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FUsED
Frequent users of the Emergency Department:
Improving and Standardising Services – a mixed methods study

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FUsED Study

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The FUsED study will at all times comply with current government and HRA advice regarding COVID-19. The Sponsor will ensure study activities will be amended as required in accordance with the latest guidance.

KEY CONTACTS:

Study enquiries	**Email: FUsED@leeds.ac.uk** **Tel: 0113 343 2442**

Chief Investigator:

Professor Elspeth Guthrie	
Professor of Psychological Medicine Leeds Institute of Health Sciences University of Leeds Leeds LS2 9NL	**Email:** e.a.guthrie@leeds.ac.uk **Tel:** 0113 343 2442

Funder:

National Institute for Health and Care Research	
NIHR Evaluation, Trials and Studies Coordinating Centre (NETSCC) University of Southampton Alpha House Enterprise Road Southampton SO16 7NS	**Email:** Alice Hawliczek Alice.hawliczek@nihr.ac.uk **Tel:** 02380594378

Sponsor:

University of Leeds	
Emma Armstrong, Head of Research Regulatory Compliance The Secretariat, The University of Leeds Woodhouse Lane Leeds LS2 9JT.	**Email:** governance-ethics@leeds.ac.uk **Tel:** 0113 343 4897

Co-investigator:

Professor Chris Burton	
Professor of Primary Medical Care University of Sheffield, Sheffield,	**Email:** chris.burton@sheffield.ac.uk **Tel:** 0114 222 2216

Co-investigator:

Professor Suzanne Mason	
Professor of Emergency Medicine University of Sheffield, Sheffield	**Email**: s.mason@sheffield.ac.uk **Tel:** 0114 222 0694

Co-investigator: Lead for Health Economics Analysis

Professor Chris Bojke	
Professor of Health Economics University of Leeds, Leeds, LS2 9NL.	**Email:** c.bojke@leeds.ac.uk Tel: 0113 343 0822

Co-investigator: Lead for Statistical Analysis

Professor Robert West	
Professor of Biostatistics Leeds Institute of Health Sciences, University of Leeds, Leeds. LS2 9NL	**Email:** R.W.West@leeds.ac.uk **Tel:** 0113 343 2735

Co-investigator:

Dr Steven Ariss	
Senior Research Fellow University of Sheffield, Innovation Centre, 217 Portobello Road Sheffield S14 DP	**Email:** s.ariss@sheffield.ac.uk **Tel:** 0114 222 5426

Co-investigator

Ms Marsha McAdam	
Expert by experience Prefers not to give private address	**Email:** mcadammarsha@yahoo.co.uk **Tel:** prefers not to give private number

Co-Investigator

Professor Christina van der Feltz-Cornelis	
Professor of Psychiatry and Epidemiology Department of Health Sciences University of York York YO10 5DD	**Email:**Christina.vanderfeltz-cornelis@york.ac.uk **Tel:** 01904 321 361

Co-Investigator

Ms Stephanie de la Haye	
Expert by experience Prefers not to give private address	**Email:** stephanie@bbn.uk.com

Co-Investigator

Dr Sam Relton	
Research Fellow in Health Data Analytics Leeds Institute of Health Sciences University of Leeds Leeds LS2 9NL	**Email:** S.D.Relton@leeds.ac.uk **Tel:** 0113 343 2725

Co-Investigator

Dr William Lee	
Consultant Liaison Psychiatrist. Cornwall NHS Foundation Trust, Cornwall, UK.	**Email: William.lee1@nhs.net** **Tel:** 01872 253477

Co-Investigator

Dr Steven Dykes	
Deputy Medical Director Yorkshire Ambulance Service NHS Trust Brindley Way Wakefield WF2 OXQ	**Email:** steven.dykes1@nhs.net **Tel:** 07824087488

Health Economics

Dr Richard Mattock	
Research Fellow Leeds Institute of Health Sciences University of Leeds Leeds LS2 9NL	**Email:** r.mattock@leeds.ac.uk **Tel:** 0113 343 0822

Statistical analysis

Catriona Marshall	
Data manager Leeds Institute of Health Sciences University of Leeds Leeds LS2 9JT	Email:c.s.marshall@leeds.ac.uk Tel: 0113 343 2725

Statistical analysis

Akshay Kumar	
Research Fellow Leeds Institute of Health Sciences University of Leeds Leeds LS2 9JT	Email: a.kumar@leeds.ac.uk Tel: 0113 343 2725

Qualitative Research Fellow

Dr Gerlinde M Pilkington	
Research Fellow University of Sheffield, Innovation Centre, 217 Portobello Road Sheffield S14 DP	**Email:** g.m.pilkington@sheffield.ac.uk **Tel:**

Programme Manager

Dr Sonia Saraiva	
Programme Manager Leeds Institute of Health Sciences University of Leeds Leeds LS2 9NL	**Email:** s.a.saraiva@leeds.ac.uk **Tel:**

Contents

1. PROJECT SUMMARY AND FLOW CHARTS

1.1. Project Summary

Project Title	Frequent users of the Emergency Department: Improving and standardising services- a mixed methods study.
Project description	A study of frequent users of the emergency department (ED) and the services provided for this group of service users. There are four major workstreams: a mapping project to identify all current services in England for frequent attenders; a large data study to identify patterns of frequent use and sub-groups of frequent users, their health costs and the impact of current services on attendance at the emergency department; a qualitative study including a realist synthesis and in-depth case studies of 4 sites with differing types of frequent users services; and the subsequent development of an implementation of 'ideal' models of service delivery, with a focus on interventions for particular sub-groups of frequent users.
Short title	Frequent Users of the Emergency Department (FUsED)
Project Design	Workstream 1: Cross-sectional mapping of current extent of services for frequent users of urgent and emergency care (UEC) networks in England, and a mixed methods study to characterise 20 representative frequent user services (5 each from 4 different types). From this we will develop early ideas about how interventions may work for different subgroups of frequent users (i.e., safely reduce urgent and emergency care use +/ - additional help and support). Workstream 2: Large data study (years 2016/17 to 2020/21) using two complementary datasets. The CUREd dataset links the urgent and emergency care network (ED, 111 and 999) data for Yorkshire and Humber Region. Hospital Episode Statistics data will be linked to ED attendance for the whole of England. We will: 1. identify patterns of frequent use and sub-groups of frequent users; 2. examine how frequent users access the whole urgent and emergency care network including multiple EDs; 3. study healthcare costs of Frequent users to understand where costs are generated and the potential for reduction; 4. conduct interrupted timeseries analysis of the impact on ED frequent users of (a) the introduction of Frequent user services, and (b) the covid-19 pandemic.

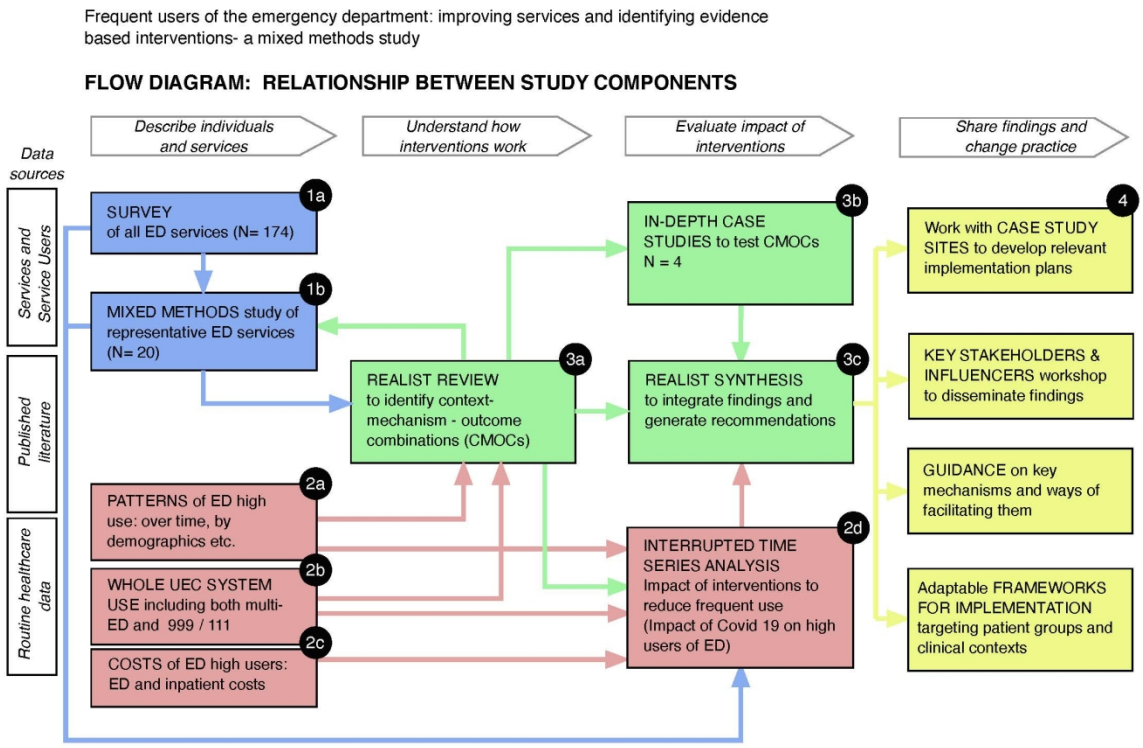
	Work stream 3: Realist synthesis to identify and test programme theories about how interventions for subgroups of frequent users produce outcomes. This includes a literature review, the early ideas from WS1 and additional in-depth case studies of 4 ED sites, each with a different type of frequent user service. Conceptually, it will draw on relevant theoretical models and take a whole systems approach across the urgent and emergency care network at micro, meso and macro levels. Work stream 4: Development of an implementation framework of 'ideal' models of service delivery tailored for the 4 different types with a focus on specific interventions for particular subgroups of frequent users.
Key inclusion criteria	a) Adults aged 18 years or over presenting at the emergency department (ED) and associated emergency care services who have been treated by or who have used a frequent user/high intensity service. b) Adults aged 18 years or over who work in frequent user/ high intensity services or other relevant parts of the emergency care system.
Planned sample size for Workstream 1	All 170 hospitals in England with an emergency department and a liaison mental health service to complete questionnaire. 20 semi-structured interviews
Planned Sample Size for Workstream 2	CUREd data - all hospitals with an ED in the Yorkshire and Humber Region (n=13) plus associated 999/111/and ambulance data. CUREd has 3.8M attendances over 3 years, covering approximately 88k frequent users. HES data - annual attendances at ED for England were as follows: 2016/2017 - 23.3M; 2017-2018 - 23.8M; 2018-2019 - 24.5M; 2019-2020 -25M; and 2020-2021 -17.4M. Our sample size estimates indicate there will be approximately 405k frequent users per year.
Planned sample size for Workstream 3	4 sites Service-user interviews: 5-8 frequent users per site (20-32 participants) Staff interviews: 5-8 members of staff per site (20-32 participants) Workshops: 15-20 members of staff from across each of the UEC networks (60-80 participants)
Duration	CUREd data is currently available for 2014/15-2016/2017. HES data will be requested for years 2016/17 to 2020/2021.

