Improvement Analytics Unit

Statistical Analysis Protocol for an evaluation of Extensive Care Service and Enhanced Primary Care for Fylde Coast NHS vanguard

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Contents

Summary

Purpose of this document

This statistical analysis plan describes in detail all aspects of the proposed Improvement Analytics Unit (IAU) evaluation of Extensive Care Service (ECS) and Enhanced Primary Care (EPC), the two interventions comprising the main components of the 'Your Care, Our Priority' Fylde Coast NHS Multispecialty Community Provider (MCP) vanguard New Model of Care programme. This is a technical document written to guide analytical processes; it includes the study design, statistical methods and variable definitions, as well as the limitations of the analysis and how these should be considered when interpreting the results.

This document has been agreed with the Fylde Coast NHS vanguard team and written before the analysis begins, to ensure that all design and methods choices are made objectively and are not influenced by what is found in the data. In rare instances, it may be necessary to make changes to the design of the study at a later stage; if so, this document will be appended accordingly. The IAU welcomes comments and questions on this document.

Purpose of this evaluation

The IAU will be conducting an evaluation to feed back on the progress being made to improve secondary care activity for individuals referred to ECS and EPC in the Fylde Coast NHS vanguard.

ECS was introduced in June 2015 with one hub covering Lytham, Ansdell and St Anne's neighbourhoods in Fylde and Wyre, and another hub covering North and Far North Blackpool neighbourhoods. Two more hubs, one in Blackpool and another in Fylde and Wyre, were commissioned in May 2016. The service was extended to all remaining neighbourhoods across both Clinical Commissioning Groups (CCGs) to ensure coverage of the whole Fylde Coast NHS vanguard region by October 2016. There are approximately 7,000 individuals who are eligible for ECS. At the end of December 2017 there had been 3,000 referrals, of whom 357 were currently active; 1,230 had been discharged; 150 were awaiting a decision; and 1,263 had refused, or been rejected by, the service. Of the 1,230 who had been discharged, 814 had been discharged for at least 6 months.

EPC was also introduced in a phased approach. The service was launched in October 2016 with six teams covering the Blackpool neighbourhoods and one team covering the two Fylde neighbourhoods. In February 2017, the service was rolled out to the Wyre neighbourhoods to ensure coverage of the whole Fylde Coast NHS vanguard. At the end of December 2017, EPC had an active caseload of 2,191 individuals and an inactive caseload of 3,132 individuals.

What the evaluation will look at

The evaluation will study the impact of ECS and EPC on secondary care activity for individuals who were registered at a GP practice in the Fylde Coast NHS vanguard region. The evaluation will be divided into two separate studies: the first study (the ECS study) will consider the

impact on individuals who were referred to ECS (the ECS intervention group); the second study (the EPC study) will consider the impact for individuals who were referred to EPC (the EPC intervention group). For the ECS study, we will examine the impact on outcomes between August 2015 and December 2017. For the EPC study, we will examine the impact on outcomes between November 2016 and December 2017. These are referred to as the study periods.

Each study will compare the outcomes of the intervention group with a retrospectively matched (e.g. by age, gender, comorbidities, locality and prior hospital activity) control group formed from individuals who were also registered in a GP practice in the Fylde Coast NHS vanguard region, but who were not referred to, or enrolled in, the intervention (the control population). Although the range of MCP services varies across the different areas of the Fylde Coast NHS vanguard region, by matching on locality we will ensure that each control will have had access to the same services within the Fylde Coast NHS vanguard region as the intervention group individual they are matched to. However, if there are not enough individuals in the control population from which to select a suitable match, then we may have to use external controls from a region identified as similar to the Fylde Coast NHS vanguard region. For ECS, an additional analysis will look separately at the impact of ECS during the period when the patient is actively enrolled and during the period after they have been discharged from the service.

If there are enough participants in the ECS study or the EPC study, further analysis will look at the impacts stratified by CCG neighbourhood groupings, risk stratification quartiles (available from local data), age (EPC study only), care home residency status, history of mental ill health and Lancashire and Cumbria Innovation Alliance (LCIA) Test Bed status. The LCIA Test Bed is a concurrent telehealth monitoring initiative operating in the Fylde Coast NHS vanguard region. The IAU will also provide a descriptive analysis of the pattern of outcomes by Patient Activation Measure (PAM) score, which are available for individuals enrolled in ECS and EPC.

Data the IAU will use

The IAU will use pseudonymised patient-level national Secondary Use Services (SUS) administrative hospital data for NHS Blackpool and NHS Fylde and Wyre CCGs from July 2012 to December 2017. Hospital data for a minimum 3-year period before each individual entered the relevant study will be used to determine key characteristics for each individual required for matching. The IAU will also use pseudonymised resident-level National Health Applications and Infrastructure Services (NHAIS) data to obtain linked individual-level address and mortality data for all individuals registered with a GP practice within the Fylde Coast NHS vanguard region.

The Fylde Coast NHS vanguard will supply a pseudonymised list of all individuals that were referred to ECS and EPC during the study period, together with applicable dates of referral, enrolment, refusal, discharge, readmission and the service location (site for ECS or neighbourhood team for EPC) they were referred to. In addition, the Fylde Coast NHS vanguard will also supply pseudonymised current and historical risk stratification data for all individuals currently registered (and not opted out) with a GP practice in the Fylde Coast region and a pseudonymised list of any individuals who have ever received the LCIA Test Bed telemonitoring service.

Pseudonymisation means that all direct identifiers (e.g. name, address, date of birth, NHS number) are removed from the data. Pseudonymisation reduces the risk that individuals can be identified from the data.

Strengths and weaknesses of the evaluation

The evaluation will study the impact of ECS and EPC on secondary care activity, which can be measured from national administrative hospital data (Secondary Uses Service (SUS) data). It will not measure utilisation of other health and care services, impacts to quality of life, staff satisfaction or the quality of working relationships. The evaluation should be viewed in conjunction with the qualitative research carried out by the local evaluation of ECS and EPC.

The intervention and matched control groups will be similar on a range of observable characteristics, making the comparison more robust than without matching. However, there is still a substantial risk that the intervention and control groups are different in ways that cannot be observed (for example, in terms of their social isolation or receptiveness to new approaches to managing their conditions) which may bias our estimate of the impact on outcomes. This is particularly an issue if individuals participated in ECS or EPC on the basis of clinical judgement, rather than set criteria (for example, using a risk prediction tool). Consequentially, all results will need to be interpreted with caution.

By using local controls, instead of controls from outside of the Fylde Coast NHS vanguard region, and matching on locality, the risk of bias due to area-level or hospital-level differences is mitigated, as both intervention and control groups will have access to the same services, with the exception of ECS and EPC.

A recent evidence review found that initiatives aiming to better manage individuals 'at risk' are often highly valued by individuals but seldom reduce hospital activity. This may in part be due to these initiatives identifying unmet need and providing more timely access to care. One of the study's primary outcomes is therefore emergency admissions due to chronic ambulatory care sensitive (ACS) conditions, i.e. conditions for which the risk of admission to hospital can be reduced by good and timely primary and community care.

The evaluation will study the impact of ECS and EPC over a period when they were continuously developing. The study periods may be too short to capture the full long-term effects of ECS and EPC. The samples sizes may also be too small to detect a statistically significant difference between the intervention and control groups. This is particularly the case for the subgroup analyses.

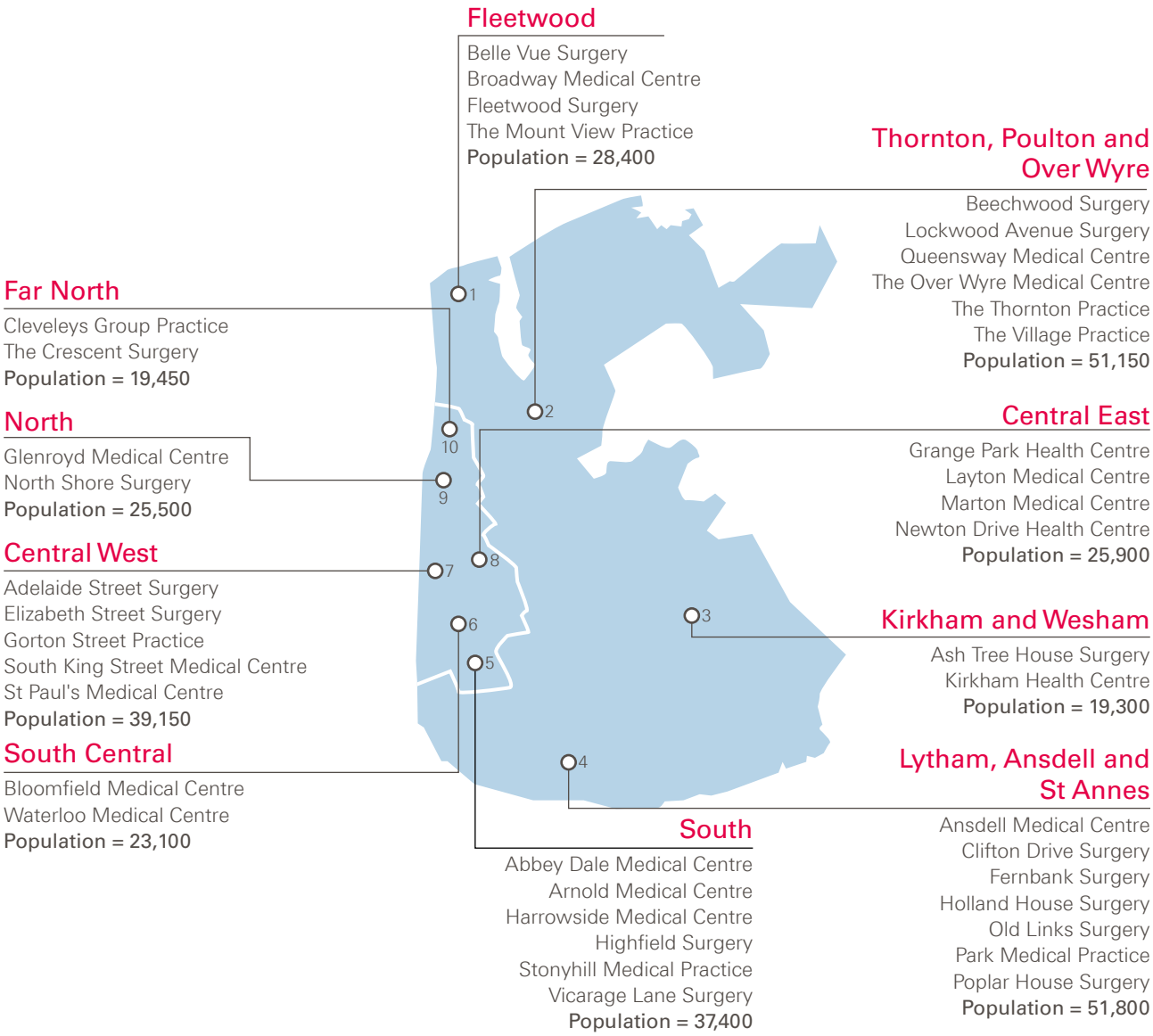
The results are nonetheless expected to enable learning that, together with the local evaluation and other evidence, will help the Fylde Coast NHS vanguard understand what is happening on the ground, assess what is working and identify potential areas for further investigation or improvement.

