Study Title: Waiting times in Emergency Departments

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Conflict of Interest statement

The chief investigator, lead investigator and all co-investigators declare no conflicts of interest.

Confidentiality Statement

This document does not contain confidential information.

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1. KEY STUDY CONTACTS

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2. LAY SUMMARY

Crowding and long waits in Emergency Departments (EDs) – previously known as Accident and Emergency (A&E) – are problems for healthcare systems worldwide. In England, there were 25 million attendances in 2019/20 – 17% more than in 2010/11. 28% of patients now wait more than four hours in EDs.

We know there is a strong link between deprivation and health. There are more ED attendances in deprived areas. Waiting times for planned operations are longer for patients from deprived areas but we do not know if the same is true for waiting times for unplanned ED care. We also do not know whether people who wait longer in EDs have worse health outcomes.

Equal access to ED care is a priority for the NHS.

This study will provide vital information to ensure ED care is fair and timely. We will:

(i) Examine whether there are inequalities in ED waits, by deprivation, age, gender, ethnicity and other factors
(ii) Analyse the impact of waiting in EDs on patients' health
(iii) Explore whether differences in the organisation of EDs lead to differences in how patients are prioritised and treated

For i) and ii) we will use data already collected by the NHS. They will be prepared for us in a way that means we cannot identify the patients. We will cover the years 2018-22 and be careful to consider the effects of the COVID-19 pandemic. We will look first at all health conditions combined, comparing patients who have the same severity (how sick patients are). We will look in detail at conditions that occur most frequently among more deprived populations: heart failure, chronic obstructive pulmonary disease, asthma.

For (iii), we will observe and talk to patients/relatives and staff in four English EDs, three of them in areas of high deprivation. We will track 20 patients in each ED from arrival/initial assessment until they are admitted into hospital or leave and shadow 15 staff members to watch what different members of staff and patients do. Across the sites we will interview up to 40 staff and 40 patients/relatives to understand their experiences. We will make detailed notes about how the EDs are organised and their different work practices and collect data about waiting times and numbers of people waiting. These data will be thematically analysed to explore differences in practices and processes.

Members of patient and public (PPI) networks we spoke to said that our research questions are important for and relevant for patients and caregivers. Our research team includes a PPI co-investigator and PPI advisory group who will support this study. We spoke to a variety of people, including ED staff, policymakers and charities, who confirmed the importance of our research questions. Our research team and advisers include ED staff, managers and policy makers in the NHS and members of two medical Royal Colleges.

We will produce research summaries, blogs and visual representations to share findings that emerge during the project. We will produce a non-technical summary of findings for patients, a policy brief and articles for professional/academic journals. We will hold a workshop with patients and healthcare professionals and managers. We will use our links with the Royal Colleges and others to spread our findings to inform future care.

3. SYNOPSIS

Study Title	Waiting times in Emergency Departments: Inequalities and impact on health outcomes
Internal ref. no. / short title	Waiting times in Emergency Departments (ED-WAITS)
Sponsor	University of Oxford
Funder	NIHR HS&DR
Study Design, including methodology	Mixed methods study: comparative case studies in 4 English Emergency departments (EDs); quantitative analysis of secondary data sources
Study Participants, including sampling strategy	Quantitative work: all patients who have attended an ED in England since 2019 Qualitative work: Healthcare professionals and other staff working in, and patients attending, four ED departments in England
Sample Size	Quantitative work: all patients who have attended an ED in England since 2019 and in greater detail all patients who have attended Addenbrookes' ED. Qualitative work: Four EDs in England offering 24-hour medical care from minor injuries to major trauma 15 staff in each ED will be shadowed (60 total) 10 staff in each ED will be interviewed (40 in total) 20 patients in each ED (80 total) will be shadowed; 10 patients in each ED will be interviewed (40 total)
Planned Study Period	Total length of project: 1st August 2023 – 30th July 2025 ED departments involvement: approx. one month in each of the EDs. Staff shadowing may be all or part of a shift (1-12 hours). Patient shadowing may also be for variable times depending on length of wait. Patient and staff interviews involvement: 15-40 minutes single episode interviews.
Planned Recruitment period	Oct 2023 – January 2025
Aim/Research Questions/Objectives	
Primary Aim	The aim of study is to examine through statistical analyses of NHS data and through rich detailed case study analysis of ED practices and organisation the relationship between inequalities and ED waits, and explore the impact of waiting on patients' health.
Research Question 1	Are there inequalities in ED waiting times by socioeconomic status and other patient characteristics, between and within hospitals, allowing for severity of the patient's presenting condition?

Research Question 2	Do longer waits translate into worse patient health outcomes, by severity of condition?
Research Question 3	Are there differences in professional behaviour and organisational cultures in EDs that influence waiting times? Are these patterned by socioeconomic status and other patient characteristics?
Objectives: WP1	1. Understand waiting time variation in EDs by socioeconomic status, age, gender, ethnicity, attendance mode (ambulance, walk-in) and referral mode (by GP or 111), controlling for patient case-mix and severity, and other factors. 2. Provide evidence showing if/how differences in waiting times affect health outcomes for patients and explore if this is patterned by socioeconomic deprivation.
Objectives: WP2	to explore differences in professional practices and organisational cultures in EDs that influence waiting times and examine if there are patterns of waiting related to socioeconomic disadvantage.
Objectives: WP3	Identify drawing on the findings of WP1 and WP2 specific practices or biases that disadvantage certain patients

