OPEL H@H

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

Protocol Version 5, 16 August 2019

Full protocols for phases 1-3

Overview of contents:

SECTION 1: Study Phase 1

STUDY PROTOCOL

PHASE 1

VERSION 1, 5 December 2016

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Detailed Project Description

1 Full title of project
Optimum 'Hospice at Home' Services for End of Life Care (OPEL-H@H project) **Phase 1 Protocol**

Hospice at home (HAH) services aim to offer the quality and ethos of hospice care at home to support dying patients to have a "good death." HAH 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] and thus 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 HAH 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 [8-10], though not all HAH services demonstrate the same outcomes. It is unclear what elements of these services deliver which outcomes and whether such outcomes are delivered in conjunction with other primary care and community services which often 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 HAH services difficult and stifles efficient service development.

To address this knowledge gap amulti-site evaluation conducted over three phases is to be conducted. This protocol describes phase 1 of the study which is an initial scoping survey of existing hospice at home services. The later project phases will involve methods that are able to capture in depth the structure, process and outcomes which can inform national policy and commissioning decisions to provide optimum HAH services.

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

Our research question is:

What is the range and variability of Hospice at Home (HAH) models operating across England?

The study objectives are to:
1. Identify the range and variation of HAH models operating across England.
2. Categorise the models by type, key features and setting.

Research Design:
A national telephone survey will be conducted of all known HAH services in the Hospice UK service directory to map the range and variation of HAH services in order to develop a typology of models. The analysis will be used to develop a sampling framework to identify case study sites and to inform phase 2 data collection.

3 Background and Rationale
In 2007 Pilgrims Hospices, which at the time 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 HAH services which was carried out at the University of Kent. The literature review [11] 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. Alongside the roll out of this service, a successful application to RfPB was made, in collaboration with the University of Kent, for an evaluation 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 [12-13]. 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 is 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 application 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 serves as an example and a snapshot of the national problem in how best to develop hospice at home services.

While our questions about how to optimise local services and improve patient and family experiences persist, and the evidence base in the literature is expanding, it is not reaching a consensus in a way that would help us to make decisions about how to improve service delivery. We have conducted a further scoping review of the literature in which we have identified evaluations of 20 services that have HAH characteristics [8-10, 14-46]. Each study has focused on an individual service and used various methods to investigate locally determined patient, carer and professional outcomes. Outcomes frequently focus on one or more of the following: place of death, fulfilment of wishes, carer satisfaction, carer bereavement, symptom management, experience of the service, and hospital admission. No study comparing different types of HAH services was identified in our literature review. 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 HAH services are that deliver desirable outcomes, the range of HAH services in existence makes it difficult to identify similar services in comparable settings. There are 132 HAH 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 HAH services developed through three national HAH stakeholder workshops held in 2011-12 [47]. The NAHH also worked with Hospice UK and conducted a survey across 76 HAH services in England, which provided some useful data to start to describe the landscape of HAH services. This survey concluded that more than one model of HAH service exists and they are not homogenous in their outcomes [48]. Research to date has explored individual HAH services and their outcomes, but no research has taken into account and capitalised on the range of different HAH service organisations and settings to generate evidence. It is this understanding of the different types of services and the settings in which they work that would be most useful to understand how our own service, and indeed other services nationally, might be improved.

4 Evidence explaining why this research is needed now

The UK is widely regarded as a world leader in End of Life Care which has evolved from modern hospice care, pioneered by Dame Cicely Saunders. The desired outcomes are ultimately to achieve a “good death” for the patient and to support carers during the final stages of their loved one’s life and adjustment in bereavement. The best ways to provide care within a patient’s home and how this can be maintained for as long as possible was identified as one of the top ten research priorities of a James Lind Alliance priority setting partnership on palliative and end of life care published in January 2015 [7]. It is also expressed as a priority in UK policy: “How we care for the dying is an indicator of how we care for all sick and vulnerable people. It is a measure of society as a whole and it is a litmus test for health and social care services.” [1, pp 10]. Hospice led, home-based community services offer an acceptable solution to meet these social and political drivers, yet their expansion has so far been haphazard.

