OPEL H@H

Optimum '**H**ospice **at H**ome' Services for **E**nd of **L**ife Care

STUDY PROTOCOL

PHASE 2

VERSION 4.0, 28 October 2018

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Protocol Authorised by:

Name and Role	Date	Signature
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This protocol describes the OPEL H@H study and provides information about procedures for entering participants. Every care was taken in its drafting, but corrections or amendments may be necessary. These will be circulated to investigators in the study. Problems relating to this study should be referred, in the first instance, to the Chief Investigator. This study will adhere to the principles outlined in the NHS Research Governance Framework for Health and Social Care (2nd edition). It will be conducted in compliance with the protocol, the Data Protection Act and other regulatory requirements as appropriate.

STUDY SUMMARY

TITLE	Optimum Hospice at Home Services for End-of-Life care
DESIGN	Realist approach utilising mixed methods research
AIMS	1. Assess the impact of hospice at home (H@H) care models on patient and carer outcomes 2. Investigate the resource implications and costs of patient care in different H@H care models 3. Explore the experiences of patients, family carers, providers and commissioners of the different H@H models 4. Identify the enablers and barriers to embedding H@H models as part of service delivery
QUANTITATIVE OUTCOMES	Quality of Death (QODD survey) Holistic patient assessment (iPOS tool) Assessment of care by bereaved relatives (VOICES survey) Ambulatory and Home Care Record (AHCR)
POPULATION	Patients receiving Hospice at Home services Carers of participants receiving H@H care Stakeholders, commissioners and service providers of H@H services
DURATION	3 years

Study summary diagram

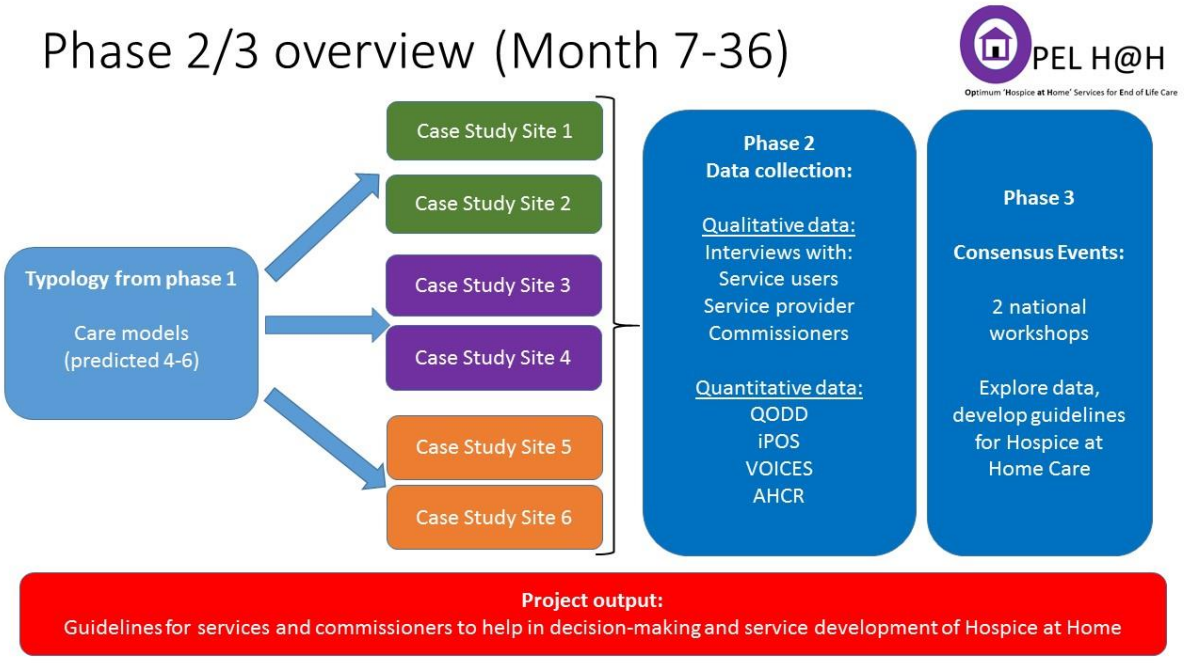


Table of Contents

GLOSSARY OF ABBREVIATIONS

OPEL H@H	Optimum Hospice at Home for End-of-life Care
H@H	Hospice at Home
HRA	Health Research Authority
NAHH	National Association of Hospice at Home
UK	United Kingdom
HCA	Healthcare Assistant
QODD	Quality of Death and Dying tool
AHCR	Ambulatory and Home Care Record
CCG	Clinical Commissioning Group
CMO	Context-Mechanism-Output
NPT	Normalisation Process Theory
BOT	Burden of Treatment
SSA	Site-Specific Assessment
NIHR	National Institute for Health Research
HS&DR	Health Services and Delivery Research
ANOVA	Analysis of Variance
AE	Adverse Event

KEYWORDS: Hospice at Home, End-of-life care, care models, health service delivery.

1. INTRODUCTION

Hospice at home (H@H) services aim to offer the quality and ethos of hospice care at home to support dying patients to have a "good death". H@H services provide patients with choice about where they receive their care at the end of life which is central to UK policy [1]. While the majority of people would wish to die at home [2] and the evidence indicates that the number of people expressing this wish is increasing [3-5], health and social care services are ill-equipped to meet this demand [6]. Identifying how care can be delivered and maintained at home was identified as a top ten priority by the James Lind Alliance in 2015 [7]. Currently the evidence for H@H services is mixed, with wide variation in service provision and the settings in which they operate. Services which have been evaluated often demonstrate positive benefits for patients, such as increased choice and death at home [8-13], though not all H@H services demonstrate the same outcomes. It is unclear what elements of these services deliver which outcomes and to what extent such outcomes are delivered in conjunction with other primary care and community services which form part of the care that end of life patients receive. Lack of clarity around what aspects of services produce which outcomes makes sharing good practice between H@H services difficult and stifles efficient service development. To address this knowledge gap, we are conducting a multi-site evaluation with methods that are able to capture in depth the structure, process and outcomes which can inform national policy and commissioning decisions to provide optimum H@H services.

In 2007, Pilgrims Hospices, which operated 3 inpatient hospices along with a community nursing service, decided to increase community provision to enable more patients to die in their own homes in response to feedback from patients and families. In order to ensure that these service changes were in line with the best available evidence, Pilgrims Hospices commissioned a literature review of the evidence for H@H services which was carried out at the University of Kent. The literature review [8] indicated that the evidence base for the efficacy of such services was weak with few controlled studies, though many qualitative studies indicated that such services were appreciated by patients and their families. Characteristics of services which appeared to produce the most favourable outcomes included: care given by palliative care specialists, out-of-hours availability, crisis intervention and rapid response capability. Based on the findings from the literature review, the hospice designed a new hospice at home service with the following features: senior healthcare assistant (HCA) led with specialist training given by the hospice, available 24/7 at 4 hours' notice, to support dying at home and families in crisis, supported by the full hospice multidisciplinary team and existing community services, and designed to add benefit by fitting around existing services. An evaluation alongside the roll out of this service was planned, in collaboration with the University of Kent, to contribute to the weak evidence base identified in the literature review. The evaluation used a quasi-experimental, cluster design and the results have been published [9-10]. We found that the new service did not improve patients' chances of dying in their preferred place (over 60% of patients were able to die in their preferred place in both intervention and control groups), though patients in areas where the hospice at home service was operating had a significantly higher preference to die at home.

From the results of this study, a number of questions remain unanswered. Is there a better service configuration than the one examined here which would allow more patients to die where they want? How does the availability of hospice at home influence patient preferences? One of the gaps with this service was difficulty in access to medications which was in part due to challenges in working with other community providers; how can we improve this with our partners in the community? Around 60% of our patients die where they want to; what would be the highest level we could hope to achieve, i.e. what is a realistic gold standard and what services are able to deliver this? Our collaboration with the National Association for Hospice at Home (NAHH) on this project confirms that these questions, and the overall question of what does an optimal hospice at home service look like, are commonly debated across the end of life care sector. These service development issues faced by

Pilgrims Hospices serve as an example and a snapshot of the national problem of how best to develop hospice at home services.

The variation in services and the settings in which they operate makes traditional comparative analyses difficult to do to achieve a meaningful synthesis of evidence which would help to inform service development and planning. In addition to there being little understanding of what the key features of H@H services are that deliver desirable outcomes, the range of H@H services in existence makes it difficult to identify similar services in comparable settings. There are 132 H@H adult services listed in the Hospice UK directory (search 16/07/2014), yet there has been little consensus as to what standards characterise such a service or what makes a service more or less effective. Services differ in terms of structure, functioning and access around the country. The National Association for Hospice at Home (NAHH) have recommended six core, national standards for H@H services developed through three national H@H stakeholder workshops held in 2011-12 [14]. The NAHH also worked with Hospice UK and conducted a survey across 76 H@H services in England, which provided some useful data to start to describe the landscape of H@H services. This survey concluded that more than one model of H@H service exists and they are not homogenous in their outcomes [15].

2. STUDY OBJECTIVES

The aim of this proposed study is to investigate the impact of the organisation and delivery of different models of H@H on patient and carer outcomes and experiences of end of life care.

Our research question is:

What are the features of H@H models that work, for whom, and under what circumstances?

The study objectives are to:

1. Assess the impact of service models and settings on patient and carer outcomes.
2. Investigate the resource implications and costs of patient care in each model.
3. Explore the experiences of patients, family carers, providers and commissioners of the different models.
4. Identify the enablers and barriers to embedding H@H models as part of service delivery.

3. STUDY DESIGN

Our research design is informed by realist evaluation [16-17] that will be used to identify candidate programme theories that will be tested and refined throughout the proposed research in order to address our objectives. The funded programme of research will be conducted in 3 phases. **This protocol outlines the research and processes for Phase 2 and subsequent Phase 3 consensus events (section 8.5)**.

Phase 1: Survey

A national telephone survey will be conducted of all known H@H services in the Hospice UK service directory to map the range and variation of H@H services in order to develop a typology of models. This phase has received HRA approval (HRA ref # 17/HRA/0299).

Phase 2: Case studies.

To ensure maximum range, we will purposively select up to 8 case studies of H@H services that vary in model 'type' and location (1-2 case studies per model). 66 patients per model type will be recruited and tracked over time (until death) through data collection from the service provider and the patient's

carer. The primary outcome will be the quality of death and will be collected post death. This will be collected using the Quality of Dying and Death (QODD) tool, a validated interview instrument conducted with bereaved carers [18-20]. Secondary outcomes will include holistic patient assessment (iPOS) [21] and assessment of care by bereaved relatives (VOICES) [22] and service use (AHCR) [23]. Regression analysis will be used to isolate the impact of each service model on quantitative outcomes. An embedded economic analysis will capture resource use and calculate costs. Barriers and enablers to service provision will be explored through in depth interviews with carers, commissioners and providers. Analysis will be iterative with the aim of testing and refining programme theories and to develop provisional context-mechanism-outcome (CMO) configurations. Normalisation Process Theory (NPT) [24] will be used to understand why a model has or has not been embedded within a whole system of care.

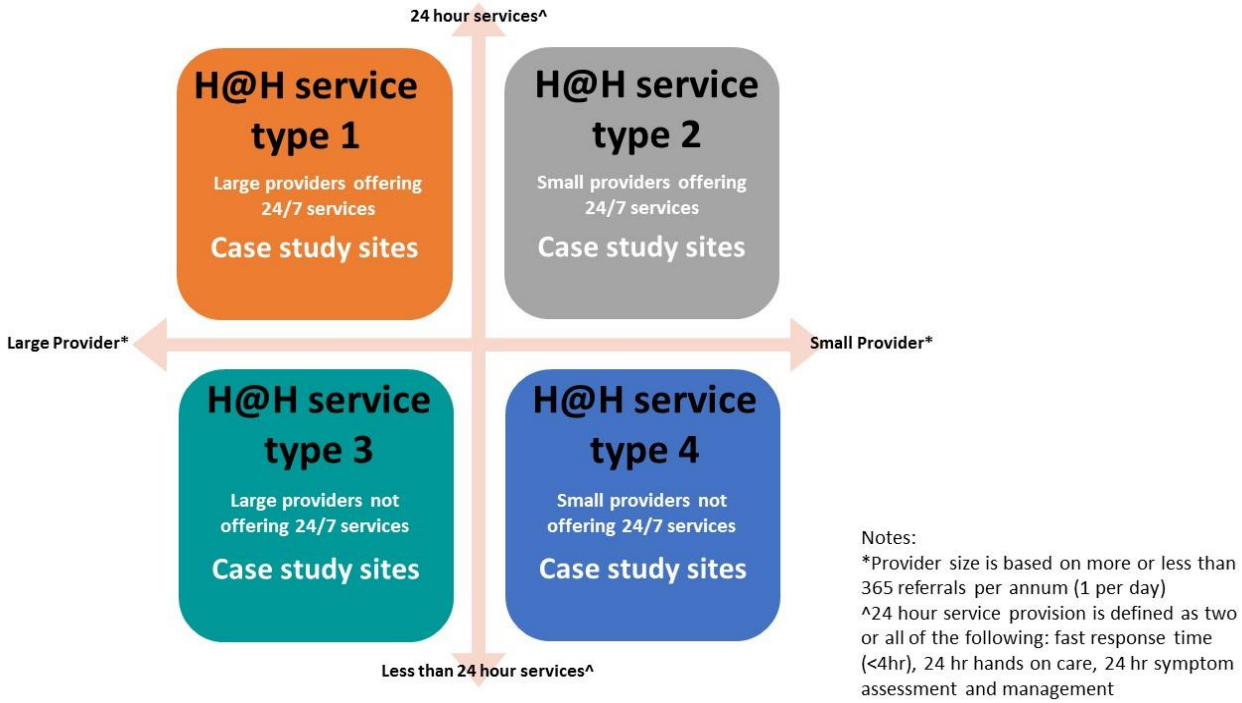
Phase 3: National consensus workshops.

Provisional CMO configurations will be presented and discussed with stakeholders in two workshops to validate interpretation of the data and to refine our understanding of what works, for whom, and under what circumstances. Guidelines will be developed for services and commissioners to help develop H@H services matched to local needs. The most appropriate format for this guidance (e.g. menu of service elements, setting characteristics etc.) will be identified through the consensus events.

4. STUDY SITES

The findings from phase 1 of the overall project were used to create a H@H service model typology comprising 4 model types (see Figure 1). This forms a sampling framework to select case study sites from H@H services in England (ideally from hospices responding to the phase 1 survey). Each type of H@H service within the typology will be represented by one or more case study sites and the H@H service model/type within the typology will be the unit of analysis. We also anticipate that the sample will incorporate geographical spread, mixture of deprivation populations and include services that are innovative or more traditionally delivered. Case study sites will be invited by the Chief Investigator to participate.

Figure 1: H@A service model typology



5. PARTICIPANT ENTRY

5.1 PATIENT CONSENT

Patients within the case study sites will be invited to participate in the study when they are admitted to the H@H service. For the purposes of this study, the definition of Hospice at Home Service is a service with the following characteristics:

- Aims to enable patients to be cared for and die in their place of choice if that is their own home;
- Employs "specialist" staff with high levels of palliative care experience;
- Ability to provide more staff time with the patient than pre-existing/other services.

Local hospice at home service staff e.g. registered nurses or health care assistants (or research nurse if they have one) will introduce the study to the patient. A patient information sheet will be given to the participants and sufficient time allowed to read the information and ask any questions they may have. If needed, the information sheet can be read out to the patient. The local hospice at home service staff member will then gain the patient's consent, using the study patient consent forms. A copy of the information sheet and consent form will be given to the patient and/or their carer, a copy filed in the patients' medical notes and a copy filed in the study site file.

Due to the nature of the patient population who will be close to the end of life, it is anticipated that some of the potential participants will be unable to provide informed consent (due to impaired cognition / impaired consciousness). For this reason a variable consenting process, involving consultee assent, will be used. The local hospice at home service team will decide and proceed using one of the options below:

- If the patient is deemed to have capacity by the local team, then consent will be sought from the patient in the normal manner.
- If the patient is deemed not to have capacity, then a personal consultee (i.e. someone who has a role in caring for the person who lacks capacity or is interested in that person's welfare but is not doing so for remuneration or acting in a professional capacity) will be approached for advice regarding the patient entering the study. In this study, the personal consultee could be a relation of the person, or a friend of the person.
- If the main carer or personal consultee is not available at the best time to approach the patient, a nominated consultee will be approached for advice regarding the patient entering the study. In this study, the nominated consultee could be a clinically qualified member of the patients care team who will not be involved in patient consent or involved in study procedures (i.e. patient data collection).

Where a personal or nominated consultee is used, they will be given an information sheet about being a consultee and the patient information sheet. They should be given appropriate time to read the information and have the opportunity to ask questions about the study, and asked whether in their opinion the patient would have any objection to taking part in the study. The local service staff member will then gain a declaration from the consultee, using the study consultee declaration form, if they agree that the patient would be willing to participate in the study.

Full training on the study and the informed consent process will be provided to local care staff involved in the study prior to the start of recruitment at the case study site.

5.1.1 INCLUSION CRITERIA

- Patient admitted to Hospice at Home services
- Patient has a carer who also agrees to take part in the study
- Ability to obtain informed consent by any of the following
    - Patient
    - Carer/Relative/Friend
    - Nominated consultee

5.1.2 EXCLUSION CRITERIA

- Inability to obtain consent from the participant (or a consultee)
- Patient without a suitable lay carer
- Patients in care homes at the time of admission to H@H service

5.2 CARER CONSENT

Carers will be invited to participate in the study when the person they are supporting or caring for is admitted to the H@H service. For the purposes of this study, the definition of a carer is someone close to the patient who provides care and support on a daily basis at home. This could be a family member, friend, partner or other person who fits this description. Carers should be approached at the same time as the patient. Local service staff e.g. registered nurses or health care assistants (or research nurse if they have one) will introduce the study and provide a carer information sheet. Once sufficient time has been allowed for participants to read the information and ask any questions they may have, the local service staff member will then gain their consent, using the study carer consent forms. A copy of the information sheet and consent form will be given to the carer a copy filed in the study site file. After consent, the carer will be asked to complete a contact details form detailing the best telephone number to contact them on and the best day/time for the research team to call to collect data.

5.3 SERVICE PROVIDER AND COMMISIONER CONSENT

Service providers and Commissioners will be invited to undertake an in depth interview about the provision of H@H services. Potential participants will be invited by email or by telephone and an information sheet and consent form sent to them by email or post. If they wish to take part, interviews will be arranged at a convenient time and location (either by telephone or in person) for the interviewee and will take no longer than 30 minutes. Prior to the interview, the participant will be asked to complete a consent form and return this to the research team.

6. DATA COLLECTION AND FOLLOW-UP

6.1 PATIENTS

After consent, a member of the participants direct care team will complete the Integrated Palliative Care Outcome Scale (iPOS) questionnaire (staff version), phase of illness and modified Karnofsky score. These data will be collected at the point of entry to the H@H service or within 24 hours of consent. The patient and carer pathway is laid out in Figure 1 below.