4. ABBREVIATIONS

BSA	British Sociological Association
COPD	Chronic obstructive pulmonary disorder
CI	Chief Investigator
COVID-19	Coronavirus Disease 2019
ECDS	Emergency Care Services Data
ED	Emergency Department
GDPR	General Data Protection Regulation
HES	Hospital Episodes Statistics
HRA	Health Research Authority
HS&DR	Health Services and Delivery Research
ICF	Informed Consent Form
ICMJE	International Committee of Medical Journal Editors
IMD	Index of Multiple Deprivation
MS IDREC	Medical Sciences Interdivisional Research Ethics Committee
NEWS-2	National Early Warning Scores
NHS	National Health Service
NIHR	National Institute for Health and Care Research
ONS	Office Of National Statistics
OSOP	One sheet of paper
PI	Principal Investigator
PIS	Patient Information Sheet
PPI	Patient and Public Involvement
R&D	NHS Trust R&D Department
REC	Research Ethics Committee
RGEA	Research Governance, Ethics and Assurance
RQ	Research Question
SSC	Study Steering Committee
UK	United Kingdom
WP	Work Package

5. BACKGROUND AND RATIONALE

The number of ED patient attendances in England has risen by 40% over the past two decades and waiting times for urgent care in EDs have rapidly increased. The proportion of waits exceeding the 4-hour target rose from 3% in 2010/11 to 16% in 2019/20 and further to 28% in March 2022 (NHS Digital, 2020). The COVID-19 pandemic has negatively impacted on triage systems and bed availability. In 2019/20, there were nearly twice as many ED attendances (3.1 million) for the 10% of the population living in the most deprived areas compared with the least deprived 10% (NHS Digital, 2020), and the last decade (pre-COVID) has seen this gap grow. There is little evidence on whether people from deprived areas experience longer waits than people from less deprived areas, or whether this affects health outcomes. Understanding variation in ED waiting times and impacts of waiting on health outcomes is important so that any inequalities can be addressed and NHS principles of equity and efficiency can be pursued.

Previous research highlights socioeconomic inequalities in health care access, notably variation in waiting times for elective procedures (e.g. Simonsen et al 2020, Moscelli et al 2016, Cookson et al 2016). A review (Landi et al 2018) found that patients with lower socioeconomic status and lower education, wait longer for diagnostic and specialist care and elective surgery. A review by Owens et al (2020) found that patient race and ethnicity impact a number of patient outcome measures following ED care, and highlighted that further research is warranted. A recent narrative review (McIntyre & Chow, 2020) reported inequality in waiting times for elective procedures, but noted that none of the contributing studies focused on waiting times for unplanned emergency care.

In the USA, there is evidence that homeless patients experience longer waiting times in EDs, (Ayala 2021), that Black patients wait longer than white patients (Qiao et al 2016) and African Americans receive lower triage scores compared to Caucasians, which is associated with longer waiting (Schrader and Lewis 2013). A retrospective observational study in New Zealand (Curtis et al 2020) found that Maori patients are more likely to be triaged at levels associated with longer time frames than non-Maori patients.

The behaviour and attitudes of staff and patients can influence what happens in ED settings. There are a number of studies demonstrating the role of organisational cultures and labelling or stereotyping when categorising and prioritising patients (Dingwall and Murray 1983, Hughes 1988, Jeffery 1979, Mannon 1976, Roth 1971 and Vassy 2001). A thematic qualitative review (Brouder et al 2020) noted that many frequent ED attenders have negative experiences of care, including long waiting times. Hillman et al 2013 described how older people are vulnerable to negative labelling and poorer treatment when attempting to access emergency care. Socioeconomic disadvantage is associated with help-seeking by many of the groups included in these previous studies (homeless people, those with alcohol or substance abuse, or mental health problems), but, to our knowledge, no previous qualitative research has focussed directly on socioeconomic disadvantage and waiting in EDs.

There are two streams of work with three overlapping work packages.

The quantitative work will estimate separate multivariable and fixed effects regressions using administrative data already collected and provided by NHS England (Hospital Episode Statistics) and data collected by Addenbrookes' hospital. The analyses using each data source will be performed separately.

The HES datasets provide unique pseudonymised patient codes that allow researchers to follow each patient across datasets and across multiple episodes and different stages of the ED attendance, eventual

admission, and out-of-hospital mortality, as well as across hospitals. The Addenbrookes' data will be provided to us at Patient level but anonymised and we will not link this data to other sources.

The Qualitative Study will explore differences in professional practices and organisational cultures in EDs that influence waiting times and examine if there are patterns of waiting related to socioeconomic disadvantage.

We will conduct four comparative ethnographic case studies. Case study methodology does not seek to produce statistically predictive findings, but can generate explanations (i.e. answer 'how', 'what' and 'why' questions). This is a low risk study involving NHS staff, patients and people who accompany patients to the ED (adult carers/accompanying adults) who volunteer to participate. There are no identified risks to participants. There are no direct benefits to participants, but knowledge gathered will inform policy and practice for future staff, professionals and service users. Staff participants in case studies will receive feedback which may be beneficial for service planning and decision making.

6. AIM / RESEARCH QUESTIONS / OBJECTIVES

Aim / Research Questions / Objectives
Aim: WP1: Quantitatively documenting inequities by analysing variation in ED waiting times by socioeconomic deprivation and other demographic factors like age, gender, and ethnicity. WP2: Contribute rich detailed case study analysis of ED practices and organisation to augment the separate statistical study which will examine the relationship between inequalities and ED waits, and explore the impact of waiting on patients' health. WP3: Relate cultural/organizational factors to quantitative measures of inequity between sites
Objectives: WP1: 1. Understand waiting time variation in EDs by socioeconomic status, age, gender, ethnicity, attendance mode (ambulance, walk-in) and referral mode (by GP or 111), controlling for patient case-mix and severity, and other factors. 2. Provide evidence showing if/how differences in waiting times affect health outcomes for patients and explore if this is patterned by socioeconomic deprivation. WP2: to explore differences in professional practices and organisational cultures in EDs that influence waiting times and examine if there are patterns of waiting related to socioeconomic disadvantage. WP3: Identify, drawing on the findings of WP1 and WP2, specific practices or biases that disadvantage certain patients

7. STUDY DESIGN

A mixed-methods study consisting of secondary data analysis and qualitative case studies/interviews.

WP1: Inequality in waiting times and impact of waiting times on outcomes

WP2: The practice and organisation of ED care, waiting and deprivation

WP3: Integration of quantitative and qualitative analyses

7.1 Work Package 1

7.1.1 Methodology

The analyses of routinely collected data will comprise analyses of NHS Emergency Care Services Data (ECDS) linked to Hospital Episodes Statistics (HES) and separate analyses of Addenbrooke's data. The analysis of Addenbrookes' data will be a valuable supplement to the analysis of ECDS/HES data especially since the Addenbrookes data contains more variables relating to the acuity of the patient's condition than the ECDS.

The study will investigate the inequality in waiting times and the impact of waiting times on outcomes. Using the two data sources separately (HES and Addenbrooke's), we will use deidentified patient level data on patients who attended the emergency department over the period January 2019 to as late as feasible in 2023. It is crucial that the data should not include any variables that would identify individual patients. The HES data will be provided to us pseudonymised; the Addenbrooke's data will be provided to us anonymised.

7.1.2 Patient Inclusion Criteria

7.1.2.1 Inclusion criteria

All patients attending an ED from financial year 2018/2019 until as recently as feasible in 2023.

7.1.2.2 Exclusion criteria

None.

7.1.3 Description of Statistical Methods

We will conduct multivariable analyses of the data to be extracted. To address RQ1, we will estimate separate multivariable regressions at the patient level for the following outcomes: time to initial nurse assessment, time to initial medical assessment, time to treatment (if such data available), time to admission (if patient admitted), time from treatment to conclusion (if such data available), total time at the ED, and probability of waiting longer than 12 hours. We will analyse the relationship between each of these waiting time measures and patient socioeconomic status (based on the IMD score), mode of arrival and source of referral, holding fixed other patient characteristics (such as age, gender, ethnicity). We will control also for the acuity of the patient's condition at time of ED attendance as indicated by their NEWS2 score and health conditions and diagnoses. It will show how much waiting times differ between the top and bottom deciles of the socioeconomic distribution, as well as by gender, ethnicity and the patient characteristics indicated above, holding other patient characteristics fixed.

Then, the regression models will progressively include, and hence hold fixed, 1) hospital-specific variables related to health care demand and hospital crowding (such as the number of ED attendees and average complexity of cases), and 2) hospital fixed effects, to control for observable and unobservable supply-side factors and differences across hospitals (e.g. hospital size, skill-mix of ED staff, characteristics of hospital organisation, and hospital location). The inclusion of hospital fixed effects will allow us to study the presence of within-hospital inequality.

To address RQ2 we will investigate the relationship between waiting times and the following outcomes: 30-day mortality in hospital (if admitted), length of stay (if admitted), same-cause readmissions (number of episodes and time between readmissions), 30-day mortality (out-of-hospital), and probability of leaving the ED before a decision on admission, treatment, or discharge. We will analyse separately each waiting time metric. The outputs of this analysis will show whether, and by how much, an increase in waiting time leads to a poorer health outcome, for each specific waiting time indicator and for each of the selected health conditions. Further, we will run separate focused analyses for the selected conditions of heart failure, COPD and asthma.

To answer both RQ1 and RQ2, we will estimate multivariable fixed effects regression models, controlling for patient and hospital characteristics and severity of condition (which we explain in further detail below). This methodology will control for hospital, catchment area, patient demographic and health characteristics and differences that could contribute to determining both waiting times and health outcomes.

We will conduct multiple sensitivity analyses to check for the robustness of the results, such as adding regressors one by one, performing multiple hypothesis testing, comparing the results obtained by excluding/including variables with numerous missing values, and running separate regressions on sites that are in the top percentiles of non-missing data entries, to compare them with the overall results and interpret our findings.

We will also account for differences related with the COVID-19 pandemic outbreak and its different phases by separating and repeating the analysis for different calendar years/quarters.

Following established best practise we will address limitations in the ECDS by:

- performing analyses on the balanced sample of hospitals that provide higher quality ECDS data (using official scores - e.g., selecting top 50% of performers) as well as analyses on the whole sample of hospitals;
- using NHS England findings about data quality to identify hospitals with the best performance to weight hospital data based on their data quality scores;
- imputing data where possible (e.g., demographics and comorbidities based on past attendance data), controlling for missing information, and analysing systematic correlations between missing data and hospital/patient factors.

Our analyses will have potential to inform the data collected in future iterations of the ECDS.

Furthermore, to consider the limitation in ECDS data we propose to examine also the National Early Warning Scores (NEWS2) as an indicator of acuity of the patient's condition: we regard acuity as an important potential confounder, which could be challenging to address. Dr Ben Bloom, co-lead for ECDS,

advised us about the inclusion of NEWS2 scores in the ECDS for some hospitals. We understand that 26 hospitals currently include in their ECDS data National Early Warning Scores (NEWS2) in their ECDS data for older people and for people arriving by ambulance. The NEWS2, which has been endorsed by NHS England, is based on a simple aggregate scoring system in which a score is allocated to physiological measurements. For those hospitals which include NEWS-2 scores in their ECDS data for older people and for people arriving by ambulance, we will include NEWS2 in our analyses as an additional indicator of acuity.

We plan to examine the relationship between time in the ED and the socioeconomic characteristics of the area of residence controlling for patient age, mode of arrival, decision to admit and NEWS2 score as an indicator of acuity and/or the acuity variable in the ECDS. The objective will be to understand and compare the effect of controlling for different indicators of acuity – the NEWS-2 score and acuity indicator in the ECDS.

Addenbrooke's hospital has kindly offered us access to an anonymised form of its ED electronic health record data. These data include for each patient details of the patient's demographic characteristics, area of residence, mode and time of arrival at the ED, presenting condition, assessments, investigations, treatments, decision to admit, time in ED, and NEWS-2 score. We will separately analyse these data as well as ECDS data for Addenbrooke's.

