Study Title: HOW BEST TO DELIVER COMPREHENSIVE GERIATRIC ASSESSMENT (CGA) IN A COST-EFFECTIVE WAY: MODERN ACUTE CARE FOR OLDER PEOPLE

Internal Reference Number / Short title: HOW BEST TO DELIVER COMPREHENSIVE GERIATRIC

ASSESSMENT (CGA)

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SYNOPSIS

Study Title	How best to deliver Comprehensive Geriatric Assessment (CGA) in a cost-effective	
	way: modern acute care for older people	
Short title	How best to deliver Comprehensive Geriatric Assessment (CGA)	
Study Design	(1) National survey of CGA in community settings and follow-up interview study.(2) Update of the Cochrane Review of CGA with individual patient data meta-analysis and multi-level modelling of cost-effectiveness, a survey of trialists and	
	refinement of a protocol logic model.	
	(3) Delphi exercise with clinicians who specialise in the care of older people and focus groups with frail older patients and carers, observational case studies and interviews.	
Study Participants	(1) Survey: Clinical Director (CD) or Clinical Lead for geriatrics in all NHS providers of community health services.	
	(2) Cochrane Review: RCTs of all models of CGA (to include hospital liaison teams), which recruited participants aged 65 years and over who were admitted to hospital for an acute medical event and are eligible for CGA.(3) Clinicians who provide CGA in a hospital at home setting and a group of frail older patients and carers who have indicated their willingness to participate in our research.	
Sample Size	 (1) NHS Community Trusts (n=26) in England, local health boards in Wales (n=7), health boards in Scotland (n=14) and health and social care trusts in Northern Ireland (n=5). (2) All samples recruited to the RCTs included in the Cochrane Review. (3) Approximately 20 clinicians, 20 patients and carers across all sites being studied. 	
Study Period	Three years	
	Objectives	Outcomes
Primary	To improve our understanding of the effectiveness and cost effectiveness of specialist led Comprehensive Geriatric Assessment (CGA) across secondary care and hospital at home settings.	Living at home (the inverse of death or living in a residential care setting) and cost-effectiveness.
Secondary	Secondary Objectives: (1) To understand the content and process of delivering CGA in NHS community settings, the barriers to implementing CGA and the cost-effectiveness of the different models of CGA being implemented.	Patient, carer, healthcare professional and organisational factors determining the delivery and implementation of CGA (including barriers) in community settings, the cost and outcomes of the different models of CGA and the extent CGA in practice differs from the evidence.
	2) Determine who is to benefit, how and when CGA should be delivered.	Define which populations are most likely to benefit from CGA and how and when CCA should be delivered.
	3) To develop consensus of the key components of CGA through incremental	Consensus statements on the key components of CGA.

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BACKGROUND AND RATIONALE

The demographic shift of a rising number of older people, combined with the relative reduction in the number of working age adults contributing to the economy, make the provision of sustainable safe healthcare for older adults a major health concern for the 21st century. In the UK nearly two thirds (65%) of people admitted to hospital are over 65 years old (1). Over the last ten years there has been a 65% increase in the number of people aged over 75 who have required secondary care, compared to a 31% increase for 15-59 year olds (2). The number of emergency admissions in England rose by 11.8% over the five-year period 2004/05 to 2008/09, a total of approximately 1.35 million extra admissions. This is a major issue and decision makers across the NHS are attempting to reconfigure services to deal with the year on year increase in hospital admissions, often with an inadequate evidence base. These changes have raised concerns that the pressure of delivering health care to greater numbers may be at odds with the provision of person centred high quality care (3). When there is a breakdown in the quality of care the consequence can be catastrophic for vulnerable patient groups, namely the frail elderly (4).

Comprehensive Geriatric Assessment (CGA) has developed over the last 30 years in response to concern that problems experienced by older people who required acute hospital level care were not being recognised and acted on (5; 6). CGA is a multidimensional interdisciplinary diagnostic process focused on determining a frail older person's medical, functional, psychological and social capability to ensure that problems are identified, quantified and managed appropriately (7). It has the potential to both improve clinical outcome (reduce mortality and the need for long-term care) and reduce the costs of health and social care. Evidence is needed on how to provide acute Comprehensive Geriatric Assessment (CGA) to older adults in greater numbers with a fixed or shrinking hospital resource. Without this perspective existing models of acute hospital CGA care will become unworkable as the health service deals with an increased number of frail older people with complex health needs.

Summary of related findings from previous studies

The evidence for Comprehensive Geriatric Assessment (CGA) is from a Cochrane Review published in 2011 (N=22 RCTs recruiting 10,315 patients across six countries) (7). The Cochrane Review concluded that older people who received CGA in a geriatric ward were more likely to be alive and in their homes at follow-up compared with those who received routine inpatient medical care (OR 1.16, 95% CI 1.05 to 1.28, p=0.003; N=7,062). There were additional benefits in terms of improved cognition, reductions in the likelihood of being admitted to residential care and a reduced likelihood of death or deterioration. These findings were most pronounced in trials of discrete wards in the care of older people. In addition whilst full economic analysis was not possible, many trials reported a reduction in cost associated with CGA care. This means that specialist organized care for older people is associated with improved independent survival and has the potential to both improve clinical outcome (reduced mortality and the need for long term care) and reduce the costs of health and social care. If services were implemented along the lines of CGA the impact on the health outcomes of this patient group could be significant. However, there is uncertainty about the optimal way of implementing CGA, both in terms of the components of the intervention, who to target and the economic implications. Our proposed research will explore the evidence to a) identify which patients should be selected for this intervention; b) identify the key components and mode of delivery of CGA; and c) conduct a detailed economic evaluation of the different models of CGA.

STUDY OBJECTIVES

The overall objective of this research is to improve our understanding of the effectiveness, implementation and cost effectiveness of specialist led Comprehensive Geriatric Assessment (CGA) across secondary care and hospital at home settings. To this end, the project will include:

(1) A national survey and follow-up interview study which will provide data of the different models of CGA in the NHS and data for modelling the costs of CGA care in a hospital and hospital at home setting.

- (2) An update of the Cochrane Review of CGA with individual patient data meta-analysis and multi-level modelling of cost-effectiveness, a survey of trialists and refinement of a protocol logic model to map out the pathways that constitute the mechanism of action of CGA.
- (3) A Delphi exercise with clinicians who specialise in the care of older people, observational case studies and interviews with healthcare providers, patients and caregivers of how CGA is implemented.

METHODS

Work Package 1: a survey of community healthcare providers, with follow-up interviews; modelling the costs of CGA care in the NHS (year 1, 12 months duration)

Participants

The survey will be conducted by Picker Europe. We will pilot the survey with NHS colleagues working in the field of geriatric medicine prior to sending it to NHS community providers. The aim of the survey is to identify the prevalence of CGA in a hospital at home setting, variation in the implementation of CGA, the degree to which CGA implemented in the NHS varies from the evidence and the major barriers to implementing CGA in practice. The survey will be sent to the Clinical Director (CD) or Clinical Lead in 'health and care' trusts (n=23) in England, local health boards in Wales (n=7), health boards in Scotland (n=14) and health and social care trusts in Northern Ireland (n=5).

Intervention

The following areas will be included in the survey, though this is not an exhaustive list:

- i) The population using the service: age, admission criteria, exclusion criteria, volume of patients using the service, case mix details and any accompanying co morbidity.
- ii) Staff providing the service: numbers, profession, seniority and specialist experience or training.
- **iii)** Organisational features: timing of admission to CGA service, bed numbers, bed occupancy, length of stay, length of time CGA has been delivered, sources of referral, arrangements for diagnosis and follow-up treatment and management, access to other services, discharge planning, case management, follow up arrangements and training of staff.
- **iv)** Care processes: how and by whom assessments are conducted and domains covered; systems in place for reviewing progress, access to specialist input (e.g. mental health expertise), engagement of patients and caregivers in goal planning, process for identifying and implementing follow-on services.
- v) Outcome assessments: type of assessment, if standardized and the measures of outcome used.
- vi) Successful implementation: for which patients and in what circumstances is the service considered to be most and least successful.
- **vii) Economic features:** our survey will be designed to collect detailed information on the resources required to deliver each model of CGA, and from that the costs to the NHS of the main models of CGA being delivered. In addition to the questions described above on numbers and type of staff involved, frequency of contact and training arrangements we will ask whether the existing service has been formally costed prior to or after implementation.

