

Statistical Analysis Protocol for an
Improvement Analytics Unit
evaluation of the Sutton Homes of Care
intervention

The Improvement Analytics Unit

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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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Glossary of acronyms

Abbreviation	Description
A&E	Accident and Emergency department
ACS	Ambulatory Care Sensitive
CCG	Clinical Commissioning Group
CQC	Care Quality Commission
EHCH	Enhanced Health in Care Homes
Emergency admission	Unplanned admission to hospital
GP	General Practitioner
IAU	Improvement Analytics Unit
NCDR	National Commissioning Data Repository
NCM	New Care Models
NHAIS	National Health Applications and Infrastructure Services
PARR	Patients At Risk of Re-admission
RECORD	The REporting of studies Conducted using Observational Routinely-collected Data
STP	Sustainability and Transformation Partnership
STROBE	STrengthening the Reporting of OBservational studies in Epidemiology
SUS	Secondary Uses Service
UTI	Urinary Tract Infection

Summary

Purpose of this document

This document is the Statistical Analysis Protocol (SAP) for an Improvement Analytics Unit's (IAU) evaluation of the intervention programme implemented for care home residents by the Sutton Homes of Care Enhanced Health in Care Homes (EHCH) Vanguard (henceforth referred to as the 'Vanguard'). This summary is designed to outline what the evaluation will cover and does not include details about the background to the Vanguard, the study method or the caveats about the evaluation.

This document is provided to the initiative being evaluated and its partners to ensure clarity of purpose. 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 analysis. The Summary section provides a more accessible overview of the proposed study.

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

Purpose of this study

This study will provide feedback on the progress of the Vanguard in reducing hospital activity by residents of nursing and residential care homes supported by the Vanguard.

What the study will look at

To evaluate the Vanguard, the study will examine a variety of hospital outcomes measured from individuals who are aged 65 years of age or over living in nursing and residential care homes in England. Specifically the study will compare hospital activity shown by Vanguard care home residents (the 'intervention group') with that instead seen in a selection of comparable care home residents not benefiting from enhanced care (the 'matched control group').

The intervention group will consist of individuals who have moved into a care home supported by the Vanguard without having previously resided in a care home. This is to ensure that no bias is introduced when forming the matched control group, since prior hospital utilisation – a variable used in the statistical matching process – is expected to differ between people living in care homes and in the community.

The process of forming the matched control group consists of two stages. Firstly, a subset of clinical commissioning groups (CCGs) in England showing demographic and socioeconomic profiles and historical emergency admission rates similar to those in Sutton, but not participating in any site-wide care home intervention that is unrepresentative of standard care, will be identified. Variables informing the matching at care home level include, but are not limited to: type (nursing or residential), bed capacity, localisation (urban or rural), and service rating (subject to availability). Secondly, residents of care homes located in those CCGs will be retained in the matched control group if they are similar to individuals in the intervention group according to individual- as well as care home-level characteristics. Variables informing this stage of the matching process include, but are not limited to: age, gender, comorbidities, frailty, and number of hospital admissions prior to entering the care home.

The evaluation will proceed by comparing indicators of hospital resource utilisation between care home residents from the intervention group and the matched control group during the duration of the study (defined in the section on Index dates and follow-up period, pp. 16–17).

These indicators include:

- number of accident & emergency department (A&E) attendances per resident
- number of potentially avoidable emergency admissions per resident
- number of planned admissions per resident
- number of emergency admissions per resident
- proportion of hospital bed days out of the duration of care home stay per resident
- number of falls, urinary tract infections (UTIs), venous thromboembolisms (VTEs) and pressure ulcers per resident
- number of outpatient attendances per resident
- proportion of deaths outside of hospital (taken as an indicator for successful end-of-life planning).

In order to further reduce any residual bias, due to unobserved differences between the intervention group and matched control group which may affect the estimated effect of enhanced care, the IAU will supplement the analysis with a risk adjustment consisting of a regression of each selected clinical outcome on a broad range of predictors. These will include, but will not be limited to, variables also used in the identification of the matched control group.

A supplementary analysis will be carried out to understand whether the Vanguard shows a different effect on hospital activity attributable to nursing homes as opposed to residential homes.

A further subgroup analysis will be carried out to assess whether the enhanced care produces a different impact on residents who joined a Vanguard care home at an earlier, as opposed to later, stage of the study duration (defined in the section on Index dates and follow-up period, pp. 16–17).

Analyses will take into account differences in the characteristics of the care home resident population and the duration of stay in the care home.

Data the Improvement Analytics Unit will use

The IAU will use patient-level administrative hospital data for England from November 2013 to April 2017. Data on when hospital patients were in care homes and care home characteristics will also be obtained.

All data used by the IAU are pseudonymised. This means that all direct identifiers (e.g. name, address, date of birth, NHS patient number and care home name) are removed from the data. Pseudonymising both patient and care home data ensures minimisation of the risk of patient identification.

Time period covered by the study

Formal statistical evaluation of the Vanguard's initiatives examined by the IAU (the 'intervention') requires establishing a date from which these are assessed. Such a date is set to 17 November 2015. This assumption was made by identifying the month and year

when the first substantial batch of Vanguard initiatives (including, but not limited to, the 'Red Bag' described in the Background section, p. 8) were rolled out across care homes. The day of the month is in turn set to the earliest day individual patient registration data become available to the IAU.

The IAU will evaluate the impact of the intervention during the period from 17 January 2016 to 16 April 2017 (the 'post-intervention' period), which is the latest care home residents are believed they can be reliably identified from data available to the IAU.

The amount of time an individual participates into the IAU evaluation (the 'follow-up') spans the period between the earliest date an individual is known to have entered a care home and the earliest date within the post-intervention period she/he is known to have either moved out of the care home or died.

A two-month gap is further assumed to separate the date the intervention starts from the beginning of the post-intervention period (the 'bedding-in' period). This is introduced in order to allow the intervention to become established in Vanguard care homes. The bedding-in period thus falls after the intervention becomes operational but before its effect is assessed.

What the study can offer

The study will quantify the size of the impact on hospital activity indicators, as shown by the data available to the IAU, measured from residents of care homes supported by the Vanguard relative to a comparable matched control group not receiving the same or analogous interventions.

The results of the evaluation are expected to contribute further learning that, in conjunction with the local evaluation and other supplementary evidence, will help the Vanguard team and more broadly the New Care Models (NCMs) programme understand the progress of the Vanguard.

Limitations to the study

The IAU has identified in particular three main limitations to the evaluation. Firstly, while the study makes reasonable attempts at isolating the effect of the intervention onto chosen secondary activity indicators, the potential persistence of unmeasurable differences between the intervention group and the matched control group prevents attributing a detected impact solely to the Vanguard.

Secondly, since the intervention caters for 29 care homes equipped with up to approximately 902 beds, the ability of the study to reach statistically significant conclusions about its effectiveness will be contingent on the intervention group comprising a sufficiently large number of residents.

And thirdly, due to the necessary working assumptions outlined in the next sections, the evaluation will only capture a simplified representation of the complex reality of the enhanced care programme delivered by the Vanguard, which comprises a broad range of initiatives implemented to varying degrees across different care homes at different times.

Background

Sutton Homes of Care is a local partnership sponsored by the National Institute for Health and Care Excellence (NICE) involving a variety of NHS, government and voluntary sector organisations.¹ As of December 2016, there are 26 general practitioner (GP) surgeries in the London Borough of Sutton associated with the Sutton Homes of Care Enhanced Health in Care Homes (EHCH) Vanguard (henceforth referred to as the 'Vanguard'), serving a resident population of over 190,000 people in Sutton that is projected to rise to 222,000 by 2021.^{1,2} As of January 2017, 18 nursing care homes and 11 residential care homes, respectively equipped with 613 and 289 beds, fall under the Vanguard's remit, totalling 29 care homes and 902 beds.³

Care home residents – especially those in a frail state of health and of advanced age, but also individuals suffering from mental health conditions or learning disabilities irrespective of age – typically have complex health care needs, often reflecting multiple long-term-conditions, significant disability, limited self-reliance and advanced frailty. Care delivered to this cohort of people is often fragmented and of varying standards, affected by high staff turnover and limited support from the wider health system.⁴

According to the 2011 Census, 14.3% of the Sutton resident population falls in the 65 years of age or over bracket and this is predicted to rise to 18.7% by 2021, in line with London, with an almost 60% increase in the number of people aged 75 years or over. The total population aged 65 years of age or over living in a care home in Sutton amounted to 905 in 2015, and is projected to increase to 1,024 (a growth rate of 1.13%) by 2020.⁵

While life expectancy in Sutton is higher than the London and England averages for both men (78.5 years of age) and women (82.4 years of age), social inequality is increasing, with some wards being among the 20% most deprived in the country. Overall Sutton features an increasing and increasingly ageing resident population whose main causes of death are circulatory diseases (including strokes) and cancer, these, along with diabetes, also represent the main causes of long-term illness and disability.²

Relative to the rest of England, Sutton hosts an unusually large proportion of small, independent care homes.⁶ As a consequence, even prior to the establishment of the EHCH Vanguard in March 2015, most care homes within Sutton Clinical Commissioning Group (CCG) had restricted ability to discharge more than 'business-as-usual' practice, suffering in particular from limited staff access to training options and from fragmented intelligence on care quality standards across the borough.⁷ These shortfalls had already been identified by Sutton CCG prior to it receiving vanguard status and tackled with the introduction from early 2014 of the Care Home Forum, the Joint Intelligence Group and the education and training Commissioning for Quality and Innovation (CQUIN) for link nurses in selected care homes.⁶ After awarding in March 2015 EHCH vanguard status to Sutton CCG, in December 2016 NHS England renewed funding to support and spread the work of the Vanguard's New Care Models (NCM) programme. Around the same time the final draft Sustainability and

¹ These comprise Sutton Care Homes, Epsom and St Helier University Hospitals NHS Trust, Sutton Health Community Services, London Ambulance Service NHS Trust, South West London and St George's Mental Health NHS Trust, London Borough of Sutton, Age UK Sutton, St Raphael's Hospice, Alzheimer's Society and Sutton Centre for the Voluntary Sector.

Transformation Plan (STP) for South West London specifically included a proposal to roll out interventions from the Sutton Vanguard programme across the footprint area, which covers a population of about 1.4 million people living in England across the Croydon, Kingston, Merton, Richmond, Sutton and Wandsworth local authorities.⁸

The EHCH model is designed to attain improved care outcomes supported by joined-up health and reablement services by focusing on proactive, person-centred, integrated and preventive care. The suite of evidence-based interventions prescribed by the EHCH framework, while introducing some elements of innovation over existing practice, contemplates a number of initiatives pre-dating the establishment of the Vanguard as it broadly sets to build on, and hone, existing good practice.⁹ Table 1 outlines the timeline of the EHCH implementation to April 2017 across the Vanguard.³

The Sutton Vanguard programme relies on the operationalisation of three 'pillars':¹⁰

Integrated Care: this pillar aims to identify new ways of delivering proactive services, harmonising care to best practice standards and promoting an approach involving care home residents and their families in decisions about their care plans.

More specifically, this pillar involves:

- weekly GP-led Health and Wellbeing Rounds taking place in selected nursing and residential care homes wards supported by a care coordinator (a trained care home member of staff) to ensure residents are proactively and regularly reviewed
- a multidisciplinary Care Home Support Team formed by link nurses, end-of-life care nurses, dementia support workers, care home pharmacists, a pharmacy technician and a dietician, delivering bespoke 1-to-1 training to care home staff (for instance on the use of the 'DeAR-GP' Dementia Assessment Referral tool) and care support and medication reviews to residents
- a Hospital Transfer Pathway (the 'Red Bag'), providing each care home resident being conveyed to hospital with a bag containing standardised clinical documents, essential medications and personal effects.

Care Home Staff Education and Development: this pillar focuses on the training needs of care home staff by contemplating a range of education and training resources and initiatives to identify and meet these requirements.

Initiatives contemplated by this pillar consist of:

- tailored training packages on continence care, dementia care and person-centred thinking administered to care home staff via e-learning modules
- a resource package comprising posters (including 'Barbara's Story', 'Concerned About A Resident' and 'End of Life Care'), films and reference cards
- the Care Home Forum for attendance by care home managers and the Care Home Pledge in support of the Vanguard.

Quality Assurance and Safety: the purpose of this pillar is to establish systems and processes facilitating access, monitoring and evaluation of information relevant to each care home resident's health, enabling partner organisations to take appropriate actions as and when required.

Outputs contemplated by this pillar are:

- forming a Joint Intelligence Group of representatives from all partners across the health sector with a statutory responsibility for care homes, meeting on a monthly basis to share intelligence across the health and social care landscape
- establishing and maintaining a Quality Dashboard reporting on a range of quality and safety indicators, including falls, urinary tract infections (UTIs), pressure ulcers, staff turnover, deaths and hospital admissions
- promoting the 'Cake, Cuppa, Chat' initiative to foster engagement with residents, families and carers.

The broad aspiration of the Sutton Vanguard programme is to bring about an improvement in the quality of life and engagement of care home residents alongside a reduction in health care costs. Factors envisioned as instrumental in achieving this two-fold objective are: better advanced care planning, improved and shared access to specialist support and knowledge, more integrated, proactive and resident-centred support, upskilled and motivated care home staff, reduced medication wastage, and a joint approach to tackling risks and issues affecting care home residents based on improved and shared intelligence across the health and social care sector.^{1,7}

Intended impact on outcomes

The Sutton Vanguard intervention is designed to affect a variety of aspects relating to the health care and well-being experienced by the care home residents. The delivery of improved, personalised and proactive care in a timely and effective fashion by a more skilled, motivated and confident care home staff body is broadly expected to lead to an improved resident experience through a reduced level of incidents negatively affecting the well-being of residents.¹⁰

Initiatives like the Health and Well-Being Rounds, the Hospital Transfer Pathway, the Care Home Support Team, the Joint Intelligence Group and Quality Dashboard are all expected to contribute to reductions in avoidable inpatient activity (notably falls, UTIs and pressure ulcers) for residents with ambulatory care sensitive (ACS) conditions, 999 calls, accident & emergency department (A&E) attendances, emergency admissions and hospital bed days as well as to generate cost savings. The reduction of avoidable illnesses and injuries foreseen in care homes receiving the Vanguard's training and resource packages should also prompt financial savings via reduced A&E, ambulance and hospital services utilisation as a result of improved health and well-being outcomes.

Objectives of the analysis

The present evaluation is concerned with quantifying the effect of the Vanguard intervention, resulting from the synergic action of the three pillars outlined earlier in this section (pp. 9-10), on residents of local care homes relatively to residents in care homes elsewhere in England not associated with the Vanguard but with otherwise similar characteristics. The study will focus on the impact on secondary care resource utilisation for the resident population of nursing and residential care homes in the Sutton CCG after a suitable 'bedding-in' period allowing the intervention to develop and become fully established. Outcomes will be estimated at the care home resident-level relative to the counterfactual outcomes that would have been expected to occur, had the intervention not been implemented across care homes in Sutton. Additionally the study will examine the proportion of care home residents dying outside of hospital, under the assumption that this is a proxy to dying in the preferred place of death.

The present evaluation will not cover mental health and learning disabilities care homes in Sutton, due to the recent and limited uptake of the Vanguard initiatives by this type of care home. The Vanguard's interventions have been implemented in different types of care homes (that is nursing, residential and mental health and learning disabilities) at different times (as indicated by Table 1) and with varying degree of coverage: for instance, the Joint Intelligence Group and Quality Dashboard covers all care homes, unlike other interventions including the Health and Wellbeing Rounds and link nurses. As such, while it would be of interest to discern which component(s) of the Sutton intervention programme may be especially effective in a specific type of care home and most plausibly replicable beyond the boundaries of Sutton CCG, this analysis would require data beyond what is available (at national, secondary level) to inform the present evaluation. Limitations in the data available to the Improvement Analytics Unit (IAU) additionally rule out an appraisal of the impact of the Vanguard's intervention onto 999 ambulance call-outs, financial costs, care home residents' quality of life, clinical quality information, medication wastage and staff satisfaction and engagement.

Methods

Study design

As mentioned earlier, quantification of the impact of the Vanguard's interventions will hinge on a formal statistical comparison between outcomes observed from care home residents in Sutton benefiting from the programme with a retrospectively matched 'control' group of care home residents from outside of Sutton (hence unaffected by the Vanguard's initiatives).

The statistical matching will be carried out in two stages. The first stage will identify a set of CCGs with a similar characterisation to Sutton CCG in terms of socio-demographic, economic, limiting long-term illness and historical emergency hospital utilisation rates. The second stage will then proceed with matching residents of care homes from control areas identified in the first stage with those instead receiving the Vanguard intervention on both care home- and resident-level characteristics. Routinely-collected national data on care homes and their residents will thus be employed to accrue separate samples of care homes and residents thereof benefiting from, and not in receipt of, the Vanguard intervention. A group of care home residents from outside the Sutton CCG remit will then be formed, with individual- and care home-level characteristics offering as close as possible a match to residents in care homes associated with the Vanguard.

Upon identification of a satisfactorily representative control sample of care home residents from the matching process, the study will proceed by undertaking a statistical comparison between selected secondary care outcomes separately measured from the intervention and control groups via formal regression modelling techniques, as described in the section on Statistical analysis (pp. 20–21).

Study cohorts

Definition of target population

The target population consists of individuals aged 65 years or over who moved into a nursing or residential care home in receipt of any intervention contemplated by the Sutton Vanguard's programme after 17 January 2016 (see section on Index dates and follow-up period (pp. 16–17) for details about this restriction).

