End of Life Care
Study Protocol – March 2023

Study Advisory Group Members

This multidisciplinary and lay group has been convened to guide the development of the study and to identify the primary aim and objectives to be met.

Alice Braga	Anaesthetist, Medical Examiner and Bereaved Carer
Joylin Brockett	Project manager NACEL
Nigel Buck	NCEPOD Lay Rep
Julia Russell	Senior Clinical and Quality Improvement Manager
Laura Chapman	Medical director and consultant in palliative medicine Marie Curie Hospice
Karl Cook	Advanced Nurse Practitioner
Hazel Cottle	Research Occupational Therapist
Sarah Cox	Association for Palliative Medicine of Great Britain and Ireland
Carolyn Doyle	RCN representative
Andrew Gibson	NCEPOD Steering Group - RCP
Jonathan Hindmarsh	Association of Specialist Palliative Care Pharmacy
Jonathan Koffman	Palliative Medicine - Wolfson Palliative Care Research Centre
Jean Macleod	NCEPOD Steering Group - RCPE
Stef Matthews	Speech Language Therapist - Clinical Lead
Catherine Millington-Sanders	RCGP & Difficult Conversations
Ollie Minton	Macmillan Representative
Paul Perkins	Palliative Medicine - Chief Medical Director Sue Ryder
Amy Proffitt	Association for Palliative Medicine of Great Britain and Ireland
Bronwen Smithers	Occupational Therapist
Jessica Walsh	Project manager NACEL
Clare White	Palliative Medicine - Northern Ireland Hospice

Clinical Coordinators

Alex Goodwin	Clinical Co-ordinator
Mark Juniper	Clinical Co-ordinator

Non-clinical staff

Neil Smith	Clinical Researcher
Dee Koomson	Researcher
Holly Hamilton	Senior Administrative Officer
Marisa Mason	Chief Executive

Introduction

End of life care is relevant to all of us. How it is delivered, however, varies considerably. People frequently do not die in their place of choice, and the quality of care they receive, although sometimes excellent, frequently is not. The population is ageing and improved treatment of many chronic diseases means that many more people are living longer with these conditions. The incidence of dementia is also increasing. There will be an increasing number of deaths where there are limited options for treatment of the underlying condition and death is expected. Excellence in palliative care is therefore becoming of increasing importance.

Each year over 500,000 people die in England and Wales, around half of these as an inpatient in hospital and approximately 75% die from long term health conditions [1] that often follow a predictable course, with death anticipated well in advance of the event. Providing the highest quality end of their life care has a positive impact on the experience of dying for patients and their families, whilst the inverse is also true.

In 2008 the first national strategy for end of life care in England identified key areas for innovation/improvement[2]. This emphasised the importance of patient choice in terms of place of care alongside equity, cost effectiveness, planning for future increases in population and quality of care and highlighted the variation in the quality of care received.

Following the review "More care, Less pathway"[3] in 2013 and the subsequent phasing out of the Liverpool care pathway, the Leadership Alliance for End of life care published "One Chance to get it right"[4] (2014) which outlined 5 principles to guide the delivery of high quality End of life care: 1) recognising imminent death 2) communication with the patient 3) communication with the family 4) the needs of families 5) an individual plan of care.

In 2015 the National Palliative and End of Life Care Partnership built on the previous work setting out a frame work to deliver 6 "ambitions"[5] of end of life care: 1) treat as an individual 2) fair access to care 3) maximise well-being 4) coordinated care 5) empathetic staff 6) community help. These principles also align with the NICE guidelines NG31[6] (2015) and the NICE quality standards 13[7] and 144[8].

National audits, National Audit for the Care of The Dying in Hospital (NCDAH; 2014)[9] and more recently, National Audit for the Care at the end of life (NACEL; 2016-present)[10] have reported on the compliance with the standards and guidelines that have been published. Whilst the quality of care has improved in many areas there remains room for improvement: particularly in the provision for a 7 day palliative care service, the use of individual care plans and in identifying the needs of families and others.

The CQC has published several reports on end of life care; In 2016 "Addressing inequalities in End of Life Care"[11], highlighted the variation in the quality of end of life care experienced by patients from minority backgrounds. The same year the ONS published the National Survey of Bereaved people (Voices) [12], which highlighted much good practice but also noted variation in quality of care, a lack of personalised advance care planning and continuity / communication between providers.

NICE recently produced a report that summarises the current state of play in End of Life Care including touching on the impact of COVID-related deaths [13].

