**STUDY PROTOCOL**

**FULL/LONG TITLE OF THE STUDY**

Understanding the acceptability of opportunistic identification of undiagnosed and untreated atrial fibrillation during unscheduled contact with emergency ambulance services: a qualitative exploration

**SHORT STUDY TITLE / ACRONYM**

Opportunistic identification of atrial fibrillation by ambulance crews

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# KEY STUDY CONTACTS

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**KEY WORDS:** Atrial fibrillation, ambulance, stroke, prevention, detection, screening

**ABSTRACT**

Atrial fibrillation (AF) is a common heart rhythm disturbance, or arrhythmia. It causes the heart to beat abnormally and is a significant risk factor for stroke. Taking oral anticoagulant (blood thinning) medications substantially reduces the risk of stroke in people diagnosed with AF. It is estimated that 400,000 people in England have undiagnosed and therefore untreated AF, leaving them at increased risk of stroke. Sometimes people don't experience any symptoms and AF gets detected incidentally during a routine clinical test or scheduled examination. Formalising such opportunities for finding undiagnosed AF could lead to more timely prescription of anticoagulant medication and a subsequent reduction in avoidable strokes. AF can be detected by electrocardiogram (ECG), which is a simple heart trace. Emergency medical services (EMS) ambulance crews encounter a wide range of people on a daily basis and perform detailed routine assessments that often include an ECG. Whilst most patients attended by EMS are conveyed to hospital for further medical assessment, investigations and treatment, many patients are treated at the scene by EMS staff and remain in the community. This group provides a novel opportunity to screen for hidden cardiovascular risk factors. Whilst pilot work by the authors estimates that many people could benefit, it is important to understand the acceptability and feasibility of identifying AF in this way from the perspective of those giving and receiving the diagnosis, as well as service managers and policy makers. This qualitative study will use semi-structured interviews and focus groups involving 10 health care and service providers and 20 members of the public to explore the acceptability of opportunistic identification of undiagnosed or untreated AF during unscheduled EMS ambulance contacts in patients not requiring hospitalisation. Data will be analysed thematically and the findings used to inform the development of new policy and a proposed care pathway for people with AF detected in the community by emergency services.

# BACKGROUND

Atrial fibrillation (AF) is a common heart rhythm disturbance or arrhythmia (British Heart Foundation, 2022). It causes the heart to beat abnormally and is a significant risk factor for stroke and systemic embolism (Lippi G., 2020). The risk of stroke in people with AF is substantially reduced by them taking blood thinning tablets called oral anticoagulants (OAC) (Hindricks G, 2021). It is estimated that around 400,000 people in England are living with undiagnosed and therefore untreated AF and a subsequent elevated risk of stroke (Public Health England, 2020). Sometimes people do not experience symptoms and their AF gets detected incidentally when having a scheduled examination for other reasons or during a routine check- up (British Heart Foundation, 2022).

Whilst policy exists to detect and treat AF and other vascular risk factors (Hindricks G, 2021), this does not include recommendations on opportunistic detection across the whole healthcare service interface. Traditionally, screening to detect such ‘silent diseases’ is through scheduled contact, or a planned appointment, with a healthcare professional in the primary care setting. However, there may be prolonged periods when risk factors go unrecognised. As stroke affects 100,000 people per year in the UK with a care cost of £26 billion, improving AF identification could bring significant benefits for society. Maximising opportunities for AF detection could facilitate earlier intervention with OAC and reduce the number of avoidable strokes. Prevention of cardiovascular diseases is a priority in the NHS Long Term Plan (NHS, 2019), but policy implementation requires innovative approaches to detect people without symptoms who do not realise they are at risk.

AF can be detected by electrocardiogram (ECG), which is a simple heart trace. Emergency medical services (EMS) attend a population representing all demographic groups and collect rich clinical data on the patients they encounter, including ECG findings. Ambulance crew and paramedics may also encounter patients who do not regularly engage with healthcare either due to a lack of need for healthcare or other barriers (Phung, 2015). Whilst most patients attended by EMS are conveyed to hospital for further medical assessment, investigations and treatment, in the United Kingdom (U.K.) a growing number of patients are treated at the scene by EMS staff. Indeed, 32% of patients attended in June 2021 by EMS in England were not transferred to hospital (NHS England, 2021). On a daily basis, and after thorough review, approximately one-third of patients attended by the North-East Ambulance Service after calling 999 do not require hospital admission. This group provides an opportunity to screen for hidden cardiovascular risk factors. This approach is increasingly important since COVID-19 has reduced primary care screening opportunities.

