection phase will be resolved by discussion between reviewers or a third party.

9 *Data items extracted*

10 We will extract the following data from each included publication (refer to Table. 1 for full data
11 details). The data extraction method has been piloted with a sample selection of papers and valid
12 data have been obtained.

13 *Table 1- Anticipated data to be extracted*

Study Characteristics	Patient/Participant demographics	Study setting	Themes	Rigor
<ul style="list-style-type: none"> • Author • Date of study • Study Type • Methodology • Country of study • Data collection methods • Journal • Data analyses 	<ul style="list-style-type: none"> • Age • Patient group • In-patient characterisation 	<ul style="list-style-type: none"> • Level of care • Hospital Type • Education 	<ul style="list-style-type: none"> • Codes 	<ul style="list-style-type: none"> • Strengths • Weaknesses • Reporting guidelines used

15 **Quality Assessment**

16 The CASP qualitative checklist (Critical Appraisal Skills Programme) will be used to assess credibility,
17 transferability, dependability and confirmability. This checklist is an extensive and comprehensive
18 tool commonly used in qualitative study assessment (16,17). As part of the CASP assessment the
19 authors will explore the potential for reporting bias within the studies and biases will be reported in
20 studies' limitations. Two researchers will discuss each study and a consensus will be reached to
21 include or exclude.

22 **Assessment of confidence in synthesised findings**

23 We will apply the Confidence in the Evidence from Reviews of Qualitative research (GRADE-CERQual)
24 criteria to judge confidence in synthesised findings (18). We will apply the CERQual criteria to each
25 study finding, assessing for methodological limitations, relevance, coherence and adequacy of data.
26 This method will generate a Summary of Qualitative of Study Findings (SoQF) table, providing a
27 transparent method with which to assess included studies and results (18).

28 **Data Analysis**

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4 1 This review aims to explore relevant theory and map barriers and facilitators to escalation of care for
5 2 which thematic synthesis is well suited (17). We are likely to undertake a thematic synthesis, using
6 3 the Thomas and Harden framework (19). This framework supports data extraction from anywhere
7 4 within the paper, and is not confined to the results alone. The three stages of the framework are:
8 5 coding findings from included studies, categorisation of codes into descriptive themes, and
9 6 categorisation of descriptive themes into analytical themes (19). Stage one involves line by line
10 7 coding of data, where each sentence is allocated a code. Stage two involves categorising each coded
11 8 sentence into descriptive, broader themes. The final stage involves generating analytical themes, or
12 9 'going beyond' the findings of the initial study, which relate to the fixed or emerging research
13 10 question. Whilst we have been explicit at this point as to the anticipated framework, it is also
14 11 justifiable for this to change once the search has been conducted (20).

16 12 NVivo software will be used to code the original text from papers. Using this software will facilitate
17 13 analysis for this evidence synthesis and will be used to record decisions (by audit trail) of coding.
18 14 Codes relating to human factors and escalation of care will be identified from anywhere within the
19 15 papers, and tables will be used to record descriptive and analytical themes. Key codes, descriptive
20 16 themes and analytical themes will be presented in the results. We will use the enhancing
21 17 transparency in reporting the synthesis of qualitative research (ENTREQ) guidelines to report
22 18 findings (21).

25 19 **Patient and Public Involvement (PPI)**

26 20 A patient representative (TD) has read and provided feedback on the protocol. As a result, some
27 21 points have been clarified and medical "jargon" removed.
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32 23 **Ethics and dissemination**

34 24 The proposed evidence synthesis will use published literature and therefore no ethical approval is
35 25 required. This publication will be limited by the quality of studies available and the rigor and
36 26 reproducibility of study findings. Original studies included in the review could themselves be limited
37 27 and it may be difficult to assess the researcher involvement and their individual bias. The two
38 28 researchers carrying out screening for this review come from different professional backgrounds,
39 29 limiting interpretation bias when assessing the studies for inclusion. A recognised assessment tool
40 30 will be used to determine study quality. Using NVivo to code studies will aid transparency and
41 31 demonstrate a clear strategy for theme identification. An audit trail kept throughout the process,
42 32 will detail decisions made and methodological steps taken.

45 33 The results from this review will be published and made freely available. A number of social media
46 34 techniques (including Twitter, Facebook, and our research group website) will be used to promote
47 35 the protocol, final paper and results. We will also aim to attend at least one conference to present
48 36 findings from this work.
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48 20 [S0964339709001074-main.pdf?_tid=42ebcfc6-34aa-11e7-a31b-](http://ac.els-cdn.com/S0964339709001074/1-s2.0-S0964339709001074-main.pdf?_tid=42ebcfc6-34aa-11e7-a31b-00000aacb362&acdnat=1494329333_5d17d9cc08ce503e7b37debb709eaa99)
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50 21 [00000aacb362&acdnat=1494329333_5d17d9cc08ce503e7b37debb709eaa99](http://ac.els-cdn.com/S0964339709001074/1-s2.0-S0964339709001074-main.pdf?_tid=42ebcfc6-34aa-11e7-a31b-00000aacb362&acdnat=1494329333_5d17d9cc08ce503e7b37debb709eaa99)
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39 [network.org/reporting-guidelines/entreq/](http://www.equator-network.org/reporting-guidelines/entreq/)
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For peer review only

1 **Contributions**

2 PW is the guarantor. JE was responsible for the overall design of the QES. JE and VW drafted the
3 manuscript. TP and JE developed the search strategy. PW and JD provided QES and qualitative
4 expertise. All authors read, provided feedback and approved the final manuscript.

