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# Last Year of Life Study-Cologne (LYOL-C) (Part II): study protocol of a prospective interventional mixed-methods study in acute hospitals to analyse the implementation of a trigger question and patient question prompt sheets to optimise patient-centred care

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## ABSTRACT

**Introduction** The Last Year of Life Study-Cologne Part I (LYOL-C I) has identified general hospital units as the most important checkpoints for transitions in the last year of life of patients. Yet, satisfaction with hospitals, as reported by bereaved relatives, is the lowest of all health service providers. Thus, the LYOL-C Part II (LYOL-C II) focuses on optimising patient-centred care in acute hospitals for patients identified to be in their last year of life. LYOL-C II aims to test an intervention for hospitals by using a two-sided (healthcare professionals (HCPs) and patients) trigger question-based intervention to 'shake' the system in a minimally invasive manner.

**Methods and analysis** Prospective interventional mixed-methods study following a two-phase approach: phase I, individual interviews with HCPs and patient representatives to design the intervention to maximise ease of implementation and phase II, exploratory study with two arms and a prepost design with patients in their last year of life. The intervention will consist of the Surprise Question and the German version of the Supportive and Palliative Care Indicators Tool (SPICT-DE) for HCPs to identify patients and provide patient-centred care, plus question prompt sheets for patients, encouraging them to initiate discussions with their HCPs. Data on transitions, changes in therapy, quality of care, palliative care integration and death of patients will be analysed. Furthermore, a staff survey (pre/post) and guided interviews with staff, patients and relatives (post) will be conducted. Finally, a formative socioeconomic impact assessment to provide evidence regarding the sustainability of the intervention will be performed.

**Ethics and dissemination** The study was approved by the Ethics Committee of the Faculty of Medicine of the University of Cologne (#20-1431). Results will be published in peer-reviewed journals and presented at national and international conferences.

**Trial registration number** DRKS00022378.

## Strengths and limitations of this study

- By choosing a controlled design with a 12-month follow-up, we can observe effects on patient-centred care over time and analyse if and at what point potential changes in processes manifest themselves in effects on patient outcomes.
- The study design also allows a socioeconomic impact assessment, which is one of the keys of value-based health and social care (VBHSC).
- By also using question prompt sheets, another feature of VBHSC can be implemented at the level of physician-patient interactions.
- One limitation is the possibility of confounding, which makes it harder to determine whether factors other than the two-sided intervention (eg, skill mix, different resources and resource use) will influence patient outcomes.
- The collected data will be partially self-reported and thus can be subject to intentional and unintentional bias and error.

## INTRODUCTION

According to data from the Federal Statistical Office,[1] 954 874 persons died in Germany in the year 2018, out of a population of a little more than 83 million, indicating that the number of the deceased was 1.2% of the overall population. One-third of the total health expenditure in a life span occurs

during the last months of life,[2 3] and there have been increases in both aggressive care and non-aggressive care at the end of life, with increasing multiple hospitalisations.[4] As shown in the Last Year of Life Study Cologne (LYOL-C) Part I Status Quo Report, 42.2% of the Cologne population died in hospitals.[5] Almost 30% of hospital patients are in their last year of life,[6] and 75% of deaths are from conditions other than cancer.[7] Other literature shows that 40%–50% of patients who died in hospitals could have died in the community with better support and training. There are strong economic arguments for supporting caregivers of people at the end of life, as caregiver involvement can reduce hospital readmission rates, thereby saving both time and money.[8 9]

International studies have shown that there is still a mismatch between current best practice recommendations and observed clinical reality (eg, in recognition of transition into the last year of life, recognition of palliative care (PC) needs, aspects of shared decision-making or care for the dying).[10] Reasons for this may lie in the obvious life-saving culture of hospitals where the norm is to prevent death by whatever means are necessary, as well as increasing time and cost pressure, without yet having established standards for patients who will die within the foreseeable future. Therefore, there is little time for reflection on the goals of care.[6] In Germany, about 47% of deaths occur in hospitals, although systematic studies are still scarce on this topic.[11 12]