Definition of study cohort

The effectiveness evaluation of the Vanguard intervention relies on a two-stage definition of study cohort at care home and resident level.

At care home level, the study will track nursing and residential care homes open at any point between 17 January 2016 and 16 April 2016 forming part of the control or intervention groups of care homes described in the section on Study design (p. 12). The start date for the time window for care home inclusion in the study cohort is set at the study's index date (defined in the section on Index dates and follow-up period (pp. 16–17)), whereas the chosen closing date ensures a minimum follow-up period for care homes of at least 12 months (defined later in this section).

The cohort will not retain care homes:

- Implementing during the follow-up period health care interventions or well-being initiatives deemed to be similar to those comprised in the Sutton Vanguard

intervention programme, or more generally being unrepresentative of standard care as provided in care homes across England. These include in particular care homes catered for by other NCM vanguards (Figure 1) and under the remit of CCGs making up, with Sutton CCG, the South West London STP (i.e. Croydon, Kingston, Merton, Richmond and Wandsworth CCGs).

- Falling into the mental health and learning disability category in that, as explained previously, these have benefited from a very limited selection of Vanguard interventions and only at a late stage of implementation. For the purpose of retaining in the study cohort only care homes genuinely catering for the frail older population, this exclusion category is expanded to include care homes registered with the Care Quality Commission (CQC) as catering for any age group other than 65 years or over or any of the following specialties: people who misuse drugs and alcohol, people with eating disorders, people detained under the Mental Health Act, and people with sensory impairment.

In addition to the 29 care homes and 902 beds catered for by the Vanguard there are also 2 residential care homes and 2 nursing care homes which, while located in the Sutton local authority, are not managed by a Sutton GP and, as such, are not within the scope of the Sutton CCG.

Care homes specialising in dementia care, mental health care or physical disability will not be automatically excluded from the study cohort since the type of residents they cater for are compatible with the frail population targeted by the Vanguard's intervention programme. Furthermore, the care home-level matching process will also be carried out on age classes accommodated for by the care homes.

At resident level, the study will examine individuals aged 65 years or over who moved into a nursing or residential care home at any time between 17 January 2016 and 16 April 2017 (that is the follow-up period subsequently described in the section on Index dates and follow-up period, pp. 16–17).

The cohort will not retain care home residents:

- without a full address record in the National Health Applications and Infrastructure Services (NHAIS) registry
- without a recorded month and year of birth
- without an existing planned or emergency admission record during the pre-study period (defined in the section on Pre-period variables, p. 17), as either is an essential prerequisite to defining baseline resident-level characteristics
- without a matched resident in the control group of care homes
- who resided in any other care home after 17 January 2016 and prior to moving into a care home associated with the Vanguard. This exclusion is motivated by the possibility of contamination (bias) of baseline resident-level characteristics by the Vanguard programme for those residents who had previously resided in a care home. It was subsequently decided to retain in the evaluation individuals who had not already been care home residents within two years of entering a care home since the beginning of the intervention.

Sources of data

The IAU will inform the evaluation of the Vanguard's intervention programme with pseudonymised – that is, anonymised according to the Information Commissioner's Office anonymisation code of practice – Secondary Uses Service (SUS) routine data held by the National Commissioning Data Repository (NCDR). The SUS is the single, comprehensive repository for health care data in England which enables a range of reporting and analyses to support the NHS in the delivery of health care services and to trigger reimbursement of secondary care activity. This information is also useful to commissioners and providers of NHS-funded care for purposes other than direct clinical care, such as health care planning, service commissioning, national tariff reimbursement and national policy development. Since 2016 NHS England has been using the NCDR as the agreed source of emergency admissions data monitoring. The NCDR was established in order to provide NHS England and other parties with a country-wide view of activity data for reporting and analysis. It includes secondary care data relating to A&E, outpatient and inpatient care in the form of spells and episodes.¹¹ A spell is defined as a single period of care under one consultant (typically a patient's entire stay in a hospital), and is made up of at least one episode (i.e. a diagnosed condition or ailment requiring treatment), both an episode and a spell end on hospital transfer, discharge or the patient's death.¹²

The IAU will request access to SUS data spanning the period 1 November 2012 – that is 3 years before the introduction of the Vanguard interventions, during which study covariates informing the modelling stage of the evaluation will be measured – to the latest date reasonably reliable data are thought to be able to be sourced from SUS (hereby set at April 2017). The NCDR also holds NHAIS records, produced on a monthly basis on the first Sunday following the 13th day of the month and dating back to August 2014, of demographic details of all individuals registered by a GP in England, including dates of birth and full residential addresses. These records are updated in NHAIS when individuals register to a new GP or notify their GP of a residential address change. NHAIS records will be queried to identify addresses of care homes both from the intervention and control pools formed as part of the Vanguard programme evaluation. The NCDR will in turn utilise this information, which is decoupled from individual-level data, to generate a pseudonymised care home indicator for all care home residents, in turn also to be linked with care home-related information stored in the CQC registry.

The NCDR will also identify from NHAIS extracts the month in which a resident has entered or left (through death or relocation, as applicable) a care home in England through an examination of changes in each resident's address history on record. The NCDR will then link NHAIS information on each care home resident's month and year of birth, death and relocation into/out of a care home in England to the SUS data-base via a pseudonymised patient identifier. To account for the possibility of time lags between consecutive NHAIS updates, only extracts up to April 2017 will be used to inform the Vanguard evaluation. In order to ensure retained NHAIS data are of reasonable quality over time, the consistency of more recent data with earlier extracts will be assessed, in particular, the reliability of death data can be verified by checking if hospital death records held in SUS also appear in NHAIS. If required, the follow-up period will be reduced.

Since 2009 the independent regulator of health and adult social care in England, the CQC regularly monitors, inspects and regulates health care services (including care homes) to ensure they meet fundamental standards of quality and safety. The IAU will obtain data from the CQC on care home type, capacity, specialties and performance rating required to meet

the exclusion criteria outlined at the care home analysis level in the section on the Definition of study cohort (p. 12). It is worth noting that the CQC registry is not designed for research purposes, nor is properly validated, as such, there is the possibility that the lists of care homes on CQC record and that supplied by the Vanguard team indicate inconsistent specialties. Care will be taken to ensure that genuine specialist care homes not fitting the inclusion criteria outlined in the Definition of study cohort section (p. 12) are excluded from the analysis pool. On the other hand, those catering for frail individuals that are also able to accommodate residents with complex needs, for example, will instead be retained.

The above-outlined data extraction and linkage strategy will enable identification of the whole care home resident population between January 2016 and April 2017 – even those with no hospital admission record during the follow-up period – required to inform the Vanguard impact evaluation. All linked secondary health care and care home data informing the present evaluation will be stored, processed and analysed by the IAU within an accredited secure data environment located in the Health Foundation. The overall approach to information governance used in this evaluation has been scrutinised by the Programme Oversight Group, which is responsible for overseeing the implementation and delivery of IAU project outcomes, and information governance experts at NHS England and NHS Digital. The IAU at no point will have access to patient identifiable information related to this evaluation, nor plans on utilising more than the strictly necessary amount of data.

Study outcomes

Primary outcomes

Primary outcomes to the present programme evaluation were chosen to be *A&E attendances* and *potentially avoidable emergency admissions* per care home resident over a period of up to 15 months. The length of the follow-up period for a given care home resident will consist of her/his duration of stay in the care home between the start – that is, the date an individual moved into a care home since 17 January 2016 – and the end – that is the earliest date between the resident's death, relocation to another care home or 16 April 2017 – of the study period.

An A&E attendance is defined as a first or follow-up visit by an individual to a hospital A&E department for a particular incident. An admission into hospital can be either arranged in advance of the actual admission (planned) or unpredictable and at short notice as prompted by clinical need (emergency). The notion of potentially avoidable emergency admission is connected to, and in fact builds on, that of ACS condition, embodying a broader scope relative to the latter and being generally more geared towards the frail (residential or nursing) older care home resident population.¹³ A vaccine-preventable, chronic or acute condition is considered ACS if it can be treated via effective community care, case management and/or lifestyle interventions instead of through a hospital admission. Examples of ACS conditions include congestive heart failure, diabetes, asthma, angina, epilepsy and hypertension.^{14,15} The notion of potentially avoidable emergency admission adapts that of ACS conditions to focus on older people experiencing health and social care, thus including: acute lower respiratory tract infections (such as acute bronchitis), chronic lower respiratory tract infections (such as emphysema and other chronic lung diseases), pressure sores, diabetes, food and drink issues (such as abnormal weight loss and poor intake of food and water due to self-neglect), food and liquid pneumonitis (inhaling food or drink), fracture and sprains, intestinal infections, pneumonia, and UTIs.¹⁶

Secondary outcomes

The secondary outcome was chosen to be the proportion of hospital-to-resident bed days per resident over a period of up to 15-months. This outcome conveys information on changes to both the length of hospital stay and the number of admissions.

