UNIVERSITY OF LINCOLN

# PROTOCOL

## FULL STUDY TITLE

Community First Responders' role in the current and future rural health and care workforce

## Short Title

Community First Responders' role in current and future rural health

Protocol Version 2.0
Date 04/05/2021

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## SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor's SOPs, and other regulatory requirement(s).

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor

I also confirm that I will make the findings of the study publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

Chief Investigator:

Signature: ..... Date: ...../...../.....

Name: Professor Niro Siriwardena

## STUDY/TRIAL CONTACTS

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| Statistician | *see above |

## FUNDER DETAILS

| FUNDER(S) | FINANCIAL AND NON FINANCIALSUPPORT GIVEN |
|---|---|
| NIHR Health Services and Delivery Research Programme | £481,126.22 |

## STUDY SUMMARY

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| Study Title | Community First Responders' role in the current and future rural health and care workforce (The CFR Study). |
| Study Design | Mixed methods with 5 linked work packages (WPs). |
| Study Participants | Patients/relatives, ambulance staff, GPs, commissioners, Community First Responders (CFRs) and CFR leads (these participants are involved in Work packages 1 and 3). |
| Eligibility Criteria | Patients (and their relatives) who have been attended by a CFR.<br><br>Staff as defined above in study participant list. |
| Planned Sample Size | Work package (WP) 1: Anonymised data from around 50,000 incidents will provide a representative and generalisable sample for the multivariable analysis. Sample size= 13,824 at 90% power and 11,008 at 80% power.<br><br>Work package (WP) 3: 60 interviews comprising approximately: 15-20 interviews of patients (and/or relatives), 15-20 interviews of CFRs/CFR leads and 15-20 interviews ambulance staff, with additional interviews of GPs and/or commissioners (10-15). |
| Study Duration | Participant duration: In work package 3 participants will be approached for a one-off interview lasting 60 minutes for patients and 40 minutes for staff.<br><br>Total study duration: 30 months. |
| Objectives | Work package 1: Describe contribution of CFRs to rural health provision in terms of numbers/timing of calls attended, types of condition and people attended.<br>Work package 2: Evaluate costs, funding sources, and consequences of CFR schemes.<br>Work package 3: Analyse CFR guidelines. Explore stakeholder (patients, relatives, ambulance staff, primary care, commissioners, CFRs and CFR scheme organisers) experiences and perceptions of CFRs' current role and potential for future developments/innovations.<br>Work package 4: Assimilate and integrate data from WPs 1-3.<br>Wok package 5: Prioritise recommendations for future developments/innovations in rural CFR provision through a consensus stakeholder workshop. |


## KEY WORDS

Community first responder, ambulance service, rural health, emergency care

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## LIST OF ABBREVIATIONS

| | |
|---|---|
| AE | Adverse Event |
| CF | Consent Form |
| CI | Chief Investigator |
| CRF | Case Report Form |
| EMAS | East Midlands Ambulance Service |
| EudraCT | European Clinical Trials Database |
| GCP | Good Clinical Practice |
| HRA | Health Research Authority |
| ICF | Informed Consent Form |
| ISF | Investigator Site File (This forms part of the TMF) |
| ISRCTN | International Standard Randomised Controlled Trials Number |
| LIH | Lincoln Institute for Health |
| NHS R&D | National Health Service Research & Development |
| PI | Principal Investigator |
| PIS | Participant Information Sheet |
| REC | Research Ethics Committee |
| SAE | Serious Adverse Event |
| SOP | Standard Operating Procedure |
| TMF | Trial Master File |
| TMG | Trial Management Group |
| TSC | Trial Steering Committee |
| UoL | University of Lincoln |
| WP | Work package |

## STUDY MANAGEMENT

### ROLE OF STUDY SPONSOR AND FUNDER

The sponsor of the study is the University of Lincoln.

The Chief Investigator has overall responsibility for the study and shall oversee all study management. As lead of Lincoln Clinical Trials Unit (LinCTU), the CI will if needed, be able to draw upon the experience and advice of colleagues in LinCTU. Subcontracts will be drawn up between the University of Lincoln and other participating institutions. The CI will have overall responsibility for budget oversight and setting and monitoring progress against a detailed project plan.

### STUDY MANAGEMENT COMMITTEES

**Trial Steering Committee**

A Study Steering Committee will be appointed in line with NIHR HS&DR guidance. It will be led by an independent chair and constituted of independent members, independent patient and public representatives and the chief investigator. The steering committee will provide independent oversight and advice to the Sponsor and the study funders. The committee will meet at least every 6 months.

**Study Steering/Management Group**

A core team will be responsible for the day to day management of the study and will meet at least monthly (more frequently in the early and later stages of the study). Each work package will be led by a co-investigator as identified in the project plan above.

A Project Management Group consisting of the co-applicants and appointed research staff will meet at least monthly for the first six months, then bimonthly for the next six months and subsequently quarterly throughout the project using a combination of face-to-face, video and telephone conference meetings. This group will review and monitor overall project progress against agreed milestones.

This will allow early identification of any barriers to the progress of the study and, if necessary, enable us to plan and execute early interventions to keep the project on track. The group will also serve as a forum for the chief and co-investigators to get peer advice and support, bringing together the strengths of our multi-disciplinary team.

Where necessary, task and finish groups, including PPI advisors will be convened as required to address specific aspects of the study including: planning interviews, deciding how best to approach patients, relatives and staff, designing interview schedules; planning the stakeholder workshop; and dissemination.

## STUDY BACKGROUND and RATIONALE

Community First Responders (CFRs) are members of the public who have received basic health training or off-duty health staff who volunteer to provide first aid, helping ambulance services provide care for people with emergencies, usually immediately life threatening conditions, such as heart attack or cardiac arrest.[1, 2]

CFRs are important for the rural health and care workforce where, because of rurality, it is more difficult to provide or access emergency care within a reasonable time, compared with

urban areas.[2] They do not replace ambulance clinicians, but they do add to the ambulance service's response.[2, 3] CFRs are broadly perceived as positive by ambulance services, CFRs and communities,[2-4] but they vary in the types of emergencies they respond to and what they are trained to do.[2] A recent systematic scoping review, conducted by members of this team, indicated that we need further evidence on how they contribute to rural services, how effective they are and at what cost, how they are perceived by patients and other health workers, and how they could be developed further.[1]

Review of existing evidence

Community First Responder (CFR) schemes have been providing healthcare to rural communities since the 1990s when the Government encouraged ambulance services to make use of voluntary, non-NHS CFR schemes to get help more quickly to people with emergencies in these areas.[2, 5] CFR schemes organise volunteers (both trained lay people and healthcare professionals) to support ambulance services to provide immediate care to people with emergencies.[1]

Numbers of CFR schemes have grown to currently around 2,431 schemes using over 12,000 volunteers. in the United Kingdom.[6] A decade ago they responded to around 2% of calls [2] but this has increased and currently, at least in one regional ambulance service, CFRs respond to a significant proportion (estimated at 10-20% of the most urgent) of calls.[7] CFRs are therefore an increasingly important part of the rural health and care workforce, where in rural compared to urban areas, it is more difficult to provide or access emergency care within a reasonable time.[2] Whilst they do not replace ambulance clinicians, they do add to the ambulance service's response.[2]

CFR schemes operate as independent charities (funded by donations and additional money from health services) working with ambulance services, or as volunteer groups overseen by ambulance services. CFRs complement the work of ambulance services, improving patients' conditions by arriving quickly, recording vital signs (such as pulse, blood pressure or temperature) and performing basic techniques, including reviving people whose heart has stopped (cardiac arrest), before handing care over to ambulance staff.[2, 6]

CFRs are broadly perceived as positive by ambulance services, CFRs and communities.[2- 4] A Delphi study of UK ambulance service chief executives, operational leads and medical directors on future EMS design found high agreement that CFRs, including trained members of the local community, should be trained and fully integrated into EMS system.[8] In participating ambulance trusts, there is a dedicated procedure which streams all incoming 999 calls for signs of critical illness or injury before deciding whether to dispatch a CFR or ambulance. The decision to dispatch the CFR is generally based on a combination of fixed dispatch criteria, clinical decision making of the dispatcher and the availability of a CFR. CFRs vary in the types of emergencies they respond to, what they are trained to do and the equipment they carry; they are classified by ambulance services according to these skills (e.g. in East Midlands Ambulance Service CFRs are classed from level 1 to level 6 with level 1 being lay first aiders and level 6 being highly trained medically responders).[2]

Our team systematically reviewed the international literature on CFRs and found that volunteers were motivated to become CFRs for altruistic reasons, wanted more feedback on their contribution to patient care, and were often confused in the public mind with ambulance staff.[1] We also conducted an interview study of CFRs' experiences with patients and ambulance staff, which also supported these findings.[4] Whereas this study explored experiences and insights of CFRs themselves, the views of other key stakeholders, including

service users (patients and others involved in contacting the ambulance service) and ambulance staff were lacking from this and previous studies.

Despite considerable investment in schemes from the volunteers themselves, donations and contributions from health services, a recent scoping review, conducted by members of this team, identified key unanswered questions: how effective are CFR schemes, how do they achieve anticipated benefits, what do they cost, how are they perceived by service users and healthcare providers, and how they might develop and be improved in future? [1] Innovations and developments currently fall into two main categories. Firstly, innovation from expanding the CFR workforce (e.g. Fire and Rescue Services providing CFR capability). Secondly, innovation in what types of emergencies CFRs attend and the skills they are trained to provide. For example in Lincolnshire CFRs have recently been commissioned to attend older people who fall and are at low risk of injury.

This proposed study will work with key stakeholder professional and public groups to examine the number and types of calls attended by CFRs, treatments given and costs. Through different but complimentary work steams it will also examine, perceptions of patients and relatives, CFRs, ambulance and other providers and commissioners on how CFR schemes work, how well they do this, at what cost and how this could be improved or expanded. This study will provide important evidence on the contribution and costs of CFR schemes to rural health as well as how these services can be optimised or developed further to benefit rural communities.

Why is this research needed now?

a). Health need: This study is important because CFRs comprise a sizeable part of the rural care workforce. The increasing use of and investment in CFR schemes by ambulance services means that it is important to know which patients and conditions they attend, the range of care they provide, the consequences of their input and at what cost, or how provision could be improved for rural communities.[1]

b). Research need/evidence gap: This proposal directly addresses a principal objective of 'HTA Commission 18/19 - Rural health and care workforce' which emphasises the importance of non-healthcare personnel as part of the rural workforce and directly cites our previous research into CFRs [1, 4] highlighting that: further research is required on the effectiveness, outcomes, and costs of CFR schemes; a wider understanding of stakeholder perceptions of CFR and CFR schemes is called for; and the need for ‘ongoing training and support (both technical skills and emotional), clear governance of the scheme, its relationship to ambulance services and the complementarity with ambulance staff response’ is needed. The Five Year Forward View supports greater engagement of communities and volunteers, including CFR schemes, in provision.[9] A consensus of ambulance service leaders has prioritised integration of CFR schemes with ambulance services [8] but further research is urgently needed to understand how this should be done.

c). Provider need: We discussed the proposed research with national groups including the National Ambulance Service First Responder Managers Forum and the National Ambulance Research Steering Group who expressed support for the work. The proposal was also strongly supported by a meeting of the Healthier Ageing PPI group which fed into this proposal. They felt the work was important because of their professional or personal experience of the benefits of CFRs, the difficulties accessing emergency care in rural areas, and a realisation that there may be possibilities to extend this role into other areas. CFR schemes and ambulance leaders

agree that CFRs should be trained and fully integrated into EMS system but research is needed to understand how this should occur.[8]

d). New knowledge: This study will provide important insights into an under-researched area of health care provision in rural areas and will provide important knowledge for ambulance services and CFR schemes on how services can be developed to meet future needs, workforce shortages and the challenges of provision to rural communities.

e). Generalisability and prospects for change: The study will involve 7 of the 10 ambulance services in England and therefore cover most of rural England. Involvement of ambulance services and CFR schemes during the research will increase the chances that the recommendations will be useful and implemented, where feasible to do so, by services.

f). Building on existing work: This proposal builds on our existing work on CFR schemes [2,7] which was highlighted in the commissioning brief. The focus of this proposal on the rural workforce is an area of research need highlighted by this specific call.