A recently completed service evaluation by the authors, that looked at the records of patients reviewed at the scene by EMS staff and not transferred to hospital, found that paramedics incidentally identified undiagnosed AF in two such patients per day in North East England (Heppenstall E, 2022 *in press*). The evaluation supports the potential for EMS clinicians to play a role in identifying patients with AF in the community setting who may then benefit from further evaluation and consideration of treatment with OAC. Formalising such opportunities for finding undiagnosed AF during unscheduled contacts with EMS could therefore lead to a subsequent reduction in avoidable strokes. As ambulance services are structured similarly in all regions and cardiovascular illness prevention is a target within the NHS Long Term Plan, the relevance is also national. Expanding this work on a larger scale could bring huge benefits to our understanding of the problem and create meaningful policy to implement relevant care processes.

A core part of the NHS strategy (NHS England) is to ‘make every contact count’ with regard to preventative interventions, but a traditional perspective is that ambulance services provide only a reactive emergency care response. Whilst early work supports the potential for expanding a more formal role of paramedics in identifying undiagnosed and untreated AF during unscheduled ambulance contacts, it is important to understand how service providers and potential service users (i.e. members of the general public) perceive this involvement of EMS in population health by active prevention. Determining the acceptability to key stakeholders of the greater involvement of paramedics in identifying AF in the community is essential for successful uptake and can highlight potential barriers to implementation. Such understanding will inform the development of new policy and a care pathway proposal to identify individuals with previously unrecognised silent risk factors for preventable diseases detected during unscheduled ambulance contact. Once such new policy is introduced further work would be needed to understand service users’ (i.e. patients attended by ambulance services) experience of having AF identified in this way.

**RESEARCH QUESTIONS**

1. How acceptable is the opportunistic identification and diagnosis-sharing of undiagnosed or untreated AF and other relevant vascular risk factors during unscheduled EMS ambulance contacts to service providers and potential service users?
2. What are the barriers and facilitators to implementing a policy of opportunistic identification and diagnosis-sharing of undiagnosed or untreated AF during unscheduled EMS ambulance contacts?

# AIMS AND OBJECTIVES

Aim: The overall aim of this study is to understand how service providers and potential service users perceive the involvement of EMS in formally identifying and disclosing AF and relevant vascular risk factors during unscheduled ambulance contacts in the community.

Objective 1: To explore the acceptability and feasibility of AF and relevant vascular risk factors being identified and disclosed during unscheduled ambulance contacts by paramedics from the perspective of a range of key stakeholders.

Objective 2: To identify potential barriers and facilitators for implementing a policy of identification and diagnosis-sharing of AF by paramedics during unscheduled EMS ambulance contacts.

Outcome: The findings of this study will contribute to the development of new policy and a care pathway proposal to identify and manage individuals with undiagnosed and untreated AF identified during unscheduled ambulance contacts.

# METHODS

Study design

A qualitative methodology, utilising one-to-one semi-structured interviews and focus groups, will be used to capture and develop a detailed understanding of participants’ views on the identification of AF by paramedics during unscheduled ambulance contacts for patients treated at the scene and not transported onwards to hospital. The chosen methods will also facilitate in-depth and iterative exploration of issues arising, salient beliefs and attitudes, and potential barriers and facilitators to successful uptake and implementation of new policy and practice. For economy and efficiency of time, the default approach will be to conduct one-to-one interviews remotely via telephone or a suitable virtual platform (Zoom or Microsoft Teams). In-person interviews will be offered where possible to participants specifically requesting this mode of interaction or who do not have access to the necessary technology. Focus groups will also be held virtually via Zoom or Teams where acceptable and accessible to participants, since this mode enables greater diversity and opportunity for participation of stakeholders from across the North East region of England. Face to face meetings can limit who can attend but this mode will still be used where there is a preference or need (e.g. in the absence of access to technology). With participant permission, each interview and focus group will be audio-recorded. Explicit informed consent to audio-record will be received from every participant before initiation of the research interview. For focus groups participants consent to audio-record will be a necessary condition of participation. Reassurances about confidentiality and anonymity of data will be reiterated to focus group participants before initiation of the group discussion as part of the general ‘ground rules’ and welcome at the outset of the meeting. Where interview participants are not comfortable with audio recording, detailed notes will be taken by the researcher during the interview, again with prior consent of the participant.

Data collection, handling and analysis

Interviews and focus groups will be supported by the use of a topic guide to ensure consistency across interviews and that key topics are discussed. Open-ended questions will be used to maximise the information elicited from participants and to reduce the risk of interviewer/facilitator bias. To account for different experiences, the topic guides will be tailored to each participant group. Audio recordings of the interviews and focus groups will be transcribed verbatim. All transcripts will be fully anonymised, with all personal and identifying details removed to ensure confidentiality. Transcripts will be analysed thematically, following Braun & Clarke (2006) (Braun V, 2006). A predominantly inductive approach will be adopted during analysis, allowing themes to emerge from the data gathered rather than being driven by a prior theoretical basis. It is, however, acknowledged that the interview guide itself, as the basis of emergent data, is grounded in the research aims and thus the analysis will be guided by some predefined concepts. NVivo (V12) software will be used to aid organisation and analysis of the qualitative data, with all transcripts being uploaded to this system to facilitate coding (QSR International Pty Ltd, 2018). All research documentation and data will be stored securely on University password protected computers.

