A Quality Improvement Collaborative Aiming for **P**roactive H**EA**lthcare of Older People in **C**are **H**omes (**PEACH**): a realist evaluation protocol.

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# **Keywords:**

- 1. Organisation of health services
- 2. Quality in health care
- 3. Protocols & guidelines

#### Word count:

4,171 words (excluding title page, abstract, summary box, figure, and references)

#### **Abstract**

#### Introduction

This protocol describes a study of a Quality Improvement Collaborative (QIC) to support implementation and delivery of Comprehensive Geriatric Assessment (CGA) in UK care homes. The QIC will be formed of health and social care professionals working in and with care homes and will be supported by clinical, quality improvement, and research specialists. QIC participants will receive quality improvement training using the Model for Improvement. An appreciative approach to working with care homes will be encouraged through facilitated shared learning events, quality improvement coaching, and assistance with project evaluation.

### Methods and analysis

The QIC will be delivered across a range of partnering organisations which plan, deliver and evaluate health services for care home residents in 4 local areas of one geographical region. A realist evaluation framework will be used to develop a programme theory informing how QICs are thought to work, for whom, and in what ways when used to implement and deliver CGA in care homes. Data collection will involve participant observations of the QIC over 18 months, and interviews/focus groups with QIC participants to iteratively define, refine, test, or refute the programme theory. Two researchers will analyse field notes, and interview/focus group transcripts, coding data using inductive and deductive analysis. The key findings and linked programme theory will be summarised as context-mechanism-outcome configurations (CMOs) describing what needs to be in place to use QICs to implement service improvements in care homes.

#### Ethics and dissemination

The study protocol was reviewed by the NHS Health Research Authority (London Bromley research ethics committee reference: 205840) and the University of Nottingham ethics committee (reference: LT07092016). Both determined that the PEACH study was as a service and quality improvement initiative. Findings will be shared nationally and internationally through conference presentations, publication in peer-reviewed journals, a graphic illustration, and a dissemination video.

### **Summary box: strengths and limitations**

- 1. A realist evaluation approach will enable an in-depth study of how a QIC intervention works (or not), for whom, and also in what ways when used to implement and deliver CGA in care homes.
- 2. Two researchers will analyse the data, and the whole study team of multidisciplinary academics will be involved in interpreting the data during the programme theory generation, testing, and consolidation to improve validity of the findings.
- 3. The study team will act as both intervention facilitators and evaluators, and thus will have first-hand experience of how a QIC approach works in this setting, for whom, and in what ways.
- 4. This dual role for the study team may introduce bias due to socially desirable responding, which will be mitigated through self-reflective techniques and member checking.
- 5. This is a study of one QIC used to implement and deliver CGA in care homes in one region of the UK, and therefore generalisability will pivot upon establishing mid-range theory applicable in other settings.

### **Introduction**

A large and growing number of older people with frailty live in care homes. The total care home population is approximately  $433,000^1$ , of whom approximately 170,000 have high dependency needs (needing 24 hour nursing care)<sup>2</sup>. The number with high dependency needs is forecast to increase to approximately 310,000 by  $2035^2$ .

This forecast presents challenges for health and social care providers. Current healthcare services do not adequately meet the needs of care home residents, let alone being prepared for future growth. Iliffe et al<sup>3</sup> reported working relationships between the NHS and care homes lack structure and purpose, with wide variation in the provision of both general and specialist healthcare services to care homes. The current challenge is to develop existing services to meet peoples' care needs<sup>4</sup>. Comprehensive Geriatric Assessment (CGA) is the accepted standard process of caring for older people with frailty. The process starts with a holistic assessment of an older person, which is then used to develop a comprehensive care plan that is then delivered using multidisciplinary, and coordinated specialist care. CGA has a strong evidence base showing improved outcomes<sup>5</sup>, however there is evidence that CGA is not currently taking place in care homes<sup>6</sup>.

One possible approach to facilitate the practice change necessary to implement CGA is a Quality Improvement Collaborative (QIC) intervention<sup>7</sup>. The QIC approach focuses on implementing evidence into practice by facilitating shared learning using 'Plan, Do, Study, Act' cycles to reflect and build upon changes made in practice in an iterative way. In a QIC, clinical and quality improvement experts provide teams with guidance, improvement ideas, structured activities, and encouragement to improve the quality of healthcare service, usually for a limited period of time (approximately 1-2 years). The way QICs are delivered vary<sup>8</sup>, but they generally comprise five essential features: (1) focus is on a specified topic; (2) provision of ideas and support for improvement by clinical and quality improvement experts; (3) participation by multi-professional teams from multiple sites; (4) utilisation of a model for improvement (setting targets, collecting data and testing changes); and (5) the requirement for collaborative participants to engage in a series of structured activities<sup>9</sup>.

Recently, Wells et al<sup>10</sup> systematically reviewed the evidence around QICs, and found that 83% of the 64 included studies reported an improvement in one or more of the study's primary effect measures. Four of the included studies were conducted in a care home setting and used the QIC intervention to improve care. The specific aims in these studies were to reduce falls<sup>11,12</sup>, reduce pressure ulcers<sup>13</sup>, and improve painmanagement processes of care and outcomes<sup>14</sup>. Three of these reported improved outcomes after the QIC, namely reduced pain prevalence<sup>14</sup>, reduced falls incidence<sup>11</sup>, and improved pressure ulcer prevention and care<sup>13</sup>.

Systematic reviews, like the one conducted by Wells, are useful in describing the effectiveness of an intervention but cast less light on the mechanisms by which it operates. QICs are complex, multifaceted, context-sensitive, social and behavioural interventions. The intervention recruits collaborative teams of people employed across different organisations, environments, and seniority levels. Effects of QIC interventions are likely to be a consequence of social interactions, and team dynamics which are influenced by organisational structures, cultures, and social norms. It is important to understand these interactions, and the different factors that influence the extent to which interventions are effective<sup>9,15</sup>. Research literature describes how QIC interventions are generally thought to work, and describes barriers and enablers of using QIC interventions in care home settings<sup>11-14</sup>. These insights are outlined in box 1, and comprise our initial programme theory.

## Insights from quality improvement literature describing how QICs are thought to work

By collaborating and comparing practice, teams will be motivated to do things differently and make changes to practice that improve patient outcomes<sup>16</sup>.

QICs are a learning organisation which empower teams to address quality problems through providing motivation, knowledge, skills and support<sup>17</sup>.

The QIC intervention creates a collaborative environment which provides an opportunity for diverse participants to come together, reflect and learn. New learning and insights are then shared across the collaborative and taken back to employing organisations<sup>18</sup>.

# Barriers and enablers of using QIC interventions in care home settings

#### Barriers:

- Fear of potential side effects when changing medication<sup>14</sup>.
- Problems occurring at the care home at the same time of the QI project (e.g. staff shortages) resulted in the QI project being seen as a low priority<sup>14</sup>.
- Difficulties applying quality improvement methodology<sup>14</sup>.
- High turnover of key members of staff involved in the QIC<sup>14</sup>.
- Complexity of the intervention and complexity of applying the change 12.

#### Facilitators:

- One-on-one mentors kept quality improvement work as priority, and simplified project tasks<sup>14</sup>.
- Providing simplified and incremental project steps to nursing home staff<sup>14</sup>.
- Effective communication (both inside and outside of formal meetings) to facilitate sharing and receiving new ideas, and passing on learning from pilot testing<sup>11</sup>.
- Allowing time for buy-in decision<sup>11</sup>.
- Engage wider range of care home staff in the process of quality improvement as multiple levels of staffing will affect the decision to adopt new care practices<sup>12</sup>.
- QIC project depended on self-selected, motivated and diligent nursing homes<sup>13</sup>.

