International 'Care Of the Dying Evaluation' (CODE):

quality of care for cancer patients as perceived by bereaved relatives

Protocol Version 1.1

International protocol

adjusted for Norway

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Table of contents

ABSTRACT

Background: In order to ensure the highest quality of care provisions for dying patients and their families, we need to first be able to robustly evaluate the current quality of care. One identified method is to assess this from the user-perspective by conducting bereaved relatives' surveys. 'Care Of the Dying Evaluation' (CODE) is a recognised, validated post-bereavement questionnaire which has been extensively used within the United Kingdom. The ERANet-LAC CODE project aims to use CODE on a wider, international level.

Aims: The present project aims to advance the international evidence in care for dying patients by undertaking an observational study of bereaved relatives' views across seven participating countries. The overall aims of the project are to:

- Refine and revise the CODE questionnaire so that it is ready for international use (Work Package 1; WP1)
- Conduct an international survey of bereaved relatives of cancer patients dying in hospitals, using the CODE questionnaire (WP2)
- Use the CODE data to provide feedback about the quality of care and level of family support at an international and national level, allowing for cross-country comparisons
- Conduct a web survey of all participating institutions to be able to interpret the survey data in view of the organisation and level of palliative care provision at each site / in each country

Methods: WP1: Using the principles of the EORTC translation procedure, the CODE questionnaire will be translated into the relevant languages for each country. Piloting with volunteers and pre-testing cognitive 'think aloud' interviews will be conducted with bereaved relatives. Using a consensus procedure, the final version of the international CODE (i-CODE) questionnaire will be developed.

WP2: Bereaved adult relatives, to adult cancer patients who had an 'expected' death in hospital, will be approached face to face, by telephone or in writing and invited to complete the CODE questionnaire. The CODE questionnaire pack will be sent out 6-8 weeks after bereavement. CODE may be completed on paper, on tablet, online, or in a telephone or face to face interview, according to what is feasible and acceptable in each country. The aim is at least 100 completed questionnaires per country. Basic demographics will be recorded for all potential participants and for the patients who died.

Analysis of results: WP1: Feedback from volunteers and bereaved relatives will be analysed thematically and collated into a Standardised Feedback Form. This will detail aspects of feedback about clarity, content, sensitivity, and response options, as well as general feedback about the

layout and formatting of the i-CODE.

WP2: Data will be analysed using SPSS and according to the CODE user guide, to present a common international report, individual country reports and cross-country comparisons. Data will be interpreted in the context of knowledge about the individual sites/countries.

Conclusions: The expected outcomes are: a translation of CODE for each country / language, a common, core, international version of i-CODE established, and an international survey and cross-country comparisons about the current quality of care for dying cancer patients as perceived by bereaved people, including key areas where care needs to be improved. The next phase of the project will use the results of the international survey to implement changes to improve the care.

LAY SUMMARY

Providing high quality care for dying patients and their families is very important. One way we can assess the care provided is to ask bereaved relatives to complete a questionnaire after their family member has died. The questionnaire can ask about their experiences and their thoughts about the care provided to their family member.

One such questionnaire is the 'Care Of the Dying Evaluation' (or CODE). CODE has been developed with the help and support of bereaved relatives and has been used extensively within the United Kingdom. In this project we want to use the CODE questionnaire to look at bereaved relatives' views about care provided in seven different countries within Europe and Latin America. Firstly, though, we need to ensure that CODE is understood and appropriate for use in these other countries.

In the first part of the project CODE will be translated into other languages using a recognized procedure. Then we will ask volunteers their views about whether or not the CODE questionnaire is easy to understand and sensitive. After that, we will ask a small group of bereaved relatives to complete CODE and be interviewed about their experience of completing the questionnaire. They will also be asked to provide feedback about whether they found the questionnaire easy to understand and complete and whether it is sensitively worded. We will use all this feedback to form a common version of CODE that is suitable for use across all the countries.

In the next stage of the project, relatives who have recently experienced a bereavement where one of their family members has died from cancer in a hospital, will be invited to complete the CODE questionnaire about two months after the patient's death. The relatives may complete CODE on paper, using a computer, or by interview. The aim is to have at least 100 completed CODE questionnaires from each of the seven countries. The data from the questionnaires will be used to make a report on the current quality of care for dying cancer patients in hospitals across the seven countries. It will also be possible to compare the care between the countries and identify areas needing improvement.

In the next phase of the project, health care professionals, researchers and bereaved relatives together will use their knowledge and experience to find effective ways to improve the weak areas identified, and assess the results of putting these changes into practice.

INTRODUCTION

In 2012, 2.35 million people died from cancer in European and Latin American (EU-LAC) countries. Patients with advanced cancer generally experience a number of distressing symptoms and face problems of a psychological, social and spiritual nature as well as physical ones. Care for dying patients is an important part of comprehensive cancer care and a central responsibility for health care on the whole. Evidence has identified challenges and disparities in the quality of care for seriously ill and dying patients, both within and across EU-LAC countries. An international project which engaged both EU and LAC countries (OPCARE9) already identified areas of common research interest and potential learning between continents.

The present project was proposed in response to the ERANet-LAC 2nd Joint Call on Research and Innovation and approved for funding under the European Commission's 7th framework program. The aim of the project is to inform and develop an evidence based approach to systematically standardize assessment and care of dying cancer patients, using relative generated outcomes. The project will be conducted in four European and three South American countries three years starting from January 2017. The project contains three Work Packages (parts). This protocol describes the work to be undertaken in Work Packages 1 and 2.

BACKGROUND

The delivery of appropriate care for dying cancer patients remains a key medical, social, economic and political issue. However, the quality of care for the dying is diverse both within and between EU-LAC countries. The Quality of Death Index 2015 (1) ranges 80 countries around the world based on 20 quantitative and qualitative indicators across five categories: the palliative and healthcare environment, human resources, the affordability of care, the quality of care, and the level of community engagement. The European countries of the present proposal all fall within the top 30 of this ranking, ranging from positions 1-26, while the South American countries have positions 32, 39 and 42 respectively. Several reports on the current state of palliative and end-of-life care in South America have been published in recent years (2, 3). They show that 80 % of Latin American countries do not acknowledge specialist palliative care as a discipline, and consequently do not include it in public health services. Only 51 % of patients in terminal stages of disease receive palliative care. Even in the United Kingdom, however, ranked as number 1 in the Quality of Death Index 2015, recent reports have shown significant variations in the care of the dying across hospitals in England (National care of the dying audit – hospitals, England 2014) (4). In Norway, ranked as number 13 overall, but number 9 in the availability of care category and 7 in the human resources category, there is a lack of robust indicators to evaluate the care given to dying patients, hampering audit and

comparisons between services. Henceforth, this indicates the need and importance for good process and outcome indicators to be in place within healthcare settings.

Based on the international evidence base, a set of core principles for care of the dying has been defined (5). These principles are applicable to the care of dying cancer patients, as well as other patients, worldwide. Several of the partners of the present consortium have led local, regional or national initiatives to improve care for dying cancer patients, especially by the use of integrated care plans applying these core international principles for care.

In order to ensure the highest quality of care provisions, we need to first be able to robustly evaluate the current quality of care. One method, as recommended by the End of Life Care Strategy (6) within the United Kingdom, is to assess this from the user-perspective by conducting bereaved relatives' surveys. As such, bereaved relatives' evaluations (both by surveys and telephone interviews) have formed a key aspect in evaluation of end-of-life care in many countries, especially within North America, and parts of Europe (7-9).

'Care Of the Dying Evaluation' Questionnaire

One such post-bereavement questionnaire is 'Care Of the Dying Evaluation' (CODE). This is a 42-item self-completion questionnaire, developed within the UK, and focused on the quality of care and the level of support provided to individuals and their families in the last days of life and the immediate post-bereavement period (10). In the UK, the NHS Friends and Family Test has also been included as an additional question within this questionnaire (11).

CODE represents a shortened and more user-friendly version of the original instrument, 'Evaluating Care and Health Outcomes - for the Dying' (ECHO-D). ECHO-D has been used with over 700 bereaved relatives within a hospice and hospital setting and shown to be valid, reliable and sensitive in detecting inequalities in care and areas of unmet need (10,12-13). Both these instruments are unique from other post-bereavement questionnaires as they specifically link with the key components representing best practice for 'care of the dying' in the last days of life (14).

ECHO-D was revised and shortened, and the 'key quality indicator' questions (based on validity and reliability measures as well as clinical importance) were used to form CODE. These questions include: aspects of symptom control; communication; nursing and medical care; provision of fluids; place of death; emotional and spiritual support. CODE has been used and validated with bereaved relatives to patients who died in their own home (15). The validation process included: undertaking cognitive 'think aloud' interviews to assess face and content validity; assessing CODE's stability over time by

conducting test-retest reliability analysis; and assessing the construct validity and internal consistency of three key composite scales within CODE.

Subsequently, CODE has been used within the context of the National Care of the Dying Audit – Hospitals which was led by the Royal College of Physicians (16); and within Merseyside and Cheshire as part of a quality assurance and benchmarking process to evaluate Care of the Dying across hospices, hospitals and community settings (17). Additionally, prior to the present project, there have been six requests for CODE to be used internationally, and over 40 requests for use within the UK healthcare setting. In order to ensure that CODE is suitable for use in all participating countries where English is not the first language, appropriate methods of translation and further pre-testing of the questionnaire is most pertinent prior to use.

Questionnaire translation

When undertaking the translation of a questionnaire from English into another native language, the process as described within the EORTC Quality of life group translation procedure is recommended (18). In essence this has the following steps:

1. Undertake two forward translations of the English version of CODE
2. Form reconciled translation
3. Translate the reconciled version back into English
4. Preliminary translation read by an external proof-reader
5. Linguistic validation, or pilot testing

Pre-testing survey methods

Questionnaire pre-testing is generally defined as 'testing a set of questions or the whole questionnaire on members of the target population' to help improve the quality of the questionnaire (19). It helps test the respondents' comprehension and interest, and also assesses whether the questionnaire has a logical flow. One comprehensive and innovative method used for 'pre-testing' includes the technique of cognitive interviewing. There are two main techniques used in cognitive interviews, the 'think aloud' method and the use of 'probes'. Cognitive interviews enable both overt and covert problems to be identified and are qualitative and flexible in nature (20).

The 'think aloud' method

One form of cognitive pre-testing is the 'think aloud' interview. This method entails training respondents to think aloud, or articulate their thoughts as they read a question, recall from their memories the information required, and turn the information they have into an answer (21). The 'think aloud' process helps gain an understanding of the cognitive processes respondents use to formulate their answers and checks whether questions have been understood correctly (19).

The 'probing' method

Probes are specific pre-prepared and spontaneous questions used to elicit reports from respondents about their thinking (22).They help identify difficulties at the different stages of the question and answer model e.g. comprehension or information retrieval problems (19). Probes can be categorised as follows:

General probes ('How did you go about answering that question?')
Comprehension probes ('What does the term 'x' mean to you?)
Recall probes ('How did you remember that?')
Response probes ('How did you feel about answering that question?')
Confidence judgement probes ('How sure of your answer are you?')
Attitude probes ('How did you decide on your answer to that question?')