LYOL-C I and II are intended to systematically assess and improve the experience of patients in their last year of life in Cologne, as a representative German urban area that already has full palliative and hospice structures. The results of LYOL-C I are the basis for this study. As reported by a representative sample of relatives, general hospital units are the most important checkpoints for transitions in the last year of life (eg, diagnosis of 'entering' the last year of life, hospitals as one of the five most frequent care transitions in the last year of life and place of death).[5] Yet, satisfaction in general hospital units is lowest among all health services, especially in comparison to care at home and in nursing homes. Therefore, LYOL-C II aims to test an intervention for general acute hospital units by using a two-sided (healthcare professionals (HCPs) and patients) trigger question-based intervention to 'shake' the system in a minimally invasive manner. According to Argyris[13]/Argyris and Schön[14], trigger thinking resp. double-loop learning will lead to questioning underlying objectives and people's own behaviours. For the professionals, we use the Surprise Question (SQ) and the German version of the Supportive and Palliative Care Indicators Tool (SPICT-DE),[15 16] since recognising increased burden of illness is suggested to be a better trigger in comparison to the SQ alone.[17 18] The SPICT is a helpful and practical tool to support the identification of patients who might benefit from PC,[15] comprising three parts: clinical indicators, condition-specific clinical indicators and recommendations for PC actions. The SPICT has already been validated in Italian,[19] Spanish,[20] Japanese[21] and Swedish[22] languages and is widely researched for use in general practice[15 21 23 24] and hospital settings.[25 26] Patients are defined as SPICT-positive if they meet two or more clinical indicators. Furthermore, in order to trigger change on the patient side, we will develop and introduce question prompt sheets (QPSs) to encourage patients to initiate discussions with their HCPs. Patients who are actively participating in care processes and decision-making are able to change the focus of the consultation and influence the duration and amount of information provided, leading to improved psychological adjustment and increased patient satisfaction.[27] QPSs are perceived as helpful in patient-physician communication and do not increase patient anxiety or prolong clinic visits.[28]

We hypothesise that our two-sided intervention will translate into significant patient benefits and possibly cost savings, which is in line with the concept of delivering value-based healthcare and thus commensurate to the overall concept of the Cologne Research and Development Network (CoRe-Net[i]).

LYOL-C II aims to develop patient QPSs and tailor the SQ and SPICT-DE (phase I and II) to test the perceived benefits of, and possible barriers to, integrating our two-sided intervention in hospitals in Germany (phase II). We assume that our intervention will improve the quality of life of patients (primary outcome) through earlier identification and meeting of PC needs. In order to test this, we also need to analyse how the intervention will best be implemented by also considering possible barriers (eg, on the organisational level).

## METHODS AND ANALYSIS

### Study design

LYOL-C II is a prospective interventional study with two arms and a prepost design, which is composed of two phases (see below).

The study will be conducted at the University Hospital Cologne, Germany. The project started in May 2020 for the duration of 36 months (planned end: April 2023). Recruitment started in February 2021.

### Phase I: modelling the intervention

Interviews with staff members from various healthcare settings and patient representatives in Cologne will be conducted to tailor and adapt the two-sided intervention and develop an implementation programme.

### Intervention

The intervention planned for use by HCPs consists of the SQ and the German version of the SPICT. The SPICT-DE is intended to be used whenever the HCP is unsure as how to answer the SQ. During the modelling phase of the project, the formal (eg, duration and number of workshops needed to provide information on the intervention) and contextual aspects of the workshop will be discussed. Thus, in collaboration with experts, a flexible

[i] https://www.core-net.uni-koeln.de/index.php/en/start_en/

implementation concept will be designed to effectively accommodate the use of the intervention on each participating ward. The intervention planned for use by patients and relatives consists of QPSs to encourage patients to initiate discussions with their HCPs. As part of the intervention, patients identified using the SQ+SPICT-DE will receive the QPSs from HCPs who participated in the workshop. Prior to the exploratory controlled study, the SQ+SPICT-DE workshop will be developed by involving HCPs from several different settings. The process of tailoring will cover common aspects of organisational aspects and end-of-life care, such as managing uncertainty, helping people achieve their preferred place of care and symptom assessment and management, as well as family and bereavement support. The aim of the SQ+SPICT-DE is to improve staff confidence and competence and provide healthcare workers with concise material on suggestions for further steps. Individual interviews will discuss draft QPSs for patients to be consented with patient representatives and healthcare workers. QPSs will be developed based on the already existing German patient guideline 'Palliative Medicine'.[29]

### Data collection

The sample will include HCPs and patient representatives (n=10) involved in caring for people in their last year of life. A snowball sampling technique will be applied, using the networks of our field access partners. Based on purposeful sampling,[30] semi-structured face-to-face narrative interviews will be conducted. The number of participants for the qualitative interviews depends on the characteristics of the interview participants and can therefore vary. A sample holding more information needs a smaller number of participants.[31] Information power is assumed to be reached with approximately 10 interviews.

### Inclusion criteria

- HCPs and patient representatives involved in caring for people in their last year of life.
- Consent has been obtained.
- Full command of the German language.
- ≥18 years old.

The exclusion of individuals from interviews occurs when the inclusion criteria are not met and when there is no experience in caring for people in the last year of life.

The semi-structured qualitative interview guide[30] revolves around three theme blocks:

- Block I: experiences, attitudes and requirements concerning the identification and standardised care of people in the last year of life.
- Block II: presentation/discussion of the planned intervention.
- Block III: tailoring (for the development of the barrier-driven implementation strategy).

Each topic will be operationalised by core questions facilitating story-telling and narrative-generating subquestions. The interview guide will be flexibly adapted to the type of expert, the position or background or the course of the conversation. The interviews will be conducted via video conference and will last about 60 min. In addition to the interviewee, two interviewers will be present. Interviews will be audiotaped, transcribed verbatim and anonymised by an external professional typist. Interviewees will provide written informed consent before the interviews.

### Data analysis

Transcripts of individual interviews will be analysed according to Miles *et al*.[30] All transcripts will be entered into MAXQDA software (VERBI GmbH, Berlin, Germany). Qualitative content analysis will be chosen to explore the participants' unique perspectives in order to extract on the descriptive level of content and not to provide a deep level of interpretation and underlying meaning. The analysis of the interview content will be conducted independently by two researchers to ensure the validity of the data interpretation by minimising the subjectivity of data interpretation. A coding frame will be developed by combining deductive and inductive approaches. Content-related codes will be constructed by descriptive coding/subcoding and provisional coding/subcoding.[30] Codes for the intervention-related information will be constructed with an inductive approach. In order to identify and structure determinants for the implementation of the intervention, codes will be constructed based on a conceptional model for the implementation of patient-centred care[32 33] interventions combined with dimensions of the Consolidated Framework for Implementation Research.[34]

### Phase II: exploratory study

The study will be conducted in at least two hospital units within the University Hospital Cologne. Each of them will start with the control group, followed by the intervention afterwards (see figure 1 for more details on the data collection process).

### Control group

#### Recruitment of control group

Patients who receive usual hospital care and relatives, if any (patients can be enrolled into the study even without a participating relative), will be recruited at the University Hospital Cologne. We will rely on the project's study nurse and research assistants to identify patients (and their relatives) for recruitment into the study by regularly taking part in handover meetings and inquiring about eligible patients during the recruitment period. Patients who might be eligible will then be screened by the treating physician using the SQ and SPICT-DE[15] that helps identify people with deteriorating health due to one or multiple advanced conditions. If the patient (and relative) is eligible and interested in participating and requests more in-depth information, the treating physician of the participating unit will hand out a flyer containing study information and a specifically developed contact form to be

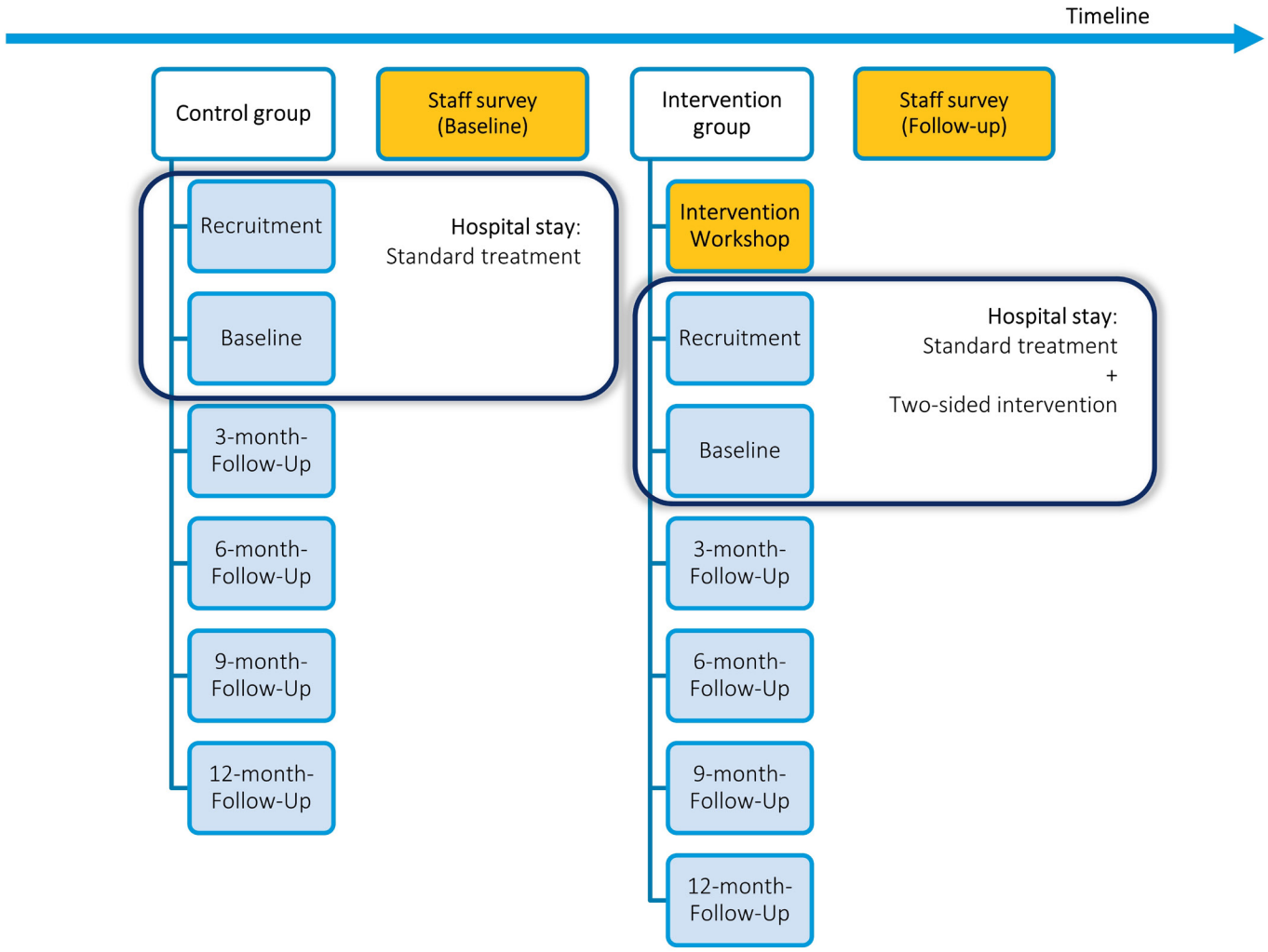


**Figure 1** Data collection process.

sent back to the research team. Patient recruitment will begin in February 2021 for the duration of 8 months.

## Outcome measures

Data will be collected on the patient's inclusion in the study (baseline assessment, T0), 3 months after inclusion (T1), after 6 months (T2), after 9 months (T3) and after 12 months (T4) wherever the patient is (eg, at hospital or at home). To minimise the burden on the patient and relative, if any, all outcome assessments will be scheduled beforehand for the complete study.

## Baseline assessment

### Quality of life

The primary outcome is patient's well-being assessed with the Short-Form-Health Survey (SF-12) (1 week version), a health-related quality of life questionnaire (at baseline and follow-up).[35]

Secondary outcomes include patients' Integrated Palliative care Outcome Scale (IPOS), Eastern Cooperative Oncology Group (ECOG) performance status, burden on relatives, experience with the intervention, perceived involvement in care and quality of care, which will be measured with a modified version of the German VOICES questionnaire every 3 months over a period of 1 year (T0–T4).

### Palliative care needs

PC needs will be assessed with the IPOS.[36] The IPOS measures patients' physical symptoms; psychological, emotional and spiritual well-being; and information and support needs. It is a validated instrument that can be used in clinical care, audit, research and training. The IPOS is specifically developed for use among people severely affected by diseases, such as cancer, respiratory, heart and neurological diseases, as well as renal and liver failure.

### Quality of care/value-based healthcare

To measure and improve the quality of care and services received in the last year of life, the Views of Informal Carers-Evaluation of Services-German (VOICES-LYOL-Cologne) questionnaire in a modified patient version will be used (at baseline and follow-up).[37]

The medical files of patients will be checked for diagnoses, comorbidities, use of medical interventions and

medications using a prestructured checklist. Furthermore, organisational data from the controlling department of the University Hospital Cologne will be collected (at baseline and follow-up).

We will also use the ECOG[38] and collect data on the perceived involvement in care scales (at baseline and follow-up).[39]

### Follow-up assessments

Patients will be asked to complete a follow-up questionnaire (identical to the baseline questionnaire) to assess changes as compared with their situation at baseline. If patients are not capable at this point, relatives will be eligible to complete the questionnaire as proxies.

Relatives are asked to complete a survey simultaneously to the patient questionnaires. Caregiver burden will be measured using the Zarit Burden Interview screening questionnaire.[40] Further items will cover the perceived support and the time required to care for the patient. For patients who have died, we will collect data about the use of medication and medical interventions during the last week of life, using a prestructured checklist that also serves to collect data for the cost-effectiveness analysis. The checklist comprises items from our VOICES-LYOL-Cologne questionnaire developed in LYOL-C I.[37]

### Inclusion criteria

Patients can be included if:

- ≥18 years old.
- Written consent has been obtained.
- Full command of the German language.
- They have been informed that his or her disease is not curable and has progressed and that the probability of surviving the disease is low.
- The SQ was answered with 'no'.
- SPICT criteria has been met.

Patients are excluded if they have already received palliative or hospice care.

Relatives can be included if:

- ≥18 years old.
- Identified by the patient as the person closest to them.
- Written consent has been obtained.
- Full command of the German language.

### Staff survey

After recruitment of the control group, we will conduct a baseline staff survey. Following this, the hospital staff will receive an intervention workshop. Afterwards, staff will apply the SQ and SPICT process and QPSs will be handed out to the patients to prepare for patient-physician conversations (intervention group). After completion of patient recruitment in the intervention group, we will conduct a second staff survey to evaluate the effects of the two-sided intervention (figure 1). The staff survey will consist of self-assessment items (to be developed) measuring staff confidence, understanding and knowledge of LYOL-C and experience with identifying PC needs and the use of QPSs.

### Inclusion criteria

- HCPs (eg, medical and nursing staff, social workers and psychologists) of the participating university hospital ward in Cologne.
- Written consent has been obtained.
- Full command of the German language.
- ≥18 years old.

### Intervention group

#### Recruitment of the intervention group

As mentioned above, following data collection in the control group, a staff survey will be conducted, which is then followed by the intervention workshop for staff members in each unit. Afterwards, patients and relatives, if any (patients can be enrolled into the study even without a participating relative), will be recruited by trained staff members applying the SQ+SPICT-DE process to identify patients in their last year of life. If the patient (and relative) is interested in participating and requests more in-depth information, the treating physician, nursing staff, social workers or psychologists who all have been trained in the use of SQ+SPICT-DE will hand out a flyer containing study information and a specifically developed contact form to be sent back to the research team. To keep the screening and recruitment period ongoing, the study nurse/research assistants will regularly contact the participating units and inquire about eligible patients during the recruitment period. Patient recruitment for the intervention group will begin in October 2021 for the duration of 12 months.

### Outcome measures

The outcome measures will be identical to the control group. We will also assess patients' experiences regarding the usability and feasibility of the QPSs.

### Baseline and follow-up assessments

Assessments will be identical to the control group.

### Inclusion criteria

Patients can be included if:

- ≥18 years old.
- Written consent has been obtained.
- Full command of the German language.
- They have been informed that his or her disease is not curable and has progressed and that the probability of surviving the disease is low.
- They were identified to be in their last year of life by the treating physician, nursing staff, social workers or psychologists who were trained in the use of the SQ+SPICT-DE (identification will be based on the SPICT-specific clinical criteria set).
- The SQ was answered with 'no'.

Patients are excluded if they already received palliative or hospice care.

Relatives can be included if:

- ≥18 years old.
- Identified by the patient as the person closest to them.
- Written consent has been obtained.

- Full command of the German language.

### Follow-up staff survey to evaluate the effects of the two-sided intervention

After completion of patient recruitment for the intervention, we will conduct a second staff survey to evaluate the effects of the two-sided intervention.

#### Qualitative interviews with staff, patients and relatives of the intervention group to evaluate the effects of the two-sided intervention

To evaluate the implementation outcomes of the two-sided intervention, we will conduct individual interviews with patients and their relatives in the intervention group and staff who participated in the intervention workshop.

#### Socioeconomic impact assessment

A formative socioeconomic impact assessment will be performed. The aim is to provide evidence with regard to sustainability by planning the intervention and, based on this evidence, model scenarios on how a sustainable use of the two-sided intervention can be achieved at the University Hospital of Cologne.

### Sample size calculation

At each site, we aim to observe an effect in the hypothesised direction with 80% probability, assuming a small standardised effect of 0.2 (Cohen's d). Although controversial, we consider a standardised difference of 0.2 as 'minimally important', at least as a starting point to design the study.[41] For this purpose, the two-sample t-test requires (n=) 36 subjects per group at one-sided type I error 50% and 80% power (Stata/SE V.16.1, StataCorp, College Station, Texas, USA; command power two means). Based on our own studies, we conservatively expect that, within 30 days of inclusion, 30% of all patients who complete the baseline assessment will either die (10%, attrition due to death), experience a significant deterioration of health (10%, attrition due to illness) or become lost to follow-up (10%, attrition due to chance).[42] Thus, the proportion who will be able to complete follow-up assessment 1 would then be 70%. To compensate, we plan to include ($n$ =) 104 (≈72/0.7) subjects . Based on linear mixed models for repeated measures, the power to detect differences between groups or over time (ie, follow-up) is assumed larger and perhaps sufficient to reach the conventional level of statistical significance (ie, 5% two-sided).

### Data analysis plan

Descriptive data are summarised by counts (percentages) and quantitative data by means±SD and percentiles. Changes in (quasi)-continuous outcome measures (ie, scores) are evaluated by linear mixed models for repeated measures with fixed effects baseline value, site, group, time and the interaction group×time, corresponding marginal means and contrast tests are derived. The robustness of results are explored in sensitivity analyses, including multiple imputations approaches to deal with values missing (not) at random, and propensity score methods to guard against selection bias or confounding.[43 44] Free-text responses and transcripts of interviews will be analysed according to Miles *et al*[30]. These data will furthermore be fed into the socioeconomic impact assessment.

### Documentation

All data relevant to the study will be documented in an electronic database in accordance with the CoRe-Net database. Data will be entered into the database during data collection using a laptop. This includes all outcome measures and sociodemographic data. In addition, the research assistant will always have paper-and-pencil versions at hand, so these can be completed in the event of technical failure and later transferred into the electronic database. Only authorised people will have access to the database and all data.

### Data protection

The provisions of data protection legislation will be observed. It is assured by the research team and the CoRe-Net Data Trust Centre that all investigational materials and data will be pseudonymised in accordance with data protection legislation before scientific analyses.

Study subjects will be informed that their pseudonymised data will be passed on in agreement with provisions for documentation and notification in accordance with applicable law. Subjects who do not agree to data handling as described in the informed consent form will not be enrolled in the study.

### Patient public involvement

There are challenges particularly pertinent for most patient public involvement activities in PC, where people can be difficult to reach due to their advanced illness or caring responsibilities. For LYOL-C II, we were lucky to have a consortium within CoRe-Net consisting of patient representatives, bereaved relatives and experts from self-help groups, as well as healthcare workers in nursing homes, hospitals, hospices, etc within the region of Cologne. They all were directly involved in the development and design of the study. Several face-to-face meetings will take place on a regular basis within the consortium to discuss outcome measures, recruitment strategies and feasibility of study conduct.

### Ethics and dissemination

The ethical principles of the Declaration of Helsinki will be respected throughout the project. Ethical approval for this study was obtained from the Ethics Commission of the Faculty of Medicine the University of Cologne (#20-1431). Patients and relatives who are eligible for the study will be informed about the goals, content and procedures of the study and will be asked to provide written informed consent to participate following legal guidelines. Consent to access medical files is specifically requested. Patients are free to withdraw from the study at any moment. Although there is increasing evidence from our own studies that patients, even those in their last year, months and days of life, want to participate in research studies,[45] great care

must be exercised during the study to ensure that undue pressure or burden is not placed on study participants.

Study results will be presented and discussed within the CoRe-Net consortium and reported back to study participants by the use of factsheets. Final results will be published in peer-reviewed scientific journals and presented at national and international conferences. During the first phase of CoRe-Net, a research database was created containing primary and secondary data on healthcare in Cologne. The evidence of this research database will also be based on data stemming from LYOL-C II. At the end of the project, we will organise a summit to discuss the outcomes of the project and their follow-up in healthcare practice and policy.

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**Collaborators** Professor Dr Christian Albus, Professor Dr Frank Jessen, Dr Nadine Scholten, Professor Dr Stephanie Stock.

**Contributors** RV, GD and JS designed the study. AK and JS wrote the draft study protocol. MH wrote the statistical methods section. RV, GD, HP, MH, IM, KIH, BW, LK, FS-N and MS reviewed and commented on the drafts of the manuscript. All authors read and approved the final manuscript.

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**Competing interests** None declared.

**Patient and public involvement** Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the 'Methods and analysis' section for further details.

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