The dynamics of frailty in older people: modelling impact on health care demand and outcomes to inform service planning and commissioning

HS&DR 16/116/43 Study Protocol

Version Number	Author	Effective Date	Reason for Change
1.0	BW	04/12/18	Protocol as submitted for final funding approval with minor edits to correct typo, layout and removing content not required in a protocol
1.1	BW, CF	15/08/19	Revised procedure for obtaining linked data from RCGP RSC, requiring IRAS and CAG application for part of the study
1.2	BW,CF	17/02/20	Revised procedure for obtaining linked data from RCGP RSC, requiring DARS approvals, and clarification of information governance and data management procedures for all data providers.
1.3	BW	20/07/20	Minor amendment to data provider organisations. Change from 3 data providers to two (RCGP RSC and SAIL).
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Contents

1. Abstract

Background - As the population ages, prevalence of frailty and associated demand for health care rise. Methods for identification and clinical management of frailty are available, but capacity and resources for delivery are limited. There is recognition of an evidence gap in relation to the planning, commissioning and delivery of services for older people living with frailty and questions remain about the incidence and prevalence of different levels of frailty and the consequences for health outcomes, service use and costs.

Objectives – To explore the incidence, prevalence, development and impact of frailty within the population to explore trends in development and progression of frailty, and the dynamics of frailty related healthcare demand, outcomes and costs in the older general practice population, to inform the development of guidelines and tools to facilitate commissioning and service development.

Study Design & Methods - Retrospective observational study design with statistical and simulation modelling using routine health care data from primary and secondary care. We will determine population prevalence, incidence and trajectories of decline in frailty within an ageing cohort using the eFI tool and data from the Royal College of General Practitioners Research Surveillance Centre (RCGP RSC) databank, with additional data from Secure Anonymised Information Linkage (SAIL) databanks.

> *Study population* - The primary data source for the study will be the RCGP RSC. The sample will comprise an open cohort of the primary care population aged 50 and over (approx. 1.1 million people) during the year 2006, followed for 10 years to 2017. The data will be linked to Hospital Episode Statistics (HES) secondary care data and Office for National Statistics (ONS) death registry data.
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> *Baseline measures* – eFI score will be calculated for all adults aged 50+, with scores re-calculated at 6-monthly intervals for the study period. The population will be stratified into robust, mild, moderate and severe frailty groups. Other variables will include age, sex, Index of Multiple Deprivation (IMD) score, ethnicity, long-term conditions diagnoses, urban/rural indicators, practice size.
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> *Outcomes* - Mortality, unplanned hospitalisations, 30-day readmissions, ED attendances, GP visits, care home transition. Costs will be estimated for service use for different frailty strata over 10 years. The influence of frailty on outcomes, service use and costs will be explored. We will use these analyses to inform the development of a prototype simulation model, which will use a System Dynamics (SD) based approach to explore the development and impact of frailty in the population and likely future scenarios over a 10-year timeframe. The simulation model population projections will be externally validated against retrospective data from the Secure Anonymised Information Linkage (SAIL) dataset.

Study outputs - The immediate project outputs are the statistical and economic analyses, algorithms and simulation model. We will collate the outputs into a commissioning toolkit, comprising guidance on drivers of frailty-related demand and simulation model outputs that can be used for prediction of future demand and exploration of different service scenarios.

2. Study team

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3. Summary of Research

The impact of frailty on demand for and outcomes of care has emerged as a significant issue for the NHS in recent years. The association between frailty and adverse outcomes such as unplanned admission, transfer to residential care and high service use is well recognised (BGS 2014/15; NIHR 2017; Clegg et al. 2013). As the population ages, prevalence of frailty and associated demand for health care rise. In the context of reduced resources and rising demand for unplanned care, the delivery of appropriate services to support people with frailty will be key to providing cost-effective, quality care for older people. Recent consensus guidelines have emphasised the importance of identification and clinical management of frailty (BGS 2014; NICE 2016) and effective interventions are available, but capacity and resources for delivery are limited. There is recognition of an evidence gap in relation to the planning, commissioning and delivery of services for older people living with frailty (NIHR 2017). Questions remain about the incidence and prevalence of different levels of frailty and the consequences for health outcomes, health and care service use and costs. Addressing these issues requires exploration of population trends in the development and impact of frailty, but this research has previously been limited because of the need for clinical assessment for the identification of frailty. The recent introduction of the electronic Frailty Index (eFI) (Clegg et al. 2016) allows routine primary care data to be used to identify the presence and severity of frailty in real-world populations. The eFI therefore facilitates the exploration of the dynamics of frailty and its impact at a population level. It enables stratification of the primary care population into robust, mild, moderate and severe frailty groups, so enabling comparison of trajectories of decline and pathways of care between these groups, which will be key to service development and commissioning.

In this study, we will explore the incidence and prevalence, development and impact of frailty within the population using retrospective data from the Royal College of General Practitioners Research Surveillance Centre (RCGP RSC) database, which holds data for 1.8m patients from 230 practices. The eFI tool will be utilised to stratify a cohort of people aged 50 and over within the database in 2006 into robust, mild, moderate and severe frailty groups. We will extract data on frailty status, health care use, and outcomes for the subsequent 10 years, calculating key service use costs from these data. Outcomes will include mortality, unplanned hospital admission, A&E attendance and GP appointments. The RCGP RSC dataset will also provide data on socio-economic factors, practice size and location and residence. We will stratify the cohort by severity of frailty and explore frailty status over time, determining incidence, prevalence and progression of frailty. We will examine the relationships between factors such as age, deprivation, ethnicity, location and comorbidities of individuals in relation to development of, and deterioration in, frailty status. The influence of frailty on outcomes, service use and costs will be explored. We will use results from these analyses to inform development of guidelines for service commissioners, developed in partnership with experts in service delivery, commissioning and our PPI representatives through stakeholder engagement. We will use these analyses to inform the development of a prototype simulation model, which will use a System Dynamics (SD) based approach to explore the development and impact of frailty in the population and likely future scenarios over a 10-year timeframe. The simulation model population projections will be externally validated against retrospective data from the Secure Anonymised Information Linkage (SAIL) Databank, which holds primary and social care data on up to 30,000 individuals in Wales . Residence data from RCGP RSC will be supplemented by data on residential care transitions and social care use by frailty status from SAIL, to inform simulation of impacts and costs beyond the health care setting. Finally, 'what if' scenarios developed with the stakeholder engagement group (SEG) will be explored via simulation modelling.

4. Plain English Summary

Older people who have complex health problems are often described as frail. People who are frail are more likely to find it difficult to deal with small changes in their health or circumstances. This means that, when they get ill, the effects are worse than for other people. Until recently, it was difficult to provide care for frail older people because it was hard to identify people who were frail without an assessment by a consultant. This meant that frail older people were not always receiving the care they needed. Better care for frail older people has become a priority for the NHS. It will improve their health and quality of life and it will also help the NHS to use its resources more efficiently.

It is now possible to use a tool called the electronic Frailty Index (eFI) to identify all the frail older people in a GP practice from their routine health care information. This will allow GPs to offer services designed for the frail older people in their practice. However, the GPs and local health NHS services need to know more about their frail older patients and what sort of health and care services they need. At the moment, they don't have enough information about the numbers of frail older people they can expect or the amount and type of health and care services that they use now and will need in the future as the population ages.

In this study, we will use routine information from GP practices across England, linked to information about hospital care, from 2006 to 2017 using the Royal College of General Practitioners Research Surveillance Centre (RCGP RSC) database. We will identify the number of frail older people and the severity of their frailty and other health problems. We will examine factors that might increase the level of frailty. We will then look at what happened to those people and what health care they needed over the following 10 years. We will use this information to tell the organisations that purchase (commission) health care and provide health care (including GPs and community health and care services) how much health care and what types of services are needed for frail older people in England. We will test this information against data from a similar database in Wales (the Secure Anonymised Information Linkage dataset).We will also use this information to build computer models (simulation) that the commissioners can use to work out how many people will become frail in their area in the future. We will use information from the RCGP RSC, and SAIL to model the health outcomes, health and care service use and costs of frailty in the ageing population. We will develop the computer models and the other information from this study into a toolkit that health and care organisations can use to work out what type of services they will need to look after frail older people in years to come. In the future, the computer models can be developed to look into other conditions, or the type, grade and number of staff needed to look after frail older people.

