Thinking Ahead: Exploring and Understanding Experiences and Decisions in End of Life Care

Study Protocol

FULL STUDY TITLE	**Thinking ahead about medical treatments in advanced illness: A qualitative study of barriers and enablers in end-of-life care planning with patients and families from Black, Asian and Minority Ethnic (BAME) backgrounds**
SHORT STUDY TITLE	**Thinking Ahead: Exploring and Understanding Experiences and Decisions in End of life Care**
PROTOCOL VERSION	**2.0**
PROTOCOL DATE	**29th May 2019**
CHIEF INVESTIGATOR	**Professor Christina Faull, LOROS Hospice**
SPONSOR	**University Hospitals of Leicester NHS Trust**
IRAS REFERENCE	**251664**

SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor's SOPs, and other regulatory requirement.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor

I also confirm that I will make the findings of the study publically available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

For and on behalf of the Study Sponsor:

Signature: Date:

..../...../.....

Name (please print):

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Position:

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Chief Investigator:

Signature: Date:

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Name: (please print):

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ABBREVIATIONS

ACP	Advance Care Planning
AE	Adverse Event
BAME	Black Asian and Minority Ethnic
CA1	Co-applicant Kristian Pollock
CA2	Co-applicant Irfhan Mururajani
CA3	Co-applicant Simon Royal
CA4	Co-applicant Simon Conroy
CA5	Co-applicant Alison Pilsworth
CA6	Co-applicant Louise Wallace
CI	Chief Investigator
CCG	Clinical Commissioning Group
CRF	Case Report Form
DNACPR	Do Not Attempt Cardiopulmonary Resuscitation
eELCA	e-End of Life Care for All programme of Health Education England E-Learning for Healthcare
EOLC	End of Life Care
EOLCP	End of Life Care Planning
FCGs	Family Care Givers/Close Friends
GCP	Good Clinical Practice
GDPR	General Data Protection Regulation
GP	General Practitioner
GSF	Gold Standards Framework
HCP	Health Care Professional
HRA	Health Research Authority
ICF	Informed Consent Form
ICH	International Conference for Harmonisation

LOROS	The Leicestershire and Rutland Hospice
LRM	LOROS Research Manager
PCBR	Public, Carers and Bereaved Relatives Research Consultation Group
PI	Principal Investigator
PID	Personal Identifiable Data
PIS	Participant Information Sheet
PMG	Project Management Group
PPI	Public and Patient Involvement
REC	Research Ethics Committee
RA	Research Associate
RF	Research Fellow
SOP	Standard Operating Procedure
SSC	Study Steering Committee

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STUDY SUMMARY

Study Title	**Thinking ahead about medical treatments in advanced illness: A qualitative study of barriers and enablers in end-of-life care planning with patients and families from Black, Asian and Minority Ethnic (BAME) backgrounds**
Internal ref. no. (or short title)	**Thinking Ahead: Exploring and Understanding Experiences and Decisions in End of life Care**
Study Funder	NIHR HS&DR 17/05/30
Study Design	This 30 month qualitative exploratory study will take place in the East Midlands, UK. LOROS Hospice is the single host / recruitment site and patients and family care givers (FCGs) from Black, Asian and minority ethnic (BAME) communities and health care professionals (HCPs) who support them will be recruited through participant identification centres (PIC sites) in primary and community care, specialist palliative care services and acute hospital services within Leicestershire and Nottinghamshire. Public and professional participants for stakeholder workshops will be recruited more widely in the East and West Midlands. There are three work streams: **Work stream 1** Longitudinal patient-centred case studies comprising a BAME patient and FCGs and a HCP nominated by the patient. Each

	participant will have opportunity for an initial interview and up to two follow-up interviews over a six month period. Up to 20 patients will be recruited and between two to ten interviews per case study will generate a maximum of 170 interviews with up to 70 participants. The different data sources for the patient centred case-study, including a review of the patient's medical records, will be triangulated. **Work stream 2** Single interviews with up to 20 bereaved BAME FCGs who have experienced the loss of a family member from advanced illness. **Work stream 3** Six public and professional stakeholder workshops in Nottingham and Leicester for up to a total of 60 people will discuss fictionalised, real-life scenarios and end of life care planning (EOLCP) practices derived from the data. Stakeholder views on how the findings could best translate to training for HCP will shape the project outputs.
Study Participants	**Work stream 1**: Patient Centred Case studies Up to: 20 Patients 30 Family care givers 20 Health Care Professionals **Work stream 2**: Interviews with Bereaved Carers

	Up to: 20 Bereaved Carers **Work Stream 3:** Public and professional stakeholder workshops Up to: 20 public 50 professionals (up to 60 participants total with no less than 1/6 (n=10)and more than 1/3 (n=20) public)
Planned Study Period	30 months 1st November 2018 – 30th April 2021
Research Question/Aim(s)	The study addresses the research question: What are the barriers and enablers to BAME patients, FCGs and HCPs engaging in EOLCP? The study aims to improve care for patients by translating the findings into training resources for health care professionals.

PROJECT MANAGEMENT

The CI will assume overall responsibility for project delivery and budget and the scientific and ethical rigour of the research. The project will be based at LOROS Hospice. The PI will be the Project Manager and will be supported by the LOROS Research Manager.

The PI will be responsible for day to day project management and the PI and CI will have weekly briefing time. LRM will work closely with the PI and the research team to effectively deliver the study in accordance with LOROS' research governance SOPs and Sponsor SOPs ensuring compliance with Sponsor and regulatory processes and requirements and in accordance with ICH GCP.

The core research team of PI and the RA and RF will meet fortnightly. The CI, LRM and CA1 will join at least monthly to review progress dependant on the phase and needs of the project.

The PMG comprising the core research team, LRM and CI and all co-applicants will meet every two months throughout the project. The close proximity of most members of the team will facilitate direct contact at meetings and informal discussion on an ad hoc basis. Teleconferencing facilities will be available at all meetings to enable participation of individuals who are not able to attend in person.

The SSC, will provide governance of the project and will meet five times during the course of the study to oversee project management and study progress and approve any proposed changes in the protocol and outputs. An external Chair will be appointed who is independent of the research team. An external qualitative expert and at least one external lay representative will also be members. We envisage that the CI, the core research team, LRM, all co-applicants, and the project advisors will attend the SSC. Representatives will be invited to attend from NHS management and CCGs, study sponsor, a senior manager/commissioner in adult social care from either Leicester or Nottingham City Councils.

Additional meetings of the SSC or PMG may be arranged to address specific issues that arise, e.g. recruitment difficulties.

PATIENT AND PUBLIC INVOLVEMENT PPI

PPI is central to the project and in ensuring that it remains grounded in the concerns and experience of patients and FCGs and conducted in an appropriate and sensitive manner. The PPI consultation group helped inform and guide the funding application. They identified key areas of concern and discussed the proposed research topic and its significance to members and prioritised the need for research concerning the interdependence of professionals, patients and families in successfully navigating the end of life. They also highlighted the importance of the professionals in acting as a guide and support throughout this time of great vulnerability and uncertainty.

We have now established a public, carers and bereaved relatives research consultation group (PCBR group). The PCBR group will support the delivery of the research by:

1. Discussing the protocol, methodology and materials for recruitment and data collection, ensuring that they are developed and implemented in an acceptable and feasible way;
2. Enhancing interpretations of findings and outputs by providing service user and family member perspectives;
3. Enabling appropriate and sensitive recruitment and dissemination of findings throughout local BAME communities via small world networks;
4. Providing additional cultural contextualisation for all aspects of the study.

One of the co-applicants CA2 is a bereaved relative from a BAME group and has led a project regarding BAME communities and end-of-life care for Leicester CCG. CA2 will convene and facilitate our PCBR group meetings with support from the project manager/PI and will act as PPI representative at research team and project management group meetings. CA2 will provide informal mentoring and support for each of the PCBR group members together with the PI. The PPI perspective is crucial for all stages of the project and CA2 as co-applicant will bring an individual lay perspective as well as professional experience of community work to the research. The wider range of views of the PCBR members will inform recruitment, and support data collection, analysis and dissemination. Study progress will be reported and discussed at meetings of the PCBR at approximately six monthly intervals.

KEY WORDS: End of Life

Advance care planning

Minority ethnic

Qualitative

Case study

Training

1 BACKGROUND

End of life care planning (EOLCP) involves a process of discussion between patients, their significant others and HCPs, about preferences and goals for future care (1) and is regarded as key to improving experience and outcomes at the end of life for patients and families. It further, optimises the use of health care resources including acute hospital care, emergency services, drug, surgical and other treatments (2-7,8). Evidence regarding the effectiveness of EOLCP is limited, but suggests that patients who have engaged in EOLCP are more likely to die at home, receive less invasive treatment in the period preceding death and report a better experience of care along with their relatives (9,10). Evidence suggest that patients from BAME backgrounds are disadvantaged with respect to all these outcomes (11-14). EOLCP is also potentially associated with lower health care costs (15).