Study setting

The study setting will span the North East Ambulance Service NHS Foundation Trust (NEAS) catchment area which serves Northumberland, Tyne and Wear, County Durham, Darlington and Teesside. Participants will be sampled from community, primary and secondary care settings across this region, reflecting the broad range of stakeholders the proposed change in EMS practice could impact on. However, since the study aims to inform national policy and practice, some stakeholders will be sampled through national professional networks.

Participants

Participants will be from two groups: healthcare service providers and members of the general public (as potential users of emergency services). Sampling reflects the constraints of limited study funding and short timescale. At this stage, achieving diversity of professional perspective in the data set is more important than reaching data saturation. Therefore up to 10 service providers will be sampled across a range of professionals: Ambulance crew (paramedics and non-paramedics), Ambulance service leads, Cardiologists, GPs, Public health leads, Policy makers, and Commissioners. Focus groups facilitate capture of multiple perspectives during a single research contact. Using this method will allow us to sample up to 20 members of the public. Purposive sampling will be used to maximise the diversity of perspectives and participants in each group (Etikan, 2016). Sampling is based on participant characteristics potentially salient to the research topic (e.g. Age, gender, ethnicity, clinical specialty). Though such defining characteristics are relatively few for the current study, sampling in this way for qualitative enquiry helps to promote broader insight and richness to the data collected. Any English-speaking member of the public who is aged 40 or above, and has capacity to give consent will be eligible to take part in the study. Sampling will stop when either the target number of participants or data saturation is reached (Braun V, 2006).

Exclusion criteria (general public): Aged <40 years, non-English speaking, lacking capacity to give consent

Recruitment

Members of the general public will be recruited from local Patient & Public Involvement research registers and networks (e.g. VOICE; Creating Connections), Voluntary, Community and Social Enterprise (VCSE) communication networks (e.g. Connected Voice), and social media platforms (e.g. Facebook and Twitter). Individuals expressing an interest in taking part will be provided with the study Participant Information Leaflet (Appended document #1), given opportunity to ask questions of the researchers and advised to discuss with others before making a decision. Travel expenses to attend face to face focus groups or interviews will be reimbursed. Clinical and front line service providers will be recruited from within NEAS via established communication networks, research webpages and newsletters. Policy makers and commissioners involved in decision making and policy implementation of healthcare policies and services will be identified and recruited via the Integrated Care System, Primary Care Commissioning Service, and NHS Improvement.

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

The study has received a favourable ethical opinion from Newcastle University Research Ethics service (Ref: 21568/2022). For elements of the study protocol that relate to the participation of NHS healthcare staff, Health Research Authority approval will also be sought via the Integrated Research Application System (IRAS), including approval of informed consent forms and other relevant documents e.g. advertisements..

**Patient & Public Involvement**

The full study protocol and all recruitment documentation to be presented to members of the general public has been reviewed for clarity and accessibility by public involvement partners. Established local PPIE research support networks and networked contacts within the North East and North Cumbria region’s voluntary, community and social enterprise (VCSE) sector will support dissemination and promotion of the study and assist in recruiting a diverse sample of members of the public from across the NE of England region. PPIE in the study will be further invited during the collaborative development of a new care pathway for people identified with AF during unscheduled contact with EMS services.

**Data protection and participant confidentiality**

All investigators will comply with the requirements of the General Data Protection Regulation 2018 with regards to the collection, storage, processing and diagnosis-sharing of personal information and will uphold the Act’s core principles.

All research documentation and data will be stored securely on University password protected computers. Any names and addresses which are gathered as part of the research process will be kept electronically in a secure folder with restricted access and separate from all other data relating to the research. All participants will be issued with a code number to ensure that no information can be identified by anyone other than the research team.

In the transcription process, all personal or identifying information will be substituted with pseudonyms to ensure anonymity. Audio recordings will be stored in a secure restricted access computer folder. Recordings will only be listened to by members of the core research team involved in transcription and analysis. Participants will not be identifiable in any documentation or publications relating to or resulting from the research.

Confidentiality would only be broken in the research if a participant discloses something which suggests there is a risk of harm to any individual or where an on-going safeguarding issue is identified. In this case, the issue would be discussed with the participant and then forwarded to the relevant support/safeguarding body.

### Dissemination policy

### The study will be presented at leading pre-hospital care and cardiology conferences, and submitted to a peer-reviewed journal. The findings will form part of a formal report to the funders, and will inform future work aimed at establishing a clinical pathway to optimise the provision of oral anticoagulation to patients with AF identified by EMS.

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# Gantt chart