6.2 CARERS

After consent, a member of the research team will contact the carer as soon as possible to collect health service use data retrospectively for up to two months prior to recruitment. This data will be collected using the Ambulatory and Home Care Record (AHCR) that has been customised for use in this study (24). Contact will then be made on a fortnightly basis, by phone to collect prospective

health service use data in the same way. This will take approximately 15 minutes every 2 weeks. The carer will be given a diary at the time of consent to be used as an aide memoire for fortnightly data collection telephone calls from the research team. The use of this diary is optional.

Around 4 months post-bereavement, a follow up letter will be sent to carers to let them know the research team will be in touch to collect further data and providing options to do this over the phone, using an online survey tool or by post. The following outcome data will be collected at two time-points: immediately post bereavement (optional, carer preference at last health resource data collection telephone contact); at 4-months post bereavement:

- Quality Of Dying and Death (QODD)– 7 day recall, Version 1
- 2 short questions about the overall care received

Where 3 attempts to contact the participating carer by telephone have been made with no success, a paper copy of the above follow up measures will be posted to the carer for completion on one occasion only. This will be accompanied by a cover letter to explain that the research team have been unable to contact them and/or if they would prefer to complete the questionnaire at home they can do so. No further attempts will then be made to contact the carer.

Where telephone data collection at 4 months post-bereavement occurs the researcher will ask the participant if they would be willing to participate in an optional in depth interview by telephone or in person to understand more about the H@H service received. This in depth interview will be completed by a subset of participants only and will include semi-structured interview questions. We will initially interview approximately 20 per service model type with a stopping criterion of 3 interviews with no new themes coded in order to achieve data saturation (see qualitative data analysis) [25]. If the carer is interested in taking part in this optional in depth interview, a final information sheet will be sent and a date arranged to undertake this further interview.

All study data will be collected by July 2019. Therefore, patients who are recruited and are still alive after 31 March 2019 will not be included in the study analysis.