Respondents will be asked to describe current services and those that have stopped being provided within the last year. Up to two reminders will be sent, initially by email and followed by a telephone call. We will supplement the survey with follow-up telephone interviews with a purposive sample of hospital at home providers, who have agreed to be re-contacted, in order to gain further understanding of how CGA has been implemented, barriers to implementing CGA and perceived successes. The criteria for selecting service providers to interview will be (i) those delivering different models of CGA (for example those whose models of CGA correspond to the models of CGA included in the Cochrane Review by employing a multi-disciplinary team to work with a specialist in geriatric medicine) and those whose models of CGA differ substantially from the evidence (for example substituting other health professionals for a specialist in geriatric medicine); (ii) the length of time the service has been established; (iii) those

who employ different criteria for inclusion in CGA services (for example an age cut-off or needs based criteria for frail older people); (iv) and, those who have ceased to provide CGA services, or changed the way CGA is delivered.

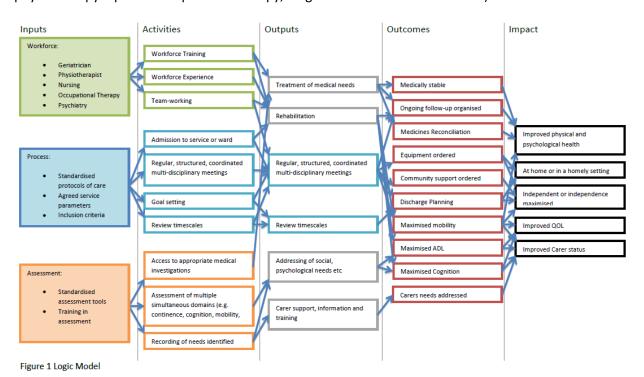
Work Package 2: Individual patient data (IPD) meta-analysis, multi-level modelling, construction of a logic model, survey and interviews of trialists (year 1 and 2)

Participants

We will include trials which recruited participants aged 65 years and over who were admitted to hospital for an acute medical event and are eligible for CGA, this will include people with a surgical diagnosis. Trials typically recruited patients on the basis of age alone (i.e. all admissions over 75) or on the basis of criteria such as changing functional status, prior disability, cognitive impairment or classic geriatric syndromes such as falls, immobility, delirium and non-specific presentations. We will establish a collaborative review group of trialists for the Cochrane Review of CGA for Older Adults. Individual patient data (IPD) will be requested from the investigators of the trials.

Intervention

The update of the Cochrane Review of CGA will include RCTs of all models of CGA (to include hospital liaison teams). CGA is a multidimensional interdisciplinary diagnostic process focused on determining a frail older person's medical, functional, psychological and social capability to ensure that problems are identified, quantified and managed appropriately (7). A tailored management plan, which includes rehabilitation, is developed and delivered by a multi-disciplinary team. The multidisciplinary team includes at a minimum specialist medical, nursing and therapy staff. Members of the multidisciplinary team are responsible for delivering the recommended treatment or rehabilitation plan (such as physiotherapy input or occupational therapy, diagnostics or medical treatment).



Outcomes

The primary outcome is living at home (the inverse of death or living in a residential care setting) and cost effectiveness.

Work Package 3: Delphi exercise of the implementation of CGA in alternative settings, case study analysis of the implementation of CGA in inpatient and alternative settings and interview study (year 2 to 3, 18 months duration).

Delphi exercise

We will use a modified Delphi process to identify 'expert' consensus on the necessary components of CGA in a hospital at home setting, conduct a case study analysis and an interview study of the implementation of CGA in a hospital and hospital at home setting. From the Cochrane Review, the survey of trialists and the logic model we will draw out a set of statements that form the core elements of CGA as researched and which lead to effective outcomes. These will relate to organisational features of inpatient CGA service delivery (staffing, number of beds); care processes (assessment, coordination of delivery, review and discharge planning); and the characteristics of patients supported.