## STUDY OBJECTIVES AND PURPOSE

### PURPOSE

We aim to work with PPI and stakeholders throughout to develop recommendations for future innovations in rural CFR provision by investigating current activity, costs of provision, and views of patients, public, CFR schemes and rural care providers.

### PRIMARY OBJECTIVE

We will describe the contribution of CFRs to rural health provision in terms of numbers/timing of calls attended, types of conditions and people attended (Work package 1)

### SECONDARY OBJECTIVE(S)

We will:

- Evaluate the costs, funding sources, and consequences of CFR schemes (Work package 2).
- Explore ambulance/CFR protocols and guidelines (Work package 3a).
- Explore stakeholder (patients, relatives, ambulance staff, primary care, commissioners, CFRs and CFR scheme organisers) experiences and perceptions of CFRs' current role and potential for future developments and innovations. We will also ask CFRs and CFR scheme organisers about challenges and solutions to recruiting, training, retaining CFRs in rural areas and how to ensure governance and accountability for safe, high quality care (Work package 3b).
- Assimilate and integrate data from WP1-3 to develop a list of recommendations for future innovations (Work package 4).
- Prioritise recommendations for future developments/innovations in rural CFR provision through a consensus stakeholder workshop (Work package 5).

## OUTCOME MEASURES/ENDPOINTS

### PRIMARY OUTCOME MEASURE/ENDPOINT

In WP 1 we will analyse data from six (of the seven participating) ambulance services to identify how many people CFRs attended, proportion of ambulance calls attended,

characteristics of people (age, sex, condition) attended, how quickly they attend and what happens to patients when the ambulance arrives.

### SECONDARY ENDPOINTS/OUTCOMES

The cost analyses in WP 2 will enable us to:

- understand the costs of CFR scheme provision.
- describe funding sources for CFR schemes.
- evaluate service value and patient consequences of CFR schemes.

In WP 3 qualitative interviews will enable us to:

- understand ambulance/CFR structures (e.g. guidelines, protocols, personnel, equipment, training) in participating ambulance services.
- explore patients' and relatives' experiences and perceptions of care provided by CFRs
- explore experiences and/or perceptions of ambulance staff, CFRs, CFR scheme organisers, primary care staff and commissioners, on the CFR role, governance of CFR schemes, and the potential for further development and innovation of the CFR role.
- explore the views of CFRs and CFR scheme organisers about challenges and solutions to recruiting, training, retaining CFRs in rural areas.

The assimilation and integration activities in WP 4 will enable us to:

- develop an 'actor-based system map' describing current CFR practice in rural areas together with the structures, processes and relationships of rural CFRs and healthcare providers and staff they interact with
- articulate a change agenda of CFR-related developments and innovations based on expressed problems and possible solutions;
- map the causal pathways, theories of action and theories of change which will increase the likelihood that recommendations for change are implemented.

The consensus workshop in WP 5 will enable us to

- present and discuss recommendations developed in WP4.
- prioritise recommendations for development and innovation using a Nominal Group Technique (NGT).

## STUDY DESIGN

We will use a quantitative cross-sectional study to investigate CFR activity and costs in relation to ambulance services. This will be complimented by a qualitative interview study to explore CFR, patient-public, ambulance service and wider stakeholder experiences and perceptions of CFRs' current role and potential for future development. This work will be followed by a stakeholder consensus workshop to agree recommendations for potential future innovations for the CFR workforce.

### DATA ANALYSIS

WP1:

A research assistant with expertise in statistics will analyse the data from WP1 under the supervision of the main study statistician. We will describe the epidemiology of CFR provision to rural health areas across the following domains:

i) numbers of all calls attended first by a CFR;

ii) the types of conditions and people (age, gender, ethnicity) who are attended;

iii) when and where this takes place (rurality, location at home or elsewhere);

iv) how quickly the CFR attended;

v) how quickly the ambulance response attended and what happened next, i.e. was the patient given further treatment or taken to hospital.

vi) characteristic descriptive statistics tables will be made to allow for group comparisons, taking into account all the above variables

vii) including clinical measurements taken, duration of CFR attendance and all ambulatory times, i.e. call time, arrival time, time spent on scene, handover time to hospital etc. .

viii) summary statistics for demographic characteristics of patients, CFR and ambulance staff will be constructed using appropriate non-parametric statistics.

Statistical models: Multivariable regression models will be developed to determine factors independently associated with CFR attendance (such as clinical condition) and transport to hospital.

We will use the models to investigate and describe whether CFRs have a significant role in reducing the time patients have to wait for a response and ambulance staff spend on scene. Because of potential for bias, which may arise through systematic errors in data collection (and recording), retrieval or analysis, we will seek to minimise bias through:

i) Use of electronic data routinely collected by ambulance staff;

ii) Standardised protocols for data retrieval from each service and database construction

across all study sites; and

iii) Appropriate use of analytic techniques.

