BACKGROUND AND RATIONALE

This proposal aims to inform NHS managers, clinicians, patients and the public about how best to organise services for frail older people in hospital. Frail older people admitted for acute inpatient hospital care are at high risk of adverse events, have long stays, high readmission rates and high rates of long term care use (1, 2). There is considerable evidence on how to assess and co-ordinate care for frail older patients with complex needs using Comprehensive Geriatric Assessment (CGA) (3). However there is continued uncertainty about how to target suitable recipients in a hospital–wide manner (4), and what is the most appropriate and cost-effective form of CGA for different settings.

Comprehensive geriatric assessment (CGA) is defined as 'a multidimensional, interdisciplinary diagnostic process to determine the medical, psychological, and functional capabilities of a frail older person in order to develop a coordinated and integrated plan for treatment and long-term follow-up' (5). CGA improves outcomes for frail older people, including survival, cognition, quality of life and reduced length of stay, readmission rates, long term care use and costs (3). CGA is the accepted gold standard method of caring for frail older people in hospital but it is unclear which types of patients benefit most.

The notion that CGA is the preferred form for frail older people is implicit in the call for this proposal, "Research to test new forms of acute medical care for frail elderly patients – how best to deliver Comprehensive Geriatric Assessment (CGA) hospital-wide in a cost-effective way?" so we will use the term "frail older people" to represent the target group for CGA throughout this document. This recognises the fact that age alone is an inadequate identifier for this group and that in the trials that showed the greatest benefit from CGA, patients were identified on the basis of need (3).

We recognise also that there is academic debate about defining the frailty phenotype. This research is not designed to resolve those debates, but will borrow the term "frail" to describe a population of (mostly) older people with health and social care needs in the medical, functional, cognitive and social domains. It is likely that this population will contain a high proportion of individuals who are measurably "frail" according to formal definitions of frailty, the precise prevalence depending upon the definition and assessment tool used to measure it.

We recognise also that while there is some debate about optimum models for delivery of CGA, the strongest evidence currently is for discrete, ward-based services, as opposed to peripatetic teams providing assessment and advice; liaison services that simply offer advice, rather than actively direct patient care, are not effective (3). Increasingly 'embedded services' - such as orthogeriatric units – are being developed in which the specialised care aspects of the service firmly embedded into the daily operational activity, often supported by specialist geriatric medicine input.

It is not clear where and when CGA should best be targeted to achieve maximum impact. The development of Stroke units is often held as an example of how to improve outcomes for a similar population group (older people with acute illness and complex disability). However frail older people tend to have a wide range of problems and may need be treated in multiple areas of the hospital (as currently conceived), in which CGA is not part of the clinical tradition (such as surgical and oncology units). The multifaceted nature of the problems that are seen in hospitalised frail older people means that a multidisciplinary approach is required; the added complexity and interdependency of the problems requires a degree of expertise. The challenge is to determine models of care that can deliver this combination effectively, efficiently and reliably in various settings. At present there is variability in service provision across the UK; this research programme seeks to exploit that natural variability to assess which models of care appear to work best in different settings.

We will describe existing models of care and develop and validate tools to deliver CGA on a hospital wide basis.

Research questions

The main questions addressed by this proposed programme of research are:

- How is CGA defined and recognised?
- How, and in what forms CGA is currently organised and delivered in the UK?
- Who receives CGA, and can we identify who benefits most?
- How can we develop tools to assist delivery of CGA on a hospital wide basis?

Aims and objectives

Aim

The overarching aim of this ambitious programme of work is:

- To provide high quality evidence to support the delivery of CGA on a hospital wide basis.

Objectives

The objectives of this proposed integrated research programme are to systematically:

- Define CGA, its processes, outcomes and costs in the published literature
- Identify the processes, outcomes and costs of CGA in existing hospital settings in the UK
- Identify the characteristics of the recipients and beneficiaries of CGA in existing hospital settings in the UK
- Use this new knowledge to develop tools which will assist in the implementation of CGA on a hospital wide basis.

We will achieve these aims and objectives using a series of interdependent workstreams, with an overarching management structure and embedded patient and public involvement, which will ensure delivery to time and budget, and relevance to key stakeholders.

A diagram of the proposed *workstreams* that we will use to deliver this programme of work their interdependencies and relationship to each other is illustrated in the project matrix diagram (see diagram of workstream interdependencies below).

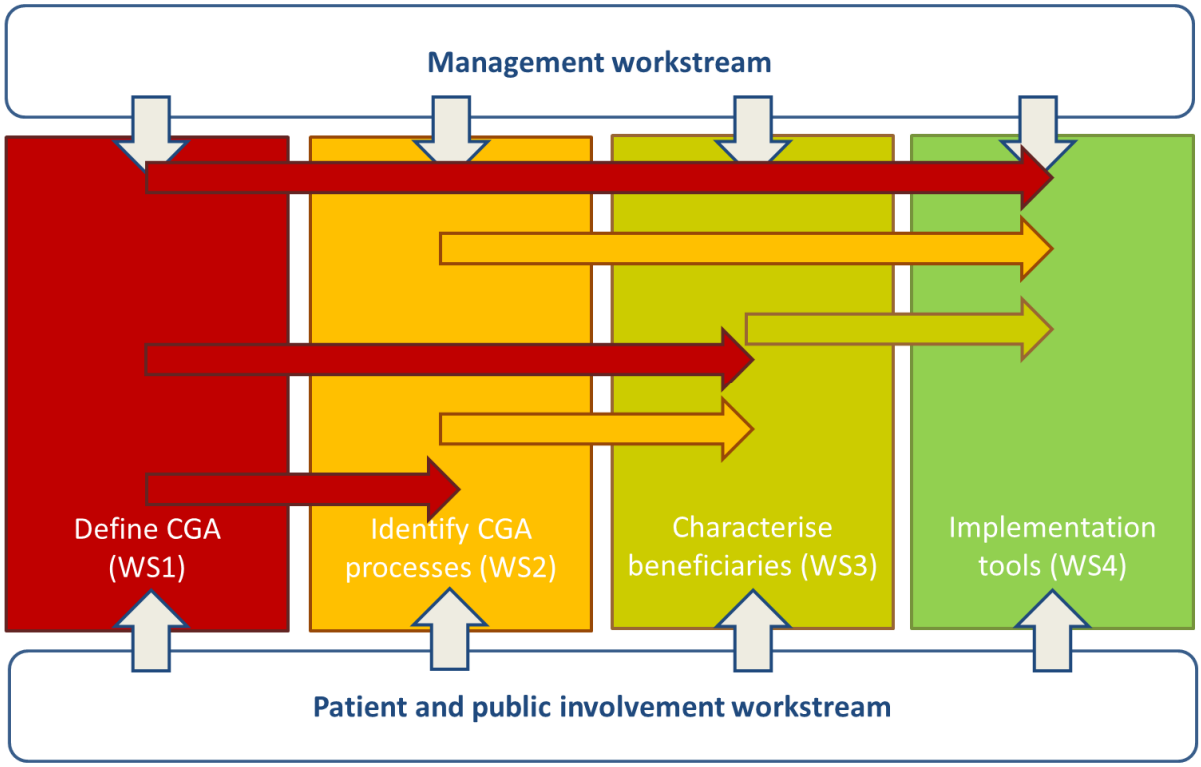

Figure:

This diagram tries to capture the project's interdependencies. It show that the two overarching work streams (management and PPI) are active throughout the full duration of the project.