AIMS & OBJECTIVES

The present project aims to advance the international evidence in care for dying patients by undertaking an observational study of bereaved relatives' views across seven participating countries, by use of the CODE questionnaire.

The overall aims of the project are to:

- Refine and revise CODE so that it is ready for international use (WP1)
- Conduct an international survey of bereaved relatives of cancer patients dying in hospitals, using the CODE questionnaire (WP2)
- Conduct a web survey of all participating institutions to aid in the interpretation of the survey data (WP2)
- Use the CODE data to provide feedback about the quality of care and level of family support at an international and national level, allowing for cross-country comparisons

The aims will be achieved by the following objectives:

WP1:

- Translation of CODE into the languages used within each of the seven countries according to the principles of the EORTC Quality of life group translation procedure (18).
- Undertake specific pre-testing of CODE using volunteer involvement and established pre-testing survey methods with bereaved relatives
- Collate all feedback from the pre-testing survey methods to establish a common, core international version of CODE (i-CODE)

WP2:

- Recruit the sufficient number of hospitals caring for adult cancer patients as study sites
- Recruit at least 100 bereaved relatives as study participants in each country. (Due to expected response rates for these types of bereaved surveys, we are anticipating that up to 3-4 times as many questionnaires will need to be disseminated to bereaved relatives. However, the expected response rate is depending on the method of recruitment, as generally more persons respond to a personal invitation than to a letter in the post.)
- Establish feasible and effective procedures for CODE data collection in each country
- Establish safe and effective methods for transfer of study data to a common database
- Develop an online survey for mapping of all participating hospitals
- Analyse the CODE data using the CODE user guide and appropriate statistical methods
- Interpret the data in view of the organisation and level of palliative care provision at each site / in each country

METHODS

WP1 – Preparation and piloting

Translation of CODE questionnaire

All partners will sign a Material Transfer Agreement for the use of CODE in the present project, as stated in the Consortium Agreement. A copy of the most recent version of the CODE questionnaire (version January 2015) will be given to the project lead in each country. The project lead will facilitate the translation process, based on the principles of the EORTC Quality of life group translation procedure (18), using the following steps:

Forward translation

A forward translation will be conducted by two independent individuals operating separately from each other. The translation will be from English into the target language. The translations should be conducted by native speakers of the native language who also have a good command of English (18).

Reconciliation

A third translator is used to reconcile the two forward translations according to a recognised standard process (18). The outcome of this process may include the following options: using one of the forward translations without changes; to slightly change one of the translations; to make a new translation by adapting from the previous two; or to prepare a completely new translation.

Back translation

The reconciled translation is translated back into English again by two translators, working independently from each other. These individuals should ideally be native speakers of English, but alternatively can be those with a good command of English.

All of the five versions (two forward translations; the reconciled translation; the two back translations) of the CODE questionnaire should be sent to the project lead for each language, with each change marked and explained. The project lead will clarify any queries, reach a consensus regarding the specific wording and prepare the preliminary translation.

Proof reading

An external proof reader will read through the preliminary translation and report any further changes needed along with an explanation about why they are needed.

Pilot testing of translated questionnaire

The pilot testing will be undertaken in two stages:

- The first stage will involve volunteers or representatives from patient and public involvement (PPI) groups
- The second stages will involve cognitive pre-testing interviews with bereaved relatives

A: Volunteers

Each country will identify potential suitable volunteers who may include individuals who are currently working as volunteers within the hospital; or representatives from patient and public forums (ideally n=5 where possible). The volunteers should not have experienced a bereavement within the last 6-8 weeks.

This stage will be facilitated as part of a group discussion forum (see Appendix 3, Guidance Template One). Ahead of the meeting, potential volunteers will be given a copy of the CODE questionnaire.

Within the meeting, they will be asked to feedback about the following:

What do they think about CODE, overall as a questionnaire, in terms of the:

- Format and layout
- Clarity to follow and complete the questionnaire

Specifically, they will also be asked about each of the individual questions in terms of the:

- Clarity
- Sensitivity

- Use of the response options

Optimally, the group interview will be audiotaped after gaining the participants' permission. Feedback from the volunteers will be collated into a Standardised Feedback Form for each country (Appendix 5).

To describe the sample, age, gender, nationality and professional background will be noted.

B: Cognitive pre-testing interviews with bereaved relatives

Eligibility criteria

Potential participants will be selected according to the following eligibility criteria.

Inclusion criteria

- Next-of-kin to a patient who died from cancer
- Are over 18 years of age
- Patient was over 18 years of age at the time of death
- Are able to give informed consent

Exclusion criteria

- Patient had a sudden and unexpected death
- Next-of-kin experienced a bereavement within the last 6-8 weeks
- Research team perceive the individual would be unduly distressed by participating in the pilot

Recruitment

For each language, a minimum of 5 bereaved relatives would be included. This is with the exception of the UK English version, where extensive pre-testing cognitive interviews have already been undertaken as part of the development and validation of both the original instrument ECHO-D and CODE (10, 15, 23). Depending on the set-up of each country, potential participants may be identified from existing bereavement support groups; by liaison with bereavement support teams who may be used to disseminate information about the study; or via patient and public involvement groups whose membership may contain bereaved relatives.

An opt-in method of approach will be adopted for this part of the study. Potential participants will either be sent or given an information sheet informing about the study and asking if they would be willing to participate. For those willing to participate, they will be asked to return a response form providing a contact telephone number. A member of the research team will then contact this individual and discuss further details about what participation would involve and provide the

opportunity for any questions to be addressed. Alternatively, the individual will phone the member of the research team directly.