7.1.4 Procedure for accounting for missing, unused and spurious data

Missing data will be handled differently depending on the variable type. The record of hospital attendances will be assumed to be complete. Missing socio-demographic characteristics, such as ethnicity, will be included as missing data categories in the modelling (unless the data are missing for just a few patients in which case those patients will be omitted from the analyses).

To minimise the amount of missing data we will extract the most recent recorded demographic and clinical data prior to the index date (date of entry into the cohort), with no other limitations on time frame.

7.1.5 Source Data

The following data will be obtained from NHS England and the Office of National Statistics (ONS):

i) The new Emergency Care Data Set (ECDS)
ii) Hospital Episode Statistics (HES) Inpatient and Outpatient datasets,
iii) HES Critical Care
iv) ONS Out-of-Hospital Mortality data (Secondary Cut).
v) Data from Addenbrookes Hospital.

7.2 Work Package 2

7.2.1 Methodology

We will conduct comparative case studies of diverse EDs to explore professional practices and organisational cultures in EDs that influence waiting times and examine if there are patterns of waiting

related to socioeconomic disadvantage. We will analyse similarities and differences across the cases and build on insights from previous studies to explore waiting and its relationship to health inequalities.

Case site Sampling

Sampling in qualitative research does not aim to be representative in a predictive statistical sense, but our sampling strategy will ensure variability and diversity across the cases, allowing transferability of our findings. We will purposively sample four English EDs. We will purposively select three Type 1 (consultant led 24-hour with resuscitation facilities) EDs that serve the most disadvantaged populations in England and one from an area in the least deprived Index of Multiple Deprivation (IMD) decile. Our choice of study sites is pragmatic and designed to capture rich data about waiting in EDs. At this stage, we have identified Blackpool Victoria Hospital, Colchester Hospital and the Royal London Whitechapel as three potential case sites that are located in areas with significant deprivation, different histories, geographies and population profiles (e.g. age and ethnicity). We can approach alternative sites with similar profiles if required. These EDs serve more deprived populations and also address the expectation that more health research should focus on areas of greatest health need (NIHR 2021). Comparative case studies often include a 'deviant' or 'atypical' case as this allows testing of emerging hypotheses/conceptual insights. This underpins our identification of a fourth site, the Royal Berkshire ED, which serves a more affluent area. Again, we can approach an alternative site with a similar profile if required.

7.2.2 Methods of Data Collection

7.2.2.1 Observation

In each ED, we will conduct non-participant observation and interviews and, where appropriate/possible, collect relevant documentation (e.g. triage and assessment guidance, blank/template forms) and/or take photographs of the layout of waiting / reception area (taking care not to capture any identifying details of individuals – in previous studies we have photographed these areas when they are empty or angled the shots so that faces are not visible) to augment these data. Handwritten notes will be made of the observations and these transcribed/digitised and de-identified by the researcher as soon as practically possible after the observation period.

Observations will include all areas of the ED (from waiting room to treatment areas) and may include informal conversations with staff, patients and accompanying adults where appropriate and only if this does not interfere in any way with patient care. We will conduct observations on different days of the week, times of day/night/year capturing approximately 160 hours per site. We will make a detailed description of each site, including activity flows, patterns in waiting etc, and from there build an understanding of practices and organisational cultures. The researcher will be experienced and trained to observe unobtrusively in ways that minimise disruption (this includes agreeing where the researcher will stand/sit to observe, being clear how requests for the researcher to leave will be made) and working in ways that maintain clinical and patient confidentiality.

As part of the observation we will shadow (follow)

- up to 15 key members of staff (including reception, triage nurses and emergency care doctors) in each site for all or part of a shift (1-12 hours), to better understand practices including assessment, care and treatment.

- the journeys of up to 20 patients or accompanying adults in each site from their arrival/initial assessment to admission or discharge to collect data about waiting times in different areas, interactions and decisions. Brief demographic data about patients will be collected with their permission during the shadowing.

Handwritten notes will be made of the shadowing and these transcribed/digitised and de-identified by the researcher as soon as practically possible after the shadowing period.

7.2.2.2 Interviews

We will interview 10 staff and 10 patients or accompanying adults in each site.

Staff interviews will include health care professionals at different grades/levels and non-clinical members of the ED team (e.g. reception staff). Staff interviews will explore the work undertaken to triage, prioritise and review the changing acuity in the waiting room, how this is communicated between staff and waiting patients or accompanying adults and views about waiting time management policies and how these are enacted. Brief information about the staff will be collected as for the shadowing described in 7.2.2.1.

Patient / accompanying adult interviews will explore experiences of waiting and views about triage processes. Accompanying adults will be asked about their own experiences of waiting in the ED (i.e. these will not be proxy interviews about the patient's views and experience, but will focus instead on their views and experience and no identifying information about accompanied patients will be collected). Brief demographic data about patients or accompanying adults will be collected at the end of the interview. The interviews may take place during waiting periods, without adding to wait times, and from experience patients are willing to use this time in this way. The researcher will ensure the clinical team are aware of their location so they do not miss their place in the queue.

Interviews will be in person or via telephone/secure video-conference facility. In person interviews will be conducted in a room that affords privacy (for example a private meeting room/office at the hospital). We anticipate these single episode interviews will be between 15-40 minutes.

Interviews will be digitally recorded with the Informed Consent of participants and transcribed verbatim by professional transcribers.

7.2.2.3 Within case site sampling

Sampling for patient/ accompanying adult interviews and shadowing of patients will be purposive to include people from vulnerable and disadvantaged groups. Where feasible with workload members of ED staff will be asked to invite patients or accompanying adults to participate in the shadowing/interview part of the study using a grid which reminds them that the researchers are especially interested in the views and experience of: people from an ethnic minority background; people who have recently moved or migrated to the UK; people with English as a second language and/or hearing or visual impairment; people living in more deprived (poorer) areas /postcodes; people who are (or appear to be) homeless; people with respiratory conditions especially COPD, asthma, or heart disease, especially heart failure, or presenting with mental health issue/s including those with alcohol/substance misuse problems, or people living with a long-term illness or disability or impairment. If a patient/accompanying adult expresses interest in participating the researcher can approach them with the patient information sheets and answer any questions they have about the study prior to recruitment. Where this is not feasible due to high

workloads of ED staff, the researcher will approach patients or accompanying adults to participate in the shadowing/interview part of the study.

7.2.3 Study Sequence and Duration

The data collection will be conducted over 18 months spending approximately 160 hours /1 month in each ED. This may be extended depending on COVID-19 restrictions or other NHS pressures.

15 staff in each ED will be shadowed for all or part of a shift (1-12 hours).

20 patients in each ED will be shadowed for all or part of the time they are in the ED.

10 patients/accompanying adults and 10 staff in each ED will be involved in a single interview of approximately 15-40 minutes duration.

7.2.4 CASE RECRUITMENT AND PARTICIPANT IDENTIFICATION

7.2.4.1 *Case site recruitment*

Recruitment of each ED site will be via direct approach by Lead Investigator (Pope) to an appropriate member of the Hospital senior management team. The study team will work with relevant Hospital personnel to obtain local R&D governance. Once this is confirmed, a lead senior ED contact will be identified as liaison, to facilitate access to staff teams in the ED (this is typically via introductory email followed by briefing at staff meetings).

7.2.4.2 *Participant recruitment*

Observations will take place in reception, waiting room and treatment areas of the ED. The observations themselves will be unobtrusive, designed not to alter or delay patient care or disrupt practice. Posters will be used to alert those present to the presence of the researcher. Posters also explain that patients, the public and staff can ask the researcher not to observe / to stop observing (at which point the researcher will move to another area. The researcher will make it clear to staff, patients and accompanying adults that they can decline to be observed at any time without giving a reason. Staff in ED will be regularly briefed that patients, the public and staff can ask the researcher not to observe / to stop observing.

Staff will be aware of the presence of the research team through staff bulletins and posters and Information leaflets will be provided in staff areas to notify staff about the study. The lead senior ED contact will inform staff about the study and advise when the researcher will be present, reminding them that they can decline to be observed, shadowed or interviewed (or withdraw at any point). Potential staff participants will be invited to take part in either the shadowing or interview by the researcher unless the lead senior ED contact indicates that they do not wish to be invited. Staff interviews will be conducted in working hours, any interviews that take place over breaks are optional. The researcher will only approach staff to invite them to participate in shadowing or an interview if this can be done without interrupting patient care.

Patients/accompanying adults will be invited to consider taking part in the shadowing or interview by reception staff who will provide a short invite to people identified as meeting criteria as specified at 7.2.2.3 ‘within case site sampling’ (above), or where this is not feasible due to a high workload for reception staff the approach may be made by the researcher after the patient/accompanying adult has registered with the ED reception staff and while they are waiting to be seen. The researcher will use a pre-prepared script

for this purpose. No personal identifiable information will be sought by the researcher prior to the researcher first approaching a patient or carer in the waiting area. Patient /accompanying adults who express an interest in participating through return of the invite to ED staff will be provided with the study information sheet. If they are approached directly by the researcher (using the pre-prepared script) they will be provided with the patient information. The researcher will talk through the patient information sheet (with the Easy Read version being used as necessary / if requested) and answer any questions they have about the study prior to seeking consent. After providing the written information and answering any immediate questions the researcher will then step away - being visible to but not within hearing distance of any conversation the patient/accompanying carer might have, and allow the potential participant approx. 20 minutes to make a decision. After this period the researcher may to make a second approach, again using guidance wording at which point the potential participant may express an interest in taking part or decline. The study design supports informal and opportunistic conversations and observations to gather information about reasons for non-participation (e.g. patients may explain that they feel they are in too much pain to participate but otherwise would have been willing to take part). The researcher will remind them that they can decline to be shadowed or interviewed (or withdraw at any point).

We will arrange text relay to support patients or accompanying adults who may have hearing impairments. To ensure non-English speakers are included we can offer the use of an established telephone translation service such as 'Language Line' for non-English speakers in interviews. It is already used by many NHS organisations.

For the patient or accompanying adult interviews we will ensure we are aware of any adaptations that might have to be made, examples of this might include (but not be limited to): Ensuring the interview takes place in a quiet room with no interruptions; Arranging the duration of the interview to suit the participant; Making sure the venue (if applicable) is accessible to the participant. Our PPI contributors will work with us to identify possible adaptations that may be necessary.

7.2.4.3 *Inclusion Criteria*

Staff

- Participant involved in registration, triage, assessment and treatment of patients attending one of the participating ED sites.
- Participant is willing and able to give informed consent for participation in the study.
- Participant is aged 18 or over.

Patients or accompanying adults

- Participant is attending one of the participating ED sites.
- Participant is willing and able to give informed consent for participation in the study.
- Participant is aged 18 or over.

Members of ED staff and/or the researcher will be asked to invite patients or accompanying adults to participate in the shadowing/interview part of the study. ED staff will be provided with a grid which reminds them that the researchers are especially interested in the views and experience of:

- people from an ethnic minority background;
- people who have recently moved or migrated to the UK;

- people with English as a second language and/or hearing or visual impairment;
- people living in more deprived (poorer) areas /postcodes;
- people who are (or appear to be) homeless;
- people with respiratory conditions especially COPD, asthma, or heart disease, especially heart failure, or presenting with mental health issue/s including those with alcohol/substance misuse problems, or people living with a long-term illness or disability or impairment.

7.2.4.4 Exclusion criteria

- All 'blue light' (ambulance emergency and resuscitation) and urgently triaged patients will be excluded from the study.
- Staff, patients, accompanying adults may request not to be included in the observation and/or shadowing and/or interviews and will be excluded.
- Staff, patients, accompanying adults who are not willing or able to give informed consent for participation in the study will be excluded.

7.2.4.5 Informed Consent

Interview and shadowing participants will be provided with the relevant participant information sheet and asked to read this and the associated consent form (the researcher may read the consent form in full if requested by the participant). The participant information sheet will detail no less than: the exact nature of the study; what it will involve for the participant; and any risks involved in taking part. It will be clearly stated that the participant is free to decline participation or withdraw from the study at any time without any impact on their care or activities in the ED, without affecting their legal rights, and with no obligation to give the reason for withdrawal. The participant (all types) will be allowed as much time as wished to consider the information, and given the opportunity to question the researcher, another member of ED staff or other independent parties to decide whether they will participate in the study. For all participants, written Informed Consent will be obtained by means of participant-dated signature and dated signature of the person who presented and obtained the Informed Consent. A copy of the signed consent form will be given (or sent by University of Oxford approved secure file transfer if consented remotely) to participants for their records. The original signed form will be retained at the University of Oxford.

Where interview participants (all types) wish to be interviewed after a site visit by the researcher we will offer the facility to be interviewed remotely. Remote Informed Consent will be obtained by means of the researcher reading the Informed Remote Consent form to the participant, and on confirmation of each statement, the researcher will initial the consent form on the participant's behalf, and add a dated signature. Where patients or accompanying adult interviews take place in the ED the researcher will ensure the clinical team are aware of their location so they do not miss their place in the queue.

It is not possible to obtain written consent from every person in the ED site during the period of observation as some people will lack capacity, be in severe distress or pain, need immediate medical care, and others will enter only briefly, and numbers of people present varies considerably at different times of day. Posters and information in the ED, and posted on the NHS organisation website/social media site about the study will notify ED visitors about the research activity and inform them that they may opt out by informing a member or staff or the researcher. The researcher will wear a University of Oxford identification badge and other identification as requested by the site (some EDs provide scrubs with observer printed on them for example). The researcher will not record personal, patient identifiable data

from these observations. However during observation the researcher may have incidental access to confidential patient data without consent (e.g. patients are often asked their name and date of birth in the semi-public area of the reception, or staff may call out patients names to invite them to a treatment area and these details can be overheard by those present). The researcher will not record any of these identifying data. Staff will be asked to ensure where possible that confidential details are not discussed in the presence of the researcher.

7.2.4.6 Screening and Eligibility Assessment

Interview and shadowing participants must satisfy all the approved inclusion and exclusion criteria before being invited to participate and sign an Informed Consent form for the study.

7.2.4.7 Subsequent Visits

Staff, patients and accompanying adults and staff who are interviewed or shadowed will only take part in one episode of this activity, but they may be present in the ED at subsequent site visits by the researcher (they will not be invited to take part in interview or shadowing more than once).

7.2.4.8 Withdrawal of Participants from Study

If a member of staff, patient or accompanying adult expresses a wish not to be observed this will be respected and the researcher will stop observing and leave the area.

Participants (all types) will be free to terminate a scheduled interview or the interview itself or shadowing activity at any point. Once they have participated in the interview or shadowing they will have two weeks to withdraw from the study should they wish to; this will be made clear at the point of recruitment and at the end of the interview/shadowing. If the participant withdraws from the study within two weeks, their data (personal data, interview data (including transcripts and recordings)) will be securely destroyed. After two weeks, participant de-identified data will be incorporated into the body of the analyses but illustrative quotes will not be used in any outputs.

7.2.4.9 *Definition of End of Study*

The end of the study is the point at which the final report is submitted to the funder.

7.2.5 Analysis

Data analysis will commence alongside data collection supported by regular team meetings during the fieldwork period. Researchers will produce de-identified summaries of contextual information. Analysis of de-identified interview data and observation notes will include initial independent open coding and research team discussion to refine codes and develop themes. Qualitative data analysis software (NVivo) will be employed to help manage data and generate reports containing all the relevant de-identified data across cases/themes. We may also use the 'One sheet of paper' (OSOP) mapping method of analysis, and matrix/charting techniques, and text summaries to identify emerging lines of argument and support constant comparison and discussion about outliers and negative cases.

7.3 Work Package 3

7.3.1 Methodology

We will look at the findings from WP1 and WP2 to explore reasons for differences in waiting times and health outcomes. Paired analyst teams (one qualitative and one quantitative researcher) will draft

summaries of the interim quantitative analyses and qualitative interpretations and discuss them before bringing these to a larger team meeting where side-by-side matrix displays will be used to aid data comparison and support analytic integration (Fetters et al 2013). These displays will help us to visualise and draw out new insights within and across cases, for example, displaying the qualitatively derived themes from our interviews and observations and interrogating the quantitative data that explains or is explained by these insights. The intent is not to create a convergent analysis, but to build a comprehensive understanding of ED waiting and its relationship to health inequalities, and to provide the basis for interpretation and explanation. We will however note and examine convergence and dissonance between the findings and interpretations offered by the two WPs. We expect that it will be possible to add a theoretical or conceptual lens to the integrative analysis but rather than deductively imposing these, we will use the analyses and our knowledge of the literature inductively to inform this process. For example, the classic work by Jeffrey (1979) identifying good and bad patients in the ED, which uses the concept of stereotyping to explain staff behaviours, may be enrolled to aid interpretations. Summary analysis displays will be shared at full team meetings and with PPI members for scrutiny, discussion and further development and will be used to bring the findings together to support overarching conclusions and recommendations. Our outputs will include reporting of the process of integrating the findings as well as examples of these summary displays.

As part of WP3, we will hold meetings every three months with representatives of WP1 and WP2 so that knowledge can be shared across the two work packages.

8. DATA MANAGEMENT

8.1 Access to Data

Oxford University will be the data controller and will be liable for the secure management of the data it generates. Direct access will be granted to authorised representatives from the Sponsor or host institution for monitoring and/or audit of the study to ensure compliance with regulations. De-identified data (e.g. transcripts, summaries of codes, categories and themes, de-identified quotes and notes) will be shared with the SSC (Study Steering Committee) for quality control purposes. Aggregate de-identified data and summaries will be shared with the study patient and public involvement representatives.

8.2 Data Recording and Record Keeping

No clinical data from patient records will be collected for this study. Digital data (e.g. interview audio recordings, case study documents, field notes, electronic consent forms and electronic scans of paper versions) will be transferred to password protected storage on University of Oxford computers/servers as soon as possible after collection and deleted from portable devices. Interview audio recordings will be given a unique identifier, encrypted and password protected before being sent securely (via a University owned file transfer interface requiring authentication) to approved transcribers at the University of Oxford, who have confidentiality and data protection contracts and a completed third party security assessment in place. Transcripts will be returned the same way. Transcribers will delete audio files and transcripts from their encrypted computer following completion of transcription. Interviews will be transcribed verbatim and de-identified at the earliest opportunity by the researcher. De-identified data

will be stored in computer files on partitioned, password protected University servers. Paper consent forms will be stored in locked filing cabinets at the Nuffield Department of Primary Care Health Sciences, University of Oxford. Contact details will be stored in separate password protected folders and the ID numbers/identifier key in a separate password-protected sub-folder only accessible to members of the study team. Qualitative data analysis software (NVivo) will be employed to manage data and generate 'reports' containing all the relevant data across cases/themes. Audio files will be deleted at the end of the study. De-identified research data will be shared between members of the study team (co-investigators and researchers who report to them, including those yet to be appointed) by granting access to password protected storage on University of Oxford computers/servers or through using encryption and password protection as described above for data transfer to transcribers.

9. QUALITY ASSURANCE PROCEDURES

The study may be monitored, or audited in accordance with the current approved protocol, relevant regulations and standard operating procedures. For transparency, the study is registered reference number: researchregistry9149.

12.1 Steering Committee

An independent Steering Committee will provide robust, relevant and proportional oversight of the study on behalf of the Project's Sponsor (University of Oxford) and Funder (NIHR). It will meet five times during the study with extra ad hoc meetings scheduled if required. It will be chaired by Dan Lasserson, Professor of Acute Ambulatory Care at the University of Warwick, and will also include Adrian Boyle (Cambridge University Hospitals), Louella Vaughan (Nuffield Trust), representatives of the Royal College of Emergency Medicine, Royal College of Physicians, Medact, Asthma UK and British Lung Foundation. We will also invite an Integrated Care Systems Commissioner of Emergency Care Services to be a member.

10. ETHICAL AND REGULATORY CONSIDERATIONS

This is a low risk study involving ED staff, patients over 18 and accompanying adults.

The key ethical issues for this project relate to the conducting of observational data collection in the care setting. Observations will be unobtrusive and non-invasive and the focus is on processes and practices, not individual patients. The researcher will introduce themselves to staff members and patients/accompanying adults when appropriate to do so. Those present will have the right to decline to be observed with no negative consequences and will be informed of the observation and their right to decline via posters placed in the ED. Staff will be informed by the lead senior ED contact and information sheet. The researcher may have incidental access to (but will not record) confidential patient information without consent (for example at reception 'booking in', or when clinicians talk to or about a patient). It is not possible to obtain written consent from every person in the ED site during the period of observation as some people will lack capacity, be in severe distress or pain, need immediate medical care, and others will enter only briefly, and numbers of people present varies considerably at different times of day. In order to limit exposure to identifiable data the researcher will not observe computer screens where patient medical records are on show (consultation areas, reception, other areas). The researcher will not record any patient identifiers (e.g. name, address, NHS numbers) during these observations.

Voluntary participation will be emphasised throughout the study and the Patient or Accompanying adult Information Sheet will be in plain English with an Easy Read version as necessary. The research team will seek advice from local clinicians/managers or the Study Steering Committee as appropriate should issues arise.

There are no identified risks to participants.

Researchers will follow all local health and safety and risk management practices in place at the time of data collection, including undertaking COVID testing and use of personal protective equipment if required.

The relevant lone working procedures will be followed for researchers, including notification of location, start and end times of visits and reporting in.

Working with the clinical lead in each site, the researcher and wider research team will establish agreed protocols regarding the reporting and management of concerns and/or problems that may arise during fieldwork. With these supports in place, we aim to minimise and mitigate any problems that may arise in conducting research in the ED environment. Escalation pathways are clear (via Principal Investigator Catherine Pope, to the chair of the Study Steering Committee, and to the Sponsor at the University of Oxford). All investigators taking part in the study will have appropriate collaborator agreements with the sponsor (University of Oxford).

The quantitative elements of the study will use only pseudonymised HES data which has already been collected by the NHS and separate analysis of anonymised data from Addenbrookes. We have approval from the Addenbrookes Study Review Committee to access their data; and from the University of Oxford (Medical Sciences Interdivisional Research Ethics Committee (MS IDREC) Ethics Approval Reference: R82412/RE001) to access and process HES data. This will be accessed via ORCHID. We will abide by the DSAs under which we will receive the data and not publish anything that could lead to anyone being identified.

10.1 Declaration of Helsinki

The Chief Investigator will ensure that this study is conducted in accordance with the principles of the Declaration of Helsinki.

10.2 Approvals

The quantitative work in WP1 that is using HES data has been approved by the Medical Sciences Interdivisional Research Ethics Committee (MS IDREC) Ethics Approval Reference: R82412/RE001.

The work using Addenbrookes data has been approved by their Study Review Committee.

Following Sponsor approval, the protocol, Informed Consent forms, Participant Information Sheets, observation poster and interview guides for WP2, have been approved by Research Ethics Committee (REC) (Essex), HRA (reference number 23/EE/0202), and host institution(s).

As with all qualitative research, there is some flexibility in the research design to allow the objectives to be met. Significant changes to the design or conduct of the study will be discussed with the Study Steering

Committee and the Funder, and when necessary the Chief Investigator will seek approval for amendments to the study documents from the Sponsor and REC. All correspondence with the REC will be retained.

10.3 Other Ethical Considerations

The researchers have undertaken Good Clinical Practice training and will comply with research best practice and local policies regarding risk management and safeguarding. The Lead Investigator (Pope) for the qualitative work (WP2) is a member of the British Sociological Association (BSA) and follows ethical principles in the BSA Statement of Ethical Practice. The team will be sensitive to the fact that individuals are attending ED feeling unwell and may be distressed; Pope has led and conducted ethnographic studies in similar settings (including on ED attendances NIHR CLAHRC Wessex IRAS ID: 239514; ambulance handovers PB-PG-0407-13084 and urgent care centres NIHR HSDR 10/1008/10).

10.4 Reporting

The Chief Investigator (Nicodemo) shall submit once a year throughout the study, or on request, an Annual Progress report to the REC Committee, HRA (where required), host organisation and Sponsor. In addition, an End of Study notification and final report will be submitted to the same parties.

10.5 Participant Confidentiality

All investigators, research staff, PPI and steering group members will comply with the requirements of the Data Protection Act 2018 and UK General Data Protection Regulation (GDPR) 2016/679 with regards to the collection, storage, processing and disclosure of data including any personal information. The Chief Investigator (Nicodemo) is the data custodian. University of Oxford is the data controller. The processing of the personal data of participants will be minimised by making use of a unique participant study number only on all study documents and any electronic database. All documents will be stored securely and only accessible by study staff, authorised personnel and responsible members of the University of Oxford for monitoring and/or audit of the study to ensure that the research is complying with applicable regulations. All personnel will safeguard the privacy of participants' personal data.

10.6 Expenses and Benefits

Patient/carer participants in the qualitative study will be given a £20 shopping voucher as a thank you for their time. EDs will receive an administration payment to cover the cost of ED staff time in interviews and for screening and identifying the patient participants. There are no direct benefits to participants, but knowledge gathered will inform policy and practice for future staff, professionals and service users. Sites participating in case studies will receive feedback which may be beneficial to service planning and decision making.

11. FINANCE AND INSURANCE

11.1 Funding

This study is funded by the National Institute for Health and Care Research Health and Social Care Delivery Research (NIHR154061).

11.2 Insurance

The University has a specialist insurance policy in place which would operate in the event of any participant suffering harm as a result of their involvement in the research (Newline Underwriting Management Ltd, at Lloyd's of London).

11.3 Contractual arrangements

Appropriate contractual arrangements will be put in place with all third parties.

12. PUBLICATION POLICY

We will integrate the findings from the Quantitative Study statistical analyses and the Qualitative Study to examine the relationship between inequalities and ED waits and explore the impact of waiting on patients' health. We will hold a workshop to disseminate findings with stakeholders, key audiences and patients/the public, offer seminars to policy and professional groups, submit papers to leading academic journals and present at conferences. We will use our links, and those of our advisers, with PPI networks, Royal Colleges, NHS and voluntary organisations and the Department of Health and Social Care to promote the impact of this study.

Study patient/accompanying adult participants will be asked if they wish to receive a lay summary of the findings. If they agree to this, this will be sent using either post or email, depending on their preference. Additionally, a study website will be set up to share the findings with the participating EDs (staff participants) and their wider patient population.

We will also produce a final report for the NIHR and provide regular updates via a dedicated project website hosted at the Nuffield Department of Primary Care Health Sciences, University of Oxford. The address of this website is: https://www.phc.ox.ac.uk/research/health-economics-research/ED-WAITS. The website will also provide links to project resources and outputs.

The anonymised case study summaries will be available as a resource for EDs and may be archived to provide qualitative data for future training and education for researchers and clinicians about ethnography and qualitative methods.

The Investigators and wider study team will be involved in reviewing drafts of the manuscripts, abstracts, press releases and any other publications arising from the study. Authors will acknowledge that the study was funded by NIHR HS&DR. Authorship will be determined in accordance with the ICMJE guidelines and other contributors will be acknowledged.

13. DEVELOPMENT OF A NEW PRODUCT/ PROCESS OR THE GENERATION OF INTELLECTUAL PROPERTY

Ownership of Intellectual Property generated by employees of the University of Oxford vests in the University. The University will ensure appropriate arrangements are in place as regards any new Intellectual Property arising from the study.

14. ARCHIVING

The interview transcripts, consent forms, field notes, and documents related to the analyses and research team meetings will be archived securely as password protected files in secure folders in the Nuffield Department of Primary Care Health Sciences University of Oxford for 10 years after completion of the study in accordance with University of Oxford policy. These will be accessible only to the study research team (co-investigators and staff line managed by them including those yet to be appointed) and other authorised personnel. After the 10-year retention period all research data (including consent forms) will be securely destroyed using the appropriate procedure advised at that time by the University of Oxford research data team. Contact details will be kept for 1 year after the end of the study to enable the circulation of summary findings to participants, and other related outputs which they may find of interest, after which they will be destroyed.

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APPENDIX A: AMENDMENT HISTORY

Amendment No.	Protocol Version No.	Date issued	Author(s) of changes	Details of Changes made
1	1.3	1/12/23	Stuart Redding	Minor changes to some text for clarification
2	1.3	1/12/23	Stuart Redding	Addition of reference numbers for approvals granted
SA 1	1.4	6/12/23	Stuart Redding	Addition of material covering WP1 and WP3
MA01	1.5	21/05/24	Vanessa Eade	Minor change to where consent forms are stored
MA02	1.6	09/04/24	Stuart Redding	Removal of exclusion criteria of 'pregnant women seeking to give birth' from secondary analysis WP1
SA 2	1.7		Vanessa Eade	Change to method of approach to potential participants in ED

List details of all protocol amendments here whenever a new version of the protocol is produced.

Protocol amendments must be submitted to the Sponsor for approval prior to submission to the REC committee, and HRA (where required).