Data collected (Workstream 1)	Site identification Total of 20 semi-structured interviews (30-40 minutes each) with a chief informant from each of the selected 20 services. The hypothesised 4-types of services for frequent users (we have established from previous work) are; 1) ED located no additional staff, 2) ED located + LMHS staff, 3) ED located + ED staff, and 4) located outside ED. Interviews will be designed to describe and differentiate services, including aspects such as: capacity (physical assets), organisational structure, financial mechanisms, patient characteristics, care processes and infrastructure across the urgent and emergency care network. There will be additional questions to refine and test initial programme theories, and to glean further areas for theoretical development.
Data collected (Workstream 2)	The main data collected will focus on ED attendances at hospitals (or hospital Trusts) in England. Attendance data will include date, time, ED mode of arrival, reason for attendance, primary and secondary diagnosis, primary and secondary investigations, and hospital frailty score. Basic demographic characteristics (excluding identifiers), reasons for attendance, diagnosis, associated hospital admissions and other healthcare use data will also be collected. CUREd data also enables access to 999/111/ambulance data which is not available via HES and acuity of presentation.
Data Collected (Workstream 3)	Work-stream 3a will consist of a synthesis of evidence from secondary data sources. The first phase involves developing and refining a set of programme theories and comprises six main activities; refining the question, developing initial programme theory, developing the search strategy, selection and appraisal of evidence (based on relevance, rigour and richness), data extraction, and synthesis of data to develop, refine and test programme theory. The second phase will involve a further conceptual development to identify and develop mid-range theories. The next phase will consist of in-depth case studies of 4 services: Data will be collected using 1) interviews with key-informant staff (ED and MH staff) and 2) service-users, 3) stakeholder workshops and 4) documentary analysis. The interview topic guides will be based upon the realist review and ongoing synthesis and will be developed to generate, refine and test emergent theory across the multiple contexts. Interviews and workshops will be audio recorded and transcribed. Workshop data will also include researcher notes and

	outputs from exercises (such as service mapping and service-user journey mapping). 1. Staff interviews: Using a maximum-divergence sampling frame, we will recruit 5-8 members of staff per site, including liaison mental health staff and any other relevant personnel involved in delivering interventions for frequent users. Interviews with staff will generate, refine and test ideas about their understanding of key actors, the perceived impact on frequent users, factors influencing service delivery at the level of the whole UEC network, and how and why they believe services could be better organised to meet the needs of frequent users. 2. Service-user interviews: Using a purposive sampling frame (informed by our realist review) to ensure maximum variation. Interviews will explore their use of the whole UEC network, and other relevant services over the previous 3 months to map their individual urgent care networks. 3. Stakeholder workshops: One workshop will be held in each of the 4 sites, including ED, ambulance service, NHS111, GPs and commissioners, and representatives from mental health and acute medical care services, third sector. These workshops will focus on the interaction between different elements of the UEC network and seek to identify issues at the interfaces of services and unintended consequences across the network. 4. Documentary analysis: key, site-specific documentation will be collected and analysed to describe the formal processes and policies at each site.
Threshold for 'frequent' ED use	The default definition of 5 or more attendances per year (~2.5% of ED users) will be used. Preliminary analysis of CUREd data indicates that the distribution of attendances per person is continuous and heavy-tailed, with no inflexion point on the curve. Based on findings from other parts of the programme about how services set thresholds we may conduct analysis with different attendance thresholds. We will also examine bursts of frequent use as well as total number of attendances. As some acute hospital trusts have multiple EDs we will analyse data at the level of both trust and ED.
Patterns and predictors of frequent ED use (WS2)	Individual patient level analysis of attendances to identify frequent use within years and over multiple years. Examination of how features relating to patients (e.g. age, gender, deprivation) and attendances (e.g. occasional bursts vs more regular in time or reason for attendance) predict further ED use. Time to next ED

	attendance and time in frequent user status will be modelled using survival trees. These analyses will be developed in the CUREd database and then repeated on a national basis using data derived from HES to investigate the generalizability of findings. Hospital Episode Statistics (HES) data will also enable the tracking of ED use across multiple sites. Analysis within CUREd will also focus on pre-hospital urgent and emergency care use (NHS 111, 999) and compare patters in ED frequent users compared to others.
Healthcare costs (WS2)	Using both HES and CUREd, established costing methods will be applied using national reference costs to HES A&E and inpatient healthcare resource groups (HRGs) (including high-cost unbundled HRGs) and exploring micro-costing approaches to more detailed CUREd data to determine the costs associated with frequent use of urgent and emergency care services and the distribution of costs across users and trusts. Comparison will be made between HES and CUREd to consider the consistency of each source.
Evaluation of Frequent User Services and impact of COVID-19 on frequent use of ED (WS2)	An interrupted time series analysis of the impact on ED frequent attendance of frequent user services will be conducted with ED attendance as the main outcome measure. Frequent user services will be identified from a Department of Health Survey of liaison mental health services which has been commissioned for 2022, data will be available from September 2022. Previous surveys have had a response rate of 100%. In the last survey 2 years ago, there were 80 (170) EDs in England which had a frequent user service. For each current service, a 12-month implementation phase following the date the service was launched, will be identified. Frequent use over all years prior to implementation and all years (and part years) after the implementation year will be examined. A comparison between EDs with a frequent user service and without will also be carried out with EDs being matched on general characteristics (e.g. pre-service annual throughput, urban/rural). A similar analysis, over shorter time periods, to examine the impact of the Covid-19 pandemic on both total ED use and on ED use by frequent users will be undertaken.

1.2. Flow Chart for whole programme



Workstream 2 is shown in salmon pink.
Workstream 3 is shown in green.

2. GLOSSARY OF TERMS

A&E	Accident and Emergency
AMB	Ambulance
APC	Admitted Patient Care
CI	Chief Investigator
CLRN	Comprehensive Local Research Network
CMOCs	Context Mechanism Outcome Combinations
CQUIN	Commissioning for Quality and Innovation
DAT	Data Analytics Team
ED	Emergency Department
GCP	Good Clinical Practice
GDPR	General Data Protection Regulation
GP	General Practitioner
HES	Hospital Episode Statistics
HI	High Intensity Services
HRGs	Healthcare Resource Groups
HS&DR	Health and Social Care Delivery Research
ICO	Information Commissioner's Office
IGARD	Group Advising on the Release of Data
LASER	Leeds Analytic Secure Environment for Research
LIDA	Leeds Institute of Data Analytics
LIHS	Leeds Institute of Health Sciences
LMHS	Liaison Mental Health Service
REC	Research Ethics Committee
MRC	Medical Research Council
NHS	National Health Service
NIHR	National Institute for Health Research
NRES	National Research Ethics Service
ONS	Office for National Statistics
PMG	Programme Management Group
PSC	Programme Steering Committee
REC	Research Ethics Committee
R&D	Research and Development
UEC	Urgent and Emergency Care

UECF	Urgent and Emergency Care Framework
VRE	Virtual Research Environment

3. BACKGROUND

3.1. Nature of the problem

Frequent attendance at the emergency department is a ubiquitous problem for most healthcare services. A recent systematic review and meta-analysis of 27 studies found frequent users make up approximately 2.5% of all ED users but account for approximately 10% of total ED attendances[1]. Evidence suggests in the UK the proportion of frequent to non-frequent users is rising [2]. National data show that 31,492 people made 10 or more emergency department (ED) visits in England in 2017-18 [3]. The cost of the 5,000 people who attend EDs more than 20 times per year, is estimated at £53 million [3]. Total hospital costs of frequent users are 3-4 times greater than routine ED users [4]: 40% of healthcare costs are generated outside the index hospitalisation, with higher ambulance and primary care use [4].

This research builds on our previous work regarding frequent use and patterns of attendance at ED [5-7], characterising non-urgent attendance at the ED [8], mental health problems in frequent users of ED [9, 10], mapping of Liaison Mental Health Services aligned to ED [11] understanding factors that shape re-attendance at ED [12] and development of programme theory for Liaison Mental Health Services [13].

A sign of distress: Frequent attendance at the emergency department (ED) is often a sign of distress and unmet need [6] and frequent users have high rates of multimorbidity, psychiatric co-morbidities and psychosocial problems [14, 15]. Failure to recognise and address frequent users' needs can potentially lead to a cycle of re-attendance. Frequent users have high rates of 12-month mortality (10-13%), most commonly attributed to suicide or alcohol /drug abuse [16].