Confounding may also lead to errors in conclusions. By using a large representative sample we will be able to mitigate some of the effects of confounding through the use of multilevel multivariable regression analyses. Multiple imputations will be used to account for missing data where there are sufficient data for this technique to be used. Sensitivity analysis will be performed to adjust for unknown confounders.

WP 2:

We will utilise four datasets for the evaluation:

(i) The rurality-informed ambulance trust episode data developed in WP1.

(ii) Primary data collection by questionnaire to a sample of CFR service providers linked to the ambulance services involved will query organisation financial details and volunteer workforce staffing details, such as duty schedules and training development resources.

Costing categories will include: CFR administration, on-duty provision, training and other support.

(iii) An existing secondary dataset collected by us (and which can be used by us for this project) that has been developed from LIVES episode records - LIVES is a third-sector charity CFR provider located in Lincolnshire – in which clinical support given by LIVES CFRs to cardiac arrest patients over a three year period April 2014-March 2017 are recorded. These patient episode data have been exactly linked to ambulance episode and hospital outcome records, enabling tracking of patient outcomes.

(iv) A fourth dataset, now being developed by us (and which will be usable by us for this project), involves rural patients identified by ambulance dispatch call operators to have suffered a minor (non-injury) fall. These episode data and patient follow-up reports are distinguished by the fact that CFRs are dispatched as the initial and sole (where an ambulance clinician is not subsequently requested) provider of first aid support and counselling advice to this group of rural patients.

Data analysis (in order of the datasets listed above):

(i) The indirect economic benefits to an NHS ambulance trust resulting from tasking a CFR to an incident will be established per observed episode as the financial value derived by ambulance services to meeting key performance indicators, such as time to attendance. The comparison will be to the hypothetical scenario of no CFR involvement in that episode. Scenario value estimates will be formed using similar, matched episodes taken from the same dataset but which exclude the use of CFRs.

(ii) We will use descriptive statistics to summarise questionnaire data. Of interest will be the contrast in cost structures across different funding models for CFR service delivery, be it a service that is entirely in-house to an NHS ambulance trust, or outsourced NHS sub-contracting to tenders such as the fire and rescue service or to third-sector providers.

(iii) We will use econometric modelling to develop statistical models of patient outcomes, with hypothesis testing focussing on CFR attendance amongst a suite of other control variables. This will allow us to assess the consequence to patient benefit resulting from the clinical support given by CFRs in a setting of severe emergency.

(iv) Ambulance practice for people classified as having had a minor fall is to assign these low-priority, typically resulting in extended time to attendance to the scene by paramedics. These new data on substitute CFR support will enable us to evaluate an aspect of service redesign for rural patients. We will again use econometric modelling to develop statistical models of patient outcomes, with comparative matching to similar minor fall episodes not involving CFRs.

WP 3:

We will use the Framework approach (with an initial framework based on the main domains covered by the interview schedule (i.e. positive vs negative experiences, facilitators vs barriers, and areas for future innovation and development) to analyse interview data in the following stages:

- familiarisation by listening to the recording and reading transcripts of the interviews in order to list key ideas and recurrent themes;

- identifying a thematic framework by drawing on issues identified from our previous studies as well as views or experiences expressed in the data, providing an initial index of codes and themes;
- indexing by annotating the transcripts with codes, subthemes and themes supported by NVivo;
- charting, by rearranging data according to the appropriate part of the thematic framework to which they relate, to form charts;
- mapping and interpretation by using the charts to define concepts, map the range and nature of themes, as well as interactions and relations between them, to provide rich descriptions and explanations for the findings.
- Where possible we will also compare perspectives of patients, relatives, CFRs and ambulance staff of the same event where a CFR attended, to look for shared or contrasting views.

WP 4:

We will synthesise the quantitative and qualitative data from each site which will enable us to describe an 'actor-based system map' for each setting consisting of current people, structures, processes and relationships between rural CFRs, patients and other health and social care staff and providers in each setting, comparing and contrasting features between the sites.

We will use a number of techniques at the integration stage. At the analysis stage we will use the technique of 'following a thread', employing an iterative approach to compare and explore findings from the QUAN (WP1 and 2) and QUAL (WP3) work packages. Next, we will use a matrix to compare and contrast QUAN and QUAL (documentary information on guidelines, policies and protocols together with interview) data at each ambulance site to gain a whole-case perspective. Finally, we will use triangulation protocol to allow us to list overall findings from QUAL and QUAN work packages to explore whether there is agreement (convergence), related information on a particular issue (complementarity), discrepancy in findings (dissonance) or silence (findings relate only to QUAL or QUAN analysis).

We will articulate a change agenda for the CFR role, based on interview data, describing the health and social care problems identified at each site expressed through the needs and views of patients, staff and other stakeholders. We will also synthesise data describing potential developments and innovations in the CFR role to solve these problems, the conditions which would need to be modified to bring change about, and transformations in structures, processes and relationships which would sustain such changes in the longer term.

Through the integration of data we will also develop possible causal impact pathways, theories of action (pathways and interventions promoting actor-level change) and the theory of change (i.e., the ways in which actor-level changes could lead to systems changes and impacts).

WP 5:

Data analysis is not required in WP 5.

### STUDY SETTING

We will conduct the study in seven rural NHS ambulance trusts which will enable us to cover most of rural England:

- East Midlands Ambulance Service (EMAS)
- West Midlands Ambulance Service (WMAS)
- Yorkshire Ambulance Service (YAS)
- South Central Ambulance Service (SCAS)
- North West Ambulance Service (NWAS)
- South East Coast Ambulance Service (SECAMB)
- South West Ambulance Service Foundation (SWAST)

These NHS Trusts have confirmed their participation and have committed to support the study. London Ambulance Service NHS Trust was not included as it is mainly urban; East of England Ambulance Service and North East Ambulance Service were not included due to a lack of electronic data.

## SELECTION OF PARTICIPANTS

### ELIGIBILITY CRITERIA

Work package 3 will involve the active recruitment of participants for interviews.