The recent report for the Minimum Data Set for Specialist Palliative Care (MDS) shows a notable rise in the numbers of patients using community-based services: 138,026 people accessed community-based specialist palliative care services alone in 2013/14 which is up from 118,861 in 2008/09 and represents nearly a quarter of the annual dying population [49]. This rise is somewhat unsurprising as evidence has shown that most people have a preference to die at home [2] and the number of patients wishing to die at home is increasing [3-5]. A cost analysis from the previous RfPB study described above found that users of the hospice at home service had significantly lower utilisation of hospital services [50]. Given that most of the population dies in NHS hospital [60], there is clearly potential to increase the number of patients accessing community care and at the same time reduce NHS acute care costs. Demographic studies predict a future of increasing numbers of older people and increasing numbers of deaths [51]. Alongside this there is a changing demographic of death at older ages, increasingly from chronic conditions and multiple co-morbidities with long periods of

decline which presents a need to reconsider models of hospice care in order to meet the changing population needs and preferences to remain at home as long as possible [52]. The proportion of people dying in hospices in England has nearly doubled since 1993, but the gap in hospice deaths between people living in the least and most deprived areas appears to be growing [52]. The need for hospice care is increasing, yet is unevenly distributed for reasons which are not well understood. A recent Health Ombudsman report highlighted how more needs to be done to support the health service in delivering quality care at the end of life [53]. HAH services are increasingly becoming an important component of community services and the Demos Dying for Change report estimated that an effective national hospice at home service could serve about 90,000 people a year and cost £150 million [6]. It is therefore important to understand how best to deliver effective HAH services, at scale and in a cost effective manner to achieve the outcomes desired.

5 Aims and objectives

The overarching aim of the whole study is to investigate the impact of the organisation and delivery of different models of HAH on patient and carer outcomes and experience of end of life care from the perspective of service users, their family carers, service providers and commissioners.

The research question for phase 1 of this study is: What is the range and variability of Hospice at Home (HAH) models operating across England?

Objectives to address the primary research question are as follows:

1. Identify the range and variation of Hospice at Home models operating across England.
2. Categorise the models by type, setting and key features.

6 Research Plan / Methods

Design

Phase 1 will be a national telephone survey of all HAH services in the 'Hospice UK' service Directory serving adult palliative care patients within England. This is to provide context for the field work in phase two. It will focus on adult services only due to the different needs of children with life-limiting illness and on England for reasons of logistics and uniformity of background healthcare service provision.

The purpose of the survey is to produce a comprehensive map of the range and variation of HAH services and to develop a typology of models. The survey will provide information on service features such as staff profile, referral criteria for accepting patients, data on service level outcomes such as speed of referral response; views on challenges and enablers of providing HAH services; and data on funding, resource implications and costs.

Adult HAH services in England and the appropriate contact (e.g. Hospice Manager, or service lead) will be identified through the Hospice UK directory (approximately 132 services) with support from NAHH and Hospice UK. The NAHH, represented by K Greene, has experience of collecting data from these organisations and will support this task. The collection of survey data via telephone interview is proposed in order to achieve a higher response and more complete data as experience from the NAHH surveying their own member services suggests that response to postal surveys could be low and incomplete data received. The results from the 2013 membership survey received a 38% response rate (26 of 67 members) [54]. 76 services responded to a joint survey of all services in England and Wales between Hospice UK and NAHH in 2012 [48].

Each service contact will be approached to take part via post when they will receive an information letter and copy of the survey. The service contact will be invited to offer a time to arrange an interview to collect the data over the phone, or otherwise to return an opt slip if they do not wish to participate. Contacts will be followed up two weeks after the mail out to arrange the interview if they have not responded. To acknowledge and encourage services to participate and engage in the project, services participating in the survey will be invited to attend the stakeholder event as part of phase 3 of the project and will receive up to £50 towards their travel expenses.

