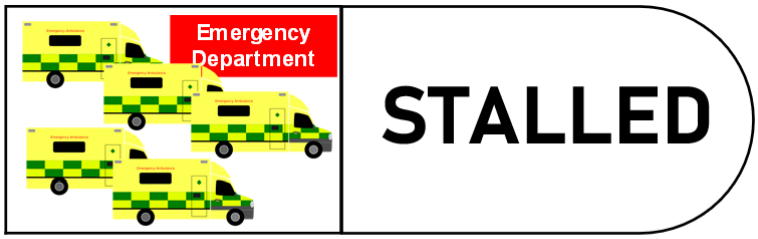

SafeTy, pAtient experience, outcomes and costs reLated to deLayed ambulance handovers at Emergency Departments

STALLED STUDY PROTOCOL

LONG TITLE

STALLED: What works to improve SafeTy, pAtient experience, outcomes and costs reLated to deLayed ambulance handovers at Emergency Departments? A whole system approach

ACRONYM / SHORT TITLE

STALLED: What works to address ambulance handover delays at Emergency Departments?

PROTOCOL VERSION NUMBER AND DATE: Version 1.1 13/12/24

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SPONSOR: Swansea University

This protocol has regard for the HRA guidance and order of content.

Document version control

Version number	Changes	Date	Author
0.5	IRAS submission	30/08/24	MK
1.0	Edits following REC review –text added on eligibility, sampling, screening, setting, study end definition. General editing/formatting. Added logo.	07/11/24	MK
1.1	Amended section on advertising study. Updated Declaration of Helsinki reference (to 2024 version).	13/12/24	MK

CONTENTS

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STUDY SUMMARY

Study Title	STALLED: What works to improve SafeTy, pAtient experience, outcomes and costs reLated to deLayed ambulance handovers at Emergency Departments? A whole system approach
Short Title	STALLED: What works to address ambulance handover delays at Emergency Departments?
Study Design	Mixed methods observational study
Planned Study Period	36 months
Abstract	There has been a problem in the UK and other countries for many years, that at busy times Emergency Departments (ED) become unable to manage the flow of patients. Patients may remain in the ambulance, sometimes for several hours. In some areas, this practice is rare; in others, it is common. When ambulances are queuing, there are 'knock-on' effects throughout the emergency care system – patients at the ED may not be receiving full ED care, while queued ambulances are unavailable to attend other patients in the wider community. We aim to provide evidence about what works to improve safety, patient experience, outcomes and costs related to ambulance queuing. Our objectives are to: 1. Describe what is already published about initiatives aimed at reducing ambulance queuing, delayed handovers and related harms 2. Identify and describe initiatives currently in use across the UK to reduce handover delays and related harms 3. Identify EDs where ambulance queuing is rare and understand what policies and practices are being used in those hospitals to avoid ambulance queuing 4. Assess impact of successful queue management on patient flows, safety, experience, health outcomes and costs 5. Predict wider impacts of initiatives on patient flow through the urgent and emergency care system 6. Produce guidance about what works to reduce delayed handovers. In this study, we will use a mix of methods to answer our questions. We will carry out an initial mapping exercise to identify relevant stakeholders and run online workshops to promote engagement within and beyond the study. We will look for existing evidence about initiatives to reduce delayed handovers at ED and carry out a survey of ambulance services (with follow up at EDs) about what initiatives exist within their areas. We will group initiatives into categories of similar types e.g. ED clinician care provided on ambulances; paramedic care within the ED; or use of additional space. We will analyse existing data to identify sites that rarely queue ambulances and sites that do this more frequently. We will present findings at a stakeholder event with participants from across the Urgent and Emergency Care system, including providers, users and commissioners of care where we will agree on criteria for selecting sites to include in more in-depth work. We will then select four sites where ambulance queues are relatively rare – and ambulance hours lost to delays are low (Group 1) and four sites where queues are more frequently seen – and ambulance hours lost to delays are higher (Group 2). We will carry out qualitative work at these sites to understand what makes a difference to their performance. We will compare important patient outcomes between patients who called 999 or attended ED in the two groups, including: 30-day mortality (primary outcome); 999 ambulance attendance; conveyance rates to ED; hospital admissions; and waiting times. We will investigate effects within vulnerable subgroups of the population, including the very elderly, people in ethnic minorities and people who make high use of emergency care. We will send questionnaires to

	a sample of patients to gather their experiences, quality of life, use of non-NHS services and safety concerns. We will carry out clinical case note reviews to compare safety issues between groups and will construct in-depth descriptions of complex cases. We will use patient flow data to determine initiatives that may be most beneficial to the NHS. We will conduct interviews with patients to find out more about their experiences. We will interview stakeholders from across the emergency care system, including ED and hospital staff, ambulance clinicians and call takers, healthcare managers and commissioners about their experiences and views. Finally, we will hold stakeholder workshops towards the end of the study to help us interpret findings. and will make recommendations about how to reduce ambulance queuing. We have worked with public contributors to develop this proposal and will include them throughout the study as members of the Research Management Group and in the Public Advisory Panels, to be appointed. We will recruit public contributors to the Independent Study Steering Group. Our research team includes clinical, academic and policy specialists.

ROLES & RESPONSIBILITIES

STUDY SPONSOR AND FUNDER

Sponsor: Swansea University
The sponsor will advise on regulatory issues and have financial and contractual oversight. They will not be involved in study design, conduct, data analysis and interpretation, manuscript writing, or dissemination of results. The sponsor will be updated on study progress, and informed if there are any deviations to protocol.

Funder: NIHR HSDR
Other than monitoring and reporting, the Funder will not have other involvement in study design, conduct, data analysis and interpretation, manuscript writing. The study team will provide updates to the funder to enable review against delivery of project milestones; these will be through regular progress reports, entries to the NIHR's study management system (e.g. REsearch Awards Lifecycle Management System (REALMS)), and ad hoc requests.
The funder will approve the protocol and outputs for publication. The funder may provide comments on such submissions to the Co-Chief Investigators for consideration in published outputs.

Funder Disclaimer
This study is funded by the National Institute of Health Research, Health and Social Care Delivery Research Programme (Reference: NIHR159967) The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.

STUDY MANAGEMENT COMMITEES/GROUPS & INDIVIDUALS

Study Steering Group
An independent study steering group (SSG) will be appointed early in the study to provide impartial advice, guidance and oversight. The group will support delivery of the study in line with appropriate standards of rigour and ethical conduct. The study team will consult with the SSG regarding any significant changes in study design or methods. The SSG will operate to a members' charter outlining roles and responsibilities of the group. We will identify appropriate

members to join the SSG including two public contributors, an ED consultant, Paramedic, Statistician, and a Health Economist.

Research Management Group
All co-applicants will be members of the Research Management Group (RMG). Co-applicants include public contributors (AB, LW) and clinical senior management representatives of participating ambulance services (AR, MB, AL, MP) and AACE (HP), indicating the strong commitment from prehospital care services, patient experience, and providing a direct route for liaison and negotiation. Meetings will take place quarterly using a combination of face to face, video and audio conference facilities to oversee project progress, locally and across all sites. ACS will co-lead with HS, and co-ordinate timescales, methodological input, data collection, analysis, interpretation, reporting and dissemination with day-to-day support from the study coordinator (MK). Data specification, extraction and management of routine data and linking of survey data will be carried out by TD under the direction of AW. MJ will conduct health economic analysis overseen by DF. The research paramedics and nurses will be in post for data collection in Phase 2. They will also join the RMG as members of the research team during their involvement in the study.

Core Team
A core research team will focus on study delivery. The core team will include the Joint Chief Investigators, study coordinator, data manager, qualitative lead, and site-based research staff. Core team meetings will be held every 2-4 weeks as necessary by video link.