The research is of great importance because the provision of excellent end of life care is an issue of major strategic significance to the NHS (4). End of life care is of relevance to every person as they confront the experience of death and dying within their social and family networks as well as, ultimately, for themselves. The relevance and timely nature of the study is evident through its engagement with research priorities identified in the recent Marie Curie/James Lind Alliance priority setting exercise for research priorities in palliative and end of life care (16), specifically six of the top ten identified priorities:

- Equitable and universal access to palliative care,
- Eliciting and implementing patient preferences for Advance Care Planning,
- Information and training to support carers and families supporting dying patients,
- Training for health care professionals to deliver palliative care,
- Best ways to deliver palliative care for those with non-cancer disease (including MND),
- Availability of core palliative care services for everyone.

The study aims directly reflect the NICE Guidance and Quality Standards for end of life care (2-7) and the six ambitions recently set out in the National Palliative and End of Life Care Partnership to improve end of life care (17):

1. Each person is seen as an individual,
2. Each person gets fair access to care,
3. Maximising comfort and wellbeing,
4. Care is coordinated,
5. All staff are prepared to care,
6. Each community is prepared to help.

National satisfaction surveys such as the VOICES post bereavement (18) and Quality Health (19) have a low representation of patients from BAME communities (2.9% and 5% respectively) and little is known, on a population-wide basis, about their satisfaction with end-of-life care. There is evidence that health care professionals (HCPs) often report both a lack of confidence, knowledge and skills in undertaking EOLCP (20,21-24) and in providing culturally sensitive end-of-life care for BAME community patients (12,15). An understanding of general cultural influences, as well as the diversity of individual preferences is essential for sensitive and effective EOLCP and to enable patients and families to understand and appraise the options open to them (25-26). The importance of such an understanding is articulated most recently in formally derived consensus recommendations from the European Association for Palliative Care (6).

Our previous work has identified that HCPs feel disempowered by the uncertainty that arises because of socio-cultural and religious complexity and that staff training needs to respond to this (14, 27, 28). Some cultural groups share familial responsibility for decision making, in tension with the emphasis on autonomy and individual choice within UK policy (29-32). Some groups prefer non-disclosure of diagnosis and prognosis (33) and discussing deterioration and planning for preferences related to dying is potentially unacceptable. Our work in cancer highlighted that professionals were concerned about offending or expressing culturally insensitive practices (14, 27, 28). As a consequence of this uncertainty, professional disempowerment and reticence resulted in inequalities and lower quality care with poorer outcomes for patients and families (14). Patient ethnicity can influence the behaviour of HCPs, resulting in disparities in care (12,34).

This study will make a substantial contribution to understanding the barriers and facilitators of EOLCP with BAME patients. The findings will facilitate culturally sensitive and effective care especially by

translating the findings to learning resources for HCPs. This responds to the needs of potentially excluded groups and ultimately to better outcomes for patients.

2 RATIONALE

Little is known about the experience, preferences and goals of care of patients and families from BAME communities (11). This is despite evidence that BAME patients are disadvantaged in terms of access to palliative care services, especially those who cannot speak English confidently (1). BAME patients less frequently access palliative care services (12-13) and may receive or prefer more intensive end-of-life treatments (13).

Despite UK policy prioritisation of EOLCP, recent HS&DR funded work by Pollock (project number 10/2002/23), found that EOLCP remains generally uncommon and problematic (20). Whilst this work added much to the body of knowledge about the real-world practice of EOLCP, it did not include patients or carers from BAME backgrounds. Nonetheless, Pollock's work alluded to the additional complexity perceived by HCPs of EOLCP with BAME patients and families. The research question of this study has been formulated with patient and public involvement. Our PPI engagement prior to this funded protocol has echoed that negotiation of information sharing and planning at the end of life between clinicians, patients and families is complex and often poorly done and they identified that improvement in this area of care was identified as of great importance to them.

Emergent findings from our previous work with HCPs (which has focused on the experiences of HCPs in one aspect of EOLCP, decision-making about resuscitation with BAME patients and families) indicate considerable challenges and desire for evidence-based training (35, 36). Additionally, our work using Q methodology (a structured way of eliciting preferences) to explore the views of BAME public participants about resuscitation discussions in advanced, terminal illness indicates both a receptiveness (in terms of both desire and acceptability) to engage in the topic of EOLCP and the enabling value to participants of receiving information about end of life issue (35, 36). Leicester City CCG has supported this work through research capability funding as it aligns with their strategic priorities of 'Better Care Together'.

The paucity of evidence about how cultural diversity impacts on the experience and anticipation of death and dying highlights the urgent need for further research in EOLCP with BAME patients and families and the development of research based materials with which to inform training. The research question 'What are the barriers and enablers to BAME patients, Family Care Givers (FCGs) and HCPs engaging in EOLCP?' directly responds to the research recommendations arising from Pollock's work and the HS&DR remit to provide evidence in an under researched area of health care which is of great importance to patients, family caregivers and HCPs.

3 THEORETICAL FRAMEWORK

Underpinning the methodological approach is a theory of cultural sensitivity and cultural competence based on earlier work of our research team and others in related fields of health promotion and professional development. The need for cultural sensitivity and appropriate competences in delivering health care in a multi-ethnic, diverse population has been recognised widely, especially in the USA. There are now multiple schools of thought and competing approaches – as reviewed by Dutta (37) and Jirwe (38). Papadopoulos et al (39) have refined these theories for use in the UK, developing especially the concepts of cultural knowledge as laid out by Purnell & Paulanka (40), and 'cultural hunger' or readiness to change (41, 42) and proposing a cycle of emergent cultural competence. It is clear from a review of much of this literature that communication is a key element (43), while noting that bases of understanding and shared conceptual models are essential to that process, as well as the possible use of language translators not only in end-of-life care (14, 44) but in all other fields of health and care delivery (e.g. 45-47). Clearly, lack of confidence among service providers and health care professionals is a major barrier to effective transcultural service delivery – sometimes referred to as a lack of organisational cultural competence (48-50).

This is an exploratory study which will be carried out within a constructivist qualitative tradition of research. Qualitative research is concerned with eliciting how participants understand and experience the world through the cultural filters internalised through developmental processes of socialisation and through interaction with others in real world situations and contexts (51). Constructivism seeks to 'see what happens' in real world settings and to illuminate the relevance of social context and processes

for resilience, self-reliance and the opportunities and constraints which govern access to resources for individuals and connected groups. This research approach aims to elicit and understand how research participants construct, negotiate and share meanings around the phenomenon of interest. In this study the phenomenon is deterioration, dying and medical treatments at the end of life.

The aim of this study is to undertake an in depth exploration of the diversity and complexity of experience within a small number of cases. Work stream 1 will use an instrumental case study method which aims to increase understanding of a phenomena through detailed exploration of a number of diverse instances, or cases, exemplifying the phenomena (52). It is not concerned with generalisation of findings from representative samples to other populations (53, 54). However, understanding of the phenomena may be increased through triangulation of findings and the transferability of concepts and theories between different studies and settings. Qualitative approaches are particularly appropriate in settings and populations which have been little researched and about which little is known. They allow flexibility to respond to emerging findings and understanding of the issues, and to refocus the investigation towards new questions, which reveal themselves to be particularly pertinent to realising the study objectives.

Qualitative research involves the researcher and participants in an in depth, reflective investigation of the topic, during which participants provide situated accounts, subject to interpretation and negotiated meanings by both parties, rather than encyclopaedic descriptions of a static, external 'reality' (55). Thus, we anticipate that participants may offer different and competing understandings and interpretations of shared experiences, communication and decisions. The case design methodology will provide data that enables acknowledgment of and synthesis of these perspectives in the process of the analysis (56). Qualitative research is not concerned with determining a 'true' or definitive account of 'how things are', but with providing an interpretation of the nature and consequences of different understandings and how they are communicated and negotiated between individuals and groups. This is an especially valuable component of the proposed methodology since opening up professional awareness of differences in understanding (for example in fictionalised case studies), to which they would not normally have access, offers greater insight into how to communicate effectively with patients and their relatives, and to deliver appropriate and culturally sensitive end of life care.

The planned outputs /outcomes from this proposed research have due regard to the background debates on cultural sensitivity and competence, and incorporate both challenges to understandings of 'culture' and 'normality', as well as information and guidance on 'knowledge' issues, and developing skills (including for example the use of interpreters in a consultation, handling family dynamics etc). We propose a learning resource based on engaging with stimulus scenarios (taken from the experience and insights of the qualitative work in this study), with reflection on this in relation to the learner's own experience, with additional provision of information and links to relevant resources. In this we shall build on the approaches of our previous work with a variety of health professional groups (28,57- 60). These are all based on well accepted theories and methods including the experiential learning cycle (Kolb) and general principles of adult learning theory (61), supported with reference to the specific cross-cultural context of the care setting.

4 RESEARCH QUESTION / AIM(S)

The study aims to improve the quality and experience of end of life care for BAME patients and their families by addressing the research question: What are the barriers and enablers to BAME patients, FCGs and HCPs engaging in EOLCP?