Background

The Fylde Coast

The Fylde Coast is the collective name for Blackpool and the boroughs of Fylde and Wyre. Health services are coordinated for the area by two CCGs: NHS Blackpool CCG & NHS Fylde & Wyre CCG. Within the CCG footprints the area is further divided into 10 distinct neighbourhoods (Figure 1).

Figure 1: The Fylde Coast neighbourhoods



Reproduced from [1]

Blackpool comprises six neighbourhoods (Far North, North, Central West, South Central, South and Central East). It has 21 GP practices belonging to NHS Blackpool CCG, serving 172,000 registered individuals over an area of 32 km^2 with a budget of £280m. The borough of Fylde is split into two neighbourhoods (Kirkham and Wesham, and Lytham, Ansdell and St Annes).

The borough of Wyre is also split into two neighbourhoods (Fleetwood, and Thornton, Poulton and Over Wyre). The Fylde and Wyre boroughs cover an area 10 times larger than Blackpool, but have a smaller registered population of 155,000 who are served by 19 GP practices belonging to NHS Fylde and Wyre CCG with a budget of £239m.

The Fylde Coast comprises a diverse population, with the city area of Blackpool experiencing significant levels of deprivation, health inequalities and life expectancy that rank among the worst in the country; and rural towns and villages facing a growing proportion of older people and greater numbers of individuals with multiple and long-term conditions (Figure 2).

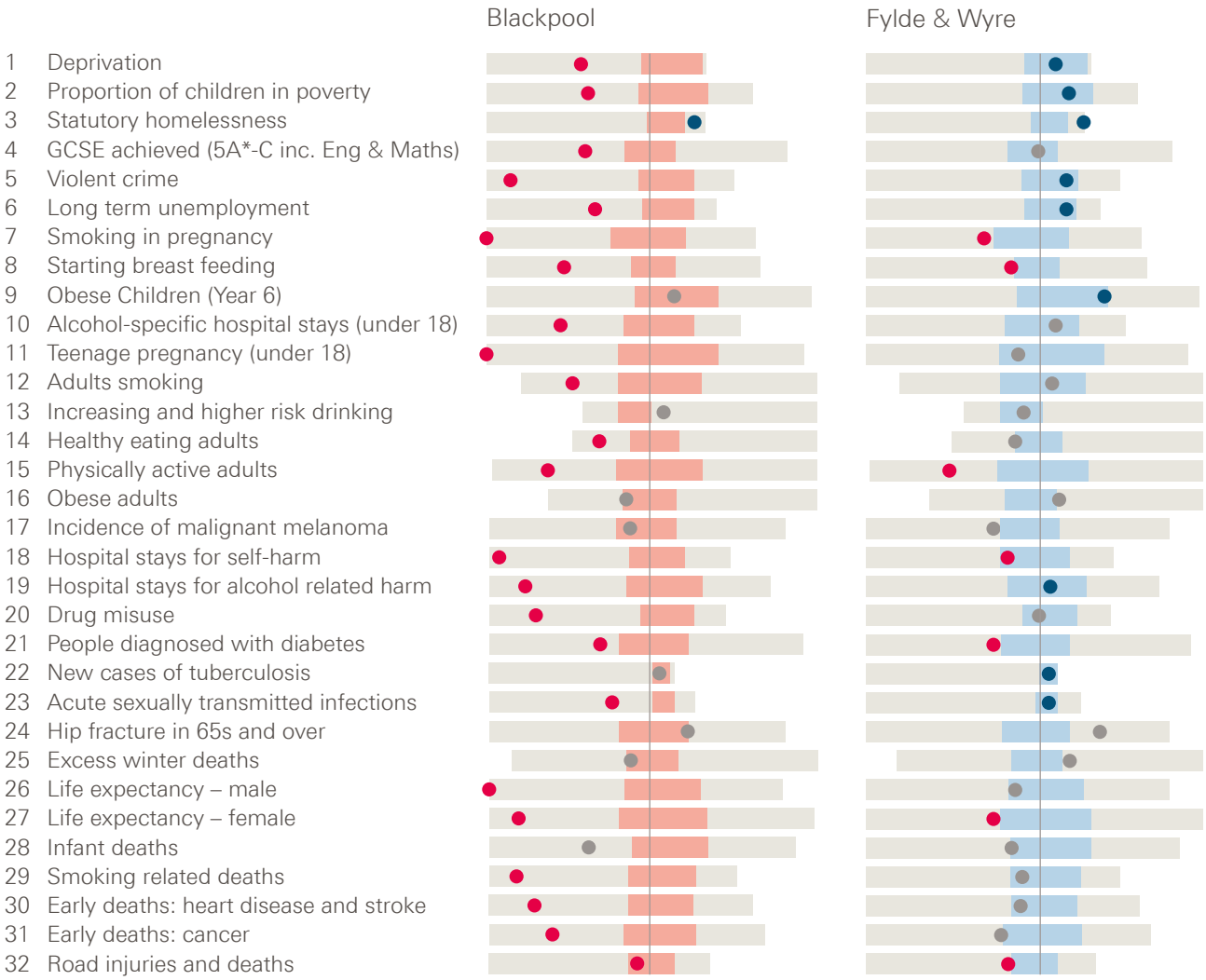
Specific challenges faced by the Fylde Coast are[2]:

- increasing numbers of older people and people with complex long-term medical conditions
- communities with a diverse range of health care needs
- unacceptable differences in the health of people who live just a few miles apart (i.e. men living in the most deprived areas die, on average, 10 years earlier than those living in the least deprived; for women, the difference is more than 6 years)
- lack of coordination in the current health and care system, leading to a poor experience for patients and their families
- many patients have conditions which are not managed as well as they could be, and so often go to hospital when they could be better supported in a community setting or at home
- the cost of providing health care is rising faster than the funding received.

In March 2015, the Fylde Coast was selected as one of the first 'vanguard' sites across the country as part of the NHS England New Care Models programme. Vanguard partners comprise NHS Blackpool CCG, NHS Fylde and Wyre CCG, Blackpool Teaching Hospitals NHS Foundation Trust, Lancashire Care NHS Foundation Trust, Lancashire County Council and Blackpool Council. Known collectively as the Fylde Coast NHS vanguard, these health and care organisations from across the region are committed to working together to improve health outcomes for their population. Their aim is 'to develop a model of integrated and coordinated health and social care so that care is delivered seamlessly, sharing data and communicating better with each other and those in need of our services, their carers and families'[3].

The Fylde Coast NHS vanguard is a multispecialty community provider (MCP) vanguard. It aims to support the population by changing the organisational form so that providers can work together more effectively and by developing new models of care, which are population-based health and social care models intended to improve health and wellbeing.

Figure 2: The Fylde Coast health challenges



Reproduced from[3] which is a schematic of data from[4]. The light (dark) grey bars show the full (25th–75th percentile) range from best to worst for each indicator for all areas across England. The vertical line represents the England average. Compared with benchmark:
● Better ● Similar ● Worse.

The New Model of Care Programme: 'Your Care, Our Priority'

The vanguard funding has allowed the Fylde Coast to implement three new models of care, namely Extensive Care Service (ECS), Enhanced Primary Care (EPC) and Episodic Care. These are implemented under the banner 'Your Care, Our Priority'. Each model is aimed at a different population cohort, but all three are collectively focused on building a proactive, systematic care planning approach that supports people to manage their conditions better from within the community and aims to reduce pressure on hospitals, GP practices and other emergency care organisations. The GP practices work within their neighbourhoods in conjunction with the new models of care and a range of service providers, including the voluntary sector. The funding has also allowed for a series of enabling work streams, e.g. technology to develop the Nexus platform and provide telehealth solutions.

Extensive Care Service (ECS)

ECS is a fundamentally different way of delivering care. It is based on the CareMore model[5], a successful model of care from the USA. Under the ECS model, all care is delivered by a dedicated team led by expert health care professionals including a consultant extensivist, GPs, advanced practitioners, clinical care coordinators, wellbeing support workers and other supporting staff. The staff work together as part of a harmonised team to provide proactive and coordinated care centred on the patient. This wrap-around care service was developed by Fylde Coast to help patients with complex long-term health needs to manage their health within the community, thus decreasing avoidable hospital admissions. The aim is to stabilise the patient and better equip them to manage their health and heath care needs in the community setting.

There are six ECS hubs serving the Fylde Coast. Phase 1 of the ECS model was launched on 29 June 2015 with one hub covering Lytham, Ansdell and St Anne's neighbourhoods, and another covering North and Far North Blackpool neighbourhoods. Two more hubs, one covering South Blackpool neighbourhoods and one covering Wyre neighbourhoods, were launched in May 2016. The service was extended to all remaining neighbourhoods across both CCGs to ensure coverage of the whole Fylde Coast NHS vanguard region by October 2016.

The ECS model was originally aimed at individuals aged over 60 years with two or more specific long-term conditions (coronary artery disease, atrial fibrillation, congestive heart failure (CHF), chronic obstructive pulmonary disease (COPD), diabetes or dementia), and a predicted risk score of admission within the next 12 months greater than or equal to 20 (based on the Combined Predictive Model: a model that uses inpatient, outpatient, A&E and GP data to stratify populations according to their risk of admission[6]). These individuals are deemed more likely to incur avoidable hospital admissions and crises, which exert unnecessary pressure on local NHS services. In February 2016, the eligibility criteria were amended to allow individuals with EITHER a risk stratification score greater than or equal to 20 OR two A&E admissions, OR two out-of-hospital contacts within the last 2 months, in addition to the original age and long-term condition criteria.

Originally, individuals could only enter the service through GP referral. However, the referral pathway was later broadened so that secondary care providers and community care providers could also refer individuals.

Once referred to their local ECS hub, an individual is triaged to confirm their eligibility and suitability for the service. After confirmation, individuals then have several contacts with ECS team members before enrolment. A wellbeing support worker makes the first contact, usually a home visit, to provide information about the service and to collect information for and arrange the initial assessment. The initial assessment consists of a mental health, functional capacity, social circumstances and environment assessment by a care coordinator, a medicine assessment with a pharmacist and medical assessment with the consultant extensivist.