Box 1 Initial programme theory - insights from the literature describing generally how QICs are thought to work, and evidence describing barriers and enablers of using QIC interventions in the care home setting

This study will address a gap in the body of knowledge. The existing literature on care home QICs comes from outside the UK. It is possible that QICs will be challenged in this context in the UK because of the complex arrangement of health and social care provision in this setting, meaning that responsibilities can either be unclear or disputed<sup>19</sup>. In addition, CGA is a particularly complex intervention, such that it may be less amenable to introduction by QIC than more straightforward approaches. Box 1 presents insights around how QICs are thought to work generally, and a description of barriers and enablers of the QIC approach used in care home setting. The current study will build on this and use a realist approach to develop a detailed programme theory presenting context-mechanism-outcome configurations which answer the questions what works, for whom, and in what ways when a QIC is used to improve delivery of CGA to people living in UK care homes.

# **Methods and analysis**

# Study framework

This study is one component of a programme of work called the Proactive HEAlthcare of Older People in Care Homes (PEACH) programme. The PEACH programme, funded by The Dunhill Medical Trust (grant number FOP1/0115), consists of 4 components. The first component, work-package one, is centred around delivering the QIC intervention, and carrying out a realist evaluation (described in this current protocol) to build a programme theory describing what works, for whom, and in what ways when a QIC intervention is used to support delivery and implementation of CGA to people living in care homes. The second component uses a realist review methodology to review the evidence base and identify and characterise a programme theory that underpins the CGA intervention<sup>20</sup>. The third and fourth work packages are orientated around evaluating the activity of the QIC, collecting data around health care service use, and care home resident well-being. This article describes the protocol for work-package one.

QIC interventions are complex human interactions9. The ability of QICs to achieve the desired outcomes of service change and improvement are context sensitive and will change over time. We chose realist evaluation as an approach to understanding this because it focusses on describing how outcomes are achieved by mechanisms which operate to a greater or lesser extent depending on context. It looks for recurrent patterns of context, mechanism and outcomes, described as demiregularities. This enables a middle-range theory to be established which can be applied outside the context of study. The realist evaluation approach is theory-driven and is based on realist philosophy<sup>21</sup>. It addresses questions around how complex social, multifaceted interventions work, and under what circumstances. One key tenet of the realist evaluation approach is that interventions have an implicit underlying theory which describes how change occurs. The findings will present a programme theory underpinned by context + mechanism = outcome (CMO) configurations describing the lessons learnt. The context (C) will describe the setting or conditions in which an intervention (in this case the QIC) is implemented. The mechanisms (M) will describe the causal forces, triggers, or interactions that generate change within a given context. The outcomes (O) will describe the actions or changes observed as a result of the QIC intervention. Each CMO configuration will present propositions stating what is it about the QIC intervention that makes it work, for whom, and in what ways to implement and deliver CGA<sup>21</sup>. This protocol follows the RAMESES standards for reporting realist evaluations<sup>22</sup>.

#### Research aim

Use a realist approach to establish the contextual and mechanistic factors associated with achieving desirable outcomes when a QIC intervention is used to improve the delivery of CGA to people living in care homes. A detailed programme theory will be developed that presents CMO configurations that describe the necessary contextual and mechanistic factors which generate desirable outcomes.

### Research question

What works, for whom, and in what ways when a QIC intervention is used to improve delivery of CGA to people living in UK care homes.

### The Quality Improvement Collaborative Intervention

The aim of the QIC intervention will be to improve the delivery of CGA to people living in care homes.

The QIC intervention will be delivered by the project improvement team (ALG, JB, JM, RD), a clinical academic geriatrician (ALG), a nurse leader with expertise in appreciative methods to promote quality of life in care homes (JM), a Health Foundation Quality Improvement Fellow (JB), and a health psychologist with interest in quality improvement (RD).

The QIC intervention (September 2016 - February 2018) will involve 4 facilitated all-day shared learning events for the 4 multi-professional groups of participants, at neutral venue, where all participants will be away from their usual work environment. These events will comprise activities to build relationships between participants, training on CGA and quality improvement methodology, opportunities to reflect on local needs/priorities, to develop quality improvement plans, update on progress and share learning with each other. The activities and group exercises will use an appreciative inquiry approach that focuses on identifying what is working well and why, envisioning how things might be, identifying how to work together to make this happen and exploring what more needs to be done to make this happen more of the time. Each meeting will include opportunities to network with other groups located in differing geographic areas but who share similar quality improvement challenges, working on the similar themed projects. In between the large-group learning sessions, participants will meet among themselves at their own site locations in order to review progress with their local quality improvement plan. On-going support from the project improvement team will be provided with coaching and mentoring, support with arranging meetings, email contact, directing teams to relevant local resources and relevant research, and support with evaluating the impact of their quality improvement plans.

### Study setting

This 24-month study (September 2016 – August 2018) will take place across four local areas of one geographical region within an area in the Midlands region of England, UK.

### Target population

The aim of the QIC intervention is to improve the delivery of CGA into care homes in four local areas. In each of the four local areas a team of mixed multi-professional health and social care professionals needed to deliver CGA will be recruited, and thus a purposive sampling technique will be used. Depending on local staff availability and willingness to take part there will be approximately 7-10 participants in each of the four groups, with the following professional roles represented in each; general practitioner, social care staff, nursing staff, therapist, geriatrician, voluntary sector, pharmacist, dementia specialist, care home workers/managers, and members of the public. To recruit these participants the person with responsibilities of planning/purchasing healthcare services for older people in each of the four local areas will be asked to identify the relevant local key health and social care professionals to take part. Those who plan/purchase healthcare services for older people will hold local knowledge and oversight of key and local health and social care staff members. Each group member will bring their expertise, experience, and local knowledge to the quality improvement project. General practitioners and care home staff will be provided with backfill payment for their time taken to attend meetings as they are independent sector workers and only able to attend meetings if adequate staff cover is arranged to cover workload.

# **Environment surrounding the evaluation**

The study will take place in a single region in the Midlands of England, UK. Care homes and NHS provider organisations within the geographical areas (4 sites) will form the focus of interest. The NHS provider organisations are responsible for healthcare delivery for 670,751 people, of which 73,301 are over the age of 70 and commission primary healthcare delivery from 114 GP practices. The region includes a mixture of urban, suburban and rural settings, and a mixture of affluence and deprivation. The NHS provider organisations interface with two local authorities which commission statutory healthcare from 185 care homes. The variety of care provision within this region is such that findings from the area are therefore likely to be generalizable to most other UK settings. The local health and social care economies have previously been involved in a number of high profile initiatives related to care homes and there is a track record of successful collaborative working in this regard.

### **Data collection**

Observations, interviews, and focus groups will be the core methods of data collection used to develop, test, and consolidate the programme theory that will describe what works, for whom, and in what ways when a QIC intervention is used to improve the delivery of CGA to care homes. These methods will enable a deeper insight and understanding into how participants interact with the QIC intervention, contextual influences, mechanistic factors, and the outcomes produced. In particular, the interviews and focus group methods will allow a deeper exploration into individual participant views, experiences, and motivations whilst taking part in the QIC intervention. Interview and focus group methods will also allow the programme theory to be the subject matter and used to guide the conversation, while also enabling the researcher to ask open ended questions to develop an understanding of the underlying particular contextual and mechanistic factors. Additional data describing the impact of the QIC will also be available, and will inform the O part of the CMO configurations in the programme theory.

## Observations

These will include ethnographic observations of collaborative learning session meetings, smaller collaborative group meetings taking place in between large meetings, and CCG area steering group meetings. In particular, these observations will look at how members of the QIC collaborative groups interact, engage, and work together, and also the factors that seems to influence group working. During these meetings groups will be observed, and field notes taken around the factors that appear to help the group to progress, and what more needs to be done to make it better.

Ethnographic observations of the CCG site steering group meetings will provide insights into other care home-related activities taking place in the CCG area, and other information that may be relevant to the

study. Observations made during the collaborative learning session meetings by the team will be reflected and discussed within team meetings. Field notes will be recorded in all the meetings observed.

### *Interviews/focus groups*

Interviews and focus groups will be carried out with the participants at each stage of theory development. These data will provide information about the QIC process and how it works. All interviews will be transcribed verbatim. Four groups of between 7-10 mixed multi-professional health and social care professional participants will take part in the QIC intervention (described above). The aim is to interview each of these participants, giving a minimum sample size of approximately 28-40 participants. Additional theoretical sampling will be guided by emerging context, mechanism and outcome frameworks and the need to inform these by insights from other professionals or care recipients with whom the collaborative have had contact. We anticipate conducting interviews/focus groups with participants more than once, and up to four times, during the course of the study, to gain an understanding of the intervention as it develops.

#### Additional data

Field notes will be made from informal discussions with the participants, and relevant documents such as relevant meeting minutes and organisational reports will be examined to look for consistent patterns (referred to as demi-regularities) in the data and possible linkages which can then inform the development of the CMOs.

#### Service level outcome data

Service level outcomes describing hospital emergency admission rates, hospital length of stay, 30-day readmission rates, ambulance use, GP out of hours use for each care home will be available. These data measure the impact of the quality improvement work, and thus will help to interpret the outcomes of the quality improvement work carried out by the QIC participants. A monthly care home level breakdown will be available, and will provide an indication of how the QIC is affecting service level use. These data will be collected using an automated algorithm designed to identify care home resident service use from NHS hospital databases<sup>23</sup>. These data will be analysed using an interrupted time series approach.

### Qualitative data analysis

Two researchers (RD, NC) will analyse field notes, and interview/focus group transcripts, coding data using both inductive and deductive analysis. Key themes describing important insights around contextual, mechanisms (resources and reasoning), outcomes will be identified. Both researchers will compare coding and any discrepancies in coding will be discussed between themselves (RD, NC), and where necessary other team members will be involved.

Coded data will be organised using NVivo software. Nodes will be created for every insight thought to be important for the programme theory describing how QICs works, for whom, and in what ways when used to improve healthcare services delivered into care homes. Nodes will be organised into folders, and coded data imported to appropriate nodes. Each broad node will contain related data (relating to CMOs) and emerging patterns will be looked for in the data and CMOs assembled.

At the stages of programme theory generation, testing and consolidation, the whole study team will be involved in data interrogation and interpretation and involved in ongoing discussions to verify interpretations and conclusions.

### Data synthesis

The insights generated from observations, interviews/focus groups, additional data (informal discussions with participants and relevant document analysis) and service level outcomes data will be synthesised. A matrix will be generated, consisting of rows where each of the 4 sites will be represented, and columns containing data on context, mechanism, and outcomes for each. Additional columns will contain service level outcome data, and linkages in data will be made, helping to identify insights around how the quality

improvement work and the impact on healthcare services. This matrix will help to synthesise the data, and thus enable the programme theory CMO configurations to be formed.

### Programme theory development

Our study findings will present a programme theory that describes what works, for whom, and in what ways when a QIC intervention is used to improve delivery of CGA in care homes. The stages of the realist enquiry will be: developing (stage 1), testing (stage 2), and consolidating (stage 3) the programme theory. This will be an iterative process, building a programme theory by collecting data from those taking part in QIC intervention activities. Data will be collected from the participants at every stage of theory development, and therefore it is likely that participants may take part in repeat observations/interviews/focus groups at different stages of programme theory development. This is in line with Pawson and Tilley's<sup>21</sup> recommendation that participant recruitment is based on 'CMO investigation potential'. Different participants will have different experiences and be able to reveal valuable insights around different parts of the underlying programme theory. Repeat observations, interviews, and focus groups will be carried out with the same participants over the programme theory development stages.

# Stage one: theory generation

During stage one, an initial rough programme theory will be developed. This will consist of initial CMO configurations generated from insights from relevant literature, interviews/focus groups, and ethnographic observations of the collaborative groups during meetings. Data from these will be used to identify themes, categories, mechanisms, and contextual factors associated with improved quality of healthcare. The relevant literature examined will include the broad quality improvement literature, broad QIC and QIC in care homes literature, and the communities of practice literature.

### Stage two: theory testing and refinement

The programme theory CMOs generated during stage one will be tested and interrogated through further observations of QIC meetings, and through conducting further interviews, and focus groups. Participants taking part in stage two data collection will be selected purposively based on their 'CMO investigation potential'<sup>21</sup>. The interviews and focus groups in this stage will take place towards the end of the QIC intervention. The programme theory CMOs will be the subject matter of these interviews and focus groups where the programme theory CMOs will be fed back and discussed with the participants. Once the CMOs are presented the participants will be asked questions around whether or not the CMOs capture their experience, whether there is anything missing, and if anything should be amended. The initial programme theory during this testing stage will either be accepted, rejected or modified. Refinement of the programme theory CMOs will be carried out iteratively and continuously tested in subsequent interviews and focus groups.

### Stage three: theory consolidation and validation

The refined programme theory will be reflected back to the participants during two consultation events. These will take place approximately three months after the QIC intervention completes. These will allow the participants to comment on the accuracy of the programme theory in mirroring their experiences of taking part in the QIC intervention. During this process the programme theory CMOs will be presented to the participants and validation will be sought by checking if the participants agree or disagree. Modifications will be made in in light of their comments. Other researcher groups known to the authors who have conducted similar projects will also be consulted in order to use their experience to help build and affirm the final programme theory.

### **Public Involvement**

Members of the public were involved in developing the overall PEACH programme; the research questions, aims/objectives, the study outcome measures, and the study design. They read draft copies of the proposal, offered their comments, feedback, and ideas. These members of the public have first-hand experience of relatives in care homes. Their views, perspectives, and priorities helped towards informing the overall PEACH programme study design.

The public will also be involved in the QIC intervention component of the PEACH programme which is described in this paper. Members of the public will be recruited to join the four groups taking part in the QIC intervention. Similar to the health and social care professionals, members of the public will take part in the QIC intervention activities. They will also form the study population from whom data will be collected throughout stages of programme theory generation, testing, and consolidation.

Members of the public will also form part of an independent steering group committee who will regularly review the conduct of the study, study progress, emerging study findings, and ensure validity and credibility.

#### Ethics and dissemination

Both the National Health Service and University of Nottingham research ethics committees considered this study to be service development project and thus full ethics approval was not required (London Bromley REC ref: 205840, University of Nottingham ref: LT07092016). The findings will be of interest to people planning and working on improving health and social care services delivered to care homes. The research community, including healthcare improvement scientists will also be interested. The findings will be shared nationally and internationally through presenting at scientific conferences, and publishing in peer-reviewed journal. The findings will also be summarised creatively through a graphic illustration, and a dissemination video, both of which will be shared nationally and internationally. Two consultation events will also be held in local care homes taking part in the PEACH programme. The audience will comprise QIC intervention participants, and the care home staff, and relatives of residents involved in the PEACH programme. At these events other potential ways of disseminating the findings will be identified.

### Authors' contributions

ALG is the principal investigator of the PEACH project. ALG, JM, JB and RD delivered the QIC intervention. RD is main researcher carrying out data collection, and data analysis. NC is the second researcher analysing and coding data. KHS, AL, AU, GH are members of the research team, with CG, JRG, TD, CB, PL, SL, and FCM who are co-investigators of the PEACH programme. All authors contributed to the writing/editing of this protocol, and read and approved the final manuscript.

### **Funding statement**

The PEACH programme is funded by The Dunhill Medical Trust (grant number FOP1/0115)

# Competing interests statement

None.

# <u>Acknowledgements</u>

QIC meetings will be funded by the East Midlands Academic Health Sciences Network Patient Safety Collaborative as part of their programme of dissemination of gold standard practice across the East Midlands. We would also like to acknowledge the contribution members of the public made to the overall PEACH programme, and to the QIC aspect of the project that is described in this paper.

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