Task and Finish Groups
Task and finish groups will be set up as required to complete individual tasks e.g. scoping review, organisation survey, qualitative work, case note review. Individuals with specialist skills will be co-opted onto task and finish groups as appropriate, to include public contributors.

Patient & Public Involvement
Our team strongly supports the active involvement of public contributors in research. We followed UK Standards for Public Involvement which were important in setting up solid foundations necessary for enabling meaningful PPIE. We have included PPIE views throughout the process of developing and preparing this application, respecting them as equal members of the research team throughout. Public co-applicants AB and LW have been Research Development Group members from the outset and part of all discussions about the scope and detail of this proposal. They have drawn on their personal experience of emergency and unscheduled healthcare, one as a patient and the other a carer. They confirm the importance and urgency of research into improving ambulance handovers at EDs and have supported the inclusion of objectives to explore effects on patients and family/carers. They reminded us to consider the effects on staff of delays in the system who can find it difficult to remain efficient and compassionate and how this contributes to patient distress. They had concerns regarding the stress that is caused to vulnerable groups such as frail elderly people, particularly those with dementia.
To provide further diversity of PPI we will also recruit two public advisory panels – as detailed below. We have included in our costings, reasonable PPIE costs to cover, RMG, SSG, and the two panels, including honorariums for preparation for meetings, reviewing documents and one-to-one meetings as needed to ensure all public contributors are up to date on all our research activities.

Public Advisory Panel:
We will convene two public advisory panels each of six members. These groups will provide an important forum for discussion and advice on study conduct and communications, while ensuring that the patient-perspective remains a core consideration.

The Panels will meet around twice a year with opportunities to meet face to face at the beginning and end of the study, as well as hybrid meetings. We will work closely with third sector organisations and existing Public and Patient Involvement and Engagement (PPIE) groups to establish these panels. We will ensure our research is inclusive and that we have a wide representation of lived experience in using emergency ambulance services and ED or supporting family members within this Panel.

Public contributor members of the RMG (AB, LW) and PPI lead (AK) will be invited to join these panels, to provide a formal link with the RMG, so that views from the panel are represented in wider discussions and information from the RMG can be fed back to the patient advisory panel.

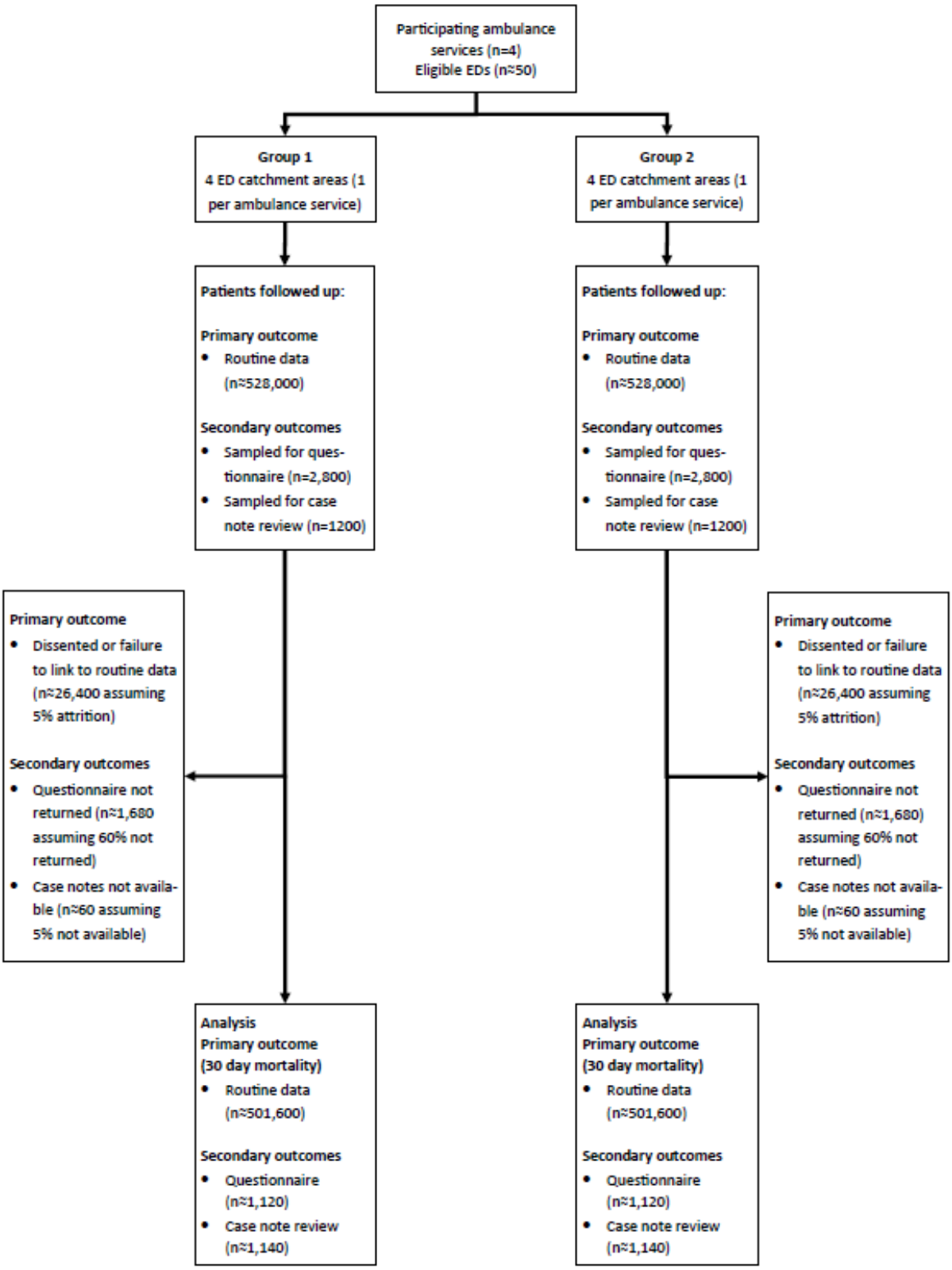
Panel members will be recruited from diverse backgrounds and experiences, with support of third sector organisations and clinicians. Both Panels will be supported to meet at key stages of the study to provide in-depth input to study design, interpretation and dissemination. Study PPIE (AB and LW) and Panel members will be invited to attend stakeholder workshops and final data synthesis meeting. In addition, we will recruit two public contributors to the independent Study Steering Group to provide independent oversight.

KEY WORDS

Emergency medical services, Prehospital Emergency Care, Hospital Emergency Services, Treatment Delay, Patient handover

STUDY FLOW CHART

Figure 1: Recruitment flow diagram



PROTOCOL

Study title: STALLED: What works to improve SafeTy, pAtient experience, outcomes and costs reLated to deLayed ambulance handovers at Emergency Departments? A whole system approach

1: BACKGROUND

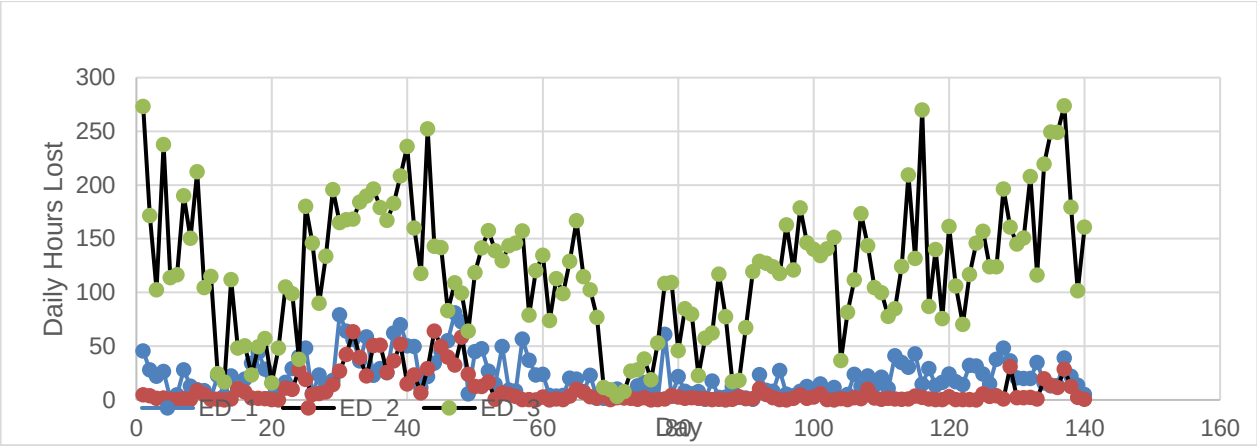
Delayed handovers of patients with queuing of ambulances outside Emergency Departments (EDs) has been a persistent problem in the UK and internationally for many years, with high media attention. Demand for urgent and emergency care (UEC) has increased, with the UEC system the subject of major national policy attention and strategic review across the UK. Handover delays and lengthy periods spent in waiting rooms are symptomatic of this increasing demand. When ambulances are delayed outside ED, the provision of definitive care to patients in those ambulances is delayed, and the ambulance is taken out of the UEC system (1-2). It is not only the care of patients held up outside the ED who are adversely affected, but also those who are waiting for the attendance of an emergency vehicle (3), and potentially, those who have arrived at ED by other means (4).

Over the last 15 years in the UK, numerous initiatives have attempted to solve this issue which is detrimental to patient experience and outcomes, and the morale, health and well-being of staff (5,6). Since 2018, over 1000 paramedics have left their profession (7). In 2012, the NHS Confederation, with the Association of Ambulance Chief Executives (AACE) produced 'Zero Tolerance: Making ambulance handover delays a thing of the past' (8) which set out recommendations for NHS service providers to help reduce delays, with an emphasis on joint responsibility; setting of performance indicators with financial penalties for delays of >60 minutes; joint reporting to provide evidence about the problem and associated burden; and a requirement for planning with regional capacity management systems. Despite this, the problem endures (9) and has worsened markedly with ongoing pressures associated with COVID-19, causing significant patient harm. Not only is the number of patients waiting increasing, but also the length of time they wait. (9,10) Overcrowding in the ED is "unsafe, inhumane, and undignified for patients" and leads to poorer patient outcomes, possibly as clinicians are unable to adhere to guideline-recommended treatment. (11)

For the most recent "winter pressures" period (November 2022-April 2023), ED-level data for 144 EDs across England on ambulance arrivals and handovers is available. (12) This data includes daily hours lost to ambulance delays; see Figure 1 on the next page for three EDs within a single Ambulance Service catchment area, with broadly comparable throughputs. Figure 2. indicates very different distributions of daily hours lost; for instance, averages over the period range from 8.8 (ED2) to 121.4 (ED3). Although each ED has some days with few or no daily hours lost; ED2 has far more of these than either ED1 or ED3; at ED3, the daily hours lost exceeds 50 on most days. The same data indicate only weak links between the number of arrivals by ambulance and daily hours lost, so that relatively high daily hours lost can occur on less busy days; while there are relatively low daily hours lost on some busy days.

The variability shown in Figure 2 is repeated in catchment areas of other ambulance services. Thus, while queuing is a problem everywhere to some extent, some EDs are much better at managing it than others. This variation provides opportunity for learning.

Figure 2: Daily Hours Lost to Ambulance Delays at 3 EDs: Nov'22-Apr'23



Why is this research important to patients and health and care services?
Handover delays and long waiting times are of high concern to healthcare professionals and the public, generating many media headlines. Not enough is known about what is being currently tried out, issues in implementation or what works to reduce handover delays, related harms and costs. We lack an understanding of approaches that work to reduce handover delays, but know it is a systemwide problem, and changes are needed in the ED and beyond e.g., Boyle et al. (2021) (13) acknowledged the potential role of: increased social care and hospital beds; virtual wards; alternative urgent care facilities such as Same Day Emergency Care (SDEC); (14) and public health interventions – such as rehabilitation centres for substance misuse.(15) Reducing delays in handover and improving patient flow through the UEC system will reduce harms and costs, improve patient experience and outcomes as well as staff morale.

How does the existing literature support this proposal?
Half of 999 patients experienced delayed handovers in 2015/16 and 500,000 care hours were lost. (16) This rate has not improved and recent reports by AACE shows over half of all handovers in England exceeded time targets since April 2018. (9,10) More than 200,000 people each month experience delays; 25,000 for more than an hour, with some waits exceeding seven hours. Even patients pre-alerted to ED because of a life-threatening condition are affected. The 2022 report (10) also focused on the results of a clinical case note review to identify queuing-associated harms across the ten English services and found that a staggering 85% of patients held in a queue for over 60 minutes potentially suffered harm, with 9% potentially suffering severe harm. Patients reviewed included patients with active seizures, COVID-19 and sepsis. AACE predicted that 160,000 patients will potentially experience harm every year if current handover delays remain.

Whilst the AACE report provides background to illustrate the current situation, it did not include measures of patient experience or health outcomes for these 999 patients directly held in

queues, or for those held up elsewhere in the UEC system. Nor did it include any comparator or baseline, so the effects of handover delays are difficult to quantify. This is particularly the case as most research on patient safety is conducted on hospital data; little is known about patient safety in ambulances. (17) Handover delays are caused by factors across the whole health system, including hospital capacity, patient discharge and bed occupancy and 'a whole-system approach is needed to tackle them.' (17) The increase in ambulance waiting times impacts staff health and well-being, including prolonged exposure to infection, and compromises inter-professional working practice between hospital, ambulance and community staff. (18) Lindridge et al. (2020) also advocated a whole system approach to understanding this complex issue, notably by acknowledging the inter-professional culture between hospitals, communities and ambulance services that affects handover delays; and called for more research to address the causes of ambulance handover delay. (19)

The problem is complex, with causes and effects across the whole healthcare system. Managing patient flows can be complicated by up- and down-stream issues, notably delayed discharges from hospital due to a lack of available resources to support people at home. We recognise this complex picture and have designed this proposal around investigating a specific bottleneck – ambulance handover at ED – that is managed in various ways and with varying degrees of success. Handover delays are a longstanding problem and a lack of systematic evaluation of processes has resulted in missed opportunities for learning and left a growing problem unresolved.

2: RESEARCH AIM AND OBJECTIVES

We aim to provide evidence-based guidance about what works to reduce ambulance handover delays and related harms.

Our objectives are to:

1. Describe what is known about initiatives aimed at reducing ambulance queuing, delayed handovers and related harms
2. Identify and describe initiatives currently in use across the UK to reduce handover delays and related harms
3. Identify EDs where ambulance queuing is rare and understand what policies and practices are being used in those hospitals to avoid ambulance queuing
4. Assess impact of successful queue management on patient flows, safety, experience, health outcomes and costs
5. Predict wider impacts of initiatives on patient flow through the UEC system
6. Produce guidance about what works to reduce delayed handovers

3: THEORETICAL FRAMEWORK

This mixed methods observational study aims to describe current practice in relation to ambulance queuing, and its effects for all patients who seek 999 emergency healthcare at times when ambulances are held up at ED, as well as families, carers and health professionals. We will also review the literature, include perspectives of a diverse range of stakeholders and identify current initiatives to avoid delayed handovers at ED. This epidemiological and contextual picture is a necessary step in the identification of harms and potential interventions, and in the development of methods for evaluation. The SEIPS 3.0 (20) human factors/ergonomics framework for studying and improving healthcare and the patient journey will be applied to the development of interview and focus group schedules, and our data collection and analysis approaches, supporting us to take a systems approach to understanding the initiatives and their impact on the people in the system. During the design of interview and focus group schedules for use with stakeholders, it will guide our holistic inquiry about existing initiatives and how they relate to, or impact on, structures, process and outcomes in and beyond ED and across the wider system. We are following the MRC guidance which details the steps required for producing definitive evidence about the safety, cost and effectiveness of complex interventions, underpinned by strong programme theory. (21)

4: STUDY DESIGN AND METHODS OF DATA COLLECTION AND DATA ANALYSIS

Study Setting
We will conduct the study in two phases. In Phase 1 we will seek data from ambulance services and emergency departments across the UK. In Phase 2 we will carry out in depth work at four sites where handover delays are relatively low (Group 1), and four sites where handover delays are higher (Group 2). In this study sites are the catchment area of a hospital ED within a regional ambulance service.

Phase 1

1a) Stakeholder engagement

We will conduct a stakeholder mapping exercise to identify key stakeholders i.e., those individuals/groups who will have an interest in patterns, effects and solutions to ambulance queuing (e.g., patient and public members; policymakers, professional body and College representatives, national clinical leads; ED staff including doctors and nurses; paramedics and ambulance service managers; ED and hospital managers). This work will play a critical role in improving relevance of our findings, identifying key policy and practice drivers, assisting with knowledge transfer, and promoting collaboration across the science – policy – practice interface (i.e., making it more likely that the results will achieve impact).

Once stakeholders are identified via the mapping exercise, we will run online workshops with each stakeholder group to understand their information requirements. This includes what information would be useful, or the evidence they need and any current evidence gaps; and how that information should be presented. Further, these workshops will explore how each

stakeholder plans to use the evidence. We will develop a knowledge mobilisation plan with each stakeholder, including upcoming opportunities to influence relevant policy / practice strategies, how they will disseminate the findings to their networks, and dissemination activities. Close collaboration with stakeholders throughout will also help knowledge mobilisation, implementation of findings into practice, and impact tracking.

1b) Scoping review

We will undertake a systematic scoping review using the methodological framework proposed by Arksey and O'Malley (22) and further refined by the Joanna Briggs Institute. (23) We will use systematic search, screening, and data extraction methods to describe what has been published, inclusive of salient health professions, management and business studies literature, about existing initiatives to reduce handover delays and related harms at EDs. This will include scientific literature as well as media publications and social media.

We will refine a search strategy to find what evidence there is about the effectiveness of interventions to reduce or prevent delayed handovers.

The scoping review database search will include: PubMed, MEDLINE, Embase, CINAHL, Web of Science, Emerald, Business Source, Cochrane Database of Systematic Reviews and hand-searching of citations and identified peer-reviewed published papers. The co-applicants will act as an expert reference group and contribute papers for inclusion in the review based on their expertise and provide access to relevant grey literature such as policy and organisational documents, quality improvement reports and opinion pieces. Searches will be re-run immediately prior to the completion of the literature analysis, and any further retrieved studies will be included. A search strategy will be piloted in PubMed and will be refined and adapted for use with the other bibliographic databases. Whilst conceptualising the study, brief pilot searches were carried out (using PubMed, 24th October 2022) and we envisage Clarey et al 2013 (24) to be the kind of study we will include since the paper describes their evaluation of triage nurses in reducing handover delays, concluding 'although such roles can bring about reduced waiting times… using this as a sole method to achieve these targets would require unacceptably low staff utilisation'.

Papers and documents identified from all database searches will be screened independently by two reviewers from the research team first by title, then abstract and full paper following a protocol which includes inclusion and exclusion criteria. All discrepancies between reviewers will be resolved by a single arbitrator (HS – co chief investigator). A custom data extraction table will also be piloted with the data from PubMed and revised as required. Data will be charted, reporting on aims, participant characteristics, study design and health outcomes including any mention of equality, diversity and inclusion and implications for policy, practice or research.

1c) Identification of current initiatives.

Sampling

We will contact all 13 ambulance services in the UK to find out what initiatives are being used in their service areas to reduce handover delays. We will also follow up with EDs identified by the ambulance services as having relatively high or low handover delays (in their service area).

Recruitment
We will email a questionnaire (as attachment) to ambulance service Chief Executives, (cc'd to Quality Improvement Leads, Governance and Risk Directors, and Heads of Research). We will request details of contacts at the EDs so that we can systematically follow up for details of initiatives with them. We plan to survey ambulance services rather than EDs as we have established contacts and good working relationships across UK services and have previously achieved very high response rates, making this much more efficient than trying to survey all EDs (n >170 in England alone). (25)

Data Collection
We will use a semi-structured questionnaire including closed and open questions to gather brief details about what initiatives are currently in place in their areas to reduce delayed handovers at EDs. We will gather more information about identified initiatives from EDs by email and telephone, including when they were introduced; target population and how often they are used; and any known advantages and disadvantages of them.

1d) Analysis of routine ambulance performance statistics

We will work with AACE to further analyse routine performance data for 2022/2023 and 2023/2024 "winter pressures" periods to appraise EDs on key variables (notably daily hours lost) relevant to handover delays.

1e) Stakeholder consultation

We will hold a stakeholder workshop to present findings from the review, survey and performance statistics (phases 1b, 1c, and 1d) to stakeholders from across the UEC, including providers, users and commissioners of care. If indicated, we will hold additional meetings with stakeholders unable to attend the workshop. We will also use the workshop/meetings to help finalise criteria for selection of sites for in-depth quantitative and qualitative study in Phase 2.

At the workshop/meetings, we will share our initial findings from the scoping review, contextualised for the UK context, and invite further comments and discussion. In addition, we will share drafts of our study materials such as surveys and case note review proformas for appraisal and feedback from stakeholders – to sense-check and support further iterations.

Phase 2

In Phase 2 we will use a use a natural experiment study design to compare data about processes and outcomes of care between patients that called 999 or had a call made on their behalf ('999 callers') or those attending EDs directly ('walk-in patients') in sites where handover delays are relatively low (Group 1), and sites where handover delays are higher (Group 2). We will use anonymised linked data from participating ambulance services, NHS Digital and eDRIS, as well as self-reported outcomes from patients. Where patients give consent, we will also link routine,

patient-reported and case note review findings. We have successfully used linked data to compare routine and self-reported outcomes in this way in other studies including SAFER2 (26) and PRISMATIC. (27) We will carry out qualitative data collection at these sites with a range of clinical and managerial staff based in ED, the ambulance service and the wider acute system - including at Integrated Care Board level. We will aim to understand differences in policy and practice that are successful in reducing handover delays and excessive waiting times in the ED.

Phase 2a) Identification of sites:

We have co-applicant representatives from four ambulance services (North West, Scottish, South Central, West Midlands) to investigate what works to avoid handover delays and related harms on 999 callers and those who attend ED direct. Using criteria determined in Phase 1, we will, select and recruit eight sites: four sites where handover delays are relatively low (Group 1), and four sites where handover delays are higher (Group 2). We will, where possible, recruit from within our partner (co-applicant) ambulance service regions, using site selection criteria determined in Phase 1.

Phase 2b) Comparison of performance across sites using routine data outcomes:

Sampling/Recruitment

We will include all patients resident in the catchment area of selected EDs who call 999 (or have a call made on their behalf) or walk in to ED (self-present) for a 12 month period (e.g. between April 1, 2024, and March 31, 2025). Ambulance service/ED staff may screen out any of those randomly selected due to safeguarding or other concerns. Patients can opt out of their data being used via the National Data Opt Out website (England) (28) or SPIRE (Scotland), (29) or by contacting their local site prior to analysis.

Data Collection

We will work with ambulance services to export 999 call and service level data to ensure high quality data can be provided while minimising the burden on ambulance services. Patients for whom a 999 call was placed will be identified by an NHS researcher at each ambulance service site. Data will be transferred securely from study sites to NHS Digital, eDRIS, and SAIL using a split-file format. (30) Patients who attend ED as walk-ins will be identified from central NHS England records and will be linked to the same data items as the 999 callers.