Definition: There is no agreed definition of frequent use of the ED and most studies have either defined frequent use by a certain number of visits within a set period of time, or a top percentile cut off (e.g. top 10 or 15%) of attendances [17]. For the purposes of this project we will define frequent attendance as 5 or more attendances at the ED in a 12-month period which was recommended in a recent systematic review of ways to define frequent use [17]. We recognise that any cut off is

somewhat arbitrary and that the distribution of attendance per individual is continuous[5], but we require a pragmatic definition of 'frequent use' for elements of the programme.

Characteristics and patterns of attendance: Frequent users of ED are a heterogeneous population [17, 18] and groups of frequent users have been described based on: a) pattern of attendance e.g. persistent frequent users (i.e. frequent attendance > 12 months) [19], multisite attenders who make up 25% of all frequent users [20] and are more likely to have mental health problems than single site users; or 'burst' attendances that may resolve spontaneously[5]; and very high users [3] b) reasons for attendance (e.g. illness concerns, suicidal thoughts/self-harm, recurrent emotional crises, multiple physical and health anxiety, social difficulties, substance misuse)[21, 22], and c) demographics and/or diagnosis (e.g. elderly physically unwell)[23].

ED culture: An ambivalent ED culture has been described with many staff believing attendances are non-urgent and inappropriate, and frequent users report feeling marginalised, stigmatised and devalued [24]. There is also evidence that the way health staff interact with patients may unwittingly lead to an increased likelihood of re-attendance, as prior experience of healthcare shapes future likelihood of attendance[12].

Experience of being an ED frequent user: There is very little work that has explored the experiences of frequent users of UEC. A recent systematic review of relevance identified only 7 qualitative studies of ED frequent users, none of which were UK-based (2 Canada, 2 Sweden, 1 USA, 1 Australia and 1 New Zealand)[23], and some of the studies were limited to very specific sub-groups of frequent users (e.g. elderly physically unwell or COPD patients). The participants' responses from the studies were divided into two areas by the reviewers; the participants' experience of their own illness and their experience of care, which was reported as being predominantly negative. Very little is known about frequent users' experience of specific interventions delivered in an urgent and emergency care setting.

3.2. Interventions to reduce ED frequent use

Between 2011/12 and 2018/19, ED attendances grew on average by 2.1 per cent each year and increased by 3.3 million (16 per cent) in total. The NHS Long Term Plan in 2019 outlined an expanded and more co-ordinated urgent and emergency care framework (UECF) to try to reduce the burden on EDs. To date, however, there is little evidence to suggest that alternatives within the UECF have achieved the intended effect of reducing ED visits.

Recent systematic reviews have examined the effectiveness of interventions to decrease ED visits by adult frequent users [25-28]. There is evidence for reductions in attendance from uncontrolled designs, but very weak evidence from the small number of randomised controlled trials that have been conducted. Several uncontrolled UK evaluations of frequent user interventions have suggested they generate large cost savings to the NHS, and that services should be expanded [29-31]. However, uncontrolled evaluations, such as the UK evaluations, result in large overestimates of service impact, most likely because of regression to the mean.

Considerable investment has also been put into ED liaison mental health services (LMHS) of the order of £120 million (https://www.england.nhs.uk/mental-health/adults/crisis-and-acute-care/transformation-funding/), so that all EDs in England now have LMHS. A national Commissioning for Quality and Innovation (CQUIN) standard was introduced in 2019 to drive the development of frequent user services by LMHS. Our research is designed so our results can be generalisable on a national scale and implemented either via LMHS or urgent and emergency care networks.

Most services for frequent users are delivered currently in the UK by LMHS based in EDs. Co-applicant WL has conducted an annual review of LMHS for the last 3 years with a 100% response rate for each survey (because of professional connections via the Faculty of Liaison Psychiatry and a buy-in from all liaison teams). We embedded two questions in the last survey (April 2019) about the types of services being provided for frequent users We know from this scoping work that services for frequent users have been rapidly developing. Out of 170 acute hospitals with EDs in England, 80 now have specific services for frequent users, with others planning service developments. We have identified 4 types of service: basic care planning with no designated staff; services with designated ED staff; services with designated LMHS staff; and services based outside ED. We found, most but not all frequent user services are run by LMHS and are developing in a piecemeal fashion, providing a range of non-evidenced based interventions for frequent users including case management, social prescribing, and specific frequent user clinics.

3.3. Longitudinal Outcome

Whilst the proportion of patients who frequently attend ED remains relatively stable, with a relatively small number consuming a large proportion of care, there is a high degree of attrition and less than one half of frequent users persist in their use for longer than 12 months [32, 33]. This means, about half of all patients who are identified as frequent users and referred to frequent user services have a high probability of ceasing attendance without any intervention at all. So-called persistent frequent users opposed to non-persistent frequent users are twice as likely to have mental health problems

and substance misuse [34], and are a more stable target group for interventions than non-persistent attenders, provided they can be identified relatively early on in their attendance journey.

COVID-19: There was a dramatic fall in attendances at ED in the context of the COVID-19 pandemic restrictions which began in March 2020. ED attendances across all age groups, all acuity levels, on all days and times fell by over 30%[35]. The greatest reductions were seen in less severe presentations, and non-respiratory indicators. As far as we are aware, the impact of the pandemic on frequent use has not been examined. This study provides an opportunity to explore the impact of a major system change on frequent use of ED and other UEC services.

In summary, frequent use of urgent and emergency care services is a costly problem for the NHS and a sign of distress for those people who attend in this fashion. Various national incentives have resulted in an expansion of services for frequent users, largely but not solely based in EDs, and usually run, but not always, by liaison mental health services. Across services, there is no agreement as to which groups of frequent users should be targeted, what kinds of interventions should be delivered, how these interventions achieve their desired outcomes and how outcomes should be measured. Local service evaluations are not able to evaluate services with sufficient robustness, and a large-scale independent study is required to determine patterns or use, costs, and impact of frequent user services.

4. SUMMARY OF HS&DR PROGRAMME GRANT

This large data project forms part of a National Institute for Health and Care Research (NIHR) funded research programme (NIHR 132852), from the Health and Social Care Delivery Research (HS & DR) funding stream which seeks to improve and standardize services for frequent users of emergency services. The title of the main grant is: Frequent users of the Emergency Department: Improving and standardizing services - a mixed methos study

4.1. Programme Aims

The aim is to improve frequent user services for urgent and emergency care by conducting a mixed methods study to:

1) Identify which interventions appear to work (provide a safe and appropriate response, whilst reducing urgent and emergency care use) for which types of frequent user in what settings and why.

2) Test these findings by in-depth comparative studies of four different types of services for frequent users and their urgent and emergency care networks
3) Produce and disseminate an implementation framework for frequent user services to optimise care.

It is divided into four workstreams.

4.2. Overall Programme Objectives

To produce:

1) A framework for describing and characterising frequent user/high intensity urgent and emergency care services (Workstream 1a & 1b)
2) An analysis of use by frequent users of the ED and wider urgent and emergency care networks, including different patterns of attendance (Workstream2a), multisite use (Workstream 2b) and healthcare costs of frequent users (Workstream 2c).
3) An analysis of the impact of current services for frequent users on overall ED use (Workstream 2d). Analysis of the impact of COVID-19 on frequent use of ED (Workstream 2d)
4) A realist synthesis, which describes programme theories about how interventions may work for frequent users in different contexts (Workstream 3)
5) An implementation framework to help plan and optimise frequent user services (Workstream 4)

5. DESIGN AND THEORETICAL CONCEPTUAL FRAMEWORK

The project is a mixed methods study and consists of four work streams.

Workstream 1 is a cross-sectional survey to map the current extent of services for frequent users of urgent and emergency care networks in England, and a mixed methods study of 20 representative frequent user services to better characterise services according to the 4 different types of frequent user service currently in operation (ED located no additional staff, ED located + LMHS staff; ED located + ED staff; and located outside ED).

Workstream 2 is a quantitative large data study to describe patterns of attendance of frequent users of urgent and emergency care, associated costs, and the impact of frequent user services in England in terms of reducing attendance at ED for frequent users.

Workstream 3 is a realist investigation and synthesis. It includes a realist review of current relevant literature, 4 in-depth realist evaluations of frequent user services (one from each of the 4 different typologies) and a realist synthesis which seeks to integrate the findings of the other workstreams, to ensure that the findings across the project are understood within a testable explanatory framework of cause and effect.

Work stream 4 is the development of an implementation framework of 'ideal' models of service delivery tailored for the 4 different service types, with a focus on specific interventions for particular subgroups of frequent users.

Conceptual Framework: There is no conceptual model of frequent demand for the emergency and urgent care system as a whole. There are existing recognised psychological and social models of health behaviour such as the Illness Action Model [36], The Common Sense Model of Self-Regulation of Health and Illness [37] and the Network Episode Model [38]. The two former models emphasise individualistic and cognitive processes in decision making about treatment whilst the latter recognises the importance of individual actions but seeks to understand them in the context of social networks with which people interact. All three models focus on the process of response to bodily symptoms. Another relevant model is Andersen and Newman's Framework of Health Services Utilisation [39], which divides determinants of health care use into three categories, predisposing characteristics, enabling resources and need factors. This model includes symptom response but also suggests that health seeking can be driven by other factors including poverty or isolation. Attachment theory also provides a framework for understanding health seeking in the context of a need for interpersonal care [40].

Existing Programme Theories: O'Cathain and colleagues have recently identified 10 programme theories to explain unnecessary use of the emergency department (ED) [41]. Although, the population in the O'Cathain study were not frequent users of ED, there is clearly some overlap with frequent users, as many attendances by frequent users are considered to be unnecessary, although most people who attend ED for an unnecessary reason are not frequent users. The programme theories developed by the team of relevance to this programme are: anxiety caused by uncertainty about symptoms; anxiety caused by past traumatic events; need to get back to normal quickly; need for immediate pain relief; inability to cope due to stressful lives; perceptions of better service from emergency care; and lack of accessibility to GP. Further programme theory has been developed in Canada to help explain how and why particular contexts, type of frequent user, and type of and quality of actions, influence the results of a case management programme for frequent users [42].

