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End of life care for infants, children and young people

Submission date	**Recruitment status**	[X] Prospectively registered
05/02/2021	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
10/02/2021	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
16/06/2025	Other	[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Around 4500 babies, children and teenagers in England and Wales will require end-of-life care each year. Currently, the provision of this care varies across the country and little is known about how this variation impacts on children and their families. There are growing numbers of specialist palliative care services and children's hospices in the UK, but there is little evidence to tell us how these services should be developed and what their role should be in supporting children and young people at the end of life. Very little is also known about the costs of care and how best to use these resources to improve care for these children and their families. This study aims to increase understanding about the different ways in which end-of-life care is provided for children and young people, and examine how these different models of providing end-of-life care impact on children and their families.

Who can participate?
1. Healthcare professionals working in neonatal units, paediatric intensive care units, children and teenage and young adult cancer treatment centres
2. Parents whose child has died in one of these units/centres between 3 months and 3 years ago (at the time of recruitment)

What does the study involve?
This study has three linked workstreams (WS).
WS1 (a survey) will identify the different models of providing end-of-life care for babies, children and young people (age 0-18) in England and Wales. To do this, the researchers will ask all cancer services for children and teenagers, and other wards that provide specialist care to babies (neonatal units) and children (paediatric intensive care units) to tell them how end of life care is provided in their service, who provides this care and how much it costs.
WS2 (a qualitative study) will learn more about these models by interviewing bereaved parents about their experiences of their child's care at the end of their life, the impacts of this care, and how care could have been improved. The researchers will also run focus groups with healthcare professionals to explore their experiences of meeting end-of-life needs and their views on the factors that influence this.
WS3 (a quantitative study) will investigate the impacts (outcomes) of the different models of end-of-life care for children and their families. The findings from study 2 will help the

researchers to decide which outcomes to measure but these are likely to include quality of care at the end of life, place of death, whether care is planned (advance care planning), and treatments at the end of life. To do this, the researchers will collect information from the medical records of around 4000 children treated in cancer services, neonatal units or paediatric intensive care units. They will also collect information from around 800 bereaved parents of children who received care in neonatal or paediatric intensive care units. They will use all this information to examine whether outcomes for children and families vary according to the different models of end of life care we identified in study 1, and assess the associated costs.

What are the possible benefits and risks of participating?
There are no direct benefits associated with taking part in this study. However, this study will provide important evidence about the current situation regarding end-of-life care for children, which will be used to improve models of care for children with life-limiting conditions in the future.
There are no risks associated with taking part in this study for any health care professionals. It is possible that some parents who take part will experience distress as a result of talking about their child's death, and the study team will ensure appropriate support is available.

Where is the study run from?
University of York (UK)

When is the study starting and how long is it expected to run for?
December 2020 to June 2025

Who is funding the study?
National Institute of Health Research Health Services and Delivery Research Programme (UK)

Who is the main contact?
Prof. Lorna Fraser
lorna.fraser@york.ac.uk

Contact information

Type(s)
Scientific

Contact name
Prof Lorna Fraser

ORCID ID
https://orcid.org/0000-0002-1360-4191

Contact details
Department of Health Sciences
Area 2 Seebohm Rowntree Building
University of York
Heslington
York
United Kingdom

YO10 5DD
+44 (0)1904 321889
lorna.fraser@york.ac.uk

Type(s)
Public

Contact name
Mr Andrew Haynes

Contact details
Department of Health Sciences
Area 2 Seebohm Rowntree Building
University of York
Heslington
York
United Kingdom
YO10 5DD
+44 (0)11904 328084
andrew.haynes@york.ac.uk

Type(s)
Scientific

Contact name
Dr Julia Hackett

Contact details
Martin House Research Centre
University of York
York
United Kingdom
YO10 5DD
+44 (0)1904 321932
julia.hackett@york.ac.uk

Additional identifiers

Integrated Research Application System (IRAS)
290143

Study information

Scientific Title
End of life care for infants, children and young people: a mixed-methods evaluation of current practice in the UK

Acronym
ENHANCE

Study objectives
Do outcomes and experiences for infants, children and their families, and resources required, vary depending on the model of end-of-life (EoL) care that they receive?
EoL services vary greatly in their professional configuration, services provided, funding sources and population served. Despite this, there is little evidence about the impact these different models might have on quality of care, resourcing and outcomes.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 02/12/2020, University of York's Health Sciences Research Governance Committee (HSRGC, Department of Philosophy, Heslington, York, YO10 5DD, UK; +44 (01904) 323253; smh12@york.ac.uk), ref: HSRGC/2020/418/G
2. Approved 18/01/2021, North West - Greater Manchester Central Research Ethics Committee (3rd Floor, Barlow House, 4 Minshull Street, Manchester, M1 3DZ, UK; +44 (0)207 1048 007; gmcentral.rec@hra.nhs.uk), REC ref: 21/NW/0009
3. Approved 17/01/2022, West of Scotland Research Ethics Committee 3 (West of Scotland Research Ethics Service, Ward 11, Dykebar Hospital, Grahamston Road, Paisley, PA2 7DE, UK; +44 (0)141 3140213; WoSREC3@ggc.scot.nhs.uk), ref: 21/WS/0170
4. Approved 16/01/2023, London - Surrey Research Ethics Committee (Nottingham Centre The Old Chapel Royal Standard Place, Nottingham, NG1 6FS, United Kingdom; 0207 104 8131; surrey.rec@hra.nhs.uk), ref: 22/PR/1525

Primary study design
Observational

Study design
Mixed methods study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
End-of-life care for infants, children and young people with life-limiting conditions

Interventions
A mixed-methods study focused on three exemplar clinical settings: cancer services, paediatric intensive care units (PICUs), and neonatal units (NNUs). The study consists of three workstreams, with the first two operating as preliminary pieces of work. WS1 will use mixed-methods (surveys and interviews) to develop care model typologies. WS2 will use qualitative methods (interviews and focus groups) to determine how these models are implemented and experienced. The final quantitative stage (WS3) is separated into two parts. Part 1 of WS3 will use routinely collected data and Part 2 will use prospective longitudinal data collection.

WS1 will systematically capture data relevant to current practice in providing EoL care and develop a typology of models of EoL care. Data will come from a questionnaire survey of clinical leads (n=250) and structured interviews with Chairs of regional paediatric palliative care networks (n=13).
WS2 will explore parents' and health professionals' experiences of EoL treatment and care. Data will come from individual interviews with bereaved parents (n=~42) and focus groups with

health care professionals (n=~162).
WS3 will compare child and parent outcomes across the models of care identified in WS1 using routinely collected data. Part 1 will assess whether the use of high-intensity treatments in children who have died from cancer varies depending on the model of EoL care that their service delivered and use retrospective secondary analysis of all children and TYAs with cancer in England who have died from 2012-2018 (n=~2750). Part 2 will explore additional individual-level outcomes and use purposively sampled data from children who are at high risk of death in Paediatric Intensive Care Units and Neonatal Units (n=~1200, in order to yield ~800 deaths).

Intervention Type
Other

Primary outcome(s)
WS3 Part 1:
The presence (or not) of the following three high-intensity treatments in the final days of each child's life, measured using retrospective secondary analysis: intravenous chemotherapy <14 days from death; more than one emergency department visit; and more than one hospitalization or intensive care unit admission <30 days from death

WS3 Part 2:
The children's quality of death, measured using an appropriate scale to be determined through consultation with the study's Parent Advisory Group

Key secondary outcome(s)
WS3:
1. Presence of mechanical ventilation (yes/no) <14 days from death
2. Place of death (hospital, home, hospice) measured using patient records

Completion date
30/06/2025

Eligibility

Key inclusion criteria
Current exclusion criteria as of 04/03/2024:

WS1: The researchers intend to recruit all clinical leads of children’s cancer services, NNUs and PICUs, and all Chairs of paediatric palliative care networks.
WS2:
1. Parents whose child has died at least 3 months prior to contact and no more than 3 years prior to contact
2. Healthcare professionals working in a children's cancer service, PICU or NNU
WS3 Part 1: All children and TYAs with cancer in England who died between 2012-2020.
WS3 Part 2: Parents of Infants and children who received treatment in either a NICU or PICU and who have died in the last 5 years.

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Previous inclusion criteria:

WS1: The researchers intend to recruit all clinical leads of children's cancer services, NNUs and PICUs, and all Chairs of paediatric palliative care networks.
WS2:
1. Parents whose child has died at least 3 months prior to contact and no more than 3 years prior to contact
2. Healthcare professionals working in a children's cancer service, PICU or NNU
WS3 Part 1: All children and TYAs with cancer in England who died between 2012-2020.
WS3 Part 2: Infants and children being treated in NNUs and PICUs and identified by staff as being at high risk of death

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
0 Years

Upper age limit
25 Years

Sex
All

Key exclusion criteria
Current exclusion criteria as of 04/03/2024:

WS2: Parents whose child died less than 3 months ago or more than 3 years ago (at the time of recruitment)
WS3 Part 1: The researchers intend to use data of all children and TYAs who died in NHS cancer treatment centres 2012-2018
WS3 Part 2: Parents not able to give informed consent or under the age of 16. Parents in cases where there are safeguarding issues.

Previous exclusion criteria:

WS2: Parents whose child died less than 3 months ago or more than 3 years ago (at the time of recruitment)
WS3 Part 1: The researchers intend to use data of all children and TYAs who died in NHS cancer treatment centres 2012-2018
WS3 Part 2: Children not identified as being at high risk of death

Date of first enrolment
01/06/2021

Date of final enrolment
31/12/2024

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Martin House Research Centre
University of York
Heslington
York
United Kingdom
YO10 5DD

Sponsor information

Organisation
University of York

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to not having permission to share the data.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		13/05/2022	15/01/2025	Yes	No
HRA research summary			28/06/2023	No	No
HRA research summary			26/07/2023	No	No
Other publications	qualitative study exploring regional perspectives of the successes and challenges	16/08/2023	15/01/2025	Yes	No
Other publications	survey information gathering on consultant-led specialised paediatric palliative care teams in the UK	09/08/2023	15/01/2025	Yes	No
Protocol file	version V1.1	27/11/2020	01/03/2021	No	No
Protocol file	version 1.5	14/12/2021	04/04/2022	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes