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**Pre-alerts v 1.3**

# Exploring the use of pre-hospital pre-alerts and their impact on patients, ambulance service and Emergency Department staff

**RESEARCH PROTOCOL**
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**This protocol has regard for the HRA guidance.**

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**Impact of pre-alerts on patients, ambulance service and ED staff**

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# Summary of research

Research Question

How are out of hospital pre-alert decisions made and communicated and what is the impact of these pre-alerts on receiving EDs and patients?

Background

Ambulance Clinicians use pre-alert calls to inform receiving Emergency Departments (EDs) of the arrival of a critically unwell or rapidly deteriorating patient who they believe requires senior clinical review and time-critical treatment immediately upon arrival. By enabling EDs to prepare for the patient's arrival, pre-alerts can lead to earlier initiation of time-critical treatment, improved processes and better clinical outcomes for patients (James et al, 2019, Kelleher et al, 2014). However, over- or inappropriate use of pre-alerts can lead to EDs diverting resources from other critically ill ED patients, which has important risks for patient safety. There is currently a lack of evidence about the impact of pre-alerts on patients, ED staff or ambulance clinicians. In particular, there is limited guidance about how pre-alerts should be undertaken, delivered and communicated with EDs, in order to optimise their use for patient benefit.

Aims and objectives

This study aims to understand how pre-alert decisions are made and implemented by pre-hospital staff, and the impact of these on receiving EDs and patients, in order to identify principles of good practice, areas of uncertainty and areas for improvement.

Objectives:

1. To map current pre-alert practice in terms of volume and types of pre-alerts and explore potential reasons for variation in practice by reviewing existing Ambulance Service patient records and mapping to local guidance. (WP1)
2. To explore and understand pre-alert decision-making by undertaking semi-structured interviews with Ambulance Clinicians from three Ambulance Services and a national survey of Ambulance Clinicians to identify key areas of uncertainty where further guidance would be useful. (WP2)
3. To identify how pre-alert decisions are communicated, and what information needs to be communicated in order to improve patient care, by interviewing pre-hospital and ED staff. (WP2 & 3)
4. To understand how pre-alerts influence patient care in the ED, including potential benefits and unintended consequences, by observing pre-alert processes and responses to them within two EDs in each of 3 Ambulance Service areas/regions. (WP3)
5. To explore whether there are specific conditions or patient groups for whom pre-alerts are most likely to lead to action, or for whom action is unlikely to provide benefit, and explore factors that affect whether action is taken within the ED. (WP3)
6. To understand service user experience of pre-alerts by interviewing patients and/or carers. (WP4)
7. To identify good pre-alert practice, areas where further guidance is needed and co-produce information to inform the development of pre-alert guidance with research participants and other key stakeholders. (WP5)

Methods

We will undertake a mixed methods study with five inter-related work packages. We will map current existing policies and guidance from ambulance services to identify areas where guidance is unclear or inconsistent. We will analyse 12 months' ambulance routine data to understand how pre-alerts are currently being used and to identify any factors that may explain variation in pre-alert use. We will explore how ambulance clinicians undertake pre-alerts by undertaking semi-structured interviews with up to 36 ambulance clinicians followed by a national survey of ambulance clinicians. This will help us to understand how pre-alerts are made, factors affecting decision-making and how they are communicated to ED, and clinician experience of undertaking pre-alerts. We will explore the impact of pre-alerts on the ED by undertaking observation of pre-alert calls and the ED response within 6 EDs, and use semi-structured interviews with ED staff to understand the impact of these calls on ED staff. We will also undertake interviews with patients and their carers to understand the impact of pre-alerts on patients. Finally, we will co-produce recommendations for improving pre-alert practice through a national feedback workshop including ED and ambulance staff and stakeholders and PPI.

Timelines for delivery

The project will take place over 29 months, including 5 months for project set up and NHS ethics and research governance approval. WP1: Mapping existing guidance and describing current pre-alert practice using routine data analysis will take place in months 6-13. WP2 (exploring how Ambulance Clinicians undertake pre-alerts), WP3 (understanding the impact of pre-alerts on the ED) and WP4 (understanding the patient perspective of pre-alerts) will take place concurrently in months 12-23). Data Analysis and integration of WPs 1-4 will take place from months 21-27, with WP5 (co-production of guidance) and dissemination of findings months 27-29.

Anticipated impact and dissemination

We anticipate that the project will deliver pragmatic recommendations developed by ambulance and ED staff, incorporating views of the public and patients, to support effective delivery and receipt of pre-alerts. We will share our findings with key professional organisations who are involved in developing guidance on the use of pre-alerts, and work to enable inclusion of pre-alert practice recommendations in training programmes for staff in the urgent and emergency care system. We will disseminate via academic conferences and open access journals, and disseminate professional and plain language summaries to professional organisations to enable them to make an evidence-based case for improvement to current practice.

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# Lay summary

When a patient is seriously ill, ambulance staff may call the Emergency Department (ED) to let them know the patient is on their way. This is known as a 'pre-alert' and can help the ED to free up a trolley space or bed and get specialist staff ready to treat the patient as soon as they arrive. If used correctly, pre-alerts can help to provide better care, earlier access to time-critical treatment and improved outcomes for patients. However, if pre-alerts are used for the wrong patients, or used too often, then the ED staff may not be able to respond properly and may stop taking them seriously.

When ED staff prepare for a pre-alerted patient, they may have to move patients who are less seriously ill, and take staff away from other work. It is therefore important that pre-alerts are only used when absolutely necessary. There is some guidance telling ambulance staff who they should do pre-alerts for, and how this should be done. However, the guidance is not always clear and varies for each ambulance service. This creates a risk that ambulance staff may not pre-alert appropriate patients, or may pre-alert when it isn't necessary. This may cause difficulties for the ED and tensions between ambulance and ED staff. There are important risks for patient safety.

Although pre-alerts are being used more often, little is known about how they are used, who they are used for or how the EDs respond to them. Given how important pre-alerts are for patient safety it is important that we understand the impact of pre-alerts on patients, ambulance staff and ED staff.

We propose to do some research to understand how pre-alerts take place at the moment and how this varies between ambulance services and between different types of ambulance staff. We will try to identify how the processes of doing pre-alerts can be improved and identify areas of good practice. We will do this within 5 separate research activities. We will involve patients and the public in designing and carrying out this research.

1. We will look at existing ambulance service policies and data to understand how pre-alerts are currently being done, and what may be causing variation.

2. We will talk to ambulance staff to understand how they decide to make pre-alert calls and which patients are difficult to decide whether to pre-alert. We will also ask what information they give to the Emergency Department staff, and how they expect Emergency Department staff to respond. We will explore findings from these interviews in a survey of all ambulance staff in 3 ambulance services to identify areas where they need improved guidance.

3. We will talk to staff in Emergency Departments and watch them taking pre-alert calls. This will help us to understand how they use the information given in a pre-alert to change what they do, and to understand what makes a useful pre-alert.

4. We will talk to patients and their friends and family to find out what they understand about pre-alerts, what they are told about pre-alerts and whether this changes their expectations once they arrive in hospital.

5. We will discuss the findings from this research in a national workshop with key people, including patients and the public, to identify how pre-alerts can be improved. We will produce short, written guidance to ambulance and Emergency Department staff about how they should manage pre-alerts in future. We will identify key areas of uncertainty that should be addressed within future national guidance.

# 1. Background

## 1.1 What is the problem being addressed?

Ambulance Clinicians use pre-alert calls to inform receiving Emergency Departments (EDs) of the arrival of a critically unwell or rapidly deteriorating patient who they believe requires senior clinical review and time-critical treatment immediately upon arrival. This enables the receiving ED to make preparations such as calling staff from other areas of the hospital (e.g. trauma team, anaesthetist) or from home, preparing specialist equipment and freeing a bed within the resuscitation area (Harrison & Cooke, 1999). It also prioritises the pre-alerted patient and ambulance, so they do not wait in a queue. Pre-alerts can lead to earlier initiation of time-critical treatment, improved processes and better clinical outcomes for patients (James et al, 2019, Kelleher et al, 2014). In England, 5 million patients were conveyed to the ED by ambulance in 2018/19 and pre-alerts undertaken in an estimated 10-15% of conveyances (Yorkshire Ambulance Service 2020, NHS England 2018) Pre-alerts are increasingly being recognised as standard practice for Ambulance Clinicians and a wider range of conditions pre-alerted.