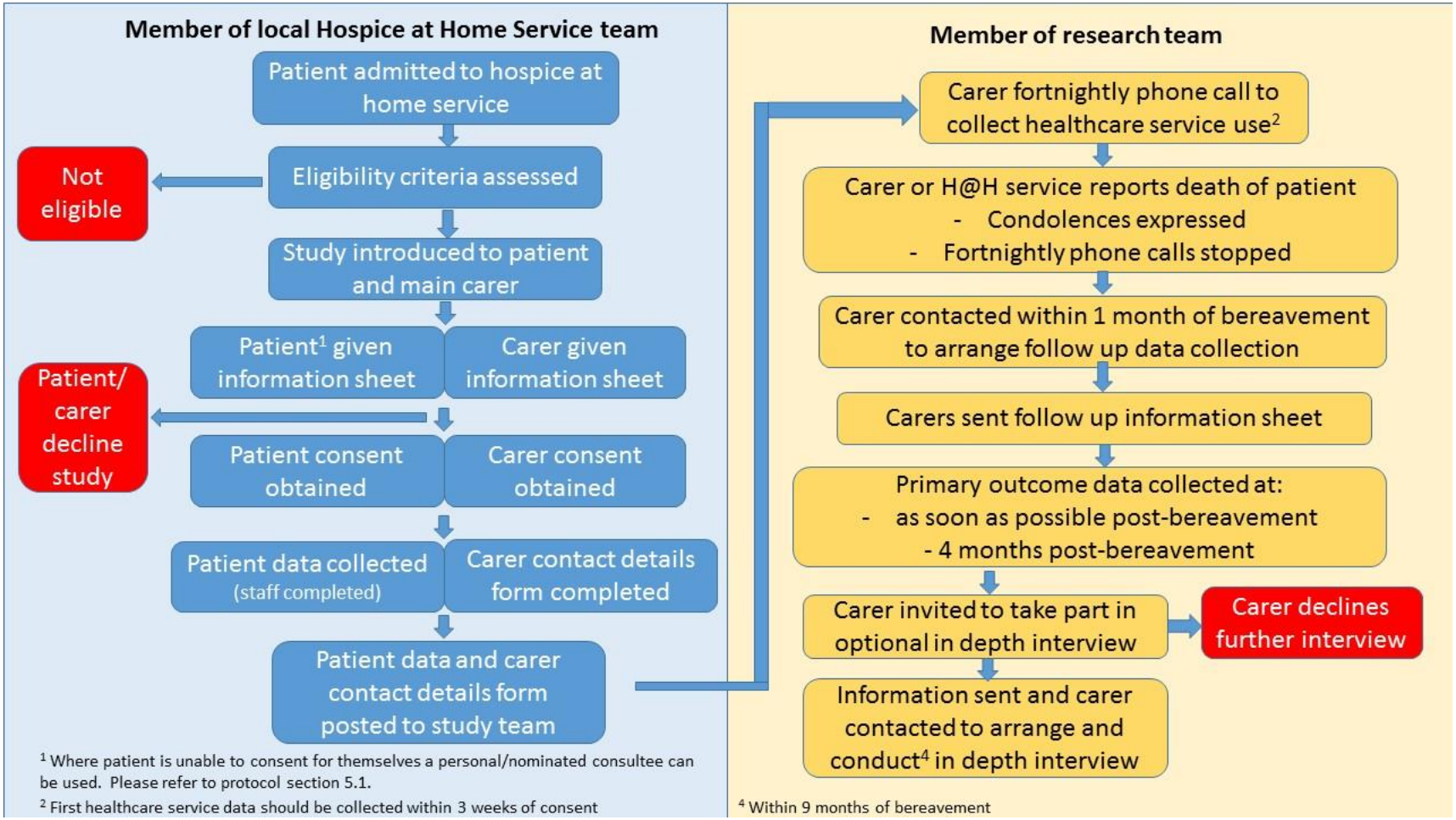
6.3 SERVICE PROVIDERS AND COMMISIONERS

The central research team will conduct semi-structured interviews with 5-10 managers, healthcare staff and commissioners per case study site. Interview schedules will contain semi-structured questions to explore the service logic, rationale, processes and contextual features facilitating or inhibiting service delivery, as well as enablers and barriers to providing H@H services. Service providers and commissioners will be approached as soon as possible after local study approvals have been granted for an initial interview. One to two interviewees will be invited to undertake a follow up interview during the last 6 months of data collection (between Jan 2019 and July 2019) to understand any changes to the service over the course of the study. The same interview guides will be used for both initial and follow up interviews.

6.4 WITHDRAWAL CRITERIA

Participants will be free to withdraw from the study at any time. Patients are made aware that this will not affect the care they receive in the patient information sheet. If a participant withdraws from the study, where possible, they will be asked if the data collected to date may still be used in the final analysis. If they do not wish for their data to be used in this way, all data collected from the participant will be destroyed. If it is not possible to consult the participant on this, data collected up to the point of withdrawal will be used according to the original consent.

Figure 2: Study patient and carer pathway



7. ADVERSE EVENTS

Adverse Event (AE): any untoward medical occurrence in a patient or clinical study subject.

As this study involves no clinical intervention, AE's are not expected. Due care and attention will be taken when collecting data from patients and carer in order to avoid distress or fatigue. In order to identify and support distressed participant, researchers will follow the study Distress Protocol (see Appendix 1) at all times.

Where an adverse event is deemed to be a result of a research activity (namely patient or carer consent or data collection), it will be reported to the Study Co-ordinator. Any questions concerning adverse event reporting should be directed to the Study Co-ordinator in the first instance. The Chief Investigator will notify the Sponsor of all relevant AEs.

If participants wish to make a complaint, they have been provided with contact details to do so in the patient information sheet.

8. STATISTICS AND DATA ANALYSIS

8.1 Sample Size

The scores for the primary outcome measure, the QODD, range from 0 to 100. Hales et al 2014 [26] identify 30 and 70 as cut-offs for distinguishing terrible/poor, intermediate and good/almost perfect quality of death. Hence, on the basis of a difference of 10 points representing a meaningful change, and using a standard deviation of 16.41 [27], at least 44 participants in each model type would be required for comparisons between any pair. In order to allow for participant drop out of 33% we propose a sample size of 66 patients per model type (up to 4 models). Our drop out rate is based on a prospective trial of an intervention which followed up with the carers of patients involved who were sent the 24 item QODD questionnaire by post 4-6 months post death. They received a 55.4% response rate and we predict that the contact through bereavement services and phone interview approach we propose will achieve a better response than the postal survey approach used in this study [28].

Based on estimated H@H service size and annual throughput of patients we estimate that recruitment of 66 per model type is achievable for medium and large units in particular. The National Minimum Data Set 2013/14 by the National Council for Palliative Care [29] grouped H@H services by size into roughly 3 equal groups:

- Small - fewer than 191 patients per annum
- Medium - 191-310 patients per annum
- Large - more than 310 patients per annum

However our final range of models and possible case study sites is unknown until interpretation of the phase 1 survey results. If sites are smaller it will be possible to recruit two or more case study sites of the same model type to reach the overall sample size of 66. In the final regression modelling process (outlined below) we would be able to employ a dummy variable to distinguish between the two providers to check for differences.

8.2 Quantitative Statistical analysis

The characteristics of patients in the different service model types will be summarised using relevant descriptive statistics (proportions, medians, ranges, means, standard deviations, 95% confidence

intervals etc.) before being compared on the basis of each patient socio-demographic, clinical and carer feature using the appropriate bivariate test (including one way ANOVA, chi square and Kruskal Wallis tests, depending on the nature of the variable). Exploratory regression modelling (including logistic regression) will be used in order to investigate the effect of each service model type on the primary outcome (QODD), after controlling for sociodemographic, clinical and carer features. Stepwise regression methods (backward elimination approach, commencing with a set of covariates which have been agreed upon as important by the research team) will be used. The fitted parameters in the final models will indicate if service type is associated with differences in QODD scores. The characteristics of service model types that result in better QODD outcomes will be identified from descriptive data collected at each site as part of the realist evaluation.

8.3 Qualitative data analysis

Interviews will be transcribed and uploaded into NVivo 10 to assist with data management and analysis. Analysis will be iterative with the aim of testing and refining programme theories and further developing provisional context-mechanism-outcome (CMO) configurations [17]. As described above, Normalization Process Theory (NPT) will be used to understand why a model has or has not been embedded within a whole system of care [24], and Burden of Treatment (BOT) will be used to understand the impact of the model on patients and carers. NPT offers a well-established framework for analysis in order to understand implementation processes through the perspectives of multiple stakeholders including: service users; service providers and commissioners [30]. Constructs from the NPT framework will form the basis of a deductive coding structure. Analysis will also seek to identify any emergent themes not covered by NPT. Synthesis of an NPT informed coding framework alongside an inductive approach [31] allows for a focused and yet open qualitative approach that allows unexpected findings to emerge [30]. As a theory-led investigation that uses a deductive and inductive approach to coding, we will use a stopping criterion of 3 interviews with no new themes coded in order to achieve data saturation [25].

8.4 Economic analysis

The economic analysis will be at two levels. First, a descriptive analysis will be conducted of the resources and costs of running each case study H@H service. This will cover: staff; service facilities, equipment, overheads; transport for home care; other sundry items associated with care delivery. These data will be collected at interview with service managers. Where hospices provide community or inpatient services in addition to the H@H, guidance on appropriate attribution of costs will be sought from the finance manager. Information on activity rates will also be gathered so that costs per patient receiving H@H can be calculated and compared between case studies. Second, a patient level analysis will be undertaken. Due to the nature of this study, patients recruited will likely have short and variable life expectancy, leading to an inconsistent time horizon for the individual patient level data captured. This lack of a normalised time integrated measure of health outcome (such as a QALY) or cost, will make a traditional comparative cost -effectiveness analysis problematic. Hence, the economic analysis will be limited to a descriptive analysis of service utilisation and cost for the different H@H models. Whole system resource use in the end-of-life care will be captured prospectively from the point of recruitment to the study for each patient. At first interview, participants will be asked to report retrospectively, via recall, on service use for the two months prior to recruitment. Service utilisation data will cover primary, community, hospital, hospice, social care, voluntary and informal care received. A customised version of the Ambulatory and Home Care Record (AHCR) [23] will be used for this purpose.

Service use data, once captured, will be grouped into 4-6 time periods of approximately equal sample size, delimited by survival time following start of service use data collection. The cut points

will be determined by the distribution of the data. In our previous study [9], 6% of patients referred to a H@H service had died within 2 days, 40% within one month, 62% within 2 months, and the remaining 38% were refer red over 2 months before death. Resource use will be converted to costs using national tariffs [32]. Informal care will be valued using replacement cost methods. For each of the model types of H@H service provision, an average cost/day of treatment will be estimated for the 4-6 time periods respectively. This will provide descriptive cost data, independent of expected survival time that can be compared between H@H model types. Alongside this analysis, a comparison of the average survival times for patients in each of the H@H models will be provided. However, caution will need to be taken when trying to infer a total cost of service from the survival data and average cost of service/day. Costs will be presented as means and median, given the typical skew in the distribution of costs. Comparison of costs between H@H model will be assessed for significance using Mann Whitney test. Sensitivity analysis for costs will be handled deterministically, varying the amount of resource use between their upper and lower limits for each H@H model type. Costs will be analysed in relation to outcomes from different models in a cost –consequences framework.

8.5 Consensus Events

Guided by realist evaluation [11], two national consensus workshops, with up to 60 participants attending in each, will be used to validate interpretation of the data and to refine our understanding of the specific features of H@H models that work, for whom, and under what circumstances. In order to maximise attendance from stakeholders across the country, one workshop will be help in the south (e.g. London) and one will be held in the north (e.g. Leeds). Participants will be identified through the NAHH and our project steering group. It is anticipated that stakeholders will include service providers, commissioners, CCG End of Life Care leads, and service user representatives. Emerging findings and relationships between context, mechanisms and outcomes will be presented to stakeholders [17]. The explicit aim of the workshops will be to refine context -mechanism-outcome configurations and develop consensus on what type of H@H services are likely to work best, and in what circumstances. The workshops will also contribute to translating findings into information that is relevant to managers and commissioners of Hospice at Home services

9. ETHICS AND REGULATORY ISSUES

9.1 ETHICS APPROVAL

The Chief Investigator has obtained approval from the NREC London – Queens Square the Health Research Authority and NHS Research Ethics Committee (ref 17/LO/0880) to undertake this study. The study must be submitted for Site Specific Assessment (SSA) at each participating site. The study will be conducted in accordance with the recommendations for physicians involved in research on human subjects adopted by the 18th World Medical Assembly, Helsinki 1964 and later revisions. As patients may not be able to consent for themselves, the study will also comply with the Mental Health Act 1983.