Participants will include adult patients, relatives, CFRs and ambulance staff identified from records of patients who have been attended by a CFR in a rural location in the previous six months. Where possible we will interview patients, relatives, CFRs and ambulance staff attending the same event. GPs will be purposively sampled from rural areas of the ambulance services involved plus we will endeavour to interview ambulance service commissioners and CFR leads.

If patient and relative recruitment proves to be difficult, then we will also recruit via social media advertisement.

If ambulance staff and CFR recruitment proves to be difficult then we will also have the option to recruit via internal adverts/emails/social media for each ambulance service involved in the study and their associated CFR schemes.

**Inclusion Criteria**
Adults capable of giving informed consent (above the age of 18 years with no upper age limit).

We will recruit a maximum variation sample of patients (according to age, sex, condition, and ethnicity), ambulance staff (sex, experience, ethnicity and role), CFR (sex, ethnicity, length of experience, skill level) and CFR scheme leads (independent charity and ambulance trust overseen schemes).

**Exclusion Criteria**
We will exclude children and adults who are unable to give informed consent from this study.

London Ambulance Service NHS Trust is not included as it is mainly urban; East of England Ambulance Service and North East Ambulance Service are not included because of lack of electronic data.

## Sampling

Samples are only required for work packages 1 and 3.

WP1:

For East Midlands Ambulance Service NHS Trust (EMAS) we have available data to estimate the numbers of records. For all emergency attendances during one year between April 2018-Mar 2019, CFRs attended 17,919 of 636,211 (3%) calls.

The five other ambulance trusts supplying data to the study have similar numbers of total attendances (i.e. 600,000-750,000) based on national data.

Therefore, we estimate around 100,000 CFR-patient contacts across 6 ambulance trusts in one year. A proportion of these are likely to be rural. Based on analysis of a sample of data from a dataset we have previously analysed our estimate of rurality is that it is a factor in approximately 50% of calls.

Our total available sample for analysis is estimated to be at least 50,000 incidents across 6 ambulance trusts meaning that self-identification of individual patients will not be possible.

WP 3:

We will purposively sample patients, relatives, and ambulance staff identified from records of patients who have been attended by a CFR in a rural location in the previous six months. Where possible we will interview patients, relatives, CFRs and ambulance staff attending the same event. GPs will be purposively sampled from rural areas of the ambulance services involved. We will recruit a maximum variation sample of patients (according to age, sex, condition, and ethnicity), ambulance staff (sex, experience, ethnicity and role), CFR (sex, ethnicity, length of experience, skill level) and CFR scheme leads (independent charity and ambulance trust overseen schemes).

Should patient and relative recruitment prove difficult, then we will also advertise the study via social media.

If ambulance staff and CFR recruitment proves to be difficult, then we will also have the option to recruit ambulance staff, CFRs and CFR leads via internal adverts/emails/social media for each ambulance service involved in the study and their associated CFR schemes.

## Size of sample

WP 1 Sample size:

The sample size for a univariate regression model with uncorrected alpha=5% and 6 predictor variables predictors (call type, clinical condition, age, sex, ethnicity, rurality) with one main outcome (transportation to hospital) and a change in R2=0.001 at 90% power is estimated to be 9472. To account for multiple-test correction we used Bonferroni correction to set alpha at

0.83% for the significance level. This will give a sample size of 13,824 at 90% power and a sample size of 11,008 at 80% power.

Data from around 50,000 incidents will provide a representative and generalisable sample for the multivariable analysis.

One ambulance trust (North West Ambulance Service NHS Trust) are unable to provide electronic data for the study but will be able to participate in other aspects of the research and has therefore been included.

WP 3 Sample size:

We will plan for around 60 interviews comprising approximately 15-20 interviews of patients (and/or relatives), 15-20 interviews of CFRs/CFR leads and 15-20 interviews ambulance staff, with additional interviews of GPs and/or commissioners (10-15) including each of the participating ambulance services. Recruitment will continue until we have completed a total of approximately 60 interviews, continuing to data saturation.

**RECRUITMENT**

WP 1:

In WP 1 we will use anonymised retrospective routine data from the ambulance call-and-dispatch system linked to electronic clinical records made when ambulance staff attend (called patient report forms) from these 6 ambulance services over a period of 12 months. We have already successfully undertaken this procedure in two ambulance services in a recently published study.[9] Data linkage is routinely performed in most of our quantitative studies with all algorithms and programming performed in STATA 14.2.

For the purposes of this study rurality will be defined according to following categories under current UK government definitions [1]: Rural: Town and Fringe (D1), Rural: Town and Fringe in Sparse Setting (D2), Rural: Village (E1), Rural: Village in Sparse Setting (E2), Rural: Hamlets and Isolated Dwellings (F1), Rural: Hamlets and Isolated Dwellings in a Sparse Setting (F2). CFRs attend approximately 20% of cases in one ambulance trust (EMAS unpublished data). We will also link this with data from CFR scheme(s) in at least two ambulance services. We have shown that this is feasible in one ambulance service through a preliminary investigation in EMAS and this is also possible for at least one other ambulance service.

We have agreed with EMAS that as proxy for patient's postcode, incident postcode will be provided as this will ensure that anonymity is preserved and chances of identifying the individual are minimised, furthermore the incident postcode will be erased immediately after the linkage to Rurality and IMD have been performed. To safeguard the data, Research Passports will be obtained for the research lead (ZA) and the new RA to be appointed.

WP 3:

WP 3 is the only package in this study where participants will be actively recruited.