4.1 Objectives

1. To explore how terminally ill patients from BAME backgrounds, their FCGs and the HCPs who support them, think ahead about deterioration and dying, whether and how they engage in EOLCP and identify barriers and enablers to this engagement.
2. To explore the experiences and reflections of bereaved BAME FCGs on end of life care, the role and value of thinking ahead and of engagement with HCPs in EOLCP.
3. To identify information and training needs to support best practices in EOLCP and to produce an e-learning module with guidance notes available free to NHS and hospice providers.

4.2 Outputs

Qualitative methods of investigation will be used to realise the research aims and objectives. These will enable an in-depth exploration of the diversity and complexity of experience to be undertaken within a small number of cases. The study will explore the extent to which current practices are drawn from cultural beliefs and/or those of biomedicine, specifically the ideology of palliative care with its particular emphasis on EOLCP as an important enabler of 'a good death'. Interviews will explore how participants engage in discussion of end of life care with family members and significant others, including HCPs. The combination of in-depth stakeholder interviews and longitudinal patient centred case studies will enable the direct and detailed exploration of participants' experience, responses, and perspectives and how these may change over time.

The collection of a substantial body of qualitative data will increase the very limited understanding and knowledge which is currently available about how patients and FCGs from BAME communities anticipate, and prepare for, illness deterioration and care towards the end of life and provide new knowledge and understanding of patient, FCG and professional perspectives and experiences of thinking ahead, planning for future deterioration and end of life care. The findings will identify how patients and families use the networks of professional care and informal support available to them and aims to identify gaps in support and resources. The findings will underpin empirically based outputs including an e-learning resource for HCPs, information resources for patients and FCGs and recommendations for service development and effective commissioning to improve the provision of culturally sensitive end of life care for patients and families from BAME groups.

5 STUDY DESIGN AND METHODS OF DATA COLLECTION AND DATA ANALYSIS

5.1 Work stream1 (WS1): Longitudinal Patient case-studies

The study will be adopting a research design and methods which have been successfully employed in previous studies carried out by the applicants (20). Recruiting severely ill patients to take part in research projects presents challenges, which will require flexibility and sensitivity in engaging FCGs and patients in a way and at a level that they can comfortably accommodate. We have adopted the case study approach because the issues are socially and culturally complex. Case studies aim to explore

complexity through an intensive, holistic focus on the components of each case, rather than obtain limited data from a larger number of single types of unconnected respondents (53, 63, 64).

Up to 20 longitudinal case studies will comprise sequential interviews over a period of up to six months with a patient, FCGs and a HCP nominated by the patient (1, 20, 62). If a patient dies during the follow up period a bereavement interview will be requested with each FCG after an appropriate time has elapsed after the death (at least eight weeks). A review of each patient's medical records will also be undertaken.

We intend to be as inclusive as possible and each case-study will be explored in its own terms. It is not necessary for case-studies to conform to a 'standard' composition and patients will be given flexibility and options in how they wish to be part of the study. Consequently the data set may include:

- patients who lack FCGs or are unwilling/unable to nominate specific FCGs or HCP will be eligible for inclusion in the study
- patients who nominate more than one FCG to take part in their case study.

In some case studies the greater part of the interview data will be drawn from interviews with FCGs and HCPs. This may be so in the circumstances when:

- patients may not wish to participate in some or all interviews but are willing for their nominated FCGs and HCP to do so and to have their notes reviewed.
- patients may give informed consent but lack capability to take part in in depth interviews(e.g. patients with motor neurone disease or stroke) or they may lose capacity or become too ill during the follow-up period to take part in interviews.
- patients who lack capacity to give full consent from the start (e.g. patients with dementia or brain tumour)

The number of interviews conducted with each participant will be determined by the circumstances of each case-study. A minimum of two interviews is needed for each case-study. A maximum of two follow-up interviews over a six month period will be undertaken with each patient and FCG. Interviews may be with patients and FCGs separately, jointly or a combination, according to participant preferences and convenience. If a patient dies during the follow up period a bereavement interview

will be requested with each FCG after an appropriate time has elapsed after the death (at least eight weeks).

A nominated HCP will be invited to take part in at least one and at most two interviews to discuss their involvement in the case.

Each case-study will include a minimum of 2 interviews per case and a maximum of three interviews with the patient and each of the FCGs and two interviews with the HCP. One of the FCG interviews may potentially be a post bereavement interview. The patient's clinical notes will be reviewed after the end of the patient's involvement in the study (6 months or date of death).

***Case Study Interviews*:**

Participants will take part in a semi-structured, audio-recorded interview arranged at their convenience. Interviews with the patient and FCG participants will be face-to-face. Where possible our aim is to interview patients and family members separately on at least one occasion. However, we seek to engage participants in the way and at a level which they find comfortable, and will accommodate preferences for all interviews to be held jointly. HCPs will be offered the option of interview by face-to-face or phone, the telephone interview will be audio recorded in the same way that the face to face one would be.

Experienced researchers will conduct all interviews. As far as possible the same researcher will conduct all the interviews with each participant in the patient's case-study. Our research team have considerable language skills to conduct interviews in the language preferred by the patient and FCG. If interpreters are required they will be appropriately briefed/debriefed before each interview.

The interview with patients and FCGs will include exploration of:

- Their experience of living with serious illness
- Their understanding of the illness and the prognosis
- Their goals and values with regards to their future care
- How they anticipate and think about the future, about decision making and treatment preferences and the significant factors influencing these
- Their preferences in how such decisions are made

- Their expectations and experiences of professional support and communication about deterioration, EOLC and EOLCP

We are mindful that the experience of taking part in the interviews may have an influence on the individuals i.e. a 'Hawthorne effect' (65). Participation in the research has the potential to change the nature of the patient and their family's way of living and coping with their illness and their future, and this will be incorporated as a topic in the interviews. The potential impact would be beneficial in that the patient/carer may communicate more effectively with care providers. The listening skills of the researcher and the facilitation of reflection and discussion may potentially change things for the participant. In subsequent interviews we will ask: How are things?; What's changed in the illness?; Have they been thinking about the future?; Have they had any conversations with family/HCP about their illness/wishes and future death (if the patient brings this into the conversation)?; Do they think that they have done anything differently do they think as a result of having these conversations /being part of the study?. Such actions will be explored as an outcome of the research and importantly such observations may provide information about potential facilitators for EOLCP. Our recent study regarding Do Not Attempt Cardiopulmonary Resuscitation (DNACPR) decision-making and BAME communities has suggested that action taken as an apparent consequence of being a participant is a valuable outcome for participants (66,34).

The interview with HCPs will include discussion of:

- Their experience of providing care and support for the patient and family
- Barriers and enablers for their care of the patient and family in:
    - Understanding the illness and prognosis
    - Thinking about the future
    - Decision making
    - EOLCP

HCPs will also be asked for their assessment about whether they feel being part of this study (either they themselves or the patient or FCG) has had an impact on their relationship with the patient/carer or any other research related outcomes.

Transcription of interviews:

Interviews in English will be transcribed verbatim. Interviews in other languages will first be verbally translated and audio recorded in English by a bi-lingual researcher or translator and then transcribed in English, a method that has previously been employed by members of the research team (67). The transcript will be checked for accuracy and anonymisation against the audio file. Turns of phrase, idioms and metaphors will be complex to translate and note will be made on the transcript of literal translation as well as the meaning constructed by the translator. Translator notes will be an important aspect of quality assurance and data accuracy.

Medical Record Review

Patients will be asked to give permission for access to relevant parts of their medical records and related documents recording future care preferences. We will inform the patient's GP that they are participants in this study to enable the GP to document this in their medical records as evidence of their participation.

At the end of patient involvement in the study (6 months or at death) (previously 4 months) the medical records, including nursing and allied health professional records, will be sourced from the services that the patient has had contact with in the previous six months. This may include palliative care services, primary care, community service and hospitals services. The records will be scrutinised for data concerning:

- discussions and information sharing about prognosis, deterioration, dying, EOLC and EOLCP;
- records relevant to recording patient views and wishes and EOLCP;
- care in the last week of life;
- place of death. Data from electronic and paper case notes will be extracted verbatim and entered into the electronic CRF for subsequent analysis. The date, place of discussion and role of the health care professional role will be noted for each data extracted. The researcher may additionally add to the verbatim data an explanation of the circumstances of the discussion to provide context for the narrative.

Completed CRF will be incorporated within the project data base and will form part of the data set relating to each case.

Analysis

There are several data sets for analysis.

- Up to 20 patient based case study comprising up to 10 interviews each and review of medical records.
- Patient data set of up to 60 interviews and up 20 medical records reviews
- FCG data set of up to 70 interviews
- HCP data set of up to 40 interviews

Each data set will be subject to both separate and integrated thematic analysis through constant comparison (68, 69). The qualitative software programme NVivo will facilitate this. Analysis will proceed through a process of open coding of initial manuscripts by two researchers independently, and then development of the coding frame through discussion of the themes between researchers (RF, RA, PI and CA1). Coding involves allocation of segments of interview transcripts to one or more broad 'nodes' (or themes) within NVivo to capture all text relating to an idea or topic. The coding frame is developed through an iterative process of reading, coding and discussion of the data between the research team to identify, compare and link 'themes' occurring within and across the interviews. After open coding has been completed, a more refined and selective process of coding-on from individual nodes is undertaken to explore, differentiate, reorganise and relate the themes identified as of greatest relevance to the study objectives. These will be grouped hierarchically within broad categories representing key themes identified in the data set.