The diagram also illustrates that each workstream builds on previous and parallel workstreams: the workstream that defines CGA will produce definitions that will be used by subsequent workstreams which identify characterise and produce implementation tools for CGA processes. This in turn will inform the characterisation of beneficiaries (as it will define that from which they benefit). Similarly the characterisation of the beneficiaries will inform the development of implementation tools (by defining - the intended target population for the tools).

Workstream 1 Defining CGA (M1-9). Parker. Workstream lead: Parker

Aim: to summarise current research evidence for Comprehensive Geriatric Assessment

Method: Rapid review of literature reviews

As this is an area where there has already been considerable research internationally and a number of systematic reviews, we will perform a rapid evidence synthesis which will focus on existing literature reviews (a 'review of reviews'). This will be supplemented by a limited review of recent trials and observational studies of direct relevance to UK clinical practice. This design will allow us to:

- rapidly review the formal evaluation literature and its messages on costs and effectiveness of models of delivery of CGA on a hospital wide basis
- explore the evidence base for and describe the service delivery and organisational features of recently developed models of direct relevance to UK clinical practice that may not yet been subject to randomised controlled trial and literature review, including work on implementation
- synthesise current understanding about how these alternative models of care are or may be implemented in the UK on a hospital wide basis

Where there are synergies with the review being carried out by Shepherd and colleagues, we will pool efforts to avoid duplication. Specific joint meetings will be established to facilitate joint working between the two teams.

The aim of the evidence synthesis is to provide NHS decision makers and the research team with an overview of the evidence relating to the models, outcomes and cost-effectiveness of hospital wide Comprehensive Geriatric Assessment (CGA).

The principle objectives of the proposed review of reviews are to define:

- the key elements of CGA, for example nurse-led models vs. geriatrician–led models and the timing of CGA
- principal outcome measures that have been used in RCTs
- the characteristics of the main beneficiaries of CGA included in the RCTs

and to summarise:

- the main findings about the cost-effectiveness of models of delivery of CGA
- gaps and weaknesses in the evidence base

We aim to do this across all relevant inpatient clinical areas (medicine, surgery, oncology etc). In addition we will aim to inform work on implementation by reviewing the recent observational literature on alternatives for delivery of CGA of relevance to the UK. During both of these research

activities we will seek to include evidence on patient and carers experience and views on the CGA process and emphasise evidence of most direct relevance to the UK/NHS context.

Research questions

The research questions for the literature review activities are also limited to the focus of the proposed programme of research, including:

- Can we identify a model of choice for hospital wide CGA using the evidence from literature reviews of CGA? If not:
- Can we identify a model of choice for hospital wide CGA in the UK using the evidence from high quality randomised controlled trials performed more recently than the most recent reviews? If not:
- Can we identify a model of choice for hospital wide CGA from the service delivery and organisational features of recently developed models in the UK that may not yet have been subject to formal evaluation? If not:
- Can we develop a CGA model that incorporates evidence from different reviews above?

The economic analysis of the literature will examine studies which report the economic impact of CGA. It will include studies which report on cost-effectiveness, cost-utility, cost-benefit and/or cost-minimisation. The review will summarise the overall health economic impact of different models of delivery of CGA, it will summarise the results with regard to:

- the scale, timing and study design
- the range of costs included and methodology employed to calculate the costs
- the outcome metrics employed
- the approach to marginal and opportunity costs.

It will also compare the factors associated with enhanced cost-effectiveness including the cost of the intervention, impact on wider use of services and improved outcomes. The review will compare the costs reported in the studies with benchmark costs across the NHS from other sources. These include the PSSRU unit cost estimates, national reference costs and tariffs (10). The dominant resource utilisation metrics such as rate of admission to hospital will be compared with national rates. Detailed descriptions of the review methods and timetable are included in Appendix 1.

Outputs from workstream 1.

1. A rapid, interim report for the research team, which will inform the further development of the project including the definitions and key elements of CGA at multiple levels (personal, operational, systemic) to be used through all the workstreams and identification of key outcomes **O1**

2. A full report detailing the review methodology and findings **O2**.
3. An executive summary summarising the key findings of the review.
4. A paper targeted at a clinical audience, summarising the key findings and providing a clinical interpretation of their relevance to UK practice **O3**.

Workstream 2. Identify CGA (M1-30) Parker, Bardsley, Conroy, Roberts

Aim: to identify and provide a description of current provision in the UK

This workstream will provide NHS decision makers and the research team with a description of the range and type of models of care which currently deliver CGA in hospitals in the UK.

Methods: a survey of current provision of CGA in the UK and creation of tools to understand the need for CGA

Workstream 2.1 a survey of current provision of CGA in the UK (M1-12). Workstream lead: Parker.

We will use the team's extensive connections within the NIHR Age and Ageing Specialty group and colleagues in the British Geriatrics Society to carry out the survey. The Age and Ageing specialty group (A&A) has nominated local group leads in 19 of the 15 NIHR Local Clinical Research Networks including those in Northern Ireland, Scotland and Wales and 16 of the 25 Comprehensive Local Research Network (CLRN) regions across England. The A&A group leads will contact senior clinicians and service managers with responsibilities in relevant acute health care services for older people (emergency department, out-patient and in patient services) in the regions of England and each of the devolved nations they are based in, and ask them to complete and return the questionnaire. In regions without A&A group leads, our colleagues in the BGS will be asked to contact the clinicians and managers to request their completion and return of the questionnaire. In the few areas with neither A&A nor BGS colleagues, we will contact the Clinical Directors by telephone and/or letter.