<u>WP 3 Primary recruitment method:</u>

Our primary method of recruitment will be to: purposively sample patients, relatives, and ambulance staff identified from records of patients who have been attended by a CFR in a rural location in the previous six months. Where possible we will interview patients, relatives, CFRs and ambulance staff attending the same event. GPs will be purposively sampled from rural areas of the ambulance services involved. We will recruit a maximum variation sample of patients (according to age, sex, condition, and ethnicity), ambulance staff (sex, experience, ethnicity and role), CFR (sex, ethnicity, length of experience, skill level) and CFR scheme leads (independent charity and ambulance trust overseen schemes).

Ambulance services will assist us with identifying and contacting participants using our primary method of recruitment. Ambulance services will also check in advance with GPs that it is appropriate to contact any participants who are former ambulance service patients. This is to avoid contacting patients who the GP considers are too ill to participate or to avoid inadvertently contacting and potentially causing distress to, relatives of patients who have died.

Any initial approach to patients using the primary method (prior to their consent) will not be made outside the clinical care team. At initial approach all participants will be provided by the ambulance service with an information sheet and consent form about/for the study (either by post or email/online) and invited to contact the research team at university of Lincoln if they have further questions.

On receipt of returned consent forms, a member of the research team will contact potential participants by telephone/letter/email to verify study eligibility, answer any further questions the participants may have and reconfirm informed consent. At this stage the researchers will also schedule a face-to-face or telephone interview at a place and time convenient to the participant.

Under the General Data Protection Regulation (GDPR), East Midlands Ambulance Service NHS Trust (EMAS) is the Data Controller for any personal information it processes. EMAS seeks general consent for sharing anonymised or pseudo-anonymised patient information for research purposes. Patients can withdraw consent for use of data at any time if they change their mind. EMAS always removes any information that may identify individual patients from anonymised or pseudo-anonymised datasets. Accordingly, statistical information, requiring anonymised data, will be used in this study. All other ambulance services will follow similar GDPR practices.

<u>WP 3 Secondary recruitment methods:</u>

We will also have the option to use social media to advertise the study to patients and their relatives as a secondary recruitment method, should recruitment of patients and relatives prove difficult using our primary method outlined above. This will give patients and relatives who are eligible, the opportunity to initiate contact directly with the research team, should they be interested. The social media advert for the study will take interested participants to either an online form or a telephone contact where they can go through an eligibility checklist. The eligibility checklist will check:

- County – to check whether they are in one of the permitted ambulance service areas. If not, they are not eligible.
- That they or their relative have made a call to an ambulance service within the previous 6 months for an emergency where a CFR attended.
- Age (≥ 18 years)

If they meet the eligibility criteria, then they will be asked to provide contact details for a phone call when formal consent will be taken for a telephone interview. A participant information sheet will also be sent to them prior to interview.

We will also have the option to use participating ambulance service and CFR scheme internal adverts/emails/social media to invite CFRs, CFR scheme leads and ambulance staff to take part in interviews.

All study documentation will be provided in English. If needed, ambulance service and translator services will be available where possible to assist with discussion of the trial, the participant information sheets, and consent forms, but the consent forms and information sheets will not be available printed in other languages.

It will be explained to the potential participants that entry into the study is entirely voluntary and that their treatment and care will not be affected by their decision. It will also be explained that they can withdraw at any time but attempts will be made to avoid this occurrence. In the event of their withdrawal it will be explained that their data collected so far may not be erased in accordance with the University's Research Privacy Notice and information given in the Participant Information Sheet and we will seek consent to use the data in the final analyses where appropriate.

**Participant Payment**
Participants will not be paid to participate. All data collection by interviews is to occur in the homes of participants or via telephone, hence, no visits in excess of usual care are expected.

**CONSENT**

All participants shall provide written informed consent. The ICF will be signed and dated by the participant before they enter the study.

Prior to obtaining consent, the participants will be provided with information sheets about the study. The information sheets give contact details for the research team so that the participant has an opportunity to ask any questions they may have concerning study participation (see WP3 recruitment section above).

One copy of the ICF will be kept by the participant and one will be kept by the Investigator.