We will compare outcomes between Groups 1 and 2. Our primary outcome will be 30-day mortality. We will define a core set of secondary outcomes to include attendance, conveyance, reattendance, timings, proportion admitted to hospital and safety (serious incident reports).

Based on data for March 2023 from NHS England and historical Ambulance Service data on attendance and conveyance rates, we expect our cohorts to include approximately 11,000 patients per site per month (approximately 1,056,000 over 12 months).
We will therefore be able to detect a standardised statistical effect size as small as 0.01 with >90% power at the 5% significance level, even after allowing for 5% attrition due to dissent or failure to link routine data. For instance, we can detect an absolute difference of 0.3%, from a 30-day mortality of 6%, (31) corresponding to 1 death in 20. We can therefore be confident of

detecting any clinically meaningful difference in our primary outcome and will be able to look at effects within subgroups such as patients from ethnic minorities, those who make high use of emergency care, and patients living in the most deprived areas.

We will describe our cohorts in terms of demographics and clinical casemix, and compare routine outcomes, adjusting for competing events where appropriate, and demographic and casemix differences.

Confidential patient data will be used in accordance with Section 251 of the NHS Act 2006.(28) We will finalise data items following the scoping review, but expect to include patient demographics and health outcomes, time of day, day of week, season, study site characteristics, and case mix.

Phase 2c) Survey of patients:

Sampling

We will randomly sample 2,800 patients from each group (5,600 in total) whose emergency care episode occurred within the most recent 1-2 months of the patient recruitment period (e.g. February 1, 2025 – March 31, 2025).

Recruitment

An NHS researcher at each site will identify potential participants from their ambulance service/ED datasets. The study team will support the site to generate a random sample from those eligible. Questionnaires will be posted to eligible patients by the site NHS research staff. The research staff will screen for death and clinical suitability to receive a questionnaire prior to distribution.

Data collection

The questionnaire will explore care experiences leading up to, during, and following their emergency episode. The questionnaire will include an SF-12 to assess Health Related Quality of Life (HRQoL), a Quality-of-Care Monitor to assess satisfaction with care, and questions to explore safety concerns related to those care episodes. Members of our team (NJW, ACS) have mapped patient-reported safety indicators from available international surveys relevant to ED care, and those questions we will use to explore safety concerns have undergone validation (focus groups and cognitive interviews) with diverse vulnerable patient populations funded by the Health and Care Research Wales Evidence Centre.

Questionnaire data will be linked to routine health outcomes. Recipients will be asked to return completed questionnaires in a prepaid envelope and will have the option to complete the questionnaire online or by telephone. This will ensure we have the best chance of reaching our predicted 40% response rate and receive n=2,240 analysable questionnaires. We will give all respondents a £10 voucher for completing the questionnaire. (32) Anonymised completed questionnaires will be managed using REDCap hosted by Swansea University. (33) Patients will be sent a unique link to enable them to complete the questionnaire online if desired. Returned paper questionnaires will be entered into REDCap by suitably trained staff at Swansea University. Patients will be tracked using their unique study ID to identify any duplicate

submissions and link questionnaires to routine electronic health records. Data entry processes, including robust quality assurance and minimum data entry checks, will be specified in a study data management plan. All appropriate Swansea Trials Unit standard operating procedures will be followed.

Power: Assuming a 40% response rate, the expected number (n=2,240, equally split by group) of analysable questionnaire responses will (using 90% power, at the 5% significance level, and assuming a standard deviation of 12.5 from previous studies (34)) enable us to detect a difference of approximately 1.7 points in SF-12 physical or mental component scores between patients in Groups 1 (low ambulance hours lost) and Group 2 (higher ambulance hours lost).

Phase 2d) Review of clinical case notes:

Sampling

To better understand the patient safety incidents arising as a result of handover and ED delays, and the consequent type and nature of harms experienced by patients, we will undertake a clinical case note review (n = 2,280, after 5% attrition) exercise on randomly sampled patients whether or not they respond to the survey. Case notes will be collated by NHS site research staff for review by external clinical reviewers.

We will stratify our sample by site, drawing a random sample of 600 cases per site, from within a Census period. To permit comparison of observations between sites with high queuing (i.e. those with high daily hours lost) and sites with low queuing (i.e. those with low daily hours lost) rates, we assume that 1140 analysable cases per arm is sufficient to detect, with 90% at 5% significance, a standardised statistical effect size of around 0.135 in outcomes between the two groups.

Data collection

By the term 'harm', we refer to “impairment of structure or function of the body and/or any deleterious effect arising there from, including disease, injury, suffering, disability and death, and may be physical, social or psychological.” (34) This will include disease, injury, suffering, disability, and death which may be physical, psychological, or social. (35) Safe care for patients includes not harming them either by actions healthcare professionals have taken or by actions they have not taken (‘avoidable harm’).

The purpose of the case note review is to identify evidence about the safety of care delivered at sites based on what is written in the notes by the healthcare professionals delivering care. This will allow us to compare the level and type of avoidable harms between Groups. This would include evidence from what is explicitly written (e.g. identifying a delay in antibiotics being prescribed and given based on a discrepancy between the time of the doctor’s prescription and the time of medication administration), or what should have been done according to the evidence base or as judged by a panel of peers if there is no clear evidence it occurred (e.g. giving key medications for a specific clinical presentation within a time stated within professional guidelines), or where key information is not documented (e.g. ECG findings, physiological observations). Where harm arising due to the care received is suspected, a narrative will be created summarising what happened, the evidence of plausible contributing factors, and the outcomes experienced by the patient (i.e. what the patient would say happened like worsening of

symptoms such as pain and breathlessness). The case note review approach helps to identify clinical care processes and their underpinning contributing factors that could be optimised or amended to improve the safety of care for future patients.

For our study, primary data sources will be the ambulance services' Patient Report Forms (PRFs) and ED records.

We will also track 48 complex patients (6 cases per site) to create illustrative cases by reviewing all of their in-patient case notes following the ED encounter. We will also combine the routine data available for those patients and seek to hypothesise differences for complex patients in their pathways of care at high and lower performing Trusts. Given our recent NIHR-funded STRETCHED study, our stratified sample of complex patients will include those with multiple chronic conditions, and/or those meeting national criteria for frequent attendance, and/or patients with re-attendances, ITU admission or death within 72 hours of 999 or ED contact. Clinicians will conduct a review informed by a series of questions that are both structured (requiring them to look for specific details/criterion in the notes suggestive of increased risk of unsafe care relevant to ED care) (36) and unstructured (drawing on their clinical experience and ability to identify issues of concern based on what is stated and not stated in the notes). A panel of ED doctors will be recruited to review ED records, and likewise several paramedics will be recruited to review PRFs at sites where they do not practice. They will identify explicit details from the notes to justify their judgements. The primary outcome for the case-note review is harm judged at least as probably avoidable, but we will also conduct analysis on harm judged at least possibly avoidable (secondary outcome). Case notes will be reviewed by at least one relevant clinician (either ED doctor or paramedic, or both if ED notes and PRF need to be reviewed), with a 10% random sample being reviewed twice alongside a 10% sensitivity sample of notes where no evidence of harm has been identified will be re-reviewed by a relevant clinician.

Where evidence of a patient safety incident has occurred, pseudonymised data will be entered onto a specially designed data collection form on a 4G/Wi-Fi enabled device for secure transfer to a server at Swansea University. The clinicians will use a structured case note review form to systematically examine records. On completion, they will write a structured narrative summarising what happened, the identified evidence, and apparent outcomes for the patient. Our team will subsequently use the comprehensive patient safety classification system developed by Cardiff University to classify the nature (type of safety incident), contributory factors (setting, types of staff, etc.), and severity of harm. (37) The Cardiff team will support data extractors to structure their case descriptions using a recursive incident analysis approach (37) to capture evidence about events leading up to the safety incident. (37) They will hold regular quality assurance meetings with clinician reviewers to ensure clarity around the case note review process. (38) Reviewers will initially judge the 'avoidability' of harm on a six-point scale and inter-rater reliability calculations will be computed. (39) Overall 'avoidability', based on evidence provided by clinical reviewers, will be judged by our team which is consistent with other studies of this nature. (37)

Phase 2e) Interviews and focus groups with key stakeholders:

Patient (and/or family/carer) interviews

Sampling

We will recruit 40 patients (and/or family/careers) (5 per site) who have been sampled as part of the patient survey in phase 2c and who have consented to be contacted for a follow-up interview. As the participants are self-selecting no further screening will be undertaken.

Proportionate sampling will be used to include representation of incidents identified via patient-reported data (n=5 from each ambulance service) and via case note reviews (n=5 from each ambulance service). We will sample patients purposively according to their responses to the survey items relating to their quality of life (from the SF-12) and quality of care and satisfaction (from the Quality-of-Care Monitor), whether the patient indicated a safety concern and whether they indicate that they experienced a delay (in ambulance service response or in ED). We will also seek participant diversity in terms of patient demographics and location.

Recruitment

An information sheet and consent form for interview will be emailed or posted to potential participants. Respondents will be given a £25 voucher for taking part in an interview which may take up to 60 minutes. Interviews will be conducted online or via telephone. Virtual interview options (i.e., online or telephone) will help to remove geographical and physical accessibility barriers. They will also promote inclusion of clinically vulnerable patients in our sample. Interviews will be conducted using an online platform (e.g., Zoom) that has proven to work effectively for a wide range of patient groups previously. Detailed instructions will be provided to the participant beforehand to minimise any technical or access difficulties. Where a participant is not comfortable using this technology, or does not have access to this technology, they will be offered a telephone interview.

To further improve accessibility, we will also be able to provide a Speech-to-Text-Reporter (STTR), or Palantypist, or British Sign Language support during the online interviews. The team have previous experience of using this during focus groups conducted with members of Disability Wales. Patients will be advised that they can stop at any time should they wish to, without needing to give a reason.

Data Collection

Members of the research team will carry out the interviews/focus groups. Audio/video recorded interviews will take place online or via telephone and will take around 1 hour maximum. We will work with public contributors to develop the patient interview guide and identify relevant topics for exploration. Earlier phases of work (e.g., Phase 1b scoping review) will also inform the interview guide.

Topics will include experiences of care, experiences of handover delay or excessive wait in the ED (if experienced); what happened to the patient while they were waiting to be moved into the ED/ waiting in the ED, how they felt during this time, and any physical, psychological, or social impacts / outcomes. We will also explore patients' views on potential mitigating strategies – what do they think could be done to help reduce the delays in handover?

To maximise our understanding of the system experienced by patients, from the perspective of safety concerns experienced (if relevant) during periods of queuing, SEIPS 3.0 human factors framework to guide part of the interview guide, encouraging patients to think about relevant contributory factors to the safety event.

We recognise the potential for STALLED interviews to provoke emotional distress either for interviewees or for interviewers. We will implement a distress protocol with guidance for interviewers on steps and measures to be taken if a participant or researcher becomes distressed. (40) Patient participants who become distressed will be referred to the NHS trust that invited them to take part for support and advice. Where appropriate, we will also offer a follow up call to interviewees to check on any issues the interview may have raised. Staff participants who become distressed will have the opportunity to debrief/offload, with a research team member of their choice, to support their wellbeing and be encouraged to make use of the services provided by their employers' occupational health support.

Interviews and focus groups with professional stakeholders

Sampling

Interviews

Professional stakeholders will be identified through stakeholder mapping with site researchers, and through chain-referral (snowball) sampling approaches. We will seek 40-48 participants (4-5 per site). We will purposively sample to ensure a range of different professionals across the care pathway and across the 8 sites. This includes ED leads/staff, ambulance service leads/commissioners/staff, and key stakeholders across the pathway – including upstream and downstream, or both (e.g. hospital/ ward managers, social care leads, integrated care board representatives).

Focus groups

We will also carry out online focus groups (n=8, one per site) with a broader range of ED clinicians and staff, paramedics, and call handlers, social care staff, virtual ward leads, leads of alternative urgent care facilities (e.g. Same Day Emergency Care (SDEC)) and leads of other public health intervention centres (e.g. rehabilitation centres for substance misuse). We will aim for 6-10 participants in each focus group, (total circa 48-80). We will supplement focus group data collection with individual interviews, if necessary, to ensure all key stakeholder groups are included. Earlier phases will guide if we conduct the focus groups on a site or professional group basis.

Recruitment

Professionals will be contacted via email inviting them to participant in an online interview. They will be sent a participant information sheet and digital consent form.

Data Collection

Interviews (approximately 1 hour) will be conducted online by members of the research team. Using the results of the scoping review (phase 1b) organisation survey (phase 1c), we will develop a summary of the initiatives that are in place at each of the sites to reduce handover delays. This will help us to have an initial understanding of the different component parts of the initiatives, including the *target level(s)* (e.g. patient, staff, hospital, health board, ambulance

service), *what* the different component parts involve, *who* is responsible for overseeing/delivering them, and *where* it sits in the system (e.g. community, at ED, hospital wards etc).

Using these summaries as a guide, interviews will explore these initiatives in detail, including awareness of the initiative, what it involves, who it involves, where it takes place, their experiences of the initiative and their views on what works and what does not work, the decision-making processes about which patients are held in a queue, the potential harms and outcomes.

The interviews will also adopt SEIPS 3.0 human factors framework (20) to understand the structures and processes perceived to underpin / exacerbate / mitigate harms cause by queuing and consider possible solutions, as well as decision making about which patients are queued, potential harms of queuing, and outcomes.

Focus groups

Online focus groups (1-2 hours) will explore awareness of the hand over delay initiatives, current practices, their experiences of managing patients whose care was delayed, inter-professional relationships and decision making, safety concerns and consequences, and views on what works and what does not work to reduce handover delays.

Focus groups will also explore their experiences of managing patients whose care was delayed, focusing on contextualising, and understanding the patient-reported safety concerns and clinical consequences as well as challenges they have experienced during similar incidents, and discussions about the feasibility and usefulness of solutions.

Data Management and Analysis

All analyses, based on 'treatment allocated' principles, will be specified in advance in the study's Statistical Analysis Plan, following relevant Swansea Trials Unit SOPs, and will specify modelling conventions, such as inclusion and exclusion rules for covariates and factors, and imputation of missing data, where considered appropriate. Residual diagnostics will be used where analyses assume Normality; if the distributions of residuals are markedly non-Normal (eg: marked skewness), data transformation techniques or bootstrapping will be considered. Outcome descriptions, summaries and comparisons will be reported using CONSORT guidelines, including estimates with 95% confidence intervals (allowing two-tailed tests at the 5% significance level).

Routine data

We will select generalised linear models with link functions appropriate to each outcome and retain site characteristics and group indicators as factors in all models. The Statistical Analysis Plan will also specify planned sensitivity and sub-group analyses.

Self-reported outcomes:

Returned patient questionnaires will be uploaded to the SAIL trusted research environment and linked with routine health data using study ID. Categorical and continuous data will be summarised (as the proportion of respondents giving each answer, or as average scores, grouped where appropriate) and compared between arms using generalised linear models as

described above. SF-12 physical and mental component scores will be calculated and used to derive Quality Adjusted Life Years for the health economics analysis. Free text questions will be passed to a qualitative expert for analysis where appropriate.

Case note review:
Our approach is designed to (i) generate structured non-identifiable coded data that can be considered in combination with the routine data; and (ii) enable an exploratory, descriptive analysis to generate summaries to understand the relationships between important concepts like incident type and contributory factors. Such relationships can highlight important opportunities to improve patient safety. As a study team with expertise in human factors and healthcare improvement, such analyses will also inform where and how to intervene to make systems safer, by utilising latent (underlying or inferred) insights.

Interviews and focus groups with key stakeholders
Audio recorded interview and focus group data will be transcribed by an external transcription company and anonymised. Using NVivo qualitative analysis software, framework analysis (informed by the results of the scoping review) will explore participants' experiences and what works to avoid handover delays and related harms; 20% transcripts will be dual coded to ensure consistency and comprehensiveness of the coding framework. The qualitative sub-group will meet regularly to refine the framework. Following framework analysis, the SEIPS 3.0 human factors framework for studying and improving healthcare will be applied to the data, allowing us to explore the nature of any safety concerns reported that resulted from the delays, and consider holistic systems-based strategies that could be used to mitigate them.

Phase 2f) Modelling of costs and wider impact of initiatives
We will undertake a model-based analysis to assess objective 4 (the relative costs associated with the consequences of successful handover management) between Groups, and objective 5 (the wider impact of initiatives on patient care through UEC). We will use a Discrete Event Simulation (DES) model (41) to enable us to capture individual course of the patient journey (over time and events) occurring through the UEC system, with the DES approach specifically designed to address 'queuing'. DES is an established approach to modelling complex healthcare situations particularly where what happens to the patient as a result of handover management may impact on subsequent events. (41) It will provide a comprehensive comparison to identify the most efficient and effective handover strategies and run 'what if' scenarios to understand the impact of making changes to patient flow to guide decision making.

We will follow good practice in the design and conduct of our analyses (42) and report following the CHEERs statement. (43) We will take an NHS and Social Services perspective for our base-case analysis, with additional consideration of broader multi-agency perspective if feasible including third sector and direct patient/family costs). We will use Phase 1 to work with stakeholders to prepare our analysis plan and produce our model schema, drawing upon the conceptual framework for STALLED, ensuring we have built good validation into our model and transparency throughout our work. (44) We expect that a de-novo model will need to be developed, and this will be confirmed through using the scoping review to formally assess whether there are existing models which can be adapted.

We will also set out our data requirements from the routine data and patient surveys including deriving health utilities from the SF-12 (45) (via SF-6D, (46)) and additional resource use questions related to other agencies that cannot be captured from the routine datasets. Our expected data requirements include arrival patterns of patients, the time spent in each "service" (in this case the time spent in each stage of the patients' journey, from 999 call/ED walk-in to admission/discharge). Data are also required which will help direct the patients through the system, for example percentages of patients being discharged, dying and requiring admission. We will validate our data inputs with stakeholders, and where necessary confirm additional inputs (e.g., from structured literature searches) and agree assumptions.

We will assign costs (valued in £ sterling) to the resources associated with the service and subsequent events using published unit costs for the latest price year available, with appropriate discounting of costs and outcomes if the 'pathway' is beyond 12 months. We will use the outcomes from our statistical analysis (including consistent methods used in any adjustments e.g. missing data) as our consequences.

We will model each site separately and take into account urban/rural status of the location and distance to hospital. The DES model will predict the wider impact these initiatives could have on patient flows through the UEC system, and the costs associated as part of a cost consequence analysis. The model developed will be a useful tool to predict the effects of handover delays at different levels of throughput and staffing on the UEC system. Scenario analyses will be conducted to explore the impact of these changes to the resource use and costs associated on the UEC system, and if feasible to estimate the costs and consequences to the wider system such as primary and social care.

Eligibility criteria

Table 1: Overview of eligibility criteria by phase

Phase	Inclusion	Exclusion
1c) Organisation survey	-UK ambulance services -ED departments identified from ambulance service questionnaire -Questionnaire completed by staff member (Age 18 – 110 – adults only)	
2b) Comparison of performance across sites using routine data	-Emergency Department walk-in patients and 999 callers at study site in 12-month period (e.g. 01/04/24 to 31/03/25) -Age: 0-110 (children and adults)	Local, national, or study specific opt out
2c) Patient survey	-Included in Phase 2b dataset. -Emergency Department walk-in or 999 call was in previous 2-month period (e.g. 01/02/25 to 31/03/25) -Age: 18-110 *(adults only)*	Deceased Deemed unsuitable to receive questionnaire by site (screened out)
2d) Clinical case note review	-Included in Phase 2b dataset *(children and adults)*	

2d) Clinical case note review (complex cases)	-Included in Phase 2b dataset *(children and adults)* -Meets study definition of complex case (those with chronic conditions, those meeting national criteria for frequent attendance, patients with re-attendances, ITU admission or death within 72 hours of 999 or ED contact).	
2e) Stakeholder interviews	-Patients: Included in Phase 2c. -Expressed interest in interview participation in questionnaire response. -Age: 18-110 *(adults only)* -Staff: has working knowledge of site -Age: 18-110 *(adults only)*	Deceased

Synthesis

We will present findings at stakeholders' workshops including PPIE contributors, policy makers, clinicians and managers from hospitals and ambulance services, and social care. We will work collaboratively to suggest solutions for implementation in the healthcare service and provide evidence, theory and guidance about policies and practice to avoid handover delays.

Study Within A Project (SWAP)

We will include a SWAP in our study to compare use of on-site (ambulance and hospital) records versus anonymised central records for retrieving outcome data. We will compare completeness of data (missing records, data fields); quality; comprehensiveness; timeliness; and cost. We are aware of one Study Within A Trial (SWAT) registered to compare trial collected and routinely collected death data only (SWAT 125). (47) There are no SWAPs currently registered to compare all routinely collected outcomes with matched study collected outcomes.

Consent and confidentiality

We will link routine anonymised records for approximately 1,003,200 patients who called 999 or walked into ED. Patients will not be directly contacted by the study team to inform them about the study and take consent as it is not practical to contact this number of patients. In addition, some patients may have died since the period under study and we would not want to cause undue distress to carers/relatives. We will make all reasonable efforts to inform patients, including advertising the study via notices in ED departments, and on ambulance service websites. We will work with our public contributors to ensure these approaches are sufficient, appropriate, and proportionate. Patients can opt out of their data being used in this study via the National Data Opt Out website (England) (28) or SPIRE (Scotland), (29) or by contacting their local site research paramedic prior to analysis. It will not be possible for patients to dissent after this point; identifiable data will be removed prior to analysis, so the study team will not be able to

identify the dissenting patient to remove them from the dataset.

5,600 of the patients whose anonymised records are linked to healthcare outcomes will be sent a questionnaire by NHS staff at each site to complete with a covering letter and Patient Information Sheet explaining the purposes of the research, along with a consent form. We will ask for consent to be contacted for interview in this questionnaire. We expect the questionnaires to take 30 minutes or less to complete. Patients will be given a £10 voucher for completing the questionnaire.

The CIs have a responsibility to ensure that patient anonymity is protected and maintained. They must also ensure that their identities are protected from any unauthorised parties. Information with regards to study patients will be kept confidential and managed in accordance with the Data Protection Act, NHS Caldicott Guardian, The Research Governance Framework for Health and Social Care and Research Ethics Committee Approval.

Safety reporting

This is a non-interventional observational study; therefore, no monitoring of adverse events is necessary.

Definition of end of study

End of study is defined as completion of data collection (end of Phase 2e – qualitative interviews and focus groups). Data analysis, reporting and dissemination will follow.

5: ETHICAL AND REGULATORY CONSIDERATIONS

Assessment and management of risk

This study is observational in nature, and does not carry significant risk to patients, staff or researchers. We recognise however that patient participants might find discussions about emergency care experiences upsetting when we explore this topic during questionnaires, interviews and focus groups. We will explain all risks in the participant information sheets and assure individuals they can stop their participation at any time. At the start of interviews and focus groups we will reiterate that if they decide not to take part, or to withdraw partway through the interview or focus group, this will have no impact on their future treatment or care. We will state that all questions are optional. We will make it clear that they are under no obligation to reveal anything about their health, or themselves more generally, unless they wish to, and that their information will be anonymised for use in our research. The interviewers, who will all be experienced qualitative researchers, familiar with the study and practised in interviewing participants on health-related topics, will be alert and sensitive to respondents' emotions and sympathetic to reactions. Participants will be made aware of the study contact details if they have any issues or queries after taking part in the study. We will use a distress protocol in interviews and focus groups to support monitoring of distress and appropriate follow up.