A hospital bed day is defined as a hospital bed that is occupied at midnight in wards open overnight.¹⁷ As such, a hospital admission followed by a discharge within the same day will not contribute towards the total number of bed days.

Additional clinical outcomes over a period of up to 15-months also worth consideration were thought to be: number of emergency admissions per resident, number of planned admissions per resident, number of falls, UTIs, venous thromboembolisms (VTEs) and pressure ulcers per resident, number of health care associated infections (HCAIs) per resident, number of outpatient attendances per resident, and proportion of deaths outside of hospital. Subject to sample size considerations, the present study will also investigate the impact of the Vanguard intervention on these indicators.

HCAIs cover a wide range of infections acquired in hospital or community settings typically as a result of health care interventions or due to contact with a health care setting.¹⁸ Inclusion of the above outcomes in the evaluation is envisaged to contribute towards a richer description of the landscape of secondary care resource utilisation in care homes. As mentioned in the Objectives of the analysis section (p. 10-11), the proportion of care home residents not dying in hospital is here taken as a proxy to dying in the preferred place of death. By not capturing deaths specifically occurring in hospices or at a family member's home, this approach falls short of offering a detailed picture of the end-of-life care as is received by care home residents, nevertheless limitations in the availability and sample size of relevant data in the IAU's possession limit the scope of the analysis.

Variable definitions

Exposure variable

An individual is considered to have received the Vanguard intervention if residing into a Vanguard care home at any time during the follow-up period, which was defined in the section on Primary outcomes (p. 15). As detailed in the Sources of data section (p. 14-15), individuals forming part of the intervention group will be identified from a list of Vanguard care home addresses matching NHAIS monthly records at any point between 17 January 2016 and 16 April 2017, which is the follow-up period chosen as warranting dependable identification of care home and resident characteristics and outcomes from data sources available to the IAU.

Index dates and follow-up period

Although the implementation of interventions undertaken by the Vanguard programme could be traced back to as early as October 2013, it could be reasonably argued that November 2015 marks the roll-out of the earliest substantial batch of Vanguard interventions across care homes in the CCG (see Table 1 for details). This date is thus adopted as the benchmark for pre- and post-intervention comparisons between the intervention and control groups of care homes and care home residents. Additionally, in order to allow for the intervention to become gradually established across Vanguard care homes, a development ('bedding-in') period is set to approximately 2.5 months (that is from 1 November 2015 to 16 January 2016).

As mentioned previously in the section on Primary outcomes (p. 15), a care home resident's follow-up period runs between the index date and the end of the study. The index date is defined as the date of the earliest NHAIS extraction recording an individual's relocation into a care home since the bedding-in period has lapsed (i.e. from 17 January 2016). The end of study is marked by the earliest between: the death date of a care home resident, the date of her/his relocation to another care home, or 16 April 2017. Of note, a care home resident's death or relocation to a care home are both set to the corresponding extraction date on earliest NHAIS record, as mentioned in the Sources of data section (pp. 14-15). In principle, taking the earliest date a death appears on NHAIS record as a proxy for the actual date of death may lead to extending a care home resident's follow-up period by up to a month. On the other hand, with the occurrence of deaths being randomly distributed within a given month, it is not expected that follow-up periods inflated due to the above convention would lead to a biased assessment of the impact of the intervention.

Pre-period

Baseline (that is prior to the beginning of an individual's residency in a care home) characteristics of care home residents will be obtained from data taken as far back as 3 years prior to the resident's index date.

Baseline variables

As subsequently described in the section on Identifying control areas (p. 19), baseline variables measured at both care home and resident level will be employed in both the statistical matching and regression modelling analysis stages.

More specifically, care home-level variables considered in the evaluation are:

- category (nursing or residential)
- number of available beds
- previous (over a 1-year look-back period) A&E attendances and potentially avoidable emergency admissions at care home level
- age specialty (only or also catering for residents aged 65 years or over)
- urban/rural classification at Lower-layer Super Output Area (LSOA) level
- ownership (independent/charity or NHS/local authority), subject to availability of this information
- overall CQC performance rating (outstanding/good/requires improvement/inadequate)
- average socioeconomic deprivation decile of the 2015 Index of Multiple Deprivation (IMD) distribution at LSOA level.

As described in the section on Sources of data (pp. 14-15), data on care homes open since 1 November 2015 (the assumed start date of the intervention) will be sourced from the CQC registry. Information on care homes that have opened later will instead be derived from CQC data as soon as they become available (normally in the month following the care home's opening date). There is an ongoing debate as to whether inspection ratings produced by the CQC offer meaningful and reliable information for research into, and comparison across, health care service providers in England.¹⁹ These concerns stem in particular from a lack of consistent standardisation of the processes of categorising, weighting and collating the evidence informing CQC service ratings.²⁰ Notwithstanding the above limitations, it is nevertheless recognised that CQC ratings offer valuable information on the quality of care

home service provision that, on one hand, would be useful to incorporate in the evaluation and, on the other, would be unlikely to significantly bias the subsequent assessment of the Vanguard's relative effect against the identified control group of residents. As such, CQC ratings will be retained in the present study subject to their availability.

Resident-level variables identified as relevant to the analysis include:

- age at index date
- gender
- ethnicity
- number of A&E attendances separately in the 3 pre-intervention years
- number of planned admissions separately in the 3 pre-intervention years
- number of emergency admissions separately in the 3 pre-intervention years
- number of potentially avoidable emergency admissions separately in the 3 pre-intervention years
- number of hospital bed days separately in the 3 pre-intervention years
- index date (in order to capture varying patterns of care over time)
- comorbidities associated to frail individuals (over a 3-year look-back period)
- comorbidities associated with emergency admissions, as identified by the Patients At Risk of Re-admission within 30 days (PARR-30) model
- the Charlson Comorbidity Index (over a 3-year look-back period).²¹

Comorbidities associated to frail, older individuals are: anxiety or depression, functional dependence, falls and significant fracture, incontinence, mobility problems, pressure ulcers, and cognitive impairment (a combination of delirium, dementia and senility).²² Although some of the listed conditions are curable, it can be reasonably assumed that any issues experienced by a care home resident over the course of 3 years are plausibly predictive of her/his likelihood of subsequently undergoing an emergency admission.

Comorbidities associated with emergency hospital admissions are identified via the PARR-30 model, which includes: congestive heart failure, peripheral vascular disease, chronic pulmonary disease, diabetes with chronic complications, renal disease, metastatic cancer with solid tumour, other malignant cancer, moderate/severe liver disease, other liver disease, haemiplegia or paraplegia, and dementia.²³

Analogously to the convention (discussed in the section on Index dates and follow-up period, pp. 16–17), followed to approximately determine a care home resident's date of death, also the date of an individual's relocation into a care home will be taken as that recorded in the earliest available NHAIS extract (where appropriate). In principle taking the earliest date a relocation into a care home appears on NHAIS record as a proxy to the actual relocation date may lead to curtailing a care home resident's pre-admission period by up to a month within the 60-day period prior to the resident's index date. Just as it was concluded for actual and estimated death dates, due to the arguably random nature of the date in a month a care home relocation occurs, it is unlikely that this would lead to a biased assessment of the impact of the intervention.

Statistical methods

Identifying control areas

As mentioned in the section on Study design (p. 12), a multi-stage statistical matching procedure will be employed in the evaluation to form a sample of care homes and residents within CCGs with similar connotation to Sutton CCG in terms of socio-demographic, economic and additional profiling characteristics measured in the study pre-intervention period.

Stage 1 of the statistical matching exercise will be discharged by adopting the Office for National Statistics method for the geographic classification of health areas,²⁴ which relies on the unweighted squared Euclidean distance to measure the degree of homogeneity between distinct areas. The methodology is informed by a range of (suitably transformed and standardised) demographic, household composition, housing, socioeconomic, employment and industry sector data taken from the census,²⁵ these will be supplemented with variables available at aggregate (i.e. CCG) level more relevant to the purpose of this evaluation. Since published information on similar CCGs is based on data covering the whole of the UK, to rescale to the context of the present evaluation the methodology will have to be re-applied to data specifically referring to England.

The first step of the analysis will thus proceed by re-calculating distances and required variable transformations/standardisations to the England context only. Preference will be given where appropriate to local variables to ensure any detected difference is not due to differences existing at local level (e.g. care home residents from the control and intervention groups making use of different hospitals). A list comprising to the order of 20 candidate CCGs found, with the above method, to be most comparable to Sutton CCG will be submitted to the Vanguard team for review. As explained in the section on the Definition of the study cohort (pp. 12–13), CCGs participating in an NCM Vanguard programme designed to affect care homes, forming part of the South West London STP or otherwise known to be implementing large-scale care home interventions deemed to be unrepresentative of standard care, will be excluded a priori from the selection process. In the event of 'ties', preference will be given to CCGs in closer geographic proximity to Sutton CCG to account for any shared or joint hospital service provision within the area. A final list of control CCGs around half the size of the candidate list will be finally agreed with the Vanguard team.

