

Statistical Analysis Protocol for an evaluation of integrated care teams as part of a primary and acute care system (PACS) in North East Hampshire and Farnham

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The Improvement Analytics Unit

The Improvement Analytics Unit is an innovative partnership between NHS England and the Health Foundation that provides robust analysis to help the NHS improve care for patients. We use advanced statistical techniques to provide evidence of whether local programmes are having an impact on improving the quality and efficiency of care. We do this by assessing whether the care delivered to patients as part a local programme (such as a new clinical model or an integrated care system) is different in any significant way from the outcomes of patients who have not experienced a similar initiative.

Our aim is that our analysis helps the local NHS and its partners identify whether implementation of an initiative is having the desired effect, or needs to change to succeed. At a national level, we support decision-makers to identify what works well and assess the impact of national priorities.

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Contents

The Improvement Analytics Unit	Error! Bookmark not defined.
Glossary.....	4
Summary	5
Purpose of this document.....	5
Purpose of this study	5
What the study will look at.....	5
Data the IAU will use.....	6
Period/patients covered by the study	6
Strengths and weaknesses of the study	6
1. Background.....	8
North East Hampshire and Farnham Clinical Commissioning Group	8
The NEHF Primary and Acute Care System	9
Integrated care teams.....	12
Intended impact of ICTs on outcomes	15
Objectives of the analysis	16
2. Methods	17
Study design.....	17
Study cohorts	17
Sources of data	18
Data derived from National Health Applications and Infrastructure Services	18
Data from NEHF CCG.....	19
Study endpoints	20
Variable definitions	23
Statistical methods.....	27
Subgroup analysis	30
Sensitivity analyses	31
Sample size calculation	32
3. Limitations and sources of bias	32
Threats to validity	32
4. Reporting	36
General reporting considerations	36
Special reporting requirements for this study	36
Tables and figures for reporting matching results.....	36
Tables and figures for reporting statistical results	36
Tables and figures for sensitivity analyses.....	37
Data cleaning and validation checks	37
Data flow diagrams	37
5. Addendum	38
Acknowledgements.....	40
References	41

Glossary

Abbreviation	Description
A&E	Accident and emergency
ACS	Ambulatory care sensitive
CCG	Clinical commissioning group
COPD	Chronic obstructive pulmonary disease
CSU	Commissioning Support Unit
EDOU	Emergency Department Observation Unit
Emergency admission	Unplanned admission to hospital
GP	General practitioner
IAU	Improvement Analytics Unit
ICT	Integrated care team
IPOPAEGP	Inpatient Outpatient A&E and GP (risk prediction model)
NCDR	National Commissioning Data Repository
NEHF	North East Hampshire and Farnham
NHS	National Health Service
PACS	Primary and acute care system
PARR	Patients at risk of re-hospitalisation
STP	Sustainability and Transformation Partnership
STROBE	STrengthening the Reporting of OBservational studies in Epidemiology
SUS	Secondary Uses Service

Summary

Purpose of this document

This statistical analysis protocol describes in detail all aspects of the proposed Improvement Analytics Unit (IAU) evaluation of the North East Hampshire and Farnham (NEHF) integrated care teams (ICTs), including the study design, statistical methods and variable definitions. In addition, it details the limitations of the analysis and how these should be considered when interpreting the results. The statistical analysis protocol is written before data was accessed, to ensure that all design and methods choices are made objectively, and are not influenced by what we find 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, these changes will be mentioned and the rationale explained in the report or the technical appendix. This document will form the basis of the final report and the technical appendix that will accompany the report.

This document has been agreed with NEHF to ensure clarity before analysis takes place. It may also be of interest to others involved in evaluation and analysis of large data sets. The IAU welcomes comments and questions on this document.

This is a technical document written to guide analytical processes. The Summary section provides a more accessible overview of the planned study.

At the completion of the study, an addendum will be appended to this document to identify whether there was any deviation from the planned approach.

Purpose of this study

To feedback on the progress being made to improve secondary care outcomes for patients referred to the ICTs in NEHF, introduced in July 2015 in each of the five localities of NEHF Clinical Commissioning Group (CCG) ('the intervention').

What the study will look at

The study will examine whether there is an impact on secondary care outcomes ('endpoints') for patients who were referred to ICTs (the 'intervention group') between July 2015 and June 2017.

The IAU will compare these outcomes with those of other patients who were also registered in a GP practice in the NEHF CCG and who were similar (e.g. in age, gender, comorbidities, number of hospital admissions in the year prior to the referral to the ICTs). This 'local matched control group' will have had access to all the same services within the CCG, apart from the ICTs. As the range of primary and acute care systems (PACS) services differed slightly across the five localities, the IAU will select controls from within the same locality as the ICT patients.

The primary outcomes examined will be:

- number of emergency admissions
- number of emergency admissions for long-term ambulatory care sensitive (ACS) conditions
- number of emergency admissions for urgent care sensitive conditions
- number of A&E attendances

- average length of stay following an emergency admission.

The secondary outcomes examined will be:

- number of emergency readmissions within 30 days of discharge
- number of elective admissions
- number of outpatient attendances
- average length of stay following an elective admission
- number of emergency bed days
- number of elective bed days
- the proportion of deaths outside of hospital (used as a proxy for end-of-life care occurring in the patient's place of choice).

Outcomes in the intervention group will be compared with those of the local matched control group over a period of up to 23 months, taking into account each person's length of time in the study.

If the sample size is large enough, further analyses will look separately at each of the five localities to estimate the impact of the ICTs in each setting. In addition, data permitting, the study will investigate the impact of ICTs on the subgroup of patients who suffer from mental ill health, since mental health professionals were core members of the ICTs.

Data the IAU will use

The IAU will use pseudonymised patient-level national administrative hospital data for NEHF CCG from July 2012 to June 2017. The IAU will also receive data on which patients were registered with a general practice within NEHF CCG and the period in which they were registered, and if they were resident in a care home.

The IAU will also use a list of pseudonymised patient identifiers (IDs) for patients who were referred to ICTs from July 2015 to June 2017, the date of the referral and locality of the ICT, supplied by NEHF CCG.

Pseudonymised means that all direct IDs (eg name, address, date of birth, NHS number for patients) are removed from the data. Pseudonymisation reduces the risk that individual patients can be identified from the data.

Period/patients covered by the study

The study will look at patients referred to ICTs from July 2015 to May 2017. During this period, most of the patients referred to ICTs were selected based on clinical judgement. The IAU will look at impacts on hospital utilisation up until June 2017.

The study will use hospital data for the three-year period before each person entered the study. This will enable the characteristics for each patient, which will be used to match patients to other similar patients, to be determined.

Strengths and weaknesses of the study

The study will evaluate the impact of the ICTs on hospital utilisation, 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 IAU evaluation should be viewed in conjunction with the qualitative research carried out by the local evaluation of the NEHF ICTs.

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) and that these differences may bias our estimate of the impact of the ICTs on outcomes, particularly as patients were selected for the ICTs based on clinical judgement, rather than set criteria (for example, using a risk prediction tool). As a result, even a statistically significant result will need to be interpreted with caution.

By using local controls, instead of controls from outside of NEHF, the risk of bias due to area- or hospital-level differences is mitigated, as both intervention and control groups will have access to the same services, with the exception of ICTs.

A recent evidence review found that initiatives aiming to better manage patients 'at risk' are often highly valued by patients 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 endpoints is therefore emergency admissions due to chronic ACS conditions, that is, conditions for which the risk of admission to hospital can be reduced by good and timely primary and community care.

It is estimated that approximately 900 patients will have been seen by an ICT during the period of our study. This may be too small a sample to detect a statistically significant difference between the intervention and control groups. This is particularly the case for the subgroup analyses on the impact in each locality and on patients with mental ill health.

The study will evaluate the impact of the ICTs in the first 23 months of the intervention, during which period the ICTs were still developing. The study period may be too short to capture the full effect of the ICTs.

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

1. Background

North East Hampshire and Farnham Clinical Commissioning Group

North East Hampshire and Farnham (NEHF) Clinical Commissioning Group (CCG) straddles the counties of Surrey and Hampshire in southern England. The CCG plans and funds health care for the 225,000 people registered at 23 GP practices across the five localities of Farnborough, Farnham, Yateley, Fleet and Aldershot.

In January 2015, the CCG was selected as a Vanguard for the New Models of Care programme. The 'Happy, Healthy, at Home' NEHF Vanguard programme, which launched in April 2015, is one of the primary and acute care systems (PACS) and aims to support its population to improve their own health and wellbeing and to provide joined-up care where needed.¹ The Happy, Healthy, at Home initiative is described in more detail in the section on NEHF PACS, p. 10; here, we attempt to place the initiative in the wider context of other changes in NEHF CCG.

Some work on integrating delivery of services and establishing a joint integration team had already started before NEHF received Vanguard status, following funding from the Better Care Fund in 2014 to Hampshire County. Hampshire County includes NEHF and four other CCGs.