Patient centred case studies will triangulate different stakeholder perspectives and data sources, including a review of medical records. Analysis of case study data will include 1. holistic in depth analysis of each case to enable an understanding of how thinking ahead and EOCLP evolve over time and 2. a systematic cross case comparison using matrix charting to show patterns in the variables and characteristics of the cases within the data set and to develop the identification and relationship between themes underpinning a coordinated explanatory model of the study findings (69, 52). 3. the interview transcripts will also be interrogated to identify if and how the interviews have influenced participants' behaviours. In practice this means coding transcripts where such instances arise. We will scrutinize these codes to discreetly consider the impact of interviews both within a single study and

across all case studies. This coding's will be integrated in the full analysis to support understanding of whether behaviours are intransigent or can be willingly modified; and what the mechanisms were which promoted self-directed initiatives in behaviour change.

Field notes will be integrated with case study findings to explore how participation in the research has made the interviewees think differently about thinking ahead in their illness. Any consequential influences each had on others as a result of this thinking differently will be noted. Such data may provide some understanding of patients, and/or families and/or health professionals who do and don't change in their approach and their behaviours in relation to thinking ahead. This will further aid the design of effective health care professional training.

Serial follow up interview data will go beyond cross-sectional and static accounts of specific participants and groups of stakeholders and will enable an understanding of how EOLCP is managed and experienced over time within a complex network of care. The additional comparative dimension afforded by thematic analysis of each participant group interviews will complete the triangulation of the different data sets(70).

5.2 Work stream 2 (WS2): Experiences of bereaved relatives

Up to 20 interviews will be undertaken, with recently bereaved FCGs of BAME patients who died following a period of advanced disease and deterioration. Interviews will be conducted by experienced researchers in participants' primary language (using translation strategies described in WS1 above). The interviews will explore participants' perspectives of:

- living with serious illness and end-of-life care;
- thinking ahead about deterioration and dying;
- information sharing, communication and decision making in illness deterioration with the patient, family members and HCPs involved in providing care;
- the role and value of EOLCP;
- The role of HCP in helping patients and family prepare for deterioration and dying.

Analysis of interview data: The audio recording of the interviews will be translated, transcribed and coded as described in WS1 above to identify themes and subthemes occurring in the data. Further exploration will be undertaken by comparing themes between WS1 and WS2 and triangulating findings

to enable an understanding of the key issues relating to EOLCP when bereaved relatives reflect on their experience and the degree of difference, overlap and mutual understanding that exists between them and FCGs involved in active caring for a patient with advanced illness, patients and HCPs.

5.3 Work stream 3 (WS3): Stakeholder Workshops

Six stakeholder workshops of up to a total of 60 participants will invite public and professional stakeholders including commissioners, health education and clinical care staff to discuss the findings of WS1&2. The workshops will inform the articulation of practices that facilitate patient-centred care and culturally sensitive EOLCP. Working closely with our PCBR group (led by CA2) fictionalised scenarios and practices derived from the data will be presented. A number of tasks, informed by the theories of cultural sensitivity and cultural competence discussed above and pertinent to the findings of WS1&2 will be presented to the participants. Workshop participants will be asked to identify best practice for HCPs and comment on the implication of these best practices for training and for service delivery. Data resulting from the tasks (e.g. flip chart notes, 'post-its', mapping), contemporaneous notes, audio recordings and semi-structured questionnaires will capture the participant's views and inform the translation of study findings into an e-learning module and accompanying resources and recommendations for HCP training.

6. SAMPLE & RECRUITMENT

6.1 Setting:

The geographical setting for the study is Leicester, Leicestershire, Nottingham and Nottinghamshire. Patient participants will be under the care of services in these areas and health professionals for WS1 and WS2 will work in these areas. FCGs for WS1 and WS2 do not have to be resident in these areas. Participants for WS3 will largely be from these areas but key stakeholders may work elsewhere in the Midlands or UK.

All research activity will take place in this geographical area and LOROS Hospice is the single recruiting research site. Interviews for FCG for WS1 and WS2 who are not resident in these areas will need to take place in a venue within a reasonable distance to LOROS.

6.2 Sample size and structure:

There are no hard and fast criteria for establishing the sample size required in qualitative research (72). Rather, this is determined by the circumstances and context of each study. Morse (73) (and Malterud et al (74)) propose that the number of participants required depends in the range and depth of information collected about each participant or case (information power): the greater this is, the fewer participants are required. A qualitative sample size of between 20 – 40 is likely to include the majority of views and experiences to be found within the target population (72) and is in line with previous longitudinal studies in end of life care adopting a similar design and method (1,20,62).

Purposive sampling, which involves participant selection being guided by strategic choices regarding the individuals or groups which can yield the most valuable and relevant information for the study, is a strategy which can optimise the depth and breadth of data in a sample and reduce the sample size required to achieve thematic saturation (ie. when no additional themes about the research topic are emerging from the participant interviews). Stake(52) cautions against increasing the number of cases much beyond 15 because the amount of qualitative data generated by a larger number of cases will become unmanageable. However, a guiding principle of qualitative research is that the nature and adequacy of the final sample must be kept continuously under review, and adjustments made if necessary, to enable the study to achieve its aims(74). Above all, it is the relevance of the participants and the quality of the data that is important, rather than the number of participants per se.

In WS1 and WS2 we will purposively sample participants across three elements of diversity:

- Religious/faith group
- Ethnic backgrounds (BAME groups).
- Disease/illness group

Findings from our recent work suggest that cultural-religious customs and mores are one of the key factors that increases the complexity of navigating EOLC and achieving patients' preferences(35,36). It is our intention that there is the greatest heterogeneity of religion/faith and ethnicity in the samples of WS1 and WS2.

This concern with cultural-religious diversity is complemented by selection criteria for recruitment across illness contexts and we will also purposively sample to achieve heterogeneity across a number of disease groups (including cancer, frailty in old age, heart and renal disease).

Additionally demographic data will be recorded including gender, age and migration-generation and aim to include the diversity of these characteristics in the sample.

A sampling frame will be utilised to target recruitment to achieve these purposive sampling aims and to construct a matrix that may be important for attribution of themes/subthemes and in our search for examples of variance within the data. The nationally agreed guidelines to characterise self-reported ethnicity into a set of 16 codes(75) will be used.

For WS3 we will purposively recruit and sample across the range of stakeholders which include:

- HCPs
- Health care educators
- Public and user groups in health
- Leaders of BAME community organisations
- Faith group leaders
- Health care commissioners
- Health care education and training commissioners
- Academics in the field

6.3 Recruitment

Taking on board best practice in recruitment for research involving BAME participants an extensive programme of awareness raising about the project will take place with community groups and organisations. This work will be informed by the networks and experiences of CA2, the PCBR and of the co-applicants and advisors to the project. The work will involve communicating the project objectives and opportunity to be involved in research through social media, traditional media; placement of flyers in organisations and services including but not limited to GP practices, LOROS services, patient and carer

support groups and community and faith groups and libraries; and attendance at meetings and events of patient and carer support groups and community and faith groups by members of the project team.

6.3.1 Interpreters

A local interpreting service which has been utilised by UHL and LOROS hospice will be used. The interpreters will be briefed about the study and their involvement prior to each interview. They will also be de-briefed post-interview to capture any additional information. The interpreters/interpreting service will sign standard UHL/LOROS contracts and confidentiality agreements as necessary. We will work with the interpreting service to provide quality assurance.

6.3.2 Work stream 1

The East Midlands NIHR Clinical Research Network (EMCRN) (in which CA3 and CI have clinical leadership roles) CCG research networks and the well established clinical and research links of co-apps CI, CA3, CA4, CA5. Collaborators including specialist nurses and research nurses within PIC site services will be engaged and utilised to promote awareness of HCPs of the study, understanding of the criteria of case eligibility and to seek identification of patients within the PIC sites which will include:

- 6-8 GP practices with a substantial population of BAME patients and the linked community nursing services;
- community and primary health care services that support a population with particularly hard to reach BAME communities (e.g. Somali).
- palliative care services in community, hospice and hospital sectors;
- community and secondary care services for heart failure, elderly and psychogeriatric care, renal medicine and oncology.

We will liaise and work with research and end of life care leads, practice managers, nurses and other workers and primary care patient participation groups to promote understanding of the study.

Patient inclusion criteria:

- Aged 18 or over.