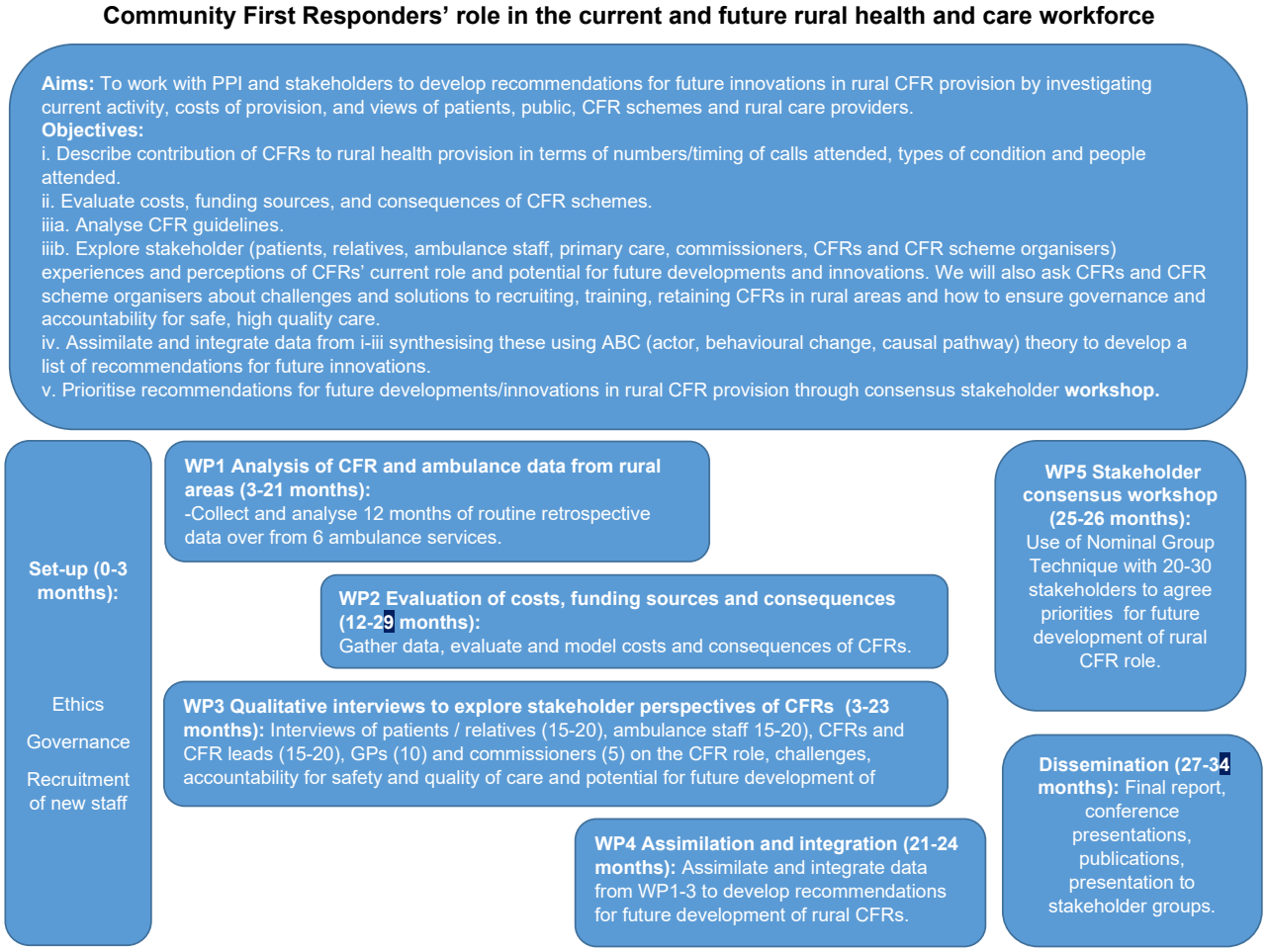
Should there be any subsequent amendment to the final protocol, which might affect a participant's participation in the study, continuing consent will be obtained using an amended Consent form which will be signed by the participant.

Consent will be re-verified by the interviewer prior to commencing the interviews (whether by phone or face to face). At this point participants will also be given another opportunity to ask any questions that they have.

## STUDY PROCEDURES/REGIMEN

**Figure 1 STUDY FLOWCHART**

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3206822/



## RANDOMISATION AND BLINDING

No randomisation or blinding processes are required in this study.

## STUDY REGIMEN

In terms of the timeline, work packages 1 to 3 can run in parallel with some overlap with work package 4. Work package 5 requires completion of earlier work packages as follows:

0. Months 1-3 (set up): Confirmation of research sites, study documents, ethics and governance, approvals, contracts and staffing.

i. Months 3-21: WP1 data analysis. Report at month 21.

ii. Months 12-23: WP2 cost-consequences analysis. Report at month 29.

iii. Months 3-23: WP3 qualitative. Report at month 23.

iv. Month 21-24: WP4 assimilation and integration. Report at month 24.

v. Months 25-26: WP5 stakeholder workshop. Report at month 26.

vi. Months 27-30: Dissemination. Complete final write-up and publications.

vii. Month 30: Submit final project report at month 34.

WP 1 processes:

For WP1 we will include data from April 1 2018-March 31 2019, which postdates the introduction of the Ambulance Response Programme (indicating the change in response time measures) in all sites. Data will be accessed in months 3-5 of the project. Payments for data will be made to ambulance trusts once these are provided and complete.

For WP1 there are two data sources to be extracted and linked: 1) ambulance call-and-dispatch (CAD) system; 2) ambulance electronic clinical record (ECR also termed the patient report form).

There are minor differences in the data fields (for example ‘clinical condition’ across the 6 sites but other data for example relating to timing, call type, age, sex, ethnicity and physiological measures are identical. We have previous and recent experience of extracting and combining data from different ambulance services in three previous studies and have included time for data cleaning.

WP 2 processes:

We will conduct an independent evaluation of the health impacts of volunteer CFR support and associated costs and consequences. CFRs deliver first aider support to patients when dispatched to the scene by ambulance call operators. Incident location is not always an overriding concern, so the correct attribution of CFR costs and patient consequences by categories of rurality will feature prominently in our research. Our design will be a non-randomised comparative study conducted across types of service providers, ambulance services, fire and rescue services and third sector providers, where this is feasible.

WP 3 processes:

We will undertake a content analysis of documents relating to ambulance/CFR structures (e.g. guidelines, protocols, personnel, equipment etc.) in each ambulance service to understand the current structures involved in CFR provision.

We will use qualitative semi-structured interviews to explore stakeholder (patients / relatives, ambulance staff, GPs and commissioners) views and perceptions of CFRs.

Interviews will be conducted face-to-face (or via telephone/skype if this is preferred by the participant), at a mutually agreed time and suitable location to ensure confidentiality is maintained. Interviews will usually last up to 40 minutes for staff, and for patients/relatives, up to an hour. Interviews will be transcribed verbatim, transcripts checked and imported into NVivo version 11 to support data analysis.

Interviews of patients/relatives, CFRs and ambulance staff will be similarly structured to aid comparisons across stakeholder groups and to address:

- Experience of the event - what happened, where, when, who attended, what they did, what happened afterwards, positive or negative aspects of the experience.

- Their reflections on the event – expectations, dilemmas, challenges, values and beliefs

- Facilitators and barriers to positive outcomes and potential for innovation of the CFR role.

### WITHDRAWAL

Participants may be withdrawn from the study either at their own request or at the discretion of the Investigator. The participants will be made aware that this will not affect their future care. Participants will be made aware (via the information sheet and consent form) that should they withdraw the data collected to date may not be erased in accordance with the University's Research Privacy Notice and information given in the Participant Information Sheet and may still be used in the final analysis.