In addition to the introduction of the Vanguard interventions, there have been several other changes within the CCG, which may affect patients' use of hospital services. In particular, Frimley Park Hospital, the main hospital serving the NEHF population (providing approximately 80% of the population's acute services), opened a 13-bed Emergency Department Observation Unit (EDOU) in October 2013. EDOUs function as a halfway house between A&E and a proper admission to a ward. They provide a period of observation or treatment, typically for four to twelve hours. An analysis by the NEHF Commissioning Support Unit (CSU) found that some admissions to the EDOU (which in the secondary care data are not distinguished from ordinary hospital admissions) are of very short duration: in 2016/17 there were approximately 1,800 admissions of two hours or less.² It is unclear to what extent admissions to EDOUs would have been replaced by either admissions to regular wards or longer stays in A&E in the absence of an EDOU. Many A&E departments in England run observation units but there is considerable variation in the way in which they function.³

Around December 2015, Frimley Park Hospital started using two wards at Farnham hospital as escalation beds. These beds were used to move delayed transfers of care patients so as to free up Frimley Park Hospital beds. There were originally 42 escalation beds but at the end of March 2017 one of the wards closed, leaving 21 beds still in use. Patients transferred to escalation beds at Farnham hospital are still recorded as Frimley Park Hospital inpatients in the Secondary Uses Service (SUS) data, meaning that the number of available beds for emergency admissions has changed over time.

In November 2016, Frimley Park Hospital opened an emergency ambulatory care unit, which aims to provide emergency care and discharge patients within the same day. While treatment within this unit would still constitute an emergency admission, it is expected this service would have an effect on the number of emergency bed days.

Plans for two Sustainable and Transformation Partnerships (STPs) covering the NEHF area were submitted in October 2016: Hampshire and the Isle of Wight and Frimley Health & Care System. STPs are looking to improve health care and financial balance by shifting the way the NHS plans its services by collaborating across NHS organisations.⁴

The NEHF Primary and Acute Care System

As already mentioned, the NEHF new model of health and social care, 'Happy, Healthy, at Home', was established in April 2015. It aims to:¹

- improve outcomes and experience for local people – helping them to be happy, healthy and where appropriate, supported at home
- provide better value for money, helping to close the gap between the available resources and the costs of providing services to meet need
- retain and recruit sufficient numbers of motivated and skilled staff to meet needs and deliver the New Models of Care.

The model is based on the following core aims:⁵

- **Strengthening focus on self-care and prevention.** Making a step change in emphasis on supporting people to stay well and to take increased responsibility for their own health.
- **Enhancing primary care.** Testing and introducing new models of primary care where practices work together and with other care professionals in the localities covered by the Vanguard to improve access to and manage the workload in primary care.
- **Introducing multidisciplinary locality teams: ICTs.** Professionals from primary care, community care, mental health, social care and the voluntary sector, working as a single team to identify those at greatest risk and to deliver joined-up health and social care for those individuals in line with an agreed, holistic care plan. This is the part of the model that will be evaluated by the IAU.
- **Improving local access to specialist expertise and care:**
 - extending rapid community response in a crisis to support people at home, and to enable timely discharge from hospital
 - providing specialist input from hospital consultants to manage complex needs in the community and to provide local access to specialist planned care.
- **Creating a shared care record.** This aim was not achieved because of technology and information governance issues.

To attain this, NEHF set out to offer a range of activities. These various activities were introduced at differing times and in different ways across the five localities of Farnborough, Farnham, Yateley, Fleet and Aldershot (see Table 1. Timelines of NEHF PACS interventions Table 1). As shown in the table, some interventions have yet to be implemented.

Table 1. Timelines of NEHF PACS interventions

Activities	Start date
Safe Haven	Pre Apr-15*
Enhanced Recovery @ Home interim service	Pre Apr-15*
ICTs in all five localities	Jul-15
Carer's Hubs (Aldershot, Farnborough, Yateley)	Sep-15
Recovery College	Apr-16
GP on the ward in Frimley Park Hospital	Apr-16
Yateley virtual Urgent Care Centre	May-16
Yateley Help Hub	May-16
Farnborough physio pilot	Jun-16
EMIS viewer live in Out of Hours Service	Jun-16
Farnham referral management service	Jul-16
Making Connections	Jul-16
EMIS viewer live in A&E at FPH	Jul-16
Farnham Pre Diabetic Education	Sep-16
Yateley physio service	Sep-16
Yateley Community Paramedic	Sep-16
MISSION pilot clinic	Sep-16
Review of multi-agency "Choice" pathway	Sep-16
New local delirium pathway	Sep-16
Increase "home first" concept and hospital@home capability	Sep-16
Improve community bed utilisation	Sep-16
Acute care pathway diagnostic	Sep-16
Winter Countdown – making preparations for winter through October 2016	Sep-16
Emergency department: Emergency Severity Index implementation	Sep-16
Practice Support Programme relaunched for 2016/17 – 1st visit 05/10/2016	Oct-16
Achieve national standards for CHC pathway delivery within 28 days	Oct-16
National priority – Discharge to Assess and Trusted assessor models	Oct-16
One "ready for discharge" list for all agencies	Oct-16
Plan to close and monitor the 61-bed gap – simple discharges before 12:00	Oct-16
Home for Christmas – 5-week escalation and capacity plan to cover Christmas and New Year	Oct-16
Ensure all "frequent attender" patients have robust community management plans	Nov-16
IRIS at Frimley Park Hospital	Jan-17
Yateley urgent care centre	Feb-17
Aldershot & Farnborough locality plans Development and expansion of ICT capacity and services Development of rapid home visiting services via community paramedics	Mar-17
Farnborough community paramedics	Apr-17

Enhanced Recovery @ Home full service	Apr-17
Carers' Hub (Fleet)	Apr-17
Out of hours prescribing pharmacists	Apr-17
National priority – NHS 111 Increasing the number of calls transferred for clinical advice	Apr-17
Additional support to Care and Nursing homes	Apr-17
Farnborough Safe Haven (Oasis) – 6-month pilot	Apr-17
Farnham urgent care centre	Jun-17
Fleet locality Development and expansion of ICT capacity and services. Development of rapid home visiting services via community paramedics	Jun-17
Fleet Web GP pilot	Jul-17
Farnham Rapid Home Visiting Service	Jul-17
Farnham Dermatology Service	Aug-17
MISSION Clinics	Oct-17

Source: NEHF CCG and Happy, Healthy, at Home Vanguard

*Before Vanguard status

CHC: Continuing Healthcare.

Some activities were set up to benefit the broader population, for example changes to primary care; a social prescribing service; urgent care hubs; carers' hubs; and Recovery College courses.

Other activities will primarily benefit patients with complex needs, long-term conditions or who are older and frail, by providing more and appropriate care in the community, thereby improving their overall health, quality of life and reducing their secondary care needs. There are many interventions that may target this group of patients:

- **ICTs (the subject of this evaluation):** Patients with highest risk and need are referred to multidisciplinary teams who regularly meet, develop care plans and deliver joined-up care for these patients. As shown in the list of core aims (p. 9), this is one of the main interventions.
- **Enhanced Recovery @ Home (ER@H) (Hampshire):**⁶ This service provides support and treatment to people in their own home, either when people are in need of help with their recovery after a hospitalisation or to avoid needing to go to hospital. The ER@H team also provides bridging support to enable patients to stay at home while packages of care are put into place. An interim recovery at home service predates the CCG becoming a Vanguard; the full service was launched in April 2017.
- **Rapid response available in community for patients at immediate risk of admissions (Farnham only):** The deployment of paramedic practitioners into primary care has enabled both practices and ICTs to support admission avoidance by offering a rapid home visiting service. Additionally, the team also provides bridging support to enable patients to stay at home while packages of care are put into place.
- **Referral management service (Farnham only):**⁷ Introduced in July 2016 in Farnham, it consists of peer review of all non-urgent referrals by a team of local GPs who meet each week. This service is expected to avoid unnecessary referrals to secondary care and/or re-direct referrals to alternative services in the community, thereby reducing variation in referral rates, improving the quality of referrals (to the

right place, at the right time) and reduce costs. The service on average diverts 10% of referrals to community services.

- **Safe Haven (Aldershot only):** Opened in March 2014, this provides out-of-hours support to people experiencing, or on the verge of, mental health crisis. It is open to everyone, without appointment. A similar service was opened in Farnborough in April 17 as a six-month pilot.
- **Mission test clinic (Farnham only):**⁸ Tested in September 2016, the Mission model of care pilot involved taking a team of respiratory specialists from secondary care to run clinics and educate/mentor staff within the primary care setting to identify, treat and manage patients with respiratory conditions (asthma, breathlessness and/or COPD). The clinic model is driven by three main objectives: proactive, early identification of patients at risk from poorly controlled disease followed by specialist intervention; effective integration between specialist and primary care; and upskilling of both patients and primary care providers to enable better self-management and increased confidence and knowledge to keep patients better and more independent.

To receive care from the ICTs, patients needed to be referred to the ICTs. Patients had access to all other services irrespective of whether they were referred to the ICTs or not.

In the first year of the Vanguard (2015/16), much of the effort focused on building relationships across organisations, developing strong engagement and involvement of all parties and establishing the foundations of the majority of individual elements of the programme.⁶ There were some unplanned delays in some elements of implementation, particularly issues relating to estates (building work, lease arrangements etc.), which delayed the implementation of urgent care hubs in Farnham and Yateley.⁶

Integrated care teams

The ICTs are one of the core parts of the NEHF New Models of Care, and the subject of this evaluation. These are multidisciplinary teams that meet weekly to discuss patients with the highest levels of risk and need, develop a single coordinated care plan for these patients and deliver joined-up care. The ICTs aim to support people to maintain independence, to manage their multiple health and care conditions locally, and provide care for people in or close to their own homes wherever possible.⁹ The core team is expected to be present at each ICT meeting and comprises a clinical lead, an ICT coordinator, a community matron, a social worker/care manager, a mental health practitioner, a medicines management pharmacist, a paramedic practitioner, a Making Connections co-coordinator, a dementia practitioner and a pharmacist. The core team is also able to draw on the expertise of other specialists on a case-by-case basis, for example from palliative care nurses, a learning disability practitioner or specialist nurses (

Table 2). However, there have been some staff recruitment issues in some of the localities, resulting in a reduced core team during some periods. In particular, three of the five localities have struggled to recruit mental health staff.

Table 2. List of ICT team members

ICT core members expected to be present for each meeting	Additional members as required
Clinical Lead	Practice Nurse
ICT Coordinator	Consultant in Elderly Medicine
Community Matron	CAHMS, learning disabilities, working age adult mental health
	Specialist Nurses
Social Worker/Care Manager	Sensory Services ICT Link Worker
Mental Health Practitioner	South East Coast and South Central Ambulance Services
Medicines Management Pharmacist	North Hampshire Urgent Care (OOH GPs etc.)
	Voluntary Services/Teams as appropriate
Ambulance service/Paramedic practitioner	Palliative Care Nurses
Making connections coordinator	Learning Disability Practitioner
Dementia practitioner	Substance Misuse Service
Pharmacist	Therapists (Physiotherapy, occupational therapy, speech and language)
	Continuing care
	Complex care pathways

Source: NEHF CCG and Happy, Healthy, at Home Vanguard

Once a patient has been referred to the ICT, they are discussed at the following ICT meeting to determine the best plan of action and the most appropriate point of contact within the team. A patient may be seen by a member of the team before this first multidisciplinary team meeting. When appropriate, the teams organise prompt visits from specialists to a person's home, for example for dementia assessments or podiatry appointments. Where these visits are done by professionals normally working in outpatient clinics, they are logged in the SUS data as outpatient attendances. However, community appointments are not documented in the SUS data, independent of whether these occur at a patient's home or at a clinic.

In the earlier stages of the programme, patients were discharged from the ICTs when they were deemed no longer in need of the ICT. However, often these patients would be re-referred to the ICTs at a later date. Now patients referred to an ICT are considered to stay on the ICT register in perpetuum, although differentiation is made between active and dormant patients.

One of the aims of the PACS was to create a shared care record, so that patients need only 'tell their story once'. However, due to both technology and information governance issues, this has not yet been made possible. Nonetheless, information about patients from various sources is shared verbally during the ICT meetings.

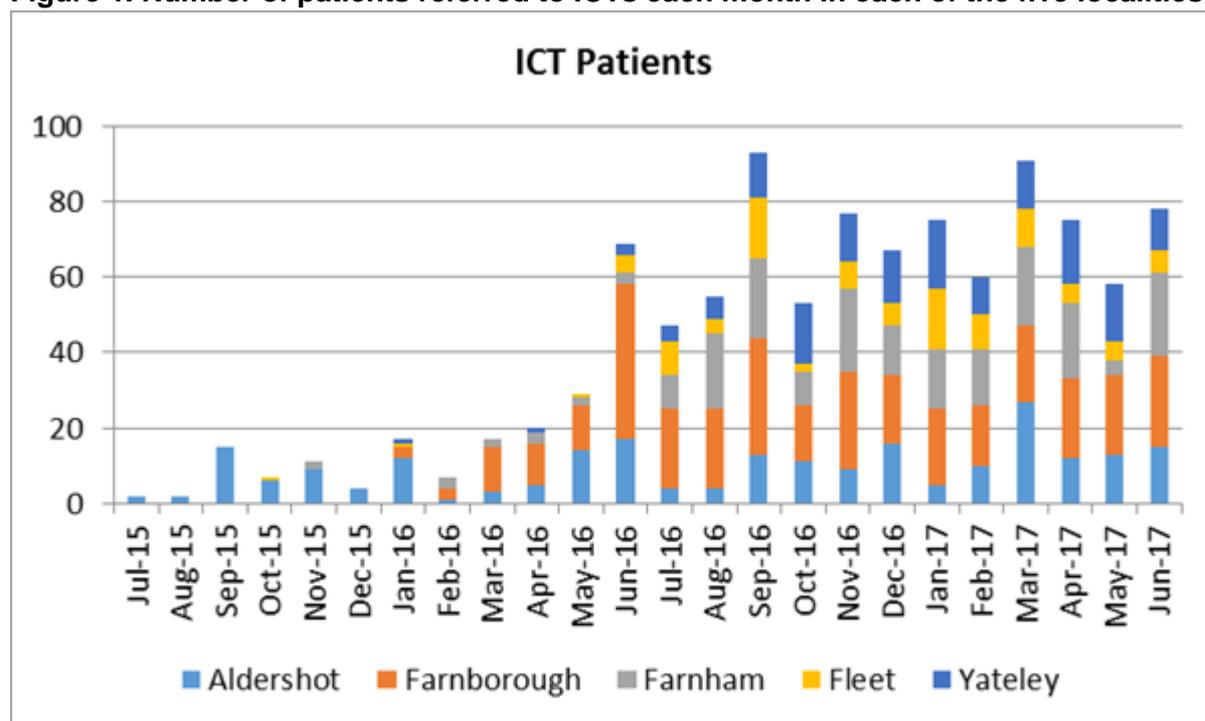
Information from ICT meetings is held on a separate ICT database (not available to the IAU). Information on whether a patient is being seen by an ICT is not routinely shared with hospital staff. The ambulance service may know if a patient is being seen by an ICT if the patient has a care plan. In such cases, if appropriate, the ambulance service would contact the ICT paramedic who would visit the patient and see if other support or services would be more appropriate.

Although the ICTs care for patients over the age of 18,¹⁰ most of the patients referred to ICTs are older – in January 2017, 61% were aged 75 or over and only approximately 5% were aged under 50.¹¹ They tend to have long-term conditions, complex care needs or are approaching the end of their life.

The ICT models were launched in all localities on 27 July 2015, at which time their core teams were in place and they were ready to see referred patients. The ICT models were not prescriptive and developed organically in each locality (Farnborough, Farnham, Yateley, Fleet and Aldershot), to best meet the local needs. For example, anecdotally, two of the ICTs, in Farnborough and Aldershot, are getting more referrals for patients with mental health issues, while another, Farnham, may be seeing more patients with dementia.

By April 2017, a total of 885 patients had been referred to ICTs across the five localities.¹² By June 2017, 1,051 patients had been referred. Although all the ICTs were launched in July 2015, they have developed at different paces, with varying levels of referrals (Figure 1). In January 2017, 25 new patients were referred in Farnborough, 19 in Farnham, 19 in Yateley, 12 in Fleet and 9 in Aldershot.⁶ This is equivalent to between 0.04% and 0.1% of the local population, depending on the locality.⁶ Over time, the Vanguard is aiming to expand to the top 2% of patients in need.

Figure 1. Number of patients referred to ICTs each month in each of the five localities



Source: NEHF CCG

Up to June 2017, patients were predominantly referred to the ICTs based on a clinical judgement, rather than through the application of pre-defined eligibility criteria. The majority of referrals came from GPs, though referrals were also received from other health care workers (eg community staff, mental health, social care).¹⁰ For example, it has been reported that in January 2017, 84 patients were referred to ICTs across the 5 localities, of which 53 were referred by GPs (63%), 14 by community staff, 11 by social care staff, 1 by mental health staff and 1 from the Medically Fit for Discharge list from Frimley Park Hospital.

Only four of the patients referred in January 2017 were reportedly identified from the predictive modelling tool Johns Hopkins ACG [Adjusted Clinical Groups] system.^{6,13}

Often a referral will be preceded by a discussion between the GP or another health professional and the patient. Therefore, the referred patient group is likely to only contain those patients who agreed to being referred to an ICT. However, anecdotally, occasionally a referred patient, for example from social services, refuses to accept a service suggested by the ICT. The IAU does not have access to these data.

Moving forwards, it is intended that the ICT model will not purely be responsive to need, but also include proactive case finding and management to target people who have the potential to become high service users in the absence of proactive management and support.¹⁴ It plans to use more systematic criteria for selection, including the use of the ACG risk stratification tool.¹³ Farnham started in April 2017 to pilot various criteria to identify complex patients who require integrated case management. NEHF CCG is currently investigating using the following threshold criteria to proactively identify patients who may benefit from ICTs, in addition to the risk stratification tool:

- multi-morbidity: patients who have four or more chronic conditions
- complex multi-morbidity: patients who have three or more chronic conditions affecting three or more body systems
- poly-pharmacy: patients prescribed 10 or more drugs
- housebound
- nursing home resident
- residential home resident.

Any one of these criteria would qualify a patient to enter an ICT register. A subset of these patients would then be selected for referral to the ICT, using the ACG tool to identify patients at rising risk of emergency hospital admission. However, for the study period of this evaluation, patients were mainly referred to ICTs based on clinical judgement, rather than through the application of formal criteria such as these.

Intended impact of ICTs on outcomes

The explicit aims of the ICTs are to:¹²

- reach the top 2% of patients at risk of emergency admission (either with crisis management, a proactive intervention to prevent crisis or supporting self-care/prevention)
- reduce A&E attendances
- reduce emergency admissions
- improve patient-reported outcome measures (PROM) scores, demonstrating a positive impact on ICT patients' health, health confidence, experience and wellbeing.

Other intended impacts of the ICTs are to reduce:¹²

- emergency admissions for ambulatory care sensitive (ACS) conditions (i.e. those conditions that are often manageable within primary care, community services or outpatient care)
- emergency readmissions within 30 days

- total hospital bed days
- delayed transfers of care.

Objectives of the analysis

The IAU evaluation will look to answer the question: Do referrals to ICTs make a difference to the outcomes of patients, over and above any effect of other services available in NEHF?

Hospital utilisation of patients who were referred to an ICT will be compared with that of a local matched control group within NEHF who were not referred to ICTs. The local matched control group within NEHF will be similar to the intervention group on a range of observable characteristics, such as age, gender, long-term conditions and prior hospital activity.

Appropriate regression models will be used to compare the outcomes of the ICT and matched control groups, thereby allowing for further adjustment for any observable differences that remain between these groups after matching.

The Vanguard programme is evolving over time and some changes, including to ICT services, will not have been implemented at the time of the analysis (Table 1). This evaluation aims to assess the effect of ICTs during the period 27 July 2015 to mid-June 2017ⁱ (see section on Sources of data, p. 18), thereby providing evidence to support continuous improvement and course correction.

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. Costs will not be evaluated in this study.

ⁱ Some dates are estimated using the patient registration extraction dates (see sections on Sources of data (p.18) and Index dates and follow-up period (p.23)).

2. Methods

Study design

The outcomes of patients referred to ICTs will be compared with those of a retrospectively matched control group formed from patients who are resident within the NEHF area. The control group will be matched so that their baseline characteristics (such as age, comorbidities and prior hospital activity) are similar to the group of patients referred to ICTs. In other words, routine patient-level information will be used to characterise the intervention patients at baseline, and then select matched controls that had similar observed characteristics. These matched patients will form the control group for the evaluation of the ICTs.

Both groups may have been affected by other PACS interventions (such as consultant clinical input for patients at immediate risk of admissions), and wider changes occurring with the NEHF area (such as the introduction of observation units in Frimley hospital). As the two groups had similar characteristics and both had access to all other PACS services, it is assumed that patients in both groups were as likely to have received the other interventions, thereby enabling us to isolate the effect of the ICTs.

Once matched controls have been selected, the effect of the ICTs compared with the control group will be estimated by fitting multivariable regression models to a selection of outcome measures (see section on Study endpoints, p.20).

Study cohorts

Definition of intervention population

The intervention population will be defined as those patients who were registered with a general practice within NEHF CCG and who were referred to an ICT between 27 July 2015 and mid-May 2017.

Definition of study cohort

The study cohort will be defined as those patients who were registered within one of the 23 general practices in NEHF during any period between mid-July 2015 and mid-May 2017. Patients can only be in the study for the period of time they were registered with a NEHF general practice.

Although the study period extends to mid-June 2017, only patients who registered with a NEHF CCG general practice by mid-May 2017 will be included, so as to allow for a follow-up period of at least one month.

The following patients will be excluded:

- patients without a recorded month and year of birth
- patients with a follow-up period of less than one month. This occurs when a patient dies within the same month of registering with a general practice within the CCG. A limitation of the derived data from the patient registration data available to the IAU is that it only allows us to determine the month within which a move or a death occurred (see section on Data derived from NHAIS, p.18). In these cases, both dates are set as the day of the extraction date on which the new address or death was recorded

- patients without a record of prior emergency or elective admission in the three-year pre-study period (defined in section on Pre-period, p.24). These will be excluded because prior hospital data are required to define baseline patient characteristics, in particular patient comorbidities
- patients referred to an ICT between mid-May and mid-June 2017.

The exclusion criterion relating to no prior admissions is likely to exclude some patients who were referred to the ICT. An analysis done by NEHF CCG found that 20% of patients referred to the ICTs by end of February 2017 had no admissions (emergency or elective) in the previous two years. By allowing a period of three years, it is hoped that the number of exclusions will be minimised, while not unduly identifying historic comorbidities that have since been resolved (see section on Pre-period, p. 24).

Patients who change general practice within the CCG will be considered to be assigned to the locality of the general practice at the start of the follow-up period. NEHF CCG has confirmed that there were only a few cases where patients who were referred to one ICT changed general practice and ICT team.

The intervention group will be identified using the pseudonymised list of patients referred to an ICT, supplied by NEHF CCG (see sections on Data from NEHF CCG (p. 19) and Exposure variable (p. 23). Patients referred to an ICT after the mid-May cut-off and before mid-June will be excluded from the intervention group as they will not have a follow-up period of at least one month. They will also be excluded from the potential control group, as they would have received the intervention within the study period. Any patients referred to ICTs after mid-June 2017 may be considered as potential controls for this study.

Sources of data

Secondary Uses Services 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.

The IAU will create the analysis data set using SUS data for the period 1 July 2012 to 30 June 2017. This period will cover the study period up to the latest point for which it will have access to reliable data, as well as three years before the study period start date, which is data needed for measuring study covariates. SUS data for recent months may be incomplete as they will not include patients who have not yet been discharged. The IAU believes that data to June 2017 will be of sufficiently good quality, but we will check that the quality of the data is similar to earlier months and if necessary shorten the follow-up period.

Data derived from National Health Applications and Infrastructure Services

In addition, the NCDR holds monthly extracts from National Health Applications and Infrastructure Services (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 general practices in

England, including date of birth, full residential address and the general practice at which the patient is registered. The date of death is also recorded in NHAIS for patients 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 patients registered with a general practice in NEHF and the period within which they were registered there. This is done by analysing the history of registration information in NHAIS and identifying in which extract the recorded general practice changed. In addition, each patient's locality can be determined from their general practice code. Furthermore, the NCDR can identify those patients 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 website.

In summary, the NCDR will derive and provide the following limited data from the NHAIS database, for patients registered with a NEHF general practice at any time during the period mid-July 2015 to mid-June 2017:

- patients' month and year of birth
- patients' month and year of death
- patients' general practice code
- patients' extract date when the general practice code changed
- flag if a patient is resident in a nursing or residential care home in NEHF at any time during the period and the date of the move into the care home.

The dates of death and registering with a practice will be estimated by using the date of the extraction.

It is believed that data to mid-June 2017 (i.e. the June 2017 extract) will be of sufficiently good quality, but the IAU will do comparisons of monthly data to check this and adjust the study period accordingly. The data derived from NHAIS will be linked to the SUS data via a pseudonymised patient identifier.

Data from NEHF CCG

The IAU will request the following information from NEHF CCG:

- pseudonymised patient IDs for patients who were referred to ICTs from 27 July 2015 to mid-June 2017
- date of referral
- the locality of the ICT to which they were referred.

Information on patient IDs and date of referral will allow the IAU to identify the intervention group and the start dates of their intervention. Although only patients referred up to mid-May will be included in the intervention group, data on patients referred until mid-June will be needed to ensure that subsequent referrals are excluded from the control group. Patients referred to an ICT after mid-June 2017 can serve as a control patient for the study period of this evaluation. Information on locality for referred patients will allow the IAU to check that the general practice codes from NHAIS can be used to derive locality correctly. This will

confirm whether matching within localities and doing subgroup analyses by locality are feasible.

As recipient data controllers, NEHF CCG/NHS England can use their powers of disclosure under the Health and Social Care Act 2012 to share data to support IAU evaluations. To facilitate this, it may be necessary for the CCG local data to be transferred securely from the Data Services for Commissioners Regional Office (DSCRO) providing services to the CCG to NHS England's DSCRO (Arden and Great East Midlands) to enable it to be de-identified and linked to NHS England's national SUS data and/or other data as required to support the evaluation. The linked data will then be anonymised further (i.e. different pseudonyms applied) to mitigate the risk of re-identification when the data are made available to analysts in the IAU who will be undertaking the evaluation.ⁱⁱ

Study endpoints

Primary outcomes

The primary outcomes to be examined by the study are:

- number of **emergency admissions** per patient over the follow-up period
- number of **chronic ACS emergency admissions** per patient over the follow-up period
- number of **emergency admissions for urgent care sensitive conditions**
- the number of **A&E attendances** per patient over the follow-up period
- **average length of stay following an emergency admission** per patient.

All count endpoints will be modelled allowing for varying study lengths, by including an offset for amount of time at risk in the statistical analysis. The length of the follow-up period for each patient will vary between 1 and 23 months, depending on the date on which they entered the study (e.g. when during the study period they were referred to an ICT) and if they died or moved away during the study period (i.e. whether their time in the study was curtailed) (see section on Index dates and follow-up period, p. 23).

Emergency admissions are defined as separate hospital spells that either occur through the emergency room or as a result of direct, urgent referrals from a GP or other professional. Many emergency admissions are not avoidable with good care; therefore, evaluating ACS admissions may be a more appropriate outcome when evaluating a health care intervention.

ACS conditions are defined as clinical conditions for which the risk of admission can be reduced by timely and effective ambulatory care.¹⁵ Ambulatory care consists of primary care, community services and outpatient care.¹⁶ 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.^{17,18} By evaluating the number of ACS hospital admissions, the IAU will try to isolate those

ⁱⁱ A document detailing the information governance framework was being finalised at the time of writing.

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.

There are a variety of definitions of ACS admissions.¹⁶ The definition used in this study will be the same as the one defined in the CCG improvement and assessment framework (CCGIAF).¹⁹ This framework was introduced in 2016/17 and was developed with input from NHS Clinical Commissioners, CCGs, patient groups and charities. It was designed to play a part in the delivery of the Five Year Forward View. Similarly to the NHS Outcomes Framework,²⁰ the CCGIAF differentiates between chronic and acute conditions. The categories are:

- unplanned hospitalisation for chronic ACS conditions (the definition is the same as that for the NHS Outcomes Framework 2.3.i and the CCG Outcomes Indicator Set 2.6.¹⁹ Conditions include epilepsy, diabetes and angina²¹
- emergency admissions for urgent care sensitive conditions. These are defined as unnecessary emergency admissions to hospital for conditions that should be dealt with effectively by the urgent and emergency care system without the need for admission to hospital. Conditions include COPD, cellulitis, deep vein thrombosis and falls.¹⁹

These definitions of ACS conditions differ from that used by NEHF CCG, which is based on the Quality Premium 2014/15 definition of avoidable emergency admissions.²² The Quality Premium measure is based on four NHS Outcomes Framework indicators, one of which (2.3.i Unplanned hospitalisation for chronic ACS conditions) is the same as above. This measure is no longer part of the Quality Premium scheme.

Length of stay following an emergency admission is defined as the number of nights spent in hospital, 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.²³ Average length of stay per person is calculated by adding a patient's emergency admission lengths of stay and dividing by the number of emergency admissions. Average length of stay was chosen as a primary endpoint over the related measure – the total number of hospital bed days. Although hospital bed days is one of the 'core metrics' used within NHS England for the New Care Models programme,²⁴ it may not adequately measure the effect of the ICTs, as this endpoint reflects the length of stay in hospital as well as the number of emergency admissions. The ICTs are trying to proactively identify patients, which may inflate the number of emergency admissions in the short term. These admissions are expected to be of shorter duration than if they had not been proactively identified. If the 'counterfactual', longer hospital stay in the control group only occurs after the end of the study period for some patients, the hospital bed days measure may not adequately reflect the changes, as no admission during the study period is equivalent to an admission with a zero length of stay. Hospital bed days are included as a secondary endpoint.

Secondary outcomes

Secondary outcomes, all calculated over the follow-up period, will be:

- number of emergency readmissions within 30 days of discharge, per patient
- number of elective admissions per patient

- number of outpatient appointments per patient (excluding 'did not attends', and defined using code Attended=5 or 6 in SUS)
- average length of stay following an elective admission per patient
- proportion of total emergency bed days per patient, relative to total number of days at risk (i.e. days in the follow-up period)
- proportion of total elective bed days per patient, relative to total number of days at risk (i.e. in the follow-up period)
- proportion of deaths outside of hospital (as proxy for dying in preferred place of death).

All count outcomes will be modelled allowing for varying study lengths, in the same way as for the primary outcomes described above.

Emergency readmissions within 30 days of discharge are defined as all-cause, emergency admissions occurring within 30 days of discharge following an earlier admission (regardless of whether the earlier admission was emergency or elective).

Length of stay following an elective admission is defined as the number of nights spent in hospital following an elective admission but excluding 'regular day/night attendances' (determined by a specific code in the raw SUS data). This is calculated in a similar way to length of stay following an emergency admission, detailed above.

An emergency bed day is defined as a night in hospital following an emergency admission. An admission and discharge within the same day will therefore not count towards the total number of bed days. This is consistent with the definitions of bed day used within NHS England²⁵ and the NHS England New Models of Care dashboard, which displays outcome data for all Vanguard sites.²⁴ This endpoint reflects changes to the length of stay in hospital as well as the number of emergency admissions.

An elective bed day is defined as a night in hospital following an elective admission but excluding 'regular day/night attendances' (determined by a specific code in the raw SUS data).

The IAU will evaluate the number of outpatient attendances and elective admissions per patient, even though these were not part of NEHF's key metrics, as they help build a fuller picture of hospital activity. Interpretation of these results will require careful consideration, as a change in these outcomes could be associated with either good- or bad-quality care. Good-quality care in ICTs could result in either an increase or decrease in these outcomes. It is possible that the number of outpatient attendances and elective admissions per patient could increase as a result of the ICTs, particularly in the short term, if the ICTs' patient reviews and care planning highlight medical needs that require hospital care. The number of these events could however also decrease, either as a result of early proactive care or of ICTs enabling patients to be treated outside of a hospital setting.

Proportion of deaths in hospital will be used as a proxy for patients dying in their preferred place of death. While patients may not die in their preferred place outside of hospital, it is assumed for the purposes of this analysis that locations outside of hospital (e.g. home, care home, hospice) would always be preferred over dying in hospital. Proportion of deaths is calculated by combining information on hospital deaths from the SUS data with information on all deaths from the NHAIS data.

Delayed transfers of care will not be evaluated, as the IAU does not have access to reliable data.

Variable definitions

Bedding-in period and study period

The ICTs were launched on 27 July 2015 across all five NEHF localities. Although the ICTs developed their capacity and services at different rates across the five localities, they were running services immediately. This study will not include a bedding-in period (i.e. a period omitted from the analysis to allow time for the interventions to become established). Although the earliest start date for the intervention group is 27 July 2015, the study period will start in mid-July 2015 (the exact date being the date of the NHAIS monthly extraction) to allow for potential control patients to be included from that date.

The study period will end mid-June 2017 (the exact date being the date of the NHAIS monthly extraction). During this period, most of the patients referred to ICTs were selected based on clinical judgement.

Exposure variable

A person is considered to be in the intervention group (i.e. exposed to the intervention) if they were registered with a NEHF general practice and referred to an ICT between 27 July 2015 and mid-May 2017. By only including patients referred up to mid-May 2017, the IAU allows for at least one month of exposure to the intervention. Persons in the intervention group will be identified from the list of referred patients, supplied in pseudonymised form from NEHF CSU.

Index dates and follow-up period

Each patient will be followed up within the study period for a length of time specific to that patient. A patient's follow-up period will start from the index date, which is defined as:

- If the patient was referred to the ICT, then the date of their first referral. For the purpose of this analysis, this is the date at which they are considered to have started the intervention.
- If the patient was not referred to the ICT (i.e. in the potential control group), then monthly potential index dates will be assigned, starting from the latest of the following:
 - the study period start date (see section on Bedding-in period and study period, p. 23)
 - date of earliest registration with a general practice in NEHF CCG, set as the date of the extraction in which they are first known to have been registered with a general practice in NEHF.

If a patient was referred more than once, only the first date is used, that is, if patients were discharged and then subsequently referred again, they are treated as though they stayed on the ICT register. No differentiation will be made between active or dormant patients (see section on Integrated care teams, p. 12).

For potential control patients, monthly index dates will be assigned from mid-July 2015 up to mid-May 2017. As the first and last monthly dates may be based on extraction dates (see

above and below), the dates set for all other months will for consistency also correspond to the extraction date of the corresponding month. This will also enable more accurate information on whether a patient was a care home resident at the index date, which is one of the potential covariates (see section on Baseline variables, p. 25).

A person's follow-up period ends when the person either dies, moves from NEHF CCG or the study period ends. Thus, the end date is defined as the earliest of the following dates:

- the end of the study period, that is mid-June 2017, set to the date of the last available NHAIS extract
- date of death, set to the date of the extraction in which death is first recorded
- date of de-registration from CCG general practice, set to the day before the date of the extraction in which they were first registered with a general practice outside NEHF.

A person's follow-up period may therefore be between approximately 1 and 23 months.

The date of death is estimated as the extraction date of when they were first recorded as having died. However, as the true death date could be as early as the day after the previous extraction date, there is a risk that the follow-up period is overestimated by up to a month, during which time the patient would have no recorded hospital activity. However, as it is unlikely that the day of the month that a person dies is other than random, this is unlikely to introduce bias between the intervention and control groups.

The date of registering with a general practice in a different CCG (i.e. going from one in NEHF to outside of NEHF, or vice versa) may also have occurred up to a month earlier. However, hospital activity will be recorded throughout and it is unlikely that the dates of moving are other than random and therefore introduce bias between the intervention and control groups.

Pre-period

Baseline variables will be assembled using data recorded during the 'pre-period', which is the period before a patient's index date.

For comorbidities, data at patient level for three years prior to the index date will be used, consistent with, for example, the Patients At Risk of Readmission (PARR) predictive model.²⁶ A three-year lookback period will allow for more patients with a prior hospital admission to be identified than a shorter lookback period.²⁷ The number of new patients identified through prior hospital admissions progressively diminishes over increasing lookback periods.²⁷ A longer lookback period also allows for more comorbidities to be identified.^{27,28} Most studies that explore varying lookback periods do not go beyond one year;²⁸ however, one study investigated up to five years' lookback.⁽²⁸⁾ A comparison of model fit and predictive ability for both modelling deaths and readmissions within 30 days found that both improved over the length of the lookback period, with a five-year lookback period being better than a three-year lookback period.²⁸ However, the magnitude of improvement progressively diminished over increasing lookback periods,^{28,29} with an increase in comorbidity prevalence of less than 1% when including admissions up to three years compared with two.²⁹ As some comorbidities may resolve over time, a three-year

lookback should adequately balance the need to identify patient characteristics while not unduly identifying historic comorbidities that have since been resolved.

Note that some patients may have received interventions other than ICTs before the index date, which may affect some of the prior hospital activity covariates. However, it is assumed that any use of these services would not be unbalanced between the groups, after matching, and any risk of an imbalance is outweighed by the benefits of including information on hospital activity just before patients were referred to ICTs in the matching process and regression model.

Baseline variables

Appropriate baseline variables will be included in both the matching and the regression models. All baseline variables are calculated on pre-period data. Potential baseline variables to include in the matching or as covariates in the modelling are listed in Table 3.

Table 3. Potential baseline variables

Category	Variables at patient level
Demographics & socio-demographics	<ul style="list-style-type: none"> • Approximate age at index date • Gender • Ethnicity • Average socioeconomic deprivation deciles, based on the Index of Multiple Deprivation (IMD) 2015, available at layer super output area (LSOA) level • Urban/rural classification at lower LSOA level, based on the 2011 census
Prior hospital use	<ul style="list-style-type: none"> • Number of emergency admissions in the last 60 days of the pre-period • Number of emergency admissions in year -1, the last year of the pre-period (i.e. 365 to 1 day before index date) • Number of emergency admissions in year -2 of the pre-period (i.e. 730 to 366 days before index date) • Number of ACS emergency admissions in the last 60 days of the pre-period • Number of ACS emergency admissions in year -1 of the pre-period • Number of ACS admissions in the year -2 of the pre-period • Number of elective admissions in year -1 of the pre-period • Number of A&E attendances in year -1 of the pre-period • Number of outpatient attendances in year -1 of the pre-period • Number of missed outpatient visits in year -1 of the pre-period • Average length of stay in year -1 of the pre-period
Health variables	<ul style="list-style-type: none"> • Elixhauser list of comorbidities, identified in the pre-period • Specific comorbidities linked to frailty, identified in the pre-period³⁰ • Other comorbidities predictive of hospital emergency admission, as identified in the Inpatient Outpatient A&E and GP(IPOPAEGP) model,³¹ identified in the pre-period

	<ul style="list-style-type: none"> • Number of Elixhauser comorbidities in the pre-period • Number of frailty comorbidities in the pre-period
Support	<ul style="list-style-type: none"> • Resident in a nursing or residential home
Time period	<ul style="list-style-type: none"> • Index date/period (quarter & year, e.g. q1y1, q2y1...)
Level of care available	<ul style="list-style-type: none"> • Locality in which the patient is registered with a GP

All comorbidities will be defined using data from any diagnosis field in any hospital admission in the pre-period.

The Elixhauser and Charlson lists of comorbidities are routinely used for risk adjustment.^{32,33,34} The Elixhauser list is broader than the Charlson list and consists of the following 30 comorbidities:^{32,34} congestive heart failure (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), 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 and depression. Most of the comorbidities on the Charlson list are covered by the Elixhauser list.^{34,33} One notable exception is dementia; however, dementia is defined within one of the frailty variables (see just below).

Work is underway within one of the two STPs that NEHF is part of on identifying frailty conditions. NEHF is considering incorporating these into the future risk stratification model used by the local team. The IAU will use the following list of comorbidities linked to frailty: anxiety or depression; functional dependence; falls and significant fracture; incontinence; mobility problems; pressure ulcers; and cognitive impairment (composite of delirium, dementia and senility), consistent with other IAU analyses.^{30,35}

The IPOPAEGP model³¹ is a risk prediction model of hospital admissions that builds on and improves on earlier models such as the PARR algorithm and identifies a number of comorbidities predictive of hospital admission.²⁶ Those included in the IPOPAEGP algorithm that are not already captured within the Elixhauser or frailty lists and can be identified from inpatient data include myocardial infarction, cerebrovascular disease, connective tissue disease and mental ill health, such as miscellaneous cognitive dysfunctions. The risk prediction model also identifies number of outpatient visits missed in the first year of the pre-period. This variable is also included in our list of potential covariates as the number of missed appointments may be correlated with how amenable a patient is to health care interventions, which may be a confounder.³⁶

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.

There is some overlap between the definitions of the health condition: 'depression' (Elixhauser list) and 'anxiety or depression' (frailty list).

It may not be possible to get balanced groups on all listed potential comorbidities. The IAU will empirically determine which covariates are most predictive of emergency admissions and optimise balance between the groups based on order of priority (see section on Choice of matching variables, p. 28). Although the IAU expects to adjust for all potential covariates in the regression models, the same priorities will apply to the regression models if not all comorbidities can be adjusted, for example due to correlation between variables.

NEHF CSU is considering including whether a person is a care home resident as a criterion for selection to ICTs. Residents in nursing or residential care homes have different hospital activity than people living at home.³⁷ Furthermore, people who are socially isolated are often at higher risk of admissions.³¹ Therefore information on whether patients were residents in nursing and residential homes at their index date will be included as a covariate.

During the study period patients in both groups may have received other care specific to the Vanguard, but the range of other PACS interventions available to patients will have differed over the time period (see Table 1). Matching and regressing on the index date (or the quarter and year of the index date) would take into consideration two aspects: differences in seasonality when patients were referred to the ICTs (or matched for the control group), as well as the extent to which other NEHF 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.

As both the ICTs and the range of other PACS services also differed slightly between localities, patients will be matched within each locality and locality will be included in the regression models. In the rare cases where a patient moved to a different locality within NEHF during the follow-up period, the IAU will analyse the patient according to the locality they were in at the start of the follow-up period. NEHF local analyses identified only a few referred patients who changed locality.

Statistical methods

Identifying 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.

Matched control observations will be selected 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.³⁸ The algorithm measures the similarity of pairs of patients using distance metrics that are generalised versions of Mahalanobis distance.^{38,39} 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.

Matching will be done without replacement if possible (i.e. each intervention patient will be matched to a unique patient in the control group). If, however, it is difficult to find balanced groups, matching will be done with replacement, that is, the same control patient can be matched to several intervention patients. Additionally, as a same potential control patient will be assigned monthly index dates, the same control patient may also be matched to several intervention patients, but with different index dates (and correspondingly potentially slightly

different baseline characteristics). The IAU will match 1:1, that is, one control patient to each intervention patient.

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. Table 4 shows those variables where special matching methods are to be applied.

Table 4. Matching variables and method of matching

Variable	Method of matching
Living at home, in a nursing home or in a residential care home	Exact

The IAU will match within each locality separately to ensure that the intervention patients have access to the same PACS services as their control patients and ensure balance within each locality.

It is expected that all intervention patients will be matched to controls.

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

Choice of matching variables

The IAU will match on patient characteristics, to ensure a similar patient case-mix between the groups. Although the IAU will ultimately assess balance across all variables detailed in the section on Baseline variables (p. 25), we are likely to only include a subset of those variables in the matching algorithm. The IAU will empirically explore which covariates are most predictive of emergency admissions among the potential control group and whether the conditions are prevalent in the intervention and control groups. The subset of variables included in the matching algorithm will be adapted to optimise balance between the two groups on those variables considered most strongly predictive of the outcome, for instance the prior numbers of emergency admissions, but will also aim to optimise balance across the wider set of variables.

Matching parameters

Table 5 gives the matching algorithm parameters to be used for this analysis.

Table 5. Matching parameters

Parameter	Value
Estimand	ATT
Number of controls per intervention patient	1
Control sampling method	Without replacement
Population size	2,000
Maximum generation	1,000

Number of generations to wait	100
-------------------------------	-----

ATT=average treatment effect for the treated

Diagnosics

Balance will be assessed across all baseline variables listed in the section on Baseline variables (p. 25), even though not all variables will be included in the matching algorithm.

Balance will be assessed using the standardised difference, which is defined as the difference in means as a proportion of the pooled standard deviation.⁴⁰ Although the standardised difference should ideally be minimised without limit, a standardised difference below 10% has been used to describe negligible imbalance.⁴¹ 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.⁴² The distribution for continuous or count variables will also be assessed.

Statistical analysis

The IAU aims to estimate the average treatment effect for the treated (ATT). Once matched controls have been selected, the IAU will estimate the effect of ICTs on the intervention group compared with the control group by fitting multivariable 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.

Explored modelling options will include multilevel models with locality as a random effect, to capture any between-locality heterogeneity in outcomes. An additional advantage of a random effect modelling approach lies in obtaining more precise local estimates in the event of issues with data sparsity from particular localities.

Each outcome will be analysed by fitting a regression model that is appropriate to the type of outcome and the distributional properties of the data.

The count variable endpoints, such as number of emergency admissions per patient, will be analysed using a generalised linear model suitable for count data, such as a Poisson, to estimate the rate ratio between intervention and matched control patients. The effect of the intervention on the absolute (as opposed to relative) number of events (e.g. admissions) will also be estimated.

Model fit will be assessed by examining diagnostic statistics and over-dispersion 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 over-dispersion is detected then an alternative model, such as a negative binomial or the zero-inflated Poisson for count data, will be fitted. Where a similarly good fit is obtained using multiple models, a choice will be made by comparing the log-likelihood ratio and the Akaike information criterion (AIC), as appropriate. The appropriateness of the random effect assumption on locality will be assessed through formal statistical checks (like the intraclass correlation coefficient) and comparison with the corresponding fixed effect model.

As a guide, Table 6 details the typical regression models and alternatives for each outcome.

Table 6. Regression models for each outcome

Type of endpoint	Outcome	Initial model	Alternative model	Diagnostics
Count data	Number of admissions / A&E attendances/outpatient visits	Poisson	Negative binomial / Zero-inflated Poisson	Over-dispersion Model fit Excess zeros
Proportions	Proportion of emergency/elective bed days (of whole follow-up period)/ Proportion of deaths in hospital/ Proportion of patients who die (sensitivity analysis)	Binomial	Quasi-binomial/Negative binomial	Model fit Distribution of model residuals Over-dispersion Heteroscedasticity diagnostics

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, for instance emergency admissions, is constant, when in fact this is unlikely to be the case. For example, a patient may use more hospital services in the final months of life. The IAU will examine the length of time people were followed up in the study and reasons for leaving the study between the groups. As detailed in the section on Index dates and follow-up period (p. 23), a patient’s follow-up period ended (was censored) when the patient either died, moved away from NEHF or the study period ended. If the length of time patients were followed up in the study or the reasons for leaving the study differed between the groups, the IAU will consider doing an alternative analysis as a sensitivity analysis.

Subgroup analysis

As the localities have differed in how they implemented the ICTs and which patients they targeted, as well as in what other interventions they offered outside of the ICTs (see Table 1), the IAU will aim to do a subgroup analysis by locality. However, there is a risk that the data are so sparse in some localities that models cannot be fitted in those localities. If the models can be fitted, the results are unlikely to show statistically significant results due to small sample sizes; however, a comparison between localities may nonetheless provide learnings to NEHF as to whether the effect is homogenous across sites and if not, which locality may be showing most potential.

It is well known that mental and physical health are interrelated and that when the mental health needs of people with physical health conditions are not adequately addressed, this also negatively impacts on physical health outcomes.^{43,44} People with mental ill health have several times higher rates of A&E attendances, emergency admissions and ACS emergency admissions than those without.⁴⁴ NEHF has included mental health professionals in the

ICTs, providing appropriate care for patients with mental health problems. As a subgroup analysis, sample size permitting, the IAU will identify patients with a history of mental ill health and evaluate the effect of ICTs on the defined outcomes (independent of whether the attendance or admission was primarily for a physical or mental need) on this subgroup. 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, that is, those who had at least one inpatient admission or outpatient appointment with a diagnosis of any mental and behavioural disorder (ICD-10, Chapter V, codes F00 to F99),⁴⁵ or, where the main specialty (medical specialty under which the hospital consultant is contracted) was mental health (NHS specialty codes 700 to 715)⁴⁶ within the previous three 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,⁴⁴ 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.

Sensitivity analyses

One of the main threats to the validity of this study is unobserved confounding. That is, although the IAU anticipates that the intervention and matched control groups will be similar in terms of observed variables (such as age and prior number of hospital admissions), there may be systematic differences between these groups that we do not observe, for example characteristics that informed clinical judgement to refer to ICTs. There is always a risk of unobserved confounding in non-randomised studies, but here the risk is larger due to patients being selected for the ICTs primarily based on clinical input from GPs or other health professionals.¹⁰ The lack of information on the subjective reasons for referring patients, together with a lack of primary care and community data, makes it difficult for us to identify what characteristics the referred patients were selected on and therefore to identify a matched control group that is similar to the intervention group in these characteristics.

Although there is no definitive way to assess the effect of unobserved confounding, it is possible to compare the rates of the intervention and matched control groups on an endpoint unrelated to the intervention.⁴⁷ 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 enrolled 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 enrolment.⁴⁸ However, there is also a possibility that good care may result in prolonged life and therefore less deaths during our follow-up period. The IAU will therefore compare the rates of all-cause mortality over the study period. The IAU will also perform a survival analysis using Kaplan-Meier estimates, censoring patients who moved or reached the end of the study period. Similar mortality and survival rates will be indicative of balanced groups, while differences would need to be interpreted with caution.

If there is found to be a difference in mortality between the intervention and control groups, the IAU will explore possible reasons for the imbalance and if possible consider subsetting the cohort in such a way as to remove any bias.

The results of all tested regression models will be presented in the technical appendix to the report, to show if the effect size and significance of the selected best model were sensitive to the choice of model.

Sample size calculation

No sample size was calculated for this study. The analysis is considered informative and will be carried out regardless of whether our study population is of a sufficient size to detect a statistically significant difference.

3. Limitations and sources of bias

Threats to validity

Internal validity

One of the main threats to the validity of this study is unobserved confounding. Unobserved confounding can occur at area, hospital, general practice or patient level. There is always a risk of unobserved confounding in non-randomised studies, but here the risk is larger due to the way patients have been selected for the ICTs, especially up to June 2017 when patients were primarily selected based on clinical judgement. This leads to potential selection bias. The majority of referrals come from GPs, though referrals are also received from other health care workers (e.g. community staff, mental health, social care).¹⁰ The lack of information on any non-clinical reasons for referring patients (for example, a close family member dying or moving away), together with a lack of primary care and community data, makes it difficult for us to identify what characteristics the referred patients were selected on and therefore to identify a matched control group that is similar to the intervention group in these characteristics. The uncertainty of the results due to potential 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 some sensitivity analysis (see section on Sensitivity analysis, p. 31) to try to assess the presence of unobserved confounding.

If important predictive covariates are omitted from the matching and regression models, then unobserved differences between the groups may contribute to any or part of any difference in outcomes. These differences would in turn then erroneously be attributed to the intervention.

However, the risk of unobserved confounding at area or hospital level is mitigated by using local controls within NEHF.⁴⁹ Here, the local control group will use the same hospital services, thereby minimising the risk of bias due to differences between hospitals, for example the availability of EDOUs (see section on NEHF CCG, p. 8); differences in coding practices (that could bias the detection of comorbidities and therefore risk adjustment);^{50,51} or hospital changes as part of the local STPs that could impact on outcomes.

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

There may be varying levels of engagement and interest in the ICTs among the health care professionals able to refer patients to the ICTs across the five localities. The decision to refer may therefore also be influenced by other factors such as primary care staff engagement or knowledge of the ICTs. As information on source of referral is not available, this cannot be accounted for in the analysis.

Some patients may have been offered a referral to an ICT but declined. If this is the case, this would introduce another selection mechanism to the treatment decision. No data are available.

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

The IAU is assuming that patients in NEHF receiving care from ICTs access the other services available, such as other PACS interventions, in a similar manner to non-ICT patients in NEHF. This assumption will not hold if, for instance, ICT patients are referred to other services by the multidisciplinary team, in which case this could bias the results. However, NEHF CSU has confirmed that this is not expected to be the case.

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

External validity

The study will evaluate the effect of ICTs in the first 23 months of the intervention, to May 2017. The ICTs have continued to develop and expand both their capacity and services over this period. This study period may therefore be too short to capture the full potential of the ICTs.

This study will evaluate the effect of ICTs on patients for a variable period of up to approximately 23 months. For many patients, the follow-up period will be much shorter. It is possible that the study period is not long enough to allow for the long-term impact of ICTs on patients to become apparent. This may be particularly the case for later referrals, if the ICTs identify unmet need, resulting in short-term hospital activity but thereby avoiding a more serious and longer hospital stay in the long term, which may only occur after the end of the study period.

The evaluation includes five different localities, each 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 particular patient populations, such as 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.^{18,52} The NEHF programme includes several of these types of interventions and this study only evaluates the incremental effect of the ICTs. It may be that the counterfactual control group is already performing at a higher level than it would have if no other interventions had been available, making it more difficult to find a statistically significant difference in outcomes due to the ICTs.

Some staff resources for the ICT are new and funded by specific Vanguard funding (e.g. an ICT coordinator), but the rest of the ICT team incorporate the time they dedicate to the ICT meetings and care into their usual working week. There is a risk that the ICT is taking away

resources from other complex patients in NEHF. This could result in a difference between the intervention and control groups that is due to deteriorating outcomes in the control group rather than attributable to improving outcomes for ICT patients.

There may also be positive unintended consequences of the ICTs on the comparator group, for example if communication and relationships across organisational boundaries improves as a result of staff participation in the ICTs.

Statistical conclusion validity

The IAU is expecting a sample size of approximately 900 patients. This may be too small a sample size to identify a significant effect at conventional 95% significance levels if the effect is small or there is large variability within the groups.

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.¹⁸ 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.¹⁸ A limitation of our study is that the IAU cannot 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

The success of an ICT is in both correctly identifying patients who would benefit from additional help and in the care they receive. This evaluation takes into account the effect of the ICTs on the patients referred to them and not the effect of the patient selection process (i.e. identifying patients most at risk who may benefit from the ICT).

SUS data is an administrative database and has not been subjected to the cleaning rules that the Hospital Episode Statistics database is. However, the IAU Data Management team will perform data checks and cleaning.

As the IAU only has access to the monthly table extracts from NHAIS and there is no date of when between the monthly snapshots a change occurred, index and end dates are sometimes approximated, using the date of the data extraction. As a result, the number of days in the study, which will be used to determine the offset in the models, will also only be approximate in some cases. Also, patients who move may only register with a new general practice once they need to be seen by a GP. Therefore the patient registration data may contain a time lag. However, as the population in this study consists of patients with complex needs and multi-morbidity, this time lag is not expected to be large, nor do we expect it to be unbalanced between the groups.

There are some limitations in the outcomes that the IAU will be analysing. The benefit of a home visit rather than having to travel to an outpatient appointment will not be reflected in the data or our outcomes. Similarly, the benefit of a prompt assessment on quality of life or longer-term health will not be apparent in our outcomes.

Other limitations

The IAU will not be able to evaluate other potential impacts of the Vanguard programme, such as quality of life or improvement in working relationships, as the IAU only had access to secondary care data. Costing secondary care data is not within the scope of this study.

This study cannot explore how the ICTs or other interventions have changed over time, for instance changes to the core members of an ICT team, and the effect this may have had on the outcomes.

The IAU evaluation will be supplemented by the local evaluation, conducted by Wessex Academic Health Science Network.

4. 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 2 decimal places for effect size and confidence intervals. P values will be shown to 2 significant digits.

Special reporting requirements for this study

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

- adherence to the STrengthening the Reporting of OBservational studies in Epidemiology (STROBE)⁵³ and the REporting of studies Conducted using Observational Routinely-collected Data (RECORD) guidelines⁵⁴
- adherence to the NHS Digital (previously Health and Social Care Information Centre, HSCIC) small number rules⁵⁵
- compliance with the statistical code of practice.

Tables and figures for reporting matching results

Tables

A baseline table showing descriptive statistics for the intervention group and the matched and unmatched control populations, with:

- 1.0 continuous variables summarised by mean (standard deviation, SD) or median (interquartile range, IQR) depending on the distribution
- 2.0 categorical variables summarised by number (%)
- 3.0 standardised differences calculated for the intervention group versus the unmatched and matched control groups, and variance ratio for continuous variables.

Figures

The following figures would be a minimal requirement:

- 1.0 dot plot showing the standardised differences from both the matched and unmatched sample
- 2.0 bar chart of comorbidities from both the matched samples.

Histograms illustrating the baseline characteristics of the intervention and matched control groups in more detail will be produced and reviewed by the IAU team. If histograms are to be included in the report, then these will be rebanded if necessary to ensure minimum cell counts of above 10.

Tables and figures for reporting statistical results

Tables

The following tables will be presented as a minimum:

- 1.0 A table showing the unadjusted estimates of treatment effect for the intervention and matched control groups:
 - 1.1 for binary outcomes the number and proportion in each group
 - 1.2 for count data the number of events and person time of exposure
 - 1.3 for continuous data the mean and standard error
 - 1.4 the size of the measure effect (e.g. odds ratio, rate ratio, hazard ratio or mean difference) together with a 95% confidence interval.

- 2.0 A table showing the adjusted results:
 - 2.1 the size of the adjusted measure together with a 95% confidence interval and p value
 - 2.2 all adjustment variables should be listed.

Figures

The following figures would be a minimal requirement:

- 1.0 forest plot showing the adjusted results for each outcome measure.

Tables and figures for sensitivity analyses

The following tables may be produced for the appendix:

- 1.0 a table for showing study length and reasons for censoring (leaving the study).

Data cleaning and validation checks

Data cleaning and data validation checks will be performed by the IAU Data Management team, in accordance with the IAU Data Management Quality Assurance Process. Where appropriate, a summary of the results can be produced for the technical appendix.

Data flow diagrams

The following diagrams will be produced for the technical appendix:

- 1.0 data linkage process diagram
- 2.0 data flow diagram of study cohort selection.

5. 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 September 2017 with this section added in July 2018.

Definition of study cohort, page 18

In addition to the exclusion criteria described on page 18 of this document, the following exclusion criteria were applied prior to the analysis:

- Patients with no valid Lower Layer Super Output Area (LSOA) geographic area – this variable was used to determine a patient’s level of socioeconomic deprivation
- For potential control patients, patients more than 2 years’ older than the oldest ICT patient or more than 2 years’ younger than the youngest ICT patient – this was to limit the size of the dataset of potential controls in the matching process

Study endpoints, page 21

Here we provide further clarification on how variables were defined.

Elective admissions are defined as those that are ‘ordinary’ or day cases and exclude maternity and regular day/night cases.

When calculating readmission rates, the NHS Outcomes Framework guidance⁵⁶ was followed, with the exception of also including elective day cases as potential offsets for the calculations. This was consistent with the definition of elective admissions described above, which includes both ‘ordinary’ and day cases.

For the variable average length of stay in the year prior to the index date, any hospital spell that starts in the pre-period but continues into the follow-up period was included in its entirety within the pre-period. For the outcome measure average length of stay in the follow-up period, we only included spells that both start and finish within the follow-up period. There is no expected bias between the ICT and matched control groups, as both had access to the same hospitals.

The IAU identified a number of ‘overlapping’ in-patient spells (stays) in the SUS data where, for example, a patient spell with one provider did not end before a spell with another provider started. When calculating average length of stay, we did not account for these overlapping spells. Instead, the average length of stay was calculated for each spell, as recorded in the data. Note: For the outcomes emergency bed days and elective bed days, bed days were not double-counted, that is the number of unique days in hospital following either emergency or elective admission were calculated.

Duplicate outpatient appointments were removed. Outpatient appointments relating to mental health services, to the extent these were recorded in the outpatient data, were included.

Index dates and follow-up, page 24

To further limit the size of the dataset of potential controls, only one potential index date per quarter was created for potential patients aged less than 65 years. Only 14% of ICT patients in the study were younger than 65 years.

Baseline variables, page 26

The variables mental ill health and serious mental ill health, as defined on page 32, were included as baseline variables, replacing the mental health definition specified in IPOPAEGP.

Connective tissue disease in the IPOPAEGP was not included as a baseline characteristic, as it overlapped with the Elixhauser definition of rheumatic arthritis. The Elixhauser variable peripheral vascular disorders was not included in error.

Identifying control group, page 28

Due to low numbers of care home residents that were referred to ICTs (<10), matching on type of residence (ie whether a person lived at home, in a nursing or a residential care home) was not done by exact matching.

Matching parameters, page 29

Due to the size of the dataset of potential control patients (approximately 750,000 records), the parameters for the genetic matching algorithm was limited to iterations based on population size 200, maximum generation 100 and number of generations to wait 10.

Statistical analysis, page 30

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-parametrised models. The most predictive variables were identified by running a lasso regression and where possible included all core variables as a minimum.⁵⁷ Variables considered 'core' were: age; gender (male or not male); IMD quintile; locality; Charlson Index; number of Elixhauser comorbidities; number of frailty comorbidities; history of mental ill health; index date quarter; hospital use in year prior to index date; and emergency admissions, CACS emergency admissions and UCS emergency admissions in the two months prior to index date.

Due to low numbers of care home residents (<10) in both ICT and matched control groups, analyses only adjusted for whether patients lived at home or in a care home (i.e. no differentiation between nursing and residential homes).

Following the analysis, it was found that outpatient appointments included community data from Virgin Care Services that had been uploaded to SUS in error. These appointments were removed from the data and the analysis of outpatient hospital use was redone. Other outcomes were not reanalysed; therefore in the case where these analyses adjusted for outpatient appointments in the year prior to the study, this variable would have contained some community outpatient appointments from Virgin Care Services.

Modelling options did not include multilevel models with locality as a random effect, as five localities were considered too few groups to adequately run such a multilevel model.

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