FULL/LONG TITLE OF THE STUDY

North East Palliative and End of Life Care Collaborative

SHORT STUDY TITLE / ACRONYM

North East Palliative and End of Life Care Collaborative

PROTOCOL VERSION NUMBER AND DATE

- Version 1.1 07/07/2022

RESEARCH REFERENCE NUMBERS

IRAS Number:	N/A
SPONSORS Number:	NU-009625
FUNDERS Number:	NIHR135278

This protocol has regard for the HRA guidance and order of content

LIST of CONTENTS

KEY STUDY CONTACTS

Chief Investigator	Dr Katherine Frew Katie.Frew1@newcastle.ac.uk katie.frew@nhct.nhs.uk 01670 529304 > Professor Barbara Hanratty Barbara.Hanratty@newcastle.ac.uk
Sponsor	Newcastle University Fiona Airey, Newcastle University, Kings Gate, Newcastle upon Tyne fiona.airey@newcastle.ac.uk
Funder(s)	NIHR
Key Protocol Contributors	Dr Felicity Shenton felicity.shenton@cntw.nhs.uk Dr Yu Fu Yu.Fu@newcastle.ac.uk Dr Paul Paes paul.paes@northumbria-healthcare.nhs.uk Dr Donna Wakefield Donna.Wakefield1@nhs.net] *Dr Adam Todd adam.todd@newcastle.ac.uk *Professor Dawn Craig dawn.craig@ncl.ac.uk Dr Felicity Dewhurst drfelicitywerrett@doctors.org.uk Dr Daniel Stow daniel.stow@ncl.ac.uk Dr Joanne Atkinson joanne.atkinson@northumbria.ac.uk

	*Professor Catherine Exley catherine.exley@newcastle.ac.uk Dr Kathryn Mannix kathrynmannix@btinternet.com *Professor Fiona Matthews fiona.matthews@newcastle.ac.uk Dr Shona Haining s.haining@nhs.net Assoc Professor s.dalkin@northumbria.ac.uk

FUNDING AND SUPPORT IN KIND

FUNDER(S) (Names and contact details of ALL organisations providing funding and/or support in kind for this study)	FINANCIAL AND NON FINANCIALSUPPORT GIVEN
NIHR	£99,256.47
Newcastle University	*Academic time in-kind

ROLE OF STUDY SPONSOR AND FUNDER

Newcastle University supports this field of research development.

NIHR 21/54 NIHR Palliative and End of Life Care Research Partnerships Funding Call

ROLES AND RESPONSIBILITIES OF STUDY MANAGEMENT COMMITEES/GROUPS & INDIVIDUALS

Study Advisory Group

1. Palliative and End of Life Care Research Partnerships North East Advisory Group

Sabine Best - Head of Research, Marie Curie

Katherine Frew - Palliative Care Consultant, Northumbria Healthcare NHS Foundation Trust and Co-Lead of NE Research Partnership

Barbara Hanratty - Professor of Primary Care and Public Health, Newcastle University and Co-Lead of NE Research Partnership

Donna Lathaen - Head of Services, Adult Social Care and Continuing Healthcare Lead, Northumberland County Council)

Nancy Preston - Professor of Supportive and Palliative Care and Co-Director of the International Observatory on End of Life Care, Lancaster University

Fliss Murtagh - Professor of Palliative Care, Hull York Medical School and Consultant in Palliative Medicine at Hull University Teaching Hospitals NHS Trust

Anosua Mitra (Notes) - ARC NENC Multimorbidity, Ageing and Frailty Theme Administrator, Newcastle University.

2. PPI

This is being convened as part of the funding proposal and award.

STUDY PLAN

Phase	PHASE 1			PHASE 2											
Milestones	Pre-funding activity			Funded activity											
Project Month	-3	-2	-1	1	2	3	4	5	6	7	8	9	10	11	12
Calendar Month	01/03/2022	01/04/2022	01/05/2022	Jun-22	Jul-22	Aug-22	Sep-22	Oct-22	Nov-22	Dec-22	Jan-23	Feb-23	Mar-23	Apr-23	May-23
Milestone 1 Research group meeting (RIPEN) (WP1)	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Milestone 2 Co-applicant meeting (WP 1-5)	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Milestone 3 Research advisory	X		X		X		X		X		X		X		X

group meeting (WP 1-5)															
Milestone 4 Data linkage meeting (WP 2)	X	X	X	X											
Milestone 5 PPI meeting (WP 5)	X	X	X		X		X		X		X		X		X
Milestone 6 Project launch (WP 1-5)			X												
Milestone 7 Research Workshop (WP 1)			X	X			X	X							
Milestone 8 Academic Research Forum (WP 1, 4)				X	X		X	X	X	X	X	X	X	X	X

Milestone 9 Research Sandpit (WP 1, 4)				X									X		
Milestone 10 ScanPal meeting (WP 3)					X		X		X		X				
Milestone 11 Data linkage analysis (WP2)				X	X	X	X								
Milestone 12 Data linkage publication draft (WP 2)								X							
Milestone 13 Data linkage submission for publication (WP 2)									X						

Milestone 14 Scan Pal demo (WP 3)													X		
Milestone 15 Scanpal launch (WP 3)															X
Milestone 16 Developing research question(s) (WP 1, 4)								X	X	X	X	X	X	X	
Milestone 17 Draft funding proposal(s) (WP 1, 4)															X

STUDY PROTOCOL

North East Palliative and End of Life Care Collaborative

1 BACKGROUND

Palliative care is a basic human right - essential for health and dignity,(1) yet in 2021, still not available to all. Inequitable access to palliative and end-of-life care services is a persistent concern, despite decades of research and advocacy. People living in disadvantaged areas experience worse health and are more likely to live with multiple long-term conditions (MLTC) and frailty. They are less likely to access high quality care at the end-of-life.(2-7) This means that some sections of society miss out on the well-known benefits of palliative approaches to end-of-life: improved quality of life for people with malignant(8) and non-malignant diseases,(9) greater likelihood of dying at home where preferred,(10) and fewer emergency department admissions.(11, 12)

Social disadvantage and inequitable access to care are critical issues for the North East (NE) of England. This area has experienced decades of social disadvantage, and life and healthy life expectancy are the lowest in England.(13) Pensioner poverty is in the top 20% for the UK, and the proportion of people age 65+ living alone is higher than anywhere else. Hospital deaths and emergency admissions in last 90 days of life are also high in the NE. Many of these are due to chronic obstructive pulmonary disease, stroke, and liver disease - conditions with a high symptom burden and unpredictable trajectories.(14) The NE presents challenges to patients and service providers, with urban disadvantage and many remote rural and coastal communities: - geographies known to drive health inequalities and moderate access to services,(15) including inpatient palliative care.(16)

COVID-19 has had a profound impact on health and social care. Disruption to routine care and hospital referrals led to delays in urgent care, and unknown impacts on the management of long-term and life limiting conditions.(17-19) Palliative and end-of-life care services are now at a turning point. Charitable giving has fallen, threatening the hospice funding model. NHS and social care services are facing unprecedented demands and the demographics of mortality are changing. As populations age, people are dying later in life, often with greater medical complexity, frailty, and multiple long-term conditions.(20, 21) Work is needed to address the challenge of recognizing the end-of-life phase in non-malignant disease,(22) and identify optimal service models to deliver palliative care to ageing, disadvantaged populations.(23) To deliver high quality palliative and end-of-life care in these circumstances, it is critical that services retain innovations from the pandemic that were effective and efficient, and develop models of care that are flexible to meet patients' current needs.

Our proposed programme of work will place research at the heart of palliative and end-of-life in the NE, and act as a focus for the development of academic palliative care. The aim is to develop a strong research culture, support local practitioners interested in research, and develop proposals for future work in our areas of expertise, older people and socioeconomic inequalities.

2 RESEARCH QUESTION/AIM(S)

Research Questions

Our aim is to develop research capacity in the NE of England to address local and national palliative and end-of-life care research priorities.

Our objectives in this collaborative-building grant will be to:

Develop a self-sustaining research culture in NE palliative and end-of-life care

Evaluate our data infrastructure and identify areas for development

Contribute to the development of an NIHR Innovation Observatory (NIHRIO) searchable platform for palliative care intelligence and innovation pipeline

Develop end-of-life research collaborations around frailty, multiple long-term-conditions and inequalities

Convene a diverse patient and public advisory group, identify training needs and refine a method for evaluation

Submit at least one research project and three fellowship applications for future funding

Research Plan / Methods

A strong collaboration between researchers, practitioners and the regional NIHR infrastructure is at the foundation of our work. We will bring researchers with appropriate methodological skills and interests, together with people from all the relevant care providing services. Existing positive relationships provide an ideal basis for development. (These are described in detail on page 4). Palliative and end-of-life research collaborations are under-developed in social care, and this will be explicitly addressed in our work.

We will be supported by the Research Design Service North East and North Cumbria (RDS NENC), and other NIHR funded infrastructure to help with all aspects of research conduct, training, and dissemination of findings. This will include the Clinical Research Network (CRN), Innovation Observatory (NIHRIO), School for Public Health Research (SPHR), Biomedical Research Centre (BRC), Applied Research Collaboration (ARC) and Policy Research Unit Older People and Frailty (PRU OPF).

Our proposed five strands of work are:

Promoting a research culture in North East palliative and end-of-life care (Objective 1) Leads: KF, SD, DW

A series of meetings (one every two months, during this award) will act as a catalyst for the development of a NE research community in palliative and end-of-life care. The content will be accessible to people with limited or no experience of research. Topics will encompass the methods, conduct and outputs of research (e.g. Evidence synthesis (led by NIHRIO), research delivery (CRN), data (findings of WP2), realist and qualitative methods (CE and SD). Recordings will be made available online (on a University webpage), with permission. We will identify a local champion in each locality, to promote CRN and cross-sector collaboration and participation amongst disciplines that are not well represented in end-of-life research (especially social care and allied healthcare professionals).

Making best use of information – A qualitative study on data linkage for end-of-life care (Objective 2) Leads DS, YF

Background: At the end-of-life, people often require input from different services and locations, including home, care home, hospice and hospital. It is vital that information about treatments and preferences follow people at this time, as they transition between settings. Data linkage is the key to co-ordinated care, and a powerful tool for research and quality improvement in health and social care.(24) Linked data support a wide range of applications, including analysis of patient pathways at national level, economic evaluations and studies to support individual patient care.(25, 26) In recent years, rapid progress has been made to link routine health data, including in the NE, with the Great North Care Record.(27-29) In this study we will build on previous work (involving SD, CE) that looked at the potential of electronic palliative care coordinating systems to share data on advanced care plans and end-of-life discussions (30, 31) In this study, we will focus on data from hospice and social care. These are seldom linked to NHS data, despite the essential contribution that these services make to the care pathway.

Aim and methods: Semi-structured qualitative interviews will explore stakeholder perceptions of the potential barriers to palliative and end-of-life data linkage, include security and privacy concerns, data ownership and control, technical and practical challenges to linking information sources, and the time and costs involved. Purposive sampling will be used to ensure diversity across organisations and disciplines. NE participants will be supplemented by interviewees with relevant national roles within the Department of Health and Social Care, NHS England/NHSX, the hospice movement and care home sector. Recruitment will be via the applicants' networks, professional and local contacts. Interviews will be conducted via telephone and video calls, recorded with permission and transcribed verbatim. Thematic analysis will draw on a framework approach.

Outputs: A report and academic publication will summarise key principles and practical issues in data linkage in end-of-life care, with particular emphasis on hospice and social care data. Findings will inform the development of research infrastructure in the NE and elsewhere, as care economies across the country address similar challenges.

A searchable database of palliative care research innovation landscape and research (Objective 3) Lead: DC

We will work with the NIHR Innovation Observatory to support them to create an open access, searchable database of the palliative care and end-of-life innovation pipeline, intelligence insights and research findings. NIHRIO has already launched ScanMedicine, a free resource for researchers, clinicians and the public, which draws from the plethora of world leading clinical trial databases and pulls information on devices, diagnostics and apps from other sources. The ScanMedicine platform is being developed in an agile manner with relevant stakeholders, clinical and citizens, involved throughout. The formation of a network of experts across the NE in palliative care offers NIHRIO an opportunity to accelerate the development of the sub-platform ScanPalliative. The tool, will collate and present the timely relevant intelligence in a readily accessible format, enabling users to filter results, as well as to view searches as visualisations and infographics for a 'quick-look' version of their results, identifying gaps and trends. This will ensure that the innovation landscape and evidence is readily available to support informed decision-making and research priorities. We are aware of the Cochrane register and the CRN Central Portfolio Management System (CPMS) in this space and will work with both the Cochrane Pain, Palliative and Supportive Care and the CRN groups.

Developing research project proposals (Objectives 4,6) Leads: KF, BH, supported by all

We will bring researchers and practitioners together, starting with a sandpit event to kickstart thinking, discussion, identification of local priorities and the drafting of research proposals focussed in our areas of strength - care of older people with frailty and multiple long-term conditions, in partnership with the Research Design Service. Exploration of socioeconomic inequalities and work with underserved communities will be a cross-cutting theme in all our work. Proposed foci include: early identification of areas of unmet need, integration of palliative care in the management of frailty and multiple long-term conditions across settings, inequalities in end-of-life care service use and changes with COVID-19; future demand and appropriate models of care, testing of effective interventions.

At least one project proposal will be submitted in Stage 2, along with NIHR advanced fellowship proposals developed by DS and FD around frailty and multiple long-term conditions, and a doctoral fellowship by DW on equitable access to palliative care. A strategy for Nurses and Allied Healthcare Professionals (AHP) has been developed by the CRN, in partnership with Northumbria University (JA, SD). Candidates for research mentoring will be sought, to encourage future pre-doctoral fellowship nurse/AHP candidates.

Patient and public involvement (PPI) (Objective 5) Lead: FS

We are passionate about capturing and listening to voices that are seldom heard, and will convene a diverse PPI partner group to help shape our research strategy. In this programme, our priorities are to a) recruit a broad membership with representatives of traditionally under-served communities, and b) agree our PPI strategy and workplan, and put in place the required structures/processes to deliver effective PPI.

Structure: Our partnership group will be co-chaired by local author Kathryn Mannix and leading patient advocate and former Chair of Newcastle University Council, Olivia Grant. Felicity Shenton, PPI engagement manager for the ARC NENC will coordinate the work. The formation of a diverse PPI partnership group will be a priority. Established PPI groups at St Oswald's Hospice, in primary care, and those convened for specific studies (e.g. our work on end-of-life care for people of Black African and Caribbean descent) and the VOICE platform will be our starting point for recruitment.

Processes: We will meet regularly with our PPI partner group to understand their expectations and aspirations, articulate group goals and identify any specific training they need to maximise their desired impact. The exact nature of activities and number of meetings will be agreed at the outset, but we expect PPI partners will wish to work with individual study proposals in the accepted approach to PPI. They may also wish to lead some wider public engagement, which could draw on – for example – the Death Café or Departure lounge approaches, to promote discussion of death and dying.(32, 33)

As we develop our research proposals for Stage 2, the PPI partners will be supported to develop a detailed specification for their involvement with individual studies, including identification of outcomes and approach to the evaluation of PPI. To provide some structure to this work, we will adapt an approach being piloted by the ARC NENC, the 'Dialogue and Change Award.' This award aims to evaluate the impact of public involvement and community engagement in Applied Health and Social Care Research. It is based on evidence provided by PPI partners about how their involvement has influenced research and it is awarded by an independent human rights organisation (Investing in Children).

3 ETHICAL AND REGULATORY CONSIDERATIONS

Ethics / Regulatory Approvals

Our proposed work around data linkage with staff in NHS bodies, local authorities/social and hospice care services will require University research ethics and NHS/Social care governance approvals. These will be sought at the beginning of the award.

Patient and Public Involvement

This is distinct work package, described in detail (Objective 5) above.

4 DISSEMINIATION POLICY

Dissemination, Outputs and anticipated Impact

Short term outputs: This award will lead to the submission of at least one major research proposal for funding and support the development of at least three fellowship applications. Insights into data linkage for palliative/end-of-life care research and creative approaches to PPI in this area will inform Stage 2 research proposals. They will also form the basis of two peer reviewed publications, and accessible summaries of findings produced for policymakers, commissioners and the public. We are experienced in generating policy briefings, and the use of websites, social, local and national media. A searchable database of the palliative care and end-of-life innovation pipeline, intelligence insights and research findings will be made freely available, developed and maintained by NIHRIO. We will also present our findings at relevant conferences and professional meetings (e.g. annual scientific meetings of the European Association of Palliative Care, Society for Academic Primary Care, British Gerontology Society).

5 REFERENCES

1. Brennan F. Palliative care as an international human right. J Pain Symptom Manage. 2007;33(5):494-9.

2. Davies JM, Sleeman KE, Leniz J, Wilson R, Higginson IJ, Verne J, et al. Socioeconomic position and use of healthcare in the last year of life: A systematic review and meta-analysis. PLOS Medicine. 2019;16(4):e1002782.

3. Lloyd-Williams M, Shiels C, Dowrick C, Kissane D. Socio-Economic Deprivation and Symptom Burden in UK Hospice Patients with Advanced Cancer-Findings from a Longitudinal Study. Cancers (Basel). 2021;13(11).

4. Morgan CL, Conway P, Currie CJ. The relationship between self-reported severe pain and measures of socio-economic disadvantage. Eur J Pain. 2011;15(10):1107-11.

5. Buck J, Webb L, Moth L, Morgan L, Barclay S. Persistent inequalities in Hospice at Home provision. BMJ Support Palliat Care. 2020;10(3):e23.

6. Tobin J, Rogers A, Winterburn I, Tullie S, Kalyanasundaram A, Kuhn I, et al. Hospice care access inequalities: a systematic review and narrative synthesis. BMJ Support Palliat Care. 2021.

7. Hanratty B, Holmes L. Social Inequality in Dying. In: Olivere D, Monroe B, Payne S, editors. Death, Dying and Social Differences. 2nd ed. Oxford: Oxford University Press; 2011.

8. Kavalieratos D, Corbelli J, Zhang D, Dionne-Odom JN, Ernecoff NC, Hanmer J, et al. Association Between Palliative Care and Patient and Caregiver Outcomes: A Systematic Review and Meta-analysisPalliative Care and Patient and Caregiver OutcomesPalliative Care and Patient and Caregiver Outcomes. JAMA. 2016;316(20):2104-14.

9. Quinn KL, Stukel T, Stall NM, Huang A, Isenberg S, Tanuseputro P, et al. Association between palliative care and healthcare outcomes among adults with terminal non-cancer illness: population based matched cohort study. BMJ. 2020;370:m2257.

10. Gomes B, Calanzani N, Curiale V, McCrone P, Higginson IJ. Effectiveness and cost-effectiveness of home palliative care services for adults with advanced illness and their caregivers. The Cochrane database of systematic reviews. 2013(6):Cd007760.

11. Henson LA, Gao W, Higginson IJ, Smith M, Davies JM, Ellis-Smith C, et al. Emergency department attendance by patients with cancer in their last month of life: a systematic review and meta-analysis. Journal of clinical oncology : official journal of the American Society of Clinical Oncology. 2015;33(4):370-6.

12. Bone AE, Evans CJ, Etkind SN, Sleeman KE, Gomes B, Aldridge M, et al. Factors associated with older people’s emergency department attendance towards the end of life: a systematic review. European Journal of Public Health. 2019;29(1):67-74.

13. Corris V, Dormer E, Brown A, Whitty P, Collingwood P, Bambra C, et al. Health inequalities are worsening in the North East of England. Br Med Bull. 2020;134(1):63-72.

14. Public Health England. Atlas of Variation for Palliative and End of Life Care in England. London: Public Health England; 2018.

15. Witty C. Chief Medical Officer’s annual report 2021: health in coastal communities. London; 2021.

16. Chukwusa E, Verne J, Polato G, Taylor R, J Higginson I, Gao W. Urban and rural differences in geographical accessibility to inpatient palliative and end-of-life (PEoLC) facilities and place of death: a national population-based study in England, UK. International Journal of Health Geographics. 2019;18(1):8.

17. Sud A, Torr B, Jones ME, Broggio J, Scott S, Loveday C, et al. Effect of delays in the 2-week-wait cancer referral pathway during the COVID-19 pandemic on cancer survival in the UK: a modelling study. Lancet Oncol. 2020;21(8):1035-44.

18. Gardner T, Fraser C, Psytrignet S. London: The Health Foundation. 2021. [cited 2021]. Available from: https://www.health.org.uk/publications/long-reads/elective-care-in-england-assessing-the-impact-of-covid-19-and-where-next.

19. ONS. Coronavirus and the social impacts on Great Britain: 20 August 2021. London: Office for National Statistics; 2021 2021.

20. Barnett K, Mercer SW, Norbury M, Watt G, Wyke S, Guthrie B. Epidemiology of multimorbidity and implications for health care, research, and medical education: a cross-sectional study. The Lancet. 2012;380(9836):37-43.

21. AgeUK. Health and care of older people in England. London: Age UK; 2019.

22. Care Quality Comission. A Different Ending: Adressing inequalities in end of life care. Newcastle upon Tyne: CQC; 2016.

23. Evans CJ, Ison L, Ellis-Smith C, Nicholson C, Costa A, Oluyase AO, et al. Service Delivery Models to Maximize Quality of Life for Older People at the End of Life: A Rapid Review. The Milbank Quarterly. 2019;97(1):113-75.

24. Health Data Research UK [Available from: https://www.hdruk.ac.uk.

25. Kelly M, O'Brien KM, Hannigan A. Using administrative health data for palliative and end of life care research in Ireland: potential and challenges. HRB Open Res. 2021;4:17-.

26. Diernberger K, Luta X, Bowden J, Fallon M, Droney J, Lemmon E, et al. Healthcare use and costs in the last year of life: a national population data linkage study. BMJ Supportive & Palliative Care. 2021.

27. Great North Care Record 2021 [Available from: https://www.greatnorthcarerecord.org.uk.

28. Leeds Care Record 2021 [Available from: https://www.leedscarerecord.org/about/.

29. Ramanah P. Whole System Integrated Care: Mental Health Dashboard 2021 [Available from: https://www.rcpsych.ac.uk/docs/default-source/events/find-an-event/better-data-better-care-presentations/priya-ramamah22a4b6c0ffdd42228024b93baed83999.pdf?sfvrsn=7e10831f_2)

30. Standing H, Patterson R, Lee M, Dalkin SM, Lhussier M, Bate A, et al. Information sharing challenges in end-of-life care: a qualitative study of patient, family and professional perspectives on the potential of an Electronic Palliative Care Co-ordination System. BMJ Open. 2020;10(10):e037483.

31. Patterson R, Standing H, Lee M, Dalkin S, Lhussier M, Exley C, et al. Paramedic information needs in end-of-life care: a qualitative interview study exploring access to a shared electronic record as a potential solution. BMC Palliat Care. 2019;18(1):108.

32. The Death Cafe 2021 [Available from: https://deathcafe.com/what/.

33. The departure lounge 2021 [Available from: https://acmedsci.ac.uk/policy/policy-projects/the-departure-lounge.