Cognitive think-aloud interviews

For those willing to be interviewed, the researcher will arrange a suitable time and place for this to occur. Following written informed consent, a structured cognitive 'think aloud' interview will be conducted. Initially the following example will be used to practice the 'think aloud' method:

'I would like you to visualise the place where you live, and think about how many windows are in that place. As you count up the windows, tell me what you are seeing and thinking about.' (24)

The interview schedule (example provided in Appendix 4, Guidance Template Two) will consist of:

- General questions asking about the layout or structure of the CODE questionnaire
- In-depth questions using the 'think aloud' method supported by 'probes'
- Opportunities for the participant to raise any other issues that hadn't been discussed

The aim of these interviews is to help improve the quality of the questionnaire as well as provide additional support for the face and content validity of CODE. Each interview will be audio taped after gaining the participant's permission and will last approximately an hour. The interviews will be transcribed *verbatim*. Comments about each question will be collated into the Standardised Feedback Form to provide a summary of the views for each question. This will subsequently be assembled with the previous feedback from the volunteers to form a summary of all the feedback from each country.

To describe the sample, age, gender, nationality, professional background and time since bereavement will be noted.

Establishing a common, core international version of CODE (i-CODE)

Each country will return copies of their final Standardised Feedback Form (incorporating all feedback from the volunteers and bereaved relatives) and the copy of their 'back translation into English' questionnaire to the WP1 Lead, Dr Catriona Mayland and the Chief Investigator, Professor Dagny Haugen. Where there are unresolved issues or concerns regarding the content or wording of the CODE questionnaire, these will be collated. A consensus process will be conducted using a tele-conference meeting. Where 4 or more countries agree that the individual question should form part of i-CODE, that particular question will be included in the final version of the i-CODE questionnaire. Where 4 or more countries think the individual question should not form part of i-CODE, then that question becomes optional. In circumstances where consensus can't be reached within the

teleconference, a final decision will be made by the WP1 Lead, Dr Catriona Mayland, the Chief Investigator, Professor Dagny Haugen and one of the Leads from the Latin American countries, Dr Vilma Tripodoro. Following this meeting, the final version of i-CODE, representing the questions that all countries will ask in their post-bereavement survey will be completed.

WP2 – CODE International Survey

Study sites

The necessary number of hospitals caring for adult cancer patients will be recruited as study sites. The study will only be performed in institutions defined as ***hospitals*** (not hospices, nursing homes or other care institutions, nor home care services). Any type of hospital caring for adult cancer patients may be used: local, central, or regional hospitals, providing secondary and/or tertiary care, with or without a palliative care inpatient unit, with public or private funding.

The following hospitals will be used for the study:

Norway: Haukeland University Hospital and Haraldsplass Deaconess Hospital, Bergen; St Olavs Hospital, Trondheim University Hospital; Bærum Hospital, Vestre Viken Hospital Trust

Poland: Hospital J. Biziel in Bydgoszcz; Pulmonological Hospital in Bydgoszcz; D. Wladyslaw Biegański Regional Specialist Hospital in Grudziądz; F. Dłutek Autonomic Public Healthcare Centre in Rypin; Provincial Specialist Hospital in name of the blessed priest Popiełuszko in Włocławek

Uruguay: Hospital Evangelico Montevideo; Hospital Evangelico Colonia; possibly also Servicio Médico Integral Hospital in Montevideo (agreement pending).

Argentina: Institute for Medical Research Alfredo Lanari, University of Buenos Aires; Hospital of Gastroenterology Carlos B Udaondo, Buenos Aires City; Private Hospital of Córdoba, Córdoba City.

Germany: University Medical Centre of the Johannes Gutenberg University of Mainz

Brazil: Sumare State Hospital Dr Leandre Francheschini; Campinas State University Hospital De Clinicas

UK: Royal Liverpool & Broadgreen University Hospitals NHS Trust, Liverpool, England

Study participants

Eligibility criteria

Potential participants will be selected according to the following eligibility criteria:

Inclusion criteria

- Next-of-kin to a patient who died an 'expected' death from cancer in hospital
- Over 18 years of age
- Has been present at the hospital together with the patient at least some of the time during the patient's last two days. (This might not always be known or recorded, therefore the participant may have the option to pass the questionnaire on to somebody better placed to complete it.)
- Patient was over 18 years of age at the time of death
- Patient had been admitted to the hospital (not any specific ward) at least three calendar days (e.g., admission August 1st, died August 3rd)
- Able to give written informed consent, which might be implied when the participant completes and returns the questionnaire, in keeping with the ethical stipulations for each country

Exclusion criteria

- Patient had a sudden and unexpected death
- Unable to complete the questionnaire due to language abilities or reduced cognitive functioning (in some countries the offer of a translator would be provided if someone wanted to complete the questionnaire but had difficulty due to languages)

Definitions:

Next-of-kin: Defined by the patient and recorded in the patient's hospital record. It may be any family relation or friend, neighbour, warden, etc.

Expected death: If not possible to check with attending physician: any cancer patient who died in hospital and was not resuscitated

Cancer patient: Any patient with a cancer diagnosis (histologically or radiologically verified), not necessarily dying from the cancer. Solid tumours as well as haematological malignancies count as cancer.

Recruitment

The relative / next-of-kin must be approached *after the patient's death*. We will approach the person recorded as next-of-kin in the patient's hospital record.

Only one completed questionnaire will be included per deceased patient, but it may be completed by more than one relative, or by somebody else than the one recorded as next-of-kin.