## ETHICAL AND REGULATORY CONSIDERATIONS

### ASSESSMENT AND MANAGEMENT OF RISK

Individual participant medical information obtained as a result of this study are considered confidential and disclosure to third parties is prohibited with the exceptions noted. Medical information may be given to the participant's medical team and all appropriate medical personnel responsible for the participant's welfare.

If information is disclosed during the study that could pose a risk of harm to the participant or others, the researcher will discuss this with the CI and where appropriate report accordingly.

### ADVERSE EVENTS

Due to the nature of this study, no adverse events are anticipated and no adverse event data will be collected.

## ETHICS REVIEW AND COMPLIANCE

The study shall not commence until the study protocol, information sheets and consent forms have been reviewed and approved from a Research Ethics Committee and relevant NHS/Social Care permission is obtained.

The sponsor will be responsible for deciding whether amendments are substantial and non-substantial in collaboration with the Chief Investigator.

Where an amendment is required to study documentation that required REC approval, changes will not be implemented until REC approval and HRA categorisation is received. Where an amendment requires local approval this shall be sought prior to the amendment be implemented at each site in accordance with the categorisation given on the HRA approval letter.

Should an amendment be required to eliminate an apparent immediate hazard to participants this may be implemented immediately and the REC/HRA and R&D will be notified as soon as possible.

Minor amendments for logistical or administrative purposes may be implemented immediately.

Amendments will be logged on the Sponsor's Study Amendment Log and stored in the Trial Master/Site File(s).

Annual Progress Reports shall be submitted to the REC within 30 days of the anniversary date on which the favourable opinion was given – until the end of the study.

A final report shall (where possible) be submitted to the REC within one year after the end of the study.

If the study is terminated prematurely the CI will notify the REC, including the reasons for premature termination.

## PEER REVIEW

This study has been independently reviewed by the NIHR HS&DR programme as part of its review process for awarding funding.

## PUBLIC & PATIENT INVOLVEMENT

Patients and the public have been involved in the development of the original project funding proposal.

Our PPI co-applicants will sit on the study steering group and provide advice on patient facing materials including study information, consent forms, and interview schedules.

The Healthier Ageing Patient and Public Involvement (HAPPI) group will be expanded to include a wider range of people of different ages, ethnicities and gender to support the study as a PPI advisory panel.

Our PPI co-applicants will also comment on the assimilation and integration of data and the recommendations which results from this before they are put forward to the stakeholder workshop.

Members of the HAPPI group will be invited as participants to the stakeholder workshop to help prioritise recommendations.

Training and support will be provided through East Midlands NIHR Research Design Service's PPI Lead and through the East Midlands INVOLVE who have previously provided training for HAPPI and academic members.

PPI members will also support the dissemination of the findings to the lay public through PPI networks and will feed into development infographics such as those we have produced for previous studies (http://communityandhealth.blogs.lincoln.ac.uk/research-impact/).

### PROTOCOL COMPLIANCE

Protocol compliance from a participant's perspective is unlikely to be an issue in this non-interventional study which involves a mixture of participant interviews and retrospective analyses of anonymised datasets.

Accidental protocol deviations may occur at any time. Accidental protocol deviations will be adequately documented on the relevant forms and reported to the Chief Investigator and Sponsor immediately. Deviations from the protocol which are found to frequently recur are not acceptable, these will require immediate action and could potentially be classified as a serious breach.

## DATA PROTECTION AND PATIENT CONFIDENTIALITY

All study staff and investigators will comply with the principles of the Data Protection Act (2018) in protecting the rights of study participants with regards to the collection, storage, processing and disclosure of personal information and will uphold the Act's/Regulations core principles.

Each participant will be assigned a study identity number, for use on study records, other study related documents and the electronic database.

Personal data, research data and the linking code will be stored in separate locations. When stored electronically, this will include using encrypted digital files within password protected folders and storage media. Personal information shall be stored separately to research data and will be kept secure, and maintained.

Personal data will be stored for 5 years following the end of the study, so that the Chief Investigator may provide participants with a summary of the research (should they wish to receive a copy).

Data generated as a result of this study will be available for inspection on request by the participating physicians, the University of Lincoln representatives, the REC, local R&D Departments and the regulatory authorities.

## INDEMNITY

Insurance and indemnity for trial participants and trial staff is covered within the NHS Indemnity Arrangements for clinical negligence claims in the NHS, issued under cover of HSG (96)48. There are no special compensation arrangements, but trial participants may have recourse through the NHS complaints procedures.

The University of Lincoln as research Sponsor indemnifies its staff, research participants and research protocols with both public liability insurance and clinical trials insurance.

### ACCESS TO THE FINAL DATASET

The final datasets for this study will only be accessible to the Chief Investigator, the Health Economist(s), the Statistician(s) and the study research assistants/staff.

## DISSEMINATION POLICY

The data custodian will be the Chief Investigator on behalf of the University of Lincoln.

This study will produce the following outputs:

- A set of prioritised recommendations, implementation guidance and supporting materials.
- Presentations at ambulance services involved, UK and international rural and EMS (e.g. 999EMS Forum conference, European EMS conference) and Health Services Research conferences.
- Publications from each work package in peer reviewed journals.
- Lay summaries of research findings.
- Blogs, infographics and social media (Twitter) to publicise findings more widely.
- A final report to the HS&DR programme board will synthesise the findings of all work packages and set out recommendations for future development of CFR schemes.

**Authorship eligibility guidelines and any intended use of professional writers**

All authors of peer-reviewed articles from this study will meet the four following criteria for authorship in line with The International Committee of Medical Journal Editors: provide substantial contribution to the conception or design of the work, or the acquisition, analysis or interpretation of data for the work; contribute to draft copies of work and revising it critically for important intellectual content; review and approve the final version for publication; and agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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