5 **Declarations**

6 *Acknowledgement*

7 We would like to thank patient representative, TD for his contribution to this work.

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14 Health and Wellcome Trust. The views expressed in this publication are those of the author(s) and
15 not necessarily those of the Department of Health or Wellcome Trust. This work was also supported
16 by the NIHR Biomedical Research Centre, Oxford.

17 *Availability of data and materials*

18 Not applicable

19 *Consent for publication*

20 Not applicable

21 *Ethics approval and consent to participate*

22 Not applicable

23 *Competing interests*

24 The authors declare that they have no competing interests.

25

Supplementary File 1 (Draft Search Strategy for MEDLINE)

1. HOSPITALIZATION/
2. TERTIARY CARE CENTERS/
3. (ward or wards).ab,ti.
4. (inhospital or inpatient* or "in hospital").ab,ti.
5. (hospitalised or hospitalized).ab,ti.
6. "general hospital".ab,ti.
7. "nurs* staff* ".ab,ti.
8. "in patient".ab,ti.
9. bedside.ab,ti.
10. outreach.ab,ti.
11. 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10
12. FAILURE TO RESCUE,HEALTH CARE/
13. "fail* to rescue ".ab,ti.
14. VITAL SIGNS/
15. MONITORING,PHYSIOLOGIC/
16. "vital sign* ".ab,ti.
17. (track and trigger).ab,ti.
- 18."early warning".ab,ti.
19. "warning score* ".ab,ti.
20. "early sign* ".ab,ti.
21. "warning system* ".ab,ti.
22. (deteriorat* or escalat*).ab,ti.
23. triggering.ab,ti.
24. HOSPITAL RAPID RESPONSE TEAM/
25. "rapid response".ab,ti.
26. "critical care outreach".ab,ti.
27. 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26
28. MEDICAL ERROR/
29. DELAYED DIAGNOSIS/
30. COMMUNICATION/
31. PATIENT CARE TEAMS/

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3 32. PATIENT SAFETY/
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5 33. ORGANIZATIONAL CULTURE/
6

7 34. LEADERSHIP/
8

9 35. "human factor* ".af.
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11 36. "human error* ".af.
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13 37. "clinical error* ".af.
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15 38. "medical error* ".af.
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17 39. "protocol adherence".af.
18

19 40. "protocol compliance".af.
20

21 41. "teamwork* ".af.
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23 42. communication.af.
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25 43. ("socio cultural" or sociocultural).af.
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27 44. "situation awareness".af.
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29 45. "organisational culture".af.
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31 46. "organizational culture".af.
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33 47. "safety culture".af.
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35 48. "patient safety".af.
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37 49. leadership.af.
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39 50. "root cause analysis".af.
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PRISMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols) 2015 checklist: recommended items to address in a systematic review protocol*

Section and topic	Item No	Checklist item	Page No
ADMINISTRATIVE INFORMATION			
Title:			
Identification	1a	Identify the report as a protocol of a systematic review	Pg 1 Line 3
Update	1b	If the protocol is for an update of a previous systematic review, identify as such	n/a
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number	Pg 2 Line 29 Pg 3 Lines 25-26
Authors:			
Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	Pg 1 Lines 6-10
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review	Pg 11 Lines 1-5
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments	n/a
Support:			
Sources	5a	Indicate sources of financial or other support for the review	Pg 1 Lines 13-16 Pg 11 Lines 7-15
Sponsor	5b	Provide name for the review funder and/or sponsor	Pg 1 Lines 13-16 Pg 11 Lines 7-15
Role of sponsor or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	n/a
INTRODUCTION			
Rationale	6	Describe the rationale for the review in the context of what is already known	Pg 2 Lines 2-12 Pg 3 Lines 1-14
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	Pg 3 Lines 15-20
METHODS			
Eligibility criteria	8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review	Pg 3 Lines 34-36 Pg 4 Lines 1-18

Information sources	9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage	Pg 3 Lines 27-32
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated	Supplementary File 1
Study records:			
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	Pg 4 Lines 36-38 Pg 5 Lines 4-8
Selection process	11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)	Pg 4 Lines 38-44
Data collection process	11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	Pg 5 Lines 4-12
Data items	12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications	Pg 4 Lines 7-10(in table)
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	Pg 4 Lines 9-10
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis	Pg 5 Lines 15-28
Data synthesis	15a	Describe criteria under which study data will be quantitatively synthesised	n/a
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I ² , Kendall's τ)	n/a
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)	n/a
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned	n/a
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)	Pg 5 Lines 15-28
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (such as GRADE)	Pg 5 Lines 22-28

***It is strongly recommended that this checklist be read in conjunction with the PRISMA-P Explanation and Elaboration (cite when available) for important clarification on the items. Amendments to a review protocol should be tracked and dated. The copyright for PRISMA-P (including checklist) is held by the PRISMA-P Group and is distributed under a Creative Commons Attribution Licence 4.0.**

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