The national audits have generally looked at a retrospective review of the care of sample of patients who died in acute hospitals of any cause (excluding sudden death). This study will complement the national audit. The review would focus on 4 exemplar conditions: heart failure, dementia, lung cancer and liver disease. These conditions were among the most common causes of death in 2019[1] which all have a reasonably predictable course with death often anticipated. The investigation would follow the whole pathway of care in and out of hospital. Peer review of the care delivered will provide an in-depth understanding of areas that national audit has shown require improvement. In addition, for practical reasons the national audit of care at the end of life has both reduced the number of case notes reviewed and limited the depth of reviews.

The resulting report recommendations would have the potential to improve the quality of care of large numbers of patients and their families. The delivery of personalised high quality end of life care is embedded in the NHS long term plan[14] so this project would align well with the long term ambitions of the NHS.

References
1. ONS 2019- Leading causes of death
2. End of Life Care Strategy. DH 2008
3. More care less pathway 2013
4.One chance to get it right 2014
5. Ambitions for Palliative and End of Life Care: A national framework for local action 2015-2020
6. NICE NG 31 (2015)
7. NICE QS 13 (2011, updated 2017)
8. NICE QS 144 (2017)
9. National Audit for the Care of The Dying in Hospital 2014
10. National Audit for the Care at the end of life 2019
11. Addressing inequalities in End of Life Care CQC, 2016
12. National Survey of Bereaved People (VOICES): England, 2015
13. NICE impact in End of life care 2020
https://www.nice.org.uk/Media/Default/About/what-we-do/Into-practice/measuring-uptake/End-of-life-care-impact-report/nice-impact-end-of-life-care.pdf
14. NHS Long term plan https://www.longtermplan.nhs.uk/online-version/chapter-1-a-new-service-model-for-the-21st-century/3-people-will-get-more-control-over-their-own-health-and-more-personalised-care-when-they-need-it/

Guidelines and standards
NICE guideline NG31: Care of dying adults in the last days of life (2015)
NICE quality standard 13: End of life care for adults (2011, revised 2017)
NICE quality standard 144: Care of dying adults in the last days of life (2017)
6 "ambitions" of end of life care - A national framework for local action 2015-2020
National Palliative and End of Life Care Partnership (2015)
One Chance to get it right – Leadership Alliance for the care of dying people (2014)

Aims and objectives

Overall aim:
To identify and explore areas for improvement in the end of life care of adults with advanced illness, focussing on the last 6 months of life.

Objectives

Organisational
To explore the organisational structures in place to deliver high quality end of life care in hospital and within the community with particular focus on the following:
- Governance arrangements, policies and protocols for end of life care
- Assessing adequate communications between healthcare providers
- Access to domiciliary and social care
- Multidisciplinary team approach
- Examining the management of the 'acute' end of life pathway and ceilings of treatment including appropriateness of interventions
- Equity of access to palliative care services
- Medications and anticipatory prescribing
- Nutrition, swallowing and hydration at the end of life

Clinical
To explore remediable factors in the process of care of patients at the end of life with particular focus on the following:
- Prompt recognition of the dying patient
- Management of multiple admissions
- Informed choices
- Recording and communicating patient's wishes across the broad healthcare team for example primary, secondary, care homes etc
- Assessing adequate communications with patient, families and carers
- Use of evidence recorded from discussions and decision making
- The extent to which patients wishes and preferences were achievable
- Benefits and burdens of advanced care planning
- Advanced care planning discussions, and their quality
- Evidence to support advanced care planning in achieving key quality outcomes.
- Treatment, escalation decisions and support for vulnerable people at the end of their lives.

Methods

Population/inclusions

All patients aged 18 or over who died in hospital between **1st April 2022** and **30th September 2022** with one or more of the following conditions, dementia, heart failure, lung cancer or liver disease. Information will be collected on prior hospital admissions to allow details of the whole end of life care pathway to be reviewed.

A sample of community deaths will also be identified by 2 different methods. Patients admitted to hospital during the study period with one of the included conditions that are subsequently discharged and die within 6 months will be identified from hospital patient administration systems. In addition community deaths in which the patient hasn't had an admission to hospital in the last 6 months of life will be identified to us by GP practices, with input from the regional community networks that are supporting the study.

Patients will be identified retrospectively using the ICD10 codes (in any position at discharge) listed in the appendix. Up to 6 cases per hospital will be included for questionnaire completion and peer review.

Exclusions

Deaths due to suicides, homicides, or self-harm related
Deaths due to trauma, drowning, drug overdose or poisoning

Participating hospitals

Data will be collected from all hospitals in England, Wales and Northern Ireland, which admit patients with dementia, heart failure, lung cancer or liver disease.

Incidence and prevalence

In 2021, there were 586,334 deaths registered in England and Wales. We have chosen to investigate three of the leading causes of death in England and Wales, where palliative care involvement may be included. In addition we will look at liver disease which is a leading cause of death in the 35-49 and 50-64 age groups

Leading causes of death of all ages persons, England and Wales, registered 2021
[https://www.ons.gov.uk/peoplepopulationandcommunity/birthsdeathsandmarriages/deaths/datasets/deathsregisteredinenglandandwalesseriesdrreferencetables]

Age group	ICD-10 code	Leading cause	Deaths	Percentage of all deaths (%)
All ages	F01, F03, G30	Dementia and Alzheimer's disease	61,250	10.4
All ages	I20 to I25	Ischaemic heart diseases	56,960	9.7
All ages	C33 to C34	Malignant neoplasm of trachea bronchus and lung	28,190	4.8
35 - 49	K70 to K76	Cirrhosis and other diseases of liver	1,848	9.6 (of age group)
50 - 64	K70 to K76	Cirrhosis and other diseases of liver	4,135	6.3 (of age group)

Hospital Episode Statistics (HES) for England data, 2020-2021

Primary diagnosis: 4-character code and description		Finished consultant episode	Admissions	Emergency
F01, F03, G30	Dementia and Alzheimer's disease	28,848	13,128	11,699
I20 to I25	Ischaemic heart diseases	322,111	205,389	128,790
C33 to C34	Malignant neoplasm of trachea bronchus and lung	103,987	86,157	12,991
I11.0, I25.5, I42.9, I50.0, I50.1, I50.9	Heart Failure	221,731	117,109	98,326
K70.0- K77.9	Liver Disease	95,704	50,008	41,380

Patient Episode Database for Wales (PEDW)

Primary diagnosis: 3-character code and description		Finished consultant episode	Admissions	Inpatient
F01, F03, G30	Dementia and Alzheimer's disease	1,074	680	1,073
I20 to I25	Ischaemic heart diseases	7,141	5,327	5,375
C33 to C34	Malignant neoplasm of trachea bronchus and lung	4,356	3,338	2,384
I11.0, I25.5, I42.9, I50.0, I50.1, I50.9	Heart Failure	8,314	4,180	8,189
K70.0- K77.9	Liver disease	3,560	1,888	3,189

Clinical and organisation data collection

Within each Trust/Health Board NCEPOD has a Local Reporter (usually employed in clinical audit) who is responsible for providing the details of cases for inclusion to NCEPOD. At the start of the study the Local Reporter will be contacted and sent details of the study criteria.

Patients who have a diagnosis of dementia, lung cancer, heart failure, or liver disease at discharge (death) will be identified retrospectively using ICD codes via completion of a spreadsheet with other selected data from central hospital records. This will include patient details (NHS number, hospital number, date of birth), admission/discharge dates, source and mode of admission, critical care admission, details of previous admissions and discharge location, if the patient did not die in hospital.

Method of data collection

Clinician questionnaire
A questionnaire will be sent to the named consultant responsible for the patient's care when they were admitted to hospital with dementia, lung cancer, heart failure or liver disease Within this there will be instruction to pass the questionnaire on to most appropriate clinician should it not be the named person.

Data collected will include information on any previous admissions that the patient had including discharge and follow up, the involvement of the (specialist) palliative care team, treatments and investigations the patient received in hospital, specialist reviews, use of protocols and clinical pathways. The questionnaire will also ask about the use of treatment escalation plans and ReSPECT (or equivalent) forms and conversations.

The questionnaires will be disseminated via the NCEPOD online questionnaire system which is accessed by NCEPOD local reporters. The local reporters will then be able email the relevant clinician, granting them access to the online questionnaire. Reminder emails will be sent at six and ten weeks where the data are outstanding. The Local Reporter will be asked to return copied extracts of the patient's case notes to NCEPOD alongside the completed questionnaires.

Hospital organisational questionnaire
An organisational questionnaire will be sent to all hospitals that treat patients with dementia, lung cancer, heart failure and/or liver disease.

Data collected will include information around the organisation of services, networks of care, multidisciplinary team working, the use of guidelines/protocols and training.

The questionnaires will be disseminated via the online questionnaire system. Local reporters will be able to invite multiple clinicians to complete the questionnaire.

Case note review
Case note review will be undertaken for a sample of patients who died with a diagnosis of dementia, lung cancer, heart failure, or liver disease.

Case notes
Photocopies of the case notes of each included patient will be requested at the time of questionnaire dissemination. A list detailing the required case note extracts will be circulated to local reporters. Upon receipt at NCEPOD the case notes will be anonymised removing patient identifiable information.

Reviewer assessment form
A multidisciplinary group of reviewers (details below) will be recruited to assess the case notes and questionnaires and give their opinions on the quality of care via the reviewer assessment form.
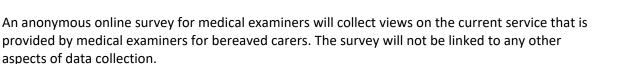
Anonymous online bereaved relative/ carer survey
An anonymous online survey will gather data on bereaved carers/relatives experience of the end of life care process. The survey will not be linked to any other aspects of data collection.

Anonymous online clinician survey
An anonymous online survey for healthcare professionals who treat patients who are at the end of their life. This questionnaire will be targeted at, but not limited to, clinicians and allied health professionals working in hospitals and community healthcare professionals including GPs and district nurses. The survey will collect data on the views of healthcare professionals regarding their own confidence and competencies in delivering end of life care. The survey will not be linked to any other aspects of data collection.

Anonymous online medical examiner survey

An anonymous online survey for medical examiners will collect views on the current service that is provided by medical examiners for bereaved carers. The survey will not be linked to any other aspects of data collection.

Below are the anticipated sample sizes of each type of data collected:

Data Source	Target Number
Hospital organisational questionnaire	~200
Clinician questionnaire	~500
Case note review	~500
Bereaved carer/ relative survey	~100
Medical examiner survey	~100
Clinician survey	~100

Study promotion

Prior to data collection, NCEPOD will contact all hospitals that admit patients with a diagnosis of dementia, lung cancer, heart failure and/or liver disease.

The study will also be promoted to bereaved carers and relatives via patient groups, NCEPOD Local Reporters (sending the study poster on to the relevant departments), via study contacts recruited as part of the case identification strategy, and via the relevant Colleges and Associations.

Study method test

The data collection methods and data collection tools will be tested to ensure they are robust.

Analysis and Review of Data
Reviewers

A multidisciplinary group of reviewers will be recruited to assess the case notes and questionnaires and provide their opinion on the care the patients received.

An advert will be sent to Local Reporters to disseminate throughout the relevant departments. It will also be placed on the NCEPOD website. Successful applicants will be asked to attend a training day where they will each assess the same two cases to ensure consistent assessment. A number of meeting dates will be arranged, and each reviewer will then be asked to attend a minimum of a further 4 meetings. NCEPOD staff will ensure there is a mix of specialties at each meeting from across the UK. Each meeting will be chaired by an NCEPOD clinical coordinator who will lead discussion around the cases under review. The meetings will either be held in person in the NCEPOD office, or over Microsoft Teams with secure and temporary access to the case notes for review (not downloadable or printable by the case reviewer). Towards the end of the study the reviewers will be invited to attend a meeting where the data will be presented to and discussed with them. The reviewers will also be sent two copies of the draft report for their comment as this is developed.

Confidentiality and data protection

All electronic data are held in password protected files and all paper documents in locked filing cabinets. As soon as possible after receipt of data NCEPOD will encrypt electronic

identifiers and anonymise paper documents. Section 251 approval has been obtained to perform this study without the use of patient consent in England and Wales.

Dissemination
On completion of the study a report will be published and widely disseminated.
Study outputs

On completion of the study a report will be published and widely disseminated to all stakeholders to encourage local quality improvement (QI) (further details available in the communication plan). In addition to the report, supporting tools will be made available including:
- A summary report and summary sheet
- Infographics
- The recommendation checklist
- An audit tool
- A slide set
- A guide for commissioners
- Quality improvement tools
- Useful links for young people and parent carers

Examples of good practice will be shared, and additional QI tools will be developed where appropriate. Key messages from the report will be shared via social media.

Following publication, the report findings will be shared at national and local conferences, study days and other events; and papers submitted to journal for consideration for publication.

Data sharing
Post-publication of the study there is the potential to share anonymised data sets with interested parties working in the same field. This will be undertaken following a strict process and will ensure the data does not become identifiable in their nature due to small numbers.

Timeline

Task	Jul-22	Aug-22	Sep-22	Oct-22	Nov-22	Dec-22	Jan-23	Feb-23	Mar-23	Apr-23	May-23	Jun-23	Jul-23	Aug-23	Sep-23	Oct-23	Nov-23	Dec-23	Jan-24	Feb-24	Mar-24	Apr-24	May-24	Jun-24	Jul-24	Aug-24	Sep-24	Oct-24	Nov-24	Dec-24
Form the SAG	█	█																												
First SAG				█																										
Write the protocol						█	█	█																						
Design the questionnaires						█	█	█	█	█	█																			
Second SAG						█																								
Submit approval requests									█																					
Advertise the study										█	█																			
Advertise for Reviewers										█	█																			
Create the database									█	█																				
Start data collection											█																			
Reviewer meetings														█	█	█	█	█	█	█										
Data analysis																		█	█	█										
Report production 1st review																						█								
Report production 2nd review																							█							
Report production 3rd review																							█	█						
To HQIP																									█					
PUBLISH																													█	

Appendix

Patients will be identified retrospectively using the following ICD10 codes in any position at discharge.

Malignant neoplasm of trachea, bronchus and lung - C33-C34	
C33	Malignant neoplasm of trachea
C34.0	Main bronchus
C34.1	Upper lobe, bronchus or lung
C34.2	Middle lobe, bronchus or lung
C34.3	Lower lobe, bronchus or lung
C34.8	Overlapping lesion of bronchus and lung
C34.9	Bronchus or lung, unspecified
Dementia and Alzheimer disease - F01, F03 & G30	
F01.0	Vascular dementia of acute onset
F01.1	Multi-infarct dementia
F01.2	Subcortical vascular dementia
F01.3	Mixed cortical and subcortical vascular dementia
F01.8	Other vascular dementia
F01.9	Vascular dementia, unspecified
F03	Unspecified dementia
G30.0	Alzheimer disease with early onset
G30.1	Alzheimer disease with late onset
G30.8	Other Alzheimer disease
G30.9	Alzheimer disease, unspecified
Ischaemic heart diseases - I20 - I25	
I20.0	Unstable angina
I20.1	Angina pectoris with documented spasm
I20.8	Other forms of angina pectoris
I20.9	Angina pectoris, unspecified
I21.0	Acute transmural myocardial infarction of anterior wall
I21.1	Acute transmural myocardial infarction of inferior wall
I21.2	Acute transmural myocardial infarction of other sites
I21.3	Acute transmural myocardial infarction of unspecified site
I21.4	Acute subendocardial myocardial infarction
I21.9	Acute myocardial infarction, unspecified
I22.0	Subsequent myocardial infarction of anterior wall
I22.1	Subsequent myocardial infarction of inferior wall
I22.8	Subsequent myocardial infarction of other sites
I22.9	Subsequent myocardial infarction of unspecified site
I23.0	Haemopericardium as current complication following acute myocardial infarction
I23.1	Atrial septal defect as current complication following acute myocardial infarction
I23.2	Ventricular septal defect as current complication following acute myocardial infarction
I23.3	Rupture of cardiac wall without haemopericardium as current complication following acute myocardial infarction
I23.4	Rupture of chordae tendineae as current complication following acute myocardial infarction
I23.5	Rupture of papillary muscle as current complication following acute myocardial infarction
I23.6	Thrombosis of atrium, auricular appendage, and ventricle as current complications following acute myocardial infarction

I23.8	Other current complications following acute myocardial infarction
I24.0	Coronary thrombosis not resulting in myocardial infarction
I24.1	Dressler syndrome
I24.8	Other forms of acute ischaemic heart disease
I24.9	Acute ischaemic heart disease, unspecified
I25.0	Atherosclerotic cardiovascular disease, so described
I25.1	Atherosclerotic heart disease
I25.2	Old myocardial infarction
I25.3	Aneurysm of heart
I25.4	Coronary artery aneurysm
I25.5	Ischaemic cardiomyopathy
I25.6	Silent myocardial ischaemia
I25.8	Other forms of chronic ischaemic heart disease
I25.9	Chronic ischaemic heart disease, unspecified
Heart Failure - I11.0, I25.5, I42.9, I50.0, I50.1, I50.9	
I11.0	Hypertensive heart disease with (congestive) heart failure
I25.5	Ischaemic cardiomyopathy
I42.9	Cardiomyopathy, unspecified
I50.0	Congestive heart failure
I50.1	Left ventricular failure
I50.9	Heart failure, unspecified
Liver disease – K70.0- K77.9	
K70	Alcoholic liver disease
K71	Toxic liver disease
K72	Hepatic failure, not elsewhere classified
K73	Chronic hepatitis, not elsewhere classified
K74	Fibrosis and cirrhosis of liver
K75	Other inflammatory liver diseases
K76	Other diseases of liver
K77	Liver disorders in diseases classified elsewhere