In the context of increased demand for emergency care services, with consequent ED overcrowding and increased ambulance handover times, (Hawarth & McLelland 2019) pre-alerts are key to ensuring patients can bypass queues and be seen immediately by the most appropriate care team. It is vital that appropriate patients are identified for pre-alert and relevant information is communicated efficiently to the receiving ED to ensure optimum patient care and resource use. However, over-use of pre-alerts and an increase in perceived inappropriate or unclear pre-alerts may result in staff frustration, lack of trust and reduced ED response to pre-alerts (pre-alert fatigue). There are clear patient safety risks when pre-alerts are not acted upon, but also when EDs act upon unnecessary pre-alerts and potentially divert attention and resources from other critically ill patients in the ED. Where miscommunications occur and expectations are not met by either ambulance or ED clinicians there may be risk of deteriorating relationships, incivility and potential for patient harm (Credland 2019, Porath & Pearson 2013).

There is currently a lack of evidence on how pre-alerts should be undertaken. In 2019, the Healthcare Safety Investigation Bureau (HSIB) Report on transfer of critically ill patients highlighted the lack of consistency in guidelines on the transfer of critically ill patients. Specifically, the Report recommended: “The Association of Ambulance Chief Executives should work with partners to define best practice standards for the criteria, format, delivery and receipt of ambulance service pre-alerts.” In response to this, the Ambulance Lead Paramedic Group (ALPG) under the National Ambulance Service Medical Directors Group (NASMeD) were tasked with drawing up guidelines for Ambulance Clinicians, but noted the lack of evidence on the subject. (HSIB 2019). The group (including MM as a co-applicant in this project) are seeking to address this absence of evidence to improve the value and utility of the guidance for future benefit of patients and integrated emergency service delivery

We aim to undertake a mixed-methods research study to understand the processes underpinning pre-alert decisions and how these are communicated and acted upon within EDs. This research is problem-driven and addresses an expressed need for research highlighted by both Ambulance Service staff and EDs. We have obtained letters of support from Dr Julian Mark (Chair of National Ambulance Service Medical Directors Group, Executive Medical Director, Yorkshire Ambulance Service), Dr Alison Walker (Medical Director for West Midlands Ambulance Service, Consultant in Emergency Medicine with a special interest in EMS, member of Joint Royal College Ambulance Liaison Committee (JRCALC) and Trauma and Emergency Speciality Lead, Yorkshire and Humber

NIHR Clinical Research Network) and Dr Matthew Inada-Kim (National Clinical Lead - Deterioration at NHS Improvement, National Clinical Advisor- Sepsis, NHS England and Health Education England).

## 1.2 Review of existing evidence: how does the existing literature support this proposal?

We undertook a scoping literature review of Medline, Embase, Cinahl and Google Scholar to identify literature from inception to July 2020 relating to the use of pre-hospital pre-alerts. We searched for derivations of the following terms: pre-alert$, alert notification, pre-arrival notification, pre-notification, prehospital/pre-hospital notification, (blue calls / red alert combined with pre-hospital). We also searched reference lists and citing articles for literature identified. This literature review highlighted evidence of clinical benefits of appropriate pre-alerts but a lack of research into how they are used, or into potential negative consequences of acting upon unnecessary pre-alerts.

### 1.2.1 Important role of pre-alerts in patient safety.

We identified evidence that pre-alerts have an important role in patient safety, with evidence of clinical benefit identified for three patient groups (stroke, trauma, sepsis). The use of pre-alerts in suspected stroke patients is associated with significantly shorter times to CT scan upon arrival in the ED, shorter door-to-needle times and increased likelihood of receiving thrombolysis within 3 hours of onset (Lin et al 2012, Sheppard et al 2015, Abdullah et al 2008, Patel et al.). For trauma patients, pre-alerts enabled the receiving ED to mobilise the trauma team and longer pre-arrival notification time was associated with improved completion of pre-arrival tasks and overall resuscitation performance (Ahmed et al, 2019) (Handolin et al. 2008). Hunter et al. (2019) identified that sepsis patients who had been pre-alerted had lower time to intravenous fluid administration, blood tests and administration of antibiotics (p<001). Studies identified that use of pre-alerts was associated with improved adherence to sepsis protocols, decreased time to antibiotic administration and reduced admissions to intensive care for patients with suspected sepsis (Kim et al 2008, Hunter et al 2019). Based on evidence of benefit from pre-alerts, guidelines for major trauma, sepsis and cardiac arrest all recommend pre-alerting (NICE 2017, NICE 2016, Resuscitation Council 2015).

We also identified an important body of research pertaining to patient safety in patient handover and communication between pre-hospital and ED care. Whilst focussing on the wider patient handovers and communication rather than focussing on the pre-alert, these studies highlight the important function of the pre-alert in patient safety (e.g. Sujan et al. 2014, Slope et al.). Sujan et al. identified risks associated with 270 different patient handovers, and recognised pre-alert as an important failure point in their study of clinical handover within the emergency care pathway and potential risks of clinical handover failure. In particular, they identified the pre-alert as the first step within handover and an important anticipatory function to allow EDs to prepare. We would build upon the findings from previous research on patient handover and communication, to focus on the pre-alert itself, the decision-making process related to the pre-alert, how these pre-alerts are communicated and in particular the ED response.

Increasing awareness of the critical nature of pre-alerts, along with increasing litigation risk for ambulance clinicians who do not pre-alert when needed (see for example HCPTS 2019, 2020), is likely to decrease the threshold for undertaking pre-alerts, increase the number of pre-alerts being undertaken and therefore increase the risk of inappropriate pre-alerts. The role of the pre-alert is to prioritise the patient, so we would expect the pre-alerted patient to benefit. However, this will conversely negatively impact on the care of other patients (and the ambulance queue) as staff and

space will be diverted to the pre-alerted patient. The more widely pre-alerts are advocated as a way of improving care, the less they achieve in terms of prioritising and the high potential for harm they cause through over-use.

### 1.2.2 Impact of inappropriate or over-use of pre-alerts. (IMPACT ON ED)

ED crowding and prolonged waiting times are associated with worse patient outcomes, including increased mortality (Rasouli et al 2019). Sujan et al. (2014) identified that the threshold for making pre-alerts may vary depending on how busy the ambulance clinicians believe the ED might be and that ED overcrowding and queues may lead to increase in use of pre-alerts, which may then lead to resources being diverted away from where they are needed. This takes resources away from patients who are more likely to benefit from prioritisation, disrupts ED processes, generally slows patient flow and increases waiting times.

Resuscitation bays in the ED are required to deliver urgent, high-intensity care but are a very limited resource. Resuscitation bays can easily be filled if pre-alerted patients are inappropriately allocated to them, thus preventing their use for other patients in greater need. In the UK, ED crowding is increasing and EDs are frequently operating at (or over) capacity (RCEM 2020), so relatively small numbers of inappropriate pre-alerts can be profoundly disruptive.

ED crowding can lead to ambulances queuing outside the ED, which can in turn lead to pre-alerts being used to bypass the queue. NHS Improvement, investigating ambulance handover delays, recommended that ED staff should assess the pre-alert information provided by paramedics so they can anticipate resource utilisation. (NHSI) When this assessment is undertaken based upon inaccurate or incomplete information during the pre-alert call, this may lead to patient risk, both for those being pre-alerted and triaged remotely by ED staff, and for those already in the ED or ambulance queue whose care may be delayed as a result. Hence the greater the strain on the emergency care system, the more important it becomes that pre-alerts are delivered, received and acted upon appropriately.

Other studies recognise the need to avoid inappropriate pre-alerting due to the potential negative consequences involved in unnecessary responses, and the challenges involved in knowing how to respond to pre-alert calls (Harrison & Cooke 1999, Sheppard et al 2016, Crystal, Bleetman & Steyn 2004, Brown & McLeod 2018). NICE guidelines for trauma recognised the risk of deploying staff for a trauma call but then not being needed could take away resources from other clinical areas and patients (NICE 2016), but identified no evidence to quantify this. Similarly, in the USA, National Association of State EMS Officials (NASEMSO) guidelines recognise the need for balance in pre-hospital notifications to maximise patient benefit but not incur costs. (NASEMSO 2018)

However, although these potential harms are well-recognised, we have identified limited research quantifying these harms and exploring how EDs respond to pre-alerts. The ongoing PHEWS (Pre-Hospital Early Warning scores) study (led by SG, Co-App) is modelling the impact of pre-alerts specifically for sepsis, modelling problems caused by misuse of pre-alerts in terms of: (1) Delayed treatment due to prioritisation behind pre-alerted patients, (2) Reduced resuscitation room access due to over-use by pre-alerted patients, (3) Reduced ED flow and prolonged waiting times incurred by managing pre-alters, and (4) Impact on clinical decision-maker workload (Goodacre et al 2019). However, this study relies on modelling, relating to a single condition. The modelling will provide insights into how pre-alerts for a specific condition could theoretically influence ED performance. This current proposal will provide insights into how ambulance and ED staff use pre-alerts in practice, and thus how the impacts identified in the modelling could be mitigated or exacerbated.

### 1.2.3 Pre-alert fatigue and incivility

Another risk associated with the inappropriate or over-use of pre-alerts is that of 'pre-alert fatigue'. This has an important immediate patient safety risk due to ED staff potentially not responding to a pre-alert. Carberry et al. identified that one of the challenges to the use of pre-alerts for sepsis is the danger of 'alert fatigue' due to the volume of pre-alerts EDs receive for other conditions (e.g. stroke, MI), leading to desensitisation. In the USA, NASEMSO (The National Association of State EMS Officials) guidelines highlight different pre-alerting practice between urban, suburban and rural settings, stating that large EDs are less likely to value pre-alerts due to the volume of EMS, and the "misconception of the value in receiving the information". At a recent Royal College of Emergency Medicine scientific conference (2019), it was stated that ED staff are less likely to respond to a pre-alert than 3 years previously (MM, personal communication)

Pre-alert fatigue may also create wider problems, including lack of trust in pre-alert calls and frustration over perceived lack of action from ED staff, leading to breakdown in Ambulance Clinician and ED staff relationships and the potential for increased incivility. Incivility can lead to increased stress, decreased work performance and may impact directly on service users (Porath 2013). Again, we identified limited evidence to support anecdotal accounts of pre-alert fatigue or the frustrations and difficulties generated by their inappropriate use or poor communication. Sheppard et al. identified disparities in how Ambulance Clinicians and receiving ED staff interpreted pre-alert protocols for suspected stroke, with Ambulance Clinicians frustrated by a lack of response by the receiving ED and disagreements over the appropriate course of action at handover (Sheppard et al 2016).

### 1.2.4 Need for guidance in how pre-alerts should be communicated.

In the current climate of increasing pressures for both ED and ambulance staff, the impact of making wrong decisions may be exacerbated, and it is important that ED and ambulance staff can share perspectives of which patients should be pre-alerted, and how this should be done, In particular, there is a need for guidance on how these should be communicated. For ED staff who are time-pressed, it is essential that information provided from the ambulance crew during the pre-alert is concise and complete. For ambulance staff experiencing unprecedented demands and increased autonomy within their roles, we need to understand where they need guidance and what may help them to make pre-alert decisions and communicate them effectively.

Poorly communicated pre-alerts or overly complex communication from the ambulance staff to the ED may result in the pre-alert not being acted upon appropriately. This may lead to patients whose care would be improved by having a pre-alert not receiving appropriate care. Sujan et al (2014) identified risks of providing unclear or inaccurate information within a pre-alert potentially leading to misinterpretation and lack of appropriate action by the receiving ED. In particular, a lack of clarity over the purpose and structure of pre-alerts may lead to over-provision of information and confusion between pre-alerts and patient handover documentation (HSIB 2019, Sheppard et al 2016).

There is evidence that the quality of information provided within pre-alerts is variable, with a significant proportion providing inaccurate, unnecessary or inadequate information to enable a meaningful response by the receiving ED. Brown et al. identified that half the pre-alerts would have required further information in order to correctly mobilise resources, whilst Rowlands et al. reported

80% of pre-notification forms contained inadequate or incomplete information (Brown & Warwick 2001, Rowlands 2003). Budd et al. reported that 40% of Ambulance Service responders stated they did not use standard content for alerting hospitals of incoming trauma, and one-third of EDs said they would not alert the trauma team based on the information provided by the Ambulance Service within a pre-alert, but did not provide reasons for this (Budd, Almond & Porter 2007).

Whilst certain conditions have well-established criteria for pre-alert and clinical pathways (e.g. stroke, STEMI, sepsis, trauma), other symptoms and conditions will warrant a higher degree of clinical judgement (e.g. unconsciousness). It is likely that patients whose acuity is less clear may be harder to make decisions on, and these pre-alert decisions may be more influenced by ambulance clinician confidence and experience than for other conditions. As with conveyance decisions, pre-alert decisions may be more difficult where guidance is unclear and there is higher need for clinical judgement (O'Hara 2015). Even where there are clear guidelines for pre-alert (e.g. trauma), pre-alerts are only used in a proportion of cases (NCEPOD 2007, Horne & Smith 2015)

Retrospective studies exploring sensitivity and specificity of pre-alerts identified inconsistencies in how pre-alerts were undertaken, reporting an estimated 13%-28% for different patient groups eligible for pre-alert but not receiving one, and 42%-56% of pre-alerted patients who were not eligible according to study criteria (James et al, 2019, Kelleher et al, 2014, Shappard et al 2016). Despite mixed results, there is clear evidence of significant variation in use of pre-alerts, variation within guidance (e.g. (Yorkshire Ambulance Service 2019, South West Ambulance Service 2018, Welsh Ambulance Service 2010) and scope for more appropriate use.

### 1.2.5 Impact on patient experience

Pre-alerts may also have an impact on the experience and expectations of patients and accompanying friends and family, who arrive at the ED in a blue-light ambulance with expectations of immediate care. We have not yet identified any literature exploring the patient perspective, but this is an important consideration and has been highlighted by our PPI stakeholders. Given the link between patient expectations and patient satisfaction with care, it is important to understand the impact of pre-alerts upon patients and accompanying friends and family.

## 1.3. Why is this research needed now?

There is currently significant variation in guidance between Ambulance Services on how pre-alerts should be managed, the clinical criteria that should trigger a pre-alert, and the information that should be provided (Yorkshire Ambulance Service 2019, South West Ambulance Service 2018, Welsh Ambulance Service 2010), and a lack of evidence of how pre-alerts are currently being used by Ambulance Services and EDs. Increasing ED waiting times and crowding can create a vicious circle, in which pre-alerts are used to mitigate harm for individual patients but can increase the pressure across the system. A good example of this is when ambulances use pre-alerts to bypass ambulance queues outside the ED, benefiting the individual patient, but increasing the pressure on the ED and thus worsening the ambulance queue. Given the potential benefits from appropriate use of pre-alerts, and harm and opportunity costs from their over-use, it is important that Ambulance Clinicians have clear guidance and understanding of how to use pre-alerts effectively. In order to produce this guidance a better understanding is needed of the processes underpinning pre-alert decisions and how these are communicated and acted upon within EDs. We aim to undertake a mixed-methods research study to inform the development of guidance on pre-alert decisions and communication to maximise the potential benefits for patients and minimise unnecessary impact on ED resources.

Guidance on criteria for pre-alert is currently being developed by National Ambulance Service Medical Directors Group and Royal College of Emergency Medicine. However, it has been noted that there is little evidence to support this guidance and individuals from both organisations have written letters of support for this research. This work will enable further evidence based review and improvement of the guidance.

# 2 Rationale

There is currently significant variation in guidance between Ambulance Services on how pre-alerts should be managed, the clinical criteria that should trigger a pre-alert, and the information that should be provided (Yorkshire Ambulance Service 2019, South West Ambulance Service 2018, Welsh Ambulance Service 2010), and a lack of evidence of how pre-alerts are currently being used by Ambulance Services and EDs. Increasing ED waiting times and crowding can create a vicious circle, in which pre-alerts are used to mitigate harm for individual patients but can increase the pressure across the system. A good example of this is when ambulances use pre-alerts to bypass ambulance queues outside the ED, benefiting the individual patient, but increasing the pressure on the ED and thus worsening the ambulance queue. Given the potential benefits from appropriate use of pre-alerts, and harm and opportunity costs from their over-use, it is important that Ambulance Clinicians have clear guidance and understanding of how to use pre-alerts effectively. In order to produce this guidance a better understanding is needed of the processes underpinning pre-alert decisions and how these are communicated and acted upon within EDs. We aim to undertake a mixed-methods research study to inform the development of guidance on pre-alert decisions and communication to maximise the potential benefits for patients and minimise unnecessary impact on ED resources.

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# 3. Research Questions / Aims

This study aims to understand how pre-alert decisions are implemented by pre-hospital staff, and the impact of these on receiving EDs, in order to identify principles of good practice, areas of uncertainty and areas for improvement.

## 3.1 Objectives

1. To map current pre-alert practice in terms of volume and types of pre-alerts and explore potential reasons for variation in practice by reviewing existing Ambulance Service patient records and mapping to local guidance. (WP1)
2. To explore and understand pre-alert decision-making by undertaking semi-structured interviews with Ambulance Clinicians from three Ambulance Services and a national survey of Ambulance Clinicians to identify key areas of uncertainty where further guidance would be useful. (WP2)

3. To identify how pre-alert decisions are communicated, and what information needs to be communicated in order to improve patient care, by interviewing pre-hospital and ED staff. (WP2 & 3)
4. To understand how pre-alerts influence patient care in the ED, including potential benefits and unintended consequences, by observing pre-alert processes and responses to them within two EDs in each of 3 Ambulance Service areas/regions. (WP3)
5. To explore whether there are specific conditions or patient groups for whom pre-alerts are most likely to lead to action, or for whom action is unlikely to provide benefit, and explore factors that affect whether action is taken within the ED. (WP3)
6. To understand service user experience of pre-alerts by interviewing patients and/or carers. (WP4)
7. To identify good pre-alert practice, areas where further guidance is needed and co-produce information to inform the development of pre-alert guidance with research participants and other key stakeholders. (WP5)

# 4. Theoretical Framework

The research is problem driven rather than theory driven; pre-alerts were developed as a pragmatic intervention to ensure urgent assessment on ED arrival rather than through a theoretical framework. We are therefore adopting a pragmatic approach by focusing on the research problem and identifying the method best suited to understand the problem (Cresswell 2014, Patton 2002). The study is designed to provide an understanding of the use of pre-alerts as a tool intended to ensure the best care is provided for time-critical patients, and minimise negative impact on all patients. This involves gaining insights at the level of the patient, staff and organisational context to understand the different perspectives of people involved in the communications. Understanding the problem from the different lenses of ED staff, ambulance staff, patients and carers as well as independent external observers will enable insights into the overall impact of pre-alerts, and findings will then be integrated to inform future guidance (O'Cathain, Murphy & Nicholl 2010).

In order to produce meaningful guidance that organisations can adhere to, we will need to consider the impact of organisational culture and behaviour, including subcultures. The qualitative data collection and analysis will take into account organisational culture within each of the different organisations, particularly in relation to patient safety and risk. We will explore, for example, how each organisation makes use of existing protocols and guidance, and how much autonomy individual healthcare professionals have.

Within our fieldwork, we will use a broad framework for organisational culture as described by Mannion et al (2018) to guide data collection within our observations and interviews. We will seek evidence of visible manifestations of healthcare culture (e.g. how staff roles are demarcated, reporting arrangements, use of protocols), shared ways of thinking (e.g. risk-aversion, blame) and deeper shared culture (e.g. perceptions of responsibility).
Even with policies and protocols in place, staff will use their own professional judgment in decision-making and are likely to have their own implicit criteria, particularly, when there is a degree of ambiguity. In such situations, risk tolerance or averseness will be influenced by competence, confidence or negative experiences. (O'Hara 2015) Within our fieldwork we will need to identify the information, knowledge and skills that will help staff to use (and respond to) pre-alerts most effectively and consider how the different services (i.e. ambulance services and EDs) can work together to deliver best care for both those patients who are pre-alerted, and those who are not.
Consideration of patient safety implications associated with pre-alert decisions will be key. Members of the research team (ROH, JC and JT) previously researched the factors influencing

risk in ambulance non-conveyance decisions and identified that different organisational orientations towards risk influenced practice (O'Hara et al, 2019). We anticipate that pre-alerts will similarly be influenced by organisational pressures, both from the ambulance service and from receiving EDs. As with the research into non-conveyance decisions, it could be anticipated that this proposed research will reveal greater complexity and variation in practice than might be expected. The research is expected to identify scope for greater consistency in the use of pre-alerts, but also consider where scope for some local variation may be desirable.

# 5. Study design, methods of data collection and data analysis.

## Design

The overall design is an observational mixed-methods study using five inter-related work packages. Work packages are described sequentially, although WP 2-4 are concurrent and interlinked. WP 1 uses routine data to provide hypotheses for exploration within WP2-4, identify potential participants for interview in WP2 and identify EDs to recruit for WP 3. WP2-4 will be undertaken concurrently, collecting data from ambulance clinicians (WP2), ED staff (WP3) and patients and carers (WP4). Within WP2 we will use semi-structured interviews to develop hypotheses which we will then explore quantitatively using a Qualtrics survey. The study will make use of multiple data sources, which will enable triangulation of data (O'Cathain, Murphy & Nicholl 2010). Months 0-5 will be spent obtaining research ethics approval, research governance approvals for all three sites.

## Study Setting

We have selected three ambulance sites in which to conduct the majority of the research. Undertaking the research within three sites will provide sufficient data to enable transferability and generalisability of findings, whilst ensuring efficient use of resources. We will expand the sample for an ambulance clinician survey (WP2) to a national sample, and will involve national stakeholder groups within a co-production event (WP5) to further improve transferability and generalisability of findings to a national audience.

The ambulance service sites were selected pragmatically, based on their high rates of electronic Patient Report Form (ePRF) completion and accessibility. We will also select 6 EDs in which to undertake observation and interviews. We will identify these during phase 1 after analysis of 3 months data to understand where pre-alerts are taking place.

## 5.1 Study Design

Each workpackage is detailed below:

### WP 1: Mapping existing guidance and describing current pre-alert practice using routine data analysis (Months 6-13))

<u>Mapping existing guidance.</u>
We will obtain the latest policies and any guidance on pre-alerts from each of the 10 Regional Ambulance Services in England and summarise guidelines and recommendations to provide context for the further WPs and identify areas of uncertainty and variation. We will write to each of the ambulance services and ask them to send us their latest policies and guidance. We will then map

guidance to understand a) which conditions are recommended for pre-alert b) conditions where advice is inconsistent across ambulance services c) advice on how pre-alerts should be given. We will also consider the new national recommendations that are being developed and whether these are consistent with service level policies and practice.

Routine data analysis.

Routine, retrospective data will be obtained from three ambulance services, which have already agreed to take part in this study (Yorkshire Ambulance Service (YAS), East Midlands Ambulance Service (EMAS) and West Midlands Ambulance Service (WMAS)). We will analyse 12 months' electronic Patient Report Form (ePRF) data for the three regional Ambulance Services to identify the total number of pre-alerts for each Ambulance Service and to explore variation in pre-alert processes and variation from ambulance service pre-alert guidance. We will use 12 months' data to allow us to look at seasonal variation, given that thresholds for pre-alerts may vary across the year. We will use the period July 2020 -June 2021. This will enable us to gather 6 months data prior to the recording of the pre-alert field being mandated for YAS, and 6 months after the mandating (see below).

Mandating the pre-alert field in the electronic patient record

As the pre-alert field is not yet mandated, these figures may under-estimate the true number of pre-alert calls being sent through to EDs. In order to improve data quality, YAS agreed to mandate the completion of the pre-alert field for the study data collection period and set up the mandated field in January 2021. This means that ambulance clinicians will be unable to complete and submit the ePRF if this section is blank. We had originally hoped to enable mandating of a field to record pre-alert in all three services but due to the timing of the new system of ePRF being negotiated by WMAS and EMAS, this will not be possible at the time of this project. However, this will enable us to estimate the scale of current under-report. However, EMAS are able to collect free-text data and will collect information on conveyances where pre-alert is mentioned in the free text field, to provide further information about completion rates.

Routine Dataset

Each participating ambulance service will provide a linked routine dataset of all conveyances occurring within the 12 month sampling time frame. The data will consist of ePRF information from the clinical assessment, Sequence of Event log data, and shift information from the Global Rostering system. Information from across the three sources will be linked using the Computer-aided Dispatch (CAD) ID, which is a unique incident identifier. The Sequence of Event log will also be used to identify individual staff shift codes. Shift codes will be matched to the Global Rostering System, which can provide detailed information about shifts, such as the time at which the pre-alert occurs in the shift. This dataset will be produced by a research paramedic and will be sent to the research team at University of Sheffield using anonymised clinician identifiers. The research paramedic will retain this list of anonymised clinician identifiers along with their ambulance service clinician identifiers to help recruit paramedics for WP2.

This dataset will include factors that have been identified as potentially explaining variation in pre-alert use, either within the existing literature (discussed above) or by ambulance clinicians consulted within the development of this proposal. This includes clinician factors (role, experience, qualification, time of pre-alert during shift), patient factors (NEWS2 score, presenting complaint, clinical working impression), hospital factors (catchment Trust, handover delay status at time of pre-alert, trauma centre status) and day/ time of day. We will describe pre-alert practice, including patient characteristics and clinical information for all conveyances with and without a pre-alert to understand which patients and clinical conditions were pre-alerted. We will then describe variation in the use of pre-alerts and use logistic regression to explain variation in terms of patient, ambulance

service or hospital factors that predict use of pre-alert. We will explore emerging findings with qualitative work in WP2 and WP3.

The ePRF usage rate is between 90% and 100% for these 3 Ambulance Services. Paper forms are still in use in some air ambulance or major trauma incidents, but this is only likely to affect a small proportion of total pre-alert cases given the high ePRF usage rate of participating ambulance services.

*Sample size*

We are currently unaware of how high the completion rate for the pre-alert field is for the different ambulance services. A data extract from YAS ePRF data for the period May-October 2019 identified a total of 8958 pre-alerts for the 6 month period, giving a likely minimum annual figure of around 17,900 (assuming pre-alert calls are lower in summer months where demand is lower). WMAS data for April 2019-March 2020 identified 64,303 pre-alerts from a total of 660612 conveyances (9.73% of the total).

## WP2: Exploring how Ambulance Clinicians undertake pre-alerts (months 12-23).

We will explore how ambulance clinicians undertake pre-alerts, and how and why decisions are made, using qualitative semi-structured interviews of ambulance clinicians within the three ambulance services, and a wider national survey of ambulance clinicians. We will undertake semi-structured interviews by telephone with up to 7-9 Ambulance Clinicians from each of the three Ambulance Services to understand: factors that influence decision-making for pre-alerts, what information they communicate and how they use guidance or decision-tools to inform pre-alert decisions. We will also explore Ambulance Clinicians' experiences of what happens on arrival at the ED following a pre-alert, their understanding of how pre-alerts will be used within the ED, the impact of the ED clinicians response to the pre-alert on their pre-alert practice, and how processes could be improved.

Recruitment of ambulance clinicians for interview.
We will use data from WP1 to identify a sample of ambulance clinicians to recruit. Using the anonymised unique clinician ID from the dataset, we will sample purposively for role, range of experience, qualifications, and high/low rate of pre-alert use (if feasible) as well as age and gender as these can impact on decision making (Sanz de Acedo Lizarraga 2007). Invitation emails to the ambulance clinicians identified will be sent out by ambulance service staff (over-seen by Ambulance Service co-applicants at each site), and ask interviewees to contact the research team at University of Sheffield directly if they are willing to take part. We will aim to speak to 5-6 ambulance clinicians at each site via this route (15-18 in total). Following observation within the ED (WP3), we will also aim to interview a further 2-3 ambulance clinicians at each site to explore specific instances of pre-alerts and enable deeper understanding of decision-making processes (see below). We will pro-actively recruit ambulance clinicians during our observation of pre-alerts at EDs. In order to boost participation rates, we will provide clinicians with a £20 Love2Shop voucher as a thank-you for their time. Additional more generic recruitment strategies may also be used to increase numbers if needed, including information in weekly staff briefings and informal dissemination by research paramedics in each service.

National survey of ambulance clinicians.
Finally, in order to determine whether the perceptions and experiences identified within the interviews are widely shared, we will use the findings from WP1 and the initial 15-18 ambulance

clinician interviews to develop an online Qualtrics™ survey exploring findings further. We will explore awareness of guidance and will use vignettes based around some of the clinical decisions highlighted within earlier qualitative work, and WP1, to explore areas of uncertainty and factors affecting decision-making. This survey design has been undertaken successfully within previous pre-hospital research studies (Miles, Coster & Jacques 2019).

To improve the generalizability of the findings we will invite all ambulance clinicians via clinical research teams at all 10 Regional Ambulance Services. We will approach the research lead in each of the Trusts to advertise the online survey link via internal staff communication channels including newsletters and social media. Paramedics are high users of social media and this approach has been successfully used for surveys of ambulance clinicians in other studies (Miles, Coster & Jacques 2019, Pilbery et al. 2016). Posters will also be prepared by the study team to advertise the study, including a QR code for direct access to the online survey.

Informed consent will be sought from participants who access the online survey. To boost response rates, surveys will also be promoted via national organisations, including College of Paramedics and National Ambulance Research Steering Group (NARSG). Using a web based platform ensures that the survey is configured for completion on multiple types of electronic devices and computer set-ups (e.g. laptop or mobile phone) and eliminates data entry errors as data is automatically downloaded into an excel spreadsheet based on the coding of the question answers. We will also provide a printed version of the questionnaire to each Ambulance Service as an alternative format to encourage completion by people who are less confident with technology, to maximise the diversity of respondents. We will offer participants the chance to enter into a prize draw for £50 Love2Shop vouchers, with one voucher for each ambulance service. Ambulance services will receive accruals for each participant.

## WP3: Understanding the impact of pre-alerts on the ED (months 12-23).

We will seek to understand the impact of pre-alerts on the ED using non-participant observation, informal interviewing and semi-structured interviews. We will use non-participant observation (Catchpole et al 2015) within EDs to understand how pre-alert information communicated by Ambulance Clinicians is received and acted on within the ED. We will undertake non-participant observation over a period of 4-6 days within 2 different EDs (Major Trauma Centre and non-Major Trauma Centre) for each of the 3 Ambulance Services (6 EDs in total). This will include a period of familiarisation within each ED in order to plan data collection for the observations. We will use data from WP1 and work with ambulance trusts to select EDs that will provide variation in population demographics (e.g. age, rurality and pre-alert rates). Based on existing pre-alert data from each individual ambulance service, we anticipate that this will enable us to observe a minimum of 20-25 pre-alerts for each ambulance service. EDs usually have a specific phone where pre-alerts are received. We will base our observation near this phone, and follow the person who receives the call to observe actions taken after the call. We will collect data on how the pre-alert was received and documented within the ED, how this is shared within the department, what actions are taken and the staff involved, and how the ED staff and ambulance staff discuss the pre-alert once the patient arrives. We will also explore the knock-on effects of the pre-alerts (e.g. the impact on other patients or staff, and on the wider system) and potential impact of pre-alerts that are subsequently "stepped down" and whose needs have been de-prioritised. We will also use informal interviewing for staff involved in the information exchange following the pre-alert to ensure we have understood the processes and information correctly. Within each of the sites, we will seek to map how pre-alerts impact on the various aspects of the system and care processes (and conversely where a pre-alert did not occur but probably should have done). We will also collate any guidelines or documentation relating to pre-alerts within the ED and explore clinician understanding of this documentation.

We will not undertake observation of pre-alerts from within the ambulance, due to the likely low numbers per shift, but instead will speak to ambulance staff after patient handover within the ED to understand how the decision-making process took place. Due to the tight turnaround times for ambulances during patient handover, we will not interview staff at the time, but will ask them for their contact details to send them information about the research (including information sheet and consent form) and ask them to contact us if they are interested in participating in a semi-structured interview, during which we will ask them about their decision-making processes for this specific handover, as well as wider questions.

In addition to observing specific instances of pre-alerts, we will undertake semi-structured interviews with up to 4-6 ED staff at each of the six EDs to understand when and why they do or do not act on pre-alerts more generally. This will include senior clinicians, ED co-ordinators and other roles that are identified as being key to understanding pre-alerts. Staff will be approached during our observations and we will ask them for their contact details to send them information about the research (including information sheet and consent form) and ask them to contact us if they are interested in participating. We will explore their perspective on what makes a useful pre-alert, what factors affect their decision to act upon pre-alerts, and how they could be improved. We will also explore the impact of pre-alerts on the wider work of the department. We will include the specific instance technique, where we ask them to consider the latest pre-alert that they were involved in and to reflect upon the events that followed, and explore factors behind the decision-making processes. Given that the observation may involve periods of waiting for pre-alerts, we will use this time to recruit staff for interview.

Interviews will be conducted either face-to-face during the periods of observation, or by telephone at a later date, depending on the preference of the staff member, and participants will be offered a £20 Love2Shop voucher. Fieldwork will be undertaken by FS and an experienced research associate (RA), with PW (PPI Co-App) also undertaking some of the observation work. The use of investigator triangulation (i.e. use of multiple observers) can help with interpretation of data by enabling consideration of individual researcher lenses. (Turner & Turner 2009). Similarly, although the majority of the interviews will be undertaken by the RA, FS will undertake some of the initial interviews to ensure the interview topic guides are structured in sufficient detail to enable main themes to be captured. We will also share early findings and anonymised data extracts with the wider project group, advisory group and PPI panel to discuss our emerging findings.