Identifying the control population

Stage 2 of the statistical matching at care home and resident level will lead to forming the control pool via genetic matching,²⁶ a flexible multivariate matching method based on the generalised Mahalanobis distance as a measure of similarity between paired units and hinging on an evolutionary search algorithm²⁷ maximising the degree of similarity in the distribution across matched intervention and control units ('balance') of observed covariates. The genetic matching strategy to be employed in the evaluation will be tentatively 1-to-1 (so that each Vanguard care home resident is paired with one control resident), with replacement (so that a control resident may be paired with at least one Vanguard resident) and with the restriction of producing an exact match by care home category and care home age specialty. The latter condition is warranted by the structural differences in operation and service provision known to exist between care homes not sharing the above specialties.

Choice of matching variables

Statistical matching to find a control group of care homes and residents balanced with that in receipt of the Vanguard intervention will be carried out jointly on care home- and resident-level characteristics, to avoid clustering of matched residents within too concentrated a sample of matched care homes. As it is advisable not to include in the matching process variables that may have been affected by the Vanguard intervention²⁸ (as they may alter the resident population mix), duration of a resident's stay in a care home will not be retained in the pool of matching variables. Furthermore, when forming the set of matching variables some preliminary variable selection strategy, based on a pooled regression of candidate covariates onto the primary outcomes, may also be adopted to discard redundant covariates.

Diagnostics

To assess the quality of the resulting matching control and intervention samples of care homes residents, a variety of graphical (e.g. paired histograms, bar plots, QQ-plots) and more formal diagnostic checks will be used. In particular the standardised bias statistic – defined as the difference in means of a given variable between the intervention and control groups, divided by the variable's standard deviation computed from the intervention group – will be computed and inspected for all the variables listed in the section on Baseline variables (pp. 17–18): hence not just those fed into the matching algorithm. In general the lower the value of the standardised bias for a given covariate, the better the balance it achieved between the control and intervention groups. As a rule of thumb, absolute values of a standardised bias lower than 0.1 are indicative of a satisfactory balance having been attained on a given variable.²⁹ Formal hypothesis tests on marginal covariate distributions across control and intervention groups are not advisable, due to their tendency to conflate changes in balance with variations in statistical power.²⁸

Statistical analysis

The target estimand in the evaluation is the Average Treatment effect among the Treated (ATT): that is the average effect of the Vanguard intervention among care home residents in the intervention group. As mentioned in the section on Study design (p. 12), separate regression models will be fitted to the matched intervention and control samples of care home residents independently for each of the primary and secondary outcome listed in the section on Study outcomes (pp. 15–16). The set of predictors used to populate each regression model will comprise all matching variables as well as any additional variable thought to be reasonably predictive of the given outcome. Similarly to what was mentioned in the section on Identifying the control population (pp. 19–20) with reference to statistical matching, stepwise variable selection may be adopted to improve a fitted model's balance between goodness of fit and parsimony.

More in detail, it is envisaged that primary outcomes (namely A&E attendances and potentially avoidable emergency admissions) will be analysed within a Generalised Linear Modelling framework suitable for count variables, including fixed-effects Poisson and Negative Binomial specifications. The main secondary outcome (that is the proportion of hospital-to-resident bed days) will instead be analysed through fixed-effects Logistic, Negative Binomial or Beta regression, which are designed to fit response variables defined as proportions. Alternative model instances, like zero-inflated or mixture models, will also be reviewed as appropriate depending on the features of the response variables (notably over-dispersion). Customary model selection – striking a balance between model adequacy (fit) and complexity (over-parameterisation) – and validation – based on inspecting residual and

deviance statistics – checks will also be carried out for all outcomes. Sample size permitting, a cross-validation approach based on splitting the full data-set into a (so-called ‘training’) subset to which the proposed models are fit, and whose predictive performance is assessed on the grounds of the remaining (‘testing’) subset, may also be carried out.³⁰

To account for attrition in the response stemming from differences in length of stay of a resident in a care home, primary outcome models will feature an offset term on the follow-up duration. This implicitly assumes that the rate of occurrence of primary events (e.g. emergency hospital admissions) is constant over time, which may be unrealistic especially in the context of a pre- vs post-intervention analysis.

Finally, it should be noted that the process of forming a control pool of care home residents through statistical matching implicitly introduces some spurious correlation among individual outcomes measured from matched pairs. The loss of statistical power inherent to performing an analysis from matched samples is a recognised issue.²⁸ To mitigate the problem, modelling adjustments based on the introduction of frequency weights may be performed.

Subgroup analysis

Inferences on the effectiveness of the Vanguard intervention will be reported at care home resident level, also to avoid the possibility of disclosure of the identity of residents residing in particularly small care homes. With the aim of quantifying any differential response to the Vanguard intervention presented by residents from care homes of different categories, the regression analysis exercise will be independently replicated based on data from the two categories of care homes separately considered.

The staggered implementation of the different initiative making up the Vanguard intervention programme (see Table 1) makes it unfeasible to ascertain how long is required for the overall intervention to reach maturity. This makes it difficult to reliably demonstrate the significance of the intervention’s effect on the care homes it is implemented to. On the other hand, it would be reasonable to expect that the longer an individual has resided in a care home, the more likely she/he would benefit from the Vanguard intervention due to prolonged exposure to the programme initiatives. As such, it is of interest to examine whether care home residents in Sutton respond differently to the intervention depending on how early or late they moved into the care home. This additionally motivates carrying out separate subgroup analyses for early and late entrantsⁱⁱ into care homes managed by the Vanguard.

Sensitivity analyses

A number of sensitivity analyses are warranted to ascertain the robustness of findings from the proposed ‘baseline’ analysis to the various assumptions underpinning it.

As in the case of any analysis based on observational data, one of the main threats to the internal validity of this study is unobserved confounding. That is, although the statistical matching stage of the evaluation is designed in principle to ensure that identified intervention and control samples are sufficiently homogeneous in terms of baseline observed

ⁱⁱ The actual determination of an ‘early’ and ‘late’ entrant to a care home is arguably programme- and context-dependent, and will be explored on the basis of preliminary examination of the data.

characteristics, there is no guarantee that it would also harmonise these groups over unobserved differences.

Reliably assessing the robustness of an intervention analysis to unobserved confounding presents a non-trivial challenge and is still the subject of ongoing research.³¹ Some evidence of the extent of this issue could be obtained by contrasting the two matched groups of care home residents on the grounds of a clinical outcome that is expected to remain unaffected by the Vanguard intervention. For instance, it appears unlikely that the Vanguard intervention will have a tangible effect on mortality among care home residents benefiting from it. As such, differences in mortality rates between the control and intervention groups of residents during the follow-up period could be regarded as indicative of a different baseline level of well-being at the point they were enrolled in the study.³² On the other hand it may as well be the case that the Vanguard programme also impacts on life expectancy, thereby reducing mortality rates among care homes in Sutton. Rates of all-cause mortality will be accordingly computed from the accrued data over a period of up to 24 months and contrasted between the control and intervention pools of care home residents. On one hand, any significant difference in mortality rates would preclude confidently ruling out the possibility of residual unobserved confounding. On the other, interpretation of consistent mortality rates across groups would still require caution as this alone cannot guarantee the absence of any unmeasured confounding.

Sample size calculation

No sample size determination assessment was carried out to inform this evaluation. The analysis is expected to produce informative inferences regardless of sample size or statistical power considerations.

Limitations and sources of bias

Threats to validity

Internal validity

There are a number of potential challenges to internal validity of this evaluation, which are outlined in the section that follows.

Unmeasured confounding hinders dependable quantification of the effect of the intervention programme.

- In the present case study, confounding due to omission of covariates driving the chosen outcomes may occur at area, care home or resident level. In general, the use of local-level, survey-type data to form a matched control group would be expected to offer better protection against confounding compared with the utilisation of data sets routinely collected at often low resolutions (e.g. at national level). This is because the former are typically designed and accrued according to contextual information and, as such, are less prone to missing information that is predictive of the outcomes of interest. Since the Vanguard intervention is rolled out across all care homes in the Sutton CCG, the determination of a sample of control care home residents at a higher resolution than the CCG level is precluded from the present evaluation.
- The analysis is designed to accommodate a broad variety of covariates at both the statistical matching and regression modelling stages also with the aim of mitigating the influence of any unmeasured confounding. Of course no guarantee can be offered in practice as to the study retaining an exhaustive selection of covariates predictive of the chosen outcomes. An additional limitation in this regard lies in the inability to match on care home-level hospital activity observed in the pre-period, due to the unavailability prior to August 2014 of the NHAIS extracts required to identify care home residents.

Care homes in the matched control group have received during either the pre- or post-intervention period interventions from either the Vanguard or other programmes of change.

- A key assumption underpinning the causal assessment of the Vanguard intervention is that care homes in the matched control group are providing a 'standard' level of care and health care to their residents that is consistent with that actually offered during the pre-intervention period by Vanguard care homes, as well as that instead expected from participating care homes in Sutton had they not taken part in the Vanguard programme. Violation of this assumption may compromise the adequacy of the formed control group as counterfactual to care homes in receipt of the Vanguard programme.
- In the light of the importance placed on promoting replicability and scalability of all EHCH vanguard interventions,^{1,9} there is indeed the possibility that care homes situated especially in neighbouring CCGs are already adopting and reproducing those aspects of the intervention perceived as most successful.
- Information on care homes selected during the statistical matching stage of the analysis will be carefully reviewed to ensure no major policy interventions influencing their outcomes have occurred in either the pre- and post-intervention periods.

- A further complication within, and potentially beyond, the scope of this evaluation could also be devised in the spread of the Vanguard interventions leading to 'contamination' of performances from care homes not only otherwise regarded as control (for the purposes of statistical matching), but also falling under the remit of other NCM or separate site-wide improvement programmes.
- The validity of this assumption cannot be realistically verified as the amount of local intelligence required on incipient or ongoing satellite programmes or improvement initiatives would be too unwieldy to gather in practice. On the other hand, it is unlikely that such contamination bias would tangibly distort findings from the present evaluation within the relatively limited time horizon it spans.

The intervention examined by the evaluation study differs from the array of initiatives rolled out by the Vanguard across its care homes.

- Limitations in the evidence base available to inform the evaluation, coupled with the necessary working assumptions intrinsic to its supporting modelling approach, only allow the IAU to capture a coarse and simplified representation of the complex reality of the Vanguard programme, which comprises a broad range of initiatives implemented to varying degrees across different care homes at different times.

External validity

Potential challenges to the external validity of this evaluation are outlined next.

Data informing the two stages of the comparative effectiveness analysis may be incomplete.

- Information both at care home and in particular at resident level may be incomplete or missing altogether for certain units. The analysis postulates the working assumption, where relevant and applicable, of data being 'Missing At Random' but unlikely 'Missing Completely At Random'. Violations of this assumption are hard to ascertain in practice and may lead to biased estimates of the effect of the Vanguard intervention.

The intervention does not reach maturity within the post-intervention period.

- The complex and multi-faceted nature of the Vanguard intervention programme, combined with its staggered implementation across care homes in Sutton CCG and over time (see Table 1), may imply that its impact may have not fully manifested during the considered time horizon. As such caution is advised when projecting estimates of the intervention impact beyond the boundaries of the post-intervention period.

Relevant outcomes are omitted from the analysis.

- Although the choice of analysis outcomes detailed in the section on Study outcomes (pp. 15–16) is expected to reasonably capture the impact of the Vanguard's programme on secondary health care resource utilisation by care homes in Sutton CCG, the possibility of there being additional outcomes affected by the Vanguard interventions pertaining to other secondary health care domains still cannot be entirely ruled out.

Statistical conclusion validity

Potential issues hampering the statistical conclusion validity of this evaluation include:

1. Care homes and/or residents are incorrectly included in or excluded from the matched control group.
 - Matching care homes and care home residents in Sutton to corresponding control units not showing a satisfactory degree of similarity in pre-intervention characteristics may lead to a biased assessment of the extent of the change introduced by the Vanguard programme among care homes in Sutton. An analogous effect would follow from exclusion of control units that are instead representative of pre-intervention care homes or individuals.
 - To avoid this issue a broad number of covariates was chosen to match on when forming the control group in the first place. As also outlined in the section on Diagnostics (p. 20), a variety of graphical and summary diagnostic checks will be additionally computed to ascertain the balance achieved by the control sample derived from the statistical matching.
2. The regression model is mis-specified.
 - Selection of an inadequate shape for the regression model of any of the outcomes of interest would likely lead to biased inferences on both the extent and accuracy of the effect of the Vanguard intervention. Moreover exclusion from the regression model of significantly predictive covariates may lead to effect estimates inadequately reflecting the case-mix actually observed in the full matched sample.
 - As indicated in the section on Statistical analysis (p. 20), all regression models will undergo formal model adequacy and selection assessments.

Construct validity

Additional issues deserving of attention stem from construct validity considerations:

1. The exposure variable may not correspond to a single, well-defined intervention.
 - As most recently remarked in the section on External validity (p. 24), different components to the Vanguard intervention programme were rolled out across different care homes in Sutton CCG at different points in time. As such, also in the light of the administrative nature of the evidence base informing the present evaluation, it is unfeasible to attribute any effect quantified from care homes in the Vanguard to a specific component of the intervention programme. Accordingly the exposure variable should only be regarded as indicative of the overall performance of the Vanguard programme over the sample period.
2. Reporting inaccuracies and inconsistent variable definitions may complicate comparisons between intervention and control groups.
 - Information on comorbidities is derived from (primary and secondary) diagnosis fields in the SUS data-base. Although the evaluation study will be informed by a single, national-level registry of secondary care activity, inconsistent coding and coding depth between hospitals³³ may in practice introduce some bias in the process of detecting comorbidities.³⁴

- Additional elements not addressed in the present evaluation that may contribute to biased assessments of impact may include different mortality rates or admission thresholds across different hospital trusts in and outside of Sutton CCG.

Additional limitations

- Care home resident identification from monthly NHAIS extracts is expected to be mostly accurate and up to date relative to the frequency of NHAIS record updates. A potential exception may be constituted by members of care home staff living on its premises, as they would be erroneously included in the study cohort. The existence and extent of this problem are not expected to compromise the integrity of the present evaluation, but will nevertheless be ascertained with the Vanguard team.
- As explained in the section on Index dates and follow-up period (pp. 16–17), follow-up index and end dates are approximate due to the monthly frequency of NHAIS record updates from August 2014 and the lack of information as to when actual changes may have occurred between consecutive NHAIS snapshots. As a consequence, the number of resident bed days used at the regression modelling stage of the analysis to determine the study duration offset will only be approximate. Moreover, as also previously remarked in this section, residents who have entered a care home prior to August 2014 will not be able to be matched based on when they enrolled.
- Furthermore, due to limitations in NHAIS record fields it will not be possible to determine whether the index date marks the start of a resident's first care home stay or a relocation from another care home (unless this was already in the study).
- As remarked in the Sources of data section (pp. 14-15), care home-level information is largely sourced from the CQC registry, which is not designed for research purposes and is not validated accordingly. However, an ad hoc validation of CQC records was carried out through comparison with local data supplied directly from the Vanguard. As a result CQC data were found to show sufficiently good and consistent quality to reliably inform the present evaluation (see the Appendix).
- The SUS registry is an administrative data-base and is not subjected to the cleaning procedures Hospital Episode Statistics (HES) is subjected to. However, the IAU Data Management Team will perform required data checks and cleaning.
- As previously observed in the section on Objectives of the analysis (p. 10-11), assessment of the impact of the Vanguard intervention onto 999 ambulance call-outs, financial costs, residents' quality of life, clinical quality information, medication wastage, and staff satisfaction and engagement is precluded by the evaluation being solely informed by routinely collected, administrative, secondary health care, resource-use data.

Reporting

General reporting considerations

Results will be reported as the relevant measure of effect, such as relative risks or ratios, associated with 95% confidence intervals and p-values. The post-matching analysis will be presented annotated with all variables used in the adjustment. Results will be presented to 2 decimal places for effect size and confidence intervals. P-values will be shown to 3 significant digits.

Special reporting requirements for this study

This study will adhere to:

- the STrengthening the Reporting of OBservational studies in Epidemiology (STROBE) standards³⁵ and the REporting of studies Conducted using Observational Routinely-collected health Data statement (RECORD)³⁶ guidelines
- the NHS Digital (previously Health and Social Care Information Centre) small number rules³⁷
- and comply with the statistical code of practice.