Recruitment will be done *prospectively*. However, in the UK recruitment will also be done retrospectively to be able to reach the desired number of participants, but will be limited to 8 weeks post bereavement.

The *method of recruitment* will be adapted as to what is feasible and in the individual country. Potential participants will be approached face to face, by telephone or in writing and invited to complete the CODE questionnaire.

Each country will insert details about their recruitment process, including how informed consent will be obtained.

Norway:

Next-of-kin are in a vulnerable situation after the patient's death. The approach must be considerate and flexible. We see three possible scenarios:

1. Information about the study is given to the next-of-kin during a conversation with the ward nurse or doctor before they leave the ward after the death of the patient. This will include both oral and written information. If more details are wanted by the next-of-kin, they will be referred to a member of the research team.

2. Written information about the study is handed out to the next-of-kin as part of the bereavement pack, before they leave the hospital.

3. In case written information has not been handed out on the ward, it is sent to the next-of-kin by post after they have left the hospital.

Data collection

CODE International Survey

Data to be collected

The CODE questionnaire is the common data collection tool of the study. It is described in the Background section above and included in the Appendix (Appendix 6). The demographic data included in CODE are the following (all information provided by the participant):
Participant:

- Relation to the patient
- Age (in groups)
- Ethnic group
- Gender
- Religious affiliation

Patient:

- Illnesses in the last days and hours of life
- Age (in groups)
- Ethnic group
- Gender
- Religious affiliation

In addition, the following information will be included for all cases, as part of the inclusion procedure:

- The patient's length of stay in the hospital
- Type of ward the patient died on (general medical or surgical ward, oncology ward, ICU, emergency ward, palliative care unit)
- The patient's cancer type (predefined groups)

Length of stay, type of ward, cancer type and age (groups) and gender of the patient and next-of-kin will be recorded for all eligible cases, included and non-included, to be able to subsequently judge whether the sample is representative of the population as a whole. Depending on national regulations, this may require special permission.

If any of the partners want to include additional items or questionnaires, they are free to do so, provided the necessary approvals are obtained and the add-ons do not negatively influence participation in the main study.
In Norway, we will include three items about advance care planning, as this has been a focus on our end-of-life care research the last years and also is a hot topic internationally.

Method of data collection

The CODE questionnaire will be sent to the participants 6-8 weeks post bereavement. If not returned, one reminder will be sent, four weeks after the first attempt. CODE International Survey was intended as a postal survey. However, due to poorly functioning postal services, illiteracy, lack of experience with postal questionnaires or very low response rates in several of the participating countries (South America), other data collection methods (data entry online, face to face interviews and telephone interviews) will also be accepted. Poland intends to use computer-assisted personal interviewing using tablets (CAPI; the computer displays the questions on screen, the interviewer reads them to the respondent, and then enters the respondent's answers).

If CODE is to be completed by the participant in writing, they may have the choice between paper and an electronic version. They will receive a letter with the paper version of CODE and a fully prepared return envelope, but the letter may also say where they can log on to complete the electronic version, depending on the ethical and data protection stipulations in each country. The paper questionnaire will be marked with the unique identifier code when sent out. When answering online, the participants themselves must enter their identifier code.

Each country will insert details about how they will perform the data collection.

Norway:

The survey will only be conducted as a postal survey. The paper questionnaire will be sent to next-of-kin together with an information sheet and a fully prepared return envelope. Informed consent is implied when the relative fills in and returns the questionnaire.

One reminder will be sent to non-responders, four weeks after the first postage.

Sample estimation

The aim is to have at least 100 completed CODE questionnaires per country.
Sample estimation: Minimum acceptable number of questionnaires per country is 100
(with this number, a 95% confidence interval will give an error margin of +/- 10% of the primary outcome).
There is no maximum acceptable number of questionnaires per country; the more, the better.

Data transfer

The electronic version and database for CODE for each country/language will be developed in Norway using the Corporate Surveyor software. There will be one database for each country. Participants entering their data online will enter them directly into the database. For paper questionnaires, either filled in by the participants themselves or by interview, the CODE data will be entered into the database by local project coworkers.
The databases will be merged in Norway for the final common analyses.
Data from Corporate Surveyors may be transferred directly to SPSS or other statistics tools.

As some analyses of the survey data may be conducted by other consortium partners, consent/approval for data transfer is included in the information sheet for survey participants and the ethics application.

Web survey of study sites

Data to be collected

In order to provide contextual information for the results of CODE International Survey of bereaved relatives, information will be gathered about each organisation (hospital) and their palliative care provision. The following information will be collected:

- Type of hospital – categories
- Number of beds in hospital; number of beds in included wards
- Public/private; if private, profit-oriented or idealistic
- Deaths per year
- Deaths from cancer per year
- Palliative care unit in the hospital – yes/no
- Advisory palliative care team – yes/no
- Outpatient palliative care clinic – yes/no
- Palliative care daycare unit – yes/no
- Structured bereavement service – yes/no
- Chaplaincy – yes/no
- Physicians, nurses, physiotherapists specialized in palliative care
- EOL care implemented in hospital's 'mission statement'
- Integrated care plan for the dying implemented – yes/no
- Level of oncological expertise (comprehensive cancer centre, oncological centre; clear definitions must be given) ('not applicable' included as answer option)
- Code status defined/identified
- Opioid access / policy

Method of data collection and transfer

The web survey of study sites will be developed using the Corporate Surveyor software.

There will be one questionnaire to be used by all participating institutions across all seven countries, and the answers will be entered into one common database. The questionnaire will be developed and answered in English.

Data analysis

Data will be analysed using the SPSS statistical package. Initial data analysis of response rates and demographic details will be conducted using descriptive statistics (proportions (%) for categorical data; means and standard deviations for continuous parametric data and medians and interquartile range for continuous non-parametric data).

A comparison of demographic details for participants and non-respondents will be conducted to assess how representative our sample is compared to the potential population as a whole. We will use Pearson X^2 statistic for categorical data, independent sample t-testing for continuous parametric data and Mann-Whitney U for continuous non-parametric data

The dataset, anonymised at patient, site and country level, will be aggregated at international level to enable an international report. The two key (primary) outcomes will be the proportion of bereaved relatives who perceived that:

- the deceased patient was treated with dignity and respect (two separate questions: by doctors, and by nurses); and
- they themselves were adequately supported in the patient's last days of life

The secondary outcomes will be the results of each of the composite and variable scales (means), and the total score, as outlined in the CODE User Guide (25). Finally, results for the individual items will be presented. Results will be summarised in tabular and graphical format, as appropriate.
Missing data: If <10% missing data: For single questions, means of what has been answered for other questions will be used, based on composite scales.
With higher degrees of missing data, multiple imputation will be used.

Descriptive statistics will be used to compare the characteristics of included and non-included cases, to see whether the final sample is representative for the population as a whole.

For each country, similar reports as described for the international level will be developed. National data will be reported back to each partner.
Data from the web survey of study sites will be analysed with descriptive statistics using SPSS.
Where appropriate, responses to CODE will be compared with hospital characteristics and level of palliative care provision using regression analyses.
Free text comments will be analysed using qualitative methods (text condensation).

Additionally, the three key composite scales within the CODE questionnaire, the CARE, the COMMUNICATION and the ENVIRONMENT scales would be assessed for their internal consistency and construct validity. These three scales represent question items which have been grouped together for their conceptual similarity. Cronbach's alpha will be used to assess the internal consistency of these scales and factor analysis techniques to assess the construct validity.

PROJECT MANAGEMENT AND WORK PLAN

An overview of the ERANet-LAC CODE consortium is included in the Appendix (Appendix 1).
All partners have signed the consortium agreement. The PIs are responsible for the CODE international survey in their respective countries. The group of PIs constitute the project General Assembly and decision-making body. Important decisions concerning both WP1 and WP2 of the present project were made at the project Initiation Meeting in Mainz, Germany, in February 2017.
Project management will be handled by the Coordinator.

WP1 (Preparation and Piloting) is designed to run from month 1 to month 7 of the project, i.e. from January to August 2017. Group discussion with volunteers may be carried out as soon as the translation process is completed. Cognitive interviews with bereaved relatives may be conducted when ethical approval is obtained.

WP2 is designed to run from month 8 to month 22 of the ERANet-LAC CODE project, i.e. from September 2017 to November 2018. Recruitment of participants for the international survey may start when the following factors are in place:

- Approval from ethics committee and other relevant agencies
- i-CODE ready for use in all relevant languages and presented as fully developed, tested and web-accessible data collection tools
- Study office with the necessary infrastructure in each country

Time line and deliverables

Confirmation of ethical approval for CODE International Survey in each country	month 6 (July 2017)
Web survey of institutions ready for use	month 6 (July 2017)
Fully developed, tested and web-accessible data collection tools	month 6 (July 2017)
i-CODE ready for use	month 7 (Aug 2017)
Completed web survey of inclusion sites	month 10 (Nov 2017)
Completed international survey with at least 600 completed CODE questionnaires	month 22 (Nov 2018)
Report on CODE International Survey data	month 22 (Nov 2018)

END OF STUDY

WP1: The end of WP1 will occur when the following outcomes are achieved:

- A translation of CODE for each country / language
- A report on the translation and pilot testing for each country / language
- Results from the pre-testing in each country collated and compared, to establish a common, core international version of CODE (i-CODE)
- International CODE ready for use, in all relevant languages

WP2: The end of WP2 will occur when the following outcomes are achieved:

- A common international report on CODE survey data
- Individual country reports and cross-country comparisons
- Identification of the two main concerns, across the countries and in the individual countries

SPONSORSHIP AND BUDGET

Financial support for the project was granted from national research funding agencies in the participating countries, except in the UK. The University of Liverpool, UK, takes part in the project as self-financed partner. Details on the agencies are provided in Appendix 1.
No commercial interests are involved in the study. No conflicts of interest have been declared. Participants receive no financial benefit for participation.

ETHICAL APPROVAL AND GOVERNANCE

The Project Lead (PI) for each country will seek the necessary approvals for CODE International Survey, from their local/regional ethics committee, and from their institutional review board as needed. The research project will adhere fully to the Declaration of Helsinki and to the requirements set out in the Health Research Governance Framework for each participating country.

As regards WP1 of the project, we do not think ethical approval is required for the pilot testing with volunteers, but each country needs to clarify their own stipulations. We will seek ethical approval for the cognitive 'think aloud' interviews and the international survey.

All potential participants will be given a Participant Information Sheet detailing the aims of the study. This information sheet emphasizes that participation is fully voluntary and that they may withdraw at any time, up to the time when the final analysis and reporting have been completed. They will be given time to consider whether they wish to participate. In addition, the full contact details for a member of the research team will be provided so that the opportunity to ask questions and request additional information is available. These measures should ensure that participation is based on fully informed consent.

PATIENT AND PUBLIC INVOLVEMENT

Seeking patient and public views is an important component of WP1 of this study. Both volunteers and bereaved relatives will be deeply involved in developing i-CODE to be used for the international survey. They will also be consulted on how to approach the participants in the survey.
After the survey has been performed, bereaved relatives will be involved in the action planning on how to address the main areas of concern identified.

CONFIDENTIALITY AND DATA MANAGEMENT

The Project Lead for each country will preserve the confidentiality of participants taking part in the study. All participants will be allocated a unique identifier number, both for transcription of

interviews, inputting of data and completion of the CODE questionnaire. The code list will be securely locked up and only available to the responsible personnel/contact person recruiting participants at each study site/ward. The list will not be available for researchers analysing the data. The code list will be destroyed by the end of the study.

All data will be anonymised and individual participants will not be identifiable from published data. Any quotations from interviews or free text comments that may lead to a participant being identifiable will be edited prior to publication of subsequent reports and publications.

Any audio recordings will be transferred immediately after the interview onto a transcription system. Electronic transcripts and all data will be stored on a secure, password protected research server. Consent forms and other paper documents will be locked in filing cabinets. Data will be stored for up to five years after the completion of the project before being confidentially shredded or deleted.

DISSEMINATION AND PUBLICATIONS

A website for the project will be established with the purpose of providing general information about the study. The website has one public part and one part with restricted access, open for the PIs and study personnel. This part will contain all common project documents and templates. Summary results from the project will be published on the open part.

The dissemination activities will be directed towards health care professionals and researchers, the general public, and health care authorities and politicians. Publications reporting results from the study will be submitted to international peer review medical journals, and presented at international meetings. Authorship will be defined according to the Vancouver Guidelines. The PI and study coordinator in each country will be co-authors on the main publication from WP2, as long as they fulfil the requirements in these guidelines. National data may be published in local reports for individual organisations and national journals by the study group in each country. Plans for additional publications including authorship must be decided or approved by the Project General Assembly.

The last project meeting with presentations and discussions of the project findings will be arranged as an open international conference.

REFERENCES

1. The 2015 Quality of Death index. Ranking palliative care across the world. The Economist Intelligence Unit. A report by The Economist Intelligence Unit. Lien Foundation 2015.
2. Pastrana T, De Lima L, Wenk R, et al. Atlas de Cuidados Paliativos de Latinoamérica. Houston, TX: IAHPC Press, 2012.
3. Pastrana T, Eisenchlas J, Centeno C et al. Status of palliative care in Latin America: looking through the Latin America Atlas of Palliative Care. Curr Opin Support Palliat Care 2013; 7:411-5.
4. National care of the dying audit for hospitals, England. National report, Royal College of Physicians, May 2014 https://www.rcplondon.ac.uk/projects/outputs/national-care-dying-audit-hospitals (last accessed 28 Feb 2017)
5. The International Collaborative for Best Care for the Dying Person. Supporting Care in the Last Hours or Days of Life. May 2014. http://www.mcpcil.org.uk/media/33890/international%20model%20documentation.pdf (last accessed 28 Feb 2017)
6. Department of Health (2008). End of life care strategy. Promoting high quality care for all adults at the end of life. Department of Health: London.
7. Burge F, Lawson B, Johnston G et al. Bereaved family member perceptions of patient-focused family-centered care during the last 30 days of life using a mortality follow-back survey: does location matter? BMC Palliat Care 2014; 13:25.
8. Office of National Statistics (2014). National Survey of Bereaved People (VOICES) 2014. Office of National Statistics. https://www.ons.gov.uk/peoplepopulationandcommunity/healthandsocialcare/healthcaresystem/bulletins/nationalsurveyofbereavedpeoplevoices/2015-07-09 (last accessed 28 Feb 2017)
9. van der Heide A, de Vogel-Voogt E, Visser AP, van der Rjt CC, van der Maas PJ. Dying at home or in an institution: perspectives of Dutch physicians and bereaved relatives. Support Care Cancer 2007; 15:1413-21.
10. Mayland CR, Williams EMI, Ellershaw JE. Assessing quality of care for the dying: the development and initial validation of a postal self-completion questionnaire for bereaved relatives. Pall Med 2012; 26:897-907.
11. Department of Health (2013) The NHS Friends and Family Test: Publication Guidelines. https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/141446/Fr

iends-and-Family-Test-Publication-Guidance-v2-FOR-PUBLIC_E2_80_A6.pdf.pdf (last accessed 28 Feb 2017)

12. Mayland CR, Williams EMI, Addington-Hall J, Cox TF and Ellershaw JE. Does the 'Liverpool Care Pathway' facilitate an improvement in quality of care for dying cancer patients? Br J Cancer 2013; 108:1942-8.
13. Mayland CR, Williams EMI, Addington-Hall J, Cox TF and Ellershaw JE. Assessing the quality of care for dying patients from the bereaved relatives' perspective: further validation of 'Evaluating Care and Health Outcomes – for the Dying'. J Pain Symp Manage 2014; 47 (4): 687-696
14. Mayland CR, Williams EMI and Ellershaw JE. How well do we care for dying patients? A review of instruments using bereaved relatives to assess the quality of end-of-life care. Palliat Med 2008; 22: 133-144.
15. Mayland CR, Lees C, Germain A et al. Caring for those who die at home: the use and validation of 'Care Of the Dying Evaluation' (CODE) with bereaved relatives. BMJ Support Palliat Care 2014; 4:167-74.
16. Mayland CR, Mulholland H, Gambles M, Ellershaw J, Stewart K. How well do we currently care for our dying patients in acute hospitals: the views of bereaved relatives? BMJ Support Palliat Care 2017 doi: 10.1136/bmjspcare-2014-000810. [Epub ahead of print].
17. Quality Assurance for Care of the Dying: Cheshire & Merseyside Strategic Clinical Network. Network Report. October 2015. http://www.nwcscnsenate.nhs.uk/strategic-clinical-network/our-networks/palliative-and-end-life-care/education-reso/care-dying-evaluation (last accessed 28 Feb 2017)
18. Kulis D, Bottomley A, Velikova G et al. on behalf of the EORTC Quality of life group. EORTC Quality of life group translation procedure 4th edition. May 2016
19. Czaja R. Questionnaire pre-testing comes of age. Marketing Bulletin 1998; 9:52-66.
20. Campanelli P, Collins D. How to do cognitive interviewing. CASS course in pre-testing survey questionnaires. London: Royal Statistical Society 2005.
21. Fowler FJ, Coppola KM, Teno JM. Methodological challenges for measuring quality of care at the end of life. J Pain Sympt Manage 1999; 17 (2): 114-119.
22. Van der Veer K, Hak T, Jansen H. The Three-Step test-Interview (TSTI): An observational instrument for pre-testing self-completion questionnaires. Paper for the International Conference of Questionnaire development, Evaluation, and Testing Methods. Charleston, South Carolina, Nov 2002.
23. Germain A, Mayland CR, Jack B. The potential therapeutic value for bereaved relatives

