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## The Optimal Study: Describing the key components of optimal healthcare delivery to UK Care Home Residents – A Research Protocol

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## **Abstract**

Long term institutional care in the UK is provided by care homes. Residents have prevalent cognitive impairment and disability, have multiple diagnoses and are subject to polypharmacy. Prevailing models of healthcare provision - ad hoc, reactive and co-ordinated by general practitioners - result in unacceptable variability of care. A number of innovative responses to improve health care for care homes have been commissioned. The organisation of health and social care in the UK is such that it is unlikely that a single solution to the problem of providing quality healthcare for care homes will be identified that can be used nationwide.

Realist evaluation is a methodology which uses both qualitative and quantitative data to establish an in depth understanding of what works, for whom, in what settings. In this paper we describe a protocol for using realist evaluation to understand the context, mechanisms and outcomes which shape effective health care delivery to care home residents in the UK. By describing this novel approach, we hope to inform international discourse about research methodologies in long-term care settings internationally.

## **Introduction**

In the UK, institutional long-term care for older people is principally provided by independently owned care homes, which provide accommodation, together with nursing or personal care. They include homes with and without 24-hour on-site nursing staff, commonly described as residential and nursing homes respectively. Care home residents are typically over 80 years old, more likely to be female and have an average life expectancy of 12-30 months. Over three quarters have cognitive impairment. Physical dependency and incontinence are common. They are commonly prescribed seven or more medications and

have six or more diagnoses. A significant proportion are clinically depressed, exhibit behavioural symptoms, have mobility problems and are in pain<sup>1</sup>.

All care home residents are entitled to 'general medical services' (GMS) from a general practitioner (GP), free at the point of contact through the National Health Service (NHS). The provision of GMS includes responsibility for the GP to refer to other health services as required. In addition, care homes are responsible for enabling access to health and social care and coordinating input from these services under standards specified by the Care Quality Commission (CQC) – the UK statutory inspectorate for health and social care. There is evidence that health care for care home residents is variable and often inadequate, with frequent prescribing errors and high levels of exemption from clinical quality frameworks<sup>2,3</sup>. Variability is attributed to the local arrangements affecting access to health care and also the heterogeneity of care homes and residents<sup>4,5</sup>. It is likely that variability in provision and issues around quality of care are causally related.

The evident inadequacies in health care for care home residents have prompted a number of commissioned responses including outreach schemes into care homes, care home specialist nurses, pharmacist-led care home services and payment schemes for enhanced services from GPs<sup>6-9</sup>. Many of these models emphasise collaborative ways of working with the care home sector or integrated working between health and social care providers. Integration has been described as taking place at strategic, service and patient levels<sup>10</sup>.

It is not clear which, if any, of the health care models developed to support care homes best meet residents' needs, or whether integration at one or all levels is required. It might be that one model could be shown to have superiority over others but, given the heterogeneity of care homes and the local health and social care economies they operate in, it is more likely that no single model of health service delivery will be similarly effective for all

residents in all settings. Research has already shown the importance of local champions and relational working in establishing effective collaboration between health providers and care homes<sup>11</sup>. Part of the reason for the emergence of different models in different regions is that championship has come from different sectors or professional groups who have tended to predominate in local service provision. If effective healthcare support to care homes is to be established and sustained, therefore, it is important to understand what makes different interventions effective in their own settings and to seek to identify differences and commonalities between them. This is the aim of the Optimal Study.

The situation, as described, is unique to the UK but the challenge of developing high quality long-term care within dynamic and shifting service contexts could describe any one of a number of countries<sup>12</sup>. Commissioning and development of services in long-term care frequently follow business and policy agendas that operate apace, making them poorly amenable to experimental evaluation. We hope that our study protocol, reported here, will provide insights into how we aim to tackle this research challenge in the UK by using realist evaluation, which may be applied or adapted elsewhere.

## **Methods**

The study will take a two phase design, both using realist evaluation methodology<sup>13</sup>. Phase 1, described elsewhere<sup>14</sup>, is a hypothesis-generating workstream designed to describe the range of health service delivery models for care homes within the UK and to propose what features of these might be 'active ingredients' associated with positive outcomes for residents. It is conducting a synthesis of: surveys of service provision in UK care homes; interviews with national and regional representatives of care home and healthcare bodies; and existing datasets from studies evaluating the relationship between health and social care providers in meeting the healthcare needs of residents.