We will pay attention to any risk of researcher effects on the observation, notably the 'Hawthorne effect' which is a term used to describe the tendency for people being observed to act in a way that is socially expected (McCambridge, Witton & Elbourne 2014). However, previous experience of observation within the ED showed that there was low risk of researcher effects within the busy environment of the ED, particularly in relation to time-critical events where staff will be highly focussed on their work (Sampson 2018).

## WP4: Understanding the patient perspective of pre-alerts (months 12-23).

We will undertake semi-structured interviews with 3-4 sets of patients and/or carers recruited during WP3 at each of 2 EDs, to explore the impact of pre-alerts on patients, how they are communicated to patients and their carers, how this affects their expectations of care once they arrive at the ED, their experience upon arrival and how expectations were managed upon arrival at the ED. We will also explore how patients feel about having to wait longer due to being pre-alerted or bypassing ambulance queues.

Where possible we will undertake these interviews by telephone or online meeting (e.g. Google Hangouts, MS Teams) and interview patients and carers together, unless they have a preference for separate interviews. Our PPI team identified a number of potential key questions which may be addressed (listed above), but we will also explore patient perspectives of themes identified during observation.

Two different recruitment strategies will be employed, as we anticipate this group being difficult to recruit for a range of reasons, including mislaying information before leaving hospital, forgetting about the research due to the immediate challenges of the situation, or being reluctant to recall the incident once recovered and at home. These approaches are as follows:

1) At two of the sites, we will identify pre-alerted patients during the periods of observation and, in consultation with ED staff, select anyone who has been pre-alerted and is able to be approached after treatment. Patients and/or carers will be approached by an ED staff member once it is considered appropriate to do so, and asked if they are willing to speak to a researcher. If so, a member of the research team will give them a reply card with brief details about the study and contact details for the research team together with a prepaid envelope. We will not obtain contact details from them but will ask them to contact us at a later date if they are interested in participating in the research.
2) At one of the sites (Derby Hospital), a revised procedure has been agreed with the clinical team to try and improve response rates. We will identify all pre-alerted patients during the periods of observation and, at the end of observation period, provide a written list of patient names to one of the research nurses. We will not approach the patients or carers at all during the observations and will not retain the list of names once leaving the hospital. The list of patients will subsequently be reviewed by a clinician who will identify which people it is appropriate to follow up, based on their clinical condition and outcome of their admission. Once discharged from hospital, a research nurse at the hospital will phone identified patients to tell them about the study and ask if they are happy to receive information by post. If they are, an invitation letter, information sheet, consent form and reply card will be sent to them together with a prepaid envelope. They will be asked to return the reply card to the university research team, who will then follow them up to arrange an interview and obtain consent at the start of the interview.

In both instances, we will provide participants with a £20 Love2Shop voucher as a thank-you for their time. We have used this approach previously to increase the diversity of our sample (O'Cathain et al 2020). We will select interview participants to ensure diversity in age, gender and socioeconomic group.

*Data Analysis and integration of WPs 1-4 (months 21-27)*

Quantitative data from WP1 will be analysed and used to give context to other WPs and identify areas of variable practice or uncertainty. This will be a descriptive analysis that will describe and compare current practice in prelarts in the 3 ambulance services.

All interviews will be digitally audio recorded and transcribed verbatim. Detailed hand-written notes will be taken during the observation, and notes will be typed up immediately following fieldwork. The interviews and observation notes will generate a large volume of data. This will be managed using NVivo qualitative analysis software(28).

Data will be analysed using thematic analysis according to the principles of Braun & Clarke (2012). Detailed field notes and research journals will be kept by both researchers during the fieldwork and

emerging themes discussed throughout the data collection phase to ensure that any emerging findings are explored within further fieldwork. ROH will not undertake fieldwork but will be involved in the analysis of data. Anonymised field notes and interview schedules will be shared with ROH and members of the PPI panel to aid interpretation of the data. Fieldwork will be undertaken cyclically over the three ambulance sites and 6 EDs. This will enable emerging findings and hypotheses developed during fieldwork to be tested at all sites.

*Integration of findings.*

Integration of findings from all four work packages is key to improving overall learning and ensuring that the whole is more than the sum of its parts (Farmer et al 2006). This research will generate routine data (WP1), survey data (WP2), informal and formal interview data and non-participant observation data (WP2-4). We will triangulate data from different work packages and different data sources using joint displays to ensure integration of all data sources (O'Cathain, Murphy & Nicholl 2010). We will be guided by the use of a triangulation protocol (Farmer et al 2006). We will also ensure any learning from literature that is identified throughout the cycle of the research is used to test emerging theories. The core team (FS, ROH, RA, JC) will feed back emerging findings into the wider project management teams, and wider PPI panel for discussion and feedback. We will develop a set of initial findings and potential recommendations in collaboration with our PPI panel and steering group.

## WP5: Co-production of guidance (month 27).

We will then take our initial findings to a national feedback workshop incorporating research participants, PPI and other key stakeholders as well as a wide range of external stakeholders (e.g. RCEM, NASMeD, National Elective and Emergency Care Directorate for NHS England, Ambulance Leadership Forum). We will ensure that we incorporate ED staff, ambulance clinicians and patients who were involved in the fieldwork in order to maximise engagement. We will also advertise the event at conferences. At the workshop we will discuss initial findings, identify improvement actions, priority areas for further guidance and develop guiding principles for undertaking pre-alerts for both Ambulance Clinicians and ED staff. We will also explore how ED staff and Ambulance Clinicians can support each other in good pre-alert practice. We appreciate that due to shift patterns and other commitments not everyone who is interested will be able to attend the event and we will provide opportunities for these people to also provide input. We will hold the event in Sheffield but will offer online participation to enable wider engagement.

We aim to improve ambulance clinician understanding of the pressures on ED and the impact of a pre-alert, and improve ED staff understanding of the pressures on, and challenges facing ambulance staff, and their reasons for pre-alert. By facilitating communication between ambulance clinicians and ED clinicians at our national feedback workshop, we would hope to improve expectation management and tolerance between the two services. Co-production can help to produce research that is "relevant, useful, useable and used" (Graham 2019) and we will be working with the users who have the authority to implement the research recommendations, which can lead to more relevant and actionable research findings. (Kent 2019).

At the national feedback workshop we will invite a creative media graphic design company (Nifty Fox) to support the co-production of easy to understand infographics and recommendations (Papoulias et al, 2017). Nifty Fox have significant experience of working as researchers and understand the research process. They are experienced in co-producing outputs and have previously worked with members of the project team to successfully develop infographics on PHOEBE and a Third Sector Organisation implementation toolkit (ISSUU 2020, University of Sheffield 2017)

We will disseminate these through ambulance services, EDs and professional bodies (see dissemination strategy section 6 below).

# 6. Dissemination and expected impact

The project is being undertaken to address a service-led research need to support guidance on use of pre-alerts for ambulance services and emergency departments. The dissemination strategy therefore needs to target key professional organisations to ensure the findings of the research are used to influence guidance and clinical decision-making and behaviour.

We expect our research to produce a set of principles guiding how and when pre-alerts should be delivered by ambulance clinicians and received by EDs to ensure optimum patient care and resource use. The improved use of pre-alerts is expected to lead to earlier initiation of time-critical treatment, improved processes and better clinical outcomes for patients These principles will be developed using our understanding of the ambulance clinician, ED staff and patient perspectives.

They will then be used to develop the guidelines that are currently being drawn up, ensuring that the guidelines maximise the benefit of pre-alerts, while minimising the potential negative consequences. These guidelines can then be implemented to improve clinical decision making by a) providing a framework to help ambulance clinicians implement recommendations and determine which individual patients should receive a pre-alert, drawing upon the principles identified by the research, and b) providing guidance around the timing, content and communication of pre-alerts to optimise effectiveness and minimise adverse consequences.

Our research will not directly determine which patient groups should receive pre-alerts. (i.e. we will not study the effectiveness of pre-alerts for particular conditions) but will identify the principles for determining which groups receive pre-alerts. For example, our research might identify a principle that patient groups should be pre-alerted if they need time-critical interventions from specialists who are not usually present in the ED. The guidelines would then use existing evidence and clinical expertise to determine which specific patient groups require pre-alert according to this principle. The research may also identify gaps in clinical knowledge or areas of uncertainty that limit the ability of ambulance clinicians to determine which conditions should be pre-alerted, or areas where further guidance may be required. These can then be highlighted as priorities for future research

The research will also enable Ambulance Services to understand baseline data for pre-alerts and provide a mechanism for future quality assurance. By mandating the pre-alert field in one Ambulance Service, we will be able to assess the impact of mandating pre-alert field on the quality of data collected. This may help Ambulance Services decide on whether their pre-alert field should be mandated in future, and if so, what data should be collected.

We will disseminate the findings of the research via NASMeD, who will take the findings to Joint Royal Colleges Ambulance Liaison Committee (JRCALC) and RCEM to discuss whether the national guidance can be reviewed in light of any findings and whether recommendations for good practice can be incorporated into the national guidance. MM (Co-App) is currently involved in the development of initial guidelines with Association of Ambulance Chief Executives and RCEM and will oversee this process. NASMeD are in support of this research being undertaken to strengthen the evidence base behind the guidance, and develop the consensus-based guidance that is currently being developed further. This has potential to feed into the Higher Education arena. Stakeholders have suggested that understanding how to undertake pre-alert calls and may be included in curriculum and placement competencies for ambulance clinicians in training, as well as including a pre-alert call in the RCEM curriculum and MRCEM and FRCEM exams.

We will work with National Ambulance Service Medical Directors Group (NASMeD), Ambulance Lead Paramedic Group, Royal College of Emergency Medicine (RCEM) and College of Paramedics to develop and disseminate summaries of the research findings, particularly recommendations and infographics generated from WP5 in order to maximise impact on frontline clinicians. We will work with our PPI group to guide wider dissemination of lay research summaries and send summaries of our findings to each ambulance service and ED.

Dissemination of research findings and implementing research findings into practice is improved when multiple methods are used, and particularly when active rather than passive methods are included (Grol 2003) We will publish our findings in high-impact, open access peer-reviewed journals and present findings at relevant national and European conferences and professional meetings, including 999EMS Research Forum, RCEM scientific conference, EMS2023, HSRUK. We will present the findings from the routine data and literature review at a national conference (999EMS Research Forum) in order to obtain feedback that may be useful for WP 2-5. This will also enable us to advertise the workshops for WP5. We will apply to present our findings at the Association for Ambulance Chief Executives (AACE) Ambulance Leadership Forum annual conference and hold a roundtable discussion about implementing recommendations, as this method of active discussion may improve the likelihood of findings being incorporated into clinical practice

Specifically, we aim to publish the following open-access peer-reviewed journal articles as a minimum:

Routine data analysis and review of guidance (Target journal: EMJ, Academic Emergency Medicine). Findings from National Survey of Ambulance Clinicians (Target Journal: EMJ). How should pre-alerts be used to improve patient care? Findings from qualitative fieldwork and national feedback workshop: (Target journal: Annals of Emergency Medicine, Health Expectations). These will also form part of the NIHR final report.

We will set up a study website and twitter account to update on study progress and any dissemination activities to ensure timely dissemination.

# 7. Project research timetable

We have based our project timetable on our extensive experience of undertaking research in the field of Emergency and Urgent care. The project will take place over 29 months. There are 4 main phases for the research; project set-up (months 1-5), WP1 (months 6-13), WP2-4 (months 12-23) and integration & dissemination (months 21-29).
We have built in time during months 1-5 to obtain the necessary permissions for the study to run. We will also turn on the mandating of the pre-alert field for YAS so that we have better quality data to use for WP1.
We have summarised the project timetable in the table below. Please see the attached GANTT chart for a more detailed breakdown of tasks.

| **Months** | **Tasks** |
|---|---|
| March 2021 | Finalise contracts. Undertake testing of pre-alerts field. |
| Apr - | Undertake study start-up tasks. Apply for NHS research ethics approval. Pre-alert field |

| | |
|---|---|
| May 2021 | turned on in YAS. PPI (OL) meeting to discuss ethics documents. Start recruiting PPI panel. |
| June - Aug 2021 | Receive ethical approval. Apply for research governance approval within the 3 ambulance services.Sign off information sharing agreements with ambulance services. Undertake PPI panel training needs assessment and arrange training. |
| Sep - Nov 2021 | WP 1 starts. Write to ambulance services to obtain latest pre-alert guidance. Research paramedic to develop data extraction code and test data linkage. Test pre-alert data linkage. |
| Dec 2021 | PPI meeting to discuss findings from pre-alert guidance summary. |
| Jan - Mar 2022 | Pre-alert linked data set sent to study team. Pre-alert data management and analysis.<br>Project Advisory Group meeting 1 (face-to-face) to discuss pre-alert guidance summary and guide analysis of pre-alert data.<br>HS&DR 12 month report<br>Obtain research passports for fieldwork at ambulance services. Identify EDs for fieldwork and obtain research governance approvals. |
| Apr 2022 | Write up WP1 and submit conference abstracts for EMS Research Forum.<br>WP2-4 start. Identify ambulance clinicians sample from WP1. Recruit clinicians for interview.<br>Non-participation observation set-up (orientation).<br>PPI meeting to discuss dissemination for WP1 and fieldwork for WP2. |
| May - July 2022 | Start fieldwork at EDs. Non-participant observation, recruit ED staff for interview, recruit patients for interview |
| Aug - Sep 2022 | PPI meeting to discuss fieldwork, patient recruitment, early observations. Field work ongoing for WP 3 &,4. Analysis of ambulance clinician interviews. Present findings of WP1 at conferences, advertising survey for WP2. |
| Oct- 2022 | Develop survey (WP2). Advisory group meeting (online) to discuss survey and emerging findings from fieldwork. Fieldwork ongoing WP 2-4 |
| Nov 2022- Dec 2022 | Survey administration (WP2). Fieldwork completion for WP3 & 4. |
| Jan- Mar 2023 | Analysis of survey data, interviews and observations. Write up survey paper. Integration of work packages. HS&DR annual report. |
| Apr - May 2023 | Integration, preparation for workshop. Engage with Nifty Fox. Face to face advisory group meeting |
| June 2023 | National feedback workshop. PPI meeting to discuss dissemination strategy. |

| | |
|---|---|
| July - Aug 2023 | Complete infographics. Submit final report. Dissemination. Assessment of PPI involvement. |

# 8. Research Ethics Committee (REC) and other regulatory review and reports.

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

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 Investigator's responsibility to produce the annual reports as required.

- The Chief Investigator will notify the REC of the end of the study.
- An annual progress report (APR) will be submitted to the REC within 30 days of the anniversary date on which the favourable opinion was given, and annually until the study is declared ended.
- If the study is ended prematurely, the Chief Investigator will notify the REC, including the reasons for the premature termination.
- Within one year after the end of the study, the Chief Investigator will submit a final report with the results, including any publications/abstracts, to the REC.

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## Amendments

The chief investigator will be responsible for making the decision to amend the protocol and for deciding whether an amendment is substantial or non-substantial and will communicate said decisions to the REC, R&D and the study advisory committee. A record of any amendments will be detailed alongside protocol variations, and for each version number.

## Consent

For the online Qualtrix (TM) survey of ambulance clinicians in WP2 we will seek informed consent from participants who access the online survey. Respondents will be sent a link to the information sheet, asked to tick a box confirming that they have read and understood the information sheet and consent will be assumed by continuing to undertake the survey.

For WP3, we will undertake non-participant observation within 6 EDs in order to understand how pre-alerts impact on the ED in practice. The observation will be based around the 'red phone' where the pre-alert calls come in and the researcher will then observe the staff who take the call to observe what changes are made. As seeking informed consent from every member of staff or patient within each ED would be unfeasible and would obstruct patient care, we will place information sheets and posters around the EDs to inform staff and patients that the research is taking place and to contact the researcher if they would like further information about the research, also providing the option to opt out if they do not wish to be observed. Any data collected that involves an individual who does not wish to be observed will be destroyed.

Staff in each of the EDs will be informed that the research is taking place by the research lead in each site and will be given the chance to ask questions prior to the observation taking place. Information sheets about the research will be made available within the department.

WP5 is a national feedback workshop in which we will share and discuss our findings with key stakeholders to get their input into how to implement and disseminate the findings. We will not be gathering data from the stakeholders involved (ie. they will not be sharing their experiences to use as data) during this phase of the research therefore we will not require informed consent from participants.

Participants will be given an information sheet and given the opportunity to ask questions prior to taking part in the research. Participants will be asked to contact us directly if they are interested in taking part, so will have sufficient time to consider whether they wish to participate. In addition to the written information, we will offer patients an option to watch a short video explaining the main points on the information sheet, or to have a conversation where we discuss the information sheet.

Capacity will be assumed for staff participants. Patients and carers will be approached initially by clinical research staff who will assess capacity prior to asking whether the individuals wish to hear about the research.