The survey will be semi-structured comprising a selection of closed and open questions and will provide information on service setting, configuration, operations and outcomes.

The Survey will include questions on:

- Local population needs and circumstances e.g. urban or rural, population size, levels of deprivation.

- Other relevant services operating in area, e.g. Marie Curie arrangements, 24h district nursing, other charities (e.g. Cross Roads, Age Concern), Continuing Healthcare funding and services. How do they integrate/liaise with other service providers?
- Access to palliative care beds: hospice beds, palliative care beds in other settings.
- Activity data for previous year: number of referrals, demographic characteristics of patients referred (age, sex, cancer/non cancer), duration in service, number of patients without a family carer in the home, total number of service hours received per patient, number of referrals rejected.
- Staffing e.g. HCAs, registered nurses, doctors and Allied Health Professionals and time allocated to HAH.
- Facilities and equipment, availability and access.
- Medications, availability and access, who gives injectable medications in an emergency?
- Referral criteria e.g. actively dying in hours/days, prevention of hospital admission, longer term care.
- How the service operates: how are referrals made? will referrals be actioned 24/7?, response time from 1st referral, assessment process (before service is accessed), out of hours visiting (which staff?), lengths of interventions (e.g. 1h, 2h, 4h, full shifts in the home), frequency of interventions available, how do patients exit the service (e.g. numbers experiencing transfer of care to social care packages, hospice or hospital admission, death).
- Service budget: income sources (NHS, Local Authority social care, donations, other) and expenditure categories (patient facing staff, administrative support, facilities, equipment, overheads).
- Outcomes: what data are collected? How are they performing against the agreed outcomes measured (e.g. death at home, responding within 4 hours to crisis), preferred place of death, actual place of death.
- Barriers and enablers to providing the defined service. If it has changed from its original brief, what is this and why.

The survey will be led by the University of Kent team, in terms of the design, identification of services, mail out of information letters and survey questions to enable the service to collect the relevant data in preparation for the telephone survey phone call. The telephone survey calls will be conducted by a registered nurse who will be able to understand and uncover differences in service configuration and operation. University of Kent will be responsible for data management; statistical analysis will be undertaken by the statistician at the University of Surrey.

Data Analysis and Interpretation

The interpretation of the survey findings will involve iterative consensus work with the project steering group and PPI advisory group to develop model categories from the survey information. Categorical variables (e.g. urban/rural, presence of hospice building(s), involvement of full-time nurse (Yes/No), etc.) will be cross-tabulated with each other in order to identify underlying associations. Continuous variables (e.g. area population, area (square miles), number of individuals employed by the service (whether full-time or part-time), yearly number of FTEs funded by the service, percentage of staff who are qualified doctors/nurses, etc.) will be compared between different categories of each categorical variable, as well as being plotted against each other, in order to identify underlying associations. These results may assist in interpreting a cluster analysis in order to identify natural groupings. From this work it is envisaged that approximately 4 high level categories of the model will be distinguishable. This estimate is based on previous survey work from the NAHH/Hospice UK which indicated there to be at least two types of model [48]. They found two groupings of providers: those that delivered high numbers of episodes of care versus services who offered significantly less, with notable differences between the two on reasons for referral, duration of episodes, who is involved in delivering care and knowledge regarding preferences and place of death. The estimate is also based on our own experience in which we have found that there are services with and without nursing provision, and those that are available with rapid access 24/7.

The typology of models will be fed back to participating services and those which did not respond to the survey to validate the model types.

The typology and specific characteristics identified through the survey results will be used to develop a sampling framework. Dependent on the findings from phase 1, the framework will be designed to ensure typicality and sufficient range across: local population needs and circumstances; availability of other local relevant services; access to palliative care beds and resources; service design and activity levels; and skill mix.

