Full title

<u>Un</u>derstanding <u>cor</u>ridor care in U<u>K</u> <u>e</u>mergency <u>d</u>epartments: A prospective observational cohort study of current practice

Short Title

The UNCORKED Study

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Version 6.0

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1. Key contacts

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2. Study summary

Title	<u>Un</u> derstanding escalation area and <u>cor</u> ridor care in U <u>K</u>				
	e mergency d epartments: An observational cohort and Delphi				
	study				
Short Title	The UNCORKED Study				
Participants	Any patient cared for in an emergency department escalation				
	area or admitted to hospital				
Planned Study Period	Commencing February 2025				
Summary of study question: What proportion of emergency department patients					
experience care in emergency department escalation areas and who are the patients that					
experience such care? What is the best definition for an emergency department escalation					
area?					

3. List of abbreviations

ED	Emergency department
DTA	Decision to admit
RCEM	Royal College of Emergency Medicine
TERN	Trainee Emergency Research Network

4. Plain English summary

Crowding in emergency departments is a recognised public health challenge. Crowding leads to patient care being delivered in areas not originally designed for this use known as 'escalation areas'. Although a formal definition of an escalation area does not exist, examples include ambulance waiting areas, repurposed clinical areas outside the usual emergency department footprint and non-clinical areas such as hospital corridors. There is a lack of data about how many patients are receiving care in such environments, and what impact this has on their care and outcomes. In this study, we will begin to address these questions by:

- 1. Estimating the number of patients cared for in escalation areas.
- 2. Describing which patients experience escalation area care.
- 3. Defining emergency department escalation areas.

The results will provide much-needed data on escalation area use, which will inform discussions on how best to address this problem and future research related to escalation area care and it's impact on patient outcomes.

5. Background and rationale

Emergency Department (ED) crowding is recognised as one of the biggest challenges posed to the effective delivery of high standard urgent and emergency care in the UK and has been described as a major public health issue that is experienced across healthcare systems in the developed world. (1,2)

ED crowding is predominantly caused by exit block due to a shortage of hospital beds resulting in significant delays between a decision to admit being made in the ED and transfer to an inpatient bedspace. The Royal College of Emergency Medicine (RCEM) has recently published guidance on the management of ED crowding. (3) This guidance recommends that patient boarding spread across inpatient areas is likely to represent a lower risk to patient safety than boarding of patients concentrated in the ED.

There has been significant attention on ED four hour performance and on delays to ambulance offloads which result from pressures on ED capacity. (4) Despite this, boarding of patients in the ED is commonplace in the UK. This occurs in both repurposed clinical areas outside the ED geographical footprint (for example outpatient clinics) and in non-clinical areas such as corridors. These areas often referred to as 'escalation areas'. Based on the number of ED cubicles available in England, average time in cubicle and average admission rates, the 2021 Emergency Medicine GIRFT Programme National Specialty report estimates that there is insufficient national cubicle capacity to avoid corridor care. (5)

Large scale data published in 2023 confirmed that significant delays to inpatient admission from the ED are associated with worse clinical outcomes. (6) The authors recognise that escalation policies unavoidably include delivering care in non-traditional and non-clinical areas and that a clinically plausible reason for worse outcomes may be that the standard of care delivered is lower. Studies conducted in the USA show that patients cared for in hallways or corridors are less satisfied with the care they receive, and that patients prefer boarding in inpatient areas rather than the ED. (7–9) RCEM recognises ED crowding as a system wide problem but at-capacity strategies to spread risk across the whole hospital such as the continuous flow model have proved controversial. (10) Despite the above and the current attention on the demand-capacity mismatch in UK emergency care, there is no published data on how many patients are receiving care in ED escalation areas and corridors and who these patients are, furthermore there is no unified definition of what an ED escalation area is.

We therefore propose a two part study which aims to define UK ED escalation areas using Delphi methods, and estimate the proportion of ED patients cared for in these areas using a prospective observational cohort study. This data will play a key role in informing interventions to reduce corridor care and understanding who is most at risk of receiving the lower standard of care that this entails.

6. Aims of the proposed research

6.1 Research questions

What proportion of ED patients receive care in ED escalation areas (clinical areas outside the usual ED footprint and non-clinical areas such as corridors) and who are the patients that experience escalation area care?

What is the most appropriate definition for an ED escalation area?

6.2 Primary objective

Estimate the proportion of patients that experience care in ED escalation areas, including hospital corridors, separated by adult and paediatric EDs.

6.3 Secondary objectives

All secondary objectives will be grouped by paediatric and adult EDs.

- 1. Report the 28 day all-cause mortality and hospital length of stay stratified by time spent in ED escalation areas.
- 2. Describe the patients who experience ED escalation area care by collecting patient demographics, deprivation index based on postcode and diagnosis.
- 3. Describe the length of time spent in ED escalation area(s), the type of escalation area(s) experienced and disposition from the ED.
- 4. Devise a consensus definition for an ED escalation area via Delphi methodology.

7. Study Design

This is a mixed-methods study that will consist of a Delphi study and a prospective observational cohort study.

7.1 Delphi study

A panel of multi-specialty and multi-disciplinary experts and stakeholders will be convened, ensuring appropriate heterogeneity, to participate in a modified Delphi process with the aim of reaching a consensus definition describing ED escalation areas. The panel will be identified via involvement in previous research in ED crowding and via relevant professional bodies (eg. Royal College of Emergency Medicine, Royal College of Nursing). This will include consultant level, SAS and training grade doctors, nursing expertise and management expertise from emergency medicine, acute medicine, care of the elderly and the ambulance service. The Delphi study will involve patient/public representatives from the RCEM Lay Advisory Group and at least one patient and/or caregiver with lived experience of escalation area care. The Delphi study will not include anyone lacking capacity, children, or prisoners. Potential participants will be invited via email. Data from at least the first phase of the observational cohort study will inform the Delphi.

The first round of the Delphi will consist of open ended questions asking respondents to consider what characteristics should be taken into account when defining ED escalation areas. Subsequent rounds will include questions on specific aspects of the proposed definition and assess consensus between respondents using a Likert scale with the opportunity to elaborate on responses through free-text response.

Respondents to the Delphi study will be appropriately consented for their involvement via an electronic consent form. They will be named as collaborators in the study manuscript. There are no risks identified to respondents or investigators in relation to the Delphi study.

7.2 Observational cohort study

A multi-centre prospective observational study will recruit patients from UK type 1 EDs at predetermined recruitment time points who experience ED escalation area care during their ED stay or are admitted to hospital. A 'snapshot' method over a 14 day period will be used. The total number of patients in the department will be collected for each snapshot time point. This will be performed at all recruiting sites.

Due to the Adults with Incapacity Act in Scotland, a proportionate waived consent model, as approved for England, Wales and Northern Ireland, was not approved for use in Scotland. Therefore, for sites in Scotland, only departmental data will be collected. No patient level data will be collected. For sites in England, Wales and Northern Ireland who cannot collect patient level data due to the functionality of the electronic health record, they will only collect departmental level data.

Data will be collected on the demographics of recruited patients and details of their ED stay such as length of stay, type of escalation area(s) experienced, length of time spent in escalation areas, disposition, ED diagnosis, hospital length of stay and 28 day mortality. Patients will be identified prospectively, but depending on resources some data may be collected retrospectively. Data will be entered into digitised case report forms (CRF).

7.3 Inclusion Criteria

Any patient present in the ED at the recruitment time points, who experience ED escalation area care during their ED stay or are admitted to hospital. Escalation areas will be defined for the purposes of identifying eligible patients as:

Any area not routinely used unless the capacity of the usual ED geographical footprint is exceeded.

This will include:

- Repurposed clinical areas and non-clinical areas such as corridors. (The study team will assist site teams in identifying these areas prior to recruitment as needed)
- Any care received in an ambulance, or ambulance cohort area or equivalent, from 15 minutes after arrival.

Exclusion Criteria

None

7.4 Recruitment

Recruitment will be conducted over 14 consecutive days with patients present in EDs at 5 predetermined snapshot time points during this 14 day period eligible for inclusion. Recruitment will take place in February-March 2025.

Assessment for eligibility and recruitment will be carried out by ED clinicians and nursing staff with support from the research nursing teams. Local study teams will generate awareness of the study amongst clinical staff via email, posters, discussion at clinical handovers, and other routes of departmental communication such as messaging groups. We anticipate that all patient identification will be done prospectively. However, in some instances sites' electronic department management systems may facilitate reliable capture of the required information retrospectively.

7.5 Consent

There is no change to clinical care as part of this study and all patient level data will be collected from routine healthcare records. There is no clinical risk to participants. Identifiable data will only be visible to local teams and at the point of upload to an appropriately secure research database (REDCap) data will be anonymised. (11) Therefore, a proportionate waived consent recruitment strategy will be employed. This approach has been used following research ethics committee approval by a previous TERN study and other examples of observational cohort studies in emergency care with similar methodology. (12–14) A pragmatic and proportionate approach to consent such as this will be key in ensuring consecutive recruitment to capture a representative cohort and avoid the under-recruitment of patient groups in whom other consent models may be difficult.

7.6 Outcome measures

The primary outcome measures are the demographics of patients present in escalation areas.

The secondary outcome measures collected will include type of escalation area(s) experienced, time spent in escalation areas, ED diagnosis, ED disposition and 28-day all-cause mortality.

7.7 Data collection items

Item	Details
Demographics	Hospital attended, gender, age, ethnicity, deprivation index
	(based on postcode)
ED Data	
Presenting complaint	As per triage
Date of arrival to ED	dd/mm/yyyy
Time of arrival to ED	24hr clock (HH:MM)
Mode of arrival to ED	Self
	Road ambulance, helicopter, police
Initial assessment/management	Minors
area	Ambulatory
	Majors
	Resus
Date and time of decision to admit	dd/mm/yyyy
	24hr clock (HH:MM)
Number of escalation areas	Number
experienced	
Escalation area type	Clinical area outside the normal ED footprint
	Corridor or other non clinical area
Total time spent in escalation	HH:MM
areas	
Date and time of admission or	dd/mm/yyyy
discharge from the ED	24hr clock (HH:MM)
Admitting specialty	Drop-down inpatient specialties
Diagnosis on admission or	Free text (diagnosis 1 +/- 2 +/- 3)
discharge from the ED	
Clinical frailty score	1-9
Disposition	Discharged
	Ward
	ICU
	Theatre/IR
	Mortuary
	Transferred to another hospital
Mortality	28 day all-cause mortality
Department summary	
Number of patients present in the	Number
ED at the recruitment time point	
Number of patients with a DTA	Number
made at the recruitment time	
point	

8. Statistical analysis plan

Data will be analysed by an independent statistician. Analysis for the primary outcome with be entirely descriptive. All analysis will be split into by the type of ED, or ED area, (adult or paediatric) the patient was seen in. The proportion of patients present in an escalation area will be reported as an average across the recruitment time points. Descriptive data on patient demographics, length of stay in the ED, time spent in an escalation area, time from DTA to inpatient admission and diagnosis on discharge from the ED will be presented in table format. Measures of time will be presented as a measure of central tendency with an appropriate description of variance. Standardised 28 day mortality will be reported, as stratified by proportion of time spent in an escalation area. Key cofounders (e.g. clustering of individual hospitals) will be accounted for in analysis.

9. Study Administration

9.1 Timeline

Data for the observational cohort study will be collected during a 2 week window in February-March 2025.

The Delphi study will run between November 2024 and November 2025.

9.2 Administration

Data will be entered and entries completed using the online platform REDCap. (11) This electronic data capture platform is fully compliant with Good Clinical Practice, 21 CFR Part 11, GDPR, 20 ISO 27001 and ISO 9001.14. It has stringent data security procedures and uses private servers.

9.3 Data management and record-keeping

Study data will be collected by appropriately trained ED clinicians, ED nursing staff and research nurses. Patient details will be held locally with pseudo-anonymised study ID numbers. Only study ID number and entirely anonymised data will be entered onto REDCap. Study data will be stored for a period of 5 years using the REDCap servers.

9.4 Assessment and follow up

Data collected will be in relation to the ED stay only and there will be no follow up beyond 28 day mortality and hospital length of stay.

10 Ethical and Regulatory Issues

10.1 Ethical approval

Ethical approval will be sought from a local ethics committee and regulatory approval will be sought from the Health Regulation Authority (HRA) and Health and Care Research Wales (HCRW).

10.2 Study conduct

The study will be conducted in accordance with the UK Policy Framework for Health and Social Care Research and other applicable guidance. The study will not commence until REC approval is confirmed.

10.3 Monitoring & audit

The study will be subject to the standard procedures for monitoring and auditing of studies by the sponsor. Any changes to the protocol will be agreed with the sponsor prior to submission to NHS Research Ethics Committee (REC) for review except for where urgent safety measures apply. Principal investigators will have completed appropriate study specific training and ICH-GCP or equivalent. Other local study team members will have completed study specific training.

10.4 Risk to participants

As there is no change to diagnostic processes or treatment, and as all information is recorded as part of routine clinical care, there is no additional clinical risk to participants of the observational cohort study over standard care. As no identifiable information will be centrally collected, the risk of data breach is low.

10.5 Risk to investigators

There are no anticipated additional risks to investigators as part of this study.

10.6 Confidentiality

Study data will be collected and managed using REDCap electronic data capture tools hosted at the University of Bristol. (11) REDCap is a secure web-based software platform designed to support data capture for research studies, providing 1) an intuitive interface for validated data capture; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages; and 4) procedures for data integration and interoperability with external sources.

No personally identifiable data will be collected on REDCap and at no point will any hospital or individual be identifiable during data either export, analysis or publication.

As part of the Delphi process their responses will remain anonymised to each other but will be identifiable to the study team. Their professional roles or status as PPI contributors will be summarised in the study manuscript and at the conclusion of the study the respondents will be offered to the chance to be named as Delphi collaborators.

10.7 PPI and stakeholder engagement

The RCEM Lay Advisory Group have been involved during study design, commenting specifically on the importance of the research questions and the acceptability of the methodology, including the model of consent. They have also agreed to provide input to the Delphi process aiming to define escalation area care. At least one patient and/or caregiver with lived experience of escalation area care in the Delphi panel alongside the stakeholders described in section 5.2 above.

The issue of ED crowding appears as number six on the most recent James Lind Alliance research priority setting refresh. (15) Patient and public input is a key part in each step in the James Lind Alliance process.

The account of a patient and/or caregiver with lived experience will be included in the write up of the study, similar to the examples referenced here. (16,17)

11. Disseminating of results and publication policy

The results of this study will be submitted for publication in an appropriate peer reviewed journal. They will be presented at emergency care focussed conferences. In addition to this they will be disseminated by social media and the TERN website.

11.1 Anticipated impact

We anticipate that the results of this work will be of interest to ED staff of all backgrounds, including management teams. It may influence further research into the impact of care in escalation areas on patient centred outcomes. It will be of interest to RCEM in their work to advocate for better conditions in UK Emergency Care. It will be of interest to the general public and may be reported in national media outlets. As no personally identifiable information is recorded, there poses no risk to confidentiality from this.

12. Funding & competing interests

The Survey platform is provided courtesy of the University of Bristol. The study will be sponsored by North Bristol NHS Trust.

FB and AC receive funding as part of their job plans from the Royal College of Emergency Medicine. TR is receives funding from the NIHR as a clinical lecturer.

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