New patients are then discussed in the next available multi-disciplinary team (MDT) huddle following initial assessment and a decision is taken as to whether the patient will benefit from ECS. If the patient will benefit then they are enrolled, a care plan is developed and the

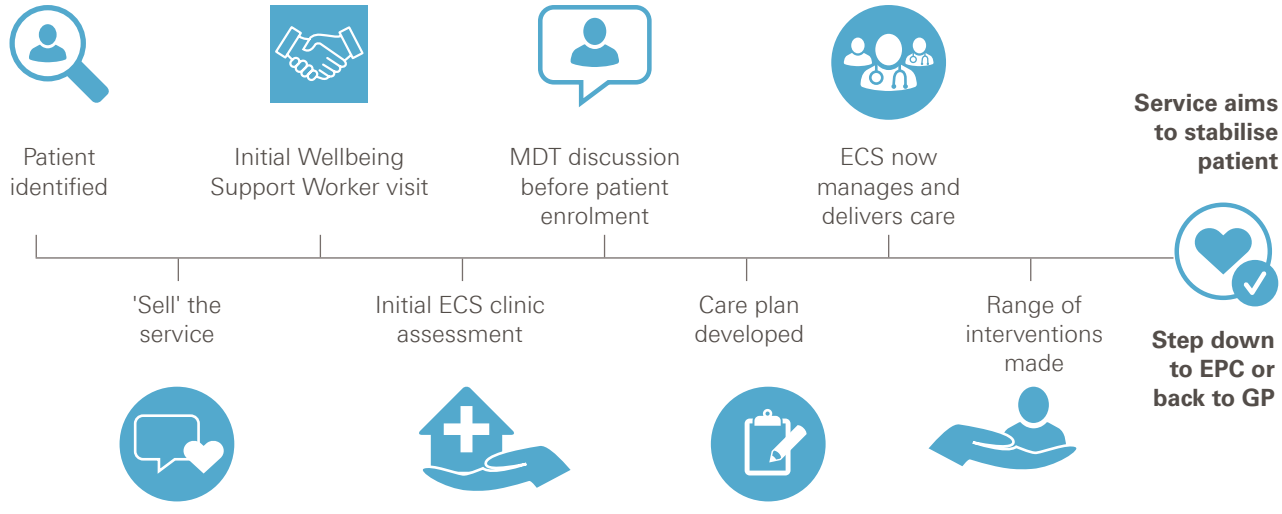
lead care coordinator and the wellbeing support worker meet with the patient to sign a joint contract confirming participation in the ECS. Any existing care plans will be reviewed as part of this process and will be superseded by the care plan developed by the extensivist team.

At this point the ECS hub takes over full clinical responsibility for the patient and the GP is informed; the ECS have clear accountability on behalf of the system for providing and coordinating the patient's care. Care plans are reviewed each month, and quarterly, by different members of the ECS. A patient is discharged back into the care of their GP once they are deemed not to benefit from further active participation in the ECS. See Figure 3 for a schematic of the patient journey.

Note that patients can be rejected from the service after triage and after the MDT assessment. Patients can also refuse to participate at any stage post referral and prior to enrolment.

An operational evaluation of ECS in September 2016 identified deviations in clinical service compared to the original clinical blueprint. These included insufficient uptake of patients into the service; lack of implementation of telehealth interventions; ECS staff not visiting ECS patients in hospital, leading to delays in discharge; lack of integration between ECS and social care; and data sharing issues between providers via EMIS Web. As a result, changes to ECS were introduced from October 2016, which addressed most points raised.

Figure 3: Extensive Care patient journey



Reproduced from[1]

There are approximately 7,000 individuals who are eligible for ECS. Data extracted from the Nexus Intelligence system indicated that, at the end of December 2017, there had been 3,000 referrals of whom 357 were currently active; 1,230 had been discharged; 150 were awaiting a decision; and 1,263 had refused or been rejected by the service. Of the 1,230 who had been discharged, 814 had been discharged for at least 6 months. GP referrals to the service are lower than planned and at that time, only 60% of the available slots in the ECS were being utilised. In May 2017, local analyses indicated that individuals participating in ECS have reductions of 14%, 18%, 23% and 4% in A&E attendance, elective admissions, non-elective admissions and outpatient activity, respectively[7].

Enhanced Primary Care (EPC)

The EPC model is aimed at individuals aged over 16 years (excluding patients actively managed under the ECS service) who a GP feels could benefit from increased support because of a long-term health condition or other factors, which mean they cannot effectively manage their own health. Under the EPC model, a local community-based neighbourhood care team – comprising nurses, therapists, mental health specialists, social workers, care coordinators and wellbeing support workers – works with GPs and other practice staff to support eligible patients. Supported by shared electronic records and a single point of contact for all out-of-hospital services, the team keep in touch with each patient to offer support and advice on both medical monitoring and social skills, where applicable, to enable individuals to self-care and to better manage their conditions, thus reducing preventable visits to their GP or hospital. EPC patients do not receive the same wrap-around care as those on ECS; instead, they receive support from individuals within their neighbourhood care team.

Initially, implementation focused on individuals with the highest level of needs and who used care services the most. Over time, the model was intended to flex to ensure that services were widened and developed to reflect the needs of the neighbourhood demographic.

The principles of EPC were first tested in the Fylde neighbourhood of Kirkham and Wesham as an early implementer site. In October 2016, seven EPC teams were mobilised: one to cover the two Fylde neighbourhoods of Kirkham and Wesham, and Lytham, Ansdell and St Annes, and six to cover the Blackpool neighbourhoods. In February 2017, another EPC team was rolled out to cover both Wyre neighbourhoods, resulting in a total of eight EPC teams across the region. Establishing EPC in neighbourhood teams optimised the ability to deliver an integrated care package by building on the existing local health, social care and voluntary services, and estate assets available. Also, by ensuring geographical proximity to patients, it ensured that problems of social isolation, loneliness and poor mental health could be effectively tackled. It is worth noting that Blackpool community services were already working in these neighbourhood groupings prior to October 2016, whereas EPC was the catalyst for Fylde and Wyre to restructure its community services on a neighbourhood basis.

Data extracted from the Nexus Intelligence system indicated that as of December 2017, 2,191 patients were active on EPC, with a similar number having being discharged; approximately 4,000 patients have used the services of EPC since it first began.

The initial referral criteria catered for individuals aged 16 years or older with a risk score greater than 20. However, the cohort generally consists of adults who have been identified by a primary care provider as someone who would benefit from enhanced support beyond that which routine primary care can offer. Examples include individuals who are non-compliant with treatment and could benefit from health coaching, and individuals with anxiety disorders rooted in financial troubles who could be supported by a wellbeing support worker.

Individuals can be referred into EPC by any other professionals, e.g. community services, GP or social services. In some of the neighbourhoods, self-referral is also an option. The referral is triaged and a visit by the most appropriate team member is planned to ensure the patient is seen quickly by the clinician who will best be able to support them. Should other needs be identified at that initial contact, subsequent visits may be planned jointly with others within the neighbourhood care team. Individuals can be rejected from EPC if the service they are

referred for is outside the scope of the EPC neighbourhood team. In this case a record of their referral will be noted. Individuals referred to EPC can refuse to attend for assessment; in this case, no record of their referral will be noted.

Due to historic patterns of care delivery and patterns of neighbourhood working, methods of coding patient referrals have varied amongst the different neighbourhoods. The EPC code for a given EPC referral is meant to indicate the kind of service provided by EPC. However, prior to September 2017, the EPC codes for repeat referrals, or for referrals for services that existed prior to the formation of EPC and which have now been subsumed by the EPC (e.g. referral to a district nurse or matron care) may have been left blank.

Episodic Care

The Episodic Care model comprises a broad range of projects aimed at releasing capacity within primary care by targeting individuals who have a minor short-term illness or health concern, for which the first point of access to support doesn't need to be their GP practice. Under Episodic Care, local health teams are devising wide-ranging programmes to educate people to make informed choices as to whether a GP visit is required, whether rest and wait is the best choice or whether support from another source (e.g. a pharmacy) will meet their need. The scheme aims to empower individuals by enabling self-care through knowledge of what to do the next time a problem occurs. Patients on both ECS and EPC have access to the interventions launched as part of Episodic Care. These interventions include Pharmacy Plus, where individuals can seek health care advice from one of 26 pharmacies without first making an appointment, and a local Directory of Services to aid signposting and self-referral to third sector or voluntary support.

Intended impacts of 'Your Care, Our Priority'

ECS, EPC and Episodic Care share a common set of aims, deliverables and outcomes. See Table 1 for full details. We note that analyses by the local site suggest that the impact of ECS is only detectable after at least six weeks' enrolment.

Table 1: Fylde Coast NHS vanguard New Model of Care programme aims, deliverables and outcomes

Aim	Deliverable	Outcome
To increase health and care services outside of hospital	Safe and effective community based services	Reductions in hospital admissions, length of stay, A&E and outpatient appointments
To integrate the public service offer across Fylde Coast	Care focused on those who are at most risk of hospital admission	Better management of complex conditions
To provide care which anticipates escalations and necessary interventions	Carefully constructed proactive care plans	Move from acute medical system responses

To provide care which increases patient confidence, knowledge and independence	Care orientated to the needs of the individual	Increased health and wellbeing
To provide care through teams with accountability on behalf of the whole system	Care which is truly integrated and unrestricted by organisational boundaries	Seamless care without gaps for patients to fall through
To increase patient adherence with best practice, improve long-term condition management and diagnose conditions earlier	Create capacity in general practice to care for more complex patients	Improve outcomes amenable to health interventions
To reduce social isolation	Networks of public and third sector services in neighbourhoods	Increased wellbeing
To move away from medically led models of care	Staff development to develop skills in promoting self-care and proactive care planning	Culture of patient activation embedded

Reproduced from[8]

Other Fylde Coast region interventions

In addition to the new care models that are part of 'Your Care, Our Priority', NHS Fylde and Wyre CCG and NHS Blackpool CCG have many different campaigns and initiatives that are available to the whole community, including those enrolled on ECS and EPC. These initiatives, which include campaigns such as Act FAST, Be Clear on Cancer bowel cancer screening, and Think! Why A&E?[9] are part of a baseline set of interventions. Our analysis aims to compare the effect of ECS and EPC over and above the baseline set of interventions that are available to all individuals registered with a GP practice in the Fylde Coast region.

Interventions that are not available to the whole community, and which we will account for in our analysis, include enhanced health in care homes and the LCIA Test Bed.

Enhanced health in care homes

NHS Fylde and Wyre CCG is committed to enhancing the quality of care within care homes under the NHS new care model framework for enhanced health in care homes, and has a number of different programmes underway and in development[10]. This includes an interim care home service provided by Blackpool Teaching Hospitals Community Services which works with primary care services, EPC, the falls services and community services. We will analyse whether the impact of ECS and EPC is different in care home residents and in Fylde and Wyre residents to take account of the different offerings to these groups.