7 Dissemination and projected outputs

Participants in the survey will receive a summary of the findings. At this point they will also be informed of phase 2 of the project which will be in depth case studies of service models and that they may be approached to be considered as a possible case study site.

A presentation of the survey stakeholders will also form but of the work for their feedback on the typology development for phase 2 of the project. This typology will be the main output of phase 1 of the study.

On completion of the whole project the results of the research will be of national importance in the UK and of interest to Hospice at Home (HAH) service providers, commissioners and patient groups; these will be the primary targets for dissemination. Internationally, the findings may require interpretation, depending on other service and funding factors, but will nevertheless have relevance.Our expected outputs will be guidelines for services and commissioners to help in decision-making and service development of HAH services. The guidelines will show what models/features of HAH services work best and at what cost. Hospices, other providers and commissioners would be able to identify what the optimum HAH service model or key features of a HAH service would be for their population in their locality and organisational systems. This approach will promote knowledge mobilisation as the findings will have a direct impact on the management of services as it will provide HAH service providers with information on the barriers and enablers to a successful service which will be relevant to their own service context. The format of this guidance will be informed as part of the consensus workshop to identify what is the most useful presentation for services and commissioners to utilise. For example, the guidance might include a 'menu' of service features (e.g. medication boxes) which would indicate in what settings they work best (e.g. poor access to pharmacies out of hours) and what types of outcomes they lead to (e.g. improved pain relief). Additionally, the consensus events themselves will offer the opportunity for service providers to come together to share challenges and discuss good practice.

The outputs from this project will aid and support HAH 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. Therefore the 'end users' who would benefit would be any person who wishes to be cared for at home at the end of life and their family/friends. It will also prevent avoidable consequences such as unwanted or inappropriate acute hospital admission, which is central to NHS and government policy.

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:

<u>Policymaker, commissioner and professional engagement</u>

- Reach commissioners through the links that our co-applicant Bee Wee has with the Commissioning Assembly, the NHS Clinical Commissioners groups and to members if the Ambitions for End of Life Care Partnership Group. Bee Wee co-chairs the latter group which consists of representatives from 25 national organisations (including ADASS, royal colleges, and third sector organisations.) She will support the dissemination of the work through the Palliative and End of Life Care Networks, the Commissioning Assembly bulletins, and NHS England's regional teams and new models of care teams.
- Results will be disseminated to national policy makers and the health minister (Ben Gummer), though the project co-applicant (Bee Wee) as a national commissioner. We will also disseminate through Hospice UK by publishing a news article in the e-Hospice newsletter of this National organisation will also assist with bringing the results of the research to national attention.
- To reach a wider professional audience and further engage commissioners we will publish in a journal such as Health Services Journal and present at a conference such as the Health Services Research Network.
- Dissemination 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.

<u>Written publications</u>

- Publication of the full and complete account of the research in the NIHR HS&DR Journal. This will allow the research to be freely and publically available via the NIHR journals library website.
- 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.
- A Plain English summary for public and patient engagement and dissemination will be written. This will also be disseminated to our research participants.

Presentations

- Oral 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.

Public engagement

- We will create a twitter account to regularly update on project progress and debate, e.g. discussions at the consensus event. This will enable participants (services and individuals) and the wider public to see in real time their contribution being used in research and which will encourage public engagement.
- 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.
- Dissemination of findings aimed at the public will be facilitated through links with specific organisations including the National Council for Palliative Care.

8 Phase 1 Survey Timetable

The timescale to complete the survey is 6 months.
Mail out and data collection will be month 1-5
Analysis of the results including typology development and consensus will be months 5-6.

9 Project Management

Claire Butler, (Chief Investigator) will take lead responsibility for the research project, with a project manager managing the project day to day (Melanie Rees-Roberts. The University of Kent (Patricia Wilson and Ferhana Hashem) will lead on the delivery of the survey with advice from the NAHH (represented by Kay Greene) and other project partners. A research with nursing experience will collect the survey data.

The University of Surrey will be responsible for the statistical analysis of quantitative data collected in phase 1 through Peter Williams. .

C Brigden at Pilgrims Hospices will facilitate and manage the PPI group associated with this project

Research team meetings will be held bi- monthly (monthly during phase set up periods). The majority of meetings will be conducted via skype video conferencing or in Kent. Lay co-applicants Graham Silsbury and Nicola Enright will attend these meetings.

The independent Study Steering Committee will ensure that key milestone of phase 1 is met, monitor the conduct of the project and the well-being of the participants from the data reported.

Team meetings and public and patient involvement work will coincide with the project steering group meetings so that information can be fed into the steering group. The timing of the meetings will enable input into study set up to support the data analysis of the project. One-two steering group meetings are planned over the course of phase 1 of the project which will be held at Hospice UK in London.

The independent Study Steering Committee will be constituted by independent researchers, including those involved with the development of the tools involved (Katherine Hunt, VOICES survey), a local commissioner (Faye Hames from Thanet CCG) and lay representatives (representatives locally from the Pilgrims Hospices lay advisory group that informed the project development and from national organisations such as Macmillan Cancer Care will be invited to attend).

10 Approval by Ethics Committee

At phase 1 involves staff as participates only ethical review has been sought from the University of Kent research ethics committee from the School of Social Policy, Sociology and Social Research.

11 Patient and Public Involvement

A lay advisory group consisting of four members was formed to support the development of the whole project proposal. This group has supported the development of the application by giving feedback on the project idea, research question, outcome measures, ethical considerations, reviewed application drafts and the plain English Summary. The group includes two bereaved carers: one was involved in the User Advisory Group for a previous RfPB funded Hospice at Home (HAH) project and the other has direct experience of HAH as a carer. The other two are members of the public (one is a hospice volunteer) who both have a keen interest in

research and in hospice care. Members of the group have met with the Pilgrims Hospices Research Facilitator (Charlotte Brigden) on two occasions during the development of the application and via email/phone. Two members of the group are co-applicants (Graham Silsbury, Nicola Enright) and will continue to support the project as part of the study team.Both have shown commitment and a keen interest in improving end of life care. As integral members of the research team it will ensure the project is iteratively informed by the end-beneficiary perspective. The two remaining lay members will be invited to continue to support the study as part of the project steering committee.

Training for the lay co-applicants will be provided by the University of Kent which has an existing PPI support programme as appropriate throughout the whole project. Support will be tailored to specific needs but will include partnership approaches to developing roles and expectations within the project; introduction to understanding research and governance approaches; and preparation and support for research meetings and qualitative analysis in the case study phase. The co-applicants will also be paid for their time on the project in line with guidance from INVOLVE, the national advisory body for public and patient involvement in research [55]. Current service users will also form part of the project PPI advisory group as they will be invited to give feedback on elements of the project. The PPI advisory group (consisting of two lay co-applicants and current service users) will help with development of information sheets, data collection tools and procedures, recruitment strategies, reporting and dissemination plans.

In addition to these local PPI activities which are based at Pilgrims Hospices, we aim to identify additional lay input at a national level e.g. Macmillan Cancer Care or other similar national organisations through representation on our project steering group. Given that our study will involve service providers as participants we have also sought involvement from relevant health professionals and stakeholders. We have presented our ideas to the National Association for the Hospice at Home (NAHH) executive committee and have received feedback on drafts of the application from committee members through Kay Greene who is the committee Vice Chair and co-applicant on this application. Their feedback was particularly helpful in identifying the range of HAH services and the most appropriate way to approach services to take part in the study. We will continue to engage with the committee through Greene throughout the course of the project. Their input will be particularly valuable in the development of the survey, case studies and stakeholder consensus event in terms of how we present the information and approach data collection to help engage HAH service providers and commissioners to participate.

12 Costs and support required

The total research grant requested for the whole project (phase 1-3) is £760,162.32.

The University of Kent will have overall responsibility for the phase 1 survey and will be supported by the NAHH for identifying services. Admin support has been provided to assist with mailing out invitations and information materials, liaising with services to help identify any missing information and assist with data entry and cleaning. The survey will be carried out by a hospice research nurse. A researcher will support data collection, interpretation and analysis. A small budget has been included for printing and mailing letters, information materials and producing a summary report of phase 1 findings which will be fed back to services for information.

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SECTION 2: Study Phases 2-3

STUDY PROTOCOL

PHASE 2-3

VERSION 4.1, 21 March 2019

SPONSOR: University of Kent

FUNDERS: National Institute for Health Research (NIHR) Health Services and Delivery Programme

STUDY COORDINATION CENTRE: University of Kent

HRA/REC reference: (17/LO/0880)

Protocol authorised by:

Name and Role: C BUTLER CI Signature: Date: 27/6/19

Study Management Group

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Clinical Queries should be directed to Melanie Rees-Roberts, Project Manager, who will direct the query to the appropriate person

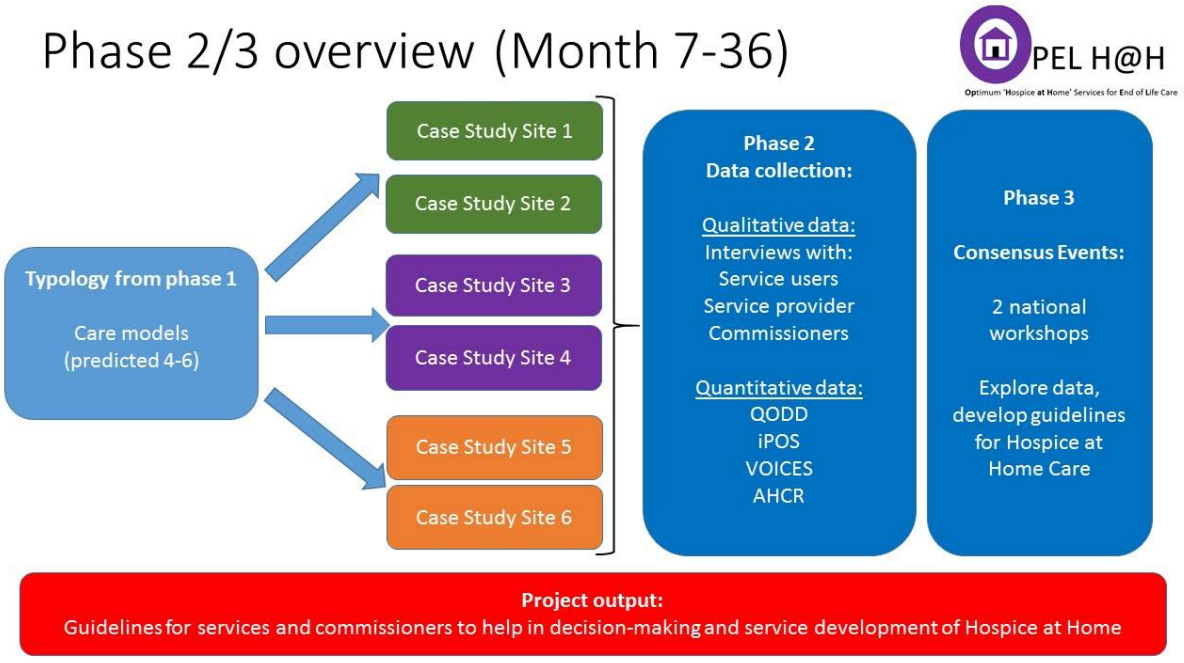
For further information regarding the sponsorship conditions, please contact the University of Kent, Research Ethics and Governance Officer, Nicole Palmer (n.r.palmer@kent.ac.uk)

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



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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.

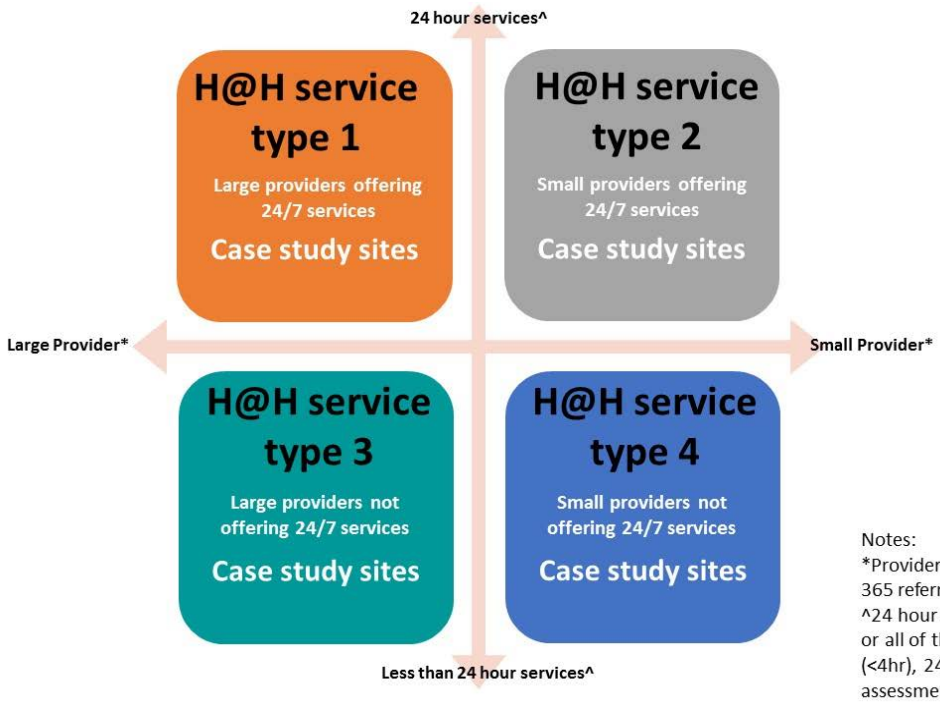
Phase 3: National consensus workshops.

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 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. 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



Notes:
*Provider size is based on more or less than 365 referrals per annum (1 per day)
^24 hour service provision is defined as two or all of the following: fast response time (<4hr), 24 hr hands on care, 24 hr symptom assessment and management

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 and 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 by the research team 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 collect some background information about the patient, 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 2 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.

<u>Post bereavement</u>

Post-bereavement, a follow up letter will be sent to carers to remind them that the research team will be in touch to collect further data. This letter will include information sheets about the QODD questionnaire and also about the in-depth interview.

Questionnaire

Participants will be given options to do the QODD over the phone, using an online survey tool or by post. The following outcome data will be collected at up to two time-points: immediately post bereavement (optional, carer preference at last health resource data collection telephone contact); at around 1-6 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.

Optional interview

An 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 QODD is collected by telephone, 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.

If the QODD questionnaire is done in the postal or online form, carers can indicate if they would be happy to take part in an optional interview at the end of the questionnaire. If the postal or online QODD questionnaire is not completed within 1-2 months, a final follow up letter will be sent to ask carers to take part in the optional interview only. No further attempts will then be made to contact the carer by telephone unless carers indicate their willingness to take part in an interview in the postal/online QODD questionnaire or final follow up letter reply slip.

All study data will be collected by October 2019. Therefore, patients who are recruited and are still alive after 30 June 2019 will not be included in the study analysis.

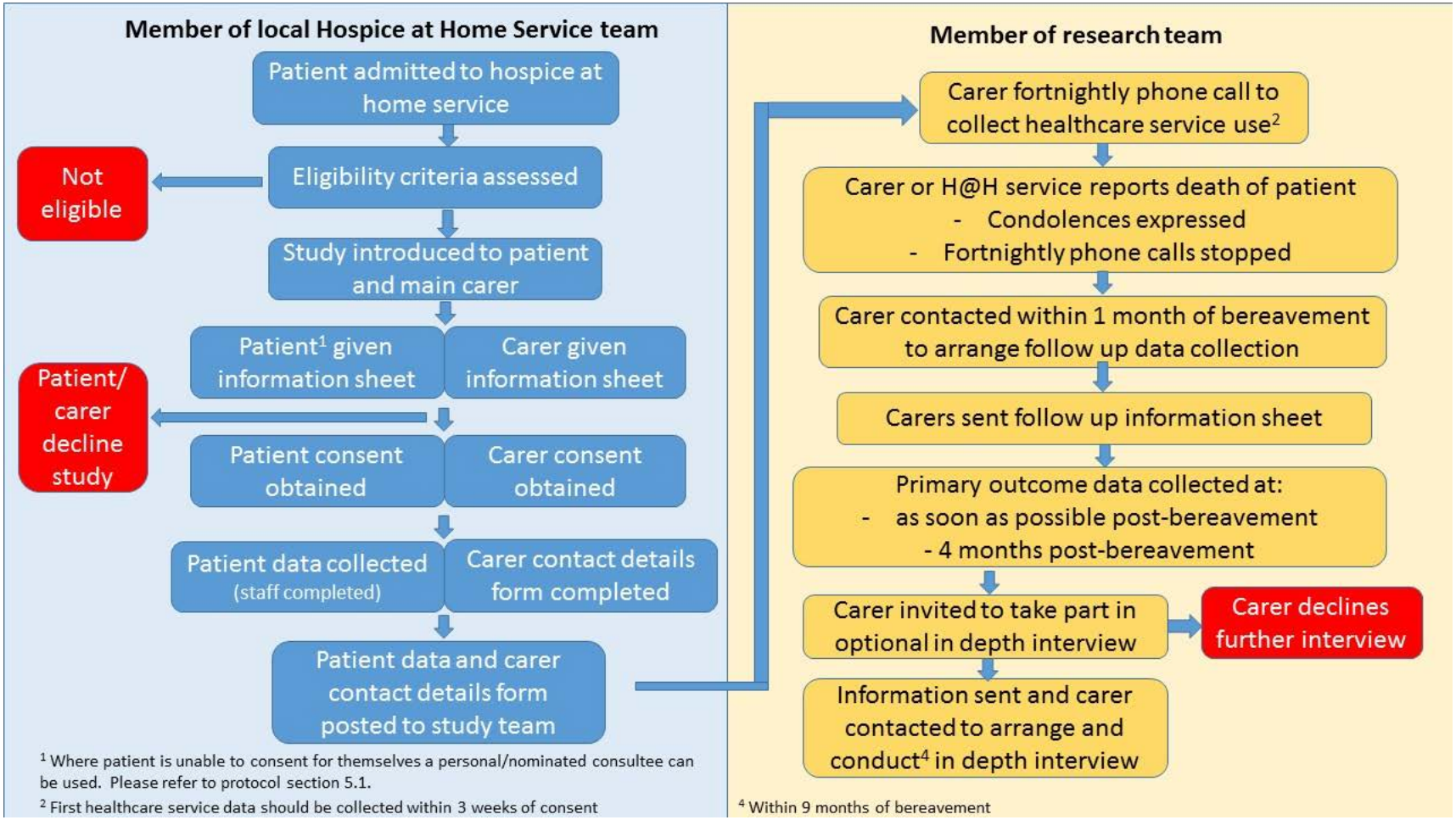
6.3 SERVICE PROVIDERS AND COMMISIONERS

The central research team will conduct semi-structured interviews with 5-10 managers, healthcare staff and commissioners per case study site. This may include local supporting service providers e.g. district nurses, who will be identified by the case study sites. 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.
- If no family or friend available. Researcher will offer any required support and ensure participant is comfortable before leaving – GP or other support service

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.