- Identified by treating health professional as being at risk of deteriorating and dying in the next year (NB the participant information sheet will address the question of why a patient has been identified using the phrase 'because you are living with a serious illness that may get worse over the next year).
- Black, Asian or Minority Ethnic background.
- Need to agree to the use of an interpreter to translate on their behalf if required

Patient exclusion criteria

- Aged less than 18
- Not receiving health care services in Leicester, Leicestershire, Nottingham or Nottinghamshire
- Identified by a treating healthcare professional of having a survival of more than a year
- Living with a non-life limiting, non-progressive or stable illness
- Unwilling to give consent
- Unwilling to agree to the use of an interpreter where required

FCG inclusion criteria:

- Aged 18 or over.
- Capacity to consent to take part.
- Nominated by the patient participant who has capacity or, for a patient lacking capacity to consent, a FCG who is closely involved in the care of the patient and nominated by the consultee.

FCG exclusion criteria:

- Aged less than 18
- Not a close carer of the patient
- Not nominated by the patient or the consultee
- Unwilling to give consent

Health care professionals (HCPs) inclusion criteria:

- HCPs will be those nominated by patients as currently significant to their care. They may be drawn from a wide range of staff (including doctors, nurses and healthcare assistants) in services within community and secondary care.
- For patients who lack capacity the consultee will be asked to nominate the HCP.

HCP inclusion criteria:

- Aged 18 or over.
- Capacity to consent to take part.
- Nominated by the patient participant who has capacity or, for a patient lacking capacity to consent, nominated by the consultee.

HCP exclusion criteria:

- Aged less than 18
- Not providing health care for the patient
- Not nominated by the patient or the consultee
- Unwilling to give consent

6.3.2.1 Patient participants:

HCPs will be asked to identify eligible patients through a variety of means, depending on their role and the systems in place within their service. HCPs will be provided with the Supportive and Palliative Care Indicators Tool (SPICT) (76) as a means of identifying patients at risk of deteriorating and dying with one or more advanced, progressive and life threatening condition and the Gold Standards Framework 'surprise' question 'Would you be surprised if this patient were to die in the next 12 months?'(77).

A HCP known to the patient will make the first approach to a patient and provide them with the participant information leaflets for patients and FCGs. Patients, or someone acting on their behalf, may contact the research team directly about their interest in the study by phone, email or returning a reply slip in a freepost envelope given to them by the HCP. Alternatively, if they prefer, they can give permission to the HCP who first approaches them to pass their contact details to the research team requesting that contact to be made with them by the team.

In cases where the patient does not speak English, the HCP will direct the patient (or FCG if they are interpreting on their behalf) to the appropriate information video on the project website via the LOROS website link to the study and/or ask if a researcher with shared language skills may contact them.

Some potential patient participants may lack the capacity to give any or full consent due to the nature of their illness (e.g Dementia). The study will be introduced to them and to their FCG by a known HCP. If the FCG considers that the patient would want to consider involvement then information about the study will be shared with both parties in the ways described above. For such patients their involvement in the study may be limited to permission to review their medical records and to a FCG and HCP to be approached to be involved. However, patients would not be excluded from contributing to the study through interviews if the consultee considers that this would be appropriate and acceptable.

The research team will discuss with the FCG the provisions of the Mental Capacity Act (MCA) 2005 with regards to research and identify with the FCG whether their relative has appointed an attorney for Health and Welfare or has a Court Appointed Deputy. If not they will identify in discussion with the FCG who would be the consultee for the study. This could be the FCG or another person.

The research team, using interpreters as needed, will make contact with patients or the consultee who have indicated that they are interested in the study and provide them with full participant information, including in audio/video format in their first language if needed. These will be available via the LOROS website link to the study. Audio/video-recorded methods of facilitating informed consent are an acceptable alternative to written consent in study populations where literacy skills are variable (78).

6.3.2.2 *Family caregiver participants:*

For patients with capacity:

During the initial discussions about the study (by the HCP first approaching them and/or by the research team) patients will know that they will be invited to nominate a FCG and HCP. They can nominate the FCG during the discussion stage with the HCP, or with the research team or later during the taking of

consent or after their first interview. The HCP and research team may share information about the study with the FCG before full consent with the patient is taken. Nominated individuals will receive a participant information leaflet +/- direction to an audio recording/video in their first language, explaining that we are interested in understanding the different perspectives and experience of patients, families and HCPs through a detailed understanding of each case. After the patient has given informed consent to their own participation in the study the research team, with an interpreter as needed, will subsequently contact the potential FCG participant and arrange face-to-face consent.

For patients who lack capacity:
The consultee will also be asked to nominate a FCG or close friend to participate in the study.

6.3.2.3 Health Care Professional participants

For patients with capacity:
During the initial discussions about the study patients (by the HCP first approaching them or by the research team) will know that they will be invited to nominate a HCP. They can nominate the HCP during the discussion stage with the research team or later during the taking of consent or after their first interview.

For patients who lack capacity:
The consultee will also be asked to nominate a HCP key informant to participate in the study.

After the patient has given informed consent to their own participation in the study the nominated HCP will receive a participant information leaflet and covering letter explaining that we are interested in understanding the different perspectives and experience of patients, families and HCPs through a detailed understanding of each case. The HCP will be asked to respond to the invitation to participate through email or post or phone to the research team. The research team will contact the HCP and arrange a phone or face-to-face interview.

6.3.2.4 Participant withdrawal

In the event that a patient withdraws or is withdrawn from the study, a pragmatic decision will be made about the feasibility of recruiting another case-study, depending on the stage of study at which withdrawal occurred. If the patient withdraws then unless they direct otherwise the information

collected so far from them, their nominated FCG and HCP will be erased up to the point of its anonymisation. Anonymised data may still be used in the project analysis. All personal identifiable data, will be erased.

Withdrawal by a patient from the study will automatically mean that the nominated FCG and HCP will also be withdrawn. The research team will write to the FCG and HCP to inform them should this occur.

Should a FCG or HCP withdraw from participation the case-study will continue with the patient and remaining nominee participant. Unless the participant directs otherwise all information collected so far from the FCG or HCP participant who is withdrawing will be erased up to the point of its anonymisation. Anonymised data may still be used in the project analysis. All personal identifiable data, will be erased.

6.3.3 Recruitment: Work stream 2

Up to 20 bereaved FCGs of BAME patients deceased from advanced illness within the previous 3-12 months will be identified by HCPs in services described in WS1. They will also be identified through community networks of CA2 and through community contacts of our current work (66, 37) and in the awareness raising programme described in 6.3 above. We will allow participants to come forward themselves to engage in the research. All participants will need to meet the recruitment criteria.

Participants will be purposively sampled in a similar way as described in WS1.

The recruitment of participants who do not speak English will be facilitated as described in WS1 above.

Inclusion criteria:

- Aged 18 or over.
- Bereaved of a close family member older than 18 years, within the past 3-12 months
- Close family member was of Black, Asian or Minority Ethnic background.
- Close family member died from a progressive illness
- Capacity to consent to take part.
- Lives within or willing to travel to interview within Leicestershire or Nottinghamshire

Exclusion criteria:

- Bereaved of a close family member who was less than 18 years old
- Bereaved less than three months
- Bereaved more than 12 months ago
- Unwilling to give consent
- Unwilling to be interviewed within Leicestershire or Nottinghamshire

6.3.3.1 Participant withdrawal

In the event that a patient withdraws or is withdrawn from the study, a pragmatic decision will be made about the feasibility of recruiting another bereaved FCG, depending on the stage of study at which withdrawal occurred. If the participant withdraws then unless otherwise directed by them the information collected so far will be erased up to the point of its anonymisation. Anonymised data may still be used in the project analysis. All personal identifiable data, will be erased.

6.3.4 Work stream 3

The recruitment of stakeholder participants will be via a process of snowballing. Here the study team and all collaborators including members of the PCBR will identify potential participants via local small world networks. Study flyers and email will be circulated. The workshops may include:

- Public stakeholder: local figure heads including Faith and community figureheads across Leicestershire and Nottinghamshire.
- Commissioners: CCG's, Health Education East Midlands, Local authority
- Health care educators: Heads of Nursing schools across Leicestershire and Nottinghamshire, medical school leads, directors of education in acute and community trusts, hospice workforce leads, programme leaders for medical training such as primary care and elderly care.
- Health care professionals
- Care home providers
- Academics in the field

6.4 Consent

The process for obtaining participant informed consent at the outset, or ongoing consent if a participant loses capacity during follow up, will be in accordance with the REC guidance, and Good Clinical Practice (GCP), GDPR (2018) and any other regulatory requirements that might be introduced.

The participant will be given a copy of the original signed and dated consent form. The original signed and dated consent form will be retained in the Trial Master File.

For patients who lack capacity a consultee will be asked to complete the consultee declaration form in accordance with the process of the mental capacity act 2005 and the HRA guidance.

The decision regarding participation in the study is entirely voluntary. The researcher shall emphasise to them that consent regarding study participation may be withdrawn at any time without penalty or affecting the quality or quantity of their future medical care, or loss of benefits to which the participant is otherwise entitled. No study-specific interventions will be done before informed consent has been obtained.