Participants

We will convene a group of clinicians (including members of the multi-disciplinary team) (n=20) who provide CGA in a hospital at home setting and who agree to participate in the online Delphi exercise. We will also conduct a Delphi round, using two focus groups, to incorporate the views of frail older patients and carers (n=20). We will ask them to comment on the key components of CGA, as delivered in the NHS and as researched, from their experience of these services as well as draw out additional user centre dimensions of delivery and the priority attached to them from their experience of these services.

Interventions

We will use the CGA as researched statements as a benchmark and will ask the Delphi group to score each of the CGA hospital at home statements on a 5-point numerical scale from 1 (no agreement) to 5 (full agreement).

Outcomes

We will assess if CGA readily transfers to other settings, namely an acute hospital at home setting, and the degree to which a change in location impacts on the fidelity of the intervention, for example, if the functions of co-ordination and continuity of care are accomplished in different ways, and patients and carers experiences of these services.

Case study and interview study

We will use a case study method to examine the content and delivery of CGA in practice: how it works from the perspective of those delivering it and how it is experienced by service users and caregivers.

Case study site selection

From among CGA services delivered within our co-applicant sites we will select two sites, one in England and one in Scotland providing CGA in inpatient and hospital at home service delivery settings (4 case studies of CGA in two settings). We will select the sites based on the type of locality (urban/rural) and the size of hospital at home service as we anticipate that these factors may impact on how the service is implemented. We will employ observation, informant conversations, qualitative interviews and collection of documents to develop a picture of CGA as delivered and experienced in each setting. These are described in detail below.

CGA as delivered

Within each case study setting we will locate CGA within the wider context of CGA in that site, extracting data from relevant documents and conducting interviews with key informants. This will include the rationale for the CGA model implemented. For example, for CGA delivered in a hospital at home setting, we will examine its history, purpose, model of provision and interface with acute hospital. This will encompass systems for patient selection, type of patients for whom it is intended and numbers supported.

We will conduct a short period of orienting observations of CGA practice and routines in each CGA setting, to include the work of therapy, nursing and medical staff, interactions between professionals and between professionals and patients. This will be followed by focused observations targeted around the care of purposively selected patients (5 patients in each site, a total of 20). Selection of patients for observation will be based on typical and extreme case sampling strategies, patients that are typical of those receiving CGA and extreme in that they pose particular challenges for the delivery of healthcare, for example on account of cognitive impairment, multiple co-morbidities and frailty that will impact on the recovery process. We will also select different models of CGA for observation, for example a specialist ward vs. a team. As data analysis will proceed simultaneously with data collection, we will leave open the possibility of undertaking a small number of additional observations to pursue promising lines of enquiry not anticipated in advance. Observations will be carried out at different times of the day, typically in 3 hour blocks in each CGA setting. We will rely on case notes until the time that medical staff indicate the patients' immediate acute care needs have stabilised and it would be appropriate to observe their treatment and care. We will follow each patient through to discharge.

Data will also be collected through observation of single professional and multi-disciplinary team meetings and informant interviews with staff to examine the process of assessment, diagnosis and treatment planning, the sequence of decision-making and discharge planning in respect of these patients; supplemented by conversations with patients and caregivers. The value of this approach is that it enables contemporaneous collection of data relating to experiences of patients and caregivers in the specific context of the delivery of healthcare services structured around CGA. This is particularly valuable for patients with dementia, since data are collected in real time it does not require either verbal facility or ability to recall. This method has been used successfully in an on-going process evaluation of training for caregivers of people who have had a stroke, led by Mary Godfrey.

Detailed descriptions of settings, events, interactions and activities will be maintained in field notes, these will be a) descriptive and contemporaneous and b) expanded accounts (8). Additionally, a chronological fieldwork journal will be maintained to include researchers' reflexive accounts of the interactions observed, as well as hunches and working hypotheses. These will include the researchers' impressions and reactions to the observations, since adopting such methods of reflexivity is an important quality check while undertaking qualitative research (9). Emerging categories or preliminary hypotheses about the data may be tested through more focused observation.

