STUDY PROTOCOL

STRETCHED - STRategies to manage Emergency ambulance Telephone Callers with sustained High needs – an Evaluation using linked Data

VERSION HISTORY

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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.

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 publically 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.

For and on behalf of the Study Sponsor:

Signature: ....

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

Name (please print): ....

Position: ....

Chief Investigator:

Date: 29 05 2019

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STUDY SUMMARY

Ambulance services are assessing how they respond to the small number of people who frequently phone 999 (more than five times a month or 12 times in three months), but usually without a medical problem requiring immediate treatment. Some services have introduced local “case management” initiatives, with referrals to a team from different agencies (social services; primary care (GP); community mental health services; Emergency Departments; ambulance service) that devises individualised ‘treatment plans’, aiming to reduce callers’ contact with emergency services.

We will study: the characteristics of people who call frequently; what is currently being done for them; what helps them to stay well and not need to call 999 or other emergency services; and assess how well case management helps them. Using routinely collected NHS data information for four ambulance services, we will: see if frequent callers have fewer emergency episodes when ‘case management’ is available; gauge the safety of this method; and determine associated costs and savings. We will also interview: patients treated through case management to explore how they feel about this service; and health, social care and other professionals involved in case management to identify operational issues in providing such initiatives.

This study will adhere to the principles outlined in the NHS Research Governance Framework for Health and Social Care (2nd edition). It will be conducted in compliance with the protocol, the Data Protection Act and other regulatory requirements as appropriate.

PPI Involvement

We had strong service user involvement throughout the planning stages for this study. PPI research team members participated in all decisions on study design including primary outcome selection and judgement of meaningful difference between study arms. We will seek to widen PPI links during the study to better reflect the diverse patient population.

Study Title	STRategies to manage Emergency ambulance Telephone Callers with sustained High needs – an Evaluation using linked Data
Study Aims	To evaluate effectiveness, safety and efficiency of case management approaches to the care of people who frequently call the emergency ambulance service; and gain understanding of barriers and facilitators to implementation
Study acronym	STRETCHED
Study Design	A mixed methods evaluation using anonymised linked routine data outcomes in a 'natural experiment' cohort design in four UK ambulance services, with 1 case management intervention site and 1 control site within each service. ***Work Package 1***: Development of a logic model building on national survey of current practice and new models of care to underpin evaluation ***Work Package 2***: Natural experiment evaluation in 4 ambulance services using anonymised routine linked data to describe and assess (i) epidemiology of 'frequent calling'; (ii) effects of new cross-

	sector 'case management' models of care on processes, outcomes, safety. and costs up to 6 months; (iii) and views and experiences of stakeholders regarding acceptability, successes and challenges, from commissioners, emergency and non-acute care providers (interviews/focus groups, n=36) and callers (patient stories, n=32) ***Work Package 3***: Synthesis of quantitative and qualitative findings informed by logic model **Outcomes** ***Primary outcome*****:** Further emergency events (999 calls, ED attendances, emergency admissions to hospital) or death up to 6 months; ***Secondary outcomes*****:** 'frequent caller' declassification and reclassification; costs; safety outcomes; adverse events (such as self-harm incident; police arrests)
Study Participants	Patients included on the ‘frequent callers’ lists within the study sites of the four ambulance services; Healthcare and allied profession staff involved in ‘case management’ implementation in the four intervention sites.
Planned Size of Sample (if applicable)	For the anonymised linked data, n=1264 - we expect to recruit 316 frequent callers per ambulance service For interviews and focus groups, n=68
Follow up duration (if applicable)	6 months
Research Question/Aim(s)	For high 999 service users: What are the demographics, case-mix and patterns of use? What are the costs and effects of case management across the emergency care system? What are the facilitators and barriers to implementation?

STUDY MANAGEMENT COMMITEES & GROUPS

Study Management Group

Alan Watkins	Interim CI; lead for statistical analysis and use of linked data
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Rabeea’h Aslam	Study manager & researcher
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Mr Bob Mcallister	PPI Representative
Mr Alan Brown	PPI representative

1. SUMMARY OF RESEARCH

The NHS is under sustained pressure, particularly in the area of emergency and urgent care, with 999 calls increasing by at least 6% every year [1,2], although fewer than 10% relate to patients with life threatening conditions [2]. All UK ambulance services have identified a clinical and operational problem with a small number of people making high use of the 999 service. This problem has a very high profile in the media and each service now has a lead for 'Frequent Callers'. Various approaches for care of this group of patients are now in place, ranging from ‘within service’ responses to cross-sectoral multi-disciplinary case management approaches [3,4]. These callers often present with complex needs, and some are known to be at high risk of mental health crises including serious self-harm, or other health crises of a varied nature [1,5,6,7]. Usual responses can be punitive – there have been instances of escalation to police involvement and prosecution - and may simply shift unmet demand from one part of the health care system to another, with major resource implications [8].

An evidence base supporting the use of case management as a response to patients who frequently call the emergency 999 service is lacking. We propose to conduct a mixed methods evaluation using anonymised linked routine data outcomes, in a 'natural experiment' cohort design, to evaluate the effectiveness, safety, and efficiency of case management approaches in the care of this group of patients. We will: examine the epidemiology of 'frequent calling', including demographics, casemix and patterns of service use; assess effectiveness, safety and costs of case management; and explore acceptability, successes and challenges to implementation with stakeholders (including commissioners, care providers and patients).

At the outset of the study, we will use the expertise and experience of clinical and lay members of the research team to consider the results of literature review recently completed by a co-applicant (JS) [9] and our national survey of UK practice, to develop a logic model which will underpin this quasi-experimental evaluation.

Based on our survey results we have selected four UK ambulance services where case management models have been implemented in one or more areas within the service (but not everywhere), to examine the impact of case management compared to usual care. In each service, we will have one intervention site and one control site, and we seek to recruit 158 high users of the 999 service at each of the eight sites (n=1264), and expect to obtain outcomes on 95% of these, with the remainder unavailable due to non-matching or dissent. The resultant 600 analysable outcomes per arm allow us to detect (at 5% significance, with at least 90% power) a standardised statistical effect as small as 0.2. For our primary outcome of further emergency events or death within 6 months, we would therefore be able to detect a decrease as low as 10% in the mean number of emergency contacts in six months from 60 per caller in control sites to 54 per caller in intervention sites. We will describe patterns of use, casemix and demographics. We will retrieve anonymised linked routine health data (via NHS Digital in England and NHS Wales Informatics Service in Wales) for patients both six months prior to and for six months after recruitment, to assess outcomes. We will analyse the four components of our composite primary outcome - 999 calls, ED attendances, emergency admissions to hospital, death - individually and cumulatively, according to the hierarchy of severity. We will gather costs of service delivery and of effects on service use. We will undertake qualitative data collection through focus groups and interviews with stakeholders, including ambulance and partner clinical and managerial staff and commissioners to understand issues in implementation. We will also gather patient stories to understand the experience of people who are making high use of the 999 service, and of the care they receive.