Provisional analysis of Phase 1 has concluded that NHS service delivery to care homes is predicated on one or more of three implicit assumptions. These are that:

- Better outcomes are achieved when health care interventions are explicitly specified and monitored through systems such as contracting, incentives and audit.
- Better outcomes are achieved when health care interventions are designed to be age-appropriate and provided by specialists in the health care of older people, such as care home support teams, care home therapy teams or community geriatricians.
- Better outcomes are achieved by approaches that foster improved collaborative working between NHS professionals and care home staff, such as through joint educational and training initiatives or service co-design.

Phase 2 will identify three regions with differing approaches to healthcare delivery in care homes, each predominantly driven by one of the three assumptions. It will look at the mechanisms employed to deliver healthcare and the outcomes for residents associated with each approach. It will assemble evidence to explain what works best, for whom and why. It will enable inferences to be drawn concerning service delivery in other, similar situations. This will enable more effective care models to be developed in the future.

### Study Objectives

These are:

- To identify, from the Phase 1 review of NHS services for care homes, three localities, each with models of care driven predominantly by one of the key assumptions.
- To investigate the effectiveness of these local services by documenting outcomes from the following domains:
  - residents' experience of healthcare
  - the health status of residents
  - healthcare resource use for care home residents

- To produce a set of evidence informed statements to guide
  - Clinical Commissioning Groups in their commissioning of NHS services.
  - Local health service providers in designing and managing services to support care home residents.
  - Work by care homes to facilitate residents' access to and use of NHS services.

### Study Design

Our research objectives call for a pragmatic understanding of how different types of health care provision are delivered to care home residents, together with how they impact on practice, staff (care home and NHS), organisations, and residents. Of particular importance are the relationships between key features (mechanisms), the situations in which they work (context), and the impact on patient wellbeing (outcomes). Such context, mechanism and outcome (CMO) relationships are central to realist evaluation<sup>13</sup>.

In considering CMO relationships, it was important that we focussed on outcomes relevant to NHS commissioners and service providers and also known to be areas where care home residents differ substantively from older people living outside of care homes. Care home residents have been shown to use out-of-hours services frequently and, when admitted to hospital, to have either very short or long stays<sup>1</sup>. They are subject to polypharmacy and frequent medication errors<sup>2</sup>. Thus we chose to measure medication use, out-of-hours service use, admissions to hospital (including to the emergency department) and length of stay in secondary care. The relevance of the lived-experience and service satisfaction amongst care home residents, and professional/family carers, was emphasised by our steering group, which includes family carer and care home provider representatives. Therefore, in addition, we included measures of resident and carer satisfaction.



## Recruitment

Recruitment will take place in three steps, summarised in figure 1.

First, three regions within England will be recruited, each operating a distinctive approach to delivering health care in care homes, driven predominantly by one of the three key assumptions. In two-out-of-three regions, those focussing on incentives and commissioning of expertise in care of older patients, Care Commissioning Groups (CCGs) will be the index of recruitment. CCGs bring together multiple neighbouring GP practices to commission elective hospital care, rehabilitation care, urgent and emergency care and most community health services for the patients on their lists. There are 210 CCGs within England (median population 225,000). In one region, where partnership between care homes and healthcare providers has been the prevailing assumption driving care, recruitment will be through the organisation facilitating partnership across the care home/healthcare interface. An example of such an organisation is the MyHomeLife scheme which is currently facilitating a number of care home leadership development schemes around the UK <sup>15</sup>.

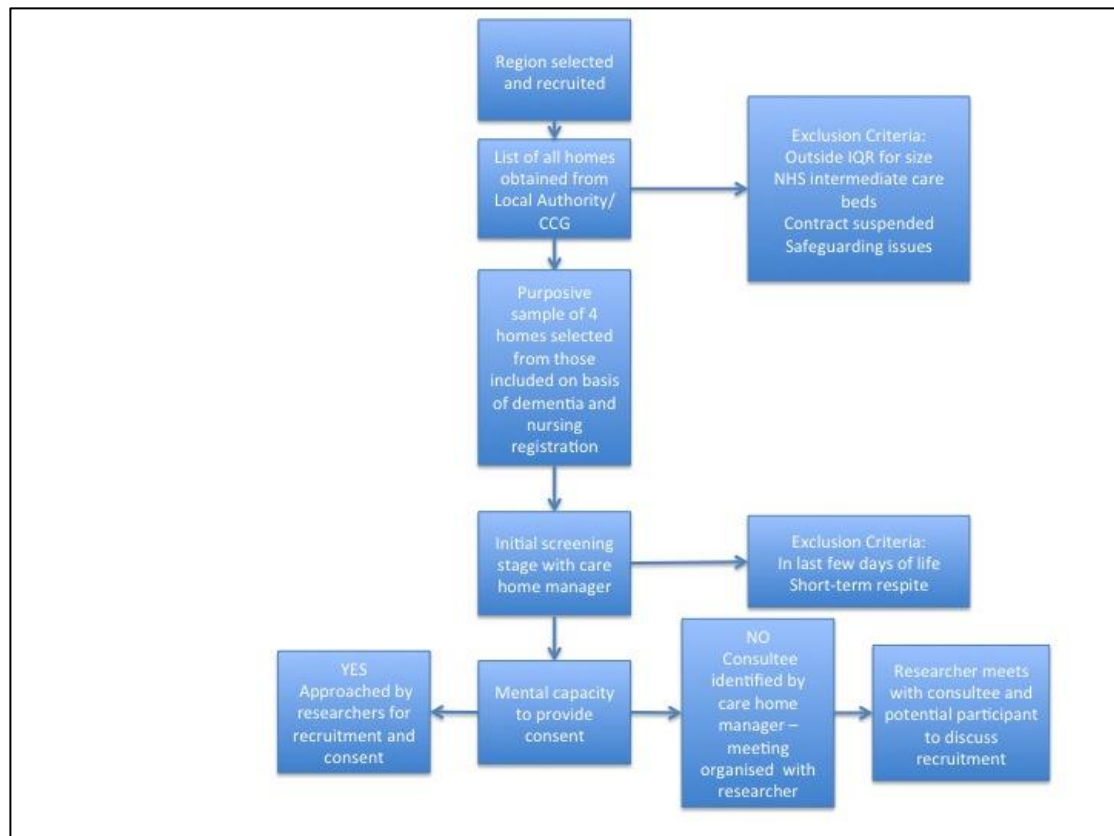


Figure 1 - **Optimal site selection and resident recruitment process**

Second, a list will be obtained from the organisation acting as the index of recruitment (either CCG or organisation facilitating partnership working) of all care homes they interface with. Homes will be eligible if they have populations within the national interquartile range for size, 20-39 residents residential and 30-49 for nursing homes<sup>16</sup>. The following will be excluded:

- homes exclusively providing care for those with learning difficulties or substance dependency, because these represent a minority of care home residents with care needs different from the majority of residents.
- homes with contracts under suspension with health or social providers, or which are currently subject to safeguarding investigations, because this will influence the quality of their interaction with health care providers and the study team.

- homes with a proportion of beds taken up by health-service commissioned intermediate care services, because this is not the predominant model and has implications for how care is financed and provided.

For all homes remaining on the list, the manager will be telephoned to introduce the study and a formal invitation to participate sent by email and letter. From the homes that volunteer to participate, a purposive sample of four care homes in each region will be designed to cover the full range, by size and type of care, of homes across the region. Homes recruited across the three regions will be matched, as far as possible, for resident population, staffing ratios and proximity to secondary care. In line with the recommended tariff for care home involvement in research ([www.enrich.dendron.nihr.ac.uk](http://www.enrich.dendron.nihr.ac.uk)), each home will receive a payment to ensure that care is not compromised through study participation.

Third, recruitment of residents will take place once care homes have agreed to participate. Residents on short-term care (e.g. respite), or identified to be in the last few days of life, will be excluded. The aim will be to recruit all remaining residents, subject to informed consent or consultee agreement in the case of lack of capacity to consent. Principles of best interests and mental capacity will be informed by the definitions in the Mental Capacity Act<sup>17</sup>.

Researchers, together with a Patient and Public Representative (PPR) will visit the care home to speak to residents, and to relatives' forums where these exist. Posters and information sheets will be left in public areas. Eligible residents who do not enrol in response to presentations, posters or information sheets, will be asked by care home staff whether they are happy to meet the researcher and PPR in order to discuss enrolment.

#### Data collection: Quantitative

InterRAI-AL (Assisted Living) and the InterRAI-LTC (Long-term care) are detailed audits of health and care status which have been internationally validated. Completion of these in

conjunction with care home staff has been shown to be feasible in a UK setting<sup>18</sup>. Neither tool fully met the needs of this study. The LTC tool contained several variables of limited relevance to the UK long-term care setting, whilst the AL tool did not record resource use with sufficient detail. With permission of the Inter-RAI group, a version based upon the AL but augmented using variables from section O of the LTC version was compiled.

At baseline, residents and/or their appointed spokespersons will report on health and mood domains of Inter-RAI. Care home staff will complete the other domains of Inter-RAI and medication administration records for each resident with support from a researcher. Anonymised and aggregated baseline data will be collected for non-participants.

Residents will be followed for 12 months, with researchers making monthly contact to document: medications; admissions to hospital (number and duration); emergency department attendances; out-of-hours GP and ambulance calls. These data will be recorded by care home staff but will undergo a 10% reliability check with residents' GP records.

Although we are using inter-RAI to control for baseline variability, we will not employ a recognised and validated long-term care quality tool, such as Inter-RAI or the Dutch LPZ<sup>22</sup>, as an outcome measure. This was a conscious choice. Such measures are not in routine use in the UK and which conceptual model of care quality to use in care homes is a source of considerable debate. In seeking to describe real-world models of health care, we sought to describe them using the outcomes that are routinely used by NHS commissioners, which are those described above. Whilst the introduction interRAI or LPZ - or data on prevalence of individual care problems in care homes - into the research protocol as outcome measures might start to address the issue of their feasibility and applicability in routine care practice in the UK care setting, this is a separate research question to that described here.

Staff members' overall satisfaction with continuing healthcare services will be recorded at

completion of data collection. Based on the scale developed by Arnetz and colleagues<sup>18</sup> we will develop a tailor-made assessment tool based on data emerging from interview transcripts about what represents good and effective healthcare delivery.

#### Data collection: Qualitative

A subset of resident participants, at least five from each care home, will be interviewed. For those residents unable to participate independently in interviews (due to cognitive impairment or communication difficulties), interviews will be held with family and friends. Interviews will be semi-structured and seek to elicit comment on the lived experience of care as well as what they would seek from care in addition to existing arrangements. Additional interviews will be undertaken with key stakeholders including care home staff, commissioners, GPs, NHS nurses and allied health professionals. Interviews will be iterative. All participants will be interviewed at least once and key informants from the different groups up to three times over the course of the year. Interviews will use, as their starting point, phase one findings on the processes necessary to provide continuing health care to residents. Follow-up interviewees will be chosen using a theoretical sampling approach, with attention focusing on those whose initial transcripts most inform emerging theoretical constructs. Although the number of interviewees from each grouping (residents, carers and other key stakeholders) is potentially quite small, we believe that data will triangulate. Thus, for example, if interviews with external stakeholders suggest gaps in our understanding that could only be addressed by recruiting further residents for interview, then we would do so under the tenets of theoretical sampling. Supplementary evidence about service delivery, in the form of NHS and care home documentation of policies and procedure, will be collected from care home managers and local health care commissioners and providers.

#### Data analysis

Data analysis is outlined in Figure 2.

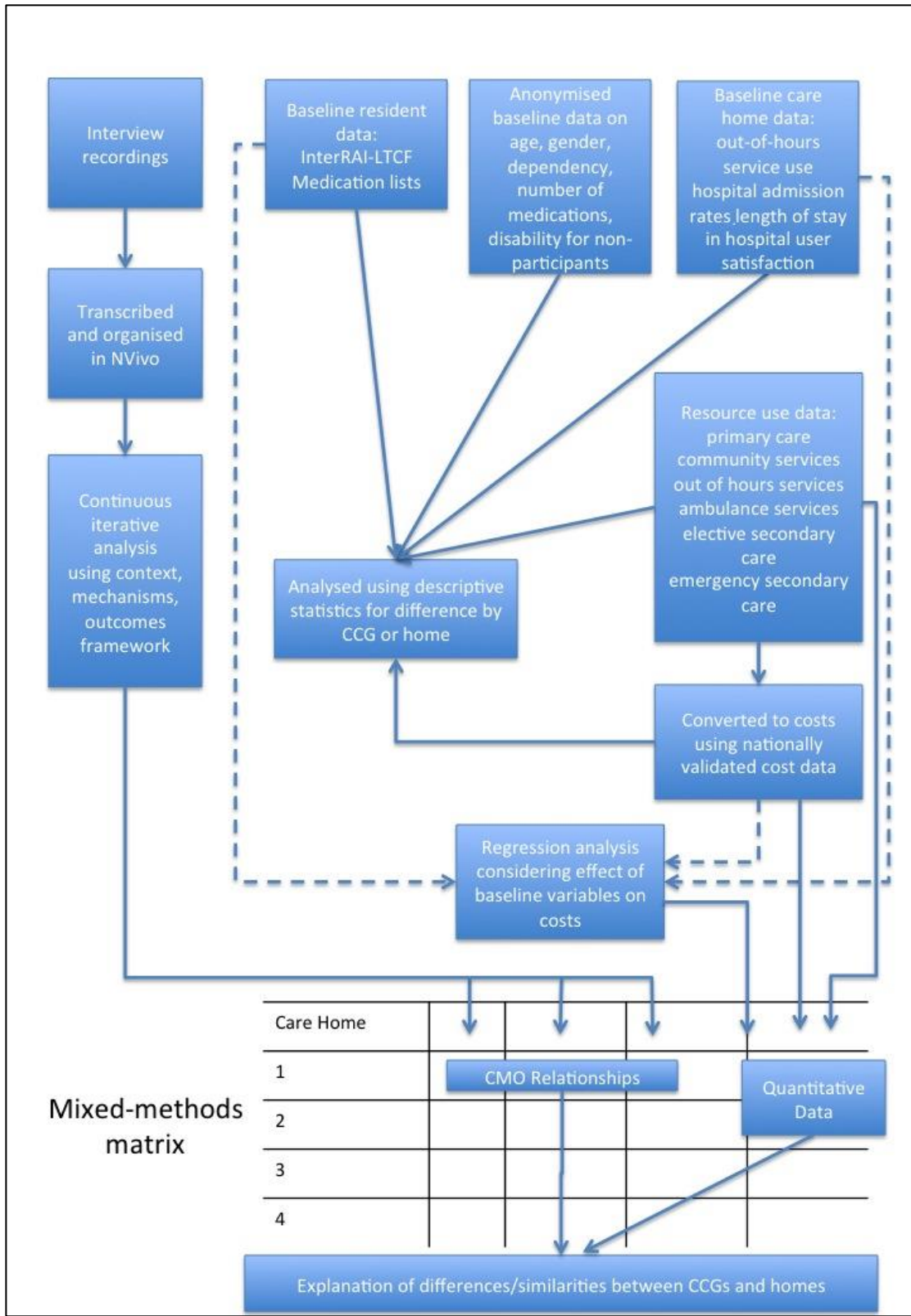


Figure 2 - Data Analysis Framework

### Qualitative Data Analysis

Data from interviews will be mapped and thematically organized to understand how participants represent their experience of health care delivery and what supports or inhibits the process.

Analysis will seek to build-upon, refine or validate the proposed Context, Mechanism, Outcome (CMO) relationships postulated during phase 1. This will involve an iterative process of pattern-matching and explanation-building for each CMO relationship. Evidence “threads” will be developed by analysing and then integrating the multiple data sources, aiming to describe the mechanisms which support the achievement of desired outcomes from NHS interventions, and the contexts in which these work. For example, an early iteration of analysis might describe that systematic and proactive care by GPs with additional training in geriatric medicine (mechanism) reduces unscheduled hospital attendances (outcome) where there are financial incentives and targets for GPs visiting care homes (context). Further analysis would then use other data sources to test whether the CMO specification works and establish, for example, what particular aspects of incentives and targets chosen (contexts) support effective care (mechanism) to improve outcomes.

### Quantitative and Health Economics Data Analysis

Quantitative data, including service use, will be reported using basic descriptive statistics, and compared across CCGs and care homes. Analysis will be conducted within the confines of case study design. For each home, the characteristics of the residents recruited and not recruited to the study will be compared to understand the implications of any differences in recruitment. Descriptive statistics will also be used to compare baseline characteristics of recruited residents from each care home using data from the augmented InterRAI-AL.

For each recruited resident the number of contacts with primary care, community services, out of hours services, ambulance services and both elective and unplanned secondary care post recruitment will be separately summed over the 12 month study period. Service use for each item will be converted to costs using validated national unit costs data<sup>20</sup>. Costs for each category of care will be summed to provide a total cost for each resident. Descriptive statistics will be used to summarise these data for each care home, with particular focus on resource use outcomes (use of out of hours services, A&E, unplanned hospitalisations and lengths of stay). Statistics on resource use will be calculated on a *pro rata* basis for residents who move out of the care home, withdraw from the study or die before the end of follow-up, and explored separately. Means, standard deviations, and frequency distributions will be examined with t-tests and chi-square tests used as appropriate.

Regression modeling (after adjustment for non-normality in the distribution of costs) will be used to investigate which characteristics of residents, care homes, and regions are most strongly associated with costs (separately for total, primary and secondary care costs). To explore the effects of the variables collected at baseline on outcomes at follow-up and also control for the effects of these variables, hierarchical linear regression will be used with the baseline variables (resident characteristics and baseline measures) entered first in the regression equation. In the second step of the regression model, we will enter care home characteristics and the region effect (dummy coded) to examine the effects of these contextual variables on the outcomes of interest that were measured at follow-up.

### Synthesis

As a final analysis, relationships between qualitative, quantitative and health economics data will be explored using accepted methods for synthesis of mixed-methods research<sup>20</sup>.



A matrix will be generated with the rows representing individual homes and columns organised to reflect the key context, mechanism and outcome propositions. Additional columns will hold the data generated from resource use and cost outcomes. Qualitative cross-case analysis will then be undertaken, taking account of similarities and differences between individual homes. The particular focus will be on what the data reveal about the interrelationships between the mechanism or features of care and how this is affected by the characteristics of the service as delivered and the wider context. Attention will also be given to the linked process outcomes of interest.

This stage will seek to further establish, or refute, the emergent context, mechanisms and outcomes framework (CMOs) and to identify insights which might be missed by considering each of the data-streams in isolation. A key step will be identifying the similarities and differences (demiregularities) in CMOs recognised and which of these are integral to effective service delivery. These demiregularities, in addition to the CMO relationships, will be used to establish practical recommendations which make sense in a clinical setting and which can be applied by health and social care commissioners.

#### Patient and Public Involvement

The Optimal Study is supported by a study steering group, which provides oversight of the entire project. This comprises two lay-members who have had family members in care homes, as well as a representative of the Relatives and Residents' Association. Care home organisations are represented by national representative bodies and care home managers, regulators through a representative of the Care Quality Commission, healthcare commissioners through the presence of an NHS commissioning manager and the health professions through the presence of a consultant geriatrician and nurse uninvolved in the design of the project. In addition to providing ongoing oversight for the project, this group will provide direct input into the analytic stage of research, contributing to and testing the

robustness of the proposed the context, mechanism, outcome threads. This will contribute to both face validity and the broader relevance and generalizability of the findings.

In addition, patient and public representatives will play an active role in supporting the recruitment and consent process as outlined in the methods above.

## **Conclusion**

The organisation and day-to-day running of long-term care facilities differs significantly between countries despite the fact that resident cohorts are very similar in terms of the types of care they require<sup>12</sup>. This has more to do with historical and political factors than with the optimal configuration for care delivery. One consequence of this has been that, despite the growing number of research studies conducted in long-term care, international collaborative studies been less common<sup>23</sup>.

If multinational studies in long-term care are to become more commonplace this will, most likely, be in the context of evaluating clinical interventions. Collaborative studies considering the organisation of day-to-day care and health care support are less likely due to the organisational issues already outlined. It is possible, however, that methodological discourse will allow the international community of long-term care researchers to learn from each other's approaches.

In the UK, we face particular challenges in reducing variability of health care provision to long-term care through strategic commissioning and development of services. Developing a research protocol which will generate evidence from existing service models to support such strategic quality improvement has led us to employ realist evaluation methodology. We are not aware that this has been used, to date, to consider models of service delivery in long-term care settings and we present it here to facilitate international methodological

discourse around research in long-term care. Clearly the methodology would require adaptation to take account of strategic and organizational differences in other nations but the fact that it uses a detailed understanding of care arrangements already in place to determine what data should be collected means that it has considerable portability, so long as adequate preparatory work is undertaken.

## **Ethical Approval and funding**

The Optimal Study is independent research commissioned through the National Institute of Health Research Health Service and Delivery Programme (HS&DR 11/1021/02). The views expressed in this presentation are those of the author(s) and not necessarily those of the NHS, the NIHR or the Department of Health. The study has received ethical approval from the UK Social Research Ethics Committee, reference number 13/IEC08/0048.

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