Departures of Sutton IAU Evaluation from Statistical Analysis Protocol

This statistical analysis protocol was completed prior to analyses taking place. During the course of the analysis, we deviated from the protocol in the following ways:

- 1.0 [§“What the study will look at”, p.8] CQC care home service ratings were ultimately not used to inform the evaluation as they weren’t available for a substantial proportion of the analysed care homes and were based on inconsistent grading schemes, due to the CQC revising its rating standards in 2013.
- 2.0 [§“Limitations to the study”, p.10] The IAU evaluation eventually relied on 28 eligible (i.e. meeting the postulated inclusion criteria) care homes, for a total capacity of 819 beds. Vanguard sources instead refer to 29 care homes and overall 902 beds, as correctly reported in §“Background”, p.11.
- 3.0 [§“Definition of study cohort”, p.16] It was specifically care homes from EHCH vanguard sites that were excluded, rather than from any NCM site.
- 4.0 [§“Definition of study cohort”, p.16] Following consultation with the vanguard, it was agreed that the evaluation would only focus on care homes within Sutton CCG’s remit.
- 5.0 [§“Definition of study cohort”, p.17] It was subsequently decided to retain in the evaluation individuals who had not been care home residents within two years of entering a care home since the beginning of the intervention.
- 6.0 [§“Sources of data”, p.18] Consistently with Item #1, service performance data were obtained from NCDR but not utilised in any stage of the evaluation.
- 7.0 [§ “Baseline variables”, pp.21-22] See Items #1, #6.
- 8.0 [§ “Identifying control areas”, p.23] See Item #3.
- 9.0 Where reference is to the Sutton Homes of Care EHCH, the capitalised term “Vanguard” is used. This was the convention adopted in the originally signed-off SAP, but was ultimately dropped in the evaluation report.
- 10.0 P-values are reported rounded to three significant digits.

Appendix

Data checks

Standard summary statistics of the distributions of care homes and residents will be produced and examined for missing, erroneous and outlying values.

Missing values

Although missingness is not expected to significantly affect the data sets used to inform the present evaluation, the extent of the presence of missing values will be examined. In most cases a complete case analysis will be performed, unless the importance of the missing data requires the use of an appropriate imputation method. In any event sensitivity analyses will be performed to understand the impact of missing values.

Outliers

Data outside their plausibility range will be examined for errors. A sensitivity analysis will be performed if the impact of the outliers is suspected to unduly affect the results of the analysis.

Validation of care home information

Care home characteristics, such as whether the care home is nursing or residential, number of beds, full address and postcode and care home specialties, such as catering for older people, are publicly available from the CQC website and will be used to identify matched control care homes.

The validity of the CQC records was examined by comparing it with data on care homes in Sutton supplied by the Vanguard team. The results indicated that the CQC data on variables of interest are of sufficient quality and reliability for use in the present evaluation.

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:

- Continuous variables summarised by mean (standard deviation) or median (inter-quartile range) depending on the distribution
- Categorical variables summarised by number (%)
- Standardised biases calculated for the intervention group versus the unmatched and matched control groups, alongside variance ratios for continuous variables

Figures

The following figures will be produced:

- Bar plots showing the standardised differences from both the matched and unmatched sample

- Histograms or other descriptive plots illustrating the baseline characteristics of the intervention and matched control groups

Tables and figures for reporting statistical results

Tables

The following tables will be produced:

- A table showing estimates of treatment effect derived from the intervention and matched control groups:
- for binary outcomes the number and proportion in each group
- for count data the number of events and person time of exposure
- for continuous data the mean and standard error
- the size of the measure effect (eg relative risk or odds ratio) alongside a 95% confidence interval and a p-value
- for a difference-in-difference type of analysis the table should show summary results in each time period, their difference and the difference between groups over time

Figures

The following figures would be a minimal requirement:

- Forest plot showing the crude and adjusted results for each outcome measure.

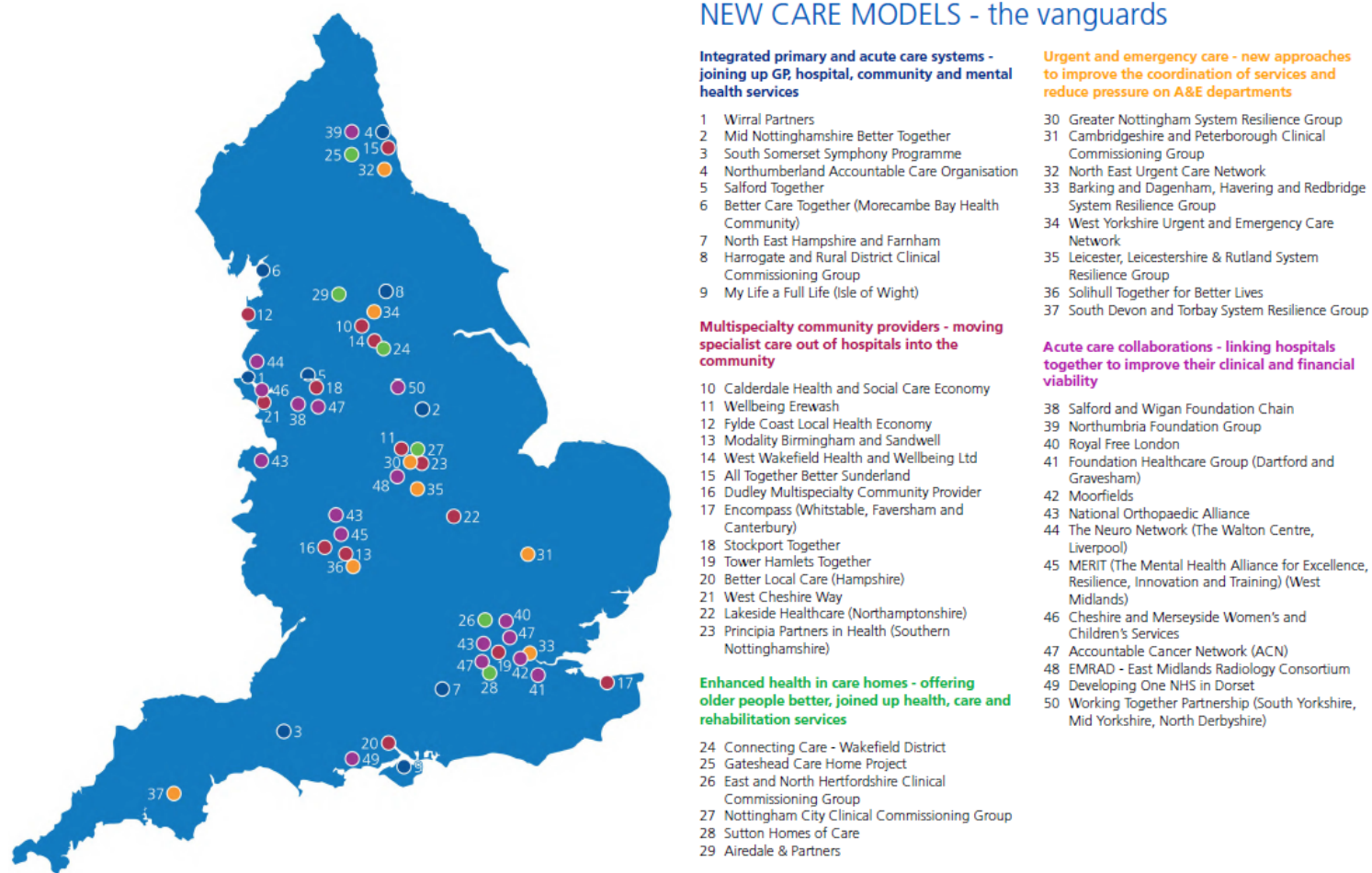
All statistical analyses will be carried out within the R programming environment.³⁸

Table 1: Timeline of Sutton Homes of Care EHCH implementation to April 2017, interventions in boldface extend to all care homes in the Vanguard.

Implementation date	Initiative
October 2013	End of life Supportive Care Home Team in nursing homes
April 2014	First Care Home Forum CQUIN for link nurses
May 2014	Joint Intelligence Group monthly meetings established
July 2014	Link nurses in selected care homes
November 2014	Concerned About A Resident poster
March 2015	EHCH vanguard status awarded
May 2015	Care Home Pledge endorsed by all nursing and selected non-nursing care homes
September 2015	Care Home Pharmacist in nursing homes
October 2015	Cake, Cuppa, Chat End of life Supportive Care Team in pilot residential homes
November 2015	Health Wellbeing Rounds began in 6 nursing care homes Hospital Transfer Pathway in all nursing and residential care homes NHS.net facility rolled out to nursing care homes
January 2016	E-learning modules distributed
February 2016	DeAR-GP tool for dementia support offered
March 2016	Reference cards distributed
April 2016	Hospital data made available NHS.net facility rolled out to residential care homes
May 2016	Quality Dashboard launched

	Student Nurse Training initiated
August 2016	End of life Supportive Care Home Team in residential homes Dementia Support Workers in selected nursing and residential care homes
November 2016	Health Wellbeing Rounds in 4 residential care homes Champion Roles announced
January 2017	Care Home Pharmacist in nursing homes Silver Letters taken up by some residents
February 2017	Dietician initiated
March 2017	Care Home Medication Policy rolled out
April 2017	Hospital Transfer Pathway enabled in selected mental health and learning disabilities care homes

Figure 1: Map of vanguard sites in England by New Care Model type as of March 2017



References

- ¹ NHS Sutton Clinical Commissioning Group. Sutton Homes of Care Value Proposition 2. February 2016. Available from: www.suttonccg.nhs.uk/vanguard1/who-we-are/Documents/Sutton-Vanguard-Value-Proposition.pdf
- ² NHS Sutton Clinical Commissioning Group. Annual Report and Accounts 2015/16.
- ³ NHS Sutton Clinical Commissioning Group. Sutton Homes of Care Measuring the Impact of Our Interventions: tracking outcomes & activity through metrics. March 2017.
- ⁴ British Geriatrics Society Communications. Hospital admissions from care homes. March 2015. Available from: <https://britishgeriatricsociety.wordpress.com/2015/03/13/hospital-admissions-from-care-homes>
- ⁵ Institute of Public Care. POPPI: Projecting Older People Population Information. Accessed May 2017. Available from: www.poppi.org.uk
- ⁶ Brown S. Evaluation of Sutton Homes of Care Vanguard – Interim Report. January 2017.
- ⁷ Brown S. Evaluation of Sutton Homes of Care Vanguard – Scoping Report. January 2017.
- ⁸ NHS. South West London Five Year Forward Plan. October 2016. Available from: www.swlccgs.nhs.uk/wp-content/uploads/2016/11/SWL-Five-Year-Forward-Plan-21-October-2016.pdf
- ⁹ NHS. NHS New Care Models: The framework for enhanced health in care homes. September 2016. Available from: www.england.nhs.uk/wp-content/uploads/2016/09/ehch-framework-v2.pdf
- ¹⁰ NHS Sutton Clinical Commissioning Group. Logic Model 2016-17.
- ¹¹ NHS England. The Better Care Fund: Operating Guidance for 2016-17. Gateway Approved: 05552. July 2016. Available from: www.england.nhs.uk/wp-content/uploads/2016/07/bcf-ops-guid-2016-17-jul16.pdf
- ¹² Health and Social Care Information Centre. Methodology to Create Provider and CIP Spells from HES APC Data. 2014. Available from: http://content.digital.nhs.uk/media/11859/Provider-Spells-Methodology/pdf/Spells_Methodology.pdf
- ¹³ The King's Fund. The King's Fund Data Briefing. Emergency hospital admissions for ambulatory care sensitive conditions: identifying the potential for reduction. April 2012. Available from: https://www.kingsfund.org.uk/sites/default/files/field/field_publication_file/data-briefing-emergency-hospital-admissions-for-ambulatory-care-sensitive-conditions-apr-2012.pdf
- ¹⁴ Walsh E.G., Wiener J.M., Haber S., Bragg A., Freiman M., Ouslander J.G. Potentially Avoidable Hospitalizations of Dually Eligible Medicare and Medicaid Beneficiaries from Nursing Facility and Home- and Community-Based Services Waiver Programs. Journal of the American Geriatrics Society. 2012, 60(5), pp.821-829. DOI: 10.1111/j.1532-5415.2012.03920.x
- ¹⁵ Walsh E.G., Freiman M., Haber S., Bragg A., Ouslander J., Wiener J.M. Cost Drivers for Dually Eligible Beneficiaries: Potentially Avoidable Hospitalizations from Nursing Facility, Skilled Nursing Facility, and Home and Community-Based Services Waiver Programs. Centers for Medicare and

Medicaid Services. August 2010. Available from: www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Reports/downloads/costdriverstask2.pdf

¹⁶ Care Quality Commission. The state of health care and adult social care in England in 2012 to 2013. November 2013. Available from: www.gov.uk/government/publications/the-state-of-health-care-and-adult-social-care-in-england-in-2012-to-2013

¹⁷ Department of Health. KH03 Quarterly Bed Availability and Occupancy. UNIFY2 Non-DCT Provider Collection. July 2010. Available from: www.england.nhs.uk/statistics/wp-content/uploads/sites/2/2013/04/dh_124212-5.doc

¹⁸ Public Health England. Health Care Associated Infection Operational Guidance and Standards for Health Protection Units. July 2012. Available from: www.gov.uk/government/uploads/system/uploads/attachment_data/file/332051/HCAI_Operationalguidancefinalamended_05July2012.pdf

¹⁹ Griffiths A., Beaussier A., Demeritt D., Rothstein H. Intelligent Monitoring? Assessing the Ability of the Care Quality Commission's Statistical Surveillance Tool to Predict Quality and Prioritise NHS Hospital Inspections. *BMJ Quality & Safety*. 2017, 26(2), pp.120-130.

²⁰ Walshe K., Addicott R., Boyd A., Robertson R., Ross S. Evaluating the Care Quality Commission's acute hospital regulatory model: final report. 2014.

²¹ Charlson M.E., Pompei P., Ales K.L., MacKenzie C.R. A New Method of Classifying Prognostic Comorbidity in Longitudinal Studies: Development and Validation. *Journal of Chronic Diseases*. 1987, 40(5), pp.373-383. DOI: 10.1016/0021-9681(87)90171-8

²² Soong J., Poots A.J., Scott S., Donald K., Woodcock T., Lovett D., Bell D. Quantifying the prevalence of frailty in English hospitals. *British Medical Journal Open*. 2015, 5(10), pp.1-10, DOI: 10.1136/bmjopen-2015-008456

²³ Billings J., Blunt I., Steventon A., Georghiou T., Lewis G., Bardsley M. Development of a Predictive Model to Identify Inpatients at Risk of Re-Admission Within 30 Days of Discharge (PARR-30). *British Medical Journal Open*. 2012, 2(4), pp.1-10. DOI: 10.1136/bmjopen-2012-001667

²⁴ Office for National Statistics. Methods for National Statistics 2001 area classification for local authorities. 2001.

²⁵ Office for National Statistics. Amendment: Local Authority Area Classification. August 2007.

²⁶ Diamond A., Sekhon J.S. Genetic Matching for Estimating Causal Effects: A General Multivariate Matching Method for Achieving Balance in Observational Studies. *The Review of Economics and Statistics*. 2013, 95(3), pp.932-945. DOI:10.1162/REST_a_00318

²⁷ Sekhon J.S., Mebane W.R. Jr. Genetic Optimization Using Derivatives: Theory and Application to Nonlinear Models. *Political Analysis*, 1998, 7(1), pp.189-203. DOI: 10.1093/pan/7.1.187

²⁸ Stuart E.A. Matching Methods for Causal Inference A Review and Look Forward. *Statistical Science*, 2010, 25(1), pp.1-21. DOI: 10.1214/09-STS313

²⁹ Imai K., King G., Stuart E.A. Misunderstandings between experimentalists and observationalists about causal inference. *Journal of the Royal Statistical Society: Series A*. 2008, 171(2), 481-502.

-
- ³⁰ Cameron A.C., Trivedi P.K. Regression Analysis of Count Data (2nd edition). May 2013, pp.xxvi+566. Cambridge University Press, Cambridge.
- ³¹ Dorie V., Harada M., Carnegie N., Hill J.A. Flexible, Interpretable Framework for Assessing Sensitivity to Unmeasured Confounding. *Statistics in Medicine*. 2016, 35(20), pp.3453-3470. DOI: 10.1002/sim.6973
- ³² Steventon A., Bardsley M., Billings J., Georghiou T., Lewis G. An evaluation of the impact of community-based interventions on hospital use. March 2011. The Nuffield Trust.
- ³³ Bottle A, Aylin P. Comorbidity scores for administrative data benefited from adaptation to local coding and diagnostic practices. *Journal of Clinical Epidemiology*. 2011, 64(12), pp.1426-1433. DOI: 10.1016/j.jclinepi.2011.04.004
- ³⁴ Wennberg J.E., Staiger D.O., Sharp S.M., Gottlieb D.J., Bevan G., McPherson K., Gilbert Welch H. Observational intensity bias associated with illness adjustment: cross sectional analysis of insurance claims. *British Medical Journal*. 2013, 346:f549. DOI: 10.1136/bmj.f549
- ³⁵ STROBE. STROBE Statement – checklist of items that should be included in reports of observational studies. 2014. Available from: www.strobe-statement.org/fileadmin/Strobe/uploads/checklists/STROBE_checklist_v4_combined.pdf
- ³⁶ Benchimol E. I., Smeeth L., Guttman A., Harron K., Moher D., Petersen I., Sørensen H. T., von Elm E., Langan S.M., RECORD Working Committee. The REporting of studies Conducted using Observational Routinely-collected health Data (RECORD) Statement. *PLOS Medicine*. 2015, 12(10), pp.1-22. doi: 10.1371/journal.pmed.1001885
- ³⁷ Health & Social Care Information Centre. Hospital Episode Statistics (HES) Analysis Guide. March 2015. Available from: http://content.digital.nhs.uk/media/1592/HES-analysis-guide/pdf/HES_Analysis_Guide_Jan_2014.pdf
- ³⁸ R Core Team (2016). R: A language and environment for statistical computing. R Foundation for Statistical Computing, Vienna, Austria. URL www.R-project.org