We have a strong record of working closely with ambulance services, anonymised routine linked data providers, multi-disciplinary care teams, other stakeholders and patient contributors, and expect to be able to translate findings from this study into real world clinical practice for the benefit of patients who frequently use the 999 service. We will disseminate findings through publication in high impact journals as well as clinical, practitioner, health policy and patient/public networks, such as MIND and Age Concern. We are able to demonstrate national and international impact on policy and practice from previous projects.

2. BACKGROUND AND RATIONALE

Demand on emergency ambulance services is growing at an unsustainable rate [2], with increasing numbers of 999 emergency calls presenting major operational challenges in a time of constrained spending on health care [10,11]. Major national policy reviews in England [12] and in the devolved administrations of the UK [12] have called for a whole systems approach to care with care pathways and protocols to be further developed across unscheduled care, along with greater clinical autonomy and decision making within the ambulance service to reduce unnecessary pressures on ED.

While 999 emergency services remain integral to providing a safety net for those with unplanned urgent and life threatening health conditions, disproportionate use of the service by a minority of patients who frequently call 999 - sometimes almost daily - is a concern [1]. Often their unresolved health or social care needs place undue pressure on the current 999 emergency service, which was designed to respond to patients with time-critical needs for clinical intervention, rather than manage long-term care needs. The volume of 999 calls to ambulance dispatch centres in England has doubled from 4.72 million in 2001/02, to 9 million in 2014/15 [2]. This dramatic rise has not been matched by an equivalent increase in resources. In addition regular media reports describe unsustainable demand for ambulance services with public and political focus on emergency response processes [13]. Operating in this pressured environment, ambulance services are required to focus resources on people with urgent or life threatening conditions [14]. The national target of reaching 75% of Category A (life threatening) calls within eight minutes was not been met for 32 consecutive months in England [15]. Resources for the care of these highest-risk patients are not available when ambulance services are responding to those with chronic and less urgent conditions.

Definitions have varied and terminology is contested [7,16] but ambulance services nationally have agreed that people who make five or more calls per month or 12 calls over a three month period should be classified as ‘frequent callers’. In London alone, 1.7 million emergency calls were received in 2014–15. During this period 1,622 people meeting ‘frequent caller’ criteria generated 49,534 ambulance attendances, at a cost of £4.4 million to the London Ambulance Service (LAS) [2]. A similar story is repeated around the country where many services struggle to meet demand [2,16,17].

Patients who call the 999 ambulance service frequently are often vulnerable patients, [1,5-7,18] who are more likely to:

- be of low socio-economic status
- live alone
- experience mental health problems
- self-harm
- live with chronic conditions
- fall

Repeated calling may be because problems are unresolved or patients are not aware of an alternative, more appropriate pathway to access care [1,7]. Research shows that patients who make use of emergency services frequently experience higher mortality rates than those calling for care less often [19]. Although patients seek to address their problems through the 999 route, without appropriate clinical or care expertise available to resolve their complex needs, they continue to call the emergency service, sometimes repeatedly. As a result, patients remain at high risk of further crises, and further deterioration in their condition can result in the need for resource-intensive, multi-agency intervention or death. With ongoing and potentially deteriorating health, people calling frequently are likely to require multiple, expert intervention from different parts of the NHS and other community-based agencies. At the same time, some patients do not require acute clinical intervention by 999 ambulance or transportation to an ED and could be better cared for at home or by an alternative community-based care provider. The Department of

Health policy documents *'Taking Healthcare to the Patient'* [12] and the Keogh report [11] encourage the establishment of alternatives to transportation to hospital for 999 ambulance patients, although uncertainties remain about how to achieve this safely and effectively.

Given the policy drive towards patient centred care [11,12,20], and mirroring initiatives in primary care to incentivise the prioritisation of care of frail older patients who are at risk of emergency admission to hospital [5], commissioners now require ambulance services to have management strategies in place for people who call frequently [3,4]. While some new whole system management approaches have emerged, on the whole the aim has been to prevent people calling 999. Interventions have sometimes been punitive in nature, even occasionally pursuing criminal sanctions [21], despite the multifactorial influences of socio-economic deprivation and health inequalities which influence these callers' health seeking behaviour.

A number of ambulance services have developed initiatives to manage patients who call 999 frequently, although approaches can vary across services. We recently completed a survey of practice by email and telephone through designated 'Frequent Caller' leads. We received responses from 12 of 13 UK ambulance services. All ambulance services compile a list of patients meeting the criteria for classification as 'Frequent caller' who are flagged on the ambulance dispatch system but subsequent responses to patients vary. Eight services reported that they had implemented cross-sector multi-disciplinary case management models in at least one area within the service, with two services reported that case management was in place across the entire service area. There was variation in the consistency of approach across services. A recent review of strategies to manage repeat users of the 999 service across the London Ambulance Service described three models of care which are in current use [22]. A 'Hear and Treat' approach is used in the ambulance call centre for callers who are assessed as not needing an emergency ambulance response. Call takers or clinical advisors in the call centre utilise protocols and local directories of services to advise self-care or to identify referral pathways for patients, if immediate ambulance support is deemed not to be required. Provision of telephone advice or referral for 999 callers without immediate clinical needs can be safe and effective [23], although the evidence base does not extend to patients who call frequently. 'See and Treat' models of care require face to face assessment by an emergency ambulance responder, who is able to discharge the patient at the scene of their emergency call without conveyance to ED. There is considerable policy support for such initiatives and a growing body of evidence supporting the safety, clinical and cost effectiveness of this approach [24,25,26,27,28,29,30]. However, people who are calling frequently may have complex medical histories and social backgrounds which can be challenging to manage in the emergency prehospital care setting 31,32].

In areas where case management approaches are in place, comprehensive care plans are developed for patients who are calling the 999 service frequently, through multi-disciplinary, cross-sector 'frequent caller' management groups or forums. The approach sets out to identify, share and manage patients collaboratively. Key decision makers from commissioning, acute, primary, secondary and charitable health and social care providers meet with ambulance service staff to share, stratify and manage patients in regular Multi-Disciplinary Team (MDT) meetings. The introduction of case management has the potential to support a change to safe and equitable out of hospital care for this patient group, and to avoid patients being shifted to another part of the emergency care system or NHS without their care needs being addressed. Some preliminary research related to this patient group reported significant reductions in calling following the introduction of case management in one area of London, although the sample size was small (n = 110) and the study design was a before and after comparison with no control group [1].

Findings from the STRETCHED study will support policy and practice related to whether or not a case management approach to care for people who use the 999 service frequently should be implemented. The additional use of linked data throughout the course of this study provides the potential to develop a holistic picture of service use in areas where multi- disciplinary case management is practised compared to areas where standard 'within-service' management is in place. The findings from the proposed evaluation will inform future service provision which is closely aligned to the current policy agenda. The NHS England Five Year Forward View report

[33] indicates the high priority given by those working in the NHS to improving the care of patients who access ED repeatedly.

National policy across the UK has encouraged patient centred care and called for greater integration of emergency ambulance care with other parts of health and social care provision, but this has proved to be complex and challenging. The introduction of case management into emergency ambulance care is part of a wider movement to improve patient experience as well as reduce the care burden in acute care. Internationally, evidence indicates improved patient care and service delivery where case management has been used in ED settings [34]. Our research will build on this knowledge to improve our understanding of service needs of those patients who call the 999 service frequently. The in-depth insights generated will benefit ambulance service commissioners to implement evidence based practice for patient benefit. Conducting this research across the UK, with its diverse organisational structures for the NHS, maximises the transferability of learning beyond any one specific healthcare system and increases relevance internationally. The research will also continue to build our capacity for research and academic links between ambulance services and universities, and patient and public involvement, ensuring that the NHS continues at the forefront of the World Health Organisation (WHO) agenda of investing in public and community based services to improve patient experience [35].

Our research team is experienced in experimental and quasi experimental evaluation methods, particularly in pre-hospital and emergency contexts, as well as the use of anonymised linked data to measure outcomes. The team benefits from strong and long standing collaboration with ambulance service partners and patients and is designed to make an immediate contribution to the delivery of emergency care affecting this group of patients. We also have established links with police and social care agencies.

3. EVIDENCE EXPLAINING WHY THIS RESEARCH IS NEEDED NOW

Ambulance services are under immense pressure to maintain a high quality and efficient service in the face of growing call numbers and patient expectations. With demand rising quickly, failure to act promptly by investigating how efficiencies can be made is likely to increase these pressures further still. Managers cannot afford to waste resources and have a range of priorities that sometimes conflict: to effectively treat each patient; ensure best possible health outcomes and patient experience; and use resources optimally across the population. Pre-hospital emergency care remains an under-researched area, with a deficit in evidence relating to the establishment of effective ambulance responses offering a safe alternative to transportation to hospital [36].

People who frequently call 999 may be vulnerable and unable to access more appropriate services, such as primary care. They seek help through the 999 route because available services do not meet their complex needs. However, this route to help seeking is often unsuccessful and inefficient, for them individually and for the NHS. This has consequences also for other patients who do not get the speedy response required when in urgent need as resources are tied up with patients who do not need acute care. Multi-disciplinary case management approaches may reduce demand on emergency services and emergency hospital admissions because people are effectively treated [37,38,39]. However, these initiatives are not based on any rigorous evidence of what works most effectively for this patient group. There is currently inadequate evidence to inform commissioning, policy or practice development [16]. While these approaches are still innovative and diverse and multi-agency interest in this work is strong, this is a unique opportunity to undertake a natural experiment to learn how to successfully respond to patients who frequently call 999. Our study will provide evidence about case mix, clinical and cost effectiveness, safety, effects on patient experience, optimum configuration of intervention and challenges in cross sector working.

Our proposed research builds directly on previous work by members of the research team which evaluated other models of care designed to appropriately manage high demand: the programme of high-impact research led by HS on alternative out of hospital pathways; and the recently completed NIHR HTA funded study of fall referral pathways for use by ambulance service, SAFER 2 [24, 25].

Community-based services tend to be complicated in terms of organisational interfaces, which represent an area of challenge for new systems. Past research that focussed primarily on frequent attendees at ED and their management through case management has some relevance to the pre-hospital context. However, research is needed to examine healthcare in the pre-hospital emergency context and away from the consulting room. By evaluating models of care within ambulance services to look after people in complex emergency situations, this research will be the first of its kind.

The proposed study is highly relevant to current developments as articulated in the Bradley Report, '*Taking Healthcare to the Patient'* [12] to increase care delivered directly by ambulance services (termed 'see and treat') and referral to alternative community providers ('treat and refer'). Comparing models of care across four ambulance services in England and Wales with diverse NHS organisational structures will offer insights into the role of ambulance services in generating greater autonomy for clinical decision making and healthcare delivered in the community.

The research is timely in that ambulance services across the UK are at various stages of implementing management protocols for the care of patients who call the 999 service repeatedly [3,4,22]. Media attention is high, with extreme cases having been publicised widely in the press and in television documentaries. A major push has come with the publication of the *Five Year Forward View* [33] encouraging improvements to pre-hospital patient care to reduce pressures in ED. Ambulance services need evidence about appropriate models of care to enhance effectiveness, efficiency and safety of patient care, while improving service users' experience.

4. AIMS AND OBJECTIVES

Research Aim: To evaluate effectiveness, safety, and efficiency of case management approaches to the care of people who frequently call the emergency ambulance service; and gain an understanding of barriers and facilitators to implementation.

Research Objectives:

1. Develop an understanding of predicted mechanisms of change to underpin evaluation
2. Describe epidemiology of sustained high users of 999 services
3. Evaluate case management approaches to the care of people who call the 999 ambulance service frequently in terms of:
    - further emergency contacts (999, Emergency Department, emergency admissions to hospital)
    - effects on other services
    - adverse events (deaths; injuries; serious medical emergencies; police arrests)
    - costs of intervention and care
    - patient experience of care
4. Identify challenges and opportunities associated with using case management models, including features associated with success, and develop theories about how case management works in this population

5. METHODS

Overall study design

We propose a mixed methods 'natural experiment' evaluation, appropriate in the context of policy and operational priority, where new models of care have already been implemented in some areas of the UK, but rather patchily, with other areas still providing standard, 'within-service list, flagging, and call back' model of care. We will use anonymised linked routine outcomes and qualitative data in three UK ambulance services with one intervention and one control site in each service.

Work package 1: Development of logic model to underpin evaluation

Research question: What are the predicted mechanisms of change of multi-disciplinary, cross-sectoral 'case management' approaches to the management of people who call 999 frequently over a sustained period?
Method: Development of a logic model in consultation with stakeholders during face to face workshop meeting, using literature review and national survey results, to underpin evaluation and inform data collection, in particular, finalisation of outcome selection. Figure 1 shows an emergent logic model developed for this proposal, to demonstrate its purpose – this draft will be used as a basis for discussion and development during WP1.

Work package 2: Natural experiment evaluation
Research questions: 1) What are the patterns of service use, demographic profiles and casemix of people who make sustained high use of the 999 service? 2) What are the costs, effects, challenges and facilitators associated with implementation of case management approaches to the care of people who call 999 frequently over a sustained period? 3) What are the views and experiences of people who have been classified as frequent caller in areas where a cross-service case management model of care is in place?
Methods: Evaluation using a natural experiment cohort design in four ambulance services

- anonymised linked routine data to describe epidemiology and assess effects on processes, outcomes, safety and costs of interventions and care up to six months, with adjustment for covariates including prior service use
- qualitative data from focus groups and interviews in each intervention site about the views and experiences of stakeholders regarding acceptability, successes and challenges (commissioners, emergency and non-acute health and social care providers) of case management approaches for this group of patients; and patient stories to gather in-depth data from a range of people within the target population

Work package 3: Synthesis of quantitative and qualitative findings
Research question: what are the implications of our findings for the provision of care and policy concerning the management of people who call 999 frequently?
Methods: Synthesis of quantitative and qualitative findings from WPs 1 and 2, informed by the logic model developed in WP3 and in consultation with stakeholders included in the research team. The quantitative and qualitative elements of this study will be managed and co-ordinated centrally as well as locally. We will draft and agree overarching analysis plans for quantitative, health economics and qualitative data. We will use the logic model to inform the synthesis of results which will be considered and interpreted at a joint meeting of the Research Management and Research Advisory Groups. Quantitative data will be used to draw conclusions about comparative costs and effects; qualitative data will help us to understand and interpret these results, and to generate theories about how the new models of care are working and any limitations to their impact [39].

Setting/context and sampling

We have invited ambulance services identified as eligible through our recent national survey to participate in the evaluation. Characteristics of sites to be included - Welsh Ambulance Service (WAST), East of England Ambulance Service (EEAST), West Midlands Ambulance Service (WMAS) and London Ambulance Service (LAS) - are summarised in Table 1.

Each participating service has agreed to provide data on people who call frequently, using nationally agreed definitions. Frequent callers will be recruited sequentially as the sites' 'frequent callers' lists are updated on a monthly basis. – this requires episode linkage within the service, which can be a resource intensive task for services whose information systems are not set up to do this (where call information is stored by telephone number and address of incident rather than patient identifying details). Each service will provide these data to NHS Digital in England and NHS Wales Informatics Service (NWIS) in Wales using the approved split file approach, whereby identifying details are separated from clinical information, for anonymised linkage to existing Emergency Department, inpatient and ONS datasets.

We will recruit 32 patients for patient story qualitative interviews (8 patients per intervention site) using a sampling strategy which aims to ensure that we talk to people with a mix of ages, gender, call frequency category, and primary presenting reason for calling. We will sample from people whose name appears on the frequent caller lists at any time between June 2020 to May 2021. Our research paramedics will work with providers of case management in each of the four ambulance service sites to select patients for invitation to interview in line with our sampling strategy and to exclude anyone they think would find participation in the study distressing. The providers will approach patients and invite them to take part in the interview and provide them with an information sheet and consent forms. We will only receive contact information for those who agree to take part.

A similar sampling strategy, using gender, age, and length of employment, will be used to recruit 32 stakeholders - front line staff (paramedics, call handlers), partner health and social care providers, commissioners and managers - to participate in interviews.

Table 1: Sites within participating services and key features of control (usual) and intervention (case management) site care

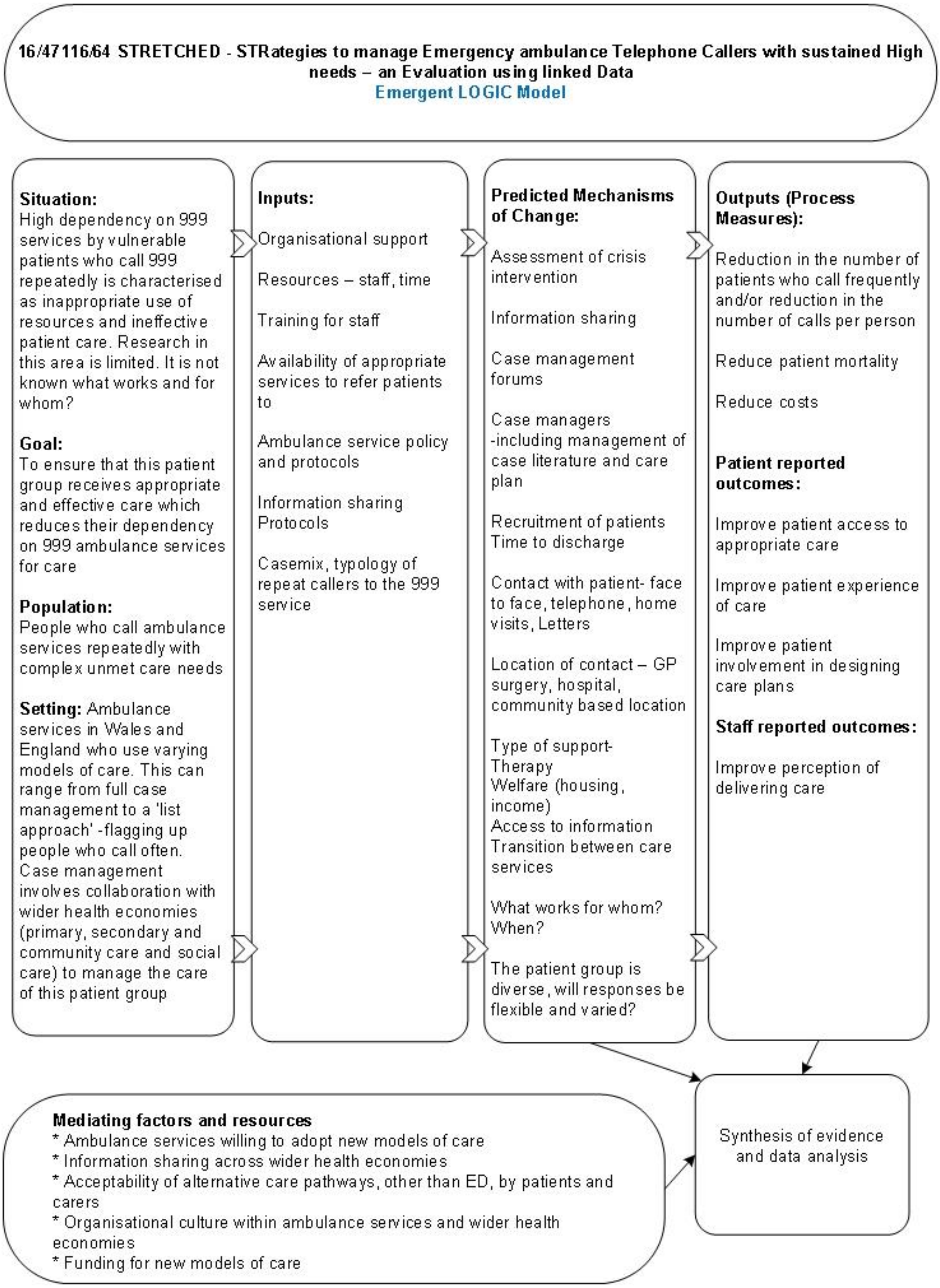
	Control site: Usual care	Intervention site: New model of care
Care models: generic description	Aim: to reduce or stop people from calling 999 Within-service management ○ Letter sent to GP and patient ○ Callers flagged, care management plan developed for use in ambulance call centre to triage patient when call comes in ○ Contact may be made with other services to intervene ○ Police action may be requested	Aim: to reduce emergency contacts by addressing complex patient needs Multi-Disciplinary Team cross-sector case management Usual care plus ○ Dedicated frequent caller nurse/prehospital care practitioner funded by CCG/HB Multidisciplinary team meetings attended by ambulance service; partnership approach with other agencies including district nursing, social workers, police, out of hours providers, mental health professionals, ED, voluntary sector, NHS 111, GPs and Occupational Therapy to develop and share joint care plans to address patient need
WAST	Aneurin Bevin Health Board	Cardiff and Vale Health Board
EEAST	West Essex CCG	North East Essex CCG
WMAS	Wolverhampton CCG	Birmingham & Solihull CCG
LAS	Barnet CCG	Lewisham CCG

Data collection

We will use a parallel cohort ‘natural experiment’ study design to determine effects on processes and outcomes of care, using anonymised linked data from NHS Digital and the NHS Wales Informatics Service (NWIS). We will use a natural experiment design because case management interventions have already been introduced (not for the purposes of research) but the variation in exposure and outcomes will allow us to carry out analysis to link effects to intervention i.e. causes [40]. We have successfully used linked data outcomes in prehospital care studies, including an evaluation of referral to falls services by paramedics funded by the NIHR Health Technology Assessment programme [25]. We will finalise data items following completion of the logic model but expect to include (up to six months): further 999 calls, ED attendances, emergency admissions, and deaths; declassification or reclassification as ‘frequent caller’; costs; and details of demographics, casemix and patterns of calls e.g. out of hours. Historical data about prior service use will allow us to adjust analyses for differences between cohorts, strengthening this study design.

To explore views concerning successes and challenges related to the new approaches to case management of high 999 service users; we will collect qualitative data at the intervention site within each participating ambulance service to explore perceptions of how the intervention works, what creates its effect (if any), why it might function differently in different settings and for different groups of people and any challenges to implementation and delivery of the intervention. We will conduct 32 patient interviews with people who have received case management or are eligible for it and four focus groups (supplement these with online, or telephone interviews) with stakeholders – including front line staff (paramedics, call handlers), partner health and social care providers, commissioners and managers (n=36). Questions will cover care management delivery processes, barriers and facilitators to changed working, perceived impact for patients, issues around diversity and terminology, strengths and weaknesses of the approach and wider organisational impact across health economies, such as information sharing, communication and continuity of care.

Figure 1: Emergent STRETCHED logic model



16/47116/64 STRETCHED - STRategies to manage Emergency ambulance Telephone Callers with sustained High needs – an Evaluation using linked Data
Emergent LOGIC Model

Situation:
High dependency on 999 services by vulnerable patients who call 999 repeatedly is characterised as inappropriate use of resources and ineffective patient care. Research in this area is limited. It is not known what works and for whom?

Goal:
To ensure that this patient group receives appropriate and effective care which reduces their dependency on 999 ambulance services for care

Population:
People who call ambulance services repeatedly with complex unmet care needs

Setting: Ambulance services in Wales and England who use varying models of care. This can range from full case management to a 'list approach' -flagging up people who call often. Case management involves collaboration with wider health economies (primary, secondary and community care and social care) to manage the care of this patient group

Inputs:

Organisational support

Resources – staff, time

Training for staff

Availability of appropriate services to refer patients to

Ambulance service policy and protocols

Information sharing Protocols

Casemix, typology of repeat callers to the 999 service

Predicted Mechanisms of Change:

Assessment of crisis intervention

Information sharing

Case management forums

Case managers
-including management of case literature and care plan

Recruitment of patients
Time to discharge

Contact with patient- face to face, telephone, home visits, Letters

Location of contact – GP surgery, hospital, community based location

Type of support-
Therapy
Welfare (housing, income)
Access to information
Transition between care services

What works for whom?
When?

The patient group is diverse, will responses be flexible and varied?

Outputs (Process Measures):

Reduction in the number of patients who call frequently and/or reduction in the number of calls per person

Reduce patient mortality

Reduce costs

Patient reported outcomes:

Improve patient access to appropriate care

Improve patient experience of care

Improve patient involvement in designing care plans

Staff reported outcomes:

Improve perception of delivering care

Mediating factors and resources
* Ambulance services willing to adopt new models of care
* Information sharing across wider health economies
* Acceptability of alternative care pathways, other than ED, by patients and carers
* Organisational culture within ambulance services and wider health economies
* Funding for new models of care

Synthesis of evidence and data analysis

To ensure we gain a strong picture of patient experience and circumstances we will also conduct 'patient story' interviews with people in intervention areas of each service who are referred for case management (n=32). We will use this method to provide an opportunity for patients to provide their own narrative about their circumstances, experiences and views regarding their need, service use and care received, including terminology (labels) used. We will work with participating services to identify and invite callers to this key patient-focused element of the study. We will sample purposively in order to include a wide range of views and experiences, and select individuals with differing demographic characteristics, length of time they have required care and management approach provided for them to include typical and atypical patient stories. We will gather eight patient stories per site. We will aim to include patients from ethnic minority groups, under the guidance of our study manager and diversity lead, Ashra Khanom. With respondents' consent, we will tape record and transcribe all individual and group interviews.

Data analysis

Work Package 2: Effectiveness analyses

We will be able to provide NHS Digital and NWIS with high quality information on our patients, which will facilitate high levels of matching to anonymised data from multiple sources; and to specify with precision the data items identified during the development of the logic model. We will create a single integrated study database for analysis within the Secure Anonymised Information Linkage (SAIL) Gateway.

We will summarise patient recruitment via a CONSORT flowchart [41], and will provide descriptive data summaries for patients, by service and by site. These summaries will cover (a) patient characteristics such as age, gender and ethnicity; (b) call characteristics reflecting time of day, day of week; (c) numbers of events, including further emergency contacts. Numbers of events will be dichotomised where contextually useful (for instance, to declassify or reclassify callers), and converted to rates when appropriate.

Our primary analyses will be by treatment allocated, so that patients meeting the criteria for 'frequent caller' status in an intervention (case management) site will be included in analysis in that arm of the study whether or not they were offered or received any intervention. The outcome measure time point will be six months from a patient's first appearance on a monthly update to the frequent callers list. This will apply to patients at control sites as well as at intervention sites. This time point is appropriate to allow us to detect any effect, as case management is a targeted, time limited intervention designed to work within six months,

We will use multilevel generalised mixed linear models to obtain adjusted comparison of outcomes in patients at intervention sites versus those in patients receiving usual care at control sites. Using linked routine data will allow us to gather retrospective data on service use for callers included in each cohort, strengthening our comparisons by enabling adjustment for historical and contemporaneous differences in service use, casemix, and demographics. Reflecting an initial focus on comparing (any) case management approach with the service list approach, coding for sites will initially assume that outcomes under usual care are similar across ambulance services, as are outcomes at intervention sites. However, we will use background information on the service interventions, the descriptive summaries and formal testing, based on flexible and nested site coding, to test and modify this assumption, as appropriate – for instance, allowing intervention outcomes to vary systematically from service to service. The precise form of models will reflect the nature of the variable under consideration (logistic models for binary variables; negative binomial models for count variables; linear models for raw and transformed measurement outcomes, including rates); the multilevel element of the model will reflect the geographical clustering of sites within services. The adjusted comparisons will incorporate information on covariates and factors based on demographic and case-mix data. We will formalise these analyses in a Statistical Analysis Plan, using the relevant Swansea Trials Unit Standard Operating Procedure, which will detail conventions on model fitting (including inclusion and exclusion rules for covariates and factors), management of missing data, and the reporting of outcomes.

Health Economics

We will undertake a cost-benefit analysis, from the perspective of the public sector, to capture resource utilisation and value for money across health and social care; including primary and secondary care (999 calls, ED attendances, emergency hospital admissions), and mental health and social services contacts, thereby covering a wide range of scenarios. Detailed costs on health and social care services will be obtained from the Personal Social Services Research Unit (PSSRU; pssru.ac.uk); their databases also cover NHS reference costs of selected mental health services. This evaluation will have two components: the estimation of costs incurred in implementing case management approaches; and the estimation of costs associated with 999 calls by frequent callers.

We will assess costs of case management approaches by detailed analyses of all relevant elements, through discussion with relevant staff and observation of their operational processes and procedures. Each element will be costed using appropriate unit costs, derived from published sources and/or consultation with relevant finance staff.

We will determine the costs associated with a sample of the 999 calls in each study area, by identifying staff inputs, along with materials, equipment, therapies, etc. utilised in responding to the call and the processes involved in its management and completion. A cost profile for 999 calls will be developed for each of geographical area, and summarised as cost per 999 call. The utilisation of other health services by frequent callers will be captured by routine data sources, and appropriate unit costs obtained from published sources. Routine data on contacts with social care and mental health services is increasingly available, with on-going improvements in both coverage and quality of these datasets. Subject to data quality validation, we will use all available routinely collected data using appropriate Client Service Receipt Inventories, such as the generic UK mental health CSRI, as a data items checklist.

Routine data on ED attendances and hospital admissions are readily available within NHS digital (England) and the SAIL databank (Wales); currently, ambulance service data is not, so we will obtain data on further 999 calls for study participants from the ambulance services. The overall resource implications for case management approaches for frequent callers will include costs of 999 calls (using derived unit costs) and of utilisation of other services. Expressed in monetary terms, the benefits - ‘expenditure avoided’ – of changes in call volumes and in service resource utilisation will be compared with the costs of case management implementation to assess the rate of return on investment.

We will consider models to describe changes in service utilisation over time, using changes in volume of calls and their occurrence. Our cost-benefit analysis will include net present value and internal rate of return estimates to assess the relative value for money of case management approaches in managing frequent callers of ambulance 999 services and whether the cost of case management services are shared across organisations. A series of sensitivity analyses will be undertaken to estimate the effect of parameter variation on baseline findings and to determine the extent to which case management of these callers is an efficient use of public funds.

Qualitative analysis

The primary aim of our qualitative research is to gain an understanding and to develop theories about how case management works in this population, what creates its effect and what helps or hinders its implementation. Analysis of focus group, telephone and patient story (unstructured) interview transcripts will be carried out by three members of the research team (BAE, AP and AK) and two Public and Patient Involvement (PPI) contributors (PG and BE) with experience in qualitative research (with further in-house training available if needed). We will remove all identifiable data from interview transcripts and assign a participant number for identification. We will use data-driven thematic approach to analysis which generates themes from the implicit and explicit ideas within participants' accounts [42]. We will follow the six stages of analysis described by Braun and Clarke [43]: data familiarisation, generating initial coding, searching for themes, reviewing themes, defining and naming themes, producing a report. One researcher (AP) will lead analysis with up to two other researchers and PPI contributors working independently supporting key stages of coding, generating themes, interpretation and encouraging a critical stance to test and confirm findings [44,45,46].

The team will meet at regular intervals to discuss, make comparisons and observe synergy between datasets. Analysis of the large volume of data (transcripts, field and observation notes) generated by the interviews will be supported by use of NVivo, computer assisted qualitative data analysis software.

We will assess data saturation [42,46] following analysis of focus groups and patient story interviews to see whether new themes are emerging by reviewing the codebook (the working document that records updates in changes to codes). We will also assess whether we have got an adequate range of participants reflected in our purposive sample. On the basis of this, and for each sub-set of participants, we will make a decision whether or not to continue interviewing additional participants to ensure full data saturation.

Work package 3

Synthesis and reporting of quantitative and qualitative findings will be informed by the STRETCHED logic model. Quantitative data will be used to draw conclusions about comparative costs and effects; qualitative data will help us to understand and interpret these results, and to generate theories about how the new models of care are working. We will bring together key themes from across all the work packages on the effectiveness, attitudes, barriers and facilitators to case management. We will interpret overall effectiveness and cost effectiveness results in the light of analysis from the qualitative data about which components of case management e.g. care plan, timing of interventions, shared decision making are perceived to work well and for whom. We will use the logic model to inform the synthesis of results which will be considered and interpreted at a joint meeting of the Research Management and Research Advisory Groups.

6. DISSEMINATION AND PROJECTED OUTPUTS

Our dissemination approach will seek to maximise stakeholder interest and understanding of the study and its outputs and maximise the impact of the findings on ambulance service policy, processes, practice and patients. It will build on the team's profile and reputation with previous studies focused on improving the quality of pre-hospital care. At an early stage we will work with our PPI contributors and co-applicants to develop a communications, publications and dissemination plan including the assessment of stakeholder needs and communications activities and milestones. The plan will include engagement with patient and professional groups, NHS managers, commissioners and policy makers. We will produce lay summaries where appropriate. Key audience groups for dissemination will include policy-makers on emergency care, care-commissioning bodies and ambulance service providers, emergency-care practitioners and the general public. The primary focus of our dissemination efforts will reflect the importance of communicating findings regarding the effectiveness or otherwise of case management approaches for people who make high use of the 999 ambulance service to relevant policy makers and to the bodies that implement policy. We will exploit our existing links with UK ambulance services; we have already engaged with FreCANN (the Frequent Caller National Network; two members are co-applicants), and we will, at an early stage in the study, present initial findings to the wider FreCANN network, seeking their input on identifying key messages which can then inform policy and practice.

We will use our strong links with ambulance services directly and through national bodies (National Ambulance Research Steering Group (NARGS), National Ambulance Services Clinical Quality Group (NASCQG), Association of Ambulance Chief Executives (AACE) and National Ambulance Services Medical Directors (NASMeD). We will further strengthen these links by making contributions to the annual Ambulance Leadership Forum (organised by AACE). We will also liaise with NHS England, clinical commissioning boards (CCGs) in England and Health Boards in Wales, Scotland and Northern Ireland; local authorities; social services and care/nursing home representatives to ensure findings can inform practice at a local community level. This is particularly relevant, as community level services often share with ambulance services patients who frequently call 999.

We will collate feedback from these targeted dissemination activities, and identify the most appropriate means of further disseminating key findings to front-line ambulance service staff – for instance, through contributions to internal ambulance boards, service briefings and bulletins, and practitioner/professional publications. We anticipate our dissemination plan will ensure outputs, and recommendations are clearly communicated to inform future practice.

Our communications, publications and dissemination plan will also contain media engagement, to include written press coverage, online media, and social networking, with the support of the dedicated marketing team in Swansea University Medical School. Given the implications for practice, policy and research we will disseminate findings through the annual 999 EMS Research Forum Emergency Care Conference http://www.999emsresearch.co.uk/en/, which is hosted each year by a UK Ambulance service and is administered by Swansea University PRIME Research Network for Unscheduled Care and brings together academics and practitioners. In addition to a full final study report, we will produce a summary version to be disseminated through the PRIME network. We will also present findings at other appropriate national and international events, such as the Health Services Research Network annual conference, the International Forum for Quality in Healthcare and the European Society for Emergency Medicine. We will ensure that the wider learning from the study (i.e. lessons which are not specific to emergency care) is disseminated to appropriate audiences.

In addition to disseminating findings through publications and through conference presentations at regional, national and international level, we will (a) hold a dissemination workshop in collaboration with the 999EMS Research Forum and/or College of Paramedics; (b) offer to present findings directly to the three participating ambulance services at dedicated workshop events in their area. We will ensure that dissemination goes beyond ambulance services to include other key health care providers and policy makers with an interest in the wider picture of urgent and emergency care. Dissemination will also target the academic community to ensure that future research in this area takes account of and builds further upon our findings.

Outputs and Impact

There is increasing pressure on ambulance clinicians to make decisions regarding onward patient care, including when it is safe to refer them to community based services instead of taking them to hospital. Appropriate models of care can support ambulance clinicians as their role shifts from that of pre-hospital care providers to autonomous clinical decision makers.

Outputs of the research will include:

1) A final comprehensive research report detailing all the work undertaken together with supporting technical appendices, abstract and executive summary. The plain English executive summary will focus on results/findings and be suitable for use separately from the report as a briefing for NHS managers, emergency care practitioners and the general public.

2) Interim reports at intervals agreed with the funders.

3) A set of PowerPoint slides which present the main findings from the research for use by the research team or others in disseminating research findings to the NHS and other stakeholders.

4) Papers for academic peer reviewed journals such as the Annals of Emergency Medicine, Emergency Medical Journal, BMC Emergency Medicine, Social Science and Medicine and Implementation Science to ensure the research forms part of the scientific literature and is available to other researchers. We support an open access model of research dissemination.

5) Articles for professional journals which are read by the NHS management community and which will be helpful in raising wider awareness of the research findings e.g. Ambulance UK, Health Services Journal.

6) Seminars, workshops, conferences at regional, national and international level or other interactive events at which the research team will present and discuss the research and its findings with NHS managers.

7) Guidance to inform the future care of patients who repeatedly use the 999 service in order to maximise their potential to support the shift of care out of hospitals and into the community.

8) User-friendly materials for service managers and commissioners/ policy makers using infographics to maximise accessibility and reach.

The study will have impact in terms of improving access and care experienced by vulnerable patients. It will improve the quality of decision making around alternative care pathways, information transfer between organisations to benefit patient safety and quality of care and streamline patient flow.

7. STUDY TIMETABLE

Key project milestones are highlighted below.

April 2019	Project commences.
April – August 2019	Study set up including research ethics, R&D permissions, and information governance approvals. Site setup. Establish Patient Advisory Panel.
June – August 2019	WP1: Logic model development through Task and Finish groups.
October 2019- March 2021	WP2: Sites identify 'frequent callers' data; 12 months recruitment period; anonymised data linkage (NHS Digital, NWIS, SAIL) Recruit patients for patient stories (n=32) and stakeholders (n=36) for focus group, online, and telephone interviews. Begin analysis of qualitative data.
March – May 2021	Analyse quantitative data – statistical and health economics. Complete analysis of qualitative data.
June - September 2021	WP3: Synthesis and reporting of findings. Working with co-applicants, PPI contributors and collaborators on funder report and plain English summary for stakeholders and the public.
September - November 2021	Disseminate findings. Write and submit papers and abstracts to peer reviewed journals and conferences to disseminate findings. Use online social media for dissemination and plan for further research.
December 2021	Project end

8. EXPERTISE IN THE TEAM AND PROJECT MANAGEMENT

The expertise of our research team will inform the delivery of the study and the interpretation of its findings. The study and research team will be led by Professor Helen Snooks (Swansea University), who has a strong track record in leading NIHR funded studies. Members of the team are experienced in running multi-site studies, such as the 'high profile' HTA-funded SAFER 2 trial of referrals by ambulance services to falls services, which had sites in London, Nottingham and South Wales. David Fletcher (research collaborator) has recently completed a Darzi Fellowship reviewing models of care for repeat users of the 999 service in the London Ambulance Service area. Both Helen Snooks and Alan Watkins (Swansea University and HDRUK) have expertise in extracting and analysing emergency care datasets from ambulance services and working with anonymised linked datasets.

Each participating ambulance service is represented on the research team as co-applicant (RP, WAST) or collaborator: Theresa Foster (EEAST), Rachel Fothergill (LAS), Andrew Rosser and Robert Cole (WMAS), ensuring that the research is designed and carried out with a high degree of local and font line knowledge and experience to ensure its relevance to service delivery.

The co-applicant group includes experience and expertise in:

- Evaluation methods

Statistics and data linkage: AW
Health economics: CP
Epidemiology and data linkage: AJ
Trials and mixed methods: HS and AE
Qualitative methods: AP, BAE, AK and AT

- PPI contribution

PG, BE, with BAE providing facilitation and support throughout the study

- Clinical, service delivery and policy context

Prehospital care: RP, JS
Public Health, suicide and self harm: AJ
Primary care: AE
Social care: HH

Michael Brown, Police Chief Inspector with responsibility for mental health at the National Police Chiefs Council, has also agreed to be a collaborator in an advisory capacity.

We have designed a concise study timetable of 33 months. All co-applicants will be members of the Research Management Group (RMG). Meetings will take place quarterly using a combination of face to face, video and audio conference facilities to oversee project progress locally and across all sites. Adherence to study projected timescales, data collection and analysis will be supervised by Helen Snooks with day to day support from the study manager (Ashra Khanom). Data specification, extraction and management of routine data will be carried out under the direction of Alan Watkins. Alan will work with four site researchers and research support paramedics, located in each of the four participating ambulance services over an 18 month period, who will extract patient identifiable data and recruit stakeholders (commissioners and service providers) and patients for focus groups and one to one interviews.

In addition, we will convene an independent Research Advisory Group to meet three times during the life of the project to provide oversight on all aspects of study management and conduct, including scrutiny of available study data. We will use our existing links with the College of Paramedics to invite representation from the College to an advisory role on this group. We will also invite representatives from groups such as Age UK, Diabetes UK and Mind with expertise on health conditions, methodologists – including a statistician – two public contributors and representatives of health service organisations providing emergency and community based care of relevance to the study.

In addition, a core research team made up of the Chief Investigator, study manager and site based research support officers will meet monthly face to face or by audio link to monitor progress against project plan.

Task and Finish groups (T&F) involving stakeholders and PPI contributors will be set up as required to complete individual tasks e.g. Research permissions; data linkage. Individuals with specialist skills will be co-opted onto T&F groups as appropriate.

A Patient Advisory Panel consisting of six members will be established once we have identified from the literature review, national survey and routine data the case mix of patients who call the 999 service on a regular basis. Our diversity lead AK will ensure that members mirror patient demographics and case mix of health and social care needs identified.

We will use established research project management techniques and software to ensure that any delays are flagged up and resolved as soon as possible. We will identify risks at the outset and review this in an ongoing manner throughout the project. The budget will be managed by Helen Snooks, with support from senior administrator.

9. ETHICAL CONSIDERATIONS

We will apply for research ethics approval and NHS R&D permissions at all participating organisations. We will not introduce change for the study, but will describe and explore current practice. We do not therefore expect to encounter major ethical challenges. However, we do propose to follow up anonymised outcomes for callers without consent. We have done this before in several studies (SAFER2 [25]; PRISMATIC [47]) and we need to agree methods for doing this with both ethics and information governance committees. We have sought views regarding this from our public contributors who are supportive.

We will follow our Standard Operating Procedures (SOPs) for gathering, storing and reporting data. Participants will include members of staff of ambulance services and partner organisations, as well as patients. Staff - in this case those involved in using, implementing and managing care models for this group of patients – will be invited by the local services to participate in focus groups, online or telephone interviews. Patients will not be approached for consent to participate in the main effectiveness study (WP2) as identifying information will be held within ambulance services only and not shared with the research team. Retrospective routine data will be linked anonymously by NHS Digital and NWIS using a split file approach, for analysis within the SAIL Gateway [48]. A small sample of current patients who are calling frequently will be invited by the participating ambulance services to participate in one to one ‘patient story’ interviews. We recognise that these patients may be vulnerable and will take care to ensure that interviews are carried out sensitively, in a place of the respondent’s choice and by appropriately trained researchers at each site. Training and procedures will be guided by our lay research team members and by BAE and AK who have extensive experience of interviewing participants from vulnerable groups e.g. patients who had self-harmed, interviewed within the ED (AK).

Focus group and interview participants will receive a participant information leaflet, and provide written consent prior to their involvement. Participation will be voluntary, and participants will be free to withdraw at any time. Interviews will be audio-recorded, with permission of participants, and the audio-recordings will be transcribed and all identifiers removed from the transcript.

10. PATIENT AND PUBLIC INVOLVEMENT

We have worked extensively with public contributors to develop a comprehensive approach to active involvement of patients and the public at all study stages [49]. We are proposing a layered approach so that people can be involved at strategic and local levels in line with their interest, experience and health. We will build on the approach we developed in the SAFER 2 study involving older people who experience falls [49]. Our aim is to enable active and meaningful involvement throughout to enhance research quality, rigour and ethical standards, i, in line with the Swansea Trials Unit SOP on service user involvement [50].

Our public co-applicants (PG, BE) have been actively involved in study design, shaping the proposal in several ways including a proposal to undertake patient stories and being involved in analysis, plus challenging biases and assumptions in the team and helping choice of appropriate language to describe people who phone 999. We have responded by explicitly adding exploration of terminology within the qualitative work stream of WP 2. We intend that both retain their involvement with the project as members of the Research Management Group. They will be actively involved in all aspects of project management, as equal members sharing decisions about data collection, interpretation, and dissemination through the RMG and subgroups. In keeping with the principles of co-production, all our public contributors will be actively involved in presentation of findings to the wider public to strengthen our communications about applicability of our results.

We will also convene a Patient Advisory Panel of six individuals recruited through community groups, support agencies and third sector networks to reflect the types of people who make frequent calls to 999 including older people, those with chronic illness and people from lower socio-economic levels. The target population for the 999 case management intervention is diverse in terms of demographics, (including ethnicity), conditions and care needs. While we recongise recruitment challenges, we will seek to ensure that public contributors within the study match this diverse population. We will recruit from the various groups, using local contacts, networks, condition specific groups such as Diabetes UK and also ambulance services. This Panel will be a less formal route for people to contribute to specific tasks such as advising on patient facing materials, sense-checking patient results and devising dissemination materials. We will hold face-to-face or virtual meetings and visit people in their homes if that is their preference, in order to ensure their involvement. PG and BE will attend and link between our wider public forum and the research team with two-way communication and reporting.

We will recruit a further two public members to the independent Research Advisory Group to bring patient perspectives to oversight and scrutiny decisions.

We have a realistic budget to support our involvement strategy in line with good practice [51]. We have costed honorariums for all activities and will reimburse expenses. We will provide training for all public contributors, proposing an induction at start of involvement and training in specific skills such as Good Clinical Practice, analysis, meeting skills and dissemination skills, as contributors require. Individuals will also have access to further public involvement training through the Involving People Network in Wales. Meetings will take place in accessible venues, online, and telephone participation will be available if travel is not convenient. Overnight accommodation and carer support will be available to enable effective collaboration. We will provide guidance and support via Dr Bridie Evans who has recently completed her PhD on patient and public involvement in health services research and she also will mentor site researchers working with public members. Our team has extensive experience of facilitating and undertaking public involvement in project development and management, and includes members of the research team which delivered the award winning model of service user involvement in the SAFER2 evaluation [49].Co-applicant Penny Gripper has a long history of involvement as a service user, both with people with physical difficulties and those with mental health problems. She was a board member of the Care Council for Wales as a service user. On a number of occasions Penny has accessed pre-hospital care, usually as a result of self harm triggered by psychosis, psychotic suicidal crisis, and following suicide attempts. She has been a participant in various research studies with the National Centre for Mental Health in bipolar disorder and schizophrenia, and with government research into experiences of participation as a service user. Penny has led a number of consultation events, focus groups and workshops with service users and carers and with a mixture of stakeholders to improve co-production in the development and evaluation of services, and has been working on local evaluation of psychological services.

Co-applicant Bethan Mair Edwards has used community and inpatient mental health services for many years and has been actively involved in a number of studies as someone who has lived experience of mental health services. This has included working as a service user research assistant on two NIHR studies exploring care planning in community and inpatient mental health services (COCAPP & COCAPP-A) and as a member of research steering and management groups for HCRW and NIHR funded studies, including Plan4Recovery and EQUIP and is a member of the National Centre for Mental Health's Service User and Carer Research Partnership Group. Bethan is also a qualified occupational therapist and works as a NHS research occupational therapist on a number of studies investigating early therapeutic interventions for people living with dementia. In this role she has, and continues, to facilitate the involvement of people living with dementia and their carers in the design, conduct and management of research.

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