participating in research: An exploratory study. Palliat Support Care 2016;14:479-87.

24. Willis GB. Cognitive interviewing. A 'How to' guide. Short course presented at the 1999 meeting of the American Statistical Association.
25. Mayland C. User-guide for 'Care of the Dying Evaluation' (CODE^{TM}). The Marie Curie Palliative Care Institute Liverpool, 2015.

APPENDICES

Appendix 1: Overview of ERANet-LAC CODE Consortium, including PIs and national funding agencies

Organisation	Country	Principal Investigator	Funding Organisation
University of Bergen	Norway	Prof Dagny Faksvåg Haugen dagny.haugen@uib.no	The Research Council of Norway (RCN / NFR)
Sue Ryder House administered by Pallmed	Poland	Prof Wojciech Leppert wojciechleppert@wp.pl	National Centre for Research and Development (NCBR)
Mutualista Asociación Hospital Evangélico	Uruguay	Dr Eduardo Garcia Yanneo eduardouruguay@hotmail.com	National Research and Innovation Agency of Uruguay (ANII)
Pallium Latinoamérica N.G.O.	Argentina	Dr Vilma Adriana Tripodoro vilma.tripodoro@gmail.com	Ministry for Science, Technology and Productive Innovation (MINCyT)
University Medical Center of the Johannes Gutenberg University of Mainz	Germany	Prof Martin Weber martin.weber@unimedizin-mainz.de	Federal Ministry of Education and Research (BMBF/DLR)
State University of Campinas	Brazil	Prof, Dr Lair Zambon lair.zambon@hes.unicamp.br	Research Support Foundation of the State of Sao Paulo (FAPESP)
University of Liverpool	UK	Dr Catriona Mayland catriona.mayland@liverpool.ac.uk	No funding agency

Appendix 2: Overview of participating hospitals and responsible persons, Norway

Sykehus	Kontaktperson
Haraldsplass Diakonale Sykehus	Overlege, forsker Katrin Sigurdardottir katrin.sigurdardottir@haraldsplass.no
Haukeland unversitetssjukehus	Seksjonsoverlege, professor Dagny Faksvåg Haugen dagny.haugen@uib.no
St Olavs Hospital	Overlege Morten Thronæs og overlege, førsteamanuensis Anne Kvikstad morten.thrones@ntnu.no anne.kvikstad@ntnu.no
Bærum Sykehus	Overlege Eva Gravdahl eva.gravdahl@vestreviken.no

List of further appendices, provided in or as separate documents

Appendix 3: Guidance Template One: Part 1 Volunteers

Appendix 4: Guidance Template Two: Part 2 Cognitive interviews

Appendix 5: Interview briefing sheet

Appendix 6: Standardised feedback form from questionnaire pre-testing

Appendices 3-6 in common document

Appendix 7: CODE questionnaire (English original) (separate document)

Appendix 8: CODE User Guide (separate document)

Appendix 9: Norwegian translation of CODE questionnaire (separate document)

Appendix 10: Information flyer, questionnaire pre-testing with cognitive think-aloud interviews (separate document) (*Informasjon om forskningsprosjektet – uttesting av spørreskjema*)

Appendix 11: Information sheet and consent form, questionnaire pre-testing with cognitive think-aloud interviews (*Forespørsel om deltakelse – uttesting av spørreskjema*)

Appendix 12: Information flyer, CODE international survey (separate document) (*Informasjon om forskningsprosjektet – utfylling av spørreskjema*)

Appendix 13: Information sheet, CODE international survey (separate document) (*Forespørsel om deltakelse – utfylling av spørreskjema*)

Appendix 14: Screening and registration of information at inclusion (separate document) (*Screening og opplysninger ved inklusjon)*

Appendix 15: Additional questions, Norway (*Tilleggsspørsmål til spørreskjemaet i Norge*)

Amendment 1, 15th February 2018: Additional participating hospitals and responsible persons, Norway

Sykehus	**Kontaktperson**
Haugesund Sjukehus, Helse Fonna	Overlege Carmen Julia Bratke carmen.julia.bratke@helse-fonna.no
Førde Sentralsjukehus, Helse Førde	Studiesykepleier Kristin Vassbotn Guldhav kristin.vassbotn.guldhav@helse-forde.no
Stavanger universitetssjukehus, Helse Stavanger	Fagansvarlig sykepleier Janet Bakken janet.bakken@sus.no