Equitable Palliative care In the Community through Primary Care (EPIC-PC): a realist study to propose a new integrated neighbourhood team approach to palliative and end of life care.

Short Title: EPIC-PC

PROTOCOL VERSION NUMBER: 1.6

Date: 26.08.25

Version Control Table

Version	Date submitted	Key revisions
1.0	28.5.24	Updated research proposal in response to Committee feedback (SM / LZ)
1.1	23.12.24	Protocol updated with detail added to research plan, specifically research WP 1 recruitment and details for research ethical approval (SM). Contents page added. Researcher details added.
1.2	22.1.25	Updated Gantt chart to reflect start date Feb 2025
1.3	30.4.25	Reviewed for accuracy and clarity. Inaccuracies and typographical errors corrected. Organisation details and acronyms updated. New IRAS number
1.4	10.6.25	Updated and amended following Sponsor / Governance review Formatting reviewed. Glossary added. WP2 wording: “areas” to replace “sites” p.19 Details added to Ethics section p.29-36 Details added to recruitment to Discrete Choice Experiment p.32
1.5	13.08.25	Updated and amended following REC review Clarification of the participant ratio Clarification of patient and carer debrief process Clarification of support and referral process, should any support, distress issues arise during the health professional interviews.
1.6	26.08.25	Updated and amended following HRA review End of study definition added

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Signatures

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 publicly 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.

Signature:
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Glossary

Ambitions Partnership for Palliative and End of Life Care	*Strategic collaboration of national organisations working to improve the quality and accessibility of palliative and end of life care across England.*
Behaviour Change Wheel	*Comprehensive framework for designing and evaluating behaviour change interventions.*
CMOC	**Context-Mechanism-Outcome Configuration:** *Key concept in realist evaluation and realist synthesis used to understand how and why interventions work (or don't) in specific settings.*
Core20PLUS5	**Core20PLUS5 identifies key population groups and clinical priorities:** *NHS England framework aimed at reducing health inequalities at a national and local level.*
DCE	**Discrete Choice Experiment:** *Quantitative research method used to understand individuals' preferences by asking them to choose between different hypothetical options or scenarios.*
Deep End Networks	*Groups of GP practices that serve patients living in the most socioeconomically deprived areas, often characterised by high levels of complex health and social needs.*
EEDI	**Equity, Equality, Diversity, and Inclusion:** *Framework and set of principles that promote fairness, representation, and respect for all individuals, particularly within organisations, education, and healthcare.*
GRIPP-2	**Guidance for Reporting Involvement of Patients and the Public, version 2:** *Standardised tool for reporting patient and public involvement (PPI) in health and social care research*
Health and Care Act 2022	*Significant piece of legislation in England that reforms the structure and delivery of health and social care services, aiming to improve integration, collaboration, and patient outcomes.*
ICB	**National Health Service Integrated Care Board:** *Statutory body within the NHS responsible for planning and funding health services in a local area in England.*
INT	**Integrated Neighbourhood Team:** *Multidisciplinary team delivering coordinated health and social care services within a local community or neighbourhood.*
i-PARIHS	**integrated Promoting Action on Research Implementation in Health Services:** *Framework used to guide the implementation of evidence-based practices in healthcare settings.*
Mobilising i-PARIHS	**Mobilising i-PARIHS:** *Process of applying i-PARIHS to facilitate successful implementation of evidence-based innovations in healthcare settings.*
NVivo	*Qualitative data analysis software used organise, code, and analyse unstructured data.*
PPI	**Patient and Public Involvement:** *Active involvement of patients, service users, carers, and members of the public in the design, delivery, and evaluation of the project*
QALY	**Quality-Adjusted Life Year:** *Measure used in health economics to assess the value of health interventions by combining the quantity and quality of life gained.*
QOF	**Quality and Outcomes Framework:** *System for performance management and payment in primary care services in the UK*
RAMESES	**Realist And MEta-narrative Evidence Syntheses: Evolving Standards:** *Set of quality and reporting standards designed to guide the conduct and publication of realist and meta-narrative systematic reviews.*
RDN	**Research Delivery Network:** *Teams that provide research resources across multiple sites, including hospitals, clinics, and community settings*
RE-EQUIPP	**RE-EQUIPP (Reducing inEQUalities through integration of Primary and Palliative Care Partnership):** *Collaborative initiative aimed at addressing health inequalities by integrating primary care and palliative care services.*
UPC	**Usual Provider of Care:** *Measure of continuity of care that reflects the proportion of a patient's visits that are with their regular or preferred healthcare provider*
WP	**Work Package:** *Defined section of work within the project*

Scientific Abstract and Summary

Research question

What are the key contexts, resources and components required for an integrated approach to palliative and end of life care to deliver improved and more equitable outcomes for patients and carers?

Background

Avoidable and unfair differences in access to high quality palliative care exist for different groups of people and communities. Primary and community care teams deliver most palliative and end of life care to people at home but the quality of care provided is highly variable in practice. This is an under-researched area and receives little attention in service design and policy.

Aims / Objectives

This realist research will investigate the key contexts, resources and components required for an integrated approach to palliative and end of life care, to achieve more equitable, beneficial outcomes.

Objectives:

1. To understand patient and carer experience, priorities, and preferences, regarding the provision of community end of life care, with a focus on areas of socioeconomic deprivation.
2. To understand the service development and training needs of primary care and specialist palliative care staff to enable delivery of integrated palliative care in the community.
3. To propose how, when why and for whom the approach improves outcomes (programme theory).
4. To define the potential economic value and impact of the integrated approach.
5. To determine the key enablers, including commissioning and contracting processes, to enable the integrated approach to be implemented in practice.

Methods

The objectives will be addressed through four work packages (WPs).

WP1 (Objectives 1&3): Multi-perspective mixed-methods study, to understand patient preferences and priorities in palliative care, with a focus on deprivation. The WP will comprise (i) qualitative interviews with patients and their family members / carers, (ii) review of their primary care case notes and (iii) a broader discrete choice experiment.

WP2 (Objectives 2&3): Realist evaluation of integrated models of palliative and end of life care comprising (1) interviews (theory-refining) and (2) focus groups (theory consolidating) with professionals. Realist analysis will bring together data from WPs 1&2, leading to a proposed integrated approach to palliative and end of life care (key contexts, beneficial outcomes, and the underlying mechanisms) and parameters to inform WP3.

WP3 (Objective 4): Dynamic simulation modelling to evaluate the impact of the proposed integrated approach on the healthcare resources needed to deliver it, quality of care and inequalities. Parameters, including estimation of healthcare costs and resources, patient demographics, and outcomes, will be informed by WPs 1&2.

WP4 (Objective 5): Two expert stakeholder workshops to determine the key enablers to implementation of the approach in practice.

Timelines for delivery

The research will be delivered within a three-year timeframe, with a dissemination strategy to inform key stakeholders including patients and families, professionals in primary care and specialist palliative care and service commissioners of findings throughout.

Anticipated impact and dissemination

The results will inform service delivery to reduce inequalities and optimise the use of finite resources to maximise impact. The research team have the professional networks necessary to deliver impact through a targeted dissemination strategy across service delivery, policy, and academia.

Lay Summary

Problem:

Palliative care and end of life care aims to improve quality of life for people with any serious illness that can't be cured in the last years, months, weeks, or days of their lives. In England, almost one-quarter of people who could benefit from palliative and end of life care do not receive it. People who live in the most deprived areas are least likely to receive palliative and end of life care.

Primary care includes general practices, community nursing and pharmacies. These are the first places that people go to for health care and treatment in the community. Primary care provides most palliative and end of life care to people at home and in care homes, but this is very variable. In England, primary care services are working more closely with specialist services, such as hospices or NHS specialist palliative care teams, in "Integrated Neighbourhood Teams". Integration could improve palliative and end of life care and reduce inequities and inequalities, but research is urgently needed to understand how this works best, when where and for whom.

Aim

This research will investigate how, when, where and for whom an integrated approach can improve palliative and end of life care for patients and their family members and carers, especially for patients living in very deprived areas.

Patient and public involvement (PPI):

We have worked with 16 patients and public members from diverse and deprived communities for 12-months in an NIHR-funded palliative care partnership. This research idea was developed and tested out with PPI members, including our PPI co-applicant. We have clear plans to work continuously and inclusively with PPI members throughout this research project.

Study plan:

1. First, we will interview patients and their family members or carers to understand their priorities and preferences for receiving palliative and end of life care, including people in very deprived areas. We will then review their medical notes for more details. We will carry out a national survey to explore more about priorities and any differences depending on where people live.
2. We will interview and hold focus groups with professionals who are working in integrated ways in primary care and specialist palliative care, to understand their perspectives on what works, when and how, including when working in very deprived areas.
3. We will analyse the findings from the interviews, medical notes review, survey, and focus groups together. We will describe how an integrated approach between primary care and specialist palliative care works 'best' to improve care, when why and for whom, including what resources are needed in different areas.
4. Finally, we will run two events with experts including healthcare leaders and managers to develop

recommendations for using and adapting the approach in practice.

How this will make a difference

This research will increase understanding about what is most important to patients with palliative care needs and / or at the end of life, and their family members or carers, including people living in very deprived areas. It will also help us to understand how services can best work together to improve palliative and end of life care. We will provide information to patients, family members, carers, and professionals, and make recommendations to the NHS, about what resources are required for people, especially from the most deprived areas, to experience much fairer palliative and end of life care in the future.

Detailed Research Plan

Background and rationale

Health inequalities are unfair and avoidable differences in health across the population and between different groups and communities and are a major research and government policy priority. Core20PLUS5, the national approach to reduce healthcare inequalities in England, targets the most deprived 20% of the population and other groups who experience social exclusion (1). Health inequalities are rising, with people in the most deprived areas living shorter lives, and more years of their life with long-term conditions, advanced disease, and ill health (2, 3). Women living in the most deprived areas of England have a healthy life expectancy at birth of 51.4 years, and men 52.3 years, compared with women and men in the least deprived areas who have healthy life expectancies of 71.2 years and 70.7 years respectively (4).

Over 50% of people in England now die in the community, including in care homes (5), but emergency hospital admissions rise towards the end of a person's life. Triggers for hospital admission for people at the end-of-life are poorly understood (6, 7) but this is costly, may be unwanted, and reducing end of life admissions is a policy priority (8). People from areas of socioeconomic deprivation are more likely to be admitted to hospital towards the end of life, suggesting that they are less well placed to cope with end of life care at home (9). Contacts with out-of-hours urgent and emergency care services rise towards the end of a person's life, with those identified as having "palliative" needs more likely to be from less deprived backgrounds than those who are not (10, 11).

Palliative care is holistic, person-centred care, focussed on quality of life for people with advanced disease, and their carers (12). There is increasing evidence to support the effectiveness and cost effectiveness of palliative care (13, 14). Identification of palliative care needs, described as a "golden ticket" to enhanced care in the community, is lacking (15), particularly for people with non-cancer conditions (16). People from areas of high socioeconomic deprivation, with non-malignant disease or from minority ethnic backgrounds are less likely to receive specialist palliative care services compared to White British people, people from more affluent areas and those with cancer (9, 17-21). These inequalities were exacerbated during the COVID-19 pandemic (22-24).

Primary care services, including general practice, deliver most palliative and end of life care in the community. Research conducted by members of this team shows that a key characteristic of good community palliative and end of life care is continuity of care with primary care teams, which is associated with less frequent emergency healthcare use towards the end of life for patients of all ages (16, 18, 25, 26). However the quality of palliative and end of life care in primary care is highly variable. Barriers include time pressures, compromised continuity of care including out-of-hours, inconsistent training, and variable integration with specialist palliative care services (27). General practices in deprived areas of England are the most stretched in terms of both funding and workforce (28). The "care of people who are terminally ill or suffering from long-term chronic disease" is classed as an essential

service within the current NHS General Practice (GP) contract, and palliative and end of life care attracts only three Quality and Outcomes Framework (QOF) points (worth a total of £640.29 per practice per year). These elements of the GP contract have changed little since 2007, the impact is under-researched, and evidence to inform change is lacking.

With the introduction of the Health and Care Act 2022, healthcare systems in England are moving towards more integrated ways of working, including through Integrated Neighbourhood Team (INT) models. These aim to improve access, experience, and outcomes for communities, particularly Core20PLUS5 populations (29). A core function is proactive identification of patients who could benefit from personalised care and continuity, both key characteristics of good community palliative and end of life care. The evidence to inform integrated models of primary and palliative and end of life care in the community is scarce.

"Integration" describes health and care services working together so that the care received by an individual is co-ordinated, personalised, and seamless. Effective integration occurs at interpersonal, team, organisational and system infrastructure to support (30). **"Neighbourhood"** is the term used to describe a population of 30,000-50,000 people served by a group of general practices, working in partnership with other health and social care (31). The INT framework includes co-located generalist and specialist multi-disciplinary teams, community engagement, and workforce development and training.

Review of existing evidence

We conducted a UK-focussed rapid systematic review in December 2023 to inform this proposal. Any empirical studies related to integrated primary and specialist palliative care services for patients with palliative and end of life care needs were included. Studies relating to palliative care provided exclusively by specialist services in the community (including hospices) or in acute hospitals, were excluded. Searches were carried out in MEDLINE, CINAHL, PsycINFO, CENTRAL and EMBASE databases, from inception to the present day, using broad search terms ("Palliative Care", "Integration," "Primary Care" "Inequalities") modified and adapted for each database. There were only five studies that met the inclusion criteria, representing a heterogenous, low level evidence base to inform integration of primary and palliative care as follows: one case note study (32), one retrospective cohort study of cancer patients primary care service use (33), one realist evaluation of an integrated care model (34), one single-blind randomised controlled trial of a short term integrated palliative care service for patients with multi-morbidity, and one mixed methods study using ethnography, qualitative interviews and service user consultation (35). Four studies were limited to one site (32, 34-36), the cohort study included primary care data from the whole UK (33).

Overall, the studies revealed poor identification of patients, especially where multi-morbidities were present, and a lack of understanding about roles, responsibilities and what constitutes good community palliative and end of life care. The key findings across the five studies were:

- Care is poorly coordinated within primary care, especially in the last year of life.
- Prompt identification of patients for palliative care registers can lead to timely assessment and care planning. Identification of patients with cancer who could benefit from palliative care is better than for those with non-malignant disease.
- Multi-morbidity and the identification of palliative care needs are associated with increased primary care consultations, more prescriptions, and referrals to specialist services. Older patients are less likely to have their palliative care needs identified.
- Integration between palliative care specialists, primary care and community nursing teams provides continuity and a means of managing or escalating difficult symptoms.

- Health record sharing is inconsistent and handover information from out-of-hours contacts may not always be helpful.
- There are inequalities of access to palliative care for different societal groups and communities. The reasons for this are unclear.

The review findings are consistent with previous research (including the work of this research team). Key issues that future integrated approaches in primary and palliative care could potentially address include:

- Improving the identification of palliative care needs in primary care, which is associated with increased primary care input and continuity.
- Understanding and addressing triggers for hospital admission at the end of life, particularly for patients in areas of socioeconomic deprivation.
- Describing effective ways of integrated working to improve continuity of care, with more clarity around the roles and responsibilities of members of the primary care and specialist palliative care teams (37, 38), to address time and resource pressures in both services.
- Describing ways to address variation in skills training and confidence, including in out-of-hours primary care, through new ways of working (27, 39-42).

The Reducing inEQUalities through integration of Primary and Palliative (RE-EQUIPP) Care Partnership (NIHR135170), co-led by SM and CE, provided important new evidence to inform this proposal (43). The 12-month partnership included a series of realist workshops with key stakeholders, leading to the development of a programme theory for integration of primary and palliative care (43). Research questions were generated and tested with extensive PPI including the RE-EQUIPP PPI "Dragon's Den" event (detailed in the PPI section of this proposal). This proposal was further informed by feedback from commissioners at a Yorkshire and Humber Palliative Care Research Network event (NIHR135115) organised and facilitated by SM and FM.

Why this research is needed now

National Health Service (NHS) Integrated Care Boards (ICBs) in England have a statutory duty to commission palliative care for all people with progressive illness or nearing the end of life, to live and die well. The need to address inequalities in palliative and end of life care through a personalised approach is emphasised in the Department of Health and Social Care Major Conditions Strategy (44). The NHS England Neighbourhood Health Guidance, published in January 2025, outlines key principles for integrated neighbourhood working. Evidence to support this model for patients with palliative care needs and those at the end of life is urgently needed.

This study will investigate how, when why and for whom new integrated approaches can improve patient outcomes and deliver more equitable palliative and end of life care. The proposed research builds upon the work of the RE-EQUIPP Care Partnership (NIHR 135170), addresses gaps in the current evidence base, and will lead to service and policy-relevant recommendations.

Aim

This research aims to propose the key contexts, resources and components required for an integrated approach to palliative and end of life care to deliver beneficial outcomes and improve inequalities. The research objectives are:

1. To understand patient and carer experience, priorities, and preferences, regarding the provision of community end of life care, with a focus on areas of socioeconomic deprivation.
2. To understand the service development and training needs of primary care and specialist palliative care staff to enable delivery of integrated palliative care in the community.
3. To propose how, when why and for whom the approach improves outcomes (programme theory).

4. To define the potential economic value and impact of the integrated approach.
5. To determine the key enablers, including commissioning and contracting processes, to enable the integrated approach to be implemented in practice.

Patient and Public Involvement

This proposal is informed by extensive and inclusive PPI undertaken in our earlier study (2022-2023) the REducing inEQUalities through Integration of Primary and Palliative (RE-EQUIPP) Care Partnership co-led by SM and CE (NIHR 135170). The partnership worked with the Yorkshire and Humber Primary Care "Deep End" PPI group (a group associated with general practices serving very deprived and diverse communities who are committed to improving care through research) to innovate new approaches to inclusive PPI. Resources developed include a framework for equitable, equal, inclusive, and diverse PPI in palliative care research (accepted for publication Dec 2023), an animation and an online recipe book for inclusive PPI for palliative care. This built on earlier work by the Deep End Group, Sheffield and utilizes novel resources co-led by CE, including an online PPI forum for palliative care.

In the RE-EQUIPP Care partnership, 16 PPI members with experience of palliative care and/or inequalities as a patient or carer participated in three stakeholder workshops on integrated primary and community palliative care, one specifically on inclusive approaches for research involvement. The workshops were open and conversational, prioritising the symbolic capital of PPI members. This approach led to striking insights into cultural norms and power imbalances, including racism, that exist in current services and hinder access. The research team engaged in a process of reflection, recognising the need to adopt allyship as a continual learning process. Our PPI co-applicant, JB, was a member of the RE-EQUIPP PPI group. He proposed and adopted the role of Equity, Equality, Diversity, and Inclusion (EEDI) Champion, holding the team to account for activities to improve EEDI. JB is an experienced PPI member of the Yorkshire and Humber "Deep End" PPI group previously, with insights into health service design and health inequalities. He will be the EEDI Champion for this research. He has personally contributed to the proposal development, reviewing the lay summary and providing clear guidance on specific aspects on the feasibility of the research methods, including the proposed strategies for patient and carer recruitment.

During the RE-EQUIPP workshops, research questions arose around current inequity in palliative and end of life care, and how this was being recognised or addressed, if at all. The poorly understood role of primary care and engagement with communities were both raised. The need for new research to provide solutions and avoid "one size fits all" services, which are inaccessible to people from minoritised communities, was clear. These insights have informed the rationale for this research, which is directly grounded in the perspectives of the population the study aims to benefit. This proposal was "pitched" and tested with a panel of PPI members at a PPI "Dragon's Den" event in November 2022. Feedback from PPI members included advice about the importance of inclusive palliative care research, ongoing PPI and the need to recruit patients and family members / carers, including those who are very unwell and living in poverty, to ensure their views and experience are present in the evidence base to improve services and address inequalities.

PPI Plan

Patient and Public Involvement for EPIC-PC is informed by learning on inclusive research approaches from the RE-EQUIPP Care Partnership. We will recruit PPI members with diverse backgrounds and a range of experience in PPI to the Patient and Family Advisory Board, using the PPI role descriptions devised during RE-EQUIPP (www.RE-EQUIPP.co.uk). We are working with local partners to reach and engage underrepresented groups. PPI will be co-led by SM and CE with PPI co-applicant, JB. A research associate with specific responsibility will be the first point of contact for PPI members, ensuring consistency and effective co-ordination of activities and processes, including training and reimbursement (Project Management p.17). PPI will be conducted in line with the UK Standards for Public Involvement in Research, reported using the GRIPP-2 Checklist, and the budget informed by NIHR guidance.

The Patient and Family Advisory Board will comprise 11-15 public members (see Research Plan, p. 17), including members with lived experience of palliative care as patients (n=4-6) or carers (n=4-6 current or bereaved carers, including close friends) and/or inequality in healthcare provision (n=3). Anonymised equality monitoring and engagement surveys will be conducted to understand our diversity (or lack of), so that we can proactively seek to provide opportunities for new members from under-represented backgrounds. Results and actions will be included as part of a regular PPI report to the study Steering Committee (Project Management p.17, Success Criteria p.20).

An iterative approach will ensure that PPI perspectives inform every stage of the research, with flexible methods and multiple opportunities to engage. The Board will meet every four months to:

- Advise on the development of accessible study information and building trusted community partnerships with people from diverse and deprived backgrounds to enhance recruitment and data collection (WP1.1 p.6-7).
- Input into the design of health economics elements of the study (WP1.2 p. 9, WP 3 p. 12).
- Support interpretation of study findings with identification of key messages and priorities from data analysis (WP1 p. 8&10, WP2 p.12)
- Participate in expert stakeholder workshops (WP4 p.14)
- Be actively involved in dissemination activities and consideration of pathways to impact, including the development of visual resources from the study and presentations to key audiences (Dissemination Strategy p. 14-15)

Two PPI members will represent the PPI Board on the Independent Study Steering group, with tailored support from SM/CE. We will seek to recruit a second, new PPI member to the research team. As an experienced PPI member, JB can provide bespoke mentorship and support with a view to building capacity in PPI for future research.

Evaluation to drive improvements in PPI will include a “you said, we did” impact log, to record the impact of PPI. We will use creative approaches, for example, using plant pot picture with space for people to draw their own plant to reflect how they feel after an activity, drawing small shoots (uncertain), or established plants (confidence), writing words around the page if they choose. Training needs will be identified and addressed, and strategies to maximise inclusive and meaningful involvement reported as part of the study dissemination plan.

Research design and theoretical framework

An integrated approach to palliative and end of life care in the community is a complex intervention, which depends on context, multiple stakeholders, and comprises many different aspects of care. This study will therefore use realist evaluation methodology, which is suitable for the study of complex interventions. Realist methodology assumes that the same will not work in the same way for everyone, everywhere. An intervention, such as integrated palliative and end of life care, is complex due to interactions with contextual factors, including the active input of individuals, social infrastructures, available resources, and organisational, economic, political, and cultural factors (45). Realist evaluation allows the investigation of how and why an intervention achieves beneficial outcomes (or not), by understanding the mechanisms (hidden cognitive or affective responses of stakeholders, in certain circumstances (46).

The proposed research draws upon an initial programme theory for integration of primary care and palliative care, developed through the RE-EQUIPP Care Partnership (NIHR 135170), which was informed by previous work to understand effective collaboration in healthcare conducted by JA (47-49). The planned research will consider the core interactions, resources and refinements needed for effective integrated approaches to palliative and end of life care in different socioeconomic contexts. A theoretical framework relevant to behaviour change and implementation in community settings, drawing on the Behaviour Change Wheel (50) and the principles outlined in the UK NIHR Medical Research Council complex intervention framework (45, 51), will inform the realist data

collection and analysis. Stakeholder workshops using the "integrated Promoting Action on Research Implementation in Health Services" (i-PARIHS) (52) framework will inform the development of principles for the implementation of the approach in practice. The research will lead to the description of an integrated approach of palliative and primary care, and economic model, (complex intervention), comprising a set of discrete components, suitable for further testing and evaluation.

Programme theory

The research undertaken by members of this team (SM, CE, JA, JB) during the 2022 RE-EQUIPP Care Partnership (NIHR135170) generated understanding and insights into integration of primary care and palliative care. Two focus groups were held with key stakeholders, including patient and public involvement members, the first focussed on effective integration, and the second considered inequalities in access to community palliative and end of life care. A total of 27 participants attended workshops in July and September 2022: patient and public members (n=6), commissioners (n=2), clinicians and researchers from primary care (n=5) and specialist palliative care (n=14). Ethnicities were White British (n=22), Asian (n=3), Black African (n=1) and British mixed race (n=1). Existing programme theory of integration informed the data collection and analysis (30). Data analysis led to description of contexts (C), mechanisms (M) and outcomes (O), and a series of explanatory Context-Mechanism-Outcome Configurations (CMOCs) (43).

Patient and public members described cultural norms and racism in current services (C1) and associated power imbalances (M1) that hinder access (O1). We proposed this as could act as a point of entry into integrated partnerships between primary care and specialist palliative care services. Increased recognition of current inequalities across the health and social care system (C2) has the potential to inform shared vision and purpose (M2), mobilising new, innovative, cross-boundary integrated partnerships to provide more equitable palliative care (partnership entry/O2). Transparency and honesty about these factors amongst both frontline professionals and service leaders (C3), underpinned by self-awareness and reflection (M3.1), and leadership behaviours that enable change (M3.2), can foster learning and commitment to improving inequalities (partnership functioning /O3).

In a healthcare system where there is competition for finite resource (C4), models of integrated primary and palliative care require trusted interpersonal relationships (M4) and clarity around roles and responsibilities between professionals (O4). Positive experiences for patients, families, and professionals, delivered through well-coordinated, multi-disciplinary care (C5), reaffirms efforts (M5), and builds confidence in the approach (partnership synergy/O5). Further enabling contexts may include co-location of professional teams, reliable record sharing, and working towards a shared goal. The theory provides a range of contextual factors amenable to change to trigger mechanisms and lead to positive outcomes for patients, families, carers and professionals.

Study setting and sampling:

The study will be carried out in the North East region of England, a region with large rural areas and cities, and the highest proportion of households (54.6%) in England who are deprived in at least one of the four dimensions of education, employment, health and housing (53). Around 10.8% of the population are from Minority Ethnic backgrounds (6.3% Asian, 1.6% Black, 2.9% mixed / other). This ethnic diversity is representative of England except for the more densely populated West Midlands and London (53).

Population demographics will inform the sampling frame for WP1 and 2. People living in areas of socioeconomic deprivation face multiple intersecting characteristics of disadvantage, including gender, ethnicity, and disability. These factors overlap and increase further people's disadvantage in (1) accessing the care and support they need, and (2) taking part in research (54).

There are four Integrated Care Boards and three "Deep End" primary care networks in the region, supported by NIHR Research Delivery Networks (RDNs), to increase research capacity in the most deprived areas through research active general practice (54). SM, LZ, MA, FM and CE have a track record of successful PPI and recruitment to palliative care studies in these areas. In West Yorkshire, SM and LZ are leading plans with the Yorkshire and Humber RDN for a Deep End network with palliative care as a strategic priority. We have identified three sites for WP2 who are already providing palliative and end of life care in the community through integrated approaches, suitable for evaluation in this study as follows:

(1) clinical Service integration in Leeds: St Gemma's Hospice and the Seacroft Primary Care Network
(2) organisational service integration in Bradford and Airedale: 24/7 Goldline, community services and the Emergency Department.
(3) administrative integration in North Tyneside: Deciding Right and North East and North Cumbria data model

The research team have strong professional networks to engage with primary care and specialist palliative care colleagues to help mitigate potential barriers to recruitment. Careful consideration has been given to the feasibility of the study and generalisability of the findings.

Research Plan / Methods

The study consists of four linked work packages as follows:

WP1: Patient and carer / family experiences and priorities for palliative and end of life care in primary care (Objective 1, Months 3-18)

METHODS: A multi-perspective, mixed-methods study, comprising qualitative interviews with patients and family members / carers, followed by a detailed case note review and a discrete choice experiment (DCE).

RESEARCH QUESTION: What are the priorities and preferences of patients, family members and carers regarding the provision of community end of life care, including those from areas of socioeconomic deprivation?

WP 1.1: Patient and family / carer experiences (Leads: SM & LZ (qualitative), MA & FM (quantitative))

DESIGN: A sequential, exploratory study with qualitative semi-structured interviews (n=35-40) with patients with palliative care needs. Where appropriate, and with the patient's permission, their family members and carers will also be interviewed or invited to attend. This will be followed by detailed patient case note review of the patient's GP practice records.

SAMPLING: Recruitment will take place via the Deep End Research Networks and Alliances across the regions (Yorkshire and Humber: Sheffield and Leeds), and North East / North Cumbria). Purposive sampling to select participants who will provide rich data relevant to the research question will take place through engagement with general practices and hospices across the North East and Yorkshire with whom we already have established professional networks (55).

The sampling frame is informed by the population demographics outlined in the 2021 Census, and recent patterns of death data (53, 56) as follows:

Sampling frame

At least 50% of participants will be from areas of socioeconomic deprivation (n=20-22), with 10% of participants from Black and Minority Ethnic populations (Asian (n=2-3), Black (n=1) and other (n=2-3)). At least 60% of patient participants will have one or more of the major conditions (cancer, dementia, respiratory and cardiovascular disease). Recruitment will be via ten general practices, including Deep End practices, geographically spread across the region, assisted by local RDN research nurses, who are already associated with Deep End research and have knowledge of local communities. Each practice team will identify potential participants (n=3-5) through a targeted

search of their palliative care registers. We will aim to recruit (and have costed for) 40-45 interviews, but we expect attrition due to participants having palliative care needs and / or approaching the end of life Potential participants will be provided with participant information by their clinical team. If they express an interest in participating and give verbal consent for the clinical team to share their contact details with a researcher, the clinical team will email the researcher to request a callback to provide the potential participant's contact information. Upon receiving the participant's details, the researcher will contact the participant, answer any questions they may have, and, if appropriate, agree on a time for the interview. The core research team at the University of Leeds will maintain an Excel database containing names and contact details. This will be stored in a secure university Teams folder, kept separately from any study data, and accessible only to team members with authorised login credentials. Participant information materials will be developed in partnership with the study PPI panel and provided in easy-read and audio formats.

Inclusion criteria:

- Adult patients (aged ≥ 18 years) with advanced serious illness, registered with a GP practice in the North East and Yorkshire, who either:
    - Receive specialist palliative care services.
    - Are aware of (i.e. had discussions about) palliative care, including inclusion on the practice palliative care register.
- Carers, including family members, (aged ≥ 18 years) of an eligible adult, invited to take part in an interview by the patient participant.

Exclusion criteria:

- Adults with advanced serious illness who are unable to participate in a conversational interview for any reason related to their condition.
- Adults with advanced serious illness who are unable to provide informed consent for any reason related to their condition (for example becoming too unwell or approaching the end of life).
- Children and young people aged < 18 years.
- Carers and / or family members who have not been invited to take part by the patient participant.

Patients will not be excluded based on their personal characteristics or healthcare condition unless they are too unwell or unable to provide informed consent to participate.

DATA COLLECTION: Each participant will take part in one interview. To gather in-depth data about patient and carer experiences, the interview will be open and conversational. Consent will be obtained (written, electronic (via University of Leeds JISC Online surveys) or audio-recorded), then the interview will begin with building rapport and collection of demographic information including age, gender, clinical condition, ethnicity, family background, and any other characteristic that the participants wish to use to describe themselves. A realist topic guide, informed by themes identified from the existing evidence base, will be piloted with two members of the PPI panel ahead of the interviews. The topic guide will comprise open questions to allow participants to speak freely about their experiences and perspectives, with a series of prompts to ensure that patient and carer priorities preferred outcomes are captured, including how and when these can be achieved. This will include details of how, when and by whom their palliative care needs were identified, their understanding of this and any impact this has had on subsequent care from their primary care team. Specific aspects of care will include care planning discussions (when and who with), and other aspects such as access to benefits via the Special Rules (SR1 form) and referral to specialist palliative services (or not).

All interviews will be conducted in person, online, or on the telephone, depending on patient choice. Face to face interviews will be conducted in a location chosen by the participant, which may include their home or another suitable venue of their choosing where privacy can be assured, such a clinic or university. Interviews will be

conducted with individual patients or carers, or together, if that is their preference. Carers will not be interviewed without the consent of the patient participant. Where interpreters are required, we will use interpreters who are employed or approved by the University of Leeds. All interpreters will sign a confidentiality agreement. Interviews will be designed to last 40-60 minutes, to cover key topics but minimise participant burden. Given the nature of the interview, it is expected that some may take longer. The interview plan has been designed carefully to ensure that the risks and burdens associated with taking part are minimal. This is particularly relevant because the subject areas discussed during interviews include end of life care. The interview will be halted, and immediate debrief offered, if any of the participants experience difficulties, such as tiredness or distress. Each interview will be followed by a standard debrief which is a brief, supportive conversation held at the end of the interview to ensure participants feel informed, respected, and supported. The debrief includes thanking participants and reminding them of the study's purpose: exploring the experiences of patients and caregivers receiving care from primary and other services for incurable conditions. It invites participants to reflect on the interview experience, checks for any distress, and provides signposting to relevant support services. It also reiterates their right to withdraw from the study, explaining the circumstances in which withdrawal may not be possible. Finally, it outlines the next steps, including how and when they will receive a summary of the study findings, with the option to decline this. All will be conducted by an experienced and appropriately qualified researcher, under the supervision of the workstream lead.

CASE NOTE REVIEWS: Detailed review of the general practice patient records of the patient participants, with their consent (n=35-40 as carers' notes will not be included) will be conducted with the intention of adding further, detailed understanding of the care provided to patients who are identified for palliative care in primary care, when why and by whom. It has the potential to reveal nuances that patients may not be aware of, such as the outcome of referrals to specialist services. Case note review has advantages over database studies as details in free text entries can be reviewed as well as clinical coding.