Lancashire and Cumbria Innovation Alliance (LCIA) Test Bed

The NHS England 'Test Beds' are collaborations between the NHS and innovators aiming to harness technology to address complex issues facing patients and the health service. The LCIA Test Bed[11] is run by the LCIA, which is a collaboration led by the Lancashire Care NHS

Foundation Trust working with the Lancaster Health Hub and other partners including the Fylde Coast NHS vanguard. The LCIA Test Bed programme is focused on supporting people aged 55 years or more with long-term conditions such as COPD, heart failure, dementia and diabetes to manage their health better using telehealth monitoring, and so avoid unnecessary hospital admissions. The intention is to increase the quality of care provided, improve patient outcomes and release capacity within hospitals and the wider health and social care services. Approximately 200 individuals from the Fylde Coast NHS vanguard region have been selected for the LCIA Test Bed. Our analysis will take account of an individual's LCIA Test Bed status and look for any evidence of a difference in the impact of ECS and EPC for patients who are also involved in the LCIA Test Bed.

Rationale

The evaluation is intended to enable understanding of the impact of the different components of the New Model of Care programme in order to provide learning and improvement as well as assurance about continued investment in the service in terms of finance and quality. A joint report on ECS and EPC will help inform projects that are currently underway that are looking at ways to foster links between the two services.

Objectives of the evaluation

This evaluation aims to study the impact of ECS and EPC on secondary care activity for individuals who were registered at a GP practice in the Fylde Coast NHS vanguard region and who benefited from either ECS or EPC, over and above the impact of any other services available to them in the Fylde Coast region. ECS and EPC are aimed at distinct population cohorts and are not expected to overlap. The study will be divided into two parts: the first part (the ECS study) will consider the impact on individuals who were referred to ECS (the ECS intervention group); the second part (the EPC study) will consider the impact for individuals who were referred to EPC (the EPC intervention group).

Other potential impacts of the interventions, such as quality of life or staff satisfaction, will not be evaluated due to the limitations of the data available to the IAU. In addition, costs will not be evaluated in this study.

For the ECS study, we will examine the impact on utilisation between August 2015 and December 2017; for the EPC study, we will examine the impact on utilisation between November 2016 and December 2017. These are the referred to as the ECS, and the EPC, study periods respectively.

Additional subgroup analyses will explore how the impacts vary across different strata of the population, e.g. by age, risk stratification profile, and whether the impacts are maintained in the long term, after discharge from the service.

The Extensivist Impact Study, conducted by NHS England, will supplement the IAU evaluation.

Methods

Study design

In both the ECS and EPC studies, the secondary care activity for the individuals from the study population who were enrolled in the intervention (the intervention group) will be compared to that of a retrospectively matched group of individuals from the study population who were eligible for, but not referred to or enrolled in, the corresponding intervention (the control group). The control group will be selected so that it matches the profile of the intervention group on a range of observable characteristics such as age, gender, long-term conditions, neighbourhood and prior hospital activity. See Box 1 for a summary of the study population, the intervention groups and the control groups.

We aim to select both intervention and control groups from the same study population to ensure that both groups have similar access to, and been similarly affected by, other changes and the wider range of services available in the Fylde coast NHS vanguard region; thus enabling us to effectively isolate the impact of ECS and EPC over and above the impact of any other activities.

If there are not enough individuals in the control population from which to select suitable matches, then we may have to select controls from an external population from a region identified as similar to the Fylde Coast NHS vanguard region. In this case, we cannot assume that the background utilisation of intervention and control groups is similar and results will only indicate the impact of ECS and EPC over and above that of a baseline pattern of usage in the similar region. However, this approach has been used successfully in past IAU studies where local matching was not viable[12].

Box 1: Study cohorts

Study population For both ECS and EPC studies, the study population comprises individuals who were registered with a GP practice in the Fylde Coast NHS vanguard region, and who were eligible for the corresponding intervention during the study period.
Intervention groups For the ECS study, the intervention group comprises individuals who were registered at a GP practice in the Fylde Coast NHS vanguard region, and who were enrolled in ECS for at least one month prior to the study end date. For the EPC study, the intervention group comprises individuals who were registered at a GP practice in the Fylde Coast NHS vanguard region, and who were enrolled in EPC for at least one month prior to the study end date. The cut-off date of one month prior is selected to allow for at least a one month follow-up period before the end of the study.
Control groups For both ECS and EPC studies, the control group comprises individuals who were registered with a GP practice in the Fylde Coast NHS vanguard region between the study start and one month prior to the study end date but who were not referred to, or enrolled in, the corresponding intervention.

Once matched controls have been selected, appropriate multivariate regression models will be applied to compare the intervention and control groups on a range of clinical outcomes. See the 'Study outcomes' section on the next page.

Subgroup analyses

For ECS, an additional analysis will look separately at the impact of ECS during the period when the patient is actively enrolled and during the period after they have been discharged from the service.

In addition, if there are enough participants in the ECS study or the EPC study, the following subgroup analyses will be attempted to provide additional learning and potential corrective action:

- To investigate heterogeneity of effect of ECS and EPC across different neighbourhoods and to allow for variation in interventions offered other than ECS and EPC across the different neighbourhoods, the IAU will perform subgroup analyses of ECS and EPC by CCG neighbourhood groupings (Blackpool versus Fylde and Wyre).
- The IAU will also perform subgroup analyses looking at the impact on outcomes stratified by risk stratification quartiles, age (EPC only), care home residency status and LCIA Test Bed status.
- It was noted in local analyses that the impact of ECS was only apparent after at least 6 weeks' enrolment in the service; hence the IAU will perform a subgroup analysis looking at the impact on outcomes stratified by duration of time (more than or less than 6 weeks) actively enrolled in ECS.
- Inadequately addressing the mental health needs of people with physical health conditions can negatively impact on physical health outcomes[13,14]. People with mental ill health have several times higher rates of A&E attendances, emergency admissions and ACS emergency admissions than those without[14]. Hence the IAU will perform a subgroup analysis for patients with a history of mental health (independently of whether the outcome relates to a physical or a mental health need).

However, if numbers are too small, there is a risk that models for the subgroup analyses cannot be fitted. If the models can be fitted, the results are unlikely to show statistically significant results due to small sample sizes; the additional analyses may nonetheless provide useful information as to the patterns of effect across different timeframes and different population subgroups.

Descriptive analyses

Patient activation measures (PAMs) are only available for patients enrolled in ECS and EPC and so we cannot assess any differences in outcomes for patients by PAM strata by making comparisons with a matched control. Additional analyses to assess the impact of PAMs within the intervention cohorts are outside the scope of the current analysis. We will instead provide a descriptive analysis of the pattern of outcomes within the ECS and EPC intervention groups.

Study outcomes

The primary and secondary outcomes that will be evaluated for both ECS and EPC studies are listed in Table 2. The secondary outcomes will be only be evaluated if there are sufficient numbers of individuals experiencing the particular outcome.

Primary outcomes

The primary outcomes have been selected to evaluate the impact on acute care. Decreases in these outcomes may indicate an improvement in the quality of care. Initiatives aiming to better manage patients 'at risk' have been found to seldom reduce hospital activity. This may be in part because these initiatives often identify unmet need and provide more timely access to hospital care[15,16]. By evaluating the number of ACS hospital admissions, as well as the number of emergency admissions, the IAU will try to isolate those emergency admissions that can be reduced as a result of good quality care in primary and community settings from, for example, those admissions resulting from unmet need.

The total number of hospital bed days (emergency or elective) is one of the core metrics used within NHS England for the New Care Models programme[17]. ECS is aimed at individuals who are most at risk of hospitalisation and therefore, while the number of emergency admissions may be inflated for ECS patients in the short term following a patient review, the total number of days in hospital following an emergency admission should be shorter because of participation in ECS.

Table 2: Primary and secondary outcomes* for the ECS and EPC studies

Primary outcomes	Number of **emergency admissions**
	Number of **emergency admissions** for **chronic** (long term) **ACS conditions**
	Number of **emergency admissions** for **acute** (urgent care) **ACS conditions**
	Number of **A&E attendances**
Secondary outcomes	Number of **emergency readmissions within 30 days of discharge**
	Number of **elective admissions**
	Number of **outpatient appointments** per patient (excluding 'did not attends', and defined using code Attended=5 or 6 in SUS data)
	Number of **emergency bed days**
	Number of **elective bed days**
	Proportion of all deaths that occur outside of a hospital setting

Note: Please refer to the Appendix, Secondary Care resource utilisation definitions, for definitions of outcomes in boldface type.

* Outcomes include number, or count, outcomes. These will be modelled to take account of varying time at risk, by including an offset in the model for total time at risk of the relevant outcome in the statistical analysis. An individual is at risk of any kind of hospital admission, readmission, A&E attendance or appointment at any time they are not in hospital: hence time at risk is equal to the length of time they are in the study less the total time spent in hospital during the study period.

Secondary outcomes

Although not part of the Fylde Coast NHS vanguard core metrics, the secondary outcomes are included to build a fuller picture of hospital activity over the study period. Interpretation of these results will require careful consideration, as the quality of care in ECS or EPC could be measured by either increases or decreases in these outcomes. For example, if the ECS patient review or care planning highlight unmet medical needs, the number of outpatient attendances and elective admissions per patient could increase because of ECS, particularly in the short term. Alternatively, the number of these events could also decrease, either because of early proactive care or the ECS service enabling patients to be treated outside of a hospital setting.

Assuming that there are sufficient numbers of patients who have died, a death outside of hospital will be used as a proxy for an individual dying in their preferred place of death. While this may not truly represent an individual dying in their preferred place, it is assumed for the purposes of this analysis that dying in a location outside of hospital (e.g. home, care home, hospice) is preferable to dying in hospital. The number of deaths is calculated by combining information on hospital deaths from the SUS data with information on all deaths from the NHAIS data.

Setting

Bedding-in period

Since ECS hubs and EPC neighbourhood teams developed their capacity and services at different rates across the different localities, services were not all running immediately, hence each study will include a short bedding-in period (i.e. a period omitted from the analysis to allow time for the interventions to become established).

Study period

Assuming a bedding-in period of approximately one month for each study, the ECS study period will start in August 2015 and the EPC study period will start in November 2016. The exact study start dates will be determined according to the date of the first enrolled individual in the relevant study. Both study periods will end in December 2017. The exact dates in the start and end months will be the dates of the corresponding NHAIS monthly extraction. Using the date of the NHAIS extract enables control group individuals to be included from that date and enables accurate assessment of whether an individual is, or has been, a care home resident, which is one of the potential covariates.