In this workstream we will:

- Develop a simple semi-structured questionnaire to survey current practice of CGA
- Pilot the questionnaire with clinicians and managers with relevant health care responsibilities locally.
- Survey relevant senior clinicians using the post-pilot questionnaire
- Analyse the questionnaire responses to provide a map of the different forms of CGA in current practice and provision in England and the devolved nations

We will work with Sasha Shepperd and colleagues to ensure the surveys to acute hospitals and community trusts include the same core set of questions. In addition we will ensure that the survey questions sent to acute trusts will include questions about hospital community outreach services to capture data on hospital at home out-reach services run by acute trusts, as well as those provided by community trusts. We will co-ordinate to ensure that survey recipients do not receive multiple approaches from our different teams, to respond to the two surveys.

Outputs from workstream 2.1

2.1 A brief report of the survey findings **O4**.

Workstream 2.2 creation of tools to understand the need for CGA (M1-30). Workstream lead: Bardsley

In this workstream we will create a series of basic tools that;

a. Stratify local populations to identify the numbers for people who may benefit from CGA

b. Apply a series of health system performance measures at area and provider level that relate to the care of frail older people

c. Develop simple interactive tools to compare patients' assessed potential benefits and costs

This workstream will use linked population level data sets (6,7) to better understand the scope for CGA. By stratifying local authority populations to mutually exclusive groups, we can identify a potential target population for CGA, when admitted to inpatient hospital care. For the sake of consistency, and acknowledging multiple caveats about the definition and measurement of the frailty syndrome, we will call this group "frail older people who may benefit from CGA". For this broad group we can identify a set of performance metrics, which we might reasonably expect to be influenced by the nature and quality of the inpatient care experience (particularly the use of CGA), for example annualised numbers of emergency admissions.

Using a population matrix to assign stratified populations to providers will enable us to provide a population level estimate of the numbers of "frail older people who may benefit from CGA", their outcomes, resource use and inpatient care settings when in hospital. These models will be refined and developed using information, as it becomes available, from the other workstreams (for example on inpatient care and a cancer diagnosis, surgical inpatient care etc.). We will validate the aggregate of these estimates against data for a subset of cases where we know that patients had CGA. This validation will be based on pseudonymous linkage from hospital records using the NHS IC- a technique that has been applied in number of evaluative studies (8,9).

These estimates will be used to develop "What if" interactive models as a tool for service providers and commissioners allowing them to explore the scope for modifications to services to (for example) reduce costs or utilisations or evaluate the potential effectiveness of interventions.

Outputs from workstream 2.2

- Report on the selection of metrics and the performance characteristics of derived measures (M1-M12) **O5**
- Report on variation in patient use/outcome measures by area/provider (M3-M12, **O6)** and revise M20- M24) <=input from workstream 3.2
- Interactive model of typical patterns of care use before/after CGA (M9-M18 and revise M24-M30) <=input from workstream 3.3

Workstream 3: Characterise beneficiaries (M1-24) Conroy, Bardsley, Roberts.,

Aim: Identify who gets, and who benefits from CGA in hospital

The existing research literature suggests that there is a greater benefit from CGA for those identified on the basis of clinical need (as opposed to age). Community based studies have shown that frailty (whether adopting the Fried criteria, the Frailty Index or any of a range of tools) does differentially identify those at risk of adverse outcomes [2, 3]. There is extensive evidence that frailty and the related problems of delirium and functional disability are associated with adverse clinical outcomes of acute illness and hospital admission (e.g. 10,11,12). It is generally assumed that clinical need for in-hospital CGA is captured by the frailty construct. However, a frailty dependant, differential response to CGA in inpatient hospital care has not been demonstrated (at least not in these precise terms).

Our own recent work tested five frailty-rating scales (Fried (CHS model) (8), Ensrud (SOF model) (14), Rothman (15), Ávila-Funes (16), a frailty index (FI) (17)) and the Identification of Seniors At Risk tool (ISAR) for their ability to identify a sub-group of older people at high risk of poor outcomes (readmission, institutionalisation, functional decline, death) following discharge from acute medical units. Although most of the scales performed better than chance in predicting a range of poor outcomes, none of them performed adequately (Area Under the Curve (AUC) <0.7), and most performed either poorly or very poorly. Those scales that included cognition (Ávila Funes, Rothman and FI) had better predictive accuracy for all outcomes bar institutionalisation ([1, 2]). However, there has been little work examining which frailty scales or risk identification tools might be most useful within the acute hospital context

Furthermore, frailty is not in routine use in ICD-10 or HES coding, so frail older people remain anonymous at the system level (in contrast to specific diseases such as stroke which are highly visible). The aim of this workstream is to assess if clinical frailty scales identify a population who are at risk of adverse outcomes, who will benefit from CGA and whether or not the frailty scales link to HES based markers.

Methods:

3.1. assess the relationship between frailty markers and longer term patient outcomes and service costs. Workstream leads: Conroy, Bardsley, Roberts

We will use existing datasets which contain a rich source of patient characteristics that allow frailty to be described, as well as detailed patient outcomes. The dataset from Nottingham Medical Crises in Older People NIHR funded programme grant (RP-PG-0407-10147) includes:

- 669 participants recruited at the point of discharge from Acute Medical Units in Nottingham and Leicester
- 250 participants with mental health issues (predominantly delirium and dementia) being managed in an acute hospital setting in Nottingham
- 227 participants from 11 purposefully selected care homes in Nottinghamshire

The dataset from Southampton collected as part of the Southampton NIHR-funded Biomedical Research Centre includes 339 participants recruited from geriatric medicine in-patient wards in Southampton.

The four datasets share common baseline data (demographics, Charlson scores, medication, Activities of Daily Living, Mini-Nutritional Assessment, Quality of Life, Mini-Mental State Examination),from which a Frailty Index can be created, as well as several frailty scales (see table below).

Common outcomes include functional ability, quality of life, mortality, institutionalisation and cumulative length of stay in hospital.

In addition to the existing outcomes collected already, it will be possible to link participants to their NHS and social care records using pseudonymised patient identifiers (14,15). This will permit the longer term assessment of health and social care outcomes, such as:

- Survival
- Living at home
- Measures of the frequency of emergency events
- Costs and activity of all health and social care use over one year

This will enable us to determine the extent to which clinical frailty rating scales predict short, medium and longer term 'need' characterised by resource use and the frequency of adverse patient events.

Table: Comparison of data available in the Nottingham and Southampton datasets.

Scale/domain	Item available in MCOP datasets	Item available in Southampton dataset
Fried		
Nutritional status	Body Mass Index; Mini-Nutritional Assessment	MUST score, Body composition –triceps skin fold, MUAC
Strength	Hand grip strength	Hand grip strength
Energy	Do you feel full of energy? (Geriatric Depression Scale)	Do you feel full of energy? (Geriatric Depression Scale)
Mobility	Walking speed, mobility from Barthel index	TUG, timed walk
Physical activity	Assessed by questions from EuroQol-5D (mobility, self-care, usual activities) OR Barthel	Assessed by mobility questions from Barthel
Ávila-Funes		
Fried plus cognition	MMSE	MMSE
Rothman		
Mobility	As above	
Physical activity		
Nutritional status		
Cognition		
Frailty Index		
Created from 70 data items	Frailty indices count the number of deficits present and describe these as a proportion of all deficits assessed; individuals with a frailty index of greater than 0.25 are at increased risk of adverse outcomes (13)	

3.2. test Hospital Episode Statistic based proxies for markers of frailty. Workstream leads: Bardsley, Conroy

If WP 3.1 indicates that frailty does indeed identify an in-patient population at risk of high resource use, we seek to link frailty to HES based markers in order to allow frail older people to be identified at the system level. This might involve algorithms of various HES codes such as dementia (F codes), syndromes such as incontinence (R codes), or dependency (Z codes). It may be that counts of these codes or specific combinations are sufficiently precisely linked to frailty to allow them to be used as proxy markers at the system level. If this is successful we will test the predictive ability of purely HES

models using techniques developed for predictive modelling of hospital admissions [16, 17]. These analyses will be used to refine the crude population base measures developed in WP2.2.
WP 3.2 will reveal the accuracy of HES based markers of frailty, which we will then be able to test the relative impact of CGA on frailty at the person level and national level in WP 3.3.

3.3. Estimate the potential impact of CGA on acute hospital care

If we are able to construct sufficiently reliable HES level markers of frailty linked to resource use, it will then be possible to estimate the potential impact of CGA for wider populations drawing on the effect sizes described in the literature (WS 1).
We will also validate these assumptions in more detail using existing randomised controlled trial data. The Nottingham programme grant includes a Randomised Controlled Trial (RCT) of a form of in-patient CGA being applied to an in-patient population of older people with physical and mental health problems (PIs Harwood and Gladman have agreed to share the data) as well as an RCT of CGA applied to a population of older people discharged from Acute Medical Units (PI Conroy). It will be possible to use the data sets to assess the differential impact of CGA according to the level of frailty using one or more of the chosen frailty scales. This will help validate the chosen frailty scales, for example by testing for a differential impact of CGA according to the level of frailty.

Understanding Cost Impacts

The analysis of costs will not conduct a formal costs effectiveness analysis but will develop estimates of resources associated with CGA. These will be used in the retrospective analysis of people who received CGA versus matched controls. General costs estimates will also be used to inform the modeling tools and to assist in planning implementation.
Cost identification is fundamental for cost and economic analyses of CGA. Most health care costs can often be derived from administrative databases such as standard NHS data such as service line reporting, tariff and reference costs. However to test the actual costs of the CGA, for example in terms of the costs of the clinical team undertaking the assessment, more direct methods are needed to collect the necessary data.
The costs associated with CGA will be split into two categories:

a. Direct costs of undertaking the assessment itself

To measure the costs associated with undertaking CGA we will employ direct methods of costing, gathering data through surveys and observation as done in prior study in geriatric management (18). The analysis will consider the following components: direct staff cost, training cost, consumables costs, some recognition of marginal overhead costs (e.g. IT, premises). Direct costs will be estimated

based on data on the time spent on assessment and the average labour costs according to level of skills. We will seek where possible to identify the marginal costs associated with CGA.
We will initially interview clinical staff to identify the key resource inputs and the nature of opportunity costs. From these interviews we will develop a basic questionnaire that will be used more widely to assess the level of resources used in new service models. The questionnaires will include elements at team level and patient level - which can be applied to selected series of CGA and non-CGA patients. These survey results will be used to estimate the direct cost of assessment by attaching national and local unit cost estimates to the measures of activity. We will develop estimates of the variability in costs inputs between delivery models.

b. Service costs of people who have had CGA

We will estimate patient level costs of care by using measures of resource and unit costs - so the results will be a form of weighted resource use rather than an actual measure of local expenditure. Though imperfect the approach provides a relative estimate of expenditure that can be used across sites and as a generalized planning tool and have been successfully used in number of prior studies (19,20). The costs elements will include:

i) *Inpatient spells.* Admitted patient care spells will be primarily costed on an HRG basis using national tariffs (21) or national reference costs (22) (adjusted for inflation). If neither of these sources provided costs for a HRG then average specialty costs will be applied.

ii) *Outpatient attendances.* As with inpatient costs, costs will be based on activity and the national tariff where there is a mandatory HRG or treatment specialty price, or otherwise derived from the 2007/08 reference costs. Costs of unbundled activity will be included where applicable.

iii) *Emergency department attendances.* ED visits will be costed using the relevant national mandatory tariff. This provides a limited set of costs, which are still assigned by the HRG3.2 code of the visit.

iv) *Social care.* Social care costs will be estimated for a subset of cases where linked data are available. Costing will be based on applying in unit costs derived from PSSRU23 to activity recorded in terms of days in nursing/residential care; hours home case; direct payments and adaptations. We will undertake sensitivity analysis to explore the scale of cost associated with self-funded social care using findings from national studies.

v) Primary and community services. As with social care cost estimate will be based on the limited records where linked data are available, and will use unit costs based on GP

contacts and community nurse inputs. These relative values will be inflated to estimate costs not covered by patient/professional contacts e.g. drugs.

Individual cost elements will be based on activity at person level as much as possible and summed over time to estimate costs per person per year. These will be analysed by patient subgroup.

Methods:

- Agreement and testing on a series of population level to be used for (a) initial population stratification to identify frail older people and (b) metrics to summarise performance of local health systems in delivering good outcomes of frail older people
- Population stratification used historically linked HES, ONS mortality files to prepare initial estimates.
- Validation and testing of derived metrics including mapping to patients identified as having received CGA via pseudonymous mapping to HESID by NHS Information centre.
- Map area level data to hospital providers using an activity matrix to assign stratified populations to providers. Measures would identify (a) Numbers of the local population stratified into risk groups (b) Series of metrics capturing 'outcomes' /resources input
- Estimates of service use associated with patient groups using additional data and selected local files (e.g. social care use) create area based measures.
- Development of interactive modelling tool to demonstrate the relationships between the scale of patient benefits, resource use and costs based on variable assumptions concerning; numbers receiving CGA, patient type and risk, relative effectiveness.

Outputs from workstream 3

- Linked data sets showing the association between frailty markers and levels of longer term provision of health and social care (M1-M7**, O8**)
- Reports (and paper) on comparative performance of frailty measures (M9**, O9**)
- Report (and paper) which identifies which HES based proxy markers are the most useful for identifying who would benefit from CGA (M9-M18**, O10**) =>input to 2.2BReport (and paper) on the relative impact of CGA on patients' service use and outcomes (M18-M24**, O11**) =>input to 2.2C

Workstream 4. Produce, disseminate and evaluate implementation tools (M0-27). Martin, , Conroy, Parker, Roberts.

Aim: Produce, disseminate and evaluate implementation toolkits to disseminate best practice in CGA

Earlier workstreams will produce knowledge about current trial-based models for delivering CGA, promising but as yet unevaluated approaches to delivering CGA in wider inpatient settings, and evidence for the relationship between CGA practice, service use and patient outcomes. Workstream 4 will synthesise this knowledge and seek to disseminate it to key decision makers in commissioning, provider and policy settings, in ways that account for the challenges of introducing and routinising a potentially disruptive intervention in complex systems. Alongside work to produce and disseminate CGA toolkits, we will undertake rigorous evaluation work to provide formative input in honing the toolkit, and summative knowledge on the feasibility and appropriateness of using this theory-driven approach to implementation.

4.1 Use outputs of workstreams 1-3 to define (and then validate) clinically and cost-effective models of care

Having defined the models of care using the survey and literature review, we will first test the face validity of the most promising models, recognising that they may need to be enhanced in these novel settings, e.g. patients in oncology may need CGA before and during therapy as identified by the DoH and MacMillan pilot sites (see (24)). This will be informed by drawing on (i) the expertise within the study team, (ii) the patient and public involvement forum, and (iii) an external reference group comprising key stakeholders, including commissioners, senior NHS managers, clinicians from different professions and specialist backgrounds, professional societies, third-sector organisations and PPI representatives through a Delphi process. This process of validating the models will help us to identify those most likely to be beneficial in clinical practice, and those models most likely to be beneficial in different contexts (e.g. surgery and oncology).

In addition we will also help identify stake holders to join the Delphi panel in Sasha Shepperd's project, using our close relationship with the NIHR Age and Ageing Specialty Network. The main criteria for selecting panel members for this purpose will be that they are informed about the implementation of CGA in different settings.

4.2 Develop implementation strategies and tools to help the commissioning and delivery of CGA on a hospital wide basis

Beginning from month 13, we will then seek to spread knowledge and use of these evidence-based, validated clinical models through the development of toolkits, the design of which will be informed by current theory on the process of knowledge translation. We recognise that increasing uptake of a new practice such as CGA widely and sustainably is unlikely to be achieved through a simple process of dissemination and implementation; rather, in a complex system such as the NHS, the process is

likely to be “messy, dynamic, and fluid” (25). An innovation like CGA—particularly novel models that take place outside geriatric medical wards - has the potential to be a very disruptive intervention, in the way that it impacts on organisational boundaries, professional jurisdictions and patient pathways. For this reason, we will draw on Normalisation Process Theory (NPT) as an overarching framework for designing, developing, evaluating and revising the toolkits, and within this framework deploy a number of evidence-based approaches to knowledge translation to seek to secure maximum uptake. In so doing we will also attend to specific domains identified as important in the implementation of disruptive change in healthcare in recent reviews (26).

We see NPT as a particularly apt framework for this task because it offers an understanding of the dimensions of disruptive organisational change in healthcare that is theoretically sophisticated and empirically informed, but also highly practical. NPT draws attention to the importance of several parallel sets of mechanisms in achieving routine embedding of new interventions in complex settings (27), and points towards the range of concerted actions by multiple actors that are needed to accomplish this (28). NPT does not suggest the exact tools and approaches that should be adopted in seeking to change healthcare practice, but rather offers a helpful, sensitising framework that informs thinking about what needs to be done by multiple stakeholders (29).

In developing both the toolkits themselves and the ‘infrastructure’ by which they are communicated to user communities, we will be informed by the key domains of NPT and the implications of these for what actions are needed by which stakeholders. We will develop strategies for getting the toolkits into practice that draw on the expertise and agency of our external reference group, gathering their insights on the content and framing of the toolkits, and harnessing their networks and influence for change. We will marry work aimed at the key professional groups involved in the delivery of inpatient care for older people with efforts to integrate CGA into organisational systems and priorities (30). We will pilot the toolkits with clinicians interested in developing CGA in their own organisations. With a view to ensuring that the toolkits are as practically useful as possible, we will work with clinicians adopting CGA (including those who have worked with us in piloting the toolkits) to develop case studies showing how it is used, how clinical processes can be adapted, and the impact on organisation of care and patient outcomes (incorporating evidence also from WP4.3 below). Existing resources will be identified (for example those produced by NHS Improving Quality and predecessor organisations to support organisational change) and new tools will be developed to fill key gaps. We anticipate that the toolkits will consist of an armoury of resources including, but not limited to, evidence summaries, best practice guidelines for commissioning and service delivery, assessment tools to assist in identifying those most likely to benefit, case studies, benchmarking tools for service delivery, and links to generic resources on organisational change. Resources

developed by the team will complement those already in existence, for example, RCP Acute care toolkit 3, BGS best practice guides. Whereas some resources will be text based, it is anticipated that maximum use will be made of social media. All resources will be available via the project website and links made with the websites of professional bodies (e.g. BSG, RCP, RCGP), Academic Health Science Networks (with several of which the team of investigators already have existing links) and third sector organisations in order to facilitate uptake. Resources will also be developed in partnership with third sector organisations such as Age UK and PPI representatives that focus specifically on the needs of patients and family carers and might include evidence summaries and key questions to ask clinicians.

4.3 Evaluate the toolkits and their implementation

Alongside this work to develop and implement the toolkits, we will also undertake a rigorous process evaluation. This will provide important formative knowledge in further developing and refining the toolkits and associated strategies. Given the relative novelty of the theory and the paucity of applications of the approach to date (especially in relation to the implementation of disruptive interventions that are not primarily IT-based), it will also offer an interesting case study of the application of NPT that will be of wider interest to the social scientific and health services research community. The study will involve both ethnographic observation and in-depth interviews with the breadth of relevant stakeholders. The first stage of the work will involve interviews with (i) project team members on their use of NPT in informing the development of the toolkits (n=~5), and (ii) expert group members on their contributions to the toolkits and views of the end product (n=~10). Building on this, we will then undertake a second stage of work the two the sites in which CGA is piloted under WP4.2 above, incorporating both ethnographic observation and further interviews. Our observational work will focus on both the 'backstage' work whereby the new intervention, and concomitant changes in processes, systems and professional relationships, are introduced and negotiated, and the 'frontstage' work of CGA in action, as used in the course of clinical encounters in new settings such as oncology and surgery. We will undertake approximately 80 hours' observational work in each site (240 hours in total). Interviews in this second stage will be with managers and clinicians involved in adopting CGA in clinical settings on the degree to which the toolkits gave rise to approaches to implementation that were successful and sustainable (n=~36 across two pilot sites, and including actors from across professional groups whose practice, role and responsibilities are affected by the introduction of CGA). Interviews will focus on the utility of NPT as an organising framework for approaching implementation (stage 1 group i only), the content and format of the toolkits themselves and the approaches to propagating their use, and the practicalities of using the toolkits in practice, including both work to integrate into clinical and organisational

systems, and clinical use of CGA with patients (stage 1 group ii and stage 2 only). We will also undertake a small number of interviews with patients and/or carers (n=~12 across the two pilot sites), with a view to ascertaining patients' and carers' views on CGA and its implementation in these settings. Interviews and ethnographic fieldnotes will be fully transcribed, and analysed integratively using the constant comparative method, as informed by sensitising concepts drawn from the NPT framework. Findings will be used to finalise toolkit content and format, to inform further strategies to support dissemination.

Outputs from WS4

Report defining evidence based clinically validated models of CGA to be tested (M1-17**,** **O12**)Developed toolkit to be evaluate in 4.3 (M22, **O13**)

Report documenting toolkits to be used to deliver CGA and strategies for applying them in clinical practice, informed by pilot studies and interviews with key stakeholders (month 30**, O14**)

PPI Workstream: Embedded PPI (M1-30) Kennedy, all workstream leads. Workstream lead: Kennedy

This workstream assures the contributions of PPI at different stages of the research process and in a range of research activities, from initial ideas generation, development of proposals through to data collection and dissemination of findings (29). To make PPI effective necessitates a whole organisation perspective and supportive infrastructure, with serious commitment from the programme, all workstream leads and appointed research staff. To achieve the benefits associated with meaningful and comprehensive PPI, funds will be allocated to:

1. Support a dedicated PPI workstream with an appointed lead to:
    a. manage, coordinate and actively support the various PPI recruitment and training activities in each of the four research workstreams (WS 1-4)
    b. advise and actively support the dedicated PPI researchers in their ongoing direct work with PPI volunteers across WS 1-4
    c. monitor and evaluate researchers and volunteers' experiences and impacts of PPI across the programme
    d. set up and manage the web-based PPI information and communication network within the proposed programme e-platform
    e. report on PPI activities to the management workstream
2. Meet with, reimburse and cover expenses of PPI volunteers and associated activities across all workstreams

3. Ensure the inclusion of PPI within the main duties and responsibilities of a dedicated individual in every workstream
4. Meet the costs of setting up and maintaining a web-based network

Work to access and recruit PPI volunteers into the programme has already begun, with support for our application and a commitment to help facilitate PPI received from AGE UK, the NIHR Ageing speciality group and NIHR Research Design Service for Yorkshire and the Humber, the Barnsley Consumer Research Advisory Group, Newcastle and Leicestershire PPI fora and a group of research partners associated with Macmillan Cancer Support. Through established contacts and colleagues in these, the CLRNs and other research and support groups and organisations we will recruit a diverse group of non-professional researchers interested in contributing to the programme.
To facilitate best practice (29), the PPI lead will provide information and support about PPI perspectives and practice to both the paid researchers and PPI volunteers. Any specific training will be informed by the generic workshop about PPI for researchers and PPI volunteers being developed by the NIHR Cancer Research Network and a research course for older carers delivered successfully by one of the co-applicants. As well as benefiting this programme, we anticipate involvement in this programme will contribute to enhanced research skills and increased capacity through enabling further community engagement in research, and PPI in the implementation of service innovations.
Impact and evaluation of PPI
The experiences and impact of PPI will be regularly monitored, evaluated and reported on. This will involve the researchers with responsibility for PPI in the four research workstreams providing regular feedback on PPI recruitment, activities and any emerging issues to the PPI programme lead for her to advise on and to collate and report as a standing item on PPI to the management group and present at a PPI event in the final year of the programme and at relevant national conferences. The findings will be published.
Reimbursement for public participation
In the different workstreams, members of the public may be asked to:

- Prepare and attend workstream meetings
- Review or provide feedback on documents (e.g. research briefs and reports)
- Undertake a range of tasks associated with the research process (e.g. comment on recruitment and sampling strategies, search terms, survey items, interview schedules; participate in teleconferences; discuss, contribute ideas and comment on implementation toolkit / resources)
- Provide verbal and or written feedback on their experiences of being involved in the project
- Attend peer support meetings and or conferences.

Members of the public who are asked to become involved will be offered payment for their involvement and to cover their expenses. The volunteers will be informed of the rates being offered for the particular type of involvement work they would like to undertake before they agree to undertake it. The rates of payment for different PPI activities will be in line with those recommended for NIHR Programmes and by INVOLVE.

Outputs from the PPI workstream

A stakeholder conference at month 20 (**O15**) will help influence the shape of the novel service to be implemented and evaluated in workstream 4

A report on PPI experiences and impact will be produced at month 30 (**O16**)

Statistical issues

Sample size calculations

Sample size calculations are provided here for the statistical modelling in workstream 3, which will use HES data to assess the impact of CGA.

Workstream 3

The primary endpoint will be the time to emergency hospital readmission or death.

It was thought important to detect a 15-20% difference in the primary endpoint (as measured by the hazard ratio) in either direction should it occur, at power 90% and p-value <0.05. Power calculations were performed in STATA v10 and assumed that:

- survival analysis will be undertaken using a log-rank test; one control is selected for each patient;
- 63% of patients will experience an emergency hospital readmission or death within a year (based on observed rates for people aged over 85 discharged from hospital during 2008/9 in England, HES data)
- a 15% reduction results in a comparison rate of 54% (we have used as reduction as this results in the larger sample size compared to a 15% increase to 73%); and
- patients are followed for one year.

Based on these assumptions, 1240 patients will be needed to detect a difference of 15%, while 706 will be needed for a difference of 20%.

Statistical Analyses

This programme of work will involve a wide array of analyses, which are best described in the context of each workstream in the detailed project plan.

Workstream 2

In workstream 2.2 the work on population stratification and the use of a range of performance metrics related to the care of older people, will exploit person level linkage of hospital records. We will test a series of direct and indirect standardisation methods to identify the impact of some potentially confounding variables in comparative analysis. These will include age, gender, measures of deprivation and variables related to local care provision (e.g. accessibility of hospital beds, social care places). Derived indicator values will be presented together with their confidence intervals.

The work on an interactive model will combine data from a number of sources including the estimates of costs; estimates of relative effectiveness; and data on the typical range of services used over time and on patient outcomes. The potential impact of changes in the volume of cases receiving CGA or varying assumptions about effectiveness on population level outcomes and overall costs will be explored using descriptive statistics to model the effects.

Workstream 3

In workstream 3 we will create statistical models to test the impact of the frailty markers on patient outcomes and future service use, standardising for other variables at person level including nature of

CGA, medical history and service use. This phase will identify those people who could benefit from CGA and their prevalence in different hospital settings, which will inform workstreams 3 and 4.

We will build a series of regression models which will assess the relative strength of different variables in influencing patient outcomes assessed in terms of:

- Survival
- Living at home
- Measures of the frequency of emergency events e.g. time to future emergency event (admissions, ED visits); hospital emergency admissions over one year. The assumption is that these represent adequate proxies for poorer health status
- Costs and activity of all health and social care use over one year

The independent variables that will be assessed will include personal characteristics such as age, gender, domicile, clinical characteristics e.g. number and type of co-morbidities, physical and cognitive function, nutritional status, frailty markers, and prior service use and informal care.

The work to test the validity of HES based markers of frailty (workstream 3.2) will assess the accuracy of case identification at person level different thresholds of 'frailty'. By using classifications based on the HES proxy values will be compared to the frailty measures in the clinical data sets using standard methods to measure sensitivity and specificity including the use ROC curves and the balance of positive predictive value and sensitivity.

Plan of investigation and timetable

The overarching programme of work is shown in the programme Gantt chart which is reproduced below

PROJECT PLAN

See attached Gantt chart

Table 1: Showing involvement of applicants in each of the different workstreams	**Work stream 1** ***1.1*** *Rapid review of systematic literature reviews (m1-9)*	**Work stream 2** ***2.1*** *Description of current provision of CGA in the UK (m1-12)* ***2.2*** *Creation of tools to understand the need for CGA (m1-30)*	**Work stream 3** ***3.1*** *Assessing the relationship between frailty markers and longer term patient outcomes and service costs (m1-12).* ***3.2*** *Testing of HES based proxies for markers of frailty (9-18)* ***3.3*** *Retrospective analyses of the impact of CGA 3 (m18-24)*	**Work stream 4** ***4.1:*** *To identify models of care which are clinically and cost-effective (m1-18).* ***4.2:*** *To develop implementation strategies and tools to help the commissioning and delivery of such interventions (m13-21).* ***4.3*** *Evaluate the toolkits and their implementation (m22-30)*	**Work stream 6** ***6****. Patient and Public Involvement (m1-30)*	**Work stream 7** **7.** Management (m1-30)
Conroy	Participate in design and interpretation	Participate in design and interpretation (2.1, 2.2)	Workstream lead (3.1,3.2,3.3). Ensure access to datasets (3.1)	Participate in design and interpretation (4.1,4.2,4.3). Ensure participation of clinical site(s) (4.3)	Interaction with PPI activities as directed by Kennedy	Workstream lead, leads executive management team Member of project board Attends steering committee
Parker	Lead literature review	Lead survey (2.1) Liaison with Oxford team (2.1)	Participate in design and interpretation (3.1,3.2,3.3).	Participate in design and interpretation (4.1,4.2,4.3). Ensure participation of clinical site(s) (4.3)	Interaction with PPI activities as directed by Kennedy	Maintain project overview. Chair and manage board meetings. Advisory role to executive management team. Mentor Conroy. Organise and support steering committee meetings.
Bardsley	Participate in design and interpretation	Participate in design, analysis and interpretation of survey (2.1)(supported by Nuffield team) Lead creation of tools to understand the need	Participate in design and interpretation (3.1,3.2,3.3). Lead work with HES data (3.2), and understanding costs (3.3) (supported by Nuffield team)	Participate in design and interpretation (4.1,4.2).	Interaction with PPI activities as directed by Kennedy	Member of project board

Table 1: Showing involvement of applicants in each of the different workstreams	**Work stream 1** ***1.1*** *Rapid review of systematic literature reviews (m1-9)*	**Work stream 2** ***2.1*** *Description of current provision of CGA in the UK (m1-12)* ***2.2*** *Creation of tools to understand the need for CGA (m1-30)*	**Work stream 3** ***3.1*** *Assessing the relationship between frailty markers and longer term patient outcomes and service costs (m1-12).* ***3.2*** *Testing of HES based proxies for markers of frailty (9-18)* ***3.3*** *Retrospective analyses of the impact of CGA 3 (m18-24)*	**Work stream 4** ***4.1:*** *To identify models of care which are clinically and cost-effective (m1-18).* ***4.2:*** *To develop implementation strategies and tools to help the commissioning and delivery of such interventions (m13-21).* ***4.3*** *Evaluate the toolkits and their implementation (m22-30)*	**Work stream 6** ***6****. Patient and Public Involvement (m1-30)*	**Work stream 7** **7.** Management (m1-30)
		for CGA (2.2) (supported by Nuffield team)				
Martin	Participate in design and interpretation	Participate in design and interpretation (2.1, 2.2)		Workstream lead (4.1,4.2,4.3).	Interaction with PPI activities as directed by Kennedy	Member of project board Member of executive management team.
Roberts	Participate in design and interpretation	Participate in design and interpretation (2.1, 2.2)	Participate in design and interpretation (3.1,3.2,3.3). Ensure access to datasets (3.1)	Participate in design and interpretation (4.1,4.2,4.3).	Interaction with PPI activities as directed by Kennedy	Member of project board
Kennedy	Participate in design and interpretation (PPI)	Participate in design and interpretation (PPI) (2.1, 2.2)	Participate in design and interpretation (PPI) (3.1,3.2,3.3).	Participate in design and interpretation (PPI) (4.1,4.2,4.3).	Lead PPI work stream (m1-30)	Member of project board

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Appendix 1

Detailed methods for the review of reviews (workstream 1).

Criteria for Considering Studies

Types of studies

- This rapid evidence synthesis will focus on existing literature reviews and where necessary, the high quality RCTs which contribute data to the reviews of comprehensive geriatric assessment for inpatients
- Randomised controlled trials, performed and reported more recently than those included in the included literature reviews
- Recent observational studies which describe models of delivery of CGA on a hospital wide basis, with direct relevance to UK clinical practice.

Literature reviews will be sought from the full range of dates available in the relevant databases. Randomised controlled trials will be sought from the past five years, unless already included in the identified literature reviews. Other studies, potentially identifying novel models of hospital wide delivery will be sought from the past five years, and through bibliographic and citation searching of the identified reviews and RCTs.

Due largely to the constraint of time in producing a rapid review to inform further development of the research, papers selected for review will be restricted to those published English.

Types of intervention and participants

We will include papers which describe the provision of comprehensive geriatric assessment in patients over 65 years of age, who are in receipt of inpatient hospital care.

Outcomes

We will describe and classify the outcomes that have been used to measure the effectiveness of CGA in hospital settings for which is likely to include (for example):

- Living at home
- Death
- Institutionalisation
- Dependence
- Death or dependence
- Activities of daily living
- Cognitive status
- Readmissions
- Length of stay
- Resource use

(from Ellis *et al* 2011 [3])

Types of comparator(s)

We will include reviews and other studies in which the delivery of comprehensive geriatric assessment is compared to usual inpatient care, or in which the comparator is CGA in an alternative setting, or usual care in another setting

Methodology

The review will be systematic (that is to say it will use a review protocol, with methods that ensure reproducibility). The review will be limited to evidence contained within literature reviews, with the exception that we will perform a limited, narrative review of recent randomised controlled trials (more recent than the most recent meta-analysis) and observational literature from the past five years of direct relevance to UK clinical practice.

Search strategy

Sources

We will use a range of sources and approaches to identify published reviews and descriptions of comprehensive geriatric assessment in inpatient care including

- searches of appropriate electronic databases
- scrutinising bibliographies of all relevant reviews for further relevant studies
- checking relevant internet sites
- searching for publications of and contact with experts in this area
- where appropriate hand searching of key health service and professional publications.

We will use a similar range of electronic databases to those used in our recent systematic review of comprehensive geriatric assessment to improve outcomes for frail frail older people being rapidly discharged from acute hospital (Conroy *et al* 2011 [4]) including:

OVID MEDLINE(R) (1966+).

EMBASE (1980+).

BNI (1985+).

HMIC.

Cochrane Library.

CINAHL.

AGEINFO (http://www.cpa.org.uk/ageinfo/ageinfo2.html).

ASSIA: Applied Social Sciences Index and Abstracts.

The National Research Register (NRR) Archive (http://portal.nihr.ac.uk/Pages /NRRArchive.aspx).

National Information Center on Health Services Research and Health Care Technology (NICHSR) (http://www.nlm.nih.gov/nichsr/db.html).

NHS CRD DARE/HTA/EED (http://www.crd.york.ac.uk/crdweb/).

Search terms

The search terms will be developed in consultation with PPI volunteers, and build upon those already used in recent and influential, literature reviews in the topic area (Rubenstein 1991 [5], Baztan 2009 [6], Conroy 2011 [4]). We will adapt the terms used in our most recent review in this area as follows:

Acute care/sub-acute care/post-acute care/inpatient care/ (identifies the setting).

Frail/geriatric assessment/health services for the aged/(geriatric unit or specialist geriatric or acute geriatric).mp./((elder$ or older or geriatric$ or aged) adj3 (unit or specialist)).tw./acute care for elder$.ti./(acute care adj3 elderly).mp./elder$ unit$.ab./geriatric$ acute care.ab. (identifies the population/process).

Activities of daily living/cost/cost benefit/cost effectiveness/mortality/health status/length of stay/discharge/readmission/quality of life/satisfaction/carer strain/carer burden (identifies the outcomes).

Search restrictions

This is a limited systematic review and the searches will be restricted by the level of evidence, so that we will only include relevant literature reviews, randomised controlled trials reported more recently than the most recent directly relevant literature review(s) and observational studies conducted in the last five years. Due to time and resource constraints, searches will be restricted to English Language papers only.

Reference management

Search results will be entered into a Reference Manager 12.0.3 for Windows database.

Inclusion and exclusion criteria

Studies will be assessed independently by two reviewers at the title and abstract stage against pre-determined inclusion criteria, based on the study type(s), participant(s), intervention(s), outcome(s) and comparator(s), as outlined above. The full-text of all studies identified for inclusion, together with any for which a decision on inclusion is not possible, will be obtained for a more detailed examination.

Quality assessment

Quality of studies identified for inclusion in the review will be assessed using appropriate quality assessment tools and criteria (eg AMSTAR, for systematic reviews, van Tulder criteria for randomised controlled trials). For observational studies we will use established quality criteria for the assessment of observational studies (CRD4).

Data extraction

Key data will be extracted from the included reviews and descriptive studies into tables which will be developed specifically for the purpose. Important components of the tabulated data will include: the key elements of CGA

principal outcomes that have been studies in RCTs

the characteristics of the main beneficiaries of CGA included in the RCTs

the main findings about the cost-effectiveness of models of delivery of CGA

gaps and weaknesses in the evidence base

The data extraction procedure will be undertaken independently by two reviewers and discrepancies will be resolved by discussion.

Care will be taken to ensure that the tabulated data retains information about the nature and quality of the evidence source from which it was extracted.

Data synthesis

The quantity and quality of the literature will be summarised in both narrative commentary and summary tables. A 'flow diagram' charting the number of references at each stage in the review process in line with the QUOROM statement [7] will be produced.

As meta-analyses will have been undertaken in many of the included papers, we will not attempt further quantitative meta-synthesis. The key results of existing meta-analyses will be summarised and used to develop a rapid interim report for the research team, to inform the development of the next stages of the project. A full report will be developed, which will include a narrative overview with detailed description of the review methodology and findings, including discussion of key messages for practitioners and managers in inpatient care for frail older people.

Proposed economic analysis

The economic analysis of the literature will examine studies which report the economic impact of CGA. It will include studies which report on cost-effectiveness, cost-utility, cost-benefit and/ or cost-minimisation. The review will summarise the overall health economic impact of different models of delivery of CGA, it will summarise the results with regard to:

the scale, timing and study design

the range of costs included (direct and in-direct) and methodology employed to calculate the costs

the outcome metrics employed

the approach to marginal and opportunity costs.

It will also compare the factors associated with enhanced cost-effectiveness including the cost of the intervention, impact on wider use of services and improved outcomes. The review will compare the costs reported in the studies with benchmark costs across the NHS from other sources. These include the PSSRU unit cost estimates, national reference costs and tariffs [8]. The dominant resource utilisation metrics such as rate of admission to hospital will be compared with national rates.

Project Timetable (literature Review)

Task	Months
First project team meeting	0-1
Finalise scope	0-1
Preliminary literature searches	0-1
Second project team meeting/discussion	1-2
Full literature searches and reference management	1-2
Selection of articles	2
Obtain articles	2
Follow-up cited references	3
Third project team meeting/discussion	3
Quality assessment	3
Data extraction	4
Fourth project team meeting/discussion	4
Data synthesis	4
Rapid report for research team	4
Fifth project team meeting/discussion	4
Report writing	4-6
Draft report	5
Sixth project team meeting/discussion	6
Final report	6
Paper for publication	6-9

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