Case note reviews will be conducted within the relevant general practice. Data for a 12-month period will be extracted to a bespoke data extraction table, with headings informed by the interviews and previous research on factors that influence the integration of primary and palliative care. Data to be extracted will include: clinical codes relating to a participant's disease type(s), deprivation (deprivation decile derived from postcode of usual place of residence), and ethnicity (for whom); the date and time of palliative care identification and being added to a palliative care register and clinical codes used (when); health professional type and setting recording palliative care need(s) and adding a participant to the palliative care register (whom); where available, free-text data will be extracted detailing the rationale for inclusion of a patient on the palliative care register (why). The impact of identification of palliative care needs will be explored by extracting the timing of and any free-text information detailing communication and consultations (including the health professionals involved), care planning, multi-disciplinary team involvement, prescribing, issuance of Special Rules (SR1) forms, and referrals (for example to social prescribers or specialist palliative care). Data will be extracted by the research fellow, supported by bespoke training and a manual to guide data extraction, and ensure its consistent use. Data will be extracted by the research fellow, supported by bespoke training and a manual to guide the extraction process and ensure consistency. Data extracted from medical records will be de-identified and anonymised on the data extraction form. Study ID code numbers will be used instead of names or health service identifiers. A small pilot will be undertaken by research team members involved in using the data extraction form using dummy data, and the data extraction form will be refined if needed following its pilot testing.

WP 1.1 DATA ANALYSIS: The first stage of qualitative data analysis from the interviews and case notes reviews will be reflexive thematic analysis, focussing on the priorities and preferences of patients, family members and carers (57), using NVivo for data management. Thematic analysis is "a method for identifying, analysing and reporting

meaningful patterns (themes) within data" (58). Analysis will begin alongside data collection, with familiarisation, reflection, and note-taking. Codes will be assigned to every item of data, then grouped into overarching conceptual categories and themes (58). The analysis will be led by the Senior Research Fellow, with emerging findings discussed at monthly research team meetings. A selection of transcripts will be reviewed and independently coded by second researchers (SM, LZ), to reduce the risk of lone researcher bias, allow for comparison and further development of codes, and lead to in-depth themes. Following thematic analysis, a realist logic will be applied to the data analysis, to identify descriptions of key beneficial outcomes from a patient and family / carer perspective, why these are important (mechanisms), how these are achieved (or not) (mechanisms), when and by whom (contexts).

Exploratory analysis of data from the case-note reviews will be conducted to identify patterns of care, drawing on data from interviews related to priorities and preferences, and examining case notes to understand more about the contexts in which these are achieved. We will determine the timing and identification of palliative care need(s), health professional(s) involved, and care received following identification of need. Analytical methods that provide insights into when, how and the resources required for patient and carer / family outcomes to be achieved will include exploration of relational continuity of care, and pathway mapping. We will document the proportion of consultations that a participant has had since identification of palliative care needs with individual professionals, to characterise longitudinal continuity of care using the Usual Provider of Care (UPC) index (59). To explore differences in the timing and receipt of care following the identification of need, for each participant we will develop a patient experience map (60). These will depict the chronology of palliative care need identification and any variations in the subsequent episodes of care (capturing professional involvement and setting where possible). Findings will be included in the realist analysis in WP2.

<u>WP1.2: Patient priorities and trade-offs in palliative and end-of-life care provision (Leads EW & MA)</u>
DESIGN: A Discrete Choice Experiment (DCE) is a survey method which will provide further information on the aspects of palliative care that matter most to patients and carers that were identified in work package 1.1 It will quantify which characteristics of community palliative and end of life care patients prioritise the most, and what trade-offs people are willing to make between them. This will help show how care which is aligned with patients' priorities can be delivered efficiently with limited resources. In line with the project's realist approach, the analysis will have an emphasis on when, how and for whom preferences differ across different groups. In particular, we will examine how preferences might differ for the most deprived participants, as well as looking at other characteristics. for example, age, gender, or ethnicity. In a DCE, participants make choices between two hypothetical options. Each option is characterised in terms of several attributes, which could for example include waiting time for a GP appointment and continuity of care, since seeing the same professional for every appointment may require a longer wait. Participants make a series of such choices, with the levels changing in each task, for example time to get an appointment could vary between one day and two weeks, and continuity of care could range from always seeing the same GP, to sometimes seeing someone else, to seeing a different GP each time. Statistical analysis of how participants' choices change as the attribute levels vary then reveals what they prioritise, and the trade-offs they are willing to make. For example, it could provide information on how long participants are willing to wait or how frequently they prefer GP appointments to maintain continuity of care.

SURVEY DEVELOPMENT: It is best practice to develop attributes using qualitative methods (61). We will draw on the findings from WP 1.1 to draw up a list of potential attributes, each describing a feature of palliative care that is important to patients. We will then conduct a prioritisation exercise with the Patient and Family Advisory Board. The results, along with input from professionals in the Independent Steering Group and the project team, will be used to select the final attributes and design a draft survey. We will ask for basic (optional) demographic information that

will be analysed and reported at aggregate level. We will not ask for identifiable information. The draft will be piloted with PPI members to ensure it is understandable, and that participant burden is minimised.

SAMPLING: The final version of the survey, developed as part of the project, will inform sample size calculations. We plan to recruit as large a sample as possible of both patients with palliative care needs and carers. This will facilitate examining preference differences over several different groups. We anticipate recruiting up to 300 participants, based on previous studies and in line with typical DCE sample sizes (62).

DATA COLLECTION: The survey will collect demographic data, as well as participants' choices between hypothetical palliative care options. We will distribute the survey via collaborative partnerships with national voluntary sector organisations for patients (of all ages), families, and carers (the Ambitions Partnership for Palliative and End of Life Care, co-chaired by SM). In addition, we will contact all Deep End networks across England to request assistance in distributing the survey. This will help ensure that responses are gathered from groups who are often underrepresented in DCE survey samples. While we anticipate that most recruitment will take place online, we will also offer a paper survey, distributed in general practices and by post, to guard against digital exclusion.

WP 1.2 DATA ANALYSIS: Data will be analysed using appropriate econometric techniques, to be defined when the final survey is developed, with an emphasis on incorporating heterogeneity, such as mixed logit and latent class. Patient and carer samples will be analysed separately, and the results compared. The findings will provide valuable new insights into patient and carer priorities, how these differ for different people in different contexts, how these may be achieved and the possible trade-offs that can be made in service design to direct finite resources most effectively in line with these priorities (62).

REALIST ANALYSIS AND OUTPUTS: WP1 will lead to new qualitative and quantitative data from three lines of enquiry: (1) patient and family / carer interviews, (2) case note reviews and (3) the Direct Choice Experiment to be reported separately in academic papers. Findings from all three will be included in realist data analysis to meet the aim of WP1. Interviews and the DCE will provide understanding into the priorities and preferences from a patient and family / carer perspective. This will inform the realist analysis by telling us whether the priorities/outcomes identified by patients are being achieved and thus whether it is helping them (the "for whom").

Data from each analysis will be extracted into a bespoke data extraction table, according to whether it provides insights into the contexts (C) in which the preferred patient and family outcomes (O) are achieved, and the underlying mechanisms (M). Outcomes will not be pre-defined but will be derived from the data collected during WP 1. Outcomes will be considered at different system levels, from patient and family related outcomes to professional outcomes, organisational and policy-relevant outcomes. Explanatory context-mechanism-outcome configurations (CMOCs) will link contexts and mechanisms to outcomes, providing new insights and understanding into the contexts in which specific mechanisms are triggered, leading to desirable outcomes.

The realist data analysis will be iterative and lead to the development of CMOCs. The process will include regular team discussion and techniques including identifying patterns in the data, retroduction (inductive reasoning to derive new theory from multiple observations), and deductive logic (testing ideas against existing theory). This stage of the realist analysis will be informed by the programme theory proposed from the RE-EQUIPP Care partnership, and the study theoretical framework drawing on the Behaviour Change Wheel (50) and the principles outlined in the UK NIHR Medical Research Council complex intervention framework (45, 51). Realist methods for analysis have distinct advantages in that multiple sources of evidence can be brought together from this WP, leading to understanding of desirable outcomes from a patient and family / carer perspective, the contexts in which these are

achieved, and underlying mechanisms, to develop and propose context-mechanism-outcome configurations (CMOCs) for further refinement in WP2.

WP2: Understanding professional perspectives of integrated approaches to achieve equitable community palliative and end of life care, to refine and consolidate programme theory (Objectives 2&3, months 15-27, leads: SM, LZ, JA)

DESIGN: Realist evaluation methodology will be employed to investigate "what works, for whom, when and in what circumstances" in integrated community palliative and end of life care across three existing integrated models of palliative and end of life care. This WP will comprise (1) interviews (theory-refining) and (2) focus groups (theory consolidating) with key professional stakeholders involved in the delivery, design, and commissioning of three services in England, each with different levels of integration. Methods will adhere to the RAMESES quality standards for realist research (46).

RESEARCH QUESTION: What are the service development and training needs of primary care and specialist palliative care staff to enable delivery of integrated palliative care in the community?

The research question for WP 2 will be addressed through a series of realist research questions:

- What are the important circumstances in which preferred patient / family outcomes are achieved in palliative and end of life care through integration of specialist and primary care services? (When and how?)
- What are the characteristics and behaviours of professionals involved? (How and whom?)
- What are the potential beneficial outcomes from the perspective of professionals? (What works and for whom? Are there any unintended consequences?)
- What are the specific considerations for providing palliative and end of life care through integration in areas of socioeconomic deprivation?

SAMPLING: We have identified three geographically dispersed and socioeconomically deprived areas in England where community palliative and end of life care is already delivered through different types of integration (clinical service integration, organisational integration, and administrative integration).

(1) clinical Service integration in Leeds: St Gemma's Hospice and the Seacroft Primary Care Network
(2) organisational service integration in Bradford and Airedale: 24/7 Goldline, community services and the Emergency Department.
(3) administrative integration in North Tyneside: Deciding Right and North East and North Cumbria data model

We will purposively sample professionals with have experience of delivering integrated palliative and end of life care based at the three sites through a "snowballing" approach, where participants help researchers to identify other potential individuals with relevant experience. Inclusion criteria are deliberately broad to enable participation from a range of practitioners from primary care and specialist palliative care services including allied healthcare professionals and care co-ordinators. Interview participants will be professionals with relevant experience from community services and primary care (n=24), and specialist palliative care (n=12). The final sampling strategy will be informed by the findings of WP1 to ensure that any key professionals identified in patient / family interviews are represented.

Following interviews, and to consolidate emerging theory, three focus groups will be held with participants including interview participants (where possible), key professionals who have not yet been represented in the sample, and commissioners and service managers for each service who can provide more specific insights into the service development requirements, including business cases, funding, and commissioning processes to support. Potential

commissioners and service managers to participate in focus groups will be identified via the existing NHS England and Integrated Care Board professional networks of the research team. To ensure that focus groups are manageable, and every participant can contribute, there will be up to 10 professionals at each. Bringing together the service manager and commissioner participants into the focus groups will allow for discussion and comparison of the relevant facilitators and barriers to service development, from their perspective.

Inclusion criteria:

- Professionals from primary care, community services and relevant specialist teams who have experience of delivering palliative and end of life care through an integrated approach,
- Professionals who have experience of providing palliative and end of life care in areas of socioeconomic deprivation, through an integrated approach.

Exclusion criteria:

- This is a community-based study so excludes participants who work exclusively in hospital trusts.

Study information will be shared widely in each of the study sites, through email newsletters, social media, and presentations from the research team. Potential participants will make an initial expression of interest directly to the researcher, following which they will be contacted by email, with further information and to plan for an interview and provide online consent (via University of Leeds JISC Online surveys).

DATA COLLECTION: There will be two stages to data collection. First, online, and in-person interviews will be conducted with professionals who deliver frontline palliative and end of life care in the community. There will be a realist topic guide for the interviews, drawing on findings from WP1, specifically patient / family priorities and preferences and how, when, and why these are achieved. Interviews will therefore be theory-refining and will be followed later by theory-consolidating focus groups with wider stakeholders, including commissioners and strategic leaders of health and care services in Integrated Care Boards.

INTERVIEWS: In person, online or telephone interviews will be conducted at a time that is mutually agreed so that it does not interfere with clinical commitments and minimises any potential inconvenience or intrusion for the participant. Each participant will be invited to take part in one interview. Voice recordings of telephone or audio call interviews will be made using encrypted recording and storage devices. The realist topic guide will be informed by the research questions, existing literature including findings of the RE-EQUIPP Care Partnership, and the findings and themes from WP1 (63). The topic guide will focus on the “programme” (delivery of integrated palliative care in the community), with proposed theory presented to participants for them to provide views and perspectives on.

FOCUS GROUPS: A minimum of three realist focus group will be held, to bring together participants with varied experiences, to test CMOCs further and consolidate the programme theory (64). Realist topic guides will provide a framework for the interviews (64). The focus will be on the contexts (C) in which mechanisms (M) are triggered to produce beneficial outcomes (O) through integration of palliative care services with primary care, and may include experiences of training, innovative workforce models, effective infrastructure including shared electronic records, and other resources. During the focus group, the researchers will use the “teacher-learner” cycle to present emerging theories to participants and ask, 'is this how you thought X should work'? (64). Interviews and focus groups will be audio-recorded, using encrypted software, and transcribed verbatim by an external, university approved and GDPR compliant transcription company with experience of health research.

The interviews and focus groups will be conducted in a deliberately informal and reflexive manner to accommodate participants’ needs. The focus groups are intended to focus on service design (where, when, why and how things work), rather than individual cases, so the risk of distress will be minimal. However, if any participants experience

any difficulties during an interview, for example, tiredness, fatigue, or the disclosure of distressing information, the researcher will offer the option to pause, stop, or explore appropriate support. Time will also be provided at the end of the session for debriefing.

During a focus group, participants may leave at any time without providing an explanation. The researcher will follow up with participants who experience difficulties to offer a debrief in private, which may include information on local support options or referrals to suitable NHS or NGO online or telephone services, depending on the nature of the issue.

DATA ANALYSIS: First, realist data analysis will be conducted from interviews from each of the three sites individually, then together. Every section of data will be coded according to whether it alludes to a context (C), mechanism (M) or outcome (O) by two researchers. The analysis will inform the further development of the context-mechanism-outcome configurations (CMOCs) from WP1, further informed by the theoretical framework for this study which draws upon the Behaviour Change Wheel concepts of capacity, capability and motivation focussing on behavioural influences on practice which are potentially amenable to change (50). Explanatory CMOCs proposed in WP 1 will be tested, refined and refuted through regular discussion and through identifying patterns in the data, retroduction (inductive reasoning to derive new theory from multiple observations), and deductive logic (testing ideas against existing theory) (65). Analysis will be led by an appropriately trained researcher (senior research fellow for the study), working closely with the work package leads (SM, LZ, and JA), and a PPI lead from the Patient and Family Advisory group. Researchers are integral to the qualitative research process, so an ongoing process of discussion and reflection on the team's experiences, values, beliefs and understanding around the topic during data analysis, is essential (58). The purpose of the WP2 focus groups will be to consolidate emerging theory, to further understanding into whether preferences differ across different groups, how beneficial outcomes differ in diverse contexts, and to tailor the CMOCs according to a range of diverse individual needs.

OUTPUT: WP2 will lead to three individual reports for each of the participating sites, and an overarching report with a series of tested and refined CMOCs presented as a programme theory. This theory will underpin the integrated approach and an explanatory logic model of integrated, equitable community palliative and end of life care at interpersonal, organisation and system levels.

WP3: To define the potential economic value and impact of the integrated approach (Objective 4, months 12-30, lead BD).

DESIGN: An early economic evaluation using a dynamic simulation modelling approach will be used to evaluate the potential impact of the proposed integrated approach to palliative and end of life care on the healthcare resources needed to deliver it, quality of care and inequalities. A dynamic simulation model allows the various ways patients can move through the healthcare system to be mapped out, for example capturing differences in timing of referral, and who delivers palliative care to different groups. These pathways can be constructed based on patient characteristics, health system resources and other external factors which could influence the ways patients access care. In this way the interactions between patients and health system actors are captured and used to predict future parts of the pathway and subsequent outcomes (66, 67).

RESEARCH QUESTION:

1. What is the potential economic value and impact on patient outcomes and inequalities of the new integrated approach to community palliative and end of life care?

METHODS: The early economic evaluation will be undertaken in two phases. In the first phase, a dynamic simulation model will be developed based on best practice methods (68) to reflect current provision of palliative care in the community and the associated care systems patients must navigate in order to access this care. This approach will

capture variation in patient navigation through the system depending on their health and sociodemographic characteristics, interactions with professionals, and the health and care implications of these interactions. Patient experience maps will be informed by data collected in WPs1-2, capturing variation in experiences in deprived versus less deprived areas, and depending on patient characteristics, and will be validated with PPI and clinician input. The associated healthcare costs and resources in current provision of palliative care in the community will be estimated by linking patient experience information, including number and type of healthcare contacts, with associated healthcare cost information from NHS unit cost of healthcare services data. Subsequent patient outcomes will be incorporated into the model using information from WP1-2 related to the types of services that participants receive. This includes (1) the beneficial outcomes they associate with each service and (2) whether they receive specialist palliative care services. To determine the events that lead to specific beneficial outcomes, defined from a patient and carer perspective, these will be linked with previous events in care pathway, and patient characteristics. This will be supplemented with quality-of-life data sourced from targeted literature searches so that variation in outcomes, based on patient profiles (demographics and clinical information) and the subsequent pathway to receipt of palliative care, is captured. In addition, the impact of spillover effects such as effective palliative care on carer quality of life will be explored by linking patient events with carer quality of life values identified from the literature in the same way. Receipt of specialist palliative care services will be linked to outcomes that patients and carers perceive are achieved through their involvement.

From our previous research, we anticipate that outcomes will be identified which relate to patient and carers (such as shared understanding that the emphasis of palliative care is placed on lessening suffering, trusted relationships leading to care planning conversations, effective pain management), as well as system-level outcomes (such as continuity of care and care in a preferred care setting). These will feed into the economic evaluation by linking them with quality-of-life data (utility values) from the literature to enable analysis of QALYs gained because of the integrated palliative care approach. This will allow quantitative estimation of the magnitude of inequalities in access to palliative and end of life care based on demographic and clinical characteristics of patients in current practice.

In the second phase, the initial model will be adapted to reflect the provision of palliative and end of life care in the community with the adoption of the new proposed integrated approach. Using information about current pathways to care and the impact of specific interactions along that pathway, we will model what is likely to happen to patients if the pathways are changed because of the new integrated approach and the resulting impact on health outcomes and healthcare costs. This part of the analysis will be informed by data and recommendations about the implementation of the integrated approach from the other WPs, but as the new approach has not yet been implemented, it will focus on identifying the potential economic value of the new approach based on current evidence and drivers of uncertainty around this impact to inform future research.

Costs will be measured from the healthcare system perspective. Healthcare resources to deliver palliative care, in current practice and with the new approach, will be estimated by linking the healthcare services used, identified in patient care pathway maps informed by WPs1-2, with estimated costs of services obtained from national sources where possible. These costs will be supplemented with evidence from the literature, or a micro-costing approach will be employed where necessary = linking estimates of provider time with the associated costs. Changes in healthcare resources required for the new approach and the change in care outcomes (distribution of patients accessing care across equity-relevant groups, change in number of emergency hospital visits and potential improvements in quality of life) will be evaluated.

ANALYSIS: The economic analysis will be guided by the recommendations of the National Institute for Health and Care Excellence (NICE) methods guide for health economic evaluations (69). The primary outcome for the economic analysis will be the incremental cost per QALY gained because of the new integrated approach compared to standard practice. Estimates of the costs and care effects associated with the new integrated approach to palliative care will be estimated and compared with those associated with current provision to provide an indication of the potential economic value of the proposed approach. Cost-effectiveness will be determined by estimating the incremental cost-effectiveness ratio (ICER) and comparing this with the NICE cost-effectiveness threshold of £20,000-30,000 per QALY gained. Given the early nature of the evaluation and limited data to inform costs and effects of the new approach, the analysis will focus on the potential scope and magnitude of likely impacts, i.e., what is likely/unlikely to effectively level-up provision of palliative care (70).

The primary analysis will include patient outcomes and quality of life only, and a secondary analysis will also explore the inclusion of impacts on carer quality of life (and costs). This will be supplemented with an additional equity-informative cost effectiveness analysis in which costs and outcomes (QALYs gained) will be estimated for different population groups and presented as a distribution. The equity of the distribution can then be measured (for example, using absolute and relative measures of inequality) and compared to the cost-effectiveness result. This will be plotted on the health-equity impact plane which demonstrates any trade-offs that may present between the cost-effectiveness and equity of the new proposed approach. Disaggregated estimates of costs and outcomes for different groups will also be presented to demonstrate the extent to which different population groups are expected to benefit from the proposed approach.

Uncertainty around cost-effectiveness estimates will be explored using sensitivity analyses, for example to explore assumptions made in the analysis or the impact of alternative parameters from different sources. Value of information analysis will identify key areas where more evidence is needed. Impacts on inequalities in access to palliative care will also be evaluated across key sociodemographic groups. If sufficient data are obtained, more comprehensive equity-informative cost-effectiveness analysis will be undertaken to estimate the distribution of impacts (costs and effects) across equity variables of interest (71).

OUTPUT: An economic evaluation of the change in healthcare resources required for the new equitable approach to integrated palliative and end of life care, and potential change in care outcomes, particularly in deprived areas and access limited groups, compared to current provision.

WP4: Workshops to develop a set of key principles to inform future service design and evaluation of integration in equitable community palliative and end of life care. (Obj 5, months 30&32, leads SM & MA).

DESIGN: Two half-day expert stakeholder consultation events will be held to co-design a set of key principles to inform future service design and evaluation of the proposed approach for integrated community palliative and end of life care, and economic model, to determine what is needed to enable implementation in practice and to develop recommendations.

QUESTION: What are the key considerations for implementation and what commissioning and contracting processes are required to support the delivery of equitable palliative and end of life care through integrated neighbourhood team approaches?

STAKEHOLDERS: Up to 20 individuals with experience of service delivery, design and commissioning in primary care and palliative care will be identified from national and regional networks for primary care and palliative care. Two joint patient and professional networks and invited to attend one of two stakeholder consultation events. This will include PPI members workshops are proposed to present the refined logic model and economic analysis of the

integrated approach. Participants will be patient and public involvement members, and clinical and managerial leaders from across England. The WP builds upon commissioner events led by SM and FM as part of the work of the Yorkshire and Humber Palliative Care Research Network (NIHR135115).

EVENT PLAN: The integrated Promoting Action on Research Implementation in Health Services (i-PARIHS) framework will be used to design the events (72). The framework prioritises a process of facilitation in the successful implementation of new innovations. It allows consideration of the intended recipients in a particular context, with identification of key barriers and enablers to implementation. This will allow us to (1) develop recommendations of immediate relevance to strategic planners of services professionals from primary care and specialist palliative care, and commissioners, with a specific focus on what resources are required to address inequalities across different contexts and recipients, and (2) consider important areas for future evaluation. Consent will be obtained in one of three formats: written or electronic (via the University of Leeds JISC Online Surveys). To structure the event discussions, we will use (PPI members (n=5), clinicians (n=10), and commissioners (n=5)). Workshops will be facilitated SM and MA, guided by the Mi-PARIHS (Mobilising i-PARIHS) Facilitation Planning Tool and resources (52). The events will begin by introducing and defining the problem and will be supported by a live scribe. Use of the framework allows consideration of flexible implementation strategies through iteration and tailoring to different contexts. It enables the identification of key barriers and enablers to implementation, and future evaluation of the new approach, across different contexts and recipients. Workshops will begin with a brief definition of the problem to be addressed (inequitable palliative and end of life care), description of the innovation (the integrated approach and economic refined logic model to inform the integrated approach, and the economic analysis) and the recipients (patients and family / carers and professionals for whom there are beneficial outcomes). The Mi-PARIHS framework will be used to facilitate detailed discussions to develop key principles for implementing the approach in specific contexts for particular recipients. Guided by the framework's domains and questions, these discussions aim to build consensus and increase understanding of enablers and barriers to implementation across different contexts, enabling the tailored integration of the approach. The possible unintended consequences will be considered, and there will be specific consideration of implementing the approach in areas socioeconomic deprivation. Discussions will inform the development of recommendations and be captured in real time by a live scribe.

OUTPUTS: A set of recommendations and visual resource outlining recommendations and guidance to accompany the new approach, to be shared with policymakers, commissioners, and clinicians.

Dissemination, outputs, and anticipated impact

The study outputs will be an important and timely contribution to the evidence base to inform integration in practice to address inequalities, as primary care networks across the country evolve into more integrated neighbourhood team ways of working. As we have described in the rationale for the study, this is an enduring policy priority, supported by statutory duties in the Health and Care Act 2022, but with a scarce evidence base. There will be nominated communications lead who will have oversight of the dissemination strategy and timeline for outputs, as well as report to the study Steering Group. The dissemination strategy will include a systematic process of dissemination to key stakeholders including patients and families, service design and policy teams, locally, regionally, and nationally throughout the study. We will work closely with PPI research team members to ensure that the study outputs are accessible, and dissemination will be through a range of professional networks across policy, professional, practice and patient organisations detailed below.

Research Outputs

The major outputs from this study will be the logic model, economic model, and recommendations to inform integrated, more equitable, neighbourhood team approaches for palliative and end of life care. The benefit of the

realist approach to this research is that the recommendations will focus on the necessary contexts and resources required to achieve beneficial patient and family outcomes. Key outputs from this study are:

- The logic model to outline an integrated, equitable approach to palliative and end of life care, accompanied by recommendations for service providers and commissioners.
- An economic model with detail of resources required.
- Briefings to promote awareness of the study for service providers and policymakers at the start of the study, followed by a series of three solution-focussed policy briefings to be produced annually.
- A minimum of six academic papers (and conference presentations) as follows:
    - Protocol paper (open access)
    - Approaches to PPI in primary care and palliative care research for people from marginalised and minoritised communities.
    - Findings of both qualitative data analysis from WPs 1 and 2
    - The results of the Direct Choice Experiment
    - Findings of the realist analysis and development of the programme theory / proposal for the integrated neighbourhood approach with details of what works, when why and for whom.
    - The economic model developed during work package 3.

Other outputs will include:

- A project website, to be developed in partnership with the Patient and Family Advisory Board, to include information about PPI, accessible resources, and the infographics of study findings.
- Policy and research briefings to include key findings and recommendations for future research.
- Final project report for the NIHR.

Dissemination Strategy

The dissemination strategy will be devised and co-ordinated by the named communications lead, working closely with SM and the Patient and Family Advisory Board to identify key stakeholder audiences and routes for dissemination. Both the Steering Group and Patient and Family Advisory Boards will feedback on our plans and approaches to communicating the study findings and targeted outputs. Planned dissemination activities are broad and will be tailored according to our audiences. An initial mapping of key stakeholders is outlined below in Figure 1.

Figure 1: Stakeholder mapping

High Power	**Priority audiences: to regularly engage** The Ambitions Partnership (Professional membership and voluntary sector organisations) NHS England Medical Director for Primary Care and Regional Medical Directors for Primary Care. NHS England Primary Care and Community Services teams, including those responsible for the GP contract and Specialist Palliative Care specifications. Research Funder: NIHR	**Priority audiences: Key players** People with lived experience: • Patients and the public • Family members and carers Primary care and specialist palliative care professionals – clinical and managerial Integrated Care Board leaders for Integrated Neighbourhood Teams and Palliative and End of Life Care NHS England national and regional palliative and end of life care and primary care teams NHS England Workforce, Training and Education Primary Care team
	Audiences for general communication Academic audiences including the Society of Academic Primary Care Palliative Care Special Interest Group	**Audiences to keep informed of progress / findings** Department of Health and Social Care Palliative Care and Primary Care teams

	Care Quality Commission The Royal College of General Practitioners The Association of Palliative Medicine	The NIHR Policy Research Unit for Palliative Care (FM co-lead, SM, LZ co-applicants) Other relevant senior NHS leaders including National Clinical Directors
Low	Low Interest High	

Outputs for priority audiences:

- Lay summaries and accessible resources including an animation or film for patients, family members, carers, and a wider public audience, as well as professional and policy audiences, to outline:
  - Study findings with new insights into inequalities in palliative care (current system issues and concerns),
  - The proposed approach to integrated community palliative care (solution)
  - The economic model and resources required (solution).
- Dissemination and knowledge exchange events to be organised in collaboration with key partners such as the Royal College of General Practitioners.
- Policy briefings and infographics to summarise key findings and recommendations (annual).
- Final report for research funder.
- Project website to include PPI-led articles, blogs, and newsletters.
- Social media posts via a project social media account (to be advised by PPI representatives)

Academic outputs: Conference presentations, academic publications, and research briefings.

The dissemination strategy outlines the range of planned outputs from the study. The co-applicant team have relevant experience and professional networks to facilitate a targeted dissemination strategy to clinical, policy and patient / public audiences. Key audiences in our planned dissemination strategy are policy makers and system leaders with responsibility for the strategic planning of healthcare services within NHS England, because this is where our policy understanding and greatest opportunity for impact exists. The team have expert understanding of NHS England and the focus on Integrated Neighbourhood Teams as the unit for operationalising new models of care to meet population need. This includes direct links to relevant NHS policy and commissioning teams locally, regionally, and nationally, partnerships with national voluntary sector organisations and three research team members as co-applicant team members for the NIHR funded Policy Research Unit (FM, SM, LZ).

We anticipate that findings from each package, and the theory to underpin the proposed new integrated approach in primary and palliative care services to address inequalities, will be relevant and have applicability across the UK and internationally. As a research team, we have professional networks that enable dissemination across the UK, through NHS Clinical Leaders meetings, as well as through the Royal Colleges, Associations such as the Association of Palliative Medicine, and with UK voluntary sector partners. Academic outputs and research briefings will be prepared for an international audience. Dissemination will include UK, European and international palliative care conferences.

Engagement with public audiences is also important and highly relevant to this study. This study will lead to recommendations relevant to patients, families, and carers who are trying to navigate a complicated and fragmented healthcare system. We will work with PPI members to produce outputs to increase public understanding about what can reasonably be expected (or demanded) from primary and community healthcare services and specialist palliative care services, to help them to effectively navigate the system.

What further funding or support will be required if this research is successful?

The EPIC-PC study is intended to make a key contribution to the evidence base for integrated neighbourhood team approaches to palliative and end of life care, as these evolve over the coming years. Robust research evidence is urgently needed to inform decisions about how existing resource is directed and funding allocated to services effectively to lead to efficient and sustainable models of integrated care. Findings will lead to recommendations relevant to national policy teams and local Integrated Care Boards who have responsibility for enacting the Statutory Duty to commission palliative and end of life care services for their population. Any support from partners including professional bodies, policy makers and voluntary sector organisations will be to support dissemination and implementation through collaborative knowledge exchange events and promotion.

What are the possible barriers for further research, development, adoption and implementation?
Potential barriers to impact exist at local, regional, and national levels. The role and responsibilities of primary care in palliative and end of life care receives little attention compared to specialist palliative care services in policy or strategic planning, including at Integrated Care Board level. Change will require engagement at both national and local levels. The research team are well placed to influence through the range of professional networks described.

What do you think the impact of your research will be and for whom?
This research is urgently needed to improve care for patients, particularly patients with palliative and end of life care needs from areas of socioeconomic deprivation, whose current care is influenced by the Inverse Care Law. While policy direction is towards integration of services, including in community palliative and end of life care, the evidence base to inform this is scarce, and there are few plans to evaluate existing primary-care based approaches. Potential for impact has influenced the choice of methods, including realist methods and health economics, to propose an approach and outputs of immediate relevance to inform service design and delivery, including a cost-effective integrated approach to care for commissioners and policy makers. Healthcare professionals will benefit from understanding into the contexts and mechanisms that achieve beneficial outcomes in integration. Patients and family / carers will benefit from this work to improve community palliative and end-of-life care and “level up” the community offer in areas of deprivation.

How will you share with study participants the progress and findings of your research?
Information about how participants can keep up to date with the study findings and progress will be provided in study information at the time of recruitment and consent. The project website, to be developed in partnership with the Patient and Family Advisory Panel, will include a range of outputs reflecting the study progress, including information about PPI, accessible versions of research briefings and infographics. Newsletters will be formulated for the Patient and Family Advisory Panel to capture study progress. These will be added to the website for public access. There will not be a mechanism to check with certainty that research participants are still alive before we share information proactively. The planned open and accessible approach is necessary because study participants who are patients have advanced serious illness may die before the end of the study. Strategies to share findings with participants must avoid any risk of distress to families and carers by sending newsletters or updates to participants who have died.

Project management

Dr Sarah Mitchell (SM) and Professor Lucy Ziegler (LZ) will co-lead this study and retain overall responsibility for its successful delivery. The co-leadership model for this project provides mentorship and supports SM’s strong trajectory to research leadership. The Study Management Team (all co-applicants) will two-monthly. Each element of the study, including the work packages, have named leads as follows:

- Patient and Public Involvement will be co-led by SM, CE and JB (PPI co-applicant). A research associate with specific responsibility for PPI will be based in Leeds, supervised directly by SM.

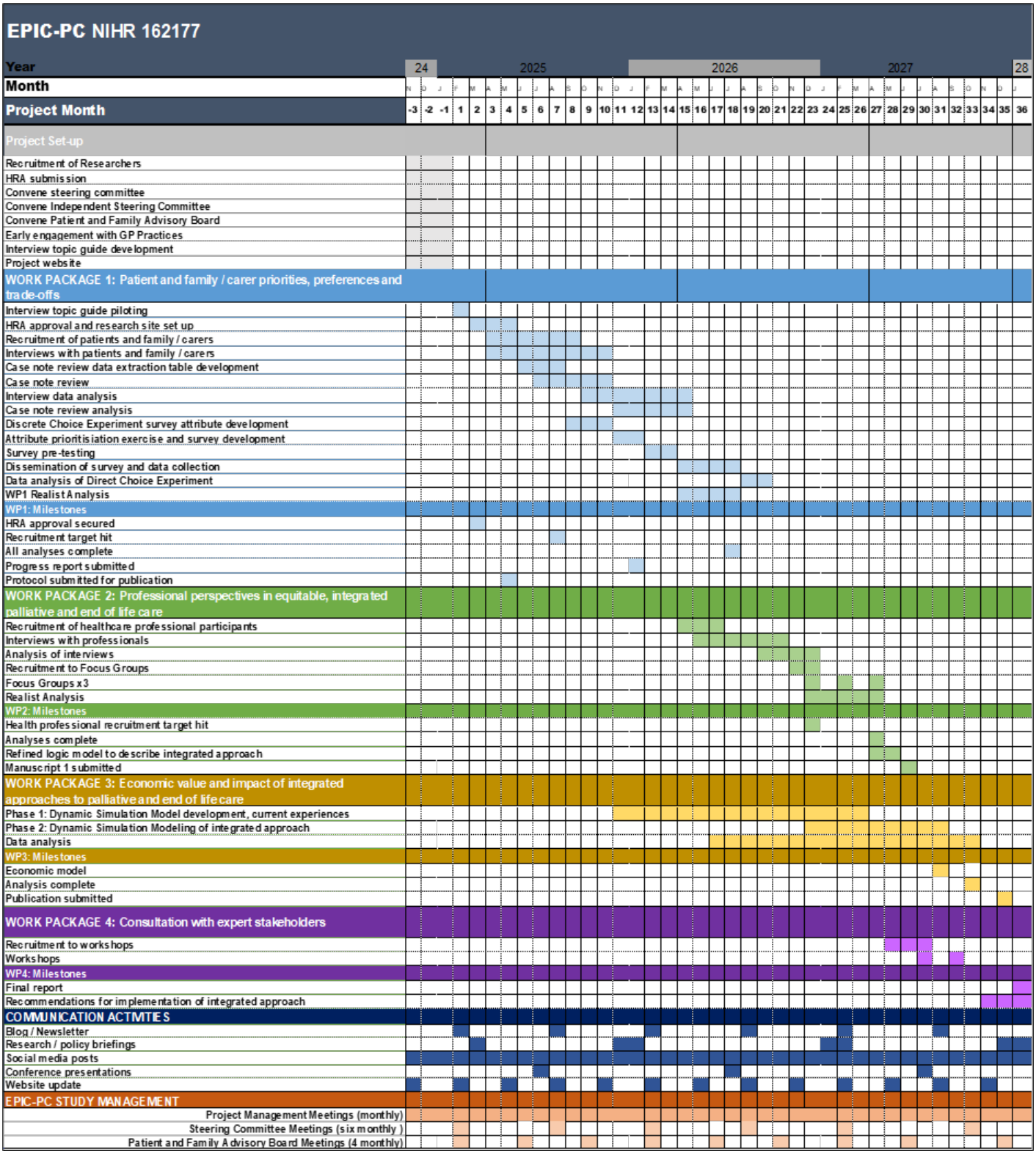
- Leadership of WP 1 will be divided across the WP 1.1 and 1.2 (SM, LZ, MA, EW, FM) , blending expertise in qualitative research with expertise in quantitative research in palliative care, and health economics. The team will provide supervision for research associates in palliative care and health economics, based at the University of Leeds.
- WP 2 will be led by LZ and SM with realist input into data collection and analysis from JA.
- WP 3 will be led by BD
- SM and MA will co-lead the design and conduct of workshops in WP 4.
- SM will co-lead plans for impact with FM and the Study Steering Committee Chair.

The proposed work will be conducted by a senior researcher with experience in interviews and focus groups on palliative care, a health economist, and a Patient and Public Involvement lead, under the supervision of experienced workstream leads. Researcher training needs will be identified and addressed through formal courses and bespoke apprenticeship, to include training in realist methods.

Strategic oversight of the project is provided by two committees. The multi-disciplinary **Independent Steering Committee** will meet at the start of the project and six monthly throughout. The steering committee will provide independent oversight through its ten members from across England, who represent all stakeholder groups including PPI members (n=2), primary, community and palliative care professionals (n=6), local and national policy makers and commissioners (n=2). A **Patient and Family Advisory Board** will be convened with PPI members, to meet at the start of the project and 4-monthly throughout. Core membership will be public members with an interest in palliative care and research (n=2), patients with palliative care needs (n=4) and family members or carers (n=4) who are currently caring for a patient or bereaved so have relevant previous experience. Due to the potential health and care challenges faced by group members, flexible methods and opportunities to engage will be offered such as group and individual meetings, email, phone, so that members can contribute as their situation allows.

The Independent Steering Committee will meet at the start of the project and six monthly throughout to assess study progress against the defined milestones and deliverables. As outlined in the PPI section of this application, the Patient and Family Advisory Board will meet three times per year. Meetings will be arranged to fit with the key points in the study which require input, but a flexible approach is planned to ensure consistent and equal opportunities to engage throughout the study.

Project / research timetable: detailed research timeline, with key milestones, is shown below:



Research Ethics Committee (REC) and other Regulatory review & reports

Before the start of the study, a favourable opinion will be sought from a REC and the Health Research Authority for the study protocol, informed consent forms and other relevant documents.

- Substantial amendments that require review by NHS REC will not be implemented until that review is in place and other mechanisms are in place to implement at site.

- All correspondence with the REC will be retained.
- The Chief Investigator will notify the REC of the end of the study.
- If the study is ended prematurely, the Chief Investigator will notify the REC, including the reasons for the premature termination.
- Within one year after the end of the study, the Chief Investigator will submit a final report with the results, including any publications/abstracts, to the REC.
- The end of the research study is defined as the date on which the final dataset has been cleaned, locked, and analysed, and all follow-up with participants is complete. This will occur after all data collection activities, including interviews, surveys, focus groups and workshops have concluded, and no further participant engagement is required.

End of the study
This this will be the date of second WP4 workshop (consultation with stakeholders) which will be the last research activity involving participants.

Regulatory Review & Compliance
Before any site can enrol patients into the study, the Chief Investigator/Principal Investigator or designee will ensure that appropriate approvals from participating organisations are in place.
For any amendment to the study, the Chief Investigator or designee (research fellow), in agreement with the sponsor will submit information to the appropriate body in order for them to issue approval for the amendment. The Chief Investigator or designee will work with sites (R&D departments at NHS sites as well as the study delivery team) so they can put the necessary arrangements in place to implement the amendment to confirm their support for the study as amended.

Amendments
Non-NHS sites: Sites that are outside of the NHS and do not require NHS REC review or NHS management approval amendments will be handled in line with the sponsors and site management organisations polices.

NHS sites:
If the Chief Investigator wishes to make a substantial amendment to the REC application or the supporting documents, they will work with the sponsor's representative to submit a valid notice of amendment to the REC for consideration. The REC will provide a response regarding the amendment within 35 days of receipt of the notice.

- The sponsor will decide whether an amendment is substantial or non-substantial for the purposes of submission to the REC. Reporting to the sponsor will be to governance-ethics@leeds.ac.uk.
- All substantial and non-substantial amendments will be communicated to the REC via IRAS via the amendment tool.
- All substantial and non-substantial amendments will be notified to the lead NHS R&D office and communicated to the participating organisations (R&D office and local research team) departments of participating sites to assess whether the amendment affects the NHS permission for that site.
- To keep track of the most recent versions, documents will be sequentially labelled and dated. The amendment history, protocol, and study documentation (e.g. information sheets, consent forms) will carry appropriate version control (date, version number and IRAS ID). Amendment details will be added to the appendices of the protocol.

Protocol compliance
All deviations and serious breaches of protocol will be reported to the sponsor within one working day of research team awareness to governance-ethics@leeds.ac.uk and serious breaches will be reported to the REC within their required timelines.

Indemnity

The University, has insurance cover in force, which meets claims arising from death or injury, which are brought against the University and where those claims arise from the Universities own negligence in its role and activities relating to the study (and which is subject to the terms, conditions and exceptions of the relevant policy). Clinical negligence indemnification will rest with the participating NHS Trust under standard NHS arrangements.

Ethical Issues
This study involves data collection from patients with advanced serious illness and their family carers and therefore raises several ethical issues, outlined below:

STUDY SETTING: The study will be conducted across the North East and Yorkshire region of England, which is the region with the most socioeconomic deprivation.

STUDY SAMPLE:

WP1.1: Participants with experiences that are relevant to addressing the research questions will be purposively sampled: patients with palliative care needs, family members and carers.

Participants will consent to one interview, followed by review of their GP case notes, in general practice.

Potential participants will be identified via the Deep End Research Networks and Alliances, geographically spread across the North East and Yorkshire region: Yorkshire and Humber (Sheffield and Leeds), and the North East / North Cumbria. Recruitment will be via ten general practices in Deep End areas. We have established professional networks with over ten general practices and several local hospices across the North East and Yorkshire. Recruitment will be approached collaboratively with local RRDN research nurses, who are already associated with Deep End research and have knowledge of local communities. Each practice team will identify potential participants (n=3-5) through a targeted search of their palliative care registers.

A sampling frame informed by the population demographics outlined in the 2021 Census, and recent patterns of death data will be implemented as follows: At least 50% of participants will be from areas of socioeconomic deprivation (n=20-22), with 10% of participants from Black and Minority Ethnic populations (Asian (n=2-3), Black (n=1) and other (n=2-3)). At least 60% of patient participants will have one or more of the major conditions (cancer, dementia, respiratory and cardiovascular disease).

SAMPLE SIZE: We will aim to recruit (and have costed for) 40-45 interviews, but we expect attrition due to participants having palliative care needs and / or approaching the end of life, so the final sample is likely to comprise 35-40 participants.

Inclusion and exclusion criteria are outlined earlier in the Research Protocol (p.13).

RECRUITMENT: People with palliative care needs are generally considered vulnerable, with limited life-expectancy and time (73, 74). They may die before outcomes of research studies they are involved in are integrated into clinical practice (75). Recruitment to palliative care research can be limited by professional gatekeeping, often based in fear of burdening the patient (76). However, participation in research has potential benefits including opportunity to contribute to society, bringing personal satisfaction and meaning to a person's life (74).

Clinical teams will be briefed and provided with study information so that they are able to make the first approach to potential participants. Clinicians will introduce the study during a routine consultation, or by telephone or email. Clinical team members will not be actively recruiting patients or be involved in the consent process. Participant information will be provided to introduce the study to eligible patients and/or family members. To mitigate against gatekeeping, clear information and rationale for the study will be provided, including the aim to ensure more

equitable opportunities for participation and to hear the views and perceptions of people who are usually under-represented in research. It will be made clear that data collection (a single interview and case note review) has been designed to ensure minimal burden to participants and may provide some benefits.

Participant information will be made available (1) electronically so it can be sent to patients and/or family members via text or email, and (2) in paper form for those who would prefer this to be sent to them by post. Participant information materials will be developed in partnership with the study PPI panel and provided in easy-read and audio formats. Potential participants will be asked to provide agreement for the research team to contact them to provide more information and arrange a time for interview, or they will contact the research team directly with the contact details in the study information. Once a potential participant has expressed an interest, the researcher will use their preferred method of contact to discuss their participation in the research, answer any questions and arrange a time for interview.

After contact by the research team, Potential participants will be given a minimum of 24 hours to decide whether they would like to participate from first finding out about the study, and a time for interview will be agreed.

DATA COLLECTION: Semi-structured interviews will be audio-recorded. The interviews will be designed so that the risks associated with taking part are minimal. The approach will be reflexive so that if a participant experiences any difficulties, such as tiredness or distress, the interview will be halted and consent to continue was sought.

All interviews will be conducted by researchers with experience in qualitative research in sensitive topic areas and training in both advanced communication skills and the management of distress. The topic guide will inform the interview, with a blend of open questions to allow participants to tell their story and build rapport, and more targeted closed questions to ensure focus on the research questions.

Participation in this study may raise issues or concerns not previously articulated and generate a need for further support. At the end of the interview, the researcher will ask if the interviewee would like to receive a follow-up contact (via telephone call, text of email) three or four days after the interview. This will accommodate interviewees wanting to share further reflections and provides an additional opportunity to articulate the need for support.

WP1.2: A Discrete Choice Experiment (DCE) will be distributed via collaborative partnerships with national voluntary sector organisations for patients (of all ages), families, and carers including the Ambitions Partnership for Palliative and End of Life Care and the Deep End practice network across the UK. The aim is that the survey reaches members of communities and groups who are often underrepresented in research, including DCE survey samples.

The survey will be hosted on an online platform (to be decided) that is approved by the University of Leeds. An invitation containing a link to the survey will be widely circulated to eligible participants registered with GP practices in the Deep End network and other participating practices serving populations with high levels of deprivation. Invitations will be sent via post, text message, or email, depending on the method of communication typically used by the participant's GP practice. While we anticipate that most recruitment will take place online, we will also offer a paper survey, distributed in general practices and by post, to guard against digital exclusion. The survey will include information about the research, and it will ask for consent. The final version of the survey, developed as part of the project, will inform sample size calculations. We plan to recruit as large a sample as possible of both patients with palliative care needs and carers, aiming for up to 300 participants, based on previous studies and in line with typical DCE sample sizes.

WP2: Interviews (theory-refining) and focus groups (theory consolidating) with key professional stakeholders.

SAMPLING: We have identified three geographically dispersed and socioeconomically deprived sites in England who are delivering community palliative and end of life care through different types of integration (clinical service integration, organisational integration, and administrative integration). Professional stakeholders with experience of delivering integrated palliative and end of life care based at the three sites will be sampled through a "snowballing" approach, where participants help researchers to identify other potential individuals with relevant experience.

We are aiming for participation from a diverse range of practitioners from primary care and specialist palliative care services including allied healthcare professionals and care co-ordinators. Interview participants will be professionals with relevant experience from community services and primary care (n=24), and specialist palliative care (n=12). The final sampling strategy will be informed by the findings of WP1 to ensure that any key professionals identified in patient / family interviews are represented.

Inclusion and exclusion criteria are outlined on Page 17.

Three focus groups will be held with up to 10 participants including professional interview participants (where possible), key professional stakeholders who have not yet been represented in the sample, and commissioners and service managers for each service.

RECRUITMENT: Study information will be shared widely in each of the study sites, through email newsletters, social media, and presentations from the research team. Potential participants will make an initial expression of interest directly to the research team, following which they will be contacted by email or phone (whichever is their preference) with further information and to plan for an interview.

INTERVIEWS: In person, online or telephone interviews will be conducted at a time that is mutually agreed so that it does not interfere with clinical commitments and minimises any potential inconvenience or intrusion for the participant. Each participant will be invited to take part in one interview. Participant information will be shared before the interview and written consent will be sought at the time of interview, using an online form. Voice recordings of telephone or audio call interviews will be made using encrypted recording and storage devices. The realist topic guide will be informed by the research questions, existing literature including findings of the RE-EQUIPP Care Partnership, and the findings and themes from WP1 (63). The topic guide will focus on the "programme" (delivery of integrated palliative care in the community), with proposed theory presented to participants for them to provide views and perspectives on.

FOCUS GROUPS: A minimum of three realist focus group will be held, to bring together participants with varied experiences, to test CMOCs further and consolidate the programme theory (64). Realist topic guides will provide a framework for the interviews (64). The focus will be on the contexts (C) in which mechanisms (M) are triggered to produce beneficial outcomes (O) through integration of palliative care services with primary care, and may include experiences of training, innovative workforce models, effective infrastructure including shared electronic records, and other resources. During the focus group, the researchers will use the "teacher-learner" cycle to present emerging theories to participants and ask, 'is this how you thought X should work'? (64). Interviews and focus groups will be audio-recorded, using encrypted software, and transcribed verbatim by an external, university approved and GDPR compliant transcription company with experience of health research.

ALL WORK PACKAGES

INFORMED CONSENT: Participation is entirely voluntary, and participants will be reminded that they are free to withdraw from the study at any time, without giving a reason, and that this will not affect their clinical care. Informed consent will be sought for all interviews, case note reviews, focus group participation and survey participation. Participants who do not have capacity to consent do not meet the eligibility criteria, and therefore will not be approached. The condition of palliative care patients can however deteriorate rapidly, which may affect a participant's ability or desire to be involved in research, so consent or confirmation of consent will be sought on the same day as any interview.

MINIMISING HARM TO THE RESEARCHER: The experienced co-applicant team has an important role in supervising and supporting researchers involved in direct data collection and data analysis and are cognisant of the potential impact on researchers. The University of Leeds has a comprehensive staff well-being service which, if appropriate, staff will be encouraged to access.

CONFIDENTIALITY: All data generated by this study will be anonymised and securely stored in Leeds Institute of Health Sciences secure systems. Personal data will be stored confidentially and separately from the other study data in a restricted folder using LASER. This will be password protected, only accessible by members of the research team, and will include scanned copies of any paper consent forms. The study will comply with the new General Data Protection principles and the Research governance framework for Health and Social Care Research. A Data Management Plan will inform the approach to data storage. Data will not be shared outside of the University of Leeds.

Data will be collected and generated according to the study protocol design and methods and will adhere to ethical and governance requirements and data sharing agreements where applicable. Data will be stored securely and backed up to the University Research Data Storage (LASER and MSTeams), thereby reducing the risk of losing any sensitive documents. Data stored on University systems is automatically backed up by IT Services.

Interview data will be recorded as .mp3 audio files, securely stored on an encrypted password-protected laptop managed by the University of Leeds, and named using a logical file-naming convention. The audio-recorded data will be immediately uploaded to the University Research Data Storage (LASER) after the interview/workshop. The audio-recordings will then be transcribed into Microsoft Word documents (.doc) by University approved transcribers. The transcripts will be checked for accuracy by the researcher, and the audio-recordings will then be permanently deleted once the quality and completeness of the transcript has been checked. Field notes will be recorded directly within a Microsoft Word document (.doc) on a University encrypted password-protected laptop. They will then be uploaded directly to the University Research Data Storage (MS Teams). Other data (including transcripts and anonymised logs) will be uploaded to the University Research Data Storage (MS Teams) and stored for ten years.

The study will include the collection of sensitive and personal data from key stakeholders including patients. This requires extra security measures. Demographic data from interview participants will include gender, sexuality, ethnicity, and disability which are considered 'special category data' under GDPR (General Data Protection Regulation). This study will take explicit consent for processing ethnicity data under Article 6a 'Consent', and Article 9a 'Explicit consent' (GDPR). The conditions and limitations of processing, and the withdrawal process will be

outlined in the Participant Information Materials. After reading, understanding and considering the information; participants will be able to consent, or withhold their consent to, the processing of any or all special category data. Personal, identifiable data will be anonymised and stored on the University Research Data Storage (LASER), which affords a higher level of security. Participants will be assigned a numerical ID, with the key linking personal details and anonymised data kept securely on a dedicated, secure University MS Teams account. Personal data will only be retained for as long as is necessary for the research and will all be destroyed by the end of the project. Given this study involves the collection of data from a range of individuals, simple codes (such as participant 01, 02, 03 and so on) will be used to index the data and to protect the identity of research participants and research sites.

The informed consent process will clearly explain the following to participants: - Participants will be made aware that the anonymised data from interviews and focus groups will be stored on the University Research Data Storage (MS Teams) for ten years. Only anonymised data, and no data that can potentially identify an individual, will be made available on reasonable request through the University of Leeds Institute of Health Sciences as follows:

- Participants will be advised that professional organisations such as journals may wish to clarify findings and may request access to the anonymised transcribed data for this purpose.
- Raw data will only be accessible if appropriate permission is sought, and only for the reason of clarification of findings.
- Quotations from participant interviews and focus groups may be included in publication outputs from the study but will be fully anonymised. No data that could potentially identify an individual will be published.

DATA ANALYSIS
Anonymised interview transcripts will be analysed using secure University managed computers. Any names or other identifiable information disclosed during the interview will be anonymised in the interview transcript and will not be used in any reports or publications of the research findings. All data will be indexed using version numbers and dates, agreed by the research team, or in accordance with the requirements of data sharing repositories in the longer term.

DATA STORAGE:
Non-identifiable electronic data (including written documents/files, spreadsheets, PDFs, data analysis outputs including Excel and NVivo files) will be stored on the secure University Research Data Storage (MS Teams) for ten years. Access to the drive will be restricted to the research team. At the end of the agreed data storage period electronic data will be securely deleted by University IT support. The study team will be responsible for archiving the data and controlling access after the study has been completed. Data will be made available on receipt of reasonable request through the University. Personal data will not be made available. Anonymised and analysed data that has participant consent to be shared will be made available upon request and with a Data Sharing Agreement in place.

Research team

The multi-disciplinary co-applicant team have a strong track record of collaboration and expertise in primary care (SM), palliative and end of life care (LZ, FM, MA, CE), realist research into healthcare integration (JA), discrete choice experiments (EW), economic evaluation of healthcare (BD) and PPI (SM, CE, JB). The clinical academic expertise in the team includes general practice (SM), district and community nursing (CE), and specialist palliative medicine (FM). Professional roles and networks enabling clear routes to impact include through FM as the co-lead for the NIHR Policy Research Unit for Palliative and End of Life Care, with CE (PPI lead), SM and LZ. The team has a breadth of experience in influencing national and international policy SM is NHS England National Clinical Director for Palliative

and End of Life Care, with direct links to NHS and Department of Health and Social Care policy teams, including those developing INT models in primary care. MA has a global palliative care research portfolio with policy and practice links for future research.

An experienced Research Fellow has been appointed to the team, Jacqueline Birtwistle (JB), who has extensive experience in qualitative research including patient interviews and professional stakeholder engagement for palliative care research. A PPI Project Manager, Aaishah Aslam (AA), has also been appointed, to lead PPI work and contribute to elements of the research, including participant recruitment, through the Leeds Deep End Research Alliance. AA may contribute to data collection, especially for patients for whom English is not a first language, with appropriate training and bespoke apprenticeship.

Success criteria and barriers to work

Success criteria for the study are based on achieving the key milestones on time and within budget:

- Successful application for HRA approval.
- Engagement with GP practices, the NIHR RDN Yorkshire and Humber team, and recruitment to target in WP1.1 across the sampling frame
- Achieving the proposed response rate for the DCE in WP1.2
- Engagement and recruitment of professionals in three sites for WP2
- Successful workshops in WP4
- Equity, equality, diversity and inclusion (EEDI) in the research team and research management structure (Independent Steering Group and Patient and Family Advisory Board)
- Producing the final report and outputs

Potential risks to this research, and mitigation plans, have been considered as follows:

- The success of this study depends on consistent and effective engagement with stakeholders and recruitment of research participants, including patients with palliative care needs and clinicians from primary care. The research team are in prime position to achieve this through professional networks and stakeholder engagement. We will ensure that both the rationale for the research and potential for impact are clear to all potential participants. Our Patient and Family Advisory Board and multi-disciplinary Steering Committee can advise on engagement with patients, family members and carers, and clinicians working day to day in primary and palliative care settings to facilitate recruitment to the study.
- Funding has been included for vouchers to incentivise participation in the research for professionals, recognising the pressures on healthcare organisations in areas of health inequality. There are also agreed NHS support costs to make it more feasible for busy professionals with conflicting demands on their time to participate. We have established partnerships with national voluntary sector organisations and Deep End networks which will enable wide circulation of the Discrete Choice Experiment Survey in WP1.2. The project fits closely with the palliative and end of life service improvement priorities locally, regionally and nationally.

Equity, equality, diversity, and inclusion

The research team are committed to improving equity, equality, diversity, and inclusion (EEDI) in palliative care research. The PPI co-researcher, JB, will act as the EEDI Champion for the study, a role he also held through the RE-EQUIPP Care Partnership and for which there is a role description. Anonymised equality monitoring and engagement surveys of the research team and oversight boards will be conducted at the start of the study, to understand our diversity (or lack of). We will proactively seek to provide opportunities for people from under-represented backgrounds based on the feedback from the engagement survey. This will be important during the researcher recruitment process, and by ensuring opportunities to observe or join activities, such as Independent Steering Group and Patient and Family Advisory Board meetings. This will be a regular agenda item for consideration at research

team and Independent Steering Committee meetings. The engagement survey will inform our activities and actions. Both surveys will be repeated at yearly intervals.

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