CGA from the provider perspective

We will conduct interviews with 3 to 4 team members from different disciplines in each study site. We will use a topic guide to examine how CGA is understood, what makes it work and for whom, the resources available and the professional, organisational and other contextual factors affecting CGA implementation from their different perspectives. Interviews will include factors that enter into decision-making on patient selection, how care is organised and delivered, the resources available and professional, organisational and other contextual factors (to include challenges and obstacles encountered). Through discussion of anonymised cases, we will explore the kinds of patients perceived as best suited to the service and most likely to benefit from the model of CGA in operation.

CGA from the patient and carer perspective

We will interview the patients selected for observation (see above), and their caregivers, in each case study site (up to 5 patients and caregivers in each site, a total of 20 across all sites) shortly before discharge from hospital to reduce problems of recall. As data analysis will proceed simultaneously with data collection, we will leave open the possibility of undertaking a small number of additional interviews to pursue promising lines of enquiry not anticipated in advance. The interviews will assess if and how they perceive the healthcare they received facilitated recovery. Attention will be on their perception of 'distance travelled' i.e. the changes that have occurred from the event that precipitated acute admission

to discharge. We will aim to interview caregivers separately, recognising that this may not always be possible.

7. DATA COLLECTION, MANAGEMENT AND ANALYSIS

1. A survey of community healthcare providers, with follow-up interviews;

We will describe the range and prevalence of the different models of CGA in a hospital at home setting, to include a set of core features using the data collected by the survey, and from the interview data.

2. A comparison of the costs of CGA hospital at home care vs inpatient care using Scottish data

We will use data collected by the Lanarkshire Health Board from consecutive patients who were admitted to Hospital-at-home services and inpatient hospital CGA services in Lanarkshire in the years 2009/10, 2010/11, 2011/12, 2012/13, 2013/14, 2014/15, and anticipate that we will receive this data by December 2016. We have also requested data from Fife. The data are collected at patient level and managed and stored by the Information Service Division (ISD), who clean and link the data across health and social care services using the Community Health Index number (CHI). To access patient level data from ISD we have completed an information data release form, and sought approval from the Caldicott guardians. We have received approval from Lanarkshire Health Board and are awaiting approval from Fife Health Board. All data will be linked and de-identified by ISD before release of the data to the researchers.

Step 1: comparison of the two patient populations (hospital-at-home vs inpatient admission):

- a) Age
- b) Male/Female
- c) Place of residence prior to admission
- d) Previous re-admission
- e) ICD 10 codes (for diagnosis on admission)
- f) Charlson comorbidity index
- g) Source of referral

Step 2: comparison of resource utilisation costs

Resource use variables:

- a) Outpatient attendance
- b) Admission to acute elective inpatient ward (with date of admission and date of discharge)
- c) Admission to hospital as an acute emergency admission (with date of admission and date of discharge)
- d) Admission to a geriatric long stay bed (with date of admission and discharge)
- e) Length of stay in a hospital bed (or date of admission and discharge)
- f) Prescribing data
- g) Accident & emergency attendance
- h) Mental health service
- i) Hospital-at-home admission (with date of admission and discharge), or length of stay in hospital-at- home
- j) Admission to residential care
- k) Social care use

I) Staff grade and time for providing hospital-at-home

Unit costs:

Resource utilisation and costs will be calculated; costs will be estimated by multiplying the resource utilisation variables with the respective unit cost from the list below:

Potential outcomes variables (to be used if the two populations are comparable):

Mortality (i.e. dead/alive)

Time-to-death (i.e. the time between the date of admission to hospital or hospital-at-home and the date of death)

Analysis

In an observational longitudinal study, we will first compare the populations in the two groups (i.e. hospital-at-home and inpatient group) in terms of patient characteristics (e.g. age, gender), morbidity prior to admission (place of residence prior to admission, previous re-admission, source of referral) and morbidity on admission (ICD-code on admission, Charlson co-morbidity index). Descriptive statistics including analysis of variance for continuous variables and cross-tabulations with chi-square tests for categorical variables will be performed.

Second, we will estimate the annual resource utilisation and costs of people after having been admitted to hospital-at-home. To do that, we will identify patients who have been admitted to hospital-at-home during the financial years 2012/13 and 2013/14. This will ensure that for each admitted patient we will have data for at least 3 years before admission and at least 1 year after admission. This is illustrated in Figure 2, where Patient A is the first admitted patient in 2012/13 and we are able to look into the patient's resource utilisation and costs in the previous 3 years, -which is the maximum period of available data for this patient. On the other hand, Patient C in Figure 2 is the latest patient to be admitted in 2013/2014 for whom there is cost data available for maximum of one year after admission. Descriptive statistics (i.e. mean, standard deviation, median, interquartile range) will be used to explore the annual costs of these patients for different health and social care services. Data permitting, the standardised (for morbidities and age) mortality rate one year after admission will also be explored. Regression analysis will be used to identify differences in annual costs between primary and secondary indications for hospital-at-home admission adjusted for age, sex, and socioeconomic status. Similar analyses will be performed for patients admitted to hospital (e.g. patients D,E,F in Figure 2).

Last, we will compare the annual costs of patients admitted to hospital-at-home with the annual costs of patients admitted to hospital to assess the relative performance of hospital-at-home services. Propensity score matching (either one-to-one with closest matching or stabilised inverse probability weighting) will be used to correct for observed confounding at admission between patients admitted to hospital-at-home and patients admitted to hospital. The propensity score will be calculated based on age, gender, primary indication for admission (based on ICD-10 codes), Charlson-index, and 3-year historical resource utilisation and costs of patients in the two groups. Two subgroup analyses will be performed to explore differences in the results between patients a) younger than 85 and over 84 years old and b) with the most costly combination of morbidities at admission.

Admitted to hospital-at-home

3-year historical data for patient B

Patient B: 1-year period after admission

3-year historical data for patient C

Patient C: 1-year period after admission

2009/10

2010/11

2011/12

2012/13

2013/14

2014/15

Patient F: 1-year period after admission

Patient D: 1-year period after admission

Patient D: 1-year period after admission

Admitted to hospital

Figure 2. Schematic overview of study design

Update of a Cochrane Review of CGA

We will request individual data from the investigators of the trials included in the Cochrane Review of CGA. The analysis plan will be reviewed in light of the availability of individual patient data but prior to any comparative analysis. Where possible, data on all patients will be included in order to conduct an intention-to-treat analysis. Results obtained from pooling trial summary statistics will be compared with results where individual patient data have been supplied and any differences investigated. Fixed and random effects models will be used for both trial and treatment effects. Tests of heterogeneity will be carried out using an I² statistic; we will not retain a pooled analysis if values of I² >70%. Additional sensitivity analyses will be conducted with data on quality of trial methodology.

Aggregate analyses will initially be undertaken to estimate treatment effects using a random effects model as, based on the published Cochrane Review, it is anticipated there will be some variation among trials in terms of study populations and type of intervention. The relationships between the outcomes of interest and the patient groupings (level of frailty), age and CGA models (along with the interactions of these variables) will be studied using stratified regression models. Hierarchical models (with individual patients at level one and trials at level two) will also be used to analyse the outcomes of interest here. Factors (such as age at randomisation, level of frailty and cognitive impairment and other significant factors from the stratified regression) will be used as covariates.

Regression models, stratified by trial, will be used to explore the effects of different models of CGA, patient groupings and age covariate interactions on the outcomes of interest. Pre-specified factors are age at randomisation, level of frailty and cognitive impairment. Two level multi-level regression models will be fitted with patients corresponding to level one units and trials as level two units for the outcomes of interest using the appropriate approach to continuous and dichotomous outcomes. Trial and treatment effects will both be represented by a random effects model. The factors included in the stratified regression analysis will be used as covariates while trial dependent factors such as the provision of CGA in a specialist ward or by a peripatetic team will also be included in the model at the trial level.

We will conduct a cost-effectiveness analysis to examine whether costs and health outcomes differ between those receiving inpatient CGA, and those not receiving CGA. A NHS health service perspective will be taken (12). Meta-analysis of published data from 16 trials, and IPD from 5 trials, will be used to estimate the incremental cost and incremental health outcomes of CGA compared with usual care. The

cost of the time spent by health care providers of delivering CGA will be calculated using data from the one trial that provided IPD on resource use (13); this trial evaluated a version of CGA that included an attending geriatrician and outpatient follow-up. Hospital length of stay is derived from seventeen studies reporting this outcome, and the relative costs valued using English unit cost price 2013/2014.

The effectiveness of delivering inpatient CGA will be measured by:

- 1) Quality Adjusted Life Years (QALYs), will be calculated by mapping the IPD for the Barthel Index from 3 trials (14,15, 16) to the EQ-5D based on <u>Kaambwa et al. 2013</u> (17), using data from studies with mean Barthel scores at baseline (range from 14.8 to 16.5, on a scale of 0 to 20) that were similar to the score reported in the mapping study of <u>Kaambwa et al. 2013</u> (17). Edmans et al. (14) also provided IPD for the EQ5D, which will be used to validate the mapping exercise by comparing the QALYs calculated using the Barthel index to the QALYs based on EQ5D in Edmans et al. 2013 (14).
- 2) Life years (LYs) will be estimated using the IPD from four trials (14, 15, 16, 18) by calculating the time-to-death in days.
- 3) We created a variable 'life years living at home' (LYLAHs) after discharge from hospital, as a measure of independence and well-being in an older population, based on IPD from two trials (14, 18).

A decision model will be constructed to estimate an incremental cost-effectiveness ratio (ICER) of inpatient CGA, compared with inpatient care without CGA. The ICER is expressed as a cost per QALY, cost per LY gained and cost per LYLAH gained from an health service perspective. The RR of living at home at the end of follow-up will be used in the decision model. The RR will be multiplied by the incremental 'life years at home' (LYLAH) to adjust LYLAH with the probability of living at home. Uncertainty in the input parameters of the model will be addressed by performing 10,000 draws of all incremental cost and incremental health outcome parameters using pre-specified distributions, and recording incremental costs, incremental QALYs, incremental life years, and incremental LYLAHs from each draw. These results will be plotted on cost-effectiveness planes and cost-effectiveness acceptability curves to display the uncertainty in the estimated ICERs.

To develop a clearer understanding of the theory of change, as employed in the RCTs, we will use the data from the survey of the trialists to obtain detailed descriptions of the CGA models evaluated in the RCTs and ask them to identify the key components, or steps in the model, that were intended to achieve the desired outcomes. We will draw on this data to refine the protocol logic model (Figure 1) to map out the chain of events, or pathways, that constitute the mechanism of action of CGA as researched. This will help identify the substantive aspects of the intervention, determine the sequence of steps or linkages to secure end point outcomes, aid the interpretation of heterogeneity among the interventions and will assist stakeholders understand the nature of the intervention and the reviewers to draw out policy relevant conclusions about the review findings (10). We will also refine and assess the elements of our protocol logic model (Figure 1) by a review of trial related publications which provide information on the population recruited to the trial, the characteristics of the intervention, its implementation and context. In addition, we will survey and interview the trialists contributing data to obtain detailed descriptions of the CGA models evaluated in the RCTs, the context in which they were delivered and ask them to identify the key components of CGA (11).

Delphi exercise

We will use κ with quadratic weights, a chance corrected measure of agreement. Weighted κ is appropriate for the analysis of data in ordered categories, such as the 5 point scale used to rate each 'researched statement,' because it does not treat all disagreements equally. Different weights are given to disagreements between raters according to the magnitude of the discrepancy. In the case of multiple raters, weighted κ is calculated by generating a κ score for each possible pair of raters for each item

being rated. An overall κ score is then generated by calculating the average of these individual κ with an appropriate overall standard error. The cut off point for an acceptable level of agreement with multiple raters will be set at $\kappa \geq 0.4$.

Case study and interview study

Field notes will be typed up and entered into NVivo computer software to facilitate management of a large dataset and the analytic process. Interviews with staff, patients and caregivers will be audio-recorded, fully transcribed and entered into NVivo software. Each service is viewed as a case study within a local health system and will be the unit of analysis. We will use a grounded theory analytic approach, combining simultaneous data collection and analysis, constant comparison and search for negative cases. Simultaneous data collection and analysis provides the opportunity to pursue lines of enquiry not fully anticipated from the literature and initial framing of the problem. Analysis will be conducted at two levels.

- 1) With the CGA case study as the analytic unit: a within case analysis will be carried out to identify the content and dimensions of the CGA model and process of implementation in each setting by means of coding and categorising, using the method of constant comparison. This will provide a descriptive narrative of each case. Next a between case comparison of models of CGA delivery that are similar to, and different from each other (inpatient/hospital at home CGA), will draw out those dimensions and characteristics of CGA models that are common across different service delivery settings; those that vary between settings and those that reflect local contextual conditions. We will then classify each model with reference to the criteria of CGA in practice and research developed in Work Packages 1 and 2.
- 2) With the patient as the unit of analysis, and drawing on all data relating to each of them, we will compare and contrast experience and outcome across patients similar to, and different from each other in terms of the nature of the event that precipitated admission and their prior characteristics (degree of frailty). Finally, using the classification of CGA types above, we will examine the relationship between the CGA model and patient/caregiver experience and perception of outcome.

STUDY COMMITTEES

In addition to the day to day study management group we will establish Study Steering Committee (SSC) to ensure delivery, governance and advice. The SSC will include:

- An independent Chair
- An independent statistician
- An independent economist
- Social Care expertise
- Clinical expertise
- Lay member (s)

The IPD Meta-analysis of the Cochrane Review of CGA will be run as a collaborative review group. Individual trialists will be approached and asked to cooperate in a review process and submit IPD. The group will meet to discuss the review process. The research fellow analysing the data will work closely with the PI (SS) and have will have regular contact with Dr Graham Ellis via email, phone and face to face meetings.

DISSEMINATION OF RESEARCH FINDINGS

Our dissemination plan will target the following communities: NHS practitioners and managers, policy makers, patients and carers and the clinical and scientific community. One vehicle for dissemination will be a dedicated website which will be designed to host information for each of these groups. We will use the website to dissminate current best evidence and information relevant to service users, healthcare managers and clinicians wanting to develop services. We will include resources such guidelines for

clinical care, business case studies where relevant, and will work towards establishing standardised service outcomes.

We have made a start at establishing a UK CGA Hospital at Home forum (led by Dr Graham Ellis), as a more direct method of knowledge translation than peer review publication, this is aimed at NHS management as well as clinicians and users. The first meeting was held in December 2012. The core purpose will be to develop evidence based specialist services for older people, to exchange practical advice and to update participants on the current evidence base and policy initiatives (both in the UK and elsewhere). We will use this forum as a vehicle to disseminate the findings of our research. We will include NHS representation on the trial steering committee.

Clinical and Scientific Community

- 1. We will present the findings at international meetings.
- 2. We will publish the findings of this research in peer review journals; the individual patient data meta-analysis and logic model for the Cochrane Review of Comprehensive Geriatric Assessment will be published in the Cochrane Database of Systematic reviews.
- 3. The dissemination of the findings of the Cochrane Reviews will be enhanced through the production of Cochrane podcasts, translating the findings for use in the Cochrane Journal Club and publishing Evidence Summaries on the website for the UK satellite of the Cochrane Effective Practice and Organisation of Care Review Group http://www.dph.ox.ac.uk/epoc/about

Management and Policy Makers

- 1. We will make the website available to NHS practitioners and managers, policy makers, patients and carers and the academic community.
- 2. We will seek publication in healthcare management literature.
- 3. We will endeavour to influence policy makers regionally and nationally through involvement of our project advisory group.

Patients and Carers

1. We will disseminate news of our research through the network of carers groups linked to the centres collaborating with this research. This has already begun in Devon and Lanarkshire. We will also advertise the website to these groups.

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Project Timeline 12/5003 WP1: Survey of Acute Hospitals WP2: Individual Patient Data Meta-WP3: Delphi exercise on and Hospital at Home Services analysis implementation of CGA in alternative settings Recruitment of programme manager and seeking of ethical consent Contact and Survey Trialists Develop Survey Protocol Development Search Strategy Search providers of CGA in NHS settings Analysis of Survey Data Meeting and interviews with trialists developing consensus on CGA, testing of logic model Initial Analysis Delphi 1: dinicians Carers focus groups Clinicians, Patients modeling and Carers Devon) including patients and carers data from Case studies IPD Meta-analysis

Areas for coordinated integration with partner bid led by Parker and colleagues

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