Research Ethics Committee (REC) and other Regulatory review & reports

Before the start of the study, a favourable opinion will be sought from NHS REC for the study protocol, information sheets, consent forms and other relevant documents.

Substantial amendments that require review by NHS REC will not be implemented until that review is in place and other mechanisms are in place to implement at site. All correspondence with the REC will be retained.

It is the Chief Investigators responsibility to produce *REC* reports as required.

- The Chief Investigator/s will notify the REC of the end of the study.
- If the study is ended prematurely, the Chief Investigator/s will notify the REC, including the reasons for the premature termination.
- Within one year after the end of the study, the Chief Investigator/s will submit a final report with the results, including any publications/abstracts, to the REC.

Amendments

The Chief Investigator/s will be responsible for making the decision to amend the protocol and for deciding whether an amendment is substantial or non-substantial. A record of any amendments will be detailed alongside protocol variations, and for each version number.

Peer review

The study has been reviewed by the NIHR Health & Social Care Delivery Research Programme panel and been subject to high quality independent peer review.

Indemnity / Compensation / Insurance

The study is sponsored by Swansea University. The University holds insurance covering liabilities arising from negligent harm caused by poor protocol design by the Chief Investigators and researchers employed by the University.

Data Handling

Record Retention and Archiving

During the course of research, all records are the responsibility of the CI and must be kept in secure conditions. When the research trial is complete, it is a requirement of the SU Research Governance to archive the data for 10 years.

Compliance: The CI will ensure that the trial is conducted in compliance with the principles of the Declaration of Helsinki (2024), and in accordance with all applicable regulatory requirements including but not limited to...:

- UK Policy Framework for Health and Social Care Research (2017)
- Medicines for Human Use (Clinical Trials) Regulations (2004)
- Medical Devices Regulations (EU MDR/IVDR 2017)

and SU policies and procedures and any subsequent amendments.

Ethical Considerations: This protocol and any subsequent amendments, along with any accompanying material provided to the patient in addition to any advertising material will be submitted by the Investigator to the Su sponsor and then to NHS Research Ethics Committee. Written Approval from the NHS REC Committee must be obtained and subsequently submitted to the SU Sponsor to circulate to participating NHS R&D Departments to obtain Final approval.

Quality Control and Quality Assurance

A study may be identified for audit by any method listed below:
A project may be identified via the risk assessment process.

An individual investigator or department may request an audit.

A project may be identified via an allegation of research misconduct or fraud or a suspected breach of regulations.

Projects may be selected at random. The Department of Health states that Trusts should be auditing a minimum of 10% of all research projects.

Projects may be randomly selected for audit by an external organisation.

Internal audits will be conducted by a sponsor's representative

Non-Compliance: A noted systematic lack of both the CI and the study staff adhering to SOPs/protocol/ICH-GCP, which leads to prolonged collection of deviations, breaches or suspected fraud

These non-compliances may be captured from a variety of different sources including monitoring visits, communications and updates. The sponsor will maintain a log of the non-compliances to ascertain if there are any trends developing which need to be escalated. The sponsor will assess the non-compliances and action a timeframe in which they need to be dealt with. Each action will be given a different timeframe dependent on the severity. If the actions are not dealt with accordingly, the Research Governance Office will agree an appropriate action, including an on-site audit.

6: DISSEMINATION

Our dissemination approach will seek to maximise stakeholder interest and understanding of the study and its findings on ambulance service and ED policies, processes, practice and patients. It will build on the team's profile and reputation with previous studies focused on improving the quality of prehospital and emergency care.

At an early stage we will work with our public contributors to develop a communication, publication and dissemination plan, including the assessment of stakeholder needs and communication activities and milestones. The plan will include engagement with patient, public and professional groups, NHS managers, commissioners and policy makers and third sector organisations. We will use the plan to guide our later stakeholder workshops, which will take place once the study data collection and analysis are complete. The stakeholder workshops will be designed to be inclusive allowing patients, members of the public, third sector organisations, service providers and policy makers the space to share their views and respond to our early findings, helping us interpret and contextualise our results. At the workshops, we will discuss and further refine our findings to ensure our results are representative and are widely shared with the community, policy makers and NHS service providers. Our public contributors will be actively involved in planning and co-delivering the sessions. They will help recruit patient and public members and support them to participate. We will build on learning from another ED-related study which co-applicants recently completed where this approach was effective. (48,49)

Our communication, publication and dissemination plan will include plans for media engagement, to include written press coverage, online media, and social networking, with the support of the dedicated marketing team at Swansea University Medical School. We will use our strong links with ambulance and health services directly and through national bodies (National Ambulance Research Steering Group, Association of Ambulance Chief Executives and National Ambulance Services Medical Directors, NHS England, NHS Improvement, Health Education England, Royal College of Emergency Medicine and College of Paramedics) to develop plans for dissemination. We will also publish findings in trade and professional publications and networks, and to ensure that our findings are incorporated into ambulance service and ED guidelines, which influence practice. Patient participants who request study findings will receive a lay summary, to be available in several languages. We will circulate this lay summary and translations to third sector partners for cascading through their networks. We will use the GRIPP2 checklist to support reporting of our patient and public involvement. (50)

Given the implications for practice, policy and research, we will publish our results in scientific journals and scientific conferences, in the UK and worldwide. The annual 999 EMS Research Forum Conference http://www.999emsresearch.co.uk/en/ which is hosted each year by a UK ambulance service with organisation by Swansea University and PRIME Research Centre Wales, brings together academics and practitioners. We will also present findings at other appropriate national and international events, such as the Health Services Research Network annual conference, the International Forum for Quality in Healthcare and the European Society for Emergency Medicine.

In addition to a full final study report, we will produce a summary version to be disseminated through the PRIME network (http://www.primecentre.wales) and NHS and third sector organisation newsletters and social media pages. Our public contributors will help us identify and target messages to patients and the public including different age or ethnic populations. Our public contributors and our co-applicants with clinical, managerial and policy expertise will help us produce study outputs in line with our dissemination strategy, so we effectively incorporate their skills and experience to improve potential for impact from this research.

Outputs

1. A final synopsis research report summarising the work undertaken together with supporting technical appendices, abstract and executive summary. The plain English executive summary will focus on results/findings and be suitable for use separately from the report as a briefing for NHS managers, emergency care practitioners and the public.
   A set of PowerPoint slides which present findings from the research for use by the research team or others in disseminating research findings to the NHS and other stakeholders.
2. Key research findings shared to each stakeholder as agreed within their bespoke knowledge mobilisation plans.
3. Recommendations on what works, and where and how existing systems can be improved to mitigate handover delay.
4. Definitive characterisation of harms resulting from delays with exemplar illustrative patient stories to raise awareness and enhance understanding of the problem.
5. Papers for academic peer reviewed journals such as the Annals of Emergency Medicine, Emergency Medical Journal and BMC Emergency Medicine to ensure the research forms part of the scientific literature and is available to other researchers. We support the open access model of research dissemination.
6. Articles for professional journals which are read by the NHS management community, and which will be helpful in raising wider awareness of the research findings e.g. Ambulance UK, Health Service Journal. This will include a report of the scoping review.
7. Seminars, workshops, conferences at regional, national and international level or other interactive events at which the research team will present and discuss the research and its findings with NHS managers and third sector organisations.
8. Mathematical model for use by stakeholders
   User-friendly materials for the public, service managers, commissioners and policy makers using infographics to maximise accessibility and reach.

7: REFERENCES

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