In all instances:

- Written consent will be taken
- Where the participant's first language is other than English, consent will be taken verbally via a digital recorder as well the participant completing a written consent form in English. The interpreter will also be asked to also sign the written consent form under 'witness signature'.
- Informed consent will take place at least 24 hours after the participant has been given the full participant information or as long as they require to decide.
- For participants who might potentially contribute data on more than one occasion process consent will be maintained, whereby the researcher, with an interpreter if required, will check that the participant remains willing to continue participation in the research verbally on each occasion, and will remain observant for any indication of discomfort or wish to withdraw throughout the interview. It will be made clear to participants, verbally and in writing, that there is no obligation to continue to participate in the study.

6.4.1 Work stream 1

6.4.1.1 Patient participants

Consent will be taken face to face, via a professional interpreter accompanying the researcher when needed. Patients may be seen in LOROS, their own home or at a suitable location of their choice. Patients will be given a copy of the signed consent form.

Participants will be asked to give consent appropriate to their level of understanding, ranging from written informed consent to account being taken of verbal and non−verbal communication in determining willingness to participate.

For those individuals thought not to have capacity to give fully informed consent, we use the provisions of the MCA 2005 and the consultee will provide information regarding the patient's wishes about participation in research.

There is potential that some patient participants may lose capacity to give on-going consent during the follow-up period. We will sensitively discuss this issue with patients at the point of initial consent to the study. Data that has been collected to that point will be used in the study and we will seek their views as to whether they would give their permission for their FCG and HCP to continue to discuss their care as participants in the research or whether this would be a point at which they would wish to be withdrawn from the study or whether they would wish their FCG or consultee to provide guidance to the research team should that arise.

6.4.1.2 FCG participants

Consent will be taken face to face, via a professional interpreter accompanying the researcher when needed. FCGs may be seen in LOROS, their own home or a suitable location of their choice.

6.4.1.3 HCP participants

Consent will be taken immediately before the interview with the HCP. For phone interviews consent will be taken verbally via a digital recorder and consent forms will be sent to the HCP and they will then sign and send the original back to us by post, fax or e-mail.

6.4.2 Work stream 2

Consent will be taken face-to-face, via a professional interpreter accompanying the researcher when needed. In most cases we anticipate this will be immediately before the interview.

6.4.3 Work stream 3

Consent will be taken immediately prior to the workshop

7. DISSEMINATION AND PROJECTED OUTPUTS

The effective dissemination of the findings is essential to this project to achieve the aim of improving the quality and experience of end of life care of BAME patients and their families. The findings are of relevance to many stakeholders and the dissemination plan is tailored to these audiences and partners, where possible via co-production. The findings of our work will be of importance to the public as they all are potential patients and family carers. We know however that the level of knowledge of the general public and especially BAME communities about these matters is low.

Media:

A variety of media will be used to share findings. A specific project Wordpress website will be developed linked through the LOROS website as we have for other projects (Continuing Bonds). The website will give details of the study and its progress as well as links to project outputs and publications, and drive interest in the e-learning product during and after it is developed. Analytics will track impact with audiences, and an option to sign up to alerts will collect information on audience type and interest along with a moderated chat forum. We would anticipate that the website will act as a facilitator of a community of clinical and research practice in this area of end of life care discussions.

A pertinent project # and @ will be developed for sharing of information through social media which will link to communication networks of our local supporting organisations (LOROS; HealthWatch; Health Education East Midlands, Leicester CCG) and national organisations such as the Hospice UK/National Council for Palliative Care. Alongside the editorial role for the journal 'Diversity and Health', one of our Advisors runs a thriving facebook page and twitter account @DiversityJnl for academic and community based groups about diversity and health. Where available 'hit' and feedback data will be used to

evaluate spread of the message and impact. Press offices of LOROS, University Hospitals of Leicester and the Universities of Nottingham and Leicester will also be engaged.

We will also use local media including multi-lingual radio stations (e.g. EAVA FM http://www.eavafm.com/contact.php) to share progress reports and findings with the public. CI will also deliver a Podcast at the beginning and end of the study.

e-learning:

A key project output and part of project objective 3 will be an e-learning session and downloadable resources (See research plan for details). This will be freely available to all HCPs through Health Education England e-ELCA who will promote its use. Pre and post self-assessment questionnaires within the session will give evidence of immediate impact on HCPs knowledge and intended practice. This course will be regularly updated over a period of 5 years post study.

Dissemination events:

With the engagement of Healthwatch and our PPI co-applicant CA2, we will disseminate the findings to local community groups and seek to attend events in Leicester and Nottingham. We will commence this in month 22 of the study but dissemination will continue post project completion. These events may be bespoke or as part of a broader event organised by health or community organisations such as Health Watch or Age UK or local religious/community organisations. A suite of visual information leaflets to support dissemination of information (e.g. infographics and presentations) will be developed with guidance from our established PCBR group and LOROS patient and carers reader groups and will be made available at community events. Where possible information will be delivered in the primary language of participants. A variety of methods will be used to capture impact and feedback. The choice of method will be determined by the event and may include comments cards, tweets, questionnaires and on-line surveys.

These community events will inform the design of materials that will be made available for others who wish to undertake such public outreach work such as in Dying Matters Awareness week. The events will also inform future grant applications which will consider more formally the impacts of information and awareness raising activities about deterioration and end of life care planning with the public.

Within 6 months of the study ending we aim to organize two events in each of our sites (Nottingham and Leicester) to disseminate the findings to public, HCPs, managers, CCG and Local Authority Commissioners, educators and regional and national voluntary sector organisations such as HealthWatch, Age UK and the Carers Federation. Evaluation of these events will be undertaken, including the use of electronic 'voting' systems to enable comparison of views in the group and further discussion about the subject matter and value of the event.

Project newsletter

A twice yearly newsletter will report the study progress. These will be posted on the project website and mailed directly to stakeholders and participants as appropriate.

Conferences

The study findings will be presented to a wide range of regional, national and international conferences and networking events involving professional, academic and public audiences, including those of the Association for the Study of Medical Education, Palliative Care Congress, European Association of Palliative Care and LOROS, Mary Secole Centre, Leicester Academy Study Ageing and NCARE events.

Publications

The team has a strong track record of publishing in high impact international peer reviewed journals such as BMJ Supportive and Palliative Care, Palliative Medicine, Age and Ageing. We anticipate a minimum of five papers will be submitted and have costed for two as open access. We will also submit articles to professional journals such as the Nursing Times.

Outputs

The greatest gains from this study will be firstly new knowledge about the negotiation of EOLCP from the perspectives of BAME patients, their FCGs and the HCPs that support them and secondly the translation of these findings to freely and readily accessible learning material for HCPs across the UK.

The study findings will specifically provide:

1. New understanding of the barriers and enablers of culturally sensitive and appropriate EOLCP with BAME patients with advanced disease in the UK (the 'answer' to the research question).

2. New knowledge about the views of BAME patients and FCGs about thinking ahead about deterioration and dying.
3. New understanding of what constitutes 'good' end of life and outcomes for BAME patients and families.
4. An exploration of the roles and support provided by professionals in navigating EOLCP with BAME patients and families and establishing patient preferences.
5. Exemplars of good practice in EOLCP between BAME patients and those close to them and their clinicians.
6. An identification of new approaches to improving the end of life care of BAME patients and their families.

7.1 Potential Outputs and Impact

The findings of the study will lead to the following outputs and potential impacts:

1. Findings will impact directly on professional practice through publications and through informing national policy for End of Life care and training for health care professionals through the teams' links to academic health science, education networks and professional bodies. Impact will be captured via citations of the interim and study outputs, (eg on Researchgate and GoogleScholar), feedback from participants at professional presentations, and by directing participants to the project website for ongoing comment and feedback on specific outputs and resources.

2. Development of educational resources (freely available on-line). The e-learning resource will include filmed case studies and resources based directly on the study data. The e-leaning will constitute a session within the e-End of Life Care for All (eELCA) programme of Health Education England E-Learning for Healthcare (eLfH) (71). This is a free resource available to HCPs including non-NHS hospice staff across the UK. Twelve healthcare professionals will be asked to evaluate the structure and content of the online resource, using a free text questionnaire. The resource will subsequently be updated in the light of their comments.

The process for the development and quality assurance of e-learning sessions is rigorous and well defined by eLfH. Sessions have visual uniformity and some mandatory structural components including a statement of learning objectives and formative assessments. The content authors are supported by

instructional designers at eLfH who have both technical and e-education expertise. The iterative and collaborative process of development of a 20-30 minute e-learning session takes place over several months. CI was the National Clinical Lead for e-ELCA (2014-17) and has the support for this collaboration from the current Association for Palliative Medicine clinical lead and the eLfH Programme Manager and Senior Project Manager.

Pre and post self-assessment of e-learning will provide evidence of immediate outcomes on HCPs' knowledge. Uptake by participants and organisations and outcomes for professionals will be tracked by e-LfH over 5 years after the session launch.

3. Development of resources for the public. These will be available at community events and downloadable through the project website. We will work with HealthWatch to develop pathways for national dissemination. Impact of this will be evaluated as described in the dissemination plan above.