Healthcare access: Two theoretical concepts from the healthcare access literature are also of relevance. EG and colleagues have shown how the concepts of candidacy and recursivity are

applicable to the urgent and emergency health care setting[12]. Developed from interpretive synthesis of literature on access to healthcare in socio-economically disadvantaged groups [43], candidacy describes how access to healthcare is framed as often requiring work for patients to achieve, and eligibility to access care is continuously negotiated in patient–practitioner interactions. The second concept, 'recursivity', describes how future demand for services, and the process of help-seeking, is determined by a patient's previous experiences [44]. Patients rely on experiential knowledge of services and practitioners to choose between services and to establish their candidacy for accessing services.

Complex Systems Theory: Frequent attendance at the ED can be understood in terms of complexity theory [5, 7]. Whilst similar distribution patterns of attendance and frequent use is found in all EDs (and many other healthcare settings), the population of the individual high users themselves is constantly changing. Complex systems display order and stability at the level of the whole system which spontaneously emerges from apparent disorder and instability at the level of the system components. Such systems typically generate skewed distributions with a 'heavy tail' which in the case of the ED is represented by frequent users. Whilst all of the previously mentioned theories primarily focus on an individual's motivations to use ED (even though they may be influenced by social networks), complexity theory focuses on the system and suggests interventions to reduce high use need to take a whole system view as any solution for a particular individual may benefit that person, but they are likely to be replaced by another person if the system is to remain stable.

The above theories are all of relevance in helping develop programme theory and testing it. They involve consideration of micro-level factors including an individual's perceptions of the severity of illness and a health professional's response to that person, but also an appreciation of system factors at a meso level that transcend individual reasons for seeking care. In addition, there are national factors such as government policy which shape service development (as we have seen with the recent dramatic increase in services for frequent users). Three conceptual issues are relevant to this study. First, as recommended in a recent evidence review[45], we will take an emergency and urgent care system-wide perspective rather than focusing on demand for ED alone. Second, the focus is on both patients and the perspectives of health professionals as little is known about either concerning the delivery of services for frequent users. Third, the focus is on factors operating at micro (person), meso (system) and macro (national) levels. A model encompassing these different perspectives will shape the programme in the context of improving care for frequent users.

6. WORKSTREAM 1

6.1. Workstream 1a Mapping and characterisation of current services for frequent users of urgent and emergency care networks in England

Aim: To map the current service provision for frequent users of urgent and emergency care networks.

Objective: To identify all services for frequent users of urgent and emergency care networks in England using an electronic survey.

Setting: 170 acute hospitals with EDs in England (all now have liaison mental health services).

Design: Cross-sectional observational study.

Methods: We will use an established annual electronic survey of liaison mental health services (LMHS) (led by co-investigator WL) to map services for frequent users across the 170 acute hospitals in England with an ED and their associated urgent and emergency care networks. In the last 3 years, the survey has had a 100% response rate and is the most efficient way to collect data about all frequent user services, including those not led by LMHS. The survey is commissioned by the Department of Health and is in its fifth iteration.

The survey includes questions that will enable us to identify current frequent user services and their typology: i.e. basic care planning with no designated staff; services with designated ED staff; services with designated LMHS staff; and services located outside ED, either in other parts of the urgent and emergency care network or community/primary care.

Is there a Frequent attenders service? If there is, what date did it start, if you know? If there used to be one, what date did it start and what date did it stop, if you know? Please include contact details for the service if it is different to your Liaison service.

Please indicate how the frequent attenders service is best described	**Please tick**
No specific staff - Case Management Meetings only.	
Designated member of staff or staff time from Liaison.	
Designated member of staff or staff time from Acute Hospital.	
Designated member of staff or staff time from another organisation, or other structure (please describe below)	

The survey also enquires about changes to service organisation and delivery during the COVID-19 pandemic and subsequent developments.

Impact of Covid-19 pandemic:

Please describe how the Covid-19 pandemic has affected your service. Please include the impact on staffing/morale/case mix/activity levels/relationships with other services. Please describe input into any specialist covid clinics.

The study is funded by the Department of Health, contracts have been signed and a designated researcher has recently started in post (April 2022). The survey will be distributed in June 2022. The survey will only provide very limited detailed information about frequent user services, as primarily it focuses on more general aspects of LMHS. It is however an efficient way to collect information about the national existence of frequent user services.

Descriptive analysis: Univariate analyses will be used to calculate the number and typology of frequent user services.

In addition, we are working with NHS England who have a High Intensity programme which has set up services for high intensity users (many of whom are frequent users of ED) across England. These services are typically small, are based in the community and run by third sector organisations. We will be able to contact a proportion of these services to participate in chief informant interviews.

6.2. Workstream 1b Detailed characterisation of frequent user/high intensity services

Aim: To characterise services and the interventions they provide for frequent users and identify 4 exemplar services for further in-depth case study in WS3.

Objectives: a) Describe the key components of the 4 different types of frequent user service b) the types of interventions they provide and c) preliminary explanations as to how interventions result in the desired outcomes (in most cases - reduction in frequent use).

Design: Cross sectional study

Setting: 20 chief informant interviews for frequent users in England.

Methods: Using the findings from the liaison survey (WS1a) and the NHS England database on high intensity services, we will randomly select services for more detailed study. We will interview remotely a key member of staff (Chief informant) from each of 20 services using a framework for describing health care organisations [46] (and informed by emerging evidence from our realist review) to characterise each service according to: capacity (physical assets), organisational structure, financial mechanisms, patient characteristics (including specific sub-groups e.g. women, super-users), care processes and infrastructure across the UEC network. This framework was created for describing important differences in health care delivery for all sizes and types of service, particularly involving a

system-orientated approach whilst maintaining a patient centred focus. We will use a semi-structured interview to obtain the quantitative data we require about each of the services. We will enquire in detail about any interventions delivered by the service, who delivers them and where, the groups of frequent users targeted, how the staff member understands the intervention brings about change, and the intended outcome. We will enquire about changes to emergency services and liaison services during the pandemic and any subsequent changes post- pandemic peak.

Analysis: The analysis will primarily involve a descriptive summary of responses. The responses about frequent user interventions will be used to feed into the realist synthesis. We will compare the similarities and differences between the programme theories identified in the literature with ideas emerging about mechanisms from the current frequent user services. From each of the 4 service types we will also select one site, judged to be representative of its category for in-depth case study (WS3b).

Output: A detailed description of 4 different types of service for frequent users of UEC services, including where they are located within (or without) the UEC network, details of the network, the types of patients they see, the interventions they deliver and relevant outcomes and preliminary explanations about how these interventions result in the desired outcomes.

7. WORKSTREAM 2

Analysis of routine healthcare data

Aim: To describe current patterns and costs of frequent UEC use and to examine the impact of services for frequent users on attendance.

Objectives:

a) Characterise patterns of frequent ED use and their associations with patient characteristics; identify early predictors of persistent frequent use.
b) Examine use of the whole UEC network by ED frequent users: specifically focusing on (i) use of 111 / 999 (ii) use of multiple EDs
c) Describe the costs (ED and inpatient) associated with frequent use
d) Conduct interrupted time series analysis of frequent ED use to understand the impact of (i) initiation of services for frequent users (ii) the COVID-19 pandemic.

7.1. Data sources

We will use two complementary datasets: 1. the CUREd regional urgent and emergency care system dataset and Hospital Episode Statistics (HES) national ED and in- and outpatient data. CUREd covers the Yorkshire and Humber region (5.6 million inhabitants and 18 EDs). Uniquely it links individual patient data for all ED attendances, NHS111 calls and 999 ambulance calls (with/without transfer to

hospital) (https://www.sheffield.ac.uk/scharr/research/centres/cure/projects). 2. National HES data (accident and emergency, inpatient, outpatient, and mental health datasets linked to ONS for date of death) will allow us to identify frequent users, their resource use and the impact of frequent user services on ED attendance on a national scale. Both datasets will link ED data to inpatient data. N.B. CUREd data enables us to examine use of the UEC network, whilst HES data focus on ED use and does not include other aspects of the UEC network.

7.2. CUREd Data Set

The CUREd data set is hosted by the University of Sheffield and holds pseudonymised individual patient level data on NHS 111 calls, emergency ambulance calls, ED attendances and emergency admissions to hospital. CUREd has National Research Ethics Service approval (18/YH/0234) and makes data available to researchers subject to a formal application process, ethics approval of the relevant project, appropriate safeguards, and a data sharing agreement.

CUREd comprises data supplied from all hospitals with emergency care services in the Yorkshire and Humber region. These are: Airedale NHS Foundation Trust, Barnsley Hospital NHS Foundation Trust, Bradford Teaching Hospitals NHS Foundation Trust, Calderdale and Huddersfield NHS Foundation Trust, Doncaster and Bassetlaw Hospitals NHS Foundation Trust, Harrogate and District NHS Foundation Trust, Hull and East Yorkshire Hospitals NHS Trust, Leeds Teaching Hospitals NHS Trust, Mid Yorkshire Hospitals NHS Trust, Northern Lincolnshire and Goole NHS Foundation Trust. Sheffield Children's NHS Foundation Trust, The Rotherham NHS Foundation Trust, York Teaching Hospital NHS Foundation Trust.

CUREd consists of 4 datasets; NHS 111 calls dataset; ambulance (AMB) incidents dataset; Accident and Emergency Attendances dataset; and admitted patient care (APC) episodes dataset (a provider spell (SPL) dataset is derived from the APC dataset).

While linkage to create CUREd used multiple patient identifiers, all individual patient identifiers except sex and ethnic category have been permanently deleted from the database. Dates and location of healthcare use are retained. Data extracts for research are risk assessed prior to release using The Information Commissioner's Office (ICO) Code of Practice on Anonymisation (https://ico.org.uk/media/for-organistions/documents/1061/anonymisation-code.pdf) to ensure it is unlikely that an individual will be identified from the data extract.

7.3. Hospital Episode Statistics

We will request data from Hospital Episode Statistics (A&E, emergency care, admissions, and outpatient datasets) and the Mental Health Services Dataset, and Office for National Statistics (ONS) mortality statistics from NHS Digital. NHS digital uses identifiers to link data to a particular individual and retains the code for this, which is not shared with outside agencies. HES data will be collected in one tranche in the second year of the project.

CURED +-There are plans to expand the CUREd dataset by linking it with HES data (A&E, emergency care, admissions, and outpatient datasets) for England between 2017/18 - 2020/21. Should this updated CUREd dataset (CURED+) be available in a timely fashion, we will use this updated data for our analyses. As with CUREd, the updated dataset would have all patient identifiers, except for sex and ethnic category, removed.

7.4. Data Collection

From the datasets we will extract data for each ED attendance linked by pseudonymized patient ID and grouped by fiscal year. Attendance data will include date, time, ED mode of arrival, reason for attendance, primary and secondary diagnosis, primary and secondary investigations and hospital frailty score. We will apply a CUREd algorithm for identifying low acuity attendance [8] as this indicates attendances which are less likely to be medically necessary.

Robust data from CUREd are currently available from 2014/15-2016/17. The application process for CUREd+ is currently progressing well and we anticipate that this will be available in early 2023 and will cover the period 2017/18-2020/21. We will apply to use HES data for 2016/17 to 2020/21. Analyses will be developed in CUREd from the start of the study then transferred to the HES data later and include CUREd+, if available.

7.5. Threshold for 'frequent' ED use

We will begin from a default definition of 5 or more attendances per year (~2.5% of ED users)[1, 7]. Preliminary analysis of CUREd data indicates that the distribution of attendances per person is continuous and heavy-tailed, with no inflexion point on the curve[7]. Based on findings from WP1

about how services set thresholds we may conduct analysis with different attendance thresholds. As some acute hospital trusts have multiple EDs we will analyse data at the level of both trust and ED.

7.6. Sample sizes

CUREd has 3.8M attendances over 3 years by adults from a total population of 5.5M.

Hospital Episode Statistics - annual attendances at ED for England were as follows 2016/2017 - 23.3M; 2017-2018 - 23.8M; 2018-2019 - 24.5M; 2019-2020 -25M; and 2020-2021 -17.4M. Approximately 75% of these attendances are by adults, so we estimate there were 17.5M adult attendances at ED in 2016-2017; 17.8M in 2017-2018; 18.3M in 2018-2019; 18.8M in 2019-2020 and 13.0M in 2020-2021.

Previous research shows that the number of service users is 66.2% of the number of attendances[47], and the number of frequent users is approximately 3.5% of the number of patients[5], leading us to n=88k in CUREd and n=405k per year in HES.

7.7. Statistical analysis

Patterns and predictors of frequent use

We will carry out individual patient level analysis of attendances to identify frequent use within years and over multiple years. We will examine how features relating to patients (e.g. age, gender, deprivation) and attendances (e.g. bursts or reason for attendance) predict further ED use. We will use probabilistic linkage to identify which 111 /999 calls were followed by an ED attendance. In addition to examining attendances individually and aggregated by person-year, we will group attendances into bursts: sequences of attendance with consecutive intervals no more than a given threshold (initially 14 days).

Time to next ED attendance refers to the time from the first attendance of an individual during the period of interest to their next attendance, and then the time elapsed between subsequent attendances; for multiple attenders this equates to the time between visit 1 and 2, then between visit 2 and 3 etc. The potential impact on statistical models of having the same individual make multiple attendances will be negated by using the patient ID as a random effect within our survival models. Time to next ED attendance and time in frequent user status, will be the primary outcomes of interest. We will start by considering the time when a patient leaves frequent user status is defined as the date

when the patient has had < 5 attendances in a 12-month window, for 12 consecutive months. This time frame may be altered in subsequent analyses if we find there are more appropriate time windows.

Due to the large number of potential diseases, interactions, and demographic variables we might consider, it is likely that a mixture model will be required. Further complications arise when accounting for the repeated observation of patients as they re-attend. Therefore, the following modelling pipeline will be utilised.

1) The main effects will be determined using a LASSO Cox model with random effects
2) Survival trees will be used to determine the most pertinent interactions terms, and to determine factors used to cluster patients within the mixture model (based on one random visit per patient to avoid biases due to repeated observation).
3) A mixture model based upon Cox models with random effects will be fit to the data, using the variables identified within the survival trees.
4) There is potential for death as a competing risk to impact the model performance (those who attend hospital many times may be more likely to die, and then cannot re-attend). We will investigate the scale of this problem and add death as a competing risk if required.

The number of attendances over the next 12 months will be modelled using a tree approach, again to capture the complexity of the interaction between patient factors and attendance history. A similar sampling technique to that described above will be utilised. Due to the skewed distribution of the number of attendances we will investigate the use of variable transforms such as the logarithm and square root, to enable more robust regression.

We expect 88k frequent users in the CUREd dataset (see section 9.1). Model evaluation will be performed using cross-validation (both with random splits and splitting at ED level), following the TRIPOD guidelines [48], to investigate the robustness of the models via standard metrics such as the concordance index and D-statistic.

Frequent use across the wider urgent and emergency care network

In this work package we will perform a similar analysis to the analysis above but on national HES data, to investigate the generalisability of our findings and look for the additional impact on model performance of tracking attendance across multiple EDs (i.e. multisite attendance). The three primary outcomes will be the time to next ED attendance, the time until an individual loses frequent user status, and the number of attendances in the next 12 months. Trees and survival trees will be used as

described previously, with additional attendance history gained by tracking patient attendance across all EDs in HES. We expect 405k frequent users per year within the HES data (see section 9.1). Model evaluation will be performed using cross-validation (both with random splits and splitting at regional level), following the TRIPOD guidelines[48].

Impact of frequent user services on use of urgent and emergency care

We will conduct interrupted time series analysis of the impact on ED frequent attendance of (i) frequent user services (ii) the COVID-19 pandemic. The analysis will include metrics and covariates identified in the previous analyses.

This analysis will be initially developed in CUREd whilst data access is arranged with NHS Digital, and then run in the national HES dataset. We will use information from the first work package of the programme to identify which EDs introduced which type of frequent user service and when. Currently we estimate that approximately 80 EDs in England have such a service and 90 do not. For each service launched during the study data period (2016/17 to 2020/21), we will allocate a 6-month implementation phase following the date the service was launched (this can begin at any point in the year). We will then examine frequent use over the years prior to implementation and subsequent use for all years (and part years) after the implementation year. We will compare time periods within EDs which introduced a service and between those EDs with and without a service. We will compare these EDs with new services with EDs with either no service or with a long-standing service. We will match EDs on general characteristics (e.g. annual throughput, size, service features, average IMD of attendees). We anticipate we should be able to evaluate services that have start up dates in the period from 2016-2019, but we may need to account for disruptions to services caused by the COVID pandemic and focus upon services that started 12 months prior to lockdown (March 2020).

The interrupted time series analysis will investigate both the change in intercept and slope of attendance figures, controlling for covariates such as the time of year. We will also include a random effect for the actual intervention itself, so that the average effect (and variance) of introducing frequent user services can be found.

We will also carry out a similar analysis, over shorter time periods, to examine the impact of the Covid-19 pandemic on both total ED use and on ED use by frequent users. This will both provide an estimate of changes in frequent user behaviour during and after restrictions and provide comparative data from EDs without a frequent user service through this period.

There are currently 80 hospital EDs with associated frequent user services in England and 90 hospital EDs without such services. We will need to establish how many of the frequent user services fall within our timeframe of evaluation but is likely that the majority will do so, as our data are from a survey carried out in 2019. Approximately 12% of attendances at ED are made by frequent users who account for 3.5.% of the ED population (defined as 5 or more attendances per 12 month period). If we are able to compare at least 60 services with matched comparators, (i.e. 120 of hospitals with EDs in the UK), we would expect to have at least 1.4M frequent user attendances per annum from the 120 hospital sites apart from 2020-2021 when there would be a drop to an estimated 1M frequent attendances, and at least 400,000 frequent attenders per annum.

7.8. Health economics

Healthcare costs of frequent users of urgent and emergency care networks

Using both HES and CUREd we will use established costing methods applying national reference costs to HES A&E and inpatient healthcare resource groups (HRGs) (including high-cost unbundled HRGs) and exploring micro-costing approaches to more detailed CUREd data to determine the costs associated with frequent use of urgent and emergency care services and the distribution of costs across users and trusts. Comparison will be made between HES and CUREd to consider the consistency of each source.

The distribution of the costs across patients and providers will be measured to understand how costs are generated and the potential for cost reduction. For example, some trusts may have higher costs than other trusts despite similar frequent user volume due to systematic differences in treating users. It may therefore be the case that removing variation in treatment may be as effective as reducing volumes of frequent users. We will also measure the expected costs due to individual patient characteristics including frequent user types as identified by the latent class analysis.

We will conduct a descriptive analysis which reports mean healthcare costs by individual characteristics including frequent user status (yes/no), frequent user type, mental health diagnosis, and demographic variables such as age, gender, and deprivation status. In addition, we will identify mean costs at the trust level by grouping individual patients by their healthcare provider. A similar descriptive analysis will be performed reporting mean costs per trust by provider level variables

including volume of frequent users, services and interventions provided for frequent users, and patient population characteristics.

We will estimate mean costs in two multivariate regression analyses (e.g. using a generalized linear model (GLM)). The first regression model will include individual patients' healthcare costs as the outcome variable and individual level covariates, including any treatment for frequent users. The second regression model will include healthcare costs per trust with provider level covariates. We may also conduct multi-level regression analysis if we identify substantial variation in costs per trust due to provider level characteristics. The multi-level model would predict mean costs for patients nested within trusts and include relevant covariates at both the individual and trust level.