5. **Background and Rationale**

5.1 What is frailty?

Frailty is a condition associated with ageing, characterised by reduced physiological reserves across multiple body systems, resulting in vulnerability to internal (e.g. infection) and external (e.g. changed environment) stressor events (Clegg et al. 2013; Gale et al. 2015; Campbell & Buchner et al. 1997). In frailty, inflammatory processes driven by ageing and chronic disease result in physiological and psychological decline (loss of strength, reduced cognitive function, atypical symptoms, sensory decline). Inevitably, as these pathological changes accumulate, there are consequences for functioning, resulting in common health problems of old age such as falls, mobility problems, reduced appetite, incontinence and depression/anxiety. Frailty is, due to these wide-ranging effects, associated with higher mortality, dependency, residential care transition, high service use, emergency admissions and reduced quality of life (B GS 2014/15; NHS England 2015; Clegg et al. 2016; Theou et al. 2016; NIHR 2017).

5.2 Frailty in the NHS

It is estimated that 1.8 million people in the UK aged 60 and over are living with frailty, although prevalence is concentrated in those aged 85 and above (NIHR 2017). Until recently, researching frailty in the population has been limited by the need for clinical assessment to identify frailty. The benefits of using routine data for risk prediction in primary care are well established (Dixon & Bardsley 2012; BGS 2014/15). Current guidelines on the recognition and management of frailty (BGS 2014, NICE 2016) recommend that older people should be assessed for frailty in encounters with health and social care professionals. Identification and stratification of frailty in primary care is intended to facilitate more effective clinical management; frail patients have been shown to benefit from interventions such as comprehensive geriatric assessment (CGA) and balance re-training. Identification and management of frailty is now a component of the 2017/18 General Medical Services (GMS) contract (GMS 2017). Co-applicant Clegg led the development and validation of the electronic Frailty Index (eFI) tool. This study used routine electronic health record (EHR) data from around 900,000 UK patients, demonstrating that the eFI is capable of predicting risk of adverse outcomes in an older population and was able to discriminate between mild, moderate and severe frailty in a UK primary care population (Clegg et al. 2016). Based on the internationally established cumulative deficit model, the eFI was found to have good predictive ability for mortality, hospitalisation and nursing home admission. The eFI has been implemented into the SystmOne, EMISWeb, Vision and Microtest primary care EHR systems, so is freely available to every general practice in England, and around 95% of all UK general practices (Improvement Academy, 2017; NHS England 2015). The eFI is specified as a relevant tool for identification of frailty in the 2017/18 GMS contract, and use is supported in the 2016 NICE Multimorbidity Guideline (GMS 2017, NICE 2016).

5.3 What is the problem being addressed?

As the population ages, demand for healthcare increases, but older people are at risk of worse outcomes and poorer quality care than younger people (Oliver et al. 2014). Commissioners and service planners must identify ways of meeting need whilst managing demand. Older people are more likely to have frailty, which is associated with poor health outcomes and high service use (Clegg et al. 2016; NIHR 2017). Targeting older people living with frailty could ensure that unplanned care is avoided whilst improving quality (BGS, 2015). Consensus guidelines on the management of frailty (Morley et al. 2013; BGS 2014, 2015) recommend identification of frailty and clinical management, goals facilitated by the national implementation of the electronic frailty index (eFI) and its incorporation into the GMS Contract (Clegg et al. 2016; 2017/18 GP GMS). Although guidance (BGS 2014, 2015) provides a framework for individual management the focus is typically on severe frailty: there is little evidence to support service commissioning across the spectrum of frailty severity. Little is known about the course of frailty and transitions between frailty states, prevention of frailty or slowing the transition from mild to severe frailty. Available evidence indicates that over half of those aged 70 and above with frailty will experience at least one frailty transition within a four-year period and that the majority of these transitions represent a decline (Gill et al. 2006). This work, however, utilised a criteria-based measure of frailty which is not directly comparable to the frailty index now being using within the NHS. With the widespread introduction of the eFI in primary care, the opportunity arises to use routine EHR data to explore resource use and outcomes in frail older people across the spectrum from robust, through mild, moderate and severe frailty.

Current guidelines for management of frailty acknowledge that there is a lack of evidence on which to base service design and commissioning (BGS 2015). A recent review (NIHR 2017) noted that improved knowledge about prevalence could aid commissioners and service providers to plan care more effectively for frail older people. Our proposed research will address significant gaps in the evidence relating to the population burden of frailty and its impact on health care use and costs over time. This analysis, and the associated simulation model, will inform guidance for commissioners and providers, development of a toolkit to support commissioning and, in the future, development of workforce planning tools.

5.4 Why is this important to the NHS now?

As the population ages, frailty will become more prevalent; frailty in the population aged over 60 was recently reported as 14%, rising to 65% of those aged 90+ (Gale et al. 2015). Frailty is more prevalent in women and is associated with deprivation and multiple morbidity. NHS England (2015) note that frail older people use considerable resources in the last 12 months of life, suggesting delayed identification and potential for earlier intervention. Measurement and identification of frailty in the primary care population is therefore likely to be a useful adjunct to existing risk stratification approaches (BGS 2014/15) and has recently become a requirement in the GMS contract. There are potential advantages to identifying frail older people in the primary care population in this way. These individuals often have non-specific and functional problems that are associated with high service use and adverse outcomes. Evidence exists to support interventions for older people living with frailty, such as Comprehensive Geriatric Assessment (CGA), a multidimensional and interdisciplinary assessment of medical, psychological and functional capabilities aimed at developing an integrated plan for treatment and care, falls prevention or balance re-training, medicines optimisation and exercise interventions, which have the potential to slow or prevent decline (NIHR 2017; Pilotto et al. 2017).

Despite increasing recognition and attention to the issue of frailty, key barriers to realising these benefits exist. Although there is considerable evidence to support the identification and management of frailty there is a lack of evidence to support planning and configuring services to meet the increased demand associated with frailty in an ageing population. Little is known about the dynamics of frailty within the population and questions remain around:

- progression from robust to mild, moderate and severe frailty states
- the impact of interventions on incidence and progression
- trends in development of frailty within the ageing population
- the impact of comorbidity and socio-economic drivers on frailty progression and associated service use
- the impact of different service delivery models and preventative interventions

Better understanding of the development and dynamics of frailty over time will facilitate service and workforce planning and commissioning.

The implementation of the eFI allows the use of routine EHR data from primary care to identify frailty across the population. We propose to use the eFI to explore the dynamics of frailty and associated health care demand over time, using data from the nationally representative Royal College of GPs Research Surveillance Centre (RCGP RSC) databank, with additional data from Leeds Data Model (LDM) and Secure Anonymised Information Linkage (SAIL) databanks. We will examine the prevalence and progression of frailty within an older cohort, exploring the relationship between frailty, demographic, service and clinical factors, service demand and costs over time.

This analysis will inform the development of a simulation model of the impact of frailty within an ageing population, externally validated using data from the Leeds Data Model (LDM), with which we will explore the impact different demographic and service scenarios.

Based on these analyses, we will produce a toolkit for commissioners, comprising the prototype simulation model and commissioning guidelines. The simulation model will be informed by the analyses above, supplemented by social and residential care data from the SAIL databank, alongside guidance from the Stakeholder Engagement Group (SEG). The simulation model will be used to explore ‘what if’ scenarios and population trends for at least 10 years into the future for outcomes and resource use and up to 25 years for population trends. The proposed study is an essential foundation for frailty service planning at national, regional and local levels.

In this study, the emphasis is therefore on a whole-system analysis of the dynamics and impact of frailty at a population level, including exploration of drivers of incidence and decline and association with outcomes and resources use. The following will be key outputs of the study:

- Information gaps about the dynamics of frailty and service use in primary care populations will be addressed to inform service planning and commissioning, allowing improved integration of care, deployment of resources, identification of areas of highest need or where new roles might be of benefit
- Service providers and commissioners will be provided with new information in the form of guidance on population trends and key drivers relevant to service planning and prevention strategies.
- A simulation model will allow prediction of trends and exploration of the impact of different demographic and service configurations which can be tailored to local contexts.
- Future implementation and research priorities, including those relating to workforce planning, will be identified

5.5 Impact on the NHS and relevance to HS&DR remit

Frailty has major resource use implications for the NHS. It is associated with common health problems of old age such as falls, mobility problems, weight loss, incontinence and depression. Frailty is also associated with higher mortality, dependency, entry to residential care, unplanned service use and reduced quality of life. Frailty-associated health care demand will continue to grow in the future as frailty becomes more prevalent in the ageing population. In line with the HS&DR remit, the issue of delivery of high-quality care for older people living with frailty is of significant strategic importance for the NHS. Improved service provision for frail older people has the potential to reduce unplanned care costs and improve outcomes. Existing evidence supports the use of specific clinical interventions to improve patient outcomes but does not provide guidance on the expected impact of frailty in the ageing population or appropriate service configuration and commissioning. The complexity of frailty and the impact of sociodemographic, clinical and organisational factors on likely demand mean that commissioners will need methods for predicting trends that are responsive to local contexts. This research will address significant gaps in the evidence relating to the population burden of frailty and its impact on health care use over time, informing improved service planning and commissioning. This study, through use of routine EHR data and simulation modelling, represents a cost-effective approach to exploration of regional and local drivers of frailty-associated demand. The study aims are therefore in line with the programme remit to provide evidence on the quality, accessibility and organisation of health services and improved delivery of services.

Outputs of the study will include guidance for commissioners, a simulation model to facilitate prediction of service demand associated with frailty and the potential for development of these resources into a workforce planning toolkit. The simulation model architecture, and the know-how relating to populating and operationalising the model, will be transferable to prediction of demand for other populations and conditions with a high population prevalence (e.g. dementia, obesity, mental health problems). The research team is experienced and brings expertise in a range of relevant settings and research methods. In line with the HS&DR remit, the audience for this research is the public, service users, clinicians and service providers and commissioners.

6. Aims & Objectives

Co-applicant Clegg led the development and validation of the electronic Frailty Index (eFI) (Clegg 2016), a frailty identification tool utilising primary care data. The eFI, specified as an appropriate tool for use in primary care (GMS Contract 2017, NICE 2016), is now available to every general practice in England and around 95% of all UK general practices (Improvement Academy 2017). Current guidance (GMS 2017) focuses on identification and clinical management of those with severe frailty. Important questions remain about how services can best be organised and commissioned to meet the health care need and demand associated with development and progression of frailty across the ageing population. Resources such as CGA are limited and commissioners and service providers will need guidance on the scale and mix of services required across the spectrum of frailty.

The overarching aim of this study is to explore trends in development and progression of frailty, and the dynamics of frailty related healthcare demand, outcomes and costs in the older general practice population, to inform the development of guidelines and tools to facilitate commissioning and service development for this patient group.

We will explore trends in development and progression of frailty, frailty-related health care demand and outcomes in an ageing cohort. These analyses will inform guidance for service planners and commissioners. They will also underpin development of a simulation model of the impact of frailty to aid resource planning at local and regional levels. The simulation model will allow exploration of projected demand and costs into the future and exploration of ‘what if’ scenarios for different demographic trends and service use and organisation patterns. The simulation model will be the basis of a tool for use in commissioning.

Study objectives are:

1. Identification of incidence and prevalence of frailty states in an ageing population
2. Identification of frailty trajectories and transitions in severity in the older population over time

Table 1: Frailty Dynamics Data Sources

Dataset	Data items	Study Phase	Access
RCGP RSC 1.8 m patients 1.1 million patients aged 50 and over 230 practices National - England Over 50	Age Gender Index of Multiple Deprivation (IMD) LTC diagnoses Ethnicity Smoking BMI Prescriptions Urban/rural Practice size eFI Mortality ED attendances Hospital Admissions Residential care	Workstream 1	Host: Surrey University Analysis: on site/secure remote access Approvals: Unlinked primary care: UoS Ethics Committee and RCGP RSC IG approvals Linkage: via NHS Digital Data Access Request Service DARS) and RCGP RSC IG approvals and UoS Ethics Committee
SAIL databank 30,000 patients Wales Primary, secondary and social care data	Age Gender IMD LTC diagnoses eFI score Mortality ED attendances Admissions Social care data (Swansea) Residential care use eFI	Workstream 2 & Workstream 4	Host: SAIL databank Analysis: Remote secure access Approvals: SAIL IG process and UoS Ethics Committee

3. Exploration of drivers of progression of frailty, including clinical, socioeconomic and demographic factors
4. Examination of the impact of frailty on service use, costs and pathways of care
5. Exploration of the relationship between frailty status, socio-economic factors, practice factors and service use and outcomes (mortality, unplanned admissions, residential care use)
6. Prediction of trends in frailty, modelling of health and care demand and costs over time and in different service contexts

7. Research Plan & Methods

7.1 Design We will use a retrospective observational study design with statistical and simulation modelling using routine health care data from primary and secondary care. We will determine population prevalence, incidence and trajectories of decline in frailty within an ageing cohort using the eFI tool and data from the Royal College of General Practitioners Research Surveillance Centre (RCGP RSC) database, with additional linked data from HES and ONS to provide information on hospital attendances and mortality. (Table 1). Relationships between demographics, practice characteristics, outcomes, service use and costs will be explored for frailty (eFI score) strata (robust, mild, moderate and severe). This analysis will inform the development of a population model for simulation of trends and exploration of ‘what if’ scenarios. The population model will be validated using the SAIL databank which provides similar primary care data variables to RCGP RSC, with associated secondary care data (Table 1).

Simulation modelling will explore the impact of demographic factors on frailty prevalence and impact over time within the specified population. Data from the RCGP RSC and SAIL will be supplemented by social care and residential care data from the SAIL Databank (Table 1) for modelling of demand related to frailty. The impact of different demographic and service drivers will be explored via modelling of 'what if' scenarios developed with the Stakeholder Engagement Group (SEG).

The project will be divided into the following workstreams (Fig 1):

- Workstream 1: statistical modelling of population trends, incidence and prevalence of frailty, stratification of frailty and related outcomes, resource use and costs. (Study Outcome (SO) 1-5)
- Workstream 2: validation of the population model (SO 1,2,5)
- Workstream 3: stakeholder engagement. (SO 3,4,6)
- Workstream 4: simulation modelling to explore impact of different service and demographic scenarios on population trends, service demand and costs in the future. (SO 4,5,6)

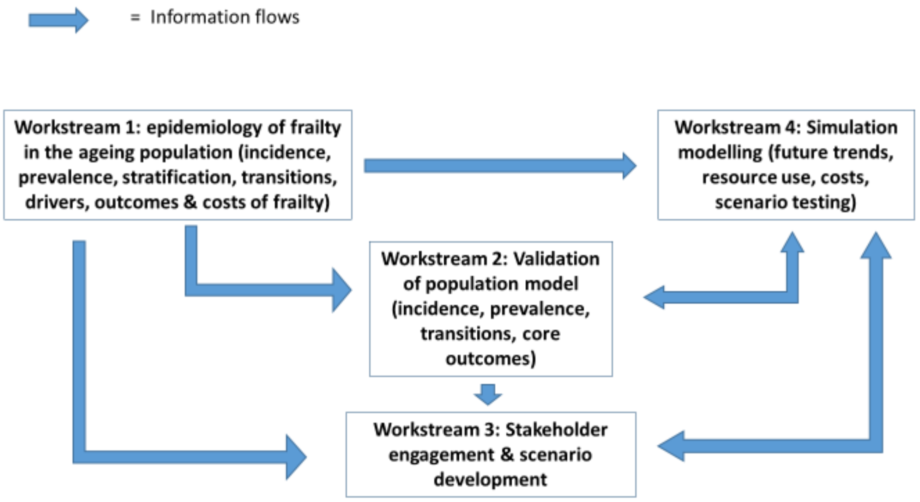

Figure 1: Content of, and information flows between, study workstreams

7.2 Setting All data will be retrospective, using routine health care data from the RCGP RSC, and SAIL databanks. Data extraction and pseudonymisation will be carried out by the RCGP RSC, and SAIL Databank analysts. The research team will have access only to the agreed data extracts. Data from all data sources will be provided to the research team in pseudonymised, de-identified format. Identifiable personal data, including NHS numbers, will be removed and individual pseudonymised IDs generated before transfer to the databank organisations. In addition, the pseudonymised ID held by the databank organisations will be replaced with ID numbers that are unique to this study. Pseudonymisation for all data extracts will therefore be non-reversible and the study team will under no circumstances have access to the keys for creation of the unique study ID numbers. The research team and analysts at RCGP RSC and SAIL will not have access to or use any patient identifiable information throughout this study. The study team will access the pseudonymised data extracts via remote linkage to secure servers. Only aggregate, anonymised results of analyses of data extracts will be exported from the secure servers for use by members of the research team, including the RFs, for simulation modelling. Pseudonymised data extracts will therefore always remain on databank secure servers. Details of the data extracts, data collection and data management are given in Section 7.3 (RCGP RSC), 7.4 (SAIL) and 7.6 (SAIL) and are summarised in Table 1.

7.3 Workstream 1: Population Trends, Frailty Progression and Outcomes

7.3.1 Design: this workstream will use linked primary and secondary care data to explore development and impact of frailty in the older population. The data extraction approach is based on the following conceptual model of frailty transitions in the population (Fig. 2).

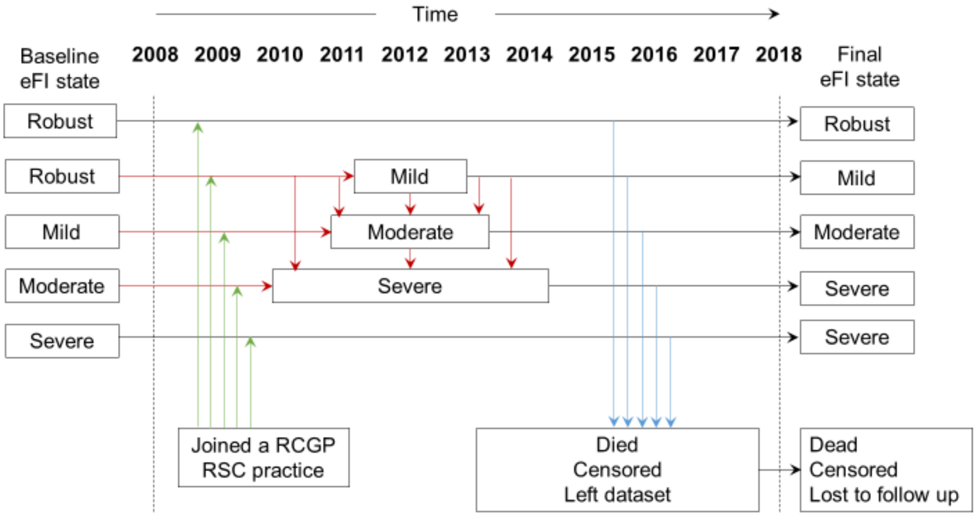

Figure 2: Conceptual Model for Frailty Transitions in the Ageing Population

7.3.2 Population and sample size: The primary data source for the study will be the RCGP RSC databank, a pseudonymised electronic health record (EHR) that collates routine primary care data from a population of 2.5 million nationwide; more than 250 GP practices. The sample will comprise an open cohort of the primary care population aged 50 and over within the RCGP RSC (approx. 1.1 million people) during the year 2006, followed for 10 years to 2017 through the retrospective data within RCGP RSC. The RCGP RSC has its secure data and analytics hub at University of Surrey, who manage data governance, encryption and access (co-applicant de Lusignan is the RCCGP RSC Medical Director). The data will be linked to Hospital Episode Statistics (HES) secondary care data and Office for National Statistics (ONS) death registry data, which allows treatment and care to be tracked across care settings and providers (see Section 7.3.3.1 for details of data linkage).

7.3.3 Data Governance and Data Management: The RCGP RSC will only use and store pseudonymised information extracted by an approved 3rd party provider, Apollo Medical Software Solutions. Before being made available for this research project, primary care data will be de-identified. Individual patient IDs are generated in the RCGP RSC data extraction process using a one-way hashing algorithm and are therefore irreversible. In addition, these hashed identifiers are then replaced, with all personal identifiers removed and replaced with ID numbers that are unique to this study. Data linkage will be by means of pseudonymised IDs generated using a non-reversible 'one-way hashing' algorithm (7.3.3.1). Patients who have opted out of sharing their data will be excluded. The RCGP project team will only have access to pseudonymised data and the pseudonyms in that data will be unique to this project.

The research team will apply for extraction of the specified data extract via the RCGP RSC Information Governance processes. The research team will only use the pseudonymised data extract and will only export aggregated, anonymised data analyses from the secure server, subject to RCGP scrutiny. The RCGP team and Southampton researchers will not have access to identifiable patient data at any point in this study. Access to the pseudonymised database will be limited to the database analysts. The research team will access the research data extract via remote access to the secure, on-line servers. Variables have been defined to minimise the risk of re-identification (e.g. by means of inference or 'jig-saw' attacks) . The strength of RCGP RSC primary care data pseudonymisation will be further enhanced by RCGP RSC through replacing all pseudonyms with a set unique to this study. The research team will not have access to the mechanism used to effect this replacement.

The pseudonymised data extract will be held on secure computer facilities at the University of Surrey. The research team and analysts at RCGP RSC will not have access to or use any patient identifiable information throughout this study. The study team will work with co-applicant de Lusignan at the Surrey site to carry out the primary data analysis, either at that site or via secure Virtual Private Network links to the Surrey secure servers. Synthesis of new variables and adjustment of data format will be carried out to facilitate analysis, e.g. re-coding of ICD-10 diagnoses into broad system categories.

7.3.3.1 Data Linkage The primary care data provided by RCGP RSC will be linked to Hospital Episode Statistics (HES) secondary care data and Office for National Statistics (ONS) death registry data, which allows treatment and care to be tracked across care settings and providers. Approval for data linkage will be via the NHS Digital Data Access Request Service (DARS). RCGP RSC data analysts, through a secure process, will provide details of their non-reversible 'one-way hashing' algorithm to NHS Digital to enable data linkage between the primary care records and secondary care (HES) and death (ONS) data. This will be the same hashing algorithm as is provided by Surrey University to Apollo Medical Software Systems for application at the point where data are extracted from GP systems These organisations apply the code to 'hash' the patient identifiers, creating unique ID codes from NHS number (the process is non-reversible). In this process, NHS number is 'hashed' in the same way in both data sets, which allows linkage to the primary care data by matching of 'hashed' NHS numbers without requiring access to patient identifiable information. The data providers then provide the pseudonymised data to RCGP RSC, where the linked, pseudonymised data extract is prepared for the research team. All other processes for management and protection of the data are as described in 7.3.3.

7.3.4 Variables/Outcomes: Baseline eFI score will be calculated for all adults aged 50+, with scores re-calculated at yearly intervals for the study period using CTV3 codes provided by co-applicant Clegg. The population will be stratified into robust, mild, moderate and severe frailty groups. Other variables will include age, sex, Index of Multiple Deprivation (IMD) score, ethnicity, long-term conditions diagnoses (Read coded in primary care, ICD-10 and OPCS4 in HES; with as single terminology SNOMED CT due to be introduced in 2018), urban/rural indicators, practice size.

7.3.5 Outcome and service use measures: mortality, unplanned hospitalisations, 30-day readmissions, ED attendances, GP visits. A household key will be calculated to determine residence in care homes. Costs will be estimated for service use for different frailty strata and average individual costs over the median follow-up period of 10 years.

*7.3.*6 Follow-up: The initial cohort will be identified within RCGP RSC for the year 2006. Patients aged 50 and over in those years will be tracked through subsequent years up to 2017.

7.3.7 Statistical Analysis of Population Trends and Service Use*:* There are two main aims for this Workstream. They are the identification of key variables that are capable of predicting frailty development and progression and the assessment of the relationship between frailty status and key clinical outcomes (including mortality and unplanned admissions). These analyses will then be used to inform the simulation modelling being conducted in Workstream 4. We will use descriptive statistics to estimate baseline prevalence, burden of frailty and transition rates between frailty states in population aged 50 and over. Multi-state models will then be used to determine what clinical, demographic and socio-economic variables are able to stratify frailty progression. Time-dependent Cox models will be used to examine the relationship between frailty state and key binary clinical outcomes (including mortality and service use). Mixed-effects negative binomial models will be used to examine the relationship between frailty state and count based clinical outcomes, such as the number of unplanned hospitalisations. The key clinical, demographic and socio-economic drivers that are identified as significant predictors of frailty progression and/or associated with outcomes or service use patterns of interest will be used to stratify the SD model, to develop agent-based, stochastic models and to inform potential ‘what if’ scenarios for simulation.

7.3.8 Cost Analysis: The cost analyses will be taken from the NHS and personal social service perspective (PSS). Resource usage date including medication, primary care consultation, outpatient visit, A&E attendance, and hospital admission will be extracted from RCGP RSC database. Itemised resource usage will be costed using corresponding unit prices based on BNF, NHS reference costs and PSSRU (Curtis & Burns, 2017).Accumulated costs for each person will be calculated over the study period with appropriate annual inflation adjustment to bring to the same year price. The datasets have hierarchical structure with individuals nested within general practices. Generalised linear mixed models will be used to estimate the costs and key clinical outcomes including frailty states, adjusting for baseline characteristics. We expect that the costs will be highly skewed; Bootstrap methods will be conducted as sensitivity analyses. Mean costs per person for different frailty and patient groups will be estimated and presented with mean and 95% confidence intervals. The estimates will be used to inform the simulation model.

7.4 ***<u>Workstream 2: Validation of the Population Model</u>***

7.4.1 Sample: The simulation model for population trends will be validated using comparable data from the SAIL databank. We will use the SAIL data, which is a pseudonymised linked database containing linked secondary and primary care data, including the same key variables as RCGP RSC, for external validation of the simulation model of population trends. The model predictions will be validated against retrospective data from SAIL.

7.4.2 Variables: Age, sex, IMD, LTC diagnoses eFI scores, mortality, ED attendances, admissions

7.4.3 Statistical Analysis: The baseline prevalence of frailty (for each combination of stratification variables and for the overall SAIL population) will be estimated from the SD model (having been informed from the RCGP RSC dataset) and this will be compared against what is seen in the SAIL dataset in both a graphical and tabular fashion. Comparisons will be performed using standard goodness-of-fit tests where comparable data are available and by plotting selected outputs as time series for visual comparison. Frailty transition rates and predicted frailty status levels at yearly time intervals will also be compared between the SD model and what is actually seen in the SAIL dataset in a similar way.

7.4.4 Data Governance and management: The research team will apply for extraction of the specified data via SAIL Information Governance Processes. The research team and analysts at SAIL will not have access to or use any patient identifiable information throughout this study. Access to the pseudonymised data extract will be limited to the database analysts. The research team will access only the SAIL research data extract, which will be accessed via remote access to secure servers. The research team will export only aggregated data analyses from the secure server. The research team will not have access to any identifiable patient data and the data extract will be further protected by replacement of the pseudonymised ID with unique study ID numbers.

7.5 Workstream 3: Stakeholder engagement and scenario development

7.5.1 Stakeholder Engagement Group Membership: Model structure and what if scenarios will be informed by the Stakeholder Engagement Group (SEG). The Stakeholder Engagement Group will meet 3 times during the course of the study, in addition to participation in the dissemination event. The SEG will be facilitated by a member of the research team (AB), a Frailty Nurse Consultant with experience of interviewing, focus groups and stakeholder engagement. Other clinical members of the research team will join the Stakeholder Engagement Group (HP, SF). The SEG will also include service commissioners and representatives from service providers, particularly from those organisations involved in local Sustainability and Transformation Plans (STPs) relevant to older people’s services (see Section 11.2 for details). The PPI representative, Mrs Vivienne Windle, and other PPI representatives recruited from the Faculty of Health Sciences Older People and Dementia Research Patient and Carer Panel, with other members of the Stakeholder Engagement Group will have an integral role in the development and completion of the modelling phase of the study.

7.5.2 Setting: SEG participants will represent commissioners, provider organisations and patients and the public (Section 11.2).

7.5.3 Engagement Process: SEG meetings will be organised at key points in the study. We will use the stakeholder engagement approach informed by that described by O’Haire et al. (2011) for use in prioritising future healthcare research needs. We will present emerging findings from each stage of the data analysis and ask participants to reflect on implications for service delivery and organisation. At each stage, the SEG will contribute to decision-making around data needs, model building, scenario development and future priorities. The following data collection methods will be used:

- Conceptual mapping to inform simulation model structures (SEG event 1)
- Focus group approach to inform recommendations and analysis (SEG 2)
- Nominal group processes to agree ‘what if’ scenarios and future priorities (SEG 3)

The SEG will ensure that patient/carer and professional experience in relation to service structures and care trajectories is central to model development. At the final stakeholder engagement event, we will present the emerging model development and findings and explore their implications for future research and practice. What if scenarios will be developed to explore the impact of different demographic trends, changed risk factors and different care scenarios on prevalence of frailty and associated demand over time.

7.5.4 Engagement Outputs: The SEG will ensure that outputs from the work streams will be reviewed by key stakeholders and that outputs from the SEG events will be fed back directly to the Study Management Group at key points in development of the model and outputs (Table 2). The SEG leads will collate the information gathered from the events in the form of contemporaneous notes and graphic. The information gathered will be shared with SEG participants to ensure a sense check and trustworthiness of the information gathered prior to sharing with the Study Management Group.

7.6 Workstream 4: Simulation modelling

7.6.1 Methods: System Dynamics (SD) is a computer simulation modelling approach whose purpose is to analyse changes over time in complex, interacting systems. SD has been used for decades in many different application areas, and is ideally suited for health and care systems (Brailsford 2004, Northridge

2016). In Workstream 4 we will use SD to model population dynamics and predict future frailty-related healthcare demand in the UK. Together with health economics modelling, the model will also allow us to explore the impact of frailty on future service use and costs. An SD model consists of stocks (accumulations) of material, and flows between them, analogous to a series of water tanks connected by pipes. The rate of flow along each pipe is governed by valves that can be turned up or down. We will develop a stock-flow model depicting patient transitions between different states. In our case, the "material" is frail patients, and the stocks are the numbers of patients in different health and social care states, following Figure 1. These states will be further broken down by those characteristics identified in Workstreams 1 & 2 as significantly impacting on demand for services, or strongly associated with specific outcomes. Potential candidate characteristics include age, gender, LTC diagnoses and IMD.

7.6.2 Sample and Data: Data from Workstreams 1 & 2 will be used to populate the simulation model to enable simulation of population trends, service use and costs. In addition, other data sources will be used to explore the impact on specific services, e.g. social care, residential care, will be sourced from the SAIL databank, a linked, pseudonymised database containing primary, secondary and social care data for Wales, hosted by the University of Swansea. The simulation model does not follow individual patients, but uses the results obtained in Workstreams 1 & 2 to calculate monthly transition probabilities between states (stocks). The simulation model will use data from workstreams 1 and 2 to capture the key clinical and demographic differences that influence these transitions, as well as information about the costs and outcomes associated with each state. Data from Workstreams 1 & 2 will be used to populate the simulation model to enable accurate simulation of population trends, service use and costs. Residence data from RCGP RSC will be supplemented by data on residential care transitions and social care use by frailty status from the Secure Anonymised Information Linkage (SAIL) Databank, which holds primary and social care data on up to 30,000 individuals in Wales, to inform simulation of impacts and costs beyond the health care setting. The SAIL data extract will provide data on social care and residential care use stratified by eFI score for the model. The anticipated time horizon for running the model is ten years (2017-27): this length of time is required to capture fully the population dynamics and the evolution of frailty. While the demographic predictions thus derived will be robust, we recognise that any cost calculations more than two or three years into the future can only be indicative, given that service delivery modalities and health and social care organizational structures are unlikely to remain fixed for the whole period. Moreover, there is bound to be considerable local variation. The model can easily take this into account by modifying the relevant parameters.

7.6.3 Data Governance and Management: The processes for RCGP RSC and SAIL data will be as described (Sections 7.3 and 7.5 respectively). Information Governance approvals will be sought for SAIL data. The SAIL databank contains linked, pseudonymised primary, secondary and social care records, from which anonymised extracts will be requested. The research team and analysts at SAIL will not have access to or use any patient identifiable information throughout this study. Unique study IDs will be applied to the data extract and the study team will have no access to the key. The SAIL Databank data extract will be analysed by the study team at one of the databank secure sites in Swansea or Cardiff or via their secure remote access servers. Access to the pseudonymised database will be limited to databank analysts. The research team will only access the anonymised data extract provided by SAIL.

7.6.4 Analysis and Use of the model: The key benefit of using simulation is that a wide range of "what-if" scenarios can be tested and compared, including demographic trends and changes to prevalence and progression rates, in addition to service delivery scenarios developed with the SEG in Workstream 3. The model outputs, which will enable comparison between scenarios, will include:

- The number of patients, and proportion of the population, in each stock over time
- Demand for services over time, aggregated or broken down by patient category
- A range of health outcome measures, aggregated or broken down by patient category
- Mortality, total or cumulative, aggregated or broken down by patient category

8. Dissemination & Projected Outputs

The clinical management of frailty will become increasingly important as the population ages, with prevalence of frailty rising from 10% of people aged over 65, to up to 50% in those aged over 85. Despite the scale of this patient group, research indicates that half of patients with frailty are not receiving effective health care interventions. In Fit for Frailty Part 2 (BGS, 2015), it is noted that there is potential for significant harm to frail patients if they receive inappropriate interventions. However, many services across the health and care system do not take adequate account of individuals' frailty and so opportunities to improve quality of care are missed. Attention to the needs of older people living with frailty could, therefore, be more effective in reducing acute bed use and improving quality of care than focusing on those at high risk of admission. At the individual patient level, guidance for patient management exists and there is general agreement about the features of good quality care. There are, however, gaps in the evidence relating to the organisation and delivery of interventions and services to optimise provision of high-quality individualised patient management across the frail older population. The improved understanding of population needs offered by this study will inform appropriate service planning and delivery, giving direct benefit for patients through provision of timely and appropriate care.

Identification of potential frailty is only the first step in ensuring high quality care; recommended areas for development include: identification of frailty in patients following unplanned hospital admission, mapping of diagnostic and referral pathways, provision of community based specialist care, palliative care, integration of care across primary care, intermediate care, care homes, mental health, ambulance services and social care. Fit for Frailty 2 notes that future service commissioning will need to be able to address the integrated care needs of this population. Care pathways will need to be identified as a precursor to development of clinical pathways that meet the needs of older people at different points in the trajectory of frailty. The BGS emphasise that "Systematic identification and recording of data on patients with frailty would facilitate better modelling of need, service planning and clinical management within the primary care system."

This study, with its emphasis on whole-system population dynamics of frailty, will explore the issues around population need, service configurations and clinical interventions highlighted above. A strength of the simulation modelling approach is that it allows for identification of different trajectories of care and key transition points, projection of future demand and rapid testing of the impact of different service configuration scenarios to aid decision-making. The proposed study will undoubtedly impact on patient care directly, for example, by identifying features of people with frailty who are more likely to have adverse outcomes, identifying risk factors for frailty progression and informing targeted prevention through identification of trajectories of frailty, so enabling better targeting of interventions and services. Indirect impact will also be important, for example, through allowing commissioners to understand different care trajectories, and therefore the likely scale and nature of service demand, or service providers to identify cost-effective approaches for their specific population and facilitating the integration of health and social care.

The study outputs will have direct benefit for commissioners; commissioning is a complex cycle involving assessment and understanding of population health needs, planning services to meet those needs, procuring appropriate and cost-effective services and monitoring their delivery and impact. The outputs of this study will have the potential to contribute at each of these stages, but will have most impact in relation to assessment of population health needs. The planning stage of the commissioning cycle is often limited by a lack of reliable data on demand, particularly data which allows for forward projections; this study will address this need in relation to older people with frailty. The simulation modelling approach proposed in this study is particularly well-positioned to support commissioning, with its recent shifts towards more local commissioning, joint working and context specific (or ‘place-based’) commissioning and a focus on integrated systems of care. Integrated care organisations and commissioners will need to become more focused on needs of patients with multiple morbidity and functional problems (consistent with the presenting problems encountered in frailty) rather than disease-specific approaches. In planning this proposal, we have been aware of the need to collaborate with commissioners and organisations involved in service planning and delivery in order to fully realise the potential benefits for commissioning. The Study Engagement Group (SEG) includes representation from our local STP, including from CCGs, local authorities and provider organisations, in addition to national commissioning representatives.

Operations Research approaches, such as that proposed for this study, have demonstrated impact in both the Wessex and Peninsula CLARHCs. Projects in these regions have contributed to service re-design, effective resource allocation and demand management whilst maintaining or improving quality, for example, informing service re-design to improve bed management, optimising the resources required for a clinical decision unit and reducing waiting time in emergency departments. We anticipate that realisable benefits from the proposed work will include guidance for commissioners and service providers on service configurations and the development of a customisable model for local exploration of service demand and configurations.

The immediate project outputs are the statistical and economic analyses, algorithms and simulation model, which will form the core of guidance for NHS commissioners and planners to aid resource planning in relation to frailty. We will use a range of dissemination approaches to reach the various target audiences for this research. Our dissemination strategy will be guided by our PPI representatives and other key stakeholders on the SEG. Our study team, SEG and collaborators include senior stakeholders relevant to development of frailty services and use of the eFI, including from provider Trusts, NHSE Older People Team and CCGs (Section 11.2). We will use the established networks of our team to share our findings with leaders in implementation and commissioning of frailty services. We will work with our PPI lead and SEG to plan dissemination to NHS staff ‘on the ground’ and also the local and wider body of patient/carers, with al focus on making the results ‘accessible’ to the wider public, both in writing and verbally, through presentations at workshops/team meetings/to patient groups. We will run a dissemination planning event to which we will invite NHS commissioners and frailty leaders to review our findings, consider their implications and implementation and explore key messages and strategies for dissemination. We will use our established formal social media networks to promote project outputs, and for dissemination. We will share the final results of the study with the public and staff in the relevant health, local and third sectors a public/patient friendly way by use of infograms, using plain English, and via use of local and national media and social media. In addition, we will summarise the findings of our work via professional journals (e.g. HSJ) and health service networks and professional organisations (Health Services Research Network, British Geriatrics Society).

In addition to the above, the core study team will lead on other study outputs, including academic journal papers. We will submit abstracts for oral and poster presentations at a minimum of two national and one international conference focusing on care of older people and aiming for the widest possible audience. We will submit at least two academic papers to high impact open access journals. These will be focused on the dynamics of frailty within the population and the impact of frailty on health care demand and outcomes. This study will provide data on incidence and prevalence of frailty, stratified by severity, in a typical older, primary care population. It will examine the relationship between individual, socio-economic and service characteristics and the development and outcomes of frailty. The long-term impact of frailty on outcomes and service demand and costs will be modelled. This study will therefore provide new, direct evidence about the impact of frailty in the ageing population. This research will have an impact on service planning and commissioning by providing new guidance on the impact of frailty at population level, specifically in relation to trends in service use as the population ages. For the first time, service planners and commissioners will have access to longitudinal data on the dynamics of frailty in relation to demographic and socio-economic features of the population. The simulation model will allow local and regional service planners and commissioners to explore a range of scenarios relevance to their specific contexts, so aiding decisions on service commissioning and design. We will collate the outputs of the study into a commissioning toolkit, comprising guidance on drivers of frailty-related demand and simulation model outputs that can be used for prediction of future demand and exploration of different scenarios. The simulation model will be capable of adaptation for exploration of different service and demographic contexts. We anticipate that this study will, in future, inform the design and development of a workforce planning tool, extending the simulation model developed in this project. We will use the extensive networks of our team to ensure that we utilise the developing evidence base on outcomes costs of frailty to inform this process. The simulation model algorithms will be transferable to modelling of other chronic conditions that are common within the ageing population.

We will produce a final research report for NIHR detailing the work undertaken and results alongside an abstract, executive summary and technical appendices. The executive summary will be suitable for use as a briefing paper for NHS managers and commissioners. In addition, we will prepare a short Powerpoint presentation to present the main findings to NHS organisations. The slides will be made available, alongside the full report, on the HS&DR programme web pages and, where possible, as additional linked material with other publications. We will work closely with the University communications team and ensure that members of the study team are given appropriate support and training in handling enquiries from the media.

9. Plan of investigation & Timetable

Table 2: Study Timetable

Month	Pre-Project	Year 1	Year 2	Year 3
1		Full team start-up meeting SSC meeting 1	SSC meeting 2 Model building	SSC Meet 3 Data cleaning & analysis
2		Data specification 1 RCGP RSC	Model building – drivers, trends RCGP data linkage specification	
3			SEG 2 Full team meeting RCGP DARS application	Populate simulation model
4			Model building – progression trajectories RCGP data linkage - outcomes	SEG event 3 Scenario development
5		Data cleaning, coding, database building	Data Specification 2 SAIL Report outcomes	Simulation testing
6			Model building – outcomes and costs Full team meeting Recommendations to stakeholders	Full team meeting Report - simulation

7		Report prevalence, trends	Model testing Data extraction 2 SAIL	SEG event 3 Scenario development Toolkit development
8		SEG 1	Data cleaning	Guideline development
9	Initiate appointments	Full team meeting	Population model parameterisation	Dissemination planning event
10	Initiate ethics applications	Report analysis – prevalence, trends, Paper	Data extraction 3 SAIL	Prepare final report
11		Report analysis – drivers	Model validation	
12	Set up SSC Set up SEG	Paper	Report model validity Paper	Final report to NIHR

10. Project Management

The project will be overseen and managed by BW. SF will deputise, and will attend the SSC, in case of unforeseen absence. Day to day project management will be provided by the senior research fellow and project coordinator. Project management will be organised as follows: Research Management Group (RMG) led by BW, comprising the PI, research fellows (Carole Fogg and Dave Evenden) and project coordinator (Francesca Lambert), which will meet weekly throughout the study; Full Research Team, comprising all co-applicants, which will meet at key points in the study; Stakeholder Engagement Group (SEG) led by AB; and the Study Steering Committee (SSC), Chaired by Prof, Simon Conroy, University of Leicester, which will provide independent oversight (see Table 2). The RMG will meet regularly to review and coordinate progress on each work stream, monitoring progress against the key project milestones. Full team meetings are scheduled at key points in data collection and analysis (Table 2). The study will be organised into work streams with co-applicants leading in their areas of expertise:

- Workstream 1: Statistical modelling of population trends, outcomes, resource use and costs using data from RCGP RSC – led by SF with SdeL as co-lead for the Surrey site, supported by AC, RFs, with support for statistical analysis from PR, SH, economic modelling from SZ.
- Workstream 2: Validation of the population model using data from SAIL – led by AC with support from the research fellows, PR, SH, SZ and SB
- Workstream 3: Stakeholder engagement to inform modelling – led by AB, supported by SF and HP
- Workstream 4: Simulation modelling of population trends, service use and costs – led by SB, with support from SH, SZ, BW, PR and the RF.

Work stream leads will involve other co-applicants as necessary. In addition to the SSC meetings, we will hold yearly meetings for the whole study team at appropriate points in the development of the study. Where possible, we will use teleconferencing and/or Skype to allow co-applicants to participate in meetings, but we have costed for co-applicants outside Southampton to attend one full team meeting each year in person, plus the dissemination event.

We propose to have a Study Steering Committee (SSC) for purposes of overall project supervision on behalf of the sponsor and funder. The SSC will focus on progress of the study, adherence to the protocol, oversight of governance and ethics processes and consideration of any new information relevant to the study. The independent Chair of the SSC will be

Professor Simon Conroy, University of Leicester. We will include at least one PPI representative on the SSC and 75% of the members will be independent of the study. We do not propose to have a Data Management and Ethics Committee (DMEC) because of the routine, retrospective nature of the data. The SSC will be assisted by the Project Management Group (PMG), led by the PI, which will focus on day to day project management. The work packages will be co-ordinated by the PI and senior RF, but will each be led by one or more co-applicants who will report to the PMG.

11. Ethics

This study will utilise routinely collected NHS patient data where explicit consent has not been gained from participants. Following guidance from HRA and CAG, we have determined that the proposed use of non-identifiable, previously collected routine data extracts from the independent databank organisations (RCGP RSC, SAIL) does not require formal ethical approval by an NHS REC or CAG approval (see Appendix 1 for HRA statement).

Although NHS ethical approvals are not required for research using the proposed de-identified, routine data extracts and analyses, we have obtained ethical approval from the Faculty of Environmental & Life Sciences Ethics Committee at the University of Southampton for access to routine, de-identified primary care data and de-identifed primary, secondary and social care data from SAIL (ERGO II 46313 – see Appendix 2).

In addition, we will seek approvals from the Faculty of Environmental & Life Sciences Ethics Committee at the University of Southampton and NHS Digital's DARS for pseudonymised data linkage between the RCGP RSC primary care data and HES and ONS. We will use approved Information Governance procedures for database access at each database organisation, including use of secure servers, analysis at secure sites and independent data analysts for data extraction and linkage. Only anonymised, aggregate data extracts will be exported from database secure servers.

Procedures for maintaining confidentiality will be as per usual standard for data of this type; all databank organisations collate pseudonymised data with direct patient identifiers removed; data extracts and aggregate analyses will be pseudonymised/anonymised as described; the research team will not seek individual patient identifiers; where required, data linkage will be achieved through 'hashing' algorithms to generate non-identifiable, unique IDs from identifiable data; as a further protection, non-reversible, pseudonymised ID numbers held be database organisations will be converted to unique study IDs, the keys to which will not be accessible to the research team; and, when using these data, we will suppress small numbers in reporting and avoid the presentation of data that can potentially be used to reveal identities. The proposed study is focused on modelling of population flows and service use, so a high level of data aggregation is used in the analysis; we do not therefore anticipate significant issues in relation to confidentiality (See Section 7 for full details of data governance and management for each data source).

The study will be registered with an appropriate register for observational studies (ClinicalTrials.gov).

12. Patient & Public Involvement

Identification and management of older people with frailty in primary care is required under the GP contract (GMS 2017/18). However, there is a lack of evidence to support service and workforce planning. At the same time, there are clear public concerns about the quality, appropriateness and accessibility of services for older people. Consumers of this research are likely to be at the commissioning and service planning level and PPI will be vital in ensuring that both this study and future service development are guided by patient priorities. In developing this proposal, we have been advised by Megan Barlow-Pay, PPI Officer with RDS South Central. We have recruited a PPI representative, Mrs Vivienne Windle, to the study. Mrs Windle has experience as a PPI representative on four previous projects about frailty. She brings together a range of personal and professional expertise relevant to this study: she is a carer; has worked as a parliamentary researcher, including on health care issues; as a Parish Councillor she sat on her local Council Health & Wellbeing panel. This combination of experiences is particularly suited to this project with its service organisation perspective. Discussion with Vivienne Windle has confirmed the importance of the study topic and has assisted in focusing the development of the proposal, particularly in relation to study outputs and the role of the Stakeholder Engagement Group (SEG). Mrs Windle will be a member of the SEG, which will be led by co-applicant Abigail Barkham (Consultant Nurse for Frailty). We will also invite members of the Health Sciences Older People and Dementia Research Patient and Carer Panel to participate in stakeholder engagement events. Also invited to participate in the SEG is Mike Simpson, Chief Executive of Age UK Mid Hampshire. Mrs Windle and Mr Simpson have access to a wide network of patients and carers, giving them broad insight into patient experience and challenges. They will be able to further involve patients and carers in the work of the SEG. PPI representatives will contribute to the dissemination strategy and will guide the Research Team on formulating messages and media aimed at the wider public. AB and VW will be invited to meetings of the Research Management Group as necessary. In addition, the simulation modelling component of the proposed study will draw on the feedback from the SEG events, the final one of which will focus on emerging findings and identification of future research and practice priorities.

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Outputs

APPENDIX 1: HRA Approvals Decision

ENQUIRY TO QUERIES LINE

Dear Bronagh,

Your query was reviewed by our Queries Line Advisers.

RE: The dynamics of frailty in older people: modelling impact on health care demand and outcomes to inform service planning and commissioning

Thank you for your email seeking additional clarity on whether your project should be classified as research and whether it requires ethical review by a NHS Research Ethics Committee (REC).

You provided the following information:

- An summary outlining your proposal
- A PDF /screenshot of the results page of the decision tool(s)
- An explanation of which questions you have difficulty in answering and why

Based on the information you have provided, our decision is that the project is **considered to be research but does not require review by an NHS Research Ethics Committee.**

In giving this decision our advisors wish to advise you that research limited to the following does not require REC review:

> **Research involving previously collected, non-identifiable information**
>
> Research limited to secondary use of information previously collected in the course of normal care (without an intention to use it for research at the time of collection) is generally excluded from REC review, provided that the patients or service users are not identifiable to the research team in carrying out the research. This exception also applies to research undertaken by staff within a care team using information previously collected in the course of care for their own patients or clients, provided that data is anonymised or pseudonymised in conducting the research.

This decision is in line with:

- The harmonised UK-wide edition of the Governance Arrangements for Research Ethics Committees (GAfREC), (updated April 2012);
- UK Policy Framework for Health and Social Care Research (2017)
- The National Research Ethics Service (NRES) guidance “Defining Research”and the algorithm *Does my project require review by a Research Ethics Committee?*

This decision should not be interpreted as giving a form of ethical approval or endorsement to your project on behalf the HRA. However, it may be provided to a journal or other body as evidence if required.

You should also be aware that:

- This response only covers whether your project is classified as research and whether it requires review by an NHS REC. You are strongly advised to consider other approvals that may be required for your project.
- All types of study involving human participants should be conducted in accordance with basic ethical principles, such as informed consent and respect for the confidentiality of participants. Also, in processing identifiable data there are legal

requirements under the Data Protection Act (2018). When undertaking an audit or service/therapy evaluation, the investigator and his/her team are responsible for considering the ethics of their project with advice from within their organisation.

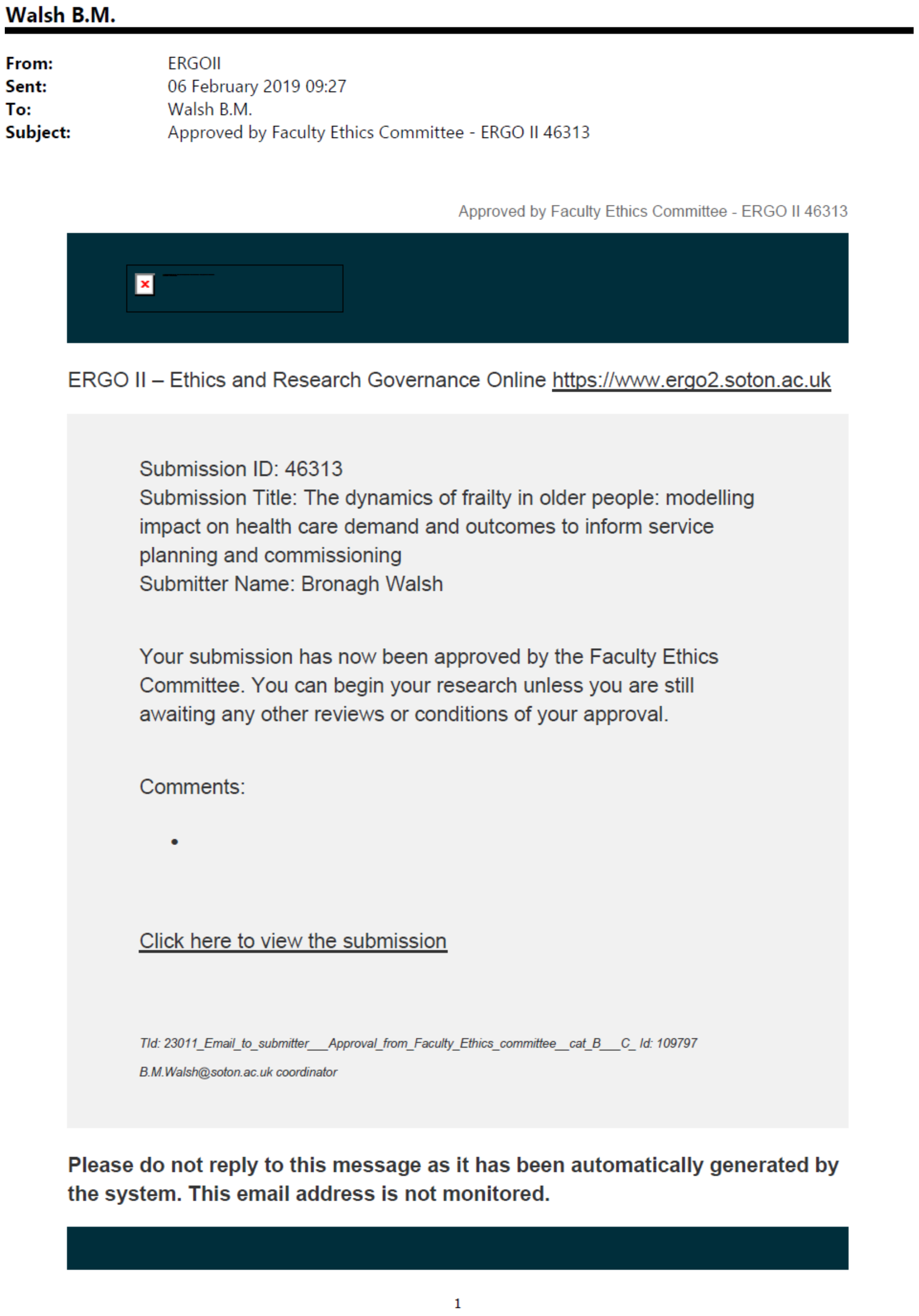
Regards
Queries Line
REF 544/55/89/81

The Queries Line is an email-based service that provides advice from HRA senior management, including operations managers based in our regional offices throughout England. Providing your query in an email helps us to quickly direct your enquiry to the most appropriate member of our team who can provide you with an accurate written response. It also enables us to monitor the quality and timeliness of the advice given by the HRA to ensure we can give you the best service possible, as well as use queries to continue to improve and to develop our processes.

Health Research Authority
Ground Floor, Skipton House| 80 London Road| London | SE1 6LH
E. hra.queries@nhs.net
W. www.hra.nhs.uk

Sign up to receive our newsletter HRA Latest.

APPENDIX 2: Faculty Ethics Committee Approval



Walsh B.M.

From: ERGOII
Sent: 06 February 2019 09:27
To: Walsh B.M.
Subject: Approved by Faculty Ethics Committee - ERGO II 46313

Approved by Faculty Ethics Committee - ERGO II 46313

ERGO II – Ethics and Research Governance Online https://www.ergo2.soton.ac.uk

Submission ID: 46313
Submission Title: The dynamics of frailty in older people: modelling impact on health care demand and outcomes to inform service planning and commissioning
Submitter Name: Bronagh Walsh

Your submission has now been approved by the Faculty Ethics Committee. You can begin your research unless you are still awaiting any other reviews or conditions of your approval.

Comments:

-

Click here to view the submission

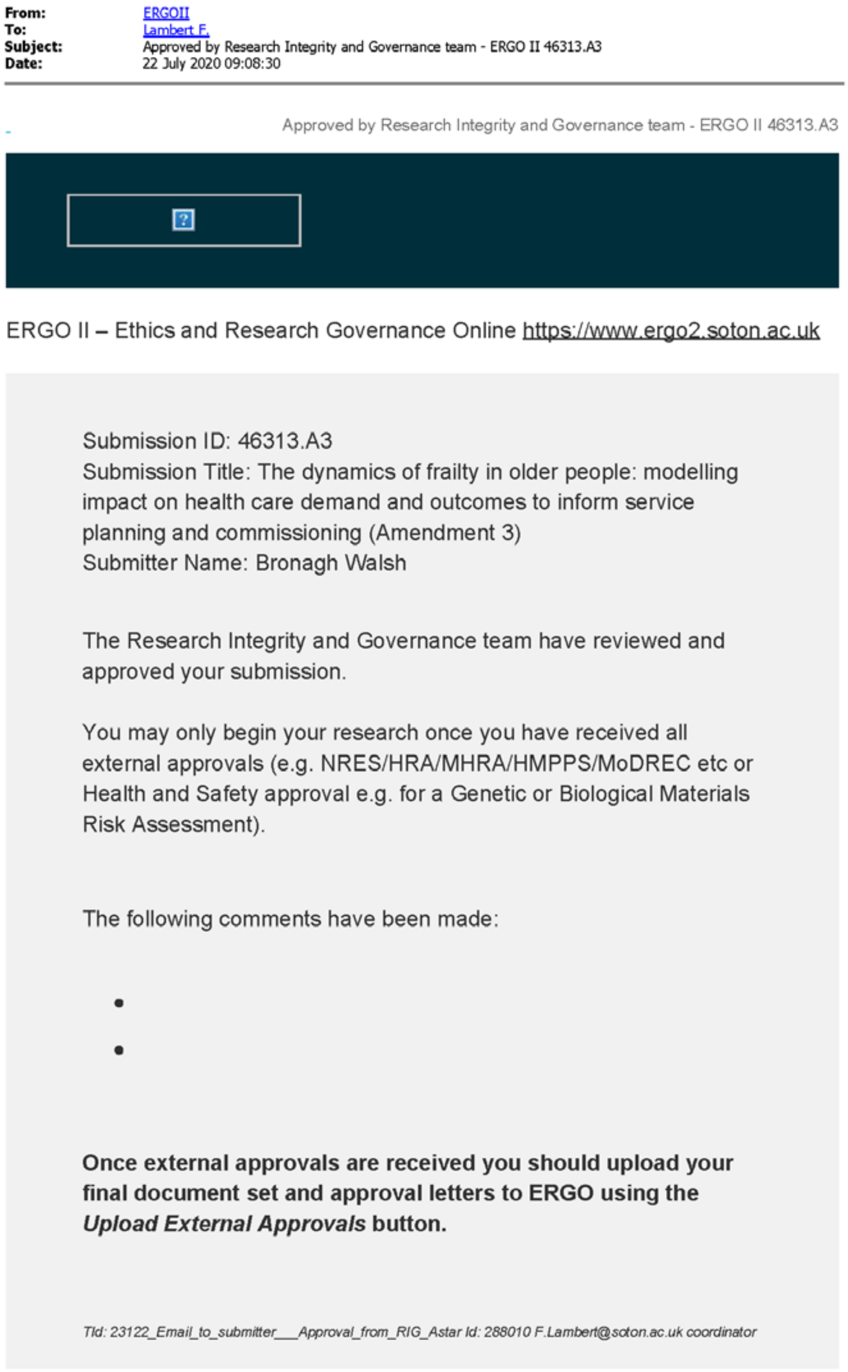
TId: 23011_Email_to_submitter___Approval_from_Faculty_Ethics_committee__cat_B___C_ Id: 109797

B.M.Walsh@soton.ac.uk coordinator

Please do not reply to this message as it has been automatically generated by the system. This email address is not monitored.

1

APPENDIX 3: Faculty Ethics Committee Approval



From: ERGOII
To: Lambert F.
Subject: Approved by Research Integrity and Governance team - ERGO II 46313.A3
Date: 22 July 2020 09:08:30

Approved by Research Integrity and Governance team - ERGO II 46313.A3

ERGO II – Ethics and Research Governance Online https://www.ergo2.soton.ac.uk

Submission ID: 46313.A3
Submission Title: The dynamics of frailty in older people: modelling impact on health care demand and outcomes to inform service planning and commissioning (Amendment 3)
Submitter Name: Bronagh Walsh

The Research Integrity and Governance team have reviewed and approved your submission.

You may only begin your research once you have received all external approvals (e.g. NRES/HRA/MHRA/HMPPS/MoDREC etc or Health and Safety approval e.g. for a Genetic or Biological Materials Risk Assessment).

The following comments have been made:

-
-

Once external approvals are received you should upload your final document set and approval letters to ERGO using the *Upload External Approvals* button.

TId: 23122_Email_to_submitter___Approval_from_RIG_Astar Id: 288010 F.Lambert@soton.ac.uk coordinator