Index date

Everyone in the study will have their own length of follow-up period. An individual's follow-up period will start from their index date:

- The index date for an individual in the ECS intervention group is their enrolment date (ECS enrolment accepted date).

- The index date for an individual in the EPC intervention group is their EPC start date (date on which EPC code was added).

For individuals in the control group, monthly index dates are assigned, starting from the latest of the study start date and the earliest date of registration[1] with a GP practice in the Fylde Coast NHS vanguard region. The date of registration for an individual is set to the date of the first available NHAIS extract with a Fylde Coast NHS vanguard region GP practice registration for that individual. Monthly index dates are assigned to facilitate an optimal match with the most suitable intervention group patient. If an individual is referred to EPC, or enrolled in ECS, more than once, only the first date is used. No differentiation will be made between active or dormant patients for the EPC study or ECS study, except in the analysis that specifically looks separately at the outcomes for patients before and after discharge from ECS.

Follow-up period

Individuals in the study will be followed from their index date to the study end date, their death or when they cease to be registered at a GP practice within the Fylde Coast NHS vanguard region. Follow-up periods can therefore range up to a maximum of 28 months in the ECS study, and 14 months in the EPC study, and end at the earliest of the following dates:

- the end of the study period in December 2017, set to the date of the last available NHAIS extract for that month
- date of death*, set to the date of the first available NHAIS extraction in which death is recorded
- date of de-registration[1] from a Fylde Coast NHS vanguard region GP practice, set to the date before the date of the first NHAIS extraction in which they are now registered with a GP practice outside the Fylde Coast NHS vanguard region.

Pre-period

The pre-period is defined for each individual as the period before his or her index date. Baseline variables will be assembled using data recorded during the pre-period.

For comorbidities, patient level data for 3 years prior to the index date will be used. This is consistent with the Patients At Risk of Readmission (PARR) predictive model[18]. A look-back period of 3 years strikes a balance between identifying as many patients as possible with a prior hospital admission while recognising that progressively fewer new patients are identified as the look-back period extends[19,20]. As comorbidities may resolve over time, a 3-year look-back should also adequately balance the need to identify patient characteristics while not unduly identifying historic comorbidities that have since been resolved.

* True date of GP registration could be up to one month earlier than estimated; true date of death or GP practice de-registration could be up to one month later than estimated. However, these errors are assumed to be randomly distributed across intervention and control groups, and therefore not expected to introduce any bias.

Inclusion/exclusion criteria

The following individuals will be excluded from the analyses:

- Individuals without a recorded month and year of birth.
- Individuals with a follow-up period of less than one month. This can occur if an individual dies within the same month of registering with a GP practice. In this case the date of registration and date of death will both be set to the date of the extraction.
- Individuals for whom it is not possible to define baseline characteristics, including patient comorbidities from either prior hospital activity or local risk stratification data. These baseline characteristics are typically extracted from records of prior emergency or elective admission in the 3-year pre-study period* but, in this study, may also be available from local data used to calculate individual risk stratification score. If the local data is unavailable, this criterion is unlikely to exclude a significant number of individuals who were eligible for ECS, as these typically comprise individuals aged over 65 years and with multiple comorbidities who are likely to have had recent hospital activity. However, it may exclude a larger proportion of individuals who are eligible for EPC, as these comprise all individuals aged over 18 years, many of whom would not have had any recent hospital activity. If it turns out that too many individuals meet this exclusion criterion, we may consider extending the pre-study period.
- Individuals who were referred to ECS, but who were not then enrolled in ECS (ECS study only).
- Individuals with any history of ECS involvement (EPC study only).
- Individuals without a valid EPC code on at least one of the EPC referral records (EPC study only).

Sources of data

Secondary Uses Services (SUS) national administrative data

The IAU will have access to pseudonymised (i.e. anonymised in line with the Information Commissioner's Office code of practice on anonymisation) SUS national administrative data, provided by the National Commissioning Data Repository (NCDR). SUS is a comprehensive repository for secondary health care data in England that is paid for by the NHS. It is used to support the NHS in the delivery of health care services and to trigger reimbursement for secondary care activity. SUS data includes month and year of birth.

The IAU will create an analysis dataset for each study using SUS data for the period from three years prior to the study start date until the end of the study. SUS data for more recent months may be incomplete, as they will not include patients who have not yet been discharged from hospital: if the quality of this later data is not comparable to earlier months, then it may be necessary to shorten the follow-up period accordingly.

* By allowing a period of 3 years, we hope to minimise the number of exclusions, while not unduly identifying historic comorbidities that have since been resolved (see "Construct validity" section).

Data derived from National Health Applications and Infrastructure Services (NHAIS)

In addition, the NCDR holds monthly extracts from NHAIS from August 2014 up to a month before the date of the data transfer to the IAU. These monthly extracts, created on the first Sunday after the 13th day of the month, contain demographic information about all registrations with GP practices in England, including date of birth, full residential address and the GP practice at which the individual is registered. The date of death (month and year) is also recorded in NHAIS for individuals who died from August 2014 to the last available data extract.

Data derived by the NCDR based on these monthly extracts will enable the IAU to identify individuals registered with a GP practice in Fylde and Wyre and the duration of their registration. This is achieved by analysing the history of registration information in NHAIS and identifying in which extract the recorded GP practice changed. In addition, the neighbourhood of each individual can be determined from each individual's GP practice code. Furthermore, the NCDR can identify those individuals living in nursing or residential care homes, by matching the address information available in NHAIS with care home addresses, available from the Care Quality Commission (CQC) website.

In summary, the NCDR will derive and provide the following limited data from the NHAIS database for the period 1 June 2015 to 31 December 2017, for individuals registered with a GP practice in Blackpool CCG and Fylde and Wyre CCG:

- month and year of death
- GP practice code
- month and year of change of GP practice registration change date, if any
- a 'flag' for any individual who is resident in a nursing or residential care home in Fylde and Wyre at any time during the period, and month and year of initial residence.

The data derived from NHAIS will be linked to the SUS data via a pseudonymised patient identifier.

Data from the Fylde Coast NHS vanguard

The IAU will request pseudonymised data relating to ECS, EPC, Test Bed and risk stratification from the Fylde Coast NHS vanguard, regulated under a data sharing agreement. Details of the data required are shown in Table 3.

Table 3: Data from the Fylde Coast NHS vanguard

Dataset	Cohort	Fields
ECS	All referrals to ECS during the ECS study period	Unique pseudonymised referral ID Pseudonymised patient ID ECS referral start date ECS hub Status flag (received, assessed and not accepted, accepted) ECS assessment date ECS enrolment accepted date ECS enrolment end date Reason for end of referral GP practice code Gender Age at accepted into ECS date Date of death if available
EPC	All referrals to EPC during the EPC study period	Unique pseudonymised referral ID Pseudonymised patient ID EPC referral date Service referred to (Blackpool or Fylde and Wyre) EPC neighbourhood team Status flag (received, assessed and not accepted, accepted) EPC start date EPC end date Reason for end of referral GP practice code Gender Age at accepted into EPC date Date of death if available
EMIS Web community observations	All telehealth and PAM activity during the ECS and EPC study periods	Pseudonymised patient ID Legacy code indicating start of end of telehealth monitoring or PAM Legacy code description PAM score (for legacy code =PAM)
Risk stratification	All risk stratification records for each individual aged over 18 years and who was registered with a GP practice within NHS Blackpool CCG or NHS Fylde and Wyre CCG	Pseudonymised patient ID Risk stratification model run date Risk score GP practice code Age and gender Long-term conditions, including: asthma; coronary heart disease; CHF; cancer; COPD; depression; diabetes; hypertension; atrial fibrillation; chronic kidney disease; dementia; epilepsy; hypothyroid; mental health register; learning disability register; osteoporosis; peripheral arterial disease; rheumatoid arthritis; palliative care; stroke or transient ischaemic attack Substance misuse flag Psychotic disorder flag GP practice submitted frailty score

Although only patients enrolled in an intervention at least one month prior to the end of the study will be included in the intervention group, data on individuals referred until the end of the study will be needed to ensure that any referrals in the last month of the study are correctly accounted for in the matching process. Individuals referred to ECS or EPC for the first time in the last month of the corresponding study period can serve in the control group.

Information on GP practice code for individuals referred to ECS and EPC, and comorbidity information from the risk stratification data, can be cross-validated with data derived independently by the IAU from SUS and NHAIS data to verify that the process of pseudonymising and linking individual data is correct. In addition, the comorbidity information from the risk stratification data can be used to increase the size of the available study population – the IAU can otherwise only obtain comorbidity information from SUS data, and so only individuals with a record of hospitalisation in the 3 years prior to the study start date have the requisite information for matching. This is particularly relevant for the EPC study which is targeted at individuals aged over 18 years, many of whom may never have visited hospital.

For more details of the information governance for the sharing of local data please refer to the Data Sharing Agreement.

Baseline variables

Appropriate baseline variables will be included in the matching process and as covariates in the regression models. All baseline variables are calculated on pre-period data. Potential baseline variables are listed in Table 4. Please refer to Statistical Analysis for how specific variables are selected for inclusion in the matching process. Note that some individuals may have received interventions other than ECS or EPC before their index date, which may affect some of the prior hospital activity covariates. However, it is assumed that the use of these services would be approximately balanced between the groups, after matching, and any risk of an imbalance is counteracted by including information on hospital activity just before individuals were enrolled in ECS, or referred to EPC, in the matching process and regression model. This excludes LCIA Test Bed, which is utilised in the matching process to ensure a similar distribution between intervention and control groups.

Table 4: Potential baseline variables to be utilised in matching and regression models

Category	Variables at patient level
Demographics and socio-demographics	Approximate age at index date Gender Ethnicity Average socioeconomic deprivation quintiles, based on the Index of Multiple Deprivation (IMD) 2015, available at Lower Layer Super Output Area (LSOA) level Urban/rural classification at LSOA level, based on the 2011 census

Prior hospital use	Primary outcomes: • in the last 60 days of the pre-period • in the last year of the pre-period (i.e. 365 to 1 day before index date) • in the penultimate year of the pre-period (i.e. 730 to 366 days before index date) Secondary outcomes: • in the last year of the pre-period (i.e. 365 to 1 day before index date)
Comorbidities and other health variables	Specific, and number of, comorbidities identified using data from any diagnosis field in any hospital admission in the pre-period: • from the Elixhauser list • linked to frailty[21] • predictive of hospital emergency admission, as identified in the Inpatient Outpatient A&E and GP (IPOPAEGP) model[22]
Support	Resident in a nursing or residential home
Time period	Index date/period (quarter and year)
Level of care available	Neighbourhood in which the individual is registered with a GP practice Registered for LCIA Test Bed Prior enrolment in EPC (for ECS study only)

Comorbidities and other health variables

The Elixhauser is a list of comorbidities that are routinely used for risk adjustment[23,24]. The Elixhauser list consists of the following 31 comorbidities: CHF; chronic pulmonary disease; hemiplegia or paraplegia; metastatic solid tumour or metastatic cancer; acquired immune deficiency syndrome or human immunodeficiency virus; peripheral vascular disease; cardiac arrhythmias; valvular disease; pulmonary circulation disorders; hypertension (uncomplicated); hypertension (complicated); other neurological disorders; diabetes (uncomplicated); and diabetes (complicated); hypothyroidism; renal failure; liver disease; peptic ulcer disease (excluding bleeding); lymphoma; solid tumour without metastasis, rheumatoid arthritis or collagen vascular diseases; coagulopathy; obesity; weight loss; fluid and electrolyte disorders; blood loss anaemia; deficiency anaemia; alcohol abuse; drug abuse; psychoses; depression.