9.2 CONSENT

Consent to enter the study will be sought from each participant or relevant consultee only after a full explanation has been given, an information leaflet offered and time allowed for consideration. The right of the participant to refuse to participate without giving reasons will be respected. All participants are free to withdraw at any time without giving reasons and without prejudicing their care.

9.3 CONFIDENTIALITY

The Chief Investigator will preserve the confidentiality of participants taking part in the study under the Data Protection Act.

9.4 SPONSOR AND INDEMNITY

The University of Kent will act as the Sponsor for this study. Delegated responsibilities will be assigned to the Hospice Sites taking part in this study.

The University of Kent holds negligent harm and non-negligent harm insurance policies which apply to this study.

9.5 FUNDING

National Institute for Health Research (NIHR) are funding this study through the Health Services and Delivery Research Programme. Where hospice staff undertake research activity, service support costs will be provided. Funding for sites is laid out in the statement of activities HRA document.

9.6 AUDITS AND INSPECTIONS

The study may be subject to inspection and audit by the University of Kent under their remit as sponsor.

10. STUDY MANAGEMENT

The day-to-day management of phase 2 of the study will be co-ordinated through the Universities of Kent and Cambridge.

11. PUBLICATION POLICY

The results of this proposed research will be of national importance in the UK and of interest to Hospice at Home (H@H) service providers, commissioners and patient groups; these will be the primary targets for dissemination. The outputs from this project will aid and support H@H services to achieve the best outcomes for patients and families at the end of life including assisting them to die at home if this is their preference, without losing sight of a 'good death' experience. Our expected outputs will be guidelines for services and commissioners to help in decision-making and service development of H@H services. The guidelines will show what models/features of H@H services work best and at what cost.

Publication of the full and complete account of the research will be in the NIHR HS&DR Journal. This will allow the research to be freely and publically available via the NIHR journals library website. Results will also be targeted at peer reviewed journals such as such as British Medical Journal, Social Science and Medicine and British Journal of General Practice to reach broad audience coverage in community services, and Health Services Journal to reach service commissioners.

To reflect the likely wide interest in the study findings from patients to policymakers, and capitalise on the potential to improve care, a range of dissemination strategies will be employed to:

- Inform National Policymakers and commissioners
- Reach commissioners through co-applicant links
- Disseminate findings through the existing network of the National Association for Hospice at Home (NAHH) which currently has a membership of 79 organisations and a regular newsletter and annual conference.

- Patients and the Public - A Plain English summary for public and patient engagement and dissemination will be written. This will also be disseminated to our research participants.

The research findings will also be disseminated through presentations at existing research forums such as the European Association of Palliative Care Congress; Clinical Research Network forums; Cicely Saunders Institute, King's College, London; Hospice UK annual conference; National Association for Hospice at Home (NAHH) conference. Findings of the study will be published through press releases of the organisations of the research team and further dissemination through their own newsletters, websites and through social media e.g. Twitter. Finally, dissemination of findings aimed at the public will be facilitated through links with specific organisations including the National Council for Palliative Care.

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13. APPENDICES

Appendix 1: Distress Protocol

Post-bereavement, carers will only be contacted after they have received the offer of local bereavement services in order to reduce any potential distress. Any distress encountered is likely to reflect the challenges of caring for someone and grieving for a family member or friend. All data collection will be carried out in person or over the telephone. Therefore, if a participant becomes distressed, the researcher will be able to support and refer participants to further support services straight away. It is possible that carers may become distressed or raise issues during the study that cause concern and/or need for further medical or emotional support. Should this occur, a member of the research team will gain consent from the patient to discuss matters with a relevant support service or the individual's General Practitioner (GP), as appropriate. All of the research team will complete study specific training on addressing distress during data collection for the study.

The following procedures will be followed in order to minimise distress and resolve any situations where distress becomes apparent to the researcher.

Before any interview/questionnaire begins the researcher will inform the participant that:

- They do not have to answer any questions they would rather not answer
- They can pause or stop the interview at anytime
- They can terminate the interview without giving a reason
- The researcher will inform the participant that some of the questions may be distressing or cause them to feel emotions that are common to feel during the grieving process.

During the interview/questionnaire, the researcher should be observant for the following signs of distress:

- Crying - Shaking - Anger - Shouting - Non-responsive to Questions

If the researcher recognises the participant is excessively distressed, they should:

- Stop the interview and acknowledge the participant's distress immediately
- Re-iterate to the participant that they may stop for a break or stop the interview if they are finding it too distressing. They can also withdraw from the study.

The researcher should discuss how the participant would like to proceed using the following options.

STOP interview and withdraw	Take a break/offer another time and day to continue	Continue with the interview

At the end of the interview, acknowledge that the participant was distressed and offer one of the following support options

- Family member or friend who can come before researcher leaves. If no one available straight away – ask participant to contact family or friend.

Where a participant becomes distressed, the distress log will be completed by the researcher and reviewed by the project team on a monthly basis. Where an occasion of distress requires senior support, the study manager will ensure this is be reviewed by the Chief Investigator as soon as possible and appropriate action taken.