Our analysis will help identify the incremental impact of frequent user services compared to the counterfactual of no frequent user services. Cost calculations will be conducted according to the costing guidance in the economic evaluation framework. We will provide a set of unit costs per attendance avoided in order to provide a cost-perspective to a) the interrupted time series analysis and b) as a resource for further researchers analyzing interventions outside of this programme of work.

8. WORKSTREAM 3

Realist investigation and synthesis

This work stream comprises a realist review, 4 in-depth studies of frequent user services, and a realist synthesis which will integrate the findings of the different workstreams. For clarity, these activities are presented as separate components. However, the findings from each will interweave with the others in an iterative fashion (e.g. findings from the review informing the questions and topic guides from WS3b, the findings of which will then be fed back into the review for further synthesis). This workstream will have a dynamic relationship with the whole project, both informing the other workstreams and bringing together findings from the different components under a comprehensive theoretical framework.

Aim: To use realist methods to explore and understand how different interventions for frequent users (and different groups of frequent users) achieve reductions in use of UEC services and/or other key outcomes (e.g. improvements in mental health) and to provide underlying theory to bring together the findings from the whole programme.

Objectives: To generate a set of programme theories which (a) describe the relationships between the actors, contextual factors, mechanisms and outcomes of different interventions for frequent

users; (b) integrate the findings of the different workstreams and (c) are practically useful for services seeking to introduce or refine services for Frequent users.

8.1. Workstream 3a Realist Review

The realist review will be iterative, searching a wide range of relevant evidence to understand how interventions work, for whom and in what circumstances. The review will consist of two main phases. The first involves developing and refining a set of programme theories and comprises six main activities; refining the question, developing initial programme theory, developing the search strategy, selection and appraisal of evidence (based on relevance, rigour and richness), data extraction, and synthesis of data to develop, refine and test programme theory[49].
The second phase will involve a further conceptual development to identify and develop mid-range theories. The mid-range theories will conceptualise findings at a level of abstraction, which transcends simple description or generalisation, so that cases are understood within a "broader explanatory schema"[50]. These will be framed around understanding outcomes in terms of mechanisms operating under various contextual conditions. We will register the proposal with PROSPERO (University of York) and use RAMESES [51] reporting guidelines.

Initial theoretical framework

In phase 1, we will search for a wide range of evidence, including qualitative studies of frequent users, national reports, and other relevant sources that include verbatim accounts of service users of how services/interventions have been helpful and have either reduced the need to attend UEC or resulted in other definable benefits (e.g. improved mental health). This will include findings from WS1b, where preliminary ideas have been developed from interviews with staff about how interventions work and for which groups of frequent users including women, superusers, people with mental health issues) . We will also include studies that examine the reasons for frequent use of UEC, as these will also inform our programme theories regarding potential interventions for frequent users. For example, qualitative research suggesting that some frequent users develop strong attachments to EDs regarding them as places of recognition and inclusion [40]. We will include attendance at all aspects of the UEC network including, ED, walk-in centres, and ambulance calls. During the iterative process of searching, extracting and analysing, we will also follow up related topics from a broader literature base (e.g. help-seeking models) to develop, refine and test theories as new directions for investigation emerge.

We will use the Consolidated Framework for Implementation Research (CFIR)[52] for systematically examining how interventions are implemented and the TIDieR template [53] as a formal framework

for identifying and describing components of the included interventions, as this has proved useful in previous realist work. We will then use a realist logic template to describe the provisional context mechanism outcome chains (CMOCs) relating to contacts with UEC services or specific intervention delivered.

We will develop and refine our programme theories through discussion within the research team and PPI members in the Project Management Group to refine the CMOCs. We will identify intervention components, contextual enabling factors, potential mechanisms that lead to (e.g. decreased attendance, improved quality of life or mental health) and relevant implementation and sustainability enablers or barriers.

8.2. Workstream 3b Realist Evaluation of services for urgent and emergency care frequent users

Aim: To refine and test our theoretical models from the realist review and other workstreams using 4 in-depth comparative realist evaluations.

Objective: Understanding of how specific interventions achieve their outcomes for certain frequent users and which organisational changes support mechanisms which lead to improved care.

This part of the project will be led by researchers from the University of Sheffield.

We will develop, test, and refine the initial programme theories developed in WS3a using interviews with key-informant staff (ED and MH staff) and service-users, stakeholder workshops and documentary analysis.

Setting: We will use the four exemplar services identified in the previous work package for in-depth study. These may include one frequent user service with no designated staff, one service run by liaison mental health services, one service run by an ED team, and one service located outside ED (either in a different part of the UEC network or in the community- a high intensity service). Research sites will either be acute hospital trusts with an emergency department, or mental health trusts who employ liaison mental health teams who in-reach to emergency departments or third sector organisations. There will be a principal investigator at each site. The Principal Investigator will normally be a medically qualified clinician, or a registered health professional with relevant experience and expertise as determined by the chief investigator of if third sector a relevant employee/manager. Sites will be required to have obtained management approval and undertake a site initiation meeting prior to the start of recruitment of participants into the study.

If one of our chosen sites includes a frequent user service which consists of a team meeting without any direct patient involvement, we will not seek to interview patient participants from this site. This is because they will have not been approached directly by the frequent user service.

Eligibility:

Inclusion criteria-members of staff

- Aged 18 or over
- NHS or Third Sector Staff
- Has been involved in some capacity with a frequent user/high intensity service, either directly work in the service, or make referrals to the service, have patients who have used the service or have some strategic connection to the service.
- Mental capacity to provide full and informed consent

Exclusion criteria-members of staff

- Has not worked in a frequent user/high intensity service or had any direct or indirect professional contact with such a service

Inclusion criteria-service users

- Aged 18 or over
- Has used urgent and emergency care 5 or more times in the 12 months prior to receiving an assessment or treatment from a frequent user service.
- Has received an assessment or treatment from a frequent user/high intensity service.
- Mental capacity to provide full and informed consent

Exclusion criteria-service users

- Lacking capacity to comply with study requirements
- Considered by a clinician as currently unsuitable to enter a research study (e.g. too physically unwell, acutely suicidal).

Sample-staff: A maximum-divergence sampling frame will be developed for each type of site. This will include members of staff that are closely involved in the delivery of services that effect frequent users and will initially involve the recruitment of 3-5 participants. These participants will be asked to suggest other key roles or individuals for consideration, and these will be included in the sampling frame if it is considered that they will provide important additional information or perspectives.

We will recruit a total of 5-8 members of staff per site to reflect as many aspects of the service as possible, including liaison mental health staff and any other relevant personnel involved in delivering interventions for frequent users.

Participant Identification: The principal investigator at each site will collaborate with the research team to apply the sampling frame for the setting. They will arrange the circulation of study information seeking volunteers to take part in interviews. All documentation will clearly state that the study is being conducted externally and that there will be no penalty for not wishing to be involved. Volunteers will then contact the research team directly, to preserve their anonymity. Information sheets and consent form will then be emailed to potential participants.

Informed Consent: Potential participants that are willing to take part in the interviews will return their signed/named consent forms by email. A reminder will be sent, approximately one-week after consent forms have been sent out, followed by a second reminder 2 weeks later. After this, it will be assumed that the potential participant no longer wishes to take part in the study. Withdrawal from the study will be possible up until the point where data are incorporated into the analysis.

Sample-frequent users (5-8 per site): We are aware that recruitment of frequent users may be challenging. We will use PPI approaches to help us in this process and any local relevant emergency care forums at each site. We will also offer £30 vouchers for recognition of participants' time and contribution to the study. We will ask staff at each site to produce a complete list of frequent users in the last 12 months who have been assessed or seen by the frequent user service. We will also seek permission to advertise the study in non-NHS organizations, such as patients' and family associations, allowing patients to directly contact the researchers to participate in the study. We will develop a purposive sampling frame [48] (informed by our realist review) to ensure maximum variation.

Participant Identification and screening: We will ask staff to apply this sampling criterion to invite potential participants by letter or by face-to-face contact (telephone or video consultation) during a routine appointment or clinical review. Staff will be provided with information about the study and a supply of participant-facing documentation. Individuals who potentially meet the study eligibility criteria will be verbally informed of the study in person or by telephone by a clinician or suitable delegate or informed by letter. Potential participants will be asked for their permission for researcher contact. If they agree to this contact, they will be asked to provide their contact details which will be sent to the research team. They will not be asked to consent to interview at this stage. Consent to researcher contact may be given either in writing or verbally by the participant. Verbal consent to contact will be recorded on the designated 'consent to contact' form by the clinician. Where service

users are contacted by letter, if there is no reply within 3 weeks, they will be sent another follow-up letter.

Those willing to take part will then be contacted by the research team and provided with study information sheets. All participants who agree to be interviewed will provide appropriate informed consent either signed or verbal.

The study will be advertised in patient associations like Sheffield Emergency Care Forum, National Survivor User Network, Battle Scars through flyers and social media, pending local management approval. Introductory information about the study, including the inclusion criteria, contact details (email and phone) of the research team, and the offer of a £30 voucher for participation, will be provided. The research team will then verify if the patient meets the inclusion criteria and supply the information and informed consent sheet. Therefore, the research team will be responsible for the assessment of the eligibility criteria and risk. All participants who agree to be interviewed will provide appropriate informed consent, either signed or verbal. Those recruited through the non NHS sites don't need to have attended one of the sites taking part in the study.

Clinical screening: For those participants identified by the research sites, prior to any invitation to participate in the research an additional clinical check will be made by reviewing the electronic case notes of any potential participant identified by the clinical staff as being suitable and who has expressed an interest in being contacted by the research team. The review will focus on the physical and mental health of the potential participant that may impact on the ability of someone to participate in the research in a meaningful way, i.e. serious physical illness such that the person would be too unwell to participate; close to death; severe deterioration of mental state-e.g. actively suicidal or acute exacerbation of severe mental illness. Guidance will be provided to sites and the details of the review will be recorded on study documentation. The review should be carried out by the PI or a suitably qualified and experienced delegate, for instance a senior nurse manager or third sector manager or professional. Sites should identify enough reviewers, so this process does not cause undue delay.

Researcher Contact : A researcher from the research team will work with staff from participating sites to follow up those consenting to researcher contact. The researcher will contact the potential participant to explain the study in more detail and, if the potential participant is still interested, establish initial eligibility over the phone. Contact should be made as soon as possible.
Where potential participants are not interested or not eligible, details will be recorded.

If the potential participant has not yet received (or has mislaid) the patient information sheet, a copy will be sent via email or post for the potential participant to read prior to the research interview. The patient information sheet (PIS) will also be available on the research website to download. The PIS will include information about the rationale, design, and personal implications of the study. Potential participants will be given at least 48 hours to read and digest the information provided and will have the opportunity to discuss this with their family and other healthcare professionals if they so wish before being asked whether they would be willing to take part in the research. There will also be the opportunity to ask the researcher questions (both prior to and during the interview).

The research interview will be performed by telephone or video calling. Video calling software will be via MICRSOFT TEAMs which has been approved by the University of Sheffield and the University of Leeds. Interviews will be audio-recorded using an encrypted device.

Informed Consent: The right of the participant to refuse consent without giving a reason will be respected. Further, the participant will remain free to withdraw from the study at any time without giving reasons and without prejudicing any further treatment.

If taking verbal consent, the researcher will use a telephone consent script which covers all clauses of the consent form. Each clause will be initialled by the researcher following the participant's response. The researcher will sign the consent form on the participant's behalf. The researcher will use their own initials and signature in this case.

Electronic methods for documenting consent may also be used. A simple electronic signature (as defined by electronic Identification, Authentication, and trust Services regulation (eIDAS) will be considered acceptable.

The original consent form will be placed in the Investigator Site File at the University of Sheffield and a copy will be included in the participant's medical records by the PI. A copy will be given or sent to the participant.

Withdrawal of Consent: The right of a participant to refuse participation without giving reasons will be accepted. The participant will remain free to withdraw at any time from the study without giving reasons and without prejudicing his/her further treatment.

Risk Escalation Protocol: Should a participant become upset/distressed during or immediately after the research interview, or phone the researcher and indicate they are in distress:

1) (If during data collection), the researcher will ask them if they would like to stop. Some participants may feel upset but wish to continue with the interview. The researcher will remind them that that they do not have to continue. Participants can take a break during the interview if they need to or completely stop.
2) For participants who call the researcher, or if participants remain distressed once they have

stopped the interview, the researcher will acknowledge their distress and provide information about resources they can access (e.g. Samaritans, GP, support worker, crisis team).

3) If participants are still distressed, (they ask for more help and/or indicate that they are worried about how they are feeling, ask if they would like the researcher to support them in accessing the help outlined in step 2), the researcher should discuss relevant actions with a senior local site clinician or senior clinician on the research team.

4) If the researcher has serious concerns about a participant's immediate safety, the researcher will inform the participant that they need to speak to someone about the participant's concerns as they are worried about their immediate welfare. The researcher will immediately contact a senior clinician at the appropriate site to obtain advice. The senior clinician or researcher will then contact the participant with appropriate advice. In most instances this will involve advice to contact local crisis teams via telephone. In rare circumstances it may involve the senior clinician contacting the participant's GP to discuss/advise suitable management. In case of patients recruited by non NHS sites, the researcher will advise to contact local crisis team and provide the appropriate phone number.

Sample – workshops (one per site with 15-20 participants): The identification and prioritisation of roles and organisations will be established through the analysis of the interview data. However, it is anticipated that will invite staff from the wider UEC network, including ED, ambulance service, NHS111, GPs and commissioners, and representatives from mental health and acute medical care services. All members of staff who participate in the study will provide informed consent.

Participant Identification: The principal investigator at each site will collaborate with the research team to apply the sampling frame for the setting. They will assist in the identification of potential participants or contacts at each organisation to distribute study information to.

They will arrange the circulation of study information seeking volunteers to take part in interviews. All documentation will clearly state that the study is being conducted externally and that there will be no penalty for not wishing to be involved. Volunteers will then contact the research team directly, to preserve their anonymity. Information sheets and consent form will then be emailed to potential participants.

Informed Consent: Potential participants that are willing to take part in the interviews will return their signed/named consent forms by email. A reminder will be sent, approximately one-week after consent forms have been sent out, and a further reminder 2 weeks later. After this, it will be assumed that the potential participant no longer wishes to take part in the study. Withdrawal from the study will be possible up until the point where data are incorporated into the analysis.

Data collection: For both sets of interviews we will use topic guides. The topic guides will be based upon the realist review and ongoing synthesis and will be developed to generate, refine and test emergent theory across the multiple contexts. Interviews will be carried out by telephone or MICROSOFT TEAMS.

Interviews with staff will generate, refine, and test ideas about their understanding of key actors, the perceived impact on frequent users, factors influencing service delivery at the level of the whole UEC network, and how and why they believe services could be better organised to meet the needs of frequent users.

Interviews with service users, will explore their use of the whole UEC network, and other relevant services over the previous 3 months to map their individual urgent care networks. We will explore their reasons for using or not using different services, any trade-offs between services and how care could be simplified and better co-ordinated. We will explore their experiences of frequent user services, their perspectives of the care received including positive and negative aspects, interactions with staff, specific types of interventions perceived as being helpful (what changes they produced and how these were achieved).

Stakeholder workshops will focus on the interaction between different elements of the UEC network and seek to identify issues at the interfaces of services and unintended consequences across the network of actions in one element. We will use emerging programme theories as seeding concepts for discussion within the workshops. Interviews and workshops will be audio-recorded and transcribed verbatim for analysis. Workshops are also likely to produce written materials from exercises. These will be either transcribed or photographed and stored electronically. Depending upon whether these written records contain sensitive data or not, they will either be securely stored or destroyed.

Analysis: Interviews and workshops will generate different types of data, for instance some will be purely descriptive of the setting and some data will explore emerging theories and other data will seek to develop new theories. We will use appropriate analytical approaches for different types of data. However, thematic analysis will be used as an initial approach to order our findings. Each transcript will be read and reread to obtain a general sense of the whole. Theories will be drawn out either by reference to theoretical topics or CMOCs developed in the realist synthesis or to new or refined CMOCs developed through 'if, then, leading to' statements. Initially data will be classified by location and exposure to specific services. Later it will be classified by individual characteristics as these emerge from the data. Reporting will follow RAMESES II guidelines [49].

8.3. Workstream 3c Realist Synthesis

The realist synthesis will run throughout the qualitative workstream as a constant process of integrating and updating information not just from the realist review and realist evaluations but from all programme workstreams. The synthesis will focus on producing a set of programme theories following the methods described above. It will test these both in the site studies and by triangulation with the findings of characterisation of services data and the quantitative work in a separate workstream, of the programme. For instance, we will map intervention features described by our emerging programme theories to individual EDs using data from the liaison survey. We will then use data from the quantitative workstream of the programme to test for evidence that what participants thought was happening was supported by quantitative data. Similarly, we will seek evidence in the qualitative data of patterns which are capable of explaining findings from the quantitative data. Given the very different forms of data, and the highly iterative realist method, this can be considered a "following the thread" approach to integration of different data types [52] rather than a more rigid convergence coding. In synthesising the findings, we will recognise the complexity and diversity of different context (patient types, EDs, services).

Output: A rich and deep understanding of the patterns and associated costs of frequent use of UEC, drivers of frequent use and the mechanisms by which interventions delivered by frequent user services reduce frequent use of urgent and emergency care whilst delivering safe and appropriate care. Particular subgroups of frequent users suited to certain interventions and which interventions are most likely to achieve cost savings.

9. WORKSTREAM 4 SHARE FINDINGS AND CHANGE PRACTICE

Aim: Produce and disseminate an implementation framework for frequent user services to optimise care.

Objective: An implementation framework for urgent and emergency care to help plan and optimise services for frequent users

There is insufficient evidence at present to support the implementation of any intervention or set of interventions for frequent users of urgent and emergency care, so we have not included an implementation phase in our programme of work. We want to establish a ground zero framework of knowledge from which further research in the UK on frequent use of urgent and emergency care can

be based, and to provide clear, practical, guidance to improve the quality and outcome of existing services, including their cost-effectiveness.

The realist work will be able to deliver an understanding of what are the core and peripheral elements of interventions, what might work where and why. i.e. what are the important mechanisms that need to be supported and how might this be achieved. The key is the understanding and embracing of complexity and diversity. This is based on the understanding that standardised interventions do not work in complex systems, but need to be adapted for the local context[53].

We will organise and present our findings in the form of an implementation framework with a view to future potential adoption and implementation by services, and will draw on both the Tidier [51]and CIFR Frameworks[50], to help present our findings in a clinically relevant format.

We will work with health professionals and administrators from our 4 cases study sites and PPI to produce an implementation framework of 'ideal' models of service delivery, with relevant interventions that are suited to the type of service, including the necessary inputs (internal e.g. staff and external e.g. training), activities, outputs and outcomes (including costs), and recognising contextual factors and potential barriers to success. Our findings and recommendations will be grounded in real world practice, have face validity, and will be simple, modifiable, and desirable. Our focus will be primarily on the nature and type of evidence for new or modifications to practice, but we will also address the contexts required for certain interventions, and the likely nature of support that will be required to adopt new or modified practice.

Our dissemination plan will involve a multi-level top approach to transfer information about our findings to relevant stakeholders. The top-down approach will involve targeting six key groups: NHS England, The Royal Colleges of Psychiatry, Emergency Medicine and General Practice, Ambulance Services, and the NHS Confederation. We will convene a workshop of relevant national stakeholders and PPI to present the findings from our programme, and to discuss the recommended improvements to services. There has already been a national CQUIN concerning frequent user services and a large investment in liaison services, so this is a key area of interest for NHS England. We will also use channels within the relevant Royal Colleges to disseminate our findings more widely within the relevant professional groups.

At an intermediate level, we will hold 4 webinars (each one focusing on a particular service type) which will be jointly presented by members of the research team and key personnel from the case site of relevance, which will be targeted at the 20 frequent user services that participated in the

characterisation of service interviews. So, each webinar will include one of the exemplar sites and 4 of the other sites with similar services. We will incorporate any relevant feedback from the webinars into our implementation framework.

At the bottom-up level, we will hold 4 further webinars which will again focus on a particular service type. We will invite all remaining frequent user services to attend one of the webinars, according to their type of service. We will again modify and revise our framework based upon the feedback we obtain.

We will finalise the framework in the remaining 2 months of the programme and make it widely available in an electronic format to all relevant services. We recognise that it will be an aid to implementation but not an implementation plan in its own right.

10. DATA STORAGE

All information collected during the study will be stored in compliance with all aspects of the 2018 Data Protection Act. Data in Leeds will be stored using the Leeds Analytic Secure Environment for Research (LASER Platform). This is a cloud based (Microsoft Azure) platform hosted in Leeds Institute of Data Analytics (LIDA). LASER securely hosts data that are highly sensitive, personally identifiable, or commercially sensitive. It provides a secure environment for the handling, processing, analysis and storage of sensitive and confidential research data, segregates projects at network level, using separate ***Virtual Research Environments (VRE)***, protecting data from the rest of the University's computing facilities and from internet access. It has been built to high security standards that comply with ISO27001 and The NHS Data Protection Toolkit. Data are classified and controlled according to data sensitivity and confidentiality. Highly secure projects being only accessible from dedicated safe rooms. It is managed and maintained by University of Leeds IT Services and operated and supported by LIDA's Data Analytics Team (DAT).

Data collected for the project (qualitative interviews and workshops) which is stored in Sheffield will be stored in an access restricted folder on the University's Shared Networked File Store. ScHARR Date Security will create secure folders with controlled access and arrange archive or deletion on request. This will be documented in an information asset register. Personal data and audio recordings and transcripts of interviews will be kept for 12 months post the end of the study and all other data will be kept for 5 years.

There are five organisations that are collaborators for this research programme. They are

- **UNIVERSITY OF LEEDS**, incorporated by Royal Charter with registered number RC000658 and having its registered office at Woodhouse Lane, Leeds LS2 9JT ('**Leeds**');

- **UNIVERSITY OF YORK**, incorporated by Royal Charter with registered number RC000679 and having its principal offices at Heslington, York YO10 5DD ('**York**);

- **UNIVERSITY OF SHEFFIELD**, incorporated by Royal Charter with registered number RC000667 and having its principal offices at Western Bank, Sheffield, S10 2TN ('**Sheffield**');

- **CORNWALL PARTNERSHIP NHS FOUNDATION TRUST**, having its principal offices at Carew House, Beacon Technology Park, Dunmere Road, Bodmin PL31 2QN ('**Cornwall**');

- **YORKSHIRE AMBULANCE SERVICE NHS TRUST**, having its principal offices at Springhill 2, Brindley Way, Wakefield, WF2 0XQ ('**YAS**');

All parties/organisations have signed a collaboration agreement.

No personal, identifiable data will be shared or transferred between the different organisations during this research programme. The data involving the 20 chief informant interviews will be held in Leeds including consent forms. The data from the 4 study sites will be held securely at the University of Sheffield, including consent forms. Raw data will not be shared between the organisations. Data that have been analysed will be shared for the purpose of writing papers and discussing results.

11. QUALITY ASSURANCE AND ETHICAL CONSIDERATIONS

11.1. Quality assurance

The research will be performed in accordance with the recommendations guiding physicians in biomedical research involving human subjects, adopted by the 18th World Medical Assembly, Helsinki, Finland, 1964, and subsequent amendments and in accordance with current MRC Good Clinical Practice (GCP) guidelines, and UK Policy Framework for Health and Social Care Research 2017. Research Ethics Committee (REC) approval, regulatory and Health Research Authority approval will be sought. The right of the patient to refuse participation without giving reasons must be respected (Workstream3). The patient must remain free to withdraw from the study at any time without giving reasons and without prejudicing their care or treatment. The study documentation will be submitted to the identified Research Ethics Committees (REC). Separate REC approvals will be sought for Workstream 2 and Workstream 1b,3 and 4. For the site work in WS 3, the study must be approved by the relevant REC and receive management approval from each participating site (Workstream 3) prior to any participants entering the research study.

11.2. Approvals for Hospital Episode Statistics Data

Relevant project documentation and associated approvals need to accompany applications to NHS Digital and will be scrutinised by the Independent Group Advising on the Release of Data (IGARD) to determine whether the application is approved. The use of HES data will be subject to a Data Sharing Framework Contract between University of Leeds and NHS Digital and a specific Data Sharing Agreement for the project, which will mandate specific technical and organisational safeguards, such as the use of specific technical infrastructures within University of Leeds for managing data.

Personal data refers to data about living people from which they can be identified. As well as data containing obvious 'identifiers' – such as name and date of birth. Data that has been pseudo-anonymised (with identifiers separated), where the dataset and identifiers are held by the same organisation, is still personal data. Data anonymised in line with the ICO 'Anonymisation code of practice' is not personal data. An example of this is when identifiers are held by another organisation with an agreement that specifies no re-identification. This will be the case regarding the data requested from NHS Digital.

11.3. Approvals for CUREd data

All requests for CUREd data require completion of a Data Access Request form and appropriate ethical approval for use of secondary data. The CUREd Data Release Committee reviews proposals on a monthly basis and provides approval for projects.

11.4. Serious Breaches

Investigators are required to promptly notify the Sponsor of a serious breach (as defined in the latest version of the National Research Ethics Service (NRES) SOP). A 'serious breach' is defined as a breach of the protocol or of the conditions or principles of GCP (or equivalent standards for conduct of non-CTIMPs) which is likely to affect to a significant degree the safety or physical or mental integrity of the research subjects (not applicable in this case), or the scientific value of the research.

11.5. Confidentiality

All information collected during the study will be kept strictly confidential. Data in Leeds will be stored using the Leeds Analytic Secure Environment for Research (LASER Platform) (see section 12.0)

and will comply with all aspects of the 2018 Data Protection Act and University of Leeds Information governance policy.

Data from the site interviews will be stored at the University of Sheffield as described in section 11.0.- in accordance with the 2018 Data Protection Act and the University of Sheffield Information and Governance Policy.

Participant name, address and telephone number will be collected when a participant provides informed consent but all other qualitative data collection forms that are used will be coded with a research number (Workstream 3). Patient names and addresses will be stored in a separate file with the research code number. To ensure confidentiality of the data collected when published, fictitious site names and pseudonyms or study numbers not linked to sites or persons will be used. All identifiable data such as research site names, address, date of birth and participants' names will be removed.

12. ARCHIVING

Data will be requested from NHS Digital for a period of 3 years from the date of the data sharing agreement. It is anticipated that this will exceed the duration of the funding by several months to allow for finalization of any related publications and dissemination. At the end of this period the data will be destroyed. Data destruction certificates will be completed for both CUREd data and HES data. Qualitative data collected as part of WS1 & WS3 will consist of interview and workshop transcripts and notes. In accordance with University Policy archived for 5-years. Data will be automatically and securely destroyed after this time.

13. STATEMENT OF INDEMNITY

The proposed study is sponsored by the University of Leeds. The University of Leeds, as the employer of the Chief Investigator will be liable for negligent harm caused by the design of the study.

14. STUDY ORGANISATIONAL STRUCTURE

Chief Investigator

As defined by the UK Policy Framework for Health and Social Care Research 2017, the Chief Investigator is responsible for the design, management and reporting of the study.

Operational structure

The **Programme Management Group** (PMG), which oversees the FUsED Programme Grant, comprises the Chief Investigator, Programme Manager, Co-Applicants and Co-Investigators. The PMG will oversee the whole programme of studies**.**

The **Programme Steering Committee (PSC)** – The PSC, with an independent Chair, will provide overall supervision of the programme, in particular progress, adherence to protocols, safety and consideration of new information. It will include an Independent Chair, no fewer than two other independent members and a patient representative. The CI and other members of the PMG may attend the PSC meetings and present and report progress. The Committee will meet annually as a minimum.

It is anticipated that the Chief Investigator, work package leads, and research fellows will regularly meet to discuss the study. They will be responsible for the set-up of the study, including gaining ethical approval, appointment of additional researchers if required, management and overall supervision of the study team, collection and analysis of data, and drafting/finalizing publications. The Chief Investigator will be responsible for the day-to-day running of study.

15. PUBLICATION POLICY

The study will be registered with an authorised registry, according to the International Committee of Medical Journal Editors (ICMJE) Guidelines. The success of the study depends upon the collaboration of all participants. For this reason, credit for the main results will be given to all those who have collaborated, through authorship and contributorship. Uniform requirements for authorship for manuscripts submitted to medical journals will guide authorship decisions. These state that authorship credit should be based only on substantial contribution to:

- conception and design, or acquisition of data, or analysis and interpretation of data,
- drafting the article or revising it critically for important intellectual content, and final approval of the version to be published,
- and that all these conditions must be met (www.icmje.org).

In light of this, the Chief Investigator and relevant members of the PMG staff will be named as authors in any publication.

The timing of any publication from the programme and this study will ensure scientific integrity is maintained. Individual collaborators must not publish data concerning their participants which is directly relevant to the questions posed in the study until the first publication of the analysis is reported. The publication policy for this study will follow the publication policy agreed by the Programme Management Group.

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