The non-participant observation will be focused on staff-staff interactions, where staff will be assumed to have capacity. Although patients will be present, they will not be considered to be research participants and we will not collect any identifiable information about patients during the research. If clinical staff do not feel that it is appropriate for us to undertake non-participant observation at any stage, we will move away from the area and stop taking notes until clinical staff feel that it is appropriate for us to return. As the focus of our research will be on the staff responses to pre-alerts and staff-staff interactions, we will not undertake any observation in private areas (e.g. where there is a curtain around a patient, or within private bays).

# 9. Peer review

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

# 10. Patient and Public Involvement (PPI)

PPI will be involved throughout, in design, planning, analysis and dissemination of research. We have built in 5 months at the outset of the project to obtain NHS ethics and research governance approvals. During this phase we will also recruit our PPI panel and assess any PPI training needs prior to the research starting.

We have involved PPI representatives from three different PPI groups in the development of the first and second stage of this proposal; patient research ambassadors from Yorkshire Ambulance Service (Peter Webster), PPI members from the Sheffield Deep End group (Linda Jones) and PPI members from the Sheffield Emergency Care Forum (SECF) (Enid Hirst, Linda Abouzeid, Alice Riddell). The Deep End group was set up in 2017 to include patient perspectives from people who live in areas with high levels of deprivation, who are often under-represented in PPI panels. SECF were set up in 2000 and have a long history of supporting research from this research team and working together to support and improve our research findings. SECF have wider links into other health related groups (e.g. HealthWatch; AgeUK, Primary Care Patient Participation Groups) which

has proved useful in helping with dissemination of results for previous studies. PW is an experienced patient research ambassador for stroke research in Leeds and PPI co-applicant on the project. He has worked with Fiona Bell (Co-App) on several ambulance service projects.

For the first stage proposal, a draft of the proposal was circulated to SECF who commented on and supported the proposal. Members of SECF and PW helped to develop the lay summary, suggesting terminology that would be widely understood. Referees commented the lay summary was well written so we have not made further changes to this for the second round.

Enid Hirst and Linda Abouzeid (members of SECF) commented on the first stage proposal and sent a list of questions for clarification, which we discussed and addressed within the second stage proposal. In particular, the PPI members helped us to clarify some of the definitions of pre-alerts, how they are recorded and what was meant by 'mandating pre-alerts'. At both stages, PPI members asked questions about the wider study which helped us to clarify the meaning of some of the text.

Due to the need for social distancing at the time of second round submission, we were unable to meet face-to-face but held meetings via Google hangouts to discuss how the proposal could be developed. In particular, we sought to consider how WP4 (patient views) could be simplified, as suggested by first round reviewers, whilst still enabling us to consider the important patient voice (see Attachment 1, Section 5, WP4). We also asked for PPI representation for the wider advisory group and recruited Alice Riddell, who has experience of ambulance pre-alerts as a carer. A further PPI member from the DeepEnd PPI group in Sheffield was unable to attend the meeting but FS shared the ideas from this discussion with her after the meeting. PW attended the wider meeting of the project management group in which the design and development of the proposal was discussed.

The PPI panel also encouraged us to consider how we would demonstrate the impact of PPI on the research and helped us to consider how to expand the panel, including training requirements. Whilst members of the panel who were involved in developing this bid did not highlight any specific training needs (largely due to their experience) for themselves, they shared examples of previous training that they had undertaken and we discussed what training new PPI members might need. The existing panel have offered to help develop information leaflets and posters to place in the ED to recruit new members.

We will follow guidance on UK standards for public involvement throughout the study (Involve 2019). We will convene a PPI panel of 6-8 people to consult with regularly throughout the research. This panel will be led and co-ordinated by an experienced PPI lead, JC (Co-app) who will be funded to undertake this important role. Panel members will include: PW, SECF members, Deep End PPI group members, new members recruited from the Emergency Department at Sheffield Teaching Hospitals NHS Trust and via the NIHR people in research website (www.peopleinresearch.org.) We will aim to recruit people from diverse cultural and socio-economic backgrounds to reflect diversity of ED users.

We will provide access to meetings via online platforms (e.g. Zoom or Google Hangouts) to enable people outside the wider geographical area to participate. Although this may restrict access for people with lower levels of access to the internet, these technologies have become more widely accessible since the Covid-19 pandemic and lockdown. We will set out clear information and terms of reference for the PPI panel, including information about expectations of their role and payment.

Our PPI co-app (PW) will attend management meetings where he will be able to influence decisions about the direction of the research, and help to interpret the findings. Alice Riddell is an experienced member of SECF and will be a member of the Project Steering Group to provide a strategic view of PPI, and how PPI can help to progress the study. JC or FS will also present a project update at each SECF quarterly meeting for the duration of the study.

PPI involvement will continue throughout the study, including development of research documents for WPs 2-4 (topic guides for interviews, information sheets, lay summary for ethics application). We will also involve PPI in the interpretation and analysis of data from fieldwork. We will share a sample of anonymised observation notes and interview scripts with the PPI panel and discuss the themes and findings as they develop. We have used this approach successfully in previous research (Sampson et al 2019). Similarly, PPI panel members will take part in WP5 feedback workshop and help with writing lay summaries of findings for dissemination.

We will obtain an honorary contract for PW, who will then have access to mandatory training for University of Sheffield. Subject to necessary research governance approvals, he will be directly involved in the fieldwork and act as an observer within the ED at one of the trusts in Yorkshire.

We will assess training needs for new members and offer existing training resources that PPI members identified (e.g.Involve resources). We will seek to offer online training where possible, or to apply to the Research Design Service for support if further training needs are highlighted. PPI members will have access to the ScHARR information governance and research ethics training. PW will offer mentorship to any new members if required.

JC will ensure that all PPI contributions at advisory and management groups meetings are logged, and the impact of these contributions will be assessed throughout the project. During the final month of the study, we will assess the impact of PPI involvement using a survey of PPI panel and project management group. (Mann et al)

We have included relevant costs to support PPI involvement, as laid out within INVOLVE guidance (Involve 2019), detailed below.

PPI: PPI participants will be reimbursed in accordance with INVOLVE guidelines. Our PPI co-applicant (PW) will paid £(x) for work as PPI co-app. We have also included costs of £3,400 for PPI. This includes £75 fee for PPI attendance at the project advisory group (4 meetings), £75 per person for virtual & face-to-face PPI group meetings (4 meetings, up to 10 participants) and travel costs for 2 face-to-face meetings.

# 11. Study Steering Committee

A Study Steering Committee will be convened during study set up. This group will provide overall supervision of the pre-alerts project in general on behalf of the trial sponsor (University of Sheffield) and funder (National Institute of Health Research, NIHR). The SSC will ensure that the study is conducted according to the planned research, with specific tasks including:

- Approval of the study protocol
- Review of study progress
- Monitoring adherence to study protocol
- Consideration of new information relevant to the research question
- Scrutiny of protocol amendments and extension requests
- Recommend appropriate actions such as changes to the protocol, additional patient information, practical solutions to potential problems (e.g. data acquisition).

The composition of the SSC is detailed in Table 1. The SSC will receive information from the Project Management Group and meetings will be convened by the CI approximately 6 monthly. The SSC chairperson will provide advice to the CI, sponsor (University of Sheffield), study sites, and funder (NIHR).

## 11.1 Table 1. Composition of Study Steering Committee

| SSC Members | Independent Yes / No | Area of expertise |
|---|---|---|
| Chair | Yes | Prehospital research |
| Member | No | Chief Investigator |
| Member | No | Emergency Department consultant and ambulance service medical director |
| Member | Yes | Consultant paramedic |
| Member | Yes | Clinical expertise, London Ambulance Service |
| Member | Yes | Statistician |
| PPI Member | Yes | PPI |
| Member | Yes | Qualitative and ethnographic research expertise |
| Member | Yes | Patient safety research, PPI involvement and engagement |

# 12. Project Management Group

A Project Management Group (PMG) will oversee day-to-day management of the project. Specific roles will include:

- Ensuring adherence with the study protocol
- Ensuring ethical and governance standards are met
- Monitoring data quality
- Developing and reviewing paperwork
- Responding to queries from the host institutions
- Developing the study protocol in response to operational challenges
- Review of results
- Dissemination of study findings

The PMG will comprise the CI, co-investigators, senior researchers and lay representatives. The PMG will meet every 4-6 weeks, depending upon the stage of the research.

# 13. Finance

The study is funded by the NIHR Health Services & Delivery Research Programme (grant number NIHR 131293). Details have been drawn up in a separate agreement.

# 14. Indemnity / compensation / insurance

The pre-alerts project is sponsored by the University of Sheffield. The University holds insurance covering liabilities arising from negligent harm caused by poor protocol design by the Chief Investigator and researchers employed by the University.

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