4. With the support of Hospice UK/National Council for Palliative Care (recently merged organisations) we will seek to form a National stakeholder group named: The End of Life Care Education Stakeholder Group. This group will meet twice during lifetime of the project and consist of stakeholders in HCP Education and workforce development. Ruth Auton, Director of Education and Workforce at LOROS and previously Senior Nurse at Health Education England will chair the National End of Life Care Education Stakeholder Group. Representatives will be invited from key national organisations with responsibility for the education and training of the healthcare workforce including General Medical Council, HEE, Royal College of Nursing, Hospice UK/NCPC, Marie Curie and National Association of Palliative Care Educators, Association for Palliative Medicine, NHS England. This group will help shape and influence the dissemination of findings from the research, reduce the translation gap and be able to help on early implementation and longer term impacts. Via this group we will work with HEE, policy makers and other key stakeholders and organisations to use the study findings to inform commissioning of education and care services that will improve the care of BAME patients with advanced disease and their families. Hospice UK and Health Education East Midlands are key collaborators in supporting for the study and facilitating implementation of its findings.

8 ETHICAL AND REGULATORY CONSIDERATIONS

The principal ethical issues concern the inclusion of seriously ill patients approaching the end of life and recently bereaved carers. It involves exploring their thinking and experiences about a personal and

emotionally sensitive topic (thinking ahead about deterioration and dying) and calls for great skill and sensitivity on the part of all concerned in approaching, consenting patients and in collecting the data through interviews. To mitigate the potential risks for participants and for the researchers themselves the work will be carried out by a research team comprising members with clinical and research expertise in palliative care, death and dying as well as knowledge and experience of research ethics. One of the co-applicants CA1 is a past member of an NHS REC and currently Research Ethics Officer for the School of Health Sciences at Nottingham University.

Patient recruitment will require sensitivity and perseverance and for the researchers to establish excellent relationships with HCPs involved in recruiting patients within the time frame of the study. Recruitment of patient participants for interviews will be facilitated by HCPs. The design of the study will ensure that the first approach to patient participants will be made by a professional with whom they already have a relationship. The discussion about the study and taking informed consent will be undertaken in the language of choice of the participant by the research team who will have training specifically for this study and these participant groups. Interpreters will be briefed and debriefed about the study individually before and after involvement in any part of the recruitment and data collection. Consent will be taken in the participant's place of choice, which might be in their home or at a health care site. Written consent will be obtained and the original consent form will be kept on file, with a copy also given to the participants. For those who give consent in a language other than English an audio recording of the consent will also be taken. For participants who might potentially contribute data on more than one occasion consent to continue will be checked verbally on each occasion, and documented, and it will be made clear that there is no obligation to continue to participate. For patient participants details of their participation and consent will be documented in their medical records.

We seek to include patients who lack capacity to give fully informed consent and will use the consultee processes described in the Mental Capacity Act 2005. It is acknowledged that there is potential for a conflict of interest where the consultee is also a FCG participant in the study. For some patients the close family carer will be best placed to represent the patient's views about participating in the research and ipso facto be the FCG who would be nominated as a potential study participant. We have sought advice from other researchers who have extensive research experience in the field of dementia and in NRES approved research (79) where both the patient with dementia and the close family member were both research participants and the family care giver acted also as the consultee (80). This conflict of

interest would seem to be of minimal risk or harm to the patient participant and the alternative strategy of always intentionally separating these two roles may be more harmful as either the consultee would know the patient less well or the FCG participant would be less involved with their family members care and support and potentially compromise the data accuracy and depth.

The research is emotionally sensitive. Many members of the research group are either highly skilled clinicians and/or have a track record of research in sensitive areas (81, 82). The interviews intentionally and necessarily explore issues of a serious nature and potentially emotionally difficult areas. Previous research has reported that participants find taking part in qualitative research to be a positive experience, even when they anticipate that this might involve discussion of distressing issues (83). Indeed, some people find the opportunity to reflect on their experience in the 'neutral' context of a research interview to be helpful (84, 85). Information sheets will clearly state that discussing the experience of serious illness may be distressing, and ask participants to consider carefully how they feel about this prospect before deciding to take part. Participants will be assured that their participation is entirely voluntary, and that they may stop an interview or withdraw from the project at any time. Only trained and supervised researchers will be allowed to contact potential participants and undertake interviews. It may be that for some, retelling their story may be a cathartic or therapeutic experience. We have made provision for how distress will be managed within the study. Our 'pyramid of support needs' comprises: (1) no support required (2) signposting to GP (3) written information provided about local third sector organisations (4) potential formal referral for counseling. The CI who is a palliative care clinician, would talk with the participant about the level of concern and seek permission to discuss this with their GP .

Patient data will be anonymised and held on protected systems in accordance with GDPR (2018). The CI will act as custodian for the data. Systems will be set up for reporting and managing any adverse events or misconduct during the study.

9. ASSESSMENT AND MANAGEMENT OF RISK AND SAFETY REPORTING

We recognise that the study deals with difficult and sensitive issues relating to the experience of serious illness and EOLCP. This prospect will be discussed with participants prior to their taking part in the study,

and assurances given that they are free to withdraw at any time, and will never be under pressure to answer questions or discuss issues that they find unwelcome All interviews will be undertaken by researchers experienced in interviewing people about sensitive topics.

We would expect the occurrence of adverse events in this type of study to be minimal. However, in the case of any adverse events occurring, they will be documented and followed up by the study team to resolution in accordance with Sponsor processes.

Due to the nature of the study population, in terms of the patient participants, it is expected that there may be prolonged periods of hospitalisation or deaths during the course of the study, and potentially during their participation, so we will not be recording or reporting these as serious adverse events.

Due to the nature of the study we would not expect any other serious adverse events, however, should there be any they will be recorded and reported in accordance with Sponsor safety reporting processes.

9.1 *RESEARCH ETHICS COMMITTEE (REC) AND OTHER REGULATORY REVIEW & REPORTS*

Should it be necessary to make any changes to the protocol, these will be made via an amendment which will be submitted for the appropriate reviews and approvals and no changes will be implemented prior to these approvals being in place. A protocol amendment intended to eliminate an apparent immediate hazard to participants may be implemented immediately (urgent safety measure) providing that the Sponsor and the HRA are notified as soon as possible and an approval is requested. Minor protocol amendments only for logistical or administrative changes may be implemented immediately; and the Sponsor and the HRA will be informed.

The study will be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki, 1996; the principles of Good Clinical Practice, and the UK Policy Framework for Health and Social Care Research 2017

9.2 Informed Consent and Participant Information

The investigator will inform the participant of any relevant information that becomes available during the course of the study, and will discuss with them, whether they wish to continue with the study. If applicable they will be asked to sign revised consent forms.

If the consent form is amended during the study, the investigator shall follow all applicable regulatory requirements pertaining to approval of the amended consent form by the HRA and the Sponsor and use of the amended form (including for ongoing participants).

10. RECORDS

Case Report Forms

Each participant will be assigned a study identifier for use on CRFs, other study documents and the electronic database. The identifier will incorporate a combination of letters and numbers to convey information about location and type of each individual respondent.

CRFs will be treated as confidential documents and held securely in accordance with regulations. The investigator will make a separate confidential record of the participant's name, age, and Participant Study Number, to permit identification of all participants enrolled in the study, in case additional follow-up is required. This enrolment log will be kept in the appropriate section of the Trial Master File, which is stored separately to the CRFs in a locked cabinet within a secure facility. Access to CRFs shall be restricted to members of the research team.

Interviews

Digitally recorded interviews will be transferred to the secure LOROS Hospice server and erased from the recording machine. Interviews that are in a language other than English will be translated and recorded in English by a bilingual researcher or translator as described in 5.1 above. A single copy of each English interview will be loaded onto an encrypted flashdrive and delivered securely to/from the transcriber. On return the transcript will be loaded to the secure hospice servicer and the flashdrive will wiped of all data. Transcribers are asked to sign a confidentiality statement specifying the procedure for safe storage and transfer of project data.

A single electronic file containing names and project code identifiers of each participant and a second containing participant names and contact details will be kept in the project folder on the secure LOROS server, access to this will be limited to members of the LOROS research team only. A paper copy of each

of these files will be kept in a locked filing cabinet in the research office. All other electronic data will be anonymised prior to storage on the LOROS Hospice server and entry into the NVivo or other databases or excel spreadsheets which will be used to facilitate data analysis and management. Project documents containing personal identifiable data (e.g. signed consent forms, reply slips etc.) will be stored in the Trial Master File in a locked filing cabinet in the research office which is locked when not in use. All documents containing personal identifiable material relating to study sites or participants will be shredded prior to disposal.

Source Documents

The Trial Master File and associated source documents shall be filed at the coordinating site, LOROS Hospice, and may include but are not limited to, consent forms, CRFs, field notes, interview transcriptions and audio records. The completed CRFs will be kept in a separately locked cabinet in the research office at LOROS.

Direct access to source data/ documents

Access to all study information and documentation will be restricted to members of the research team and authorised representatives of the Sponsor and regulatory authorities for monitoring and audit purposes only.

