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Last Year of Life Study Cologne (LYOL-C): a cross-sectional mixed methods study to examine care trajectories and transitions in the last year of life until death

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Abstract

Introduction: The last year of life constitutes a particularly vulnerable phase for patients, involving nearly all health and social care structures. Yet, little scientific evidence is available that provides insight into the trajectories including the number and types of care setting transitions, transitions into palliative care and the dying phase. Only few studies have focused on difficulties associated with having to move between health and social care settings in the last year of life, although patients face a significant risk of adverse events. The Last Year of Life Study Cologne (LYOL-C) aims to fill this gap.

Methods and analysis: LYOL-C is a mixed methods study composed of four steps. i) Claims data collected by the statutory health insurance funds of deceased persons will be analyzed with regard to patient care trajectories, health service transitions and costs in the last year of life. ii) Patient trajectories and transitions in health care will additionally be reconstructed by analyzing the retrospective accounts of bereaved relatives (n=400) using a culturally adapted version of the VOICES-SF (Views of Informal Carers – Evaluation of Services Short Form) questionnaire and the PACIC-SF (Patient Assessment of Care for Chronic Conditions Short Form) questionnaire adapted for relatives. iii) Qualitative interviews with bereaved relatives (n=40-60) will provide in-depth insight into reasons for transitions and effects on patients' quality of life. iv) Focus groups (n=3-5) with Health Care Professionals will be conducted to discuss challenges associated with transitions in the last year of life.

Ethics and dissemination: Ethical approval has been obtained from the Ethics Commission of the Faculty of Medicine of Cologne University (#17-188). Results will be submitted for publication in peer-reviewed journals and presented at national and international conferences.

Trial registration: The study is registered in the German Clinical Trials Register (DRKS00011925) and in the Health Services Research Database (VfD_CoRe-Net_17_003806).

Words: 300

Keywords: end-of-life care, mixed methods, palliative care, health services research, dying phase

Strengths and limitations of the study

- LYOL-C will be the first study in Germany to examine health and social care trajectories and transitions of patients in their last year of life until death (independent of patient age, underlying diagnoses or care settings) within an entire region that possesses optimal palliative and hospice care structures.
- Our survey sample will be recruited through multiple channels and with a comparatively large sample size (n=400) for palliative settings to ensure variety in care trajectories and places of death.
- The mixed methods design enables a multidimensional view to reconstruct the last year of life including the reports of bereaved relatives as well as health care professionals.
- Claims data can be validated externally with our survey data and vice versa while the interviews and focus groups enable a clarification of claims data and survey results with a multi-stakeholder perspective.
- The perspective of relatives can't be seen as a direct substitute for a self-assessment of patients, although moderate agreement between patient and proxy ratings develops over time [1].

BACKGROUND

About 1% of the German population dies each year (e.g., in the year 2015, 925 200 deaths out of a total population of 81.6 million)[2]. For each patient who passes away, there are approx. three to four relatives who go through a subsequent bereavement period. This means that 5% of our population is affected by death each year, with the relative and absolute numbers increasing with changes in demography. In the year 2013, 46% of patients in Germany died in hospitals, with mortality rates increasing with age: 55% dying in hospitals were aged 65 and above. In North-Rhine-Westphalia, 49% died in hospitals, yet most people prefer to die at home, and hospitals have been perceived as giving only little support to patients´ needs at the end of life. Furthermore, home care is cost-effective when shifting the care of the dying patients from hospital to home [3-5]. This is even more important as about one-third of the total health expenditure in a life span occurs during the last months of life [6 7] and there have been increases in both aggressive and non-aggressive care at the end of life with increasing multiple hospitalizations [8].

The last year of life therefore constitutes a particularly vulnerable phase in life for patients, involving nearly all health and social care structures. Yet, so far, only very little scientific evidence is available that provides insight into the trajectories including the number and types of care setting transitions. Only few studies have focused on difficulties associated with having to move between health and social care settings in the last year of life, such as the burden to caregivers and cost of hospital transfers [9 10], although patients face a significant risk of adverse events, for instance during the transition from hospital to home [11]. The Last Year of Life Study Cologne (LYOL-C) aims to fill this gap by being the first study in Germany to examine patient trajectories (independent of age, underlying diagnoses or care settings) and transitions between care settings and experiences in the last year of life including palliative care integration and the dying phase within a specific region (Cologne). Trajectories are defined as "(…) a course of illness over time plus the actions taken by patients, families and health professionals to manage or shape the course"[12]. Gill et al.[13] have found that the illness leading to death does not predict a patient´s trajectory. Therefore it is necessary to identify typical trajectories in the last year of life and to thereby provide time frames and patterns of probable needs and support from health and social services for patients (and carers)[14]. A transition "(...) occurs between two locations or settings of care, for example moving from hospital to a care home. It may also represent a shift in the nature of care, such as the decision not to continue with curative treatments"[15]. Regarding LYOL-C, we therefore concentrate (a) on transitions within the disease trajectory, i.e. from a curative to a palliative approach as well as the dying phase and (b) transitions between health care structures, e.g., hospital to home, nursing home to hospital. It is important to study the patients´ and professionals' point of view on (i) which transitions take place, (ii) what are the reasons and determinants for these transitions (e.g., DRG-related factors), (iii) what are the effects on patient quality of life, (iv) whether how and when a palliative care approach was introduced and finally, (v) where and how patients die. Cologne, with its one million inhabitants, is representative of the German urban setting and already possesses optimal palliative and hospice care structures [16]. The LYOL-C study is the first step in developing a stable regional End of Life Care Network, similar to the National End of Life Network in the UK [17], which will bring together all stakeholders caring for people at the end of life. This network will also serve as the basis for immediate and future patient-centered and value-based changes derived from the initial descriptive and hypothesis-generating data obtained within the Cologne Research and Development Network (CoRe-Net). LYOL-C, being one of the CoRe-Net subprojects, aims to improve the management of patients in their last year of life including the dying phase.

Patient preferences and values must be integrated more into the development of health care structures [18]. This is especially relevant for and apparent in the last year of life, which is a major contributor to overall health care costs [6]. Palliative Care encompasses central elements associated with patient-centered and value-based care, including physical comfort and emotional support, dignity and respect during the dying process, shared decision making, identifying and meeting the patient's needs and values, and coordinating care [19 20]. Internationally it has been reported that despite the growing use of palliative and hospice care structures, there has been an increase in the number of transitions in the last year of life [15 21]. The primary contributors to this are structural factors (e.g., financial, legal) and a lack of emphasis on increasing value for patients and relatives [22]. The Patient-Centered Outcomes Research Institute has found that poorly executed transitions between health care settings can harm patients and lead to additional hospital visits [23] which can be burdensome and decrease quality of life [21 24]. In the US, hospital readmission follows 12-25% of hospital discharges in the last year of life, with almost 50% of readmissions going through an emergency room [25]. The fact that caregivers are often emotionally and physically burdened with providing home care is one factor leading to admission into inpatient care settings, despite the fact that relatives´ and patients´ preferences for home care have not changed. A recent study has found that a greater understanding of family caregivers' preferences is needed to identify how best to support families at the end of life and to ensure more patients are cared for in a value-based way [26].

For Germany, scientific evidence on the benefits of Palliative Care has emerged in recent years, currently mainly on specific aspects of care structures (e.g., discharge after stay in a palliative care unit) [27-29] or restricted to clinical questions, e.g., pain or breathlessness [30-32]. A general health services research approach incorporating all regional care structures is still missing. The city of Cologne, which is home to Germany's first palliative care unit founded at the University Hospital of Cologne in 1983, currently offers an area-wide palliative and hospice care setting including all care structures currently offered by the German system. Cologne even has a three-level palliative care structure – general (general practitioners [GPs], nursing), intermediate (qualified palliative care physicians and palliative care nursing [QPA]) and specialized palliative outpatient care (SAPV) – which is unique to the North-Rhine area. The city, therefore, provides the optimal urban setting for studying future health service developments in end-of-life care in Germany.

LYOL-C therefore aims to

I. examine care trajectories and transitions in the last year of life until death in Cologne,
II. improve the management of patients in their last year of life including the dying phase by consented immediate action in a patient-centered and value-based way,
III. derive further care innovations based on initial descriptive and hypothesis-generating data that could be evaluated in future studies.

METHODS AND ANALYSIS

LYOL-C is a mixed methods study and consists of four phases:

Phase I: Claims Data Analysis on the patient epidemiology of the last year of life

Several statutory health insurance funds (SHI) will provide anonymised claims data, covering together ~55% of the Cologne population. With regard to Cologne, about 800.000 people are insured with the SHI. Taking into account that 1% of them die each year (~8.000) [33], we are able to analyze patient trajectories of all deceased insurees of the participating SHI funds. Counting backward from date of death, the last year of life can be assessed for those continuously insured until death using data from the respective SHI fund. In a first step, deceased patients are characterized according to age, sex, medication (e.g., polypharmacy), morbidity (e.g., Charlson and Elixhauser comorbidity measures assessed by ICD 10 codes), utilization of long term nursing care (level and place of care) and other health problems highly prevalent in patients at the end of life (e.g., oral health issues). In addition, direct medical costs will be estimated for the last year of life according to sectors of care. Master data (e.g., insurance time, pseudonymized unique patient identifier) will be used for defining the study population, while master data (sex, age, nursing care) and information from all sectors of care will be used for describing the population and analyzing influencing factors on the outcome variables (e.g. number of transitions, place of death) using multiple regression analysis. Trajectories between sectors of care can be analyzed with the help of the pseudonymized patient identifiers. Emergency visits and hospital referrals according to doctor's specialty will be assessed. Analysis will be performed for all patients who died (excluding accidents and homicides). Analysis will provide a status quo of main care trajectories to be analyzed in the following steps.

Inclusion criteria: Deceased person who lived in Cologne and died aged 18 years or older.

Phase II: Quantitative survey with bereaved informal caregivers to analyze patient trajectories in the last year of life

Patient trajectories and transitions in health care will be reconstructed by analyzing the retrospective accounts of bereaved relatives (n=400). A questionnaire will be used, covering e.g., the number and types of transitions between care settings, use of palliative care services and (best) timing of admission to palliative care services. Data will also be collected using the validated Views of Informal Carers – Evaluation of Services Short Form (VOICES-SF) questionnaire. VOICES is a postal questionnaire about experiences of end of life care in the last months of life, focusing on quality of care and services received. Using the post-bereavement method it gathers information from bereaved relatives, friends or carers acting as proxies [34]. Within our study, we will adapt the questions of VOICES-SF to the German health care system and translate them into German. Procedures for translation and assessment are based on the team translation approach described by Harkness ("TRAPD") [35] which is also applied in cross-national social surveys (e.g. European Social Survey [36], Programme for the International Assessment of Adult Competencies [37]). To analyze patient-centeredness, the Patient Assessment of Care for Chronic Conditions Short Form (PACIC-SF) [38-40] will be applied. The instrument measures the extent to which patients receive care that is patient-centered, proactive, planned and includes collaborative goal setting, problem-solving and follow-up support. It is a validated patient self-report instrument and will be adapted for usage with bereaved relatives. Participants will be recruited mainly via our field access partners. Recruitment will also be done via newspaper advertisements, GPs, local GP networks (snowballing technique) and local bereavement groups run by palliative hospice structures. We expect recruitment to go smoothly, as recruitment also went rapidly in previous research projects, such as on living wills and multiple sclerosis [41 42].

The survey design allows comparisons to be made between the quality of care given to people dying at different ages (for example less than 65 years, 65-79 years or 80 years or more) and different causes of death (cardiovascular, cancer or other) and for people receiving care in different settings during the last months of life (for example home, hospital, care home and/or hospice). Analysis is undertaken in various statistical packages using weights and the sampling stratification. The VOICES survey e.g. calculates a weight for each response to the survey, to account for biases within the sample design, adjust for non-response bias and calibrate weights to the population of the sampling frame. These weights are used to calculate weighted percentages. Data will be analyzed using SPSS Statistics 24.

Inclusion Criteria: Relatives, friends, carers and volunteers can be included if i) they are 18 years or older, ii) they have cared for a deceased person in his/her last year of life, iii) the deceased person was 18 years or older, iv) his/her death has occurred in the last 12 months.

Exclusion Criteria: Accidental death and killing.

Phase III: In-depth interviews with bereaved informal caregivers to gain insight into patient trajectories

Qualitative interviews (n=40 to 60, by means of purposeful sampling to secure maximum heterogeneity) with bereaved relatives will provide in-depth insight into the reasons for transitions and the effects on the quality of life of the patients, including in the dying phase. Relatives will be recruited based on the type of care trajectory, the five most frequent types of trajectories (as reconstructed from the claims data analysis and questionnaire survey), site of death, underlying diagnoses, living situation, age and sex of the deceased. Interviews will follow a topic guide to ensure consistency across interviews. Interviews will be conducted during the first 12 months after death to ensure that relatives' memories are sufficiently fresh for them to provide details about their experiences. They can decide by themselves about the best timing for them to participate in the interview and feel able to speak about their experiences without becoming too upset. All interviews will be recorded, transcribed verbatim and anonymized.

Krueger & Casey (2000) advocate the use of a computer-based approach for cutting, pasting, sorting, arranging and rearranging data through comparing and contrasting the relevant information. For this purpose we will use MAXQDA, professional software for qualitative data analysis, as already mentioned for analyzing patient trajectories via qualitative interviews. Data will be analyzed according to Fisseni [43] and applying qualitative content analysis according to Flick [44] which has already been successfully performed in some of our own studies [45 46].

Inclusion criteria: see phase II

Exclusion criteria: see phase II

Phase IV: Focus Groups with Health Care Professionals (HCPs) to analyze views on transitions

Focus groups (n=3-5) with HCPs will be conducted to discuss challenges associated with transitions in the last year of life and identify key issues and possibilities for improvements in the organization. Following analysis of the data extracted in phases I to III, focus groups will be conducted with key health and social care providers involved in the care of people in the last year of life within hospital and outpatient settings, nursing homes, hospices, etc. The aim is to explore current practice in health and social care management and the way that transitions to a palliative care approach and transitions between structures are managed in different settings and how the care organizations are able to assess patient needs, preferences and health literacy. This phase will be conducted with support from our field access partners. Purposive sampling will be used to select a diverse range of HCPs and achieve the maximum possible variation of experience and opinion. Data will be analyzed according to Fisseni [43] and applying qualitative content analysis according to Flick [44].

Inclusion criteria: HCPs involved in the care of people in the last year of life in Cologne.

The study period will be from February 2017 to January 2020.

ETHICS AND DISSEMINATION

People who are approaching the end of life are particularly vulnerable. We will therefore analyze the views of bereaved relatives as well as health professionals and analyze claims data to describe patients' trajectories. The Oxford Textbook of Palliative Medicine [47] sets out five ethical aspects that should be considered when undertaking palliative care research: the study's potential benefits to future patients, the study's potential benefits to subjects, the study's risk to subjects, subjects' decision-making capacity, and the voluntariness of subjects' choices about research participation. All these aspects will be addressed within our project and all respondents will only participate with an informed consent. Ethical approval for this study was obtained from the Ethics Commission of the Faculty of Medicine of Cologne University (#17-188).

Restructuring complex care for vulnerable patients at the end of life is highly needed in Germany because these patients often are lost in transition between multi-professional and multi-institutional care providers. This generates unnecessary costs, ill-health and thus low value for patient and their relatives and caregivers. The results of our study will be disseminated within the region of Cologne via the Cologne lab conferences and CoRe-Net public relations. To further implement regional changes, CoRe-Net will be immediately "available" as a "Cologne lab" with collaboration partners, a large database and standardized pathways derived from the projects. Possible changes that can be directly implemented after the first funding phase (years 1-3) of LYOL-C are, e.g., "round tables" for health professionals treating patients in their last year of life in order to discuss sign-posts for transitions.

Results of all four phases will be submitted for publication in peer-reviewed journals and presented at national and international conferences.

List of Abbreviations

CoRe-Net – Cologne Research and Development Network

GP – General Practitioner
HCPs – Health Care Professionals
LYOL-C – Last Year of Life Study Cologne
PACIC-SF - Patient Assessment of Care for Chronic Conditions Short Form
QPA - qualified palliative care physicians
SAPV - specialized palliative outpatient care
SHI – Statutory Health Insurance Funds
VOICES-SF - Views of Informal Carers – Evaluation of Services Short Form

Declarations

- Authors´ contributions

JS is Principal Investigator and responsible for the study design and project management

GH is responsible for the operative management of LYOL-C, the recruitment, data collection, data analysis, dissemination

NS is responsible for the recruitment, data collection, data analysis, dissemination

HP and UK are principal investigators of CoRe-net and responsible for methodological consulting

CR is Principal Investigator and responsible for the study design and project management

RV is Principal Investigator and responsible for the study design and project management

All authors read an approved the final manuscript.

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- Ethics approval and consent to participate

Ethical approval for this study was obtained from the Ethics Commission of the Faculty of Medicine of Cologne University (#17-188).

- Consent of publication

Not applicable.

- Availability of data and material

The datasets generated and/or analyzed during the current study are available from the corresponding author on reasonable request.

- Competing interests

The authors declare that they have no competing interests.

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Last Year of Life Study Cologne (LYOL-C): protocol for a cross-sectional mixed methods study to examine care trajectories and transitions in the last year of life until death

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Last Year of Life Study Cologne (LYOL-C): protocol for a cross-sectional mixed methods study to examine care trajectories and transitions in the last year of life until death

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Abstract

Introduction: The last year of life constitutes a particularly vulnerable phase for patients, involving nearly all health and social care structures. Yet, little scientific evidence is available that provides insight into the trajectories including the number and types of care setting transitions, transitions into palliative care and the dying phase. Only few studies have focused on difficulties associated with having to move between health and social care settings in the last year of life, although patients face a significant risk of adverse events. The Last Year of Life Study Cologne (LYOL-C) aims to fill this gap.

Methods and analysis: LYOL-C is a mixed methods study composed of four steps. i) Claims data collected by the statutory health insurance funds of deceased persons will be analyzed with regard to patient care trajectories, health service transitions and costs in the last year of life. ii) Patient trajectories and transitions in health care will additionally be reconstructed by analyzing the retrospective accounts of bereaved relatives (n=400) using a culturally adapted version of the VOICES-SF (Views of Informal Carers – Evaluation of Services Short Form) questionnaire and the PACIC-SF (Patient Assessment of Care for Chronic Conditions Short Form) questionnaire adapted for relatives. iii) Qualitative interviews with bereaved relatives (n=40-60) will provide in-depth insight into reasons for transitions and effects on patients' quality of life. iv) Focus groups (n=3-5) with Health Care Professionals will be conducted to discuss challenges associated with transitions in the last year of life.

Ethics and dissemination: Ethical approval has been obtained from the Ethics Commission of the Faculty of Medicine of Cologne University (#17-188). Results will be submitted for publication in peer-reviewed journals and presented at national and international conferences.

Trial registration: The study is registered in the German Clinical Trials Register (DRKS00011925) and in the Health Services Research Database (VfD_CoRe-Net_17_003806).

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Keywords: end-of-life care, mixed methods, palliative care, health services research, dying phase

Strengths and limitations of the study

- LYOL-C will be the first study in Germany to examine health and social care trajectories and transitions of patients in their last year of life until death (independent of patient age, underlying diagnoses or care settings) within an entire region that possesses optimal palliative and hospice care structures.
- Our survey sample will be recruited through multiple channels and with a comparatively large sample size (n=400) for palliative settings to ensure variety in care trajectories and places of death.
- The mixed methods design enables a multidimensional view to reconstruct the last year of life including the reports of bereaved relatives as well as health care professionals.
- Claims data can be validated externally with our survey data and vice versa while the interviews and focus groups enable a clarification of claims data and survey results with a multi-stakeholder perspective.
- The perspective of relatives can’t be seen as a direct substitute for a self-assessment of patients, although moderate agreement between patient and proxy ratings develops over time.

BACKGROUND

About 1% of the German population dies each year (e.g., in the year 2015, 925 200 deaths out of a total population of 81.6 million)[1]. For each patient who passes away, there are approx. three to four relatives who go through a subsequent bereavement period. This means that 5% of our population is affected by death each year, with the relative and absolute numbers increasing with changes in demography. In the year 2013, 46% of patients in Germany died in hospitals, with mortality rates increasing with age: 55% dying in hospitals were aged 65 and above. In North-Rhine-Westphalia, 49% died in hospitals, yet most people prefer to die at home, and hospitals have been perceived as giving only little support to patients´ needs at the end of life. Furthermore, home care is cost-effective when shifting the care of the dying patients from hospital to home [2-4]. This is even more important as about one-third of the total health expenditure in a life span occurs during the last months of life [5 6] and there have been increases in both aggressive and non-aggressive care at the end of life with increasing multiple hospitalizations [7]. Furthermore, recent studies report of worsening symptom prevalence in the last year of life and raise concerns about shortcomings in end-of-life care and that there remain persistent gaps in addressing symptoms near the end of life[8 9] .

The last year of life therefore constitutes a particularly vulnerable phase in life for patients, involving nearly all health and social care structures. Yet, so far, only very little scientific evidence is available that provides insight into the trajectories including the number and types of care setting transitions. Only few studies have focused on difficulties associated with having to move between health and social care settings in the last year of life, such as the burden to caregivers and cost of hospital transfers [10 11], although patients face a significant risk of adverse events, for instance during the transition from hospital to home [12]. The Last Year of Life Study Cologne (LYOL-C) aims to fill this gap by being the first study in Germany to examine patient trajectories (independent of age, underlying diagnoses or care settings) and transitions between care settings and experiences in the last year of life including palliative care integration and the dying phase within a specific region (Cologne). Trajectories are defined as “(…) a course of illness over time plus the actions taken by patients, families and health professionals to manage or shape the course”[13]. Gill et al.[14] have found that the illness leading to death does not predict a patient´s trajectory. Therefore it is necessary to identify typical trajectories in the last year of life and to thereby provide time frames and patterns of probable needs and support from health and social services for patients (and carers)[15]. A transition “(...) occurs between two locations or settings of care, for example moving from hospital to a care home. It may also represent a shift in the nature of care, such as the decision not to continue with curative treatments”[16]. Regarding LYOL-C, we therefore concentrate (a) on transitions within the disease trajectory, i.e. from a curative to a palliative approach as well as the dying phase and (b) transitions between health care structures, e.g., hospital to home, nursing home to hospital. It is important to study the patients´ and professionals' point of view on (i) which transitions take place, (ii) what are the reasons and determinants for these transitions (e.g., DRG-related factors), (iii) what are the effects on patient quality of life, (iv) whether how and when a palliative care approach was introduced and finally, (v) where and how patients die. Cologne, with its one million inhabitants, is representative of the German urban setting and already possesses optimal palliative and hospice care structures [17]. The LYOL-C study is the first step in developing a stable regional End of Life Care Network, similar to the National End of Life Network in the UK [18], which will bring together all stakeholders caring for people at the end of life. This network will also serve as the basis for immediate and future patient-centered and value-based changes derived from the initial descriptive and hypothesis-generating data obtained within the Cologne Research and Development Network (CoRe-Net). LYOL-C, being one of the CoRe-Net subprojects, aims to improve the management of patients in their last year of life including the dying phase.

Patient preferences and values must be integrated more into the development of health care structures [19]. This is especially relevant for and apparent in the last year of life, which is a major contributor to overall health care costs [5]. Palliative Care encompasses central elements associated with patient-centered and value-based care, including physical comfort and emotional support, dignity and respect during the dying process, shared decision making, identifying and meeting the patient's needs and values, and coordinating care [20 21]. A recent study showed that community-based specialist palliative care was associated with hospital cost reductions across multiple life-limiting conditions [22]. Internationally it has been reported that despite the growing use of palliative and hospice care structures, there has been an increase in the number of transitions in the last year of life [16 23]. The primary contributors to this are structural factors (e.g., financial, legal) and a lack of emphasis on increasing value for patients and relatives [24]. The Patient-Centered Outcomes Research Institute has found that poorly executed transitions between health care settings can harm patients and lead to additional hospital visits [25] which can be burdensome and decrease quality of life [23 26]. In the US, hospital readmission follows 12-25% of hospital discharges in the last year of life, with almost 50% of readmissions going through an emergency room [27]. The fact that caregivers are often emotionally and physically burdened with providing home care is one factor leading to admission into inpatient care settings, despite the fact that relatives´ and patients´ preferences for home care have not changed. A recent study has found that a greater understanding of family caregivers' preferences is needed to identify how best to support families at the end of life and to ensure more patients are cared for in a value-based way [28].

For Germany, scientific evidence on the benefits of Palliative Care has emerged in recent years, currently mainly on specific aspects of care structures (e.g., discharge after stay in a palliative care unit) [29-31] or restricted to clinical questions, e.g., pain or breathlessness [32-34]. A general health services research approach incorporating all regional care structures is still missing. The city of Cologne, which is home to Germany's first palliative care unit founded at the University Hospital of Cologne in 1983, currently offers an area-wide palliative and hospice care setting including all care structures currently offered by the German system. Cologne even has a three-level palliative care structure – general (general practitioners [GPs], nursing), intermediate (qualified palliative care physicians and palliative care nursing [QPA]) and specialized palliative outpatient care (SAPV) – which is unique to the North-Rhine area. The city, therefore, provides the optimal urban setting for studying future health service developments in end-of-life care in Germany.

LYOL-C therefore aims to

I. examine care trajectories and transitions in the last year of life until death in Cologne,
II. improve the management of patients in their last year of life including the dying phase by consented immediate action in a patient-centered and value-based way,
III. derive further care innovations based on initial descriptive and hypothesis-generating data that could be evaluated in future studies.

The study period will be from February 2017 to January 2020.

METHODS AND ANALYSIS

LYOL-C is a mixed methods study and consists of four phases:

Phase I: Claims Data Analysis on the patient epidemiology of the last year of life

Several statutory health insurance funds (SHI) will provide anonymised claims data, covering together ~55% of the Cologne population. With regard to Cologne, about 800.000 people are insured with the SHI. Taking into account that 1% of them die each year (~8.000) [35], we are able to analyze patient trajectories of all deceased insurees of the participating SHI funds. Counting backward from date of death, the last year of life can be assessed for those continuously insured until death using data from the respective SHI fund. In a first step, deceased patients are characterized according to age, sex, medication (e.g., polypharmacy), morbidity (e.g., Charlson and Elixhauser comorbidity measures assessed by ICD 10 codes), utilization of long term nursing care (level and place of care) and other health problems highly prevalent in patients at the end of life (e.g., oral health issues). In addition, direct medical costs will be estimated for the last year of life according to sectors of care. Master data (e.g., insurance time, pseudonymized unique patient identifier) will be used for defining the study population, while master data (sex, age, nursing care) and information from all sectors of care will be used for describing the population and analyzing influencing factors on the outcome variables (e.g. number of transitions, place of death) using multiple regression analysis. Trajectories between sectors of care can be analyzed with the help of the pseudonymized patient identifiers. Emergency visits and hospital referrals according to doctor's specialty will be assessed. Analysis will be performed for all patients who died (excluding accidents and homicides). Analysis will provide a status quo of main care trajectories to be analyzed in the following steps.

Inclusion criteria: Deceased person who lived in Cologne and died aged 18 years or older. We relate to deaths that have occurred in the last 12 months prior to the survey (November 2016 to April 2018).

Phase II: Quantitative survey with bereaved informal caregivers to analyze patient trajectories in the last year of life

Patient trajectories and transitions in health care will be reconstructed by analyzing the retrospective accounts of bereaved relatives (n=400). A questionnaire will be used, covering e.g., the number and types of transitions between care settings, use of palliative care services and (best) timing of admission to palliative care services. Data will also be collected using the validated Views of Informal Carers – Evaluation of Services Short Form (VOICES-SF) questionnaire. VOICES is a postal questionnaire about experiences of end of life care in the last months of life, focusing on quality of care and services received. Using the post-bereavement method it gathers information from bereaved relatives, friends or carers acting as proxies [36]. Within our study, we will adapt the questions of VOICES-SF to the German health care system and translate them into German. Procedures for translation and assessment are based on the team translation approach described by Harkness ("TRAPD") [37] which is also applied in cross-national social surveys (e.g. European Social Survey [38], Programme for the International Assessment of Adult Competencies [39]). To analyze patient-centeredness, the Patient Assessment of Care for Chronic Conditions Short Form (PACIC-SF) [40-42] will be applied. The PACIC-SF adapted for relatives will be validated in the course of our project. The instrument measures the extent to which patients receive care that is patient-centered, proactive, planned and includes collaborative goal setting, problem-solving and follow-up support. It is a validated patient self-report instrument and will be adapted for usage with bereaved relatives. Participants will be recruited mainly via our field access partners, e.g. hospices, care facilities, nursing homes, specialized outpatient palliative care services, palliative care units, ecclesiastical institutions, community centers, funeral homes. Recruitment will also be done via newspaper advertisements, GPs, local GP networks (snowballing technique) and local bereavement groups run by palliative hospice structures. We expect recruitment to go smoothly, as recruitment also went rapidly in previous research projects, such as on living wills and multiple sclerosis [43 44].

The survey design allows comparisons to be made between the quality of care given to people dying at different ages (for example less than 65 years, 65-79 years or 80 years or more) and different causes of death (cardiovascular, cancer or other) and for people receiving care in different settings during the last months of life (for example home, hospital, care home and/or hospice). Analysis is undertaken in various statistical packages using weights and the sampling stratification. The VOICES survey e.g. calculates a weight for each response to the survey, to account for biases within the sample design, adjust for non-response bias and calibrate weights to the population of the sampling frame. These weights are used to calculate weighted percentages. Data will be analyzed using SPSS Statistics 24.

Inclusion Criteria: Relatives, friends, carers and volunteers can be included if i) they are 18 years or older, ii) they have cared for a deceased person in his/her last year of life, iii) the deceased person was 18 years or older, iv) his/her death has occurred in the last 12 months.

Exclusion Criteria: Accidental death and killing.

Phase III: In-depth interviews with bereaved informal caregivers to gain insight into patient trajectories

Qualitative interviews (n=40 to 60, by means of purposeful sampling to secure maximum heterogeneity) with bereaved relatives will provide in-depth insight into the reasons for transitions and the effects on the quality of life of the patients, including in the dying phase. Relatives will be recruited based on the type of care trajectory, the five most frequent types of trajectories (as reconstructed from the claims data analysis and questionnaire survey), site of death, underlying diagnoses, living situation, age and sex of the deceased. Interviews will follow a topic guide to ensure consistency across interviews. Interviews will be conducted during the first 12 months after death to ensure that relatives' memories are sufficiently fresh for them to provide details about their experiences. They can decide by themselves about the best timing for them to participate in the interview and feel able to speak about their experiences without becoming too upset. All interviews will be recorded, transcribed verbatim and anonymized.

Krueger & Casey (2000) advocate the use of a computer-based approach for cutting, pasting, sorting, arranging and rearranging data through comparing and contrasting the relevant information. For this purpose we will use MAXQDA, professional software for qualitative data analysis, as already mentioned for analyzing patient trajectories via qualitative interviews. Data will be analyzed according to Fisseni [45] and applying qualitative content analysis according to Flick [46] which has already been successfully performed in some of our own studies [47 48].

Inclusion criteria: see phase II

Exclusion criteria: see phase II

Phase IV: Focus Groups with Health Care Professionals (HCPs) to analyze views on transitions

Focus groups (n=3-5) with HCPs will be conducted to discuss challenges associated with transitions in the last year of life and identify key issues and possibilities for improvements in the organization. Following analysis of the data extracted in phases I to III, focus groups will be conducted with key health and social care providers involved in the care of people in the last year of life within hospital and outpatient settings, nursing homes, hospices, etc. The aim is to explore current practice in health and social care management and the way that transitions to a palliative care approach and transitions between structures are managed in different settings and how the care organizations are able to assess patient needs, preferences and health literacy. This phase will be conducted with support from our field access partners. Purposive sampling will be used to select a diverse range of HCPs and achieve the maximum possible variation of experience and opinion. Data will be analyzed according to Fisseni [45] and applying qualitative content analysis according to Flick [46].

Inclusion criteria: HCPs involved in the care of people in the last year of life in Cologne.

Patient and Public Involvement (PPI)

PPI has been embedded in the study from conception, one PPI contributor for instance was a cooperation partner and bereaved relative. We had support in the development of the research design from several collaboration partners to discuss the relevance of the study and that it will be participant friendly and ethically sound.

To enhance PPI even further, a meeting with field access partner was conducted to inform each phase of the study design. Furthermore, a network meeting took place with more than 70 participants. This meeting intended to inform about CoRe-Net and create the future of the Cologne Research and Development Network together. The meeting was attended by patient and relative representatives, representatives from health insurances and the medical chamber, science and medical professions, besides many others involved in health and social care in Cologne. Each meeting was constructed around various phases of the research project. The face-to-face meetings included presentations by the research team about the study and its progress.

With regard to disseminating results to study participants, the results and deliverables will be disseminated within the region of Cologne via the Cologne lab conferences and CoRe-Net-Public Relations. Through the networks and projects in which the members of CoRe-Net are key stakeholders, national and international dissemination of experience can be assured. For

LYOL-C, dissemination will be done via e.g., the National Society for Palliative Care, the National Palliative Care Strategy, the European Association for Palliative Care, the European Academy of Palliative Care, and the UK End-of-Life Network with our collaboration partner Prof. Dr. Sheila Payne.

ETHICS AND DISSEMINATION

People who are approaching the end of life are particularly vulnerable. We will therefore analyze the views of bereaved relatives as well as health professionals and analyze claims data to describe patients' trajectories. The Oxford Textbook of Palliative Medicine [49] sets out five ethical aspects that should be considered when undertaking palliative care research: the study's potential benefits to future patients, the study's potential benefits to subjects, the study's risk to subjects, subjects' decision-making capacity, and the voluntariness of subjects' choices about research participation. All these aspects will be addressed within our project and all respondents will only participate with an informed consent. Ethical approval for this study was obtained from the Ethics Commission of the Faculty of Medicine of Cologne University (#17-188).

Restructuring complex care for vulnerable patients at the end of life is highly needed in Germany because these patients often are lost in transition between multi-professional and multi-institutional care providers. This generates unnecessary costs, ill-health and thus low value for patient and their relatives and caregivers. The results of our study will be disseminated within the region of Cologne via the Cologne lab conferences and CoRe-Net public relations. To further implement regional changes, CoRe-Net will be immediately "available" as a "Cologne lab" with collaboration partners, a large database and standardized pathways derived from the projects. Possible changes that can be directly implemented after the first funding phase (years 1-3) of LYOL-C are, e.g., "round tables" for health professionals treating patients in their last year of life in order to discuss sign-posts for transitions.

Results of all four phases will be submitted for publication in peer-reviewed journals and presented at national and international conferences.

List of Abbreviations

CoRe-Net – Cologne Research and Development Network
GP – General Practitioner
HCPs – Health Care Professionals
LYOL-C – Last Year of Life Study Cologne
PACIC-SF - Patient Assessment of Care for Chronic Conditions Short Form
QPA - qualified palliative care physicians

SAPV - specialized palliative outpatient care

SHI – Statutory Health Insurance Funds

VOICES-SF - Views of Informal Carers – Evaluation of Services Short Form

Declarations

- Authors´ contributions

JS is Principal Investigator and responsible for the study design and project management

GH is responsible for the operative management of LYOL-C, the recruitment, data collection, data analysis, dissemination

NS is responsible for the recruitment, data collection, data analysis, dissemination

HP and UK are principal investigators of CoRe-net and responsible for methodological consulting

CR is Principal Investigator and responsible for the study design and project management

RV is Principal Investigator and responsible for the study design and project management

All authors read an approved the final manuscript.

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- Ethics approval and consent to participate

Ethical approval for this study was obtained from the Ethics Commission of the Faculty of Medicine of Cologne University (#17-188).

- Consent of publication

Not applicable.

- Availability of data and material

The datasets generated and/or analyzed during the current study are available from the corresponding author on reasonable request.

- Competing interests

The authors declare that they have no competing interests.

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Ludwig Kuntz, Department of Business Administration and Health Care Management, Faculty of Management, Economics and Social Sciences (FMESS), UoC, Dr. Ingrid Schubert, PMV Health Care Research Group, FM, UoC, Prof. Dr. Frank Schulz-Nieswandt, Institute for Sociology and Social Psychology, FMESS, UoC, Prof. Dr. Stephanie Stock, Institute for Health Economics and Clinical Epidemiology, FM, UHC. We would also like to thank Dieter Jänsch for his support as a patient adviser and relative for his enormous support.

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