The list of comorbidities for frailty is consistent with previous analyses[21,25] and consists of: anxiety or depression; functional dependence; falls and significant fracture; incontinence; mobility problems; pressure ulcers; and cognitive impairment (composite of delirium, dementia and senility). Note that there is some overlap between the definitions of the health condition ‘depression’ (Elixhauser list) and ‘anxiety or depression’ (frailty list).

The Inpatient Outpatient A&E and GP (IPOPAEGP) model[22] is a risk prediction model of hospital admissions that builds on and improves earlier models, such as the PARR algorithm. The IPOPAEGP algorithm identifies a number of comorbidities that are predictive of hospital admission[18]. Comorbidities that can be captured from inpatient data and which are not already captured within the Elixhauser or frailty variables include myocardial infarction, cerebrovascular disease, connective tissue disease and mental ill health, e.g. miscellaneous cognitive dysfunctions. Health variables include the number of outpatient visits missed in

the first year of the pre-period, which is identified as predictive of hospital admission in the IPOPAEGP model on the basis that the number of missed appointments may be correlated with how amenable a patient is to health care interventions and hence may be a confounder in our analyses[26].

The mental health subset cohort will be classified as those who can be identified in hospital data as having had a diagnosis for mental ill health, i.e. those who had at least one inpatient admission or outpatient appointment with a diagnosis of any mental and behavioural disorder (Chapter V of the ICD-10 classification code F*)[27], or where the main specialty (medical specialty under which the hospital consultant is contracted) was mental health (NHS specialty codes 700 to 715) within the previous 3 years. The subset will include those with a serious mental illness, such as schizophrenia, bipolar disorder or psychosis, as well as less severe mental ill health. The definition is similar to that of previous research[14] but identifies patients with any diagnosis, whether primary or secondary, while the previous research only included those with a primary diagnosis of mental ill health. Although some of the comorbidities can be cured, it is assumed that any issues reported in the pre-period will be relevant to the overall health or frailty of the person and therefore can be included as a potential covariate.

Support variables

Residents in nursing or residential care homes have different patterns of hospital activity than people living at home[12]. Furthermore, people who are socially isolated are often at higher risk of admissions[22]. Therefore, information on whether patients were residents in nursing and residential homes at their index date will be included as a covariate.

Time period variables

During the study period, individuals in both groups may have received other care specific to the vanguard, and the range of other interventions available to individuals will have differed over the time period. Matching and regressing on the index date would take into consideration two aspects: differences in seasonality when intervention group individuals were referred or enrolled (or matched for the control group), as well as the extent to which other interventions were available at the time of referral. By balancing the groups on index date, we will be allowing for similar availability of services between the intervention and control groups.

Level of care available variables

As both the ECS and the range of other MCP services also differed slightly between localities, individuals will be matched within each neighbourhood and neighbourhood will be adjusted for in the regression models. In the rare cases where an individual moved to a different neighbourhood within the Fylde Coast NHS vanguard region during the follow-up period, the individual will be assigned to the neighbourhood they were in at the start of the follow-up period. It is anticipated that only a few intervention group individuals will have moved neighbourhood during the study period.

Identifying the control group

The control group will be determined using matching methods to optimise similarity with the intervention group with respect to variables that are likely to be predictive of any of the outcomes.

The matching algorithm

We will perform matching using the genetic matching algorithm, which is a computer-intensive search procedure that produces more closely balanced groups than traditional approaches such as nearest neighbour matching or the propensity score[28,29]. The algorithm measures the similarity of pairs of individuals using distance metrics that are generalised versions of Mahalanobis distance[32]. The distance metric contains weight parameters, which are optimised to produce a matched control group that is as similar as possible to the intervention group.

The matching process

The genetic matching algorithm will try various distance functions to determine the 'closeness' of the match. However, for some variables a match may be required to be exact or to fall within a pre-fixed 'caliper', whereby the variables are required to be within a fixed distance of one another; variables falling into this category include living at home, in a nursing home or in a residential care home.

Matching will be done without replacement if possible (i.e. each intervention group individual will be matched to a unique individual in the control group). If, however, it is difficult to find balanced groups, matching will be done with replacement, i.e. the same control group individual may be matched to several intervention group individuals. Additionally, as a control group individual will be assigned monthly index dates, they may be matched to several intervention group individuals, but with different index dates (and correspondingly potentially slightly different baseline characteristics). It is expected that all intervention patients will be matched and no exclusions will be necessary.

To ensure balance within each neighbourhood, the IAU will match within each neighbourhood separately to ensure that individuals in the intervention group have access to the same MCP services as their counterparts in the control group.

Choice of variables to include in matching

To ensure a similar distribution of patient characteristics across intervention and control groups, the IAU will aim to match on the baseline variables listed in Table 4. Although we will ultimately assess balance across all these variables, we are likely to only include a subset of those variables in the matching algorithm. The subset of variables included in the matching algorithm will be selected empirically to optimise balance between the two groups on those variables considered most strongly predictive of the outcome, e.g. the prior numbers of emergency admissions, but also aiming to optimise balance across the wider set of variables.

As matching will not take place on the length of follow-up period (as this could be correlated with quality of care), the intervention and their control group matches may differ in this respect. The IAU will conduct descriptive analyses regarding length of follow-up period, and address differences using an offset in the model, which will allow for differences in time at risk.

Ideally, all variables included in the matching will also be adjusted for in regression models although this is not always possible, e.g. due to correlation between variables.

Matching diagnostics

Balance will be assessed, across all baseline variables listed in Table 4, using the standardised difference between intervention and control groups. The standardised difference is defined as the difference in means as a proportion of the pooled standard deviation[30]. Although the standardised difference should ideally be minimised without limit, a standardised difference below 10% has been used to describe negligible imbalance[31]. The standardised difference is a better measure of balance than formal statistical tests, as the latter depend on the size of the groups, as well as on the level of similarity[32]. The distribution for continuous or count variables will also be assessed.

Statistical analysis

We aim to estimate the Average Treatment effect for the Treated (ATT). Once matched controls have been selected, we will estimate the effect of each intervention on each outcome in the corresponding intervention group compared to that outcome in the matched controls by fitting multivariate regression models, both unadjusted and adjusted for covariates. The adjusted model will contain all variables that were used in the matching process to adjust for any remaining observed imbalance, as well as any other covariates predictive of outcome. Index date will be included as a quarter/year categorical variable. Modelling checks for collinearity will be carried out and, if appropriate, the list of covariates will be changed accordingly.

The appropriate multivariate regression model will be determined based on the distributional properties of the outcome being analysed (Table 5).

Table 5: Regression models for each type of outcome

Type of outcome	Outcome	Initial model	Alternative model	Diagnostics
Count data	Number of admissions/ A&E attendances/ outpatient visits/ emergency bed days/ elective bed days	Poisson	Negative binomial/ Zero-inflated Poisson	Overdispersion Model fit Excess zeros
Proportions	Proportion of total deaths occurring outside of a hospital setting/ Proportion of patients who die (sensitivity analysis)	Binomial	Quasi-binomial/ Poisson (bed days)	Model fit Distribution of model residuals Overdispersion Heteroscedasticity diagnostics

Model fit will be assessed by examining diagnostic statistics and overdispersion parameters (e.g. the ratio of the residual deviance to the residual degrees of freedom), and excess zeros by comparing predicted and observed proportion of zero counts. If overdispersion is detected then an alternative model, such as a Negative Binomial or the zero-inflated Poisson for count data, will be fitted. The appropriate choice of model will be made by comparing the log-likelihood ratio and the Akaike Information Criterion (AIC).

To account for differing attrition arising from death, moving away from the area or different entry dates into the study, an offset of the number of days in the study will be added to the model. However, the offset assumes that the number of days that are 'missing' is random and that the rate of outcomes, e.g. emergency admissions, is constant, when in fact this is unlikely to be the case. For example, an individual may use more hospital services in the final months of life. As detailed in Inclusion/exclusion criteria, an individual's follow-up period ended (was censored) when the individual either died, moved away from the Fylde Coast vanguard region or the study period ended. If the length of time individuals were followed up in the study or the reasons for leaving the study differed between the groups, the IAU will consider an appropriate sensitivity analysis.

Limitations and sources of bias

Validity and Generalisability

Internal validity

Internal validity refers to the extent to which a study is conducted well.

Selection bias and confounding are two of the main methodological challenges that constitute a threat to the internal validity of observational studies. Selection bias is the bias that results from unrepresentative sampling of individuals or groups for an analysis. Selection bias can occur in observational studies of interventions, or treatments when there is non-random variation in the way in which individuals are selected for, or referred to, an intervention, e.g. because of different characteristics of individuals, clinicians or environments. This may especially be the case when there are strict eligibility criteria for participation. 'Healthy volunteer bias' is another type of selection bias, which occurs when those who participate in an intervention are generally healthier, or more active or engaged, than those who do not.

Selection bias can lead to confounding. Confounding occurs if the factors underlying the variation in the way in which individuals are selected for an intervention are also related to the outcome, but are not accounted for in the analysis. If the factors are not observable, e.g. clinician judgement, patient activation, then this is called unobserved confounding and it cannot be accounted for in the analysis. This can lead to an underestimate or an overestimate of the true effect of an intervention, or to type I errors where an effect is falsely attributed to an intervention rather than to the confounding variables.

Types of selection bias observed in the ECS and EPC study may occur at the following stages of patient referral and enrolment:

- Referrals to ECS and EPC are received mainly from GPs, but also from other health care workers (e.g. community staff, mental health, social care). Although eligibility for ECS and EPC is verified based on strict risk stratification criteria after referral, variation in clinical judgement and varying levels of engagement and interest in ECS or EPC among the health care professionals may lead to variability in the type of individuals referred, hence selection bias.
- For ECS, a significant number of individuals were offered a referral or enrolment but refused. No data are available on the reasons for refusal, but it is assumed that those who did not refuse are more receptive to treatment, or to novel interventions, than those who refused. This constitutes a form of 'healthy volunteer' bias. Note that individuals who refused, or who were rejected by the ECS service as unsuitable based on eligibility criteria or otherwise, are excluded from the study and cannot therefore be selected as a control.

The lack of information on any non-clinical reasons for referring individuals, or reasons for any individual refusal, together with a lack of primary care and community data, makes it difficult for us to observe or quantify the characteristics leading to any selection bias. Since the characteristics are unobserved or unquantifiable, they cannot be accounted for in the

statistical analysis in the usual way of matching intervention patients to controls based on these characteristics, or by adjusting for them in regression analyses. Hence there may be confounding in the ECS and EPC studies.

For example, if individuals with the highest risk profile have been referred to ECS first, the control pool, which comprises eligible individuals who have not yet been referred, will mainly comprise those individuals with either (a) a different risk profile to the active ECS patient or (b) those who are not receptive (i.e. those who have not had the opportunity to refuse ECS yet, or for whom referral has been deemed unsuitable). Since receptiveness cannot be observed, there is a greater likelihood of matching an ECS patient with a control individual who is less receptive. This may bias results: underestimating the impact of ECS, if unreceptive individuals are likely to incur greater hospital usage; or conversely overestimating the impact of ECS, if they are likely to incur less hospital usage.

The uncertainty of the results due to any unobserved confounding will not be reflected in the confidence intervals or p-values, as these capture other kinds of uncertainties. Therefore, even a statistically significant result will need to be interpreted with caution. The IAU will perform a sensitivity analysis (see Sensitivity Analyses) to try to assess the presence of unobserved confounding.

At the hospital or area level, the risk of unobserved confounding is mitigated by using local controls[33]. This is because the local control group will use the same hospital services, thereby minimising the risk of bias due to differences between hospitals; differences in coding practices (that could bias the detection of comorbidities and therefore risk adjustment)[34,35]; or hospital changes as part of ongoing transformation plans that could impact on outcomes. Here, it is assumed that individuals in each intervention group can access additional services, outside of the scope of the intervention, in a similar manner to individuals who are not in the intervention group. This assumption will not hold if, for example, individuals enrolled in an intervention are specifically referred to, or not allowed access to, these additional services as a consequence of being on the intervention. .

Furthermore, although matching will not ensure balanced groups on unobservable characteristics, it will ensure that the control and intervention groups within each neighbourhood are similar in observable variables to a reasonable degree. This is expected to produce a more similar control group than a non-matched control group.

If the regression model is misspecified, this could lead to biased inferences. However, matching on key variables before running the regression decreases the dependency on the specification.

The IAU uses the pre-period to determine hospital activity at baseline. However, individuals in both the intervention and control groups may have received other services in that period. If there were an imbalance between the groups on who received such interventions, this would introduce a bias. However, there is no reason to believe that there should be a difference.

External validity

External validity refers to the extent to which the results of a study can be generalised to other populations. Here, external validity may be affected by the following situations:

- ECS and EPC have continuously developed and expanded capacity over the study period. The study periods may therefore be too short to capture the full potential of the intervention. For example, if the intervention identifies an unmet need resulting in increased hospital activity in the short term, rather than perhaps a more serious episode in the long term, there may be insufficient follow-up time for some of the intervention group patients to capture the long-term benefits of the intervention. This is particularly relevant for those patients who join the intervention later in the study period.
- Each study includes 10 different neighbourhoods, with different implementations depending on the local population. This heterogeneity is expected to make the results more generalisable.
- A systematic review of published evaluative studies found that the interventions that are most successful at moving care out of hospital have: targeted specific patient populations, e.g. those in care homes, with specific conditions or approaching the end of life; improved access to specialist expertise in the community; or provided active support to patients, including continuity of care[16,36]. The Fylde Coast NHS vanguard includes several of these types of interventions and these studies only evaluate the incremental effects of ECS and EPC. It may be that the counterfactual control group is already performing at a higher level than they would have if no other interventions had been available, making it more difficult to find a statistically significant difference in outcomes due to ECS or EPC.
- There may also be positive spillover of the effects of ECS on the control group, for example if communication and relationships across organisational boundaries improve due to staff participation in ECS.

Statistical conclusion validity

Statistical conclusion validity refers to the extent to which the conclusions of the study are founded on an adequate analysis of the data. Here, statistical conclusion validity may be affected by the following situations:

- For both the ECS and the EPC study, it is possible that sample sizes may be too small to detect a statistically significant difference between the intervention and control groups at conventional 95% significance levels if the effect is small, or there is large variability within the groups. This is particularly the case for the additional subgroup analyses.
- A recent evidence review suggested that initiatives aiming to better manage patients 'at risk' are often highly valued by patients but seldom reduce hospital activity[16]. There are several contributing factors, including limitations of risk stratification tools to identify patients before they deteriorate and that these initiatives often identify unmet need and provide more timely access to care. A limitation of our study is that the IAU can't distinguish between additional hospital activity that is due to good and timely care and other hospital activity. However, by evaluating the number of ACS hospital admissions, we may be able to identify any reductions in emergency admissions due to good quality primary and community care.

Construct validity

Construct validity relates to how well a test measures what it is supposed to measure. Here, construct validity might be affected by the following situations:

- The ECS study is aiming to evaluate the impact of ECS on secondary care outcomes in a frail elderly population. If ECS is recruiting patients who do not meet the intended criteria, then the study will not be reporting results for the population it is purporting to. Since the impact of ECS will depend on providing a high quality of care to the patients who can benefit most from it, targeting the wrong population will likely lessen the impacts of ECS.
- SUS data is an administrative database and has not been subjected to rigorous data cleaning and validation. The IAU Data Management team will perform data checks and cleaning to ensure robustness of the data used in the analysis.
- Changes to patient registration data are provided in monthly table extracts from NHAIS in which no information is given on the specific timings within the month when a new registration, or an end of registration, occurred. Hence patient new registration and end of registration dates are approximated to the date of the first and last monthly extract, respectively, in which they appear. Therefore, it is possible that an individual's new registration could be dated one month later, and their end of registration one month earlier, than actually occurred. Hence an individual's estimated follow-up period could be an error by up to a maximum of 2 months. Further, individuals are more likely to register with a GP practice when they require the services of a GP, so there may be further errors in the length of the follow-up period. However, since ECS and EPC are aimed at individuals with complex needs and multi-morbidity, this is not expected to be a problem. In general, any errors in estimated follow-up period are expected to be balanced between intervention and control group patients and so should not adversely affect the analysis.

Sensitivity analyses

Although there is no definitive way to assess the effect of unobserved confounding, it is possible to compare intervention and matched control groups with respect to an outcome that is unrelated to the intervention[37], e.g. death and length of follow-up time in the study. On the assumption that the intervention is unlikely to have had a large positive or negative impact on overall mortality within the follow-up period, then differences in mortality rates would make us doubt the performance of the matching. For example, if intervention patients died at a higher rate than matched control patients, this might suggest that they were in worse health than controls at the point of joining the intervention[38]. However, there is also a possibility that good care because of the intervention may result in fewer deaths during the follow-up period. The IAU will therefore estimate risk (hazard ratio) of death during the study period using survival analysis techniques. No difference in risk of death will be indicative of balanced groups, while differences would need further investigation, possibly requiring stratification of the cohort in such a way as to remove biases.

Other limitations

The IAU only has access to secondary care data and will not be able to evaluate the impact of ECS on other outcomes of interest, such as those that impact the quality of life, longer-term health or improvements in working relationships.

Nor will this study be able to explore how changes to the delivery of services by ECS or EPC impact outcomes, or how other vanguard interventions impact outcomes.

Costing secondary care data is not within the scope of this study.

Reporting

General reporting considerations

Results will be reported as the relevant measure of effect, such as odds or rate ratios, plus 95% confidence intervals and p-values. Absolute numbers may also be presented, where appropriate. Both the post-matching unadjusted and adjusted analysis will be presented and the variables used in the adjustment noted. Results will be presented to two decimal places for effect size and confidence intervals. P values will be shown to two significant digits.

Special reporting requirements for this study

At a minimum, the following are requirements for this study:

- adherence to the STROBE[39] and RECORD guidelines[40]
- adherence to the NHS Digital (previously Health and Social Care Information Centre, HSCIC) small number rules[41]
- compliance with the statistical code of practice.

Tables and figures for reporting results

Table 6 describes the tables and figures that will be produced as part of this study.

Table 6: Minimum required tables and figures to be produced

Analysis type	Output type	Description	Details
Matching	Table	Baseline characteristics	Descriptive statistics for the intervention group and the matched and unmatched control populations, with: • continuous variables, including count variables, summarised by mean (standard deviation, SD) or median (interquartile range, IQR) depending on the distribution • categorical variables summarised by number (%) • standardised differences calculated for the intervention group versus the unmatched and matched control groups, and variance ratio for continuous variables
	Figure	Balance diagnostics (forest plot)	Forest plot to assess balance before and after matching using standardised mean differences from both the matched and unmatched sample
		Comorbidities bar chart	A bar chart displaying the proportion of important comorbidities in both the intervention and matched control groups
Main analysis	Table	Unadjusted estimates	Unadjusted estimates for the intervention group and the matched control group, including: • for binary outcomes, the number and proportion in each group • for count data, the number of events and person time of exposure • for continuous data, the mean and standard error • the size of the measure effect (e.g. odds ratio, rate ratio, hazard ratio or mean difference) together with a 95% confidence interval • for a difference in difference type analysis the table should show summary results in each time period, their difference and the difference between groups over time
		Adjusted estimates	A table showing the adjusted results, including: • the size of the adjusted measure together with a 95% confidence interval and p-value • all adjustment variables listed, and in some cases included in the table with the relevant effect sizes and 95% confidence intervals
	Figure	Unadjusted and adjusted results (forest plot, time series plot)	Forest plot showing the crude and adjusted results for each outcome measure. Time series plot showing estimates of impact on outcomes before and after the interventions.

Appendix

Secondary Care resource utilisation definitions

A&E attendance

An A&E attendance is a non-duplicate visit by an individual to a hospital A&E department for a particular incident. A duplicate visit is defined as a recorded attendance by an individual to the same provider either at the same date and time as a previously recorded attendance, and where the primary diagnosis and treatment codes are the same; or within one hour of a previously recorded attendance. Depending on the analysis being undertaken, an A&E attendance may be further defined as one of the following:

- a non-duplicate, planned or unplanned visit
- a non-duplicate visit where the patient was seen
- a non-duplicate, planned or unplanned visit where the patient was seen.

Avoidable admission

An avoidable admission is an emergency admission for a condition that could have been managed or treated by timely or effective care within the community and hence which could have been avoided. Sets of clinical conditions which may lead to an avoidable admission include:

- A set of conditions that focus on older people experiencing health and social care – these include acute lower respiratory tract infections (such as acute bronchitis); chronic lower respiratory tract infections (such as emphysema and other chronic lung diseases); pressure sores; diabetes; food and drink issues (such as abnormal weight loss and poor intake of food and water due to self-neglect); food and liquid pneumonitis (inhaling food or drink); fractures and sprains; intestinal infections; pneumonia; and urinary tract infections[42]. An avoidable admission resulting from a condition in this set is referred to as a potentially avoidable admission.
- Ambulatory care sensitive (ACS) conditions – ACS conditions are a set of clinical conditions for which the risk of emergency admission can be reduced by timely and effective ambulatory care[43]. Ambulatory care consists of primary care, community services and outpatient care[44]. There are a variety of definitions of ACS conditions. The definition used by the IAU will be the same as defined in the CCG improvement and assessment framework (CCGIAF)[45]. This framework was introduced in 2016/17 and was developed with input from NHS Clinical Commissioners, Clinical Commissioning Groups (CCGs), patient groups and charities. It was designed to play a part in the delivery of the Five year forward view for the NHS in England. Similarly to the NHS Outcomes Framework[46], the CCGIAF differentiates between chronic and acute conditions:
  - Chronic ACS conditions: the definition of chronic ACS is the same as that for the NHS Outcomes Framework 2.3.i and CCG Outcomes Indicator Set 2.6[45]. Conditions include epilepsy, diabetes and angina[47].

— Acute ACS conditions, also called urgent care sensitive conditions: urgent care sensitive conditions are defined as unnecessary emergency admissions to hospital for conditions that should be dealt with effectively by the Urgent Care system without the need for admission to hospital. Conditions include chronic obstructive pulmonary disease (COPD), cellulitis, deep vein thrombosis and falls[45].

Elective admission

An elective admission is defined as an admission that has been arranged in advance, either planned, booked in advance or from a waiting list. It does not include an emergency admission, a maternity admission or a transfer from a hospital bed in another health care provider. Depending on the analysis being undertaken, an elective admission may include one, some or all of the following patient classifications:

- ordinary admission
- day case admission
- regular day admission
- regular night admission
- mother and baby using delivery facilities only.

Elective bed days

An elective bed day is defined as a night in hospital following an elective admission. Some elective admissions may be excluded from bed days calculations depending on the patient classifications being included in the definition of an elective admission (see above).

Emergency admission

An emergency admission is defined as a separate hospital spell that either occurs through an A&E department, or because of direct, urgent referrals from a GP or other professional.

Emergency bed days

An emergency bed day is defined as a night in hospital following an emergency admission. An admission and discharge within the same day will result in a length of stay of zero days[48], and therefore not count towards the total number of bed days. This is consistent with the definitions of bed day used within NHS England[49] and the NHS England New Models of Care dashboard, which displays outcome data for all vanguard sites[50].

Emergency readmissions within 30 days of discharge

An emergency readmission within 30 days of discharge is defined as an emergency admission occurring within 30 days of discharge following an earlier hospital admission (regardless of whether the earlier admission was emergency or elective). Admissions for cancer and obstetrics are excluded as they may be part of the patient's care plan[45].

Length of stay following an elective admission

Length of stay following an elective admission is defined as the number of nights spent in hospital following an elective admission, calculated as the difference in days between the date of discharge and the date of admission. Some elective admissions may be excluded from length of stay calculations depending on the patient classifications being included in the definition of an elective admission (see above). An admission and discharge within the same day will result in a length of stay of zero days[48].

Length of stay following an emergency admission

Length of stay following an emergency admission is defined as the total number of nights spent in hospital following an emergency admission, calculated as the difference in days between the date of discharge and the date of admission. An admission and discharge within the same day will result in a length of stay of zero days[48].

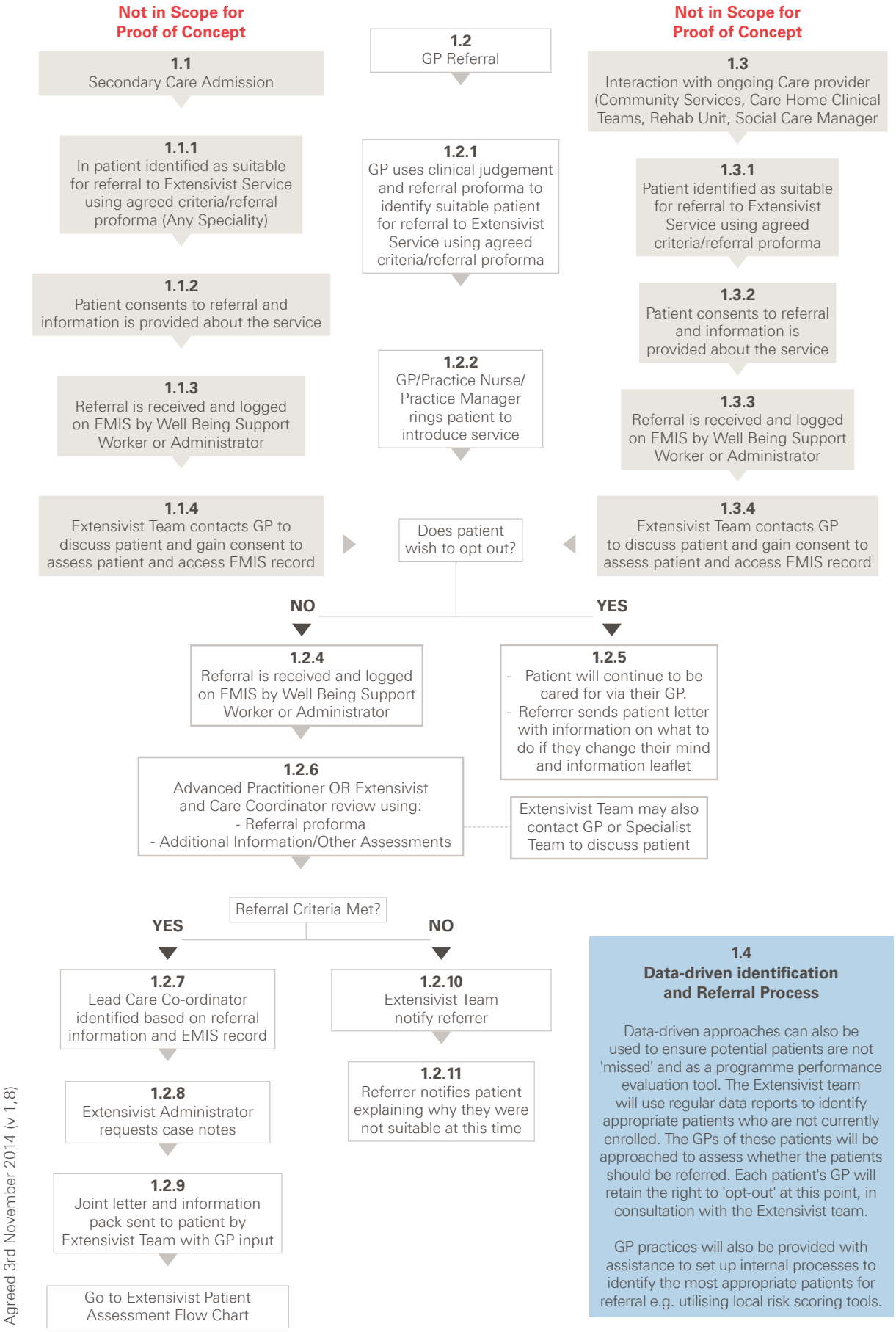
Outpatient appointment

An outpatient appointment is a non-duplicate appointment for a patient to see, or have contact with, a care professional at an outpatient clinic. A duplicate appointment is defined as a recorded appointment by an individual to the same provider, at the same date and time as a previously recorded appointment, and where the main specialty and treatment function codes are the same. Depending on the analysis being undertaken, an outpatient appointment may be further defined as one of the following:

- a non-duplicate appointment where the patient was seen
- a non-duplicate appointment with an acute provider
- a non-duplicate appointment with an acute provider where the patient was seen.

Supplementary figures

Figure 4: Patient identification, referral and enrolment flowchart for ECS



Reproduced from[51].

Addendum

This section has been added to the original statistical analysis protocol (SAP) document to provide further clarifications and information on modifications to the original SAP. The original SAP was agreed in October 2018, with this section added in November 2019.

Subgroup analyses

Due to small numbers of people in the intervention group, we did not perform subgroup analyses looking at the impact on outcomes stratified by absolute risk stratification quartiles, age (EPC only), care home residency status and LCIA Test Bed status.

Study outcomes

The number of emergency readmissions within 30 days of discharge was not examined as an outcome in our study due to challenges with identifying a consistent definition for this metric. Furthermore, some of the other outcomes examined might not be reported in the case that results are inconclusive or unreliable. However, we examined different follow-up periods for primary outcomes, as detailed in the technical report.

Study period

The end of the study period was extended from December 2017 to April 2018.

Data from the Fylde Coast NHS vanguard

After receiving the data from Fylde Coast NHS vanguard, we identified that data were missing for individuals who had died or left the area. The vanguard were able to send us additional risk score data for individuals who had died but no additional data for comorbidities. This meant that we were unable to cross-check comorbidities recorded in the local data with comorbidities identified using hospital data.

Data from the Fylde Coast NHS vanguard (Table 3)

Risk scores were missing for a small proportion of records. Missing risk score data was imputed using last observation carried forward imputation for individuals with less than 50% of observations missing. Any remaining missing risk score data was imputed using predictive mean matching with 15 imputations.

Baseline variables

No indicator on whether someone was a care home resident was included in the matching or regression due to data quality concerns.

Identifying the control group, page 28

Due to the large number of potential controls and the resulting long run time of the genetic algorithm, the matching was run in two stages. In the first stage, 150 or 100 (ECS and EPC respectively) control patients were selected for each intervention patient and only age, risk score, total count of comorbidities, and A&E visits and emergency admissions in the last year were included. The resulting dataset was then used to run the genetic matching on the full set of variables specified in Table 4.

Statistical analysis, page 29

Modelling options also included adjusting for only a list of 'core' variables and those variables considered most predictive of the outcome, as the low number of events for some of the outcomes may otherwise have led to over-parameterised models. The most predictive variables were identified by running a lasso regression and where possible included all core variables as a minimum. Variables considered 'core' were: age; sex (male or not male); ethnicity (white or not); IMD quintile; number of frailty comorbidities; hospital use in year prior to index date; index date (quarter); and risk scores after multiple imputation.

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