11. DATA PROTECTION

The University Hospitals of Leicester NHS Trust (UHL) is the Sponsor for this study based in the UK. LOROS and UHL will be using information from you in order to undertake this study and UHL will act as the data controller for the study. The research team will endeavour to protect the rights of the study's participants to privacy and informed consent, and will adhere to the GDPR 2018. The CRF will only collect the minimum required information for the purposes of the study. Paper copies of the CRFs will be held securely, in a locked room, or locked cupboard or cabinet. Access to the information will be limited to the research team, the study Sponsor and any relevant regulatory authorities for monitoring and audit purposes (see above). Electronic data including the study databases will be held securely and password protected. All data will

be stored on a secure dedicated web server. Access will be restricted by user identifiers and passwords (encrypted using a one way encryption method).

Information about the study in the participant's medical records / hospital notes will be treated confidentially in the same way as all other confidential medical information.

Electronic data will be backed up every 24 hours in accordance with LOROS Hospice IT processes.

12. QUALITY ASSURANCE & AUDIT

Insurance and Indemnity

Insurance and indemnity for study participants and staff is covered within the NHS Indemnity Arrangements for clinical negligence claims in the NHS, issued under cover of HSG (96)48. There are no special compensation arrangements, but study participants may have recourse through the NHS complaints procedures.

LOROS has indemnity through its insurers for the conduct of the study and research activity at this site.

Study conduct

The study will be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki, 1996; the principles of ICH Good Clinical Practice, and the UK Policy Framework for Health and Social Care Research 2017

The study will be subject to monitoring and audit by the Sponsor and will be included in their risk based monitoring and audit programme.

The study will be monitored internally by the Research Manager at LOROS, this will include a comprehensive consent audit.

13. STUDY DATA

Study data shall include confirmation of informed consent; source data verification; CRFs and audio recordings as well as, transcripts.

Record retention and archiving

In compliance with the ICH/GCP guidelines and applicable regulations, the Chief Investigator will oversee the set-up and maintenance of all records and documents regarding the conduct of the study. These will be retained for at least 7 years. If the CI is no longer able to maintain the study records, a second person will be nominated to take over this responsibility, in this case the study sponsor will be informed.

The study documents held by the Chief Investigator on behalf of the Sponsor shall be archived at secure archive facilities at LOROS Hospice while there is adequate space to allow this. In the case of secure space becoming an issue the study will be archived off site in a secure archiving facility in accordance with Sponsor processes. This archive shall include all study databases and associated passwords or encryption codes.

Discontinuation of the study by the sponsor

The Sponsor reserves the right to discontinue this study at any time for failure to meet expected enrolment goals, for safety or any other administrative reasons. The Sponsor shall take advice as appropriate in making this decision.

Statement of confidentiality

Individual participant medical or personal information obtained as a result of this study is considered confidential and disclosure to third parties is prohibited with the exceptions noted above.

Participant confidentiality will be further ensured by utilising participant identification codes for data in the CRFs and the electronic computer files.

14. Peer review

This study has been subject to rigorous external peer review, as part of the NIHR HS&DR programme application and funding process.

15. STUDY FINANCES

Funding source

Funding acknowledgement

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Department of Health and Social Care disclaimer

The views expressed are those of the authors(s) and not necessarily those of the NHS, the NIHR or the Department of Health and Social Care.

Participant stipends and payments

Participants will each be given a £20 voucher as a 'thank you' for participation at each interview in keeping with INVOLVE guidelines. They are not expected to incur any expenses as a result of their involvement as it is expected that researchers will be travelling to them in most cases. However, should they wish not to be interviewed in their own home, a mutually agreed venue will be arranged and any participant travel costs incurred may be reimbursed up to £20 per interview on production of either a receipt or calculation of mileage which will be paid at the standard rate.

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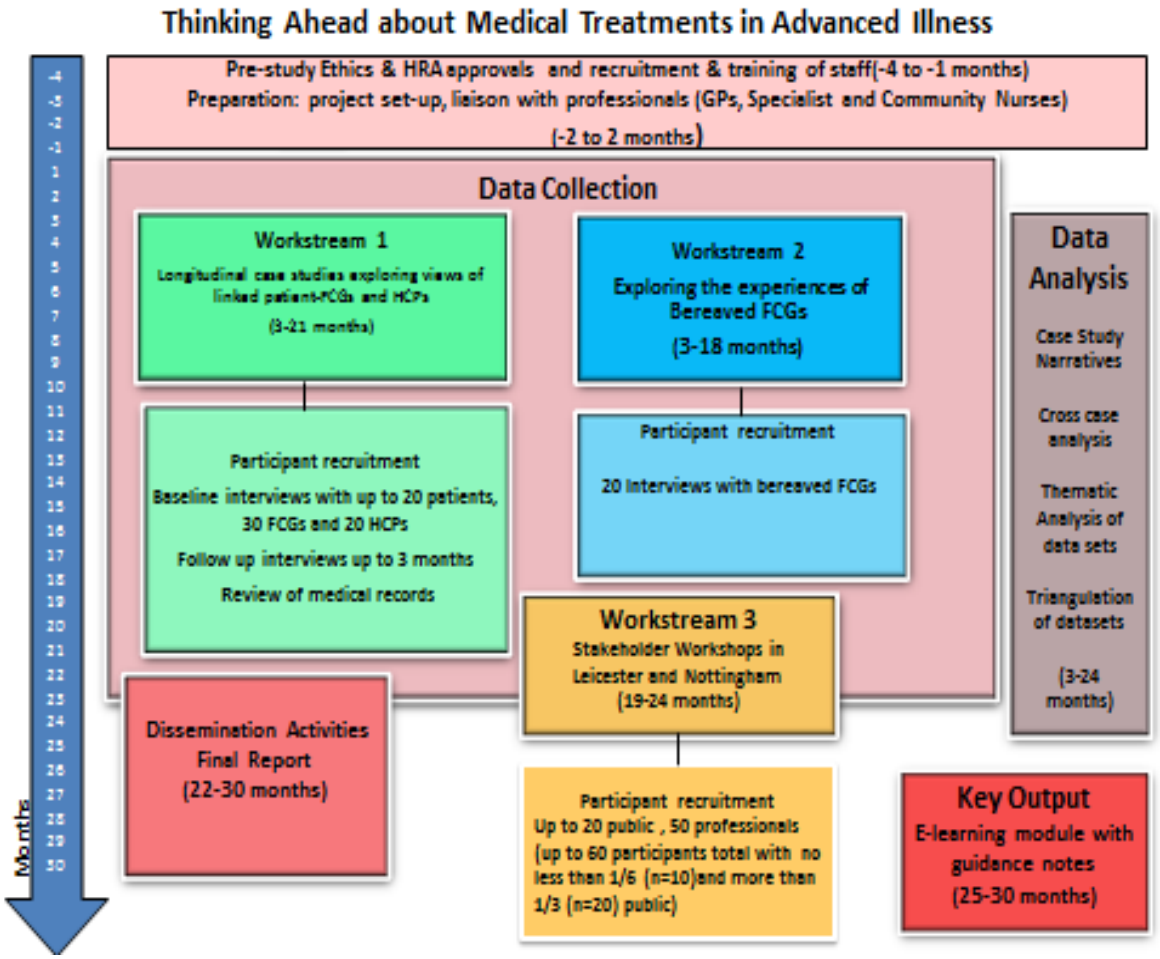
17. APPENDICES

Appendix 1: Thinking Ahead Project Flowchart



Appendix 2: Thinking Ahead GANTT Chart

Thinking Ahead: Exploring and understanding Experiences and Decisions in End of Life Care

	Pre-Study				Year 1												Year 2												Year 3					
Month number	-4	-3	-2	-1	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30
Month	Jul	Aug	Sept	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr
Pre-study: Ethics and R&D approval																																		
Pre-study: Recruitment and training of Staff																																		
Preparation and set-up; liaison with professionals and services																																		
WS 1: Longitudinal patient case studies																																		
Case study recruitment and interviews with 20 patients, 20 FCG,20 HCPs, follow-up, analysis																																		
WS 2: Experiences of bereaved relatives																																		
Recruitment and interviews with 20 bereaved relatives and analysis																																		
WS3: Stakeholder workshops																																		
Recruitment, set-up and conducting workshops in Leicester and Nottingham																																		
Output: Development of E-learning Module and HCP feedback																																		
Analysis, follow-up & write-up and dissemination																																		
Interview Transcription																																		
Data analysis and triangulation of data from WS 1 and 2																																		
Dissemination/write report/preparation for publication																																		
Milestones																																		
Ethical Approval				◊																														
Completion of WS1 data collection																									◊									
Completion of WS2 data collection																						◊												
Completion of Stakeholder Workshops WS3																												◊						
PMG Meetings					◊		◊		◊		◊				◊		◊		◊			◊		◊		◊		◊		◊		◊		◊
PCBR Group Meeting						◊							◊					◊										◊						
SSC Meetings						◊							◊								◊						◊					◊		
National End of Life Education Stakeholder Group Meetings																◊												◊						
Project Newsletters						◊								◊								◊						◊					◊	
Interim and final report										◊						◊						◊						◊					◊	
Month number	-4	-3	-2	-1	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30
Month	Jul	Aug	Sept	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr