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Getting palliative medications right across the contexts of homes, hospitals, and hospices: protocol to synthesise scoping review and ethnographic methods in an Activity Theory analysis

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Title: Getting palliative medications right across the contexts of homes, hospitals, and hospices: protocol to synthesise scoping review and ethnographic methods in an Activity Theory analysis

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Abstract

Introduction

Prescribing and medication use in palliative care is a multi-step process. It requires systems coordination and is enacted through activities of patients, informal carers and professionals. This study compares practice to idealised descriptions of what should happen; identifying when, how and why process disturbances impact on quality and safety. Our objectives are to:

1. document an intended model (phase 1, scoping review);
2. refine the model with study of practice (phase 2, ethnography);
3. use the model to pinpoint 'hot' (viewed as problematic by participants) and 'cold' spots (observed as problematic by researchers) within or when patients move across three contexts - hospice, hospital, and community (home);
4. create learning recommendations for quality and safety targeted at underlying themes and contributing factors.

Methods and analysis

The review will scope Ovid Medline, CINAHL and Embase, Google Scholar and Images - no date limits, English language only. The Population (palliative), Concept (medication use), Context (home, hospice, hospital) framework defines inclusion/exclusion criteria. Data will be extracted to create a model illustrating how processes ideally occur, incorporating multiple steps of typical episodes of prescribing and medication use for symptom control. Direct observations, informal conversations around acts of prescribing and medication use, and semi-structured interviews will be conducted with a purposive sample of patients, carers and professionals. Drawing on Activity Theory, we will synthesise analysis of both phases. The analysis will identify when, how and why activities affect patient safety and experience. Generating a rich multivoiced understanding of the process will help identify meaningful targets for improvement.

Ethics and dissemination

Ethical approval is obtained. A patient and public involvement (PPI) co-investigator, a multi-professional steering group and a PPI engagement group are working with the research team. Dissemination of findings is planned through peer-reviewed publications, and a stakeholder (policymakers, commissioners, clinicians, researchers, public) report/dissemination event.

Article Summary

Strengths and limitations of this study

- There has been no previous mapping of idealised intended multi-step processes associated with prescribing and medication use in palliative care.
- Evidence of real-life practices of prescribing and medication use in palliative care across different contexts will illuminate understanding underlying themes and contributing factors to disruptions in intended processes.
- Analysis of activity systems, comparing between the intended and practice process models, will inform areas to target innovation and improvement.
- This study adopts the method of activity theory analysis to interrogate local service provision in palliative medication use in one area of England, but can offer a template by which to investigate prescribing also in other clinical and geographical areas.

- The cross-sectional design will provide a detailed snapshot of activity but cannot formally track longitudinal change due to resource limitations.

Keywords: Activity Theory; Palliative Care; Prescription Drugs; Qualitative Research

Lay summary developed with PPI co-investigator and approved by funder

Background
People with palliative care needs use prescription medications to achieve symptom control. 'Daily hassles' with medications are commonly reported. What happens in 'real life' and the effort required to achieve effective medication use in palliative care is poorly understood.

Aims
The study will collect information from patients, carers and professionals to:
1. Map 'real life' practices underlying medication use including:
   - Decision-making
   - Prescribing
   - Monitoring and supply
   - Use (Administration)
   - Stopping/disposal of medications
   - Moving across healthcare and other contexts, such as homes.
2. Understand challenges patients and carers face and what they do/do not do to achieve effective medication use.
3. Understand impact of professional practices on medication use.

Design and Methods
Three types of context will be identified in order to recruit from home, hospital and hospice. We will develop a pictorial (visual) process model of how using prescription medications should work in palliative care. We will then observe and explore what really happens and collect information about people's experiences of medication use to develop a 'real life' model. Activity theory, which can be used to good effect in analysing healthcare processes and practices, will help us to understand what happens, who does what, and what occurs when a patient moves across contexts.

Patient and Public Involvement (PPI)
Consultation with patients, families, friends, carers and healthcare professionals helped us to develop this proposal. A PPI co-applicant and co-author is part of the team, they will:
   - Provide an 'expert-by-experience' perspective
   - Assist the research team to engage a wider PPI population
   - Co-produce study dissemination products and activities
   - All participants will be invited to a dissemination event and receive the study report.

Main Text

Introduction

Prescribing and medication use for symptom control in palliative care is a multi-step process that encompasses everything from identifying need to deciding what to prescribe, prescribing, dispensing, delivering, use/administration and disposal. Each step involves complex risk-prone tasks with frequent errors.[1,2,3,4,5,6,7,8]Of 475 NHS (National Health Service, England & Wales) serious incident reports (2002-2014) involving palliative patients, 91 (~20%) related to medications.[9] These mostly occurred in patients' own homes, half of which were when care was not provided by specialists.

Evidence specific to prescribing, medication use and error prevention in palliative care is scarce, with an absence of studies of the multiple steps involved or how these link in practice.[10] Absence of evidence prevents policy and other interventions targeting underlying themes and contributing factors when problems occur.[11] A better understanding of practices experienced, as distinct from intended processes, can identify targets for system change, new ways of working and new forms of practice.[12,13,14,15,16] To address this, the multi-step process of prescribing and medication use should be conceptualised as a series of socially constructed practices in which patients, informal carers and professionals are required to collaborate across locations and organisational boundaries.[17,18,19]

Optimal prescribing and medication use are influenced by 'etiquette'; socially mediated evolutionary rules and boundaries, with unclear divisions of labour, shaping practice and disrupting intended processes.[10,20,21,22,23,24,25,26,27,28] Expectations of primary and acute care professionals prescribing for symptom control[29] contrast with reported hindrances of lack of time, confidence and skills.[30,31,32] Existing research[17,33] also reports high patient/carer workload, all groups involved experiencing struggles with multi-step processes and practices, plus a lack of shared understanding of roles and responsibilities between patients/carers and different professionals.[33,34,] Often only patients (and by proxy their carers) experience all components of healthcare systems, as they move across contexts, gaining insight into where system redesign is needed.[14] This protocol addresses a *"high priority research area that is important clinically and in the community, as mismanaged medication can be frightening for carers and families"*.[35]

Methods and analysis

Aims

1. compare how prescribing and medication use appear in practice to idealised descriptions of what should happen in the multi-step process;
2. identify when, how and why process disturbances affect quality and safety.

Research questions

1. What are the experiences of patients, carers and professionals of prescribing and medication use?
2. Who does what, when and where in the multi-step process of prescribing and medication use for symptom control in palliative care?
3. What impact do differences between the idealised intended process and the realities of practice have?

Objectives

Prescribing and medication use in palliative care will be studied across three contexts:: community (home), hospital and hospice to:

1. document an intended model of activities and outcomes of prescription medication use in palliative care for symptoms control …. (phase 1, scoping review);
2. refine and elaborate the model with an ethnographic study of what happens in practice (phase 2, ethnography).
3. use the refined model to pinpoint 'hot' spots (viewed as problematic by participants) and 'cold' spots (observed as problematic by research team) within a single context or when patients move across hospice, hospital, and home contexts
4. create a learning and recommendation toolkit for improvement targeted at understanding underlying themes and contributing factors to process disturbances in practice.

Theoretical orientation and study design

This study draws on activity theory (AT, also known as Cultural-Historical-Activity-Theory, CHAT)[36] to examine processes and practices including workarounds dependent on interactions between the agency of people and system structures. It extends and complements the work of others[37,38] through a systematic view of patient safety and risk in palliative care, applied to prescribing and medication use.

Our approach builds on a proof-of-concept study in antibiotic prescribing.[10] An identified limitation of this antibiotic study was the single perspective (captured solely in interview data) and single setting. Our work will offer an in depth analysis of 'what happens on paper' and 'what happens in the real world' of the palliative care medication activity from multiple perspectives within and across multiple contexts.[39]

The concept of activity describes 'the fundamental interaction between humans and the world - humans behave actively toward the world (fragments of it), change it (them), and change themselves in this process. Humans as active subjects make fragments of the world objects (goals) of their activity and the same time are affected by the world (fragments of it)'.[40] Definitions and an explanatory figure of other key AT concepts are in Supplementary Files: Supplementary Table 1 and Supplementary Figure 1.

Because AT considers reciprocal interactions between (1) theory and practices and processes and (2) systems and people (community), it provides a framework to analyse how interactions evolve (or fail), when a group of people are (or should be) working to achieve a shared goal.[41]

AT acknowledges that intended process descriptions differ from actual execution because processes are only partially scripted strings of actions, influenced and interacting with other parallel processes.[42,43] This is especially important in palliative care since provision is within and across complex contexts, encompassing multiple providers and communities. To conduct our analysis we will work from the perspective of patients' activity systems focused on the object (goal) of achieving symptom control through accurate and effective prescribing and medication use. A theoretically informed, empirically-evidenced model will be produced to identify targets for innovation and improvement in prescribing and medication use across palliative care contexts.

The study has two phases: a scoping review and an ethnographic study. In the final analysis the findings from each of these will be synthesised together to meet the overarching objectives of the work.

Patient and public involvement(PPI)

This study addresses issues identified by the James Lind Alliance Palliative and End-of-Life Care Priority Setting Partnership.[52] The PPI co-investigator was recruited to co-produce the study from inception. Two independent PPI representatives were consulted (pre- and post-funding award) in addition to sharing the study design with the Marie Curie Research Voices PPI group. A PPI engagement group (n=10) has been recruited. Consultation with stakeholders through our PPI and Steering Groups (clinical and methodology experts) will continue throughout study execution and dissemination.

Phase 1: Scoping Review

This scoping review will use the nine-step Joanna Briggs Institute (JBI) framework methodology.[44,45,46,47]

Step 1: Review objectives

We seek to identify key definitions, concepts, characteristics and factors related to activities and outcomes of prescription medication use in palliative care for symptoms control. Specifically, the review objectives are to establish evidence for an idealised intended process for prescribing and medication use, documenting from whose perspectives, and what contexts this has been studied. We will also note any evidence of challenges in the process steps, and proposed solutions to these, to guide the empirical ethnography of phase 2.

Step 2: Aligning the inclusion criteria with objectives

Figure 1 demonstrates the relationship between the review objectives, questions and inclusion criteria. The Population (receiving palliative care), Concept (prescribing and medication use), Context (home, hospice, hospital) framework defines our inclusion criteria (Figure 1). Exclusions are shown in Box 1. We will include empirical research (quantitative and qualitative), review studies (if answering a novel question), policy documents, practice standard and guidelines, organisational flowcharts, and reports focusing on how the processes should occur or gaps between any benchmark and what does occur. No date limits, English language only.

Insert approx. here. Figure 1: Relationship between review objectives, questions and inclusion criteria

Box 1. Scoping review exclusion criteria

Box 1: Scoping review exclusion criteria

- Studies focussed on neonatal, paediatric or adolescent populations
- Studies on palliative care as a result of trauma or attempted suicide
- Studies focussed on medication prescribed for indications other than symptom control or generic medication use principles without application to palliative care.
- Ethical dilemmas associated with prescribing in palliative care.
- Opinion pieces, anecdotes, editorials, narratives or commentaries without reference to any form of intended process or practice (e.g. solely first person experience of

Step 3: Design for evidence searching, selection, data extraction, and presentation

Preliminary searches of Prospero, Medline (Ovid), CINAHL Plus (EBSCOhost), Embase (Ovid), Open Science Framework and JBI Evidence Synthesis (July 2021) established absence of an evidence-based understanding for prescribing and medication use in palliative care. This will therefore be followed by a comprehensive second search, reference and citation snowballing.[47] To gain an overview of the scope of evidence we will undertake an iterative mind-mapping exercise to extract descriptive data of process steps before using the richest sources of data to chart using an extraction form (supplementary file 2) and then build into a model illustrating how processes ideally occur, incorporating the multiple steps of typical episodes of prescribing and medication use for symptom control.

Step 4: Searching

The review will scope Medline Ovid, CINAHL (EBSCO) and Embase Ovid, Google Scholar and Google Images (seeking organisational flowcharts and policies). Keywords and index terms in relevant papers identified in the preliminary search together with stakeholder suggestions[48] form the comprehensive search strategy (see Supplementary file 3 for this in Medline Ovid). National Institute for Health and Care Excellence (NICE), Department of Health (DH), NHS England (also includes Wales), NHS Scotland, and other UK policy data policy database searches will be conducted. All identified citations will be uploaded into Endnote and de-duplicated. Reference and citation snowballing will be undertaken in Scopus for included full text sources. The reviewers will contact any relevan7-8t authors for additional information if required. Further searching for unpublished evidence will occur iteratively, following leads from the above and/or recommendations from local collaborators. This will enable us to contextualise our empirical data within a localised scoping of the intended processes.

Step 5: Selecting evidence

Titles and abstracts, then full texts will be independently screened by two independent reviewers (SY and SAF). Disagreements will be resolved by discussion, if required, with a third reviewer. The results of the search will be reported using Preferred Reporting Items for Systematic Reviews and Meta-analyses extension for scoping reviews (PRISMA-ScR).[49]

Step 6: Extracting evidence

Our data extraction is designed around a basic process framework of decision-making, prescribing, monitoring and supply, use (administration), stopping/disposal of medications and moving across healthcare contexts.

Following initial mapping by two researchers, one (SAF) will chart essential descriptive data: authors, year of publication, country of origin, main aim, study design, perspectives represented (context (home, hospital, hospice or transitions between these), process steps included, problems and challenges reported, potential solutions or workarounds suggested. Although we will not exclude studies on the basis of quality, we will use a 5-point 'strength score' to stratify evidence (Figure 2). A second researcher (SY) will verify charting for consistency and rigour. Interim findings will be discussed with the wider research team, steering and engagement groups to ensure focus remains on 'what matters most'. Any iterative modifications to the draft data charting tool will be detailed in the full report.

Insert approx. here: Figure 2. Strength score (Researcher-derived strength score descriptors adapted for use in quality assessment for secondary analysis[50])

Step 7: Analysis

We will draw on the model of the intended processes developed by Kajamaa et al[10] in their AT analysis of antibiotic prescribing, together with our own provisional model developed from stakeholder engagement in prescribing and using palliative medication.[48] Once we have established the range, methods and content of existing evidence we will consider if further analysis is likely to add new interpretations, such as using meta-ethnography techniques.[50]

Step 8: Presentation of results

The evidence will be presented as a model with accompanying descriptive summary representing all parts of the multi-step intended processes that have been studied, from each perspective and in which context. The model will expose problems, challenges and potential solutions or workarounds in existing sources, as well as help to identify evidence gaps.

Step 9: Summarizing, making conclusions and noting implications

We intend to refine and elaborate the model during the empirical ethnography of what happens in practice (Phase 2) by asking participants to 'think aloud' about the multistep processes, drawing on the intended model derived from the scoping review as a prompt on which to elaborate.

Phase 2: Empirical ethnography

A rapid, focused ethnography will be conducted using a cross-sectional approach.[51]

Setting

An English local health economy functioning as a meta-system of palliative care provision incorporating NHS and voluntary sector services. Within this, the contexts of hospital, hospice and 'home' function as three interacting systems. Previous work on prescribing experiences identified greater differences within each context studied than across different contexts.[10]

We will use a minimum of one acute hospital, one community palliative care team and one hospice as study sites. We anticipate also using additional sites such as general practices and community pharmacy services. We have defined 'home' as a person's usual place of residence within a community setting: this might be a private home, supported living, care home or other dwelling.

Recruitment and selection

The study population groups are defined in Box 2. We will work with a lead local clinical collaborator at each site to identify potential participants. Recruitment strategies include poster advertising, presentations and provision of study materials for dissemination to professionals/patients/carers. Participants will be purposively selected by role and site for interviews as shown in Table 1. A similar range of participants will be sought to participate in observation work. Exclusion criteria are:

- Not employed within, sharing care with or receiving care from the services under study.
- Clinical grounds/concern relating to psychological distress flagged by healthcare teams.

Box 2: Study population groups

Box 2: Study population groups

1. **Patients**: the person receiving palliative care, including either direct or indirect care from a specialist team.
   Inclusion criteria:
   - The 'last phase of life' is defined as having potentially life-limiting irreversible or progressive conditions requiring general or specialist palliative care. Patients may have prognoses between weeks and short years.
   - Receiving one or more prescription medications for symptom control. The study remit includes all medications used by patient when this criterion is met.
   - Over the age of 18 years.
2. **Carers:** anyone identified by the patient as having a role supporting them in their healthcare needs or illness who is not doing so because they are employed to do so. Carers can include family, friends, neighbours and/or anyone else who is important to the patient. Paid carers who are employed by a health or social care agency or other organisation are not included in this definition as medication use is usually explicitly excluded from their employment remit.
3. **Ward doctors/nurses/pharmacists:** professionals working in inpatient wards of hospices or hospitals.
4. **Clinical Nurse Specialists in Palliative Care:** Clinical Nurse Specialists in Palliative Care working within either hospital or community specialist palliative care services.
5. **Palliative Medicine Doctors:** Speciality Trainees and Consultants working within either hospital or community specialist palliative care services.
6. **Non-medical prescribers**: professionals who are not doctors but who are qualified to prescribe medications for symptom control. May include nurses, pharmacists or other professionals.
7. **Community Pharmacists:** may include pharmacists employed by NHS Trusts, Clinical Commissioning Groups, General Practice or independent Pharmacists (running their own business or employed in the private sector to provide high street pharmacy services).
8. **GPs:** General practitioners
9. **District Nurses:** community nurses providing care to people at home.

Table 1. Purposive sampling strategy for interviews

Hospital	Hospice	'Home' (usual place of residence)	Total
Patients (n=5)	Patients (n=5)	Patients (n=5)	15
Informal carer (e.g. relative, friend) (n=5)	Informal carer (n=5)	Informal carer (n=5)	15

Ward doctors (n=2)	Ward doctors, not specialising in palliative care (n=2)	GPs (n=4 individuals from at least 2 different practices)	8
Ward nurses (n=3)	Ward nurses (n=3)	District Nurses (n=3)	9
Clinical Nurse Specialists(CNS) in Palliative Care (prescribers and non-prescribers) (n=4)	Any non-medical prescribers available and willing to participate (n=2)	CNS Palliative Care (prescribers and non-prescribers) (n=4)	10
Palliative medicine doctors (n=2)	Palliative medicine doctors (n=2)	Palliative Medicine Doctors (n=2)	6
Ward pharmacists (n=2 or all willing to participate if fewer than 2 working in this field)	Hospice pharmacist (n=1)	Community Pharmacists (n=3) Community NHS Trust Pharmacist / Outreach Pharmacist (n=1 if post filled and willing to participate)	7

Data generation

Direct observations (n= 15 whole day equivalents) of everyday work and practices, plus informal conversations around the acts of prescribing and medication use, will be undertaken. We are seeking 'typical' process examples and so will not be selecting sites in the expectation of particularly positive or negative experiences. Doctors, nurses and pharmacists will be shadowed, and asked to describe processes, giving examples of decisions, practices and significant events. The researcher will engage patients, and if present, informal carers in informal conversations during the observations. For example, while the researcher is shadowing a professional who visits a patient, the patient and/or others in the household might be asked to show the researcher anything they use to help them remember or manage their medications, or how they store their medication, and the researcher will make note of any items around the room or house that may be contributing to medication practices.

Following these, semi-structured interviews will be conducted with a purposive sample of patients, informal carers and professionals in which we will explicitly discuss our model (see supplementary file 4).

Data collection methods will include field notes, including pictorial representations of processes, during observations and video/audio-recording of interviews. In addition the research team will keep reflective diaries and notes of team discussions.

Contingency plans have been made to transfer the ethnography to a remote working design in the event of further COVID-19 restrictions.

Data analysis

Reflexive analysis concurrent with data collection will allow iterative exploration of the data within the AT framework. Constant comparative thematic coding of activities/work/effort related to prescribing and medication use will be undertaken. The presence or absence of reference to each model step will be coded, identifying volume of talk: 'hot spots' – memorable examples and stories related to incidents, disturbances, learning experiences; and 'cold spots' - areas that are not talked about (but may still be problematic)

Disturbances in the process will be analysed to categorise types and identify underlying themes and contributing factors. The precedent study using this methodology in antibiotic use identified five categories: consultation challenges, lack of overview, process variation, challenges of handover, loss of the object (goal).[10] We will specifically seek these while remaining alert to new and alternative categories. Attention will be paid to normal and out-of-hours care, different contexts and points of transition.

Synthesis of Phases 1 and 2

Activity Theory provides a framework to make sense of data, building a rich multivoiced picture of work and effort. Ethnographic findings will be integrated with the initial process model to develop it into an experience/practice-based model for practices to ensure people with palliative care needs receive the right medications and with the right support at the right time. We will identify how symptom control can best be effective when processes are distributed across roles and contexts as well as using the final model to identify safety concerns with a focus on understanding underlying themes and contributing factors so that these can become targets for intervention and improvement.

Initial searches were conducted to develop the search strategy for the study protocol. The main study will commence in February 2022. The study end date is October 2023.

Ethics and dissemination

NHS Regional Ethics Committee approval has been obtained. A multi-professional/expert steering group is supporting the research team. We have consulted widely to consider ethical issues. We recognise that participants may find discussing care and service provision distressing if this prompts reflection on examples where all did not go well. Equally, some participants may find the research encounters therapeutic or useful for reflexive professional practice. We will develop a support protocol for this with each local site / clinical team and will signpost to, or facilitate, referral to additional services as necessary. Both the research fellow (registered pharmacist) and the CI (doctor) are experienced in working in clinical settings and adhering to the standards of confidentiality required.

Anticipated outcomes

Understanding the effort and work practices required day-to-day in the use of prescription medications, and the underlying themes and contributing factors in disruptions is crucial to designing, testing and implementing more efficient care models. This study will produce:

- A theoretically informed, empirically evidenced, model of how prescribing and medication use, as a complex multi-step process involving multiple people, occurs in a 'typical' English local healthcare economy
- Understanding of underlying themes and contributing factors to challenges in the system
- Identification of forms of collaborative action in prescribing and medication use
- Recommendations for system quality indicators
- A toolkit for patients and carers to empower them in conversations with professionals, and for professionals to assess the current processes for prescription medications in their local context. Scrutinising prescribing and medication use practices by applying our model may reduce the need for unanticipated care provision and decrease patient/carer burdens.

Dissemination

Findings will be disseminated through academic publications, a stakeholder dissemination event and a Plain English report circulated to policymakers, commissioners, clinicians, researchers and the public. We will seek informed consent for data archiving and use for secondary research purposes including sharing anonymised data with other researchers.

Figure Legends:

Figure 1: Relationship between review objectives, questions and inclusion criteria
Figure 2: Strength score (Researcher-derived strength score descriptors adapted for use in quality assessment for secondary analysis[50])

Authors' contributions: BDF, MEO, AK and KM co-produced the study design from inception led by SY, making substantive contributions to gaining funding, ethical approval, and writing this protocol. SAF was recruited to join the research team once funding was secured, making substantive contributions to refining the study design and writing this protocol. All authors have approved the final version.

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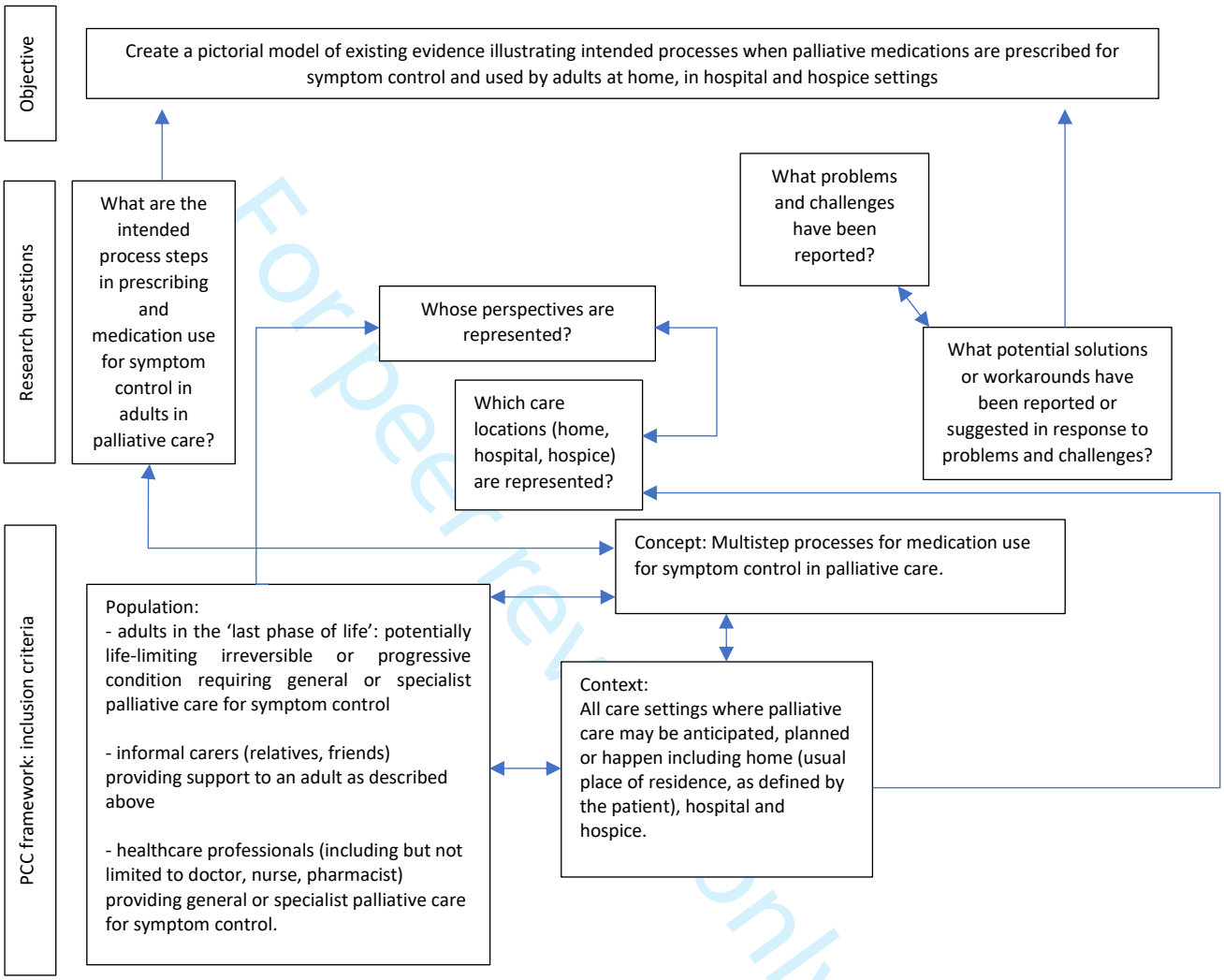


Strength score	Adapted score descriptors used for secondary analysis	Outcome
S1	No clear methods leading to results and conclusions; not significant	Exclude paper
S2	Methods lack detail, although results may suggest a trend (e.g. article covers something unique)	Include paper
S3	Methods appropriate for our research question (population, data generated, data presented)	Include paper
S4	Methods are very clear and very likely to yield important data	Include and consider as key paper
S5	Methods have produced data that are unequivocal	Include and consider as key paper

Supplementary Files

Supplementary file 1

Supplementary Table 1: Activity Theory Concepts and Definitions

Supplementary Figure 1: Applied representation for this study

Supplementary file 2

Data extraction form

Supplementary file 3

Scoping review search strategy in Medline Ovid

Supplementary file 4

Interview guide

Supplementary file 1

Supplementary Table 1: Activity Theory Concepts and Definitions

Key concept	Definition	**Application in prescribing and medication use**	**Explanatory notes**
Activity	The work and effort undertaken by people to achieve an object (see below). Always collective, activities include ambiguity, surprise and sensemaking, all of which are considered to generate the potential for change, i.e. expansion of the object, and/or new ways of achieving it.	Processes, work, and efforts undertaken by patients, informal carers and healthcare professionals in prescribing and medication use for symptom control.	At its very simplest the task of getting the right medication to the right patient at the right time requires six broad steps: 1. Recognition of need, clinical assessment and decision-making 2. Agreeing a prescription (choice of medication, formulation, route of administration) and ensuring this is completed by an appropriately qualified and competent professional 3. Transfer of the prescription to a pharmacy for dispensing of medication 4. Delivery of the medication back to the patient 5. Administration either by the patient or by an appropriate person according to prescribing instructions 6. Monitoring for clinical effects and side-effects as well as levels of supply and repeat requests and the disposal of medications no longer required A commonly overlooked additional step when patients die at home is the management of medications during the post-death bereavement period. These steps demonstrate that to view prescribing and medication use as the activity of an individual is a flawed approach[1] and greater understanding is needed of how each is achieved, by whom if we are to understand the sources of frustration in prescribing and medication use for patients, carers and professionals then identify potential improvement targets that are meaningful to them.
Activity System	Historically evolving systems within organisations/contexts where activities take place.	For this study we have centred our focus on the patient. Therefore, our unit of analysis is patients' activity system incorporating the whole multi-step task of getting the right medication at the right time, and we will consider how their activity system has interacted with each context in their narratives of experiences at home, in hospice and in hospital and when moving between these.	Increasingly in healthcare the boundaries between activity systems are blurred. With respect to prescribing and medication use, each context of home, hospice and hospital might each be considered as a separate activity system. However, the object of prescribing and medication use within each activity system can also be conceptualised as shared activities, within any setting in a local health economy where people with palliative care needs might be found. This is because the whole multi-step task of prescribing and medication use encompasses everything from identifying a palliative care need that requires medication to deciding what to prescribe, prescribing, dispensing and delivering supply to patients and administration in the context of providing holistic symptom control for people according to need, and regardless of diagnosis or location.

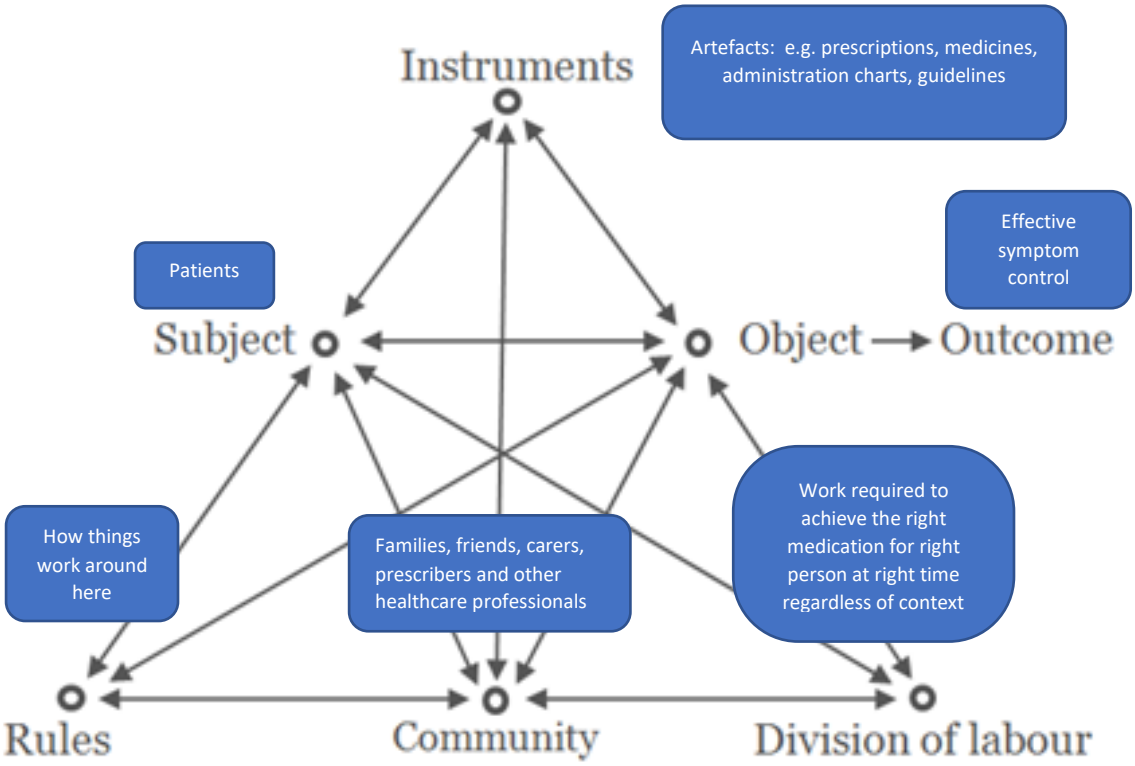
Community	People around the subject who are engaged in activities to achieve the object.	Achieving the object requires collective action of a large community of professionals together with patients and their informal network of carers (such as family and friends).	Multiple relations should be analysed while seeking to also analyse the systemic whole. Further complexities arise from societal myths and misconceptions about the purpose of palliative care and intended outcomes of using medications. The emotionally charged nature of interactions within palliative care may place particular demands on patients, those significant to them and professionals, with implications for their wellbeing.
Contradictions	Contradictions occur within and between activity systems on several levels: Primary contradictions occur when there are internal contradictions within the elements of the activity system, e.g. use value vs. exchange value in the object. Secondary contradictions occur between different elements of the system e.g. subject vs rules. Tertiary contradictions occur when there is difference between the object of the prevailing activity and a new activity through resistance to change. Quaternary contradictions arise in parallel with the generalization of the new activity between the new activity and its neighboring activities (conflicts with others).	We will explore contradictions as a cause of disturbances in the study. Contradictions and disturbances in activity processes do create problems – such as the daily hassles of prescribing and medication use reported by patients, carers and healthcare staff alike – but also offer targets for new collectively generated solutions: "*The distance between the present everyday actions of the individuals and the historically new form of the societal activity that can be collectively generated as a solution to the double bind potentially embedded in everyday actions*"[2]	Examples of each type will be sought. These might include things such as who should be prescribing and following up medication use, how different contexts permit different levels of patient choice in medication use or when an expert may choose to deviate from usual practice for specific reasons but this is not clearly communicated to others. Equally from a patient perspective, contradictions may arise between different priorities e.g. achieving good pain control versus beliefs about the use of strong analgesia such as opioids. Contradictions may also arise in different perceptions and assumptions about whose role or responsibility it is to contribute what activity within and when a patient moves between settings. Rather than viewing contradictions negatively within activity theory these will be viewed as sources of disturbance that hold the key to change and potential for improvement and learning.
Disturbances/ Deviations (used interchangeably in Activity Theory literature)	These are: *"deviations from the normal scripted course of events in the work process, normal being defined by plans, explicit rules and instructions, or tacitly assumed traditions. A disturbance may occur between*	The concept of disturbance will be used to explore prescribing and medication use processes, presented as chronological patient experiences and in our study, are treated as important tools for rethinking and developing healthcare processes.	Activity systems (of patients, carers and professionals within and during transitions between home, hospital and hospice) are interdependent and at the same time potentially tension-laden relationships with each other, generating disturbances. Disturbances in care processes and may hinder holistic management of patient care. However, instead of being viewed as error-causing phenomena, we view disturbances as an inherent feature of work processes and as drivers for change and development.[4,5,6,7] Deviations may occur because of competing pressures or priorities. For example, while effective symptom control may be the intended

	people and their instruments, or between two or more people. Disturbances appear in the form of an obstacle, difficulty, failure, disagreement, or conflict"[3]		object of activity competing objects such as the desire to please or avoid confrontation may cause disturbances in the process as may system failures or guidelines/protocols that are not practical to apply.
Divisions of labour	The divisions of labour describe how different individuals / roles act on the object of the activity.	Who is responsible to enact and ensure safety in each step of the process describes the division of labour. In reality this may not be clear or straightforward in all situations.	Divisions of labour tend to occur through use of implicit as well as explicitly developed norms (i.e. how we do things around here as well as officially promoted ways of how things should be done). Power is an important consideration in divisions of labour as inequalities in power will alter how divisions occur and are understood. Divisions may also evolve over time but will be influenced by what has historically been in place.
Expansive learning	In activity theory positive evolution and development of practice is framed as 'expansive learning' – that is learning which occurs through people interacting each other and co-producing new ways of working that better suit the goal to which they are working.	In order to understand how this can be achieved and where system breakdowns, barriers and facilitators or problems lie study of the existing practice and workplace context in which a particular goal, such as prescribing safety and effectively, is needed. In doing so it is important to pay attention to anything that creates a disturbance from ideal/intended/what happens on paper practice.	This type of learning can often start as in-situ 'work-arounds' that people develop informally. Research attempts to capture this so that it can be utilised further, bringing frontline innovations and initiatives into improvement strategies.
Mediating artefacts	The use of artefacts (tools and instruments) ideally driven by collective object-related motives to mediate actions between subjects and objects in the context of work.	Examples include: Using pathway protocols to standardize care procedures Medication administration / Drug charts Prescriptions (known as FP10s) Equipment for medication use	People both use inanimate mediating artefacts in their interactions with each other and assign these artefacts a place in the system. Understanding when an artefact has 'taken on a life of its own' i.e. is being used beyond its original intent or in novel ways to achieve / disrupt achievement of an object is important in understanding the dynamics of the community.
Object (goal)	Essentially what the subject needs and what the system and community should be trying to achieve. The object includes a collective motive (goal/outcome) and	The object of prescribing and medication use in palliative and end-of-life care is to achieve the best possible symptom control by delivering the right medication to the right person in a timely manner.	The sense and meaning of actions are attached to the object of an activity. Best possible symptom control is a collective object which enables a wider understanding of patient care and 'patient centredness' than the various specific potentially competing objects held by the many people involved in the process (i.e. professionals and carers as well as patients may also have other objects they pursue simultaneously, for example seeking to contain risks from potential side effects, or seeking to either share in or opt-out of prescribing decisions)

	connects actions of individuals to larger systems.		The concept of ***object*** can potentially widen our understanding of why disturbances take place. The existence of the multiple, specific and sometimes competing objects typically causes disturbances in care processes. The flexible aligning of the different and competing objects calls for the collective reflection, negotiation and reconceptualization of the object to enhance collaboration in the provision of patient care.[8]
Rules	The parameters within which activities take place.	These can be implicit (how things work around here) or explicit (e.g. legal regulations).	Due to the medications used there are complex and variable systems for prescribing, dispensing and administering in different settings and perspectives on division of labour to achieve this vary. The rules by which different people in the system are guided and constrained also vary and members of the community of professionals may or may not be party to understanding the context and capabilities of others.
Subject	The person who the object should serve.	In this case the patient.	
While we note that objects, rules, community and division of labour can be unclear, implicit and/or fluctuating this table provides an overview of these and other key concepts in Activity Theory. Understanding different perspectives on the specifics of the listed concepts is an essential part of using Activity Theory as a guiding framework for research. We have given a brief definition for each, followed by its potential application in our study of prescribing and medication use, and provided further explanatory notes to help those unfamiliar with this sociocultural theoretical approach. These have been modified from previous work studying antibiotic prescribing by members of the research team.[9]			

Supplementary Figure 1: Applied representation for this study[10]

Activity Theory is our methodological framework for understanding the processes and practices occurring from point of clinical decision that medication is needed to patient administration.



Using this framework we can place the patient and prescriber as subjects within a wider community of families, friends, carers and healthcare professionals between whom interactions will occur and the work of achieving the goal of symptom control through provision of the right medication at the right time regardless of setting requires a functional division of labour that meets everyone's understanding of the rules of 'how things work around here'.

The upper part of the diagram represents individual and group actions embedded in a collective system. The subject is whoever the activity (work, effort) is designed to benefit, for example patients. The instruments (tools, signs, artefacts) are the things used to achieve the benefit (for example a written prescription). The object is the goal of the activity (for example, medication for pain control) and the outcome is both the impact of the activity (does the patient get the medication when they need it and does it relieve them of pain) and the sense or meaning created by the patient and others about the activity.

The bottom part of the diagram provides a collective focus on the patient's environment, relationships and context. The community represents others around them (for example informal carers, healthcare professionals). The rules describe how formal systems and informal practices shape the activity – these may be written in policies (for example prescribing guidelines) or unwritten accepted norms (for example local preferences for one sort of medication over another for pain). The division of labour represents the differing roles and responsibilities of everyone involved in the activity. Divisions of labour are commonly characterised by ambiguity, interpretation and potential for change in complex systems involving many different people.

Supplementary file 2

Data extraction form

Reference: Authors and year of publication	Country of origin	Main study aim	Study design	Perspectives represented (e.g. doctor, nurse, pharmacist, patient, carer)	Context: home, hospital, hospice or transitions between these	Steps in processes included in study	Problems and challenges reported	Potential solutions or workarounds reported or suggested	Other key findings that relate to the scoping review question/s	Strength score

Supplementary file 3

Scoping review search strategy

Medline (Ovid)
Search conducted 14 July 2021

Search	Query	Records retrieved
S1	exp Patients/ OR exp Caregivers/ OR exp Spouses/ OR exp Family/ OR exp Friends/ OR Partner*.mp. OR carer*.mp. OR care giv*.mp. OR caregiv*.mp.	660,455
S2	Nurs*.mp. OR pharmacist*.mp. OR clinician*.mp. OR doctor*.mp.	1,142,041
S3	S1 OR S2	1,705,544
S4	exp medication therapy management/ OR prescri*.mp. OR exp Pharmacy Service, Hospital/ OR medic* management.mp. OR medic* reconcil*.mp. OR medic* safety.mp. OR medic* treatment.mp. OR exp Medication Errors/ OR medic* error.mp. OR exp Inappropriate Prescribing/ OR Inappropriate prescrib*.mp. OR suboptimal prescribe*.mp. OR exp Patient Safety/ OR patient safety.mp. OR side effect.mp. OR drug related side effects.mp. OR adverse drug reaction.mp. OR exp "Drug-Related Side Effects and Adverse Reactions"/ OR prescrip* appropriate*.mp. OR drug prescriptions.mp. OR exp Drug Prescriptions/ OR prescription appropriateness.mp. OR medic* review.mp. OR drug related problems.mp. OR Drug Interactions/ OR (drug adj1 safety).mp. OR patient harm.mp. OR Patient Harm/ OR exp Medication Systems/ OR exp Drug Utilization/ OR drug utilisation review.mp. OR exp "Drug Utilization Review"/ OR (utiliz* OR utilis* OR dispens*).mp. OR exp Patient-Centered Care/ OR patient centred care.mp. OR exp Pharmaceutical Preparations/ OR exp Drug Dosage Calculations/ OR exp Drug Prescriptions/ OR exp Polypharmacy/ OR self administration.mp. OR exp Self Administration/ OR exp Prescription Drugs/ OR exp "Off-Label Use"/ OR exp Infusion Pumps/ OR exp Infusions, Subcutaneous/ OR exp Injections, Subcutaneous/ OR medication*.mp. OR medicine*.mp.	3,299,100
S5	exp after-hours care/ OR exp "delivery of health care, integrated"/ OR exp practice patterns, pharmacists'/ OR exp practice patterns, nurses'/ OR exp practice patterns, physicians'/ OR exp professional practice gaps/ OR exp patient care team/ OR exp nursing, team/	149, 956
S6	S4 OR S5	3,396,358
S7	exp Terminally Ill/ OR exp Terminal Care/ OR exp Palliative Care/ OR (Hospice and palliative care nursing).mp. OR exp Hospice Care/ OR exp Palliative Medicine/ OR palliat*.mp. OR CSCI.mp. OR Continuous subcutaneous infusion.mp. OR Just in case medic*.mp. OR symptom control.mp. OR syringe pump.mp. OR syringe driver.mp. OR McKinley.mp.	150,547
S8	S6 AND S7	29, 153
S9	S3 AND S8	9, 537

Supplementary file 4

Interview guide

Interviews with be conducted using a semi-structured approach with:

- *Patients and informal carers (if carer interviewed separately tailor questions to ask about their perspective on the person they care for)*
- *Professionals*

1. **Experiences of medications for symptom control in palliative care**
    a. Ask participant to describe their experiences as a patient/carer/professional
    b. Prompt for specific examples and explanations
        i. What was happening?
        ii. Who was involved?
        iii. What needed to be done before/during/after each event or activity?
        iv. What was good / worked well?
        v. What wasn't good / didn't work?
        vi. What could have made a difference?
    c. Probe for detail on each step of the process (i.e each unit of analysis in the process) and the links/breakdowns between steps
        i. Decision-making/Starting a medication
        ii. Discussion of risks and benefits
        iii. Prescribing /Taking/Adding a medication
        iv. Monitoring and supply / Reviewing a medication
        v. Administration
        vi. Repurposing medications
        vii. Addressing new concerns
        viii. Stopping medications
        ix. Moving across healthcare contexts
    d. Ask about objects/tools mentioned and how these are used e.g. lists, prescriptions, medication boxes, reminders etc.
    e. Ask who is responsible for what in each part of the process?
    f. Ask how decisions are made?
    g. Ask about 'how things work around here?' – what are the informal ways of working / getting things done? Are there 'rules' or understandings of things that 'are just how it is done'
2. **Differences between settings**
    a. How do things work at home v hospice v hospital (as applicable to each participants experience)?
    b. What happens when people move between settings
        i. Admissions and discharges
3. **Discussion of AT framework:**
    a. Explain framework (as shown in figure 1) to participant and seek their feedback on how use of medication for symptom control in palliative care plays out within the system
        i. Thinking about the system from different perspectives – ask participants how they think others see the system: patients/carers/professionals and how the system is viewed from hospice/hospital to home and vice versa?
        ii. Where are there contradictions or breakdowns in the system?
4. **Anything else the participant would like to add?**

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Integrated checklist drawing on relevant sections of checklists by choice of method: Getting palliative medications right across the contexts of homes, hospitals, and hospices: protocol to synthesise scoping review and ethnographic methods in an Activity Theory analysis

1. Scoping review We have used the Joanna Briggs Institute Manual for Evidence Synthesis with particular reference to Chapter 2: Systematic reviews of qualitative evidence and Chapter 11: Scoping reviews as the standard to inform design of our scoping review and qualitative meta-ethnography to synthesise the data. We have cross checked this against the JBI recommended SUMARI_Protocol_Template_Scoping_Reviews. Aromataris E, Munn Z (Editors). *JBI Manual for Evidence Synthesis.* JBI, 2020. Available from https://synthesismanual.jbi.global. https://doi.org/10.46658/JBIMES-20-01

2. **Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) Checklist**

SECTION	ITEM	PRISMA-ScR CHECKLIST ITEM	REPORTED ON PAGE #
TITLE			
Title	1	Identify the report as a scoping review.	Title page (1)
ABSTRACT			
Structured summary	2	Provide a structured summary that includes (as applicable): background, objectives, eligibility criteria, sources of evidence, charting methods, results, and conclusions that relate to the review questions and objectives.	Abstract page (2)
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known. Explain why the review questions/objectives lend themselves to a scoping review approach.	5
Objectives	4	Provide an explicit statement of the questions and objectives being addressed with reference to their key elements (e.g., population or participants, concepts, and context) or other relevant key elements used to conceptualize the review questions and/or objectives.	5-6
METHODS			
Protocol and registration	5	Indicate whether a review protocol exists; state if and where it can be accessed (e.g., a Web address); and if available, provide registration information, including the registration number.	Not applicable
Eligibility criteria	6	Specify characteristics of the sources of evidence used as eligibility criteria (e.g., years considered, language, and publication status), and provide a rationale.	7
Information sources*	7	Describe all information sources in the search (e.g., databases with dates of coverage and contact with authors to identify additional sources), as well as the date the most recent search was executed.	7-8
Search	8	Present the full electronic search strategy for at least 1 database, including any limits used, such that it could be repeated.	Supplementary file 3
Selection of sources of evidence†	9	State the process for selecting sources of evidence (i.e., screening and eligibility) included in the scoping review.	7-8
Data charting process‡	10	Describe the methods of charting data from the included sources of evidence (e.g., calibrated forms or forms that have been tested by the team before their use, and whether data charting was done independently	8 and supplementary file 2

SECTION	ITEM	PRISMA-ScR CHECKLIST ITEM	REPORTED ON PAGE #
		or in duplicate) and any processes for obtaining and confirming data from investigators.	
Data items	11	List and define all variables for which data were sought and any assumptions and simplifications made.	8
Critical appraisal of individual sources of evidence§	12	If done, provide a rationale for conducting a critical appraisal of included sources of evidence; describe the methods used and how this information was used in any data synthesis (if appropriate).	8
Synthesis of results	13	Describe the methods of handling and summarizing the data that were charted.	8-9
RESULTS			
Selection of sources of evidence	14	Give numbers of sources of evidence screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally using a flow diagram.	N/A at protocol stage
Characteristics of sources of evidence	15	For each source of evidence, present characteristics for which data were charted and provide the citations.	N/A at protocol stage
Critical appraisal within sources of evidence	16	If done, present data on critical appraisal of included sources of evidence (see item 12).	N/A at protocol stage
Results of individual sources of evidence	17	For each included source of evidence, present the relevant data that were charted that relate to the review questions and objectives.	N/A at protocol stage
Synthesis of results	18	Summarize and/or present the charting results as they relate to the review questions and objectives.	N/A at protocol stage
DISCUSSION			
Summary of evidence	19	Summarize the main results (including an overview of concepts, themes, and types of evidence available), link to the review questions and objectives, and consider the relevance to key groups.	N/A at protocol stage
Limitations	20	Discuss the limitations of the scoping review process.	N/A at protocol stage
Conclusions	21	Provide a general interpretation of the results with respect to the review questions and objectives, as well as potential implications and/or next steps.	N/A at protocol stage
FUNDING			
Funding	22	Describe sources of funding for the included sources of evidence, as well as sources of funding for the scoping review. Describe the role of the funders of the scoping review.	11

JBI = Joanna Briggs Institute; PRISMA-ScR = Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews.

* Where *sources of evidence* (see second footnote) are compiled from, such as bibliographic databases, social media platforms, and Web sites.

† A more inclusive/heterogeneous term used to account for the different types of evidence or data sources (e.g., quantitative and/or qualitative research, expert opinion, and policy documents) that may be eligible in a scoping review as opposed to only studies. This is not to be confused with *information sources* (see first footnote).

‡ The frameworks by Arksey and O'Malley (6) and Levac and colleagues (7) and the JBI guidance (4, 5) refer to the process of data extraction in a scoping review as data charting.

§ The process of systematically examining research evidence to assess its validity, results, and relevance before using it to inform a decision. This term is used for items 12 and 19 instead of "risk of bias" (which is more applicable to systematic reviews of interventions) to include and acknowledge the various sources of evidence

that may be used in a scoping review (e.g., quantitative and/or qualitative research, expert opinion, and policy document).*From:* Tricco AC, Lillie E, Zarin W, O'Brien KK, Colquhoun H, Levac D, et al. PRISMA Extension for Scoping Reviews (PRISMAScR): Checklist and Explanation. Ann Intern Med. 2018;169:467–473. doi: 10.7326/M18-0850.

3. Sections of GRIPP2 applicable to study protocols regarding PPI

Section and topic	Item	Reported on page No
Section 1: Abstract of paper		
1a: Aim	Report the aim of the study	2
1b: Methods	Describe the methods used by which patients and the public were involved	2
1e: Keywords	Include PPI, "patient and public involvement," or alternative terms as keywords	Not appropriate as not a study of PPI per se
Section 2: Background to paper		
2a: Definition	Report the definition of PPI used in the study and how it links to comparable studies	7
2b: Theoretical underpinnings	Report the theoretical rationale and any theoretical influences relating to PPI in the study	6-7
2c: Concepts and theory development	Report any conceptual models or influences used in the study	6-7
Section 3: Aims of paper		
3: Aim	Report the aim of the study	5
Section 4: Methods of paper		
4a: Design	Provide a clear description of methods by which patients and the public were involved	7
4b: People involved	Provide a description of patients, carers, and the public involved with the PPI activity in the study	7
4c: Stages of involvement	Report on how PPI is used at different stages of the study	7
4d: Level or nature of involvement	Report the level or nature of PPI used at various stages of the study	7

4. SRQR: Standards for Reporting Qualitative Research: A Synthesis of Recommendations

O'Brien, Bridget C.; Harris, Ilene B.; Beckman, Thomas J.; Reed, Darcy A.; Cook, David A. Academic Medicine89(9):1245-1251, September 2014. doi: 10.1097/ACM.0000000000000388

Item	Page no.
Title and abstract	
Title	1
Abstract	2
Introduction	
Problem formulation	5
Purpose or research question	5-6
Methods	
Qualitative approach and research paradigm	6
Researcher characteristics and reflexivity	11

Context	9
Sampling strategy	9 and Box 2, Table 2
Ethical issues pertaining to human subjects	11
Data collection methods	9-10
Data collection instruments and technologies	9-10 and Supplementary file 4
Units of study	Not applicable at protocol stage
Data processing	Available on request. Not standard to include in protocol papers.
Data analysis	10
Techniques to enhance trustworthiness	6
Results/Findings	
Synthesis and interpretation	Not applicable at protocol stage
Links to empirical data	Not applicable at protocol stage
Discussion	
Integration with prior work, implications, transferability and contributions to the field	Not applicable at protocol stage
Limitations	See strengths and limitations summary p4. Additional discussion will be provided with the results papers
Other	
Conflicts of interest	11
Funding	11

BMJ Open

Getting palliative medications right across the contexts of homes, hospitals, and hospices: protocol to synthesise scoping review and ethnographic methods in an Activity Theory analysis

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Title: Getting palliative medications right across the contexts of homes, hospitals, and hospices: protocol to synthesise scoping review and ethnographic methods in an Activity Theory analysis

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Abstract

Introduction

Prescribing and medication use in palliative care is a multi-step process. It requires systems coordination and is enacted through activities of patients, informal carers and professionals. This study compares practice to idealised descriptions of what should happen; identifying when, how and why process disturbances impact on quality and safety. Our objectives are to:

1. document an intended model (phase 1, scoping review);
2. refine the model with study of practice (phase 2, ethnography);
3. use the model to pinpoint 'hot' (viewed as problematic by participants) and 'cold' spots (observed as problematic by researchers) within or when patients move across three contexts - hospice, hospital, and community (home);
4. create learning recommendations for quality and safety targeted at underlying themes and contributing factors.

Methods and analysis

The review will scope Ovid Medline, CINAHL and Embase, Google Scholar and Images - no date limits, English language only. The Population (palliative), Concept (medication use), Context (home, hospice, hospital) framework defines inclusion/exclusion criteria. Data will be extracted to create a model illustrating how processes ideally occur, incorporating multiple steps of typical episodes of prescribing and medication use for symptom control. Direct observations, informal conversations around acts of prescribing and medication use, and semi-structured interviews will be conducted with a purposive sample of patients, carers and professionals. Drawing on Activity Theory, we will synthesise analysis of both phases. The analysis will identify when, how and why activities affect patient safety and experience. Generating a rich multivoiced understanding of the process will help identify meaningful targets for improvement.

Ethics and dissemination

Ethical approval granted by the Camden & Kings Cross NHS Regional Ethics Committee [21/LO/0459]. . A patient and public involvement (PPI) co-investigator, a multi-professional steering group and a PPI engagement group are working with the research team. Dissemination of findings is planned through peer-reviewed publications, and a stakeholder (policymakers, commissioners, clinicians, researchers, public) report/dissemination event.

Article Summary

Strengths and limitations of this study

- There has been no previous mapping of idealised intended multi-step processes associated with prescribing and medication use in palliative care.
- Evidence of real-life practices of prescribing and medication use in palliative care across different contexts will illuminate understanding underlying themes and contributing factors to disruptions in intended processes.
- Analysis of activity systems, comparing between the intended and practice process models, will inform areas to target innovation and improvement.

- This study adopts the method of activity theory analysis to interrogate local service provision in palliative medication use in one area of England, but can offer a template by which to investigate prescribing also in other clinical and geographical areas.
- The cross-sectional design will provide a detailed snapshot of activity but cannot formally track longitudinal change due to resource limitations.

Keywords: Activity Theory; Palliative Care; Prescription Drugs; Qualitative Research

Lay summary developed with PPI co-investigator and approved by funder

Background
People with palliative care needs use prescription medications to achieve symptom control. 'Daily hassles' with medications are commonly reported. What happens in 'real life' and the effort required to achieve effective medication use in palliative care is poorly understood.

Aims
The study will collect information from patients, carers and professionals to:
1. Map 'real life' practices underlying medication use including:
    - Decision-making
    - Prescribing
    - Monitoring and supply
    - Use (Administration)
    - Stopping/disposal of medications
    - Moving across healthcare and other contexts, such as homes.
2. Understand challenges patients and carers face and what they do/do not do to achieve effective medication use.
3. Understand impact of professional practices on medication use.

Design and Methods
Three types of context will be identified in order to recruit from home, hospital and hospice. We will develop a pictorial (visual) process model of how using prescription medications should work in palliative care. We will then observe and explore what really happens and collect information about people's experiences of medication use to develop a 'real life' model. Activity theory, which can be used to good effect in analysing healthcare processes and practices, will help us to understand what happens, who does what, and what occurs when a patient moves across contexts.

Patient and Public Involvement (PPI)
Consultation with patients, families, friends, carers and healthcare professionals helped us to develop this proposal. A PPI co-applicant and co-author is part of the team, they will:
- Provide an 'expert-by-experience' perspective
- Assist the research team to engage a wider PPI population
- Co-produce study dissemination products and activities
- All participants will be invited to a dissemination event and receive the study report.

Main Text

Introduction

Prescribing and medication use for symptom control in palliative care is a multi-step process that encompasses everything from identifying need to deciding what to prescribe, prescribing, dispensing, delivering, use/administration and disposal. Each step involves complex risk-prone tasks with frequent errors.[1,2,3,4,5,6,7,8]Of 475 NHS (National Health Service, England & Wales) serious incident reports (2002-2014) involving palliative patients, 91 (~20%) related to medications.[9] These mostly occurred in patients' own homes, half of which were when care was not provided by specialists.

Evidence specific to prescribing, medication use and error prevention in palliative care is scarce, with an absence of studies of the multiple steps involved or how these link in practice.[10] Absence of evidence prevents policy and other interventions targeting underlying themes and contributing factors when problems occur.[11] A better understanding of practices experienced, as distinct from intended processes, can identify targets for system change, new ways of working and new forms of practice.[12,13,14,15,16] To address this, the multi-step process of prescribing and medication use should be conceptualised as a series of socially constructed practices in which patients, informal carers and professionals are required to collaborate across locations and organisational boundaries.[17,18,19]

Optimal prescribing and medication use are influenced by 'etiquette'; socially mediated evolutionary rules and boundaries, with unclear divisions of labour, shaping practice and disrupting intended processes.[10,20,21,22,23,24,25,26,27,28] Expectations of primary and acute care professionals prescribing for symptom control[29] contrast with reported hindrances of lack of time, confidence and skills.[30,31,32] Existing research[17,33] also reports high patient/carer workload, all groups involved experiencing struggles with multi-step processes and practices, plus a lack of shared understanding of roles and responsibilities between patients/carers and different professionals.[33,34,] Often only patients (and by proxy their carers) experience all components of healthcare systems, as they move across contexts, gaining insight into where system redesign is needed.[14] This protocol addresses a *"high priority research area that is important clinically and in the community, as mismanaged medication can be frightening for carers and families"*.[35]

Methods and analysis

Aims

1. compare how prescribing and medication use appear in practice to idealised descriptions of what should happen in the multi-step process;
2. identify when, how and why process disturbances affect quality and safety.

Research questions

1. What are the experiences of patients, carers and professionals of prescribing and medication use?
2. Who does what, when and where in the multi-step process of prescribing and medication use for symptom control in palliative care?
3. What impact do differences between the idealised intended process and the realities of practice have?

Objectives

Prescribing and medication use in palliative care will be studied across three contexts:: community (home), hospital and hospice to:

1. document an intended model of activities and outcomes of prescription medication use in palliative care for symptoms control …. (phase 1, scoping review);
2. refine and elaborate the model with an ethnographic study of what happens in practice (phase 2, ethnography).
3. use the refined model to pinpoint 'hot' spots (viewed as problematic by participants) and 'cold' spots (observed as problematic by research team) within a single context or when patients move across hospice, hospital, and home contexts
4. create a learning and recommendation toolkit for improvement targeted at understanding underlying themes and contributing factors to process disturbances in practice.

Theoretical orientation and study design

This study draws on activity theory (AT, also known as Cultural-Historical-Activity-Theory, CHAT)[36] to examine processes and practices including workarounds dependent on interactions between the agency of people and system structures. It extends and complements the work of others[37,38] through a systematic view of patient safety and risk in palliative care, applied to prescribing and medication use.

Our approach builds on a proof-of-concept study in antibiotic prescribing.[10] An identified limitation of this antibiotic study was the single perspective (captured solely in interview data) and single setting. Our work will offer an in depth analysis of 'what happens on paper' and 'what happens in the real world' of the palliative care medication activity from multiple perspectives within and across multiple contexts.[39]

The concept of activity describes 'the fundamental interaction between humans and the world - humans behave actively toward the world (fragments of it), change it (them), and change themselves in this process. Humans as active subjects make fragments of the world objects (goals) of their activity and the same time are affected by the world (fragments of it)'.[40] Definitions and an explanatory figure of other key AT concepts are in Supplementary Files: Supplementary Table 1 and Supplementary Figure 1.

Because AT considers reciprocal interactions between (1) theory and practices and processes and (2) systems and people (community), it provides a framework to analyse how interactions evolve (or fail), when a group of people are (or should be) working to achieve a shared goal.[41]

AT acknowledges that intended process descriptions differ from actual execution because processes are only partially scripted strings of actions, influenced and interacting with other parallel processes.[42,43] This is especially important in palliative care since provision is within and across complex contexts, encompassing multiple providers and communities. To conduct our analysis we will work from the perspective of patients' activity systems focused on the object (goal) of achieving symptom control through accurate and effective prescribing and medication use. A theoretically informed, empirically-evidenced model will be produced to identify targets for innovation and improvement in prescribing and medication use across palliative care contexts.

The study has two phases: a scoping review and an ethnographic study. In the final analysis the findings from each of these will be synthesised together to meet the overarching objectives of the work.

Patient and public involvement(PPI)

This study addresses issues identified by the James Lind Alliance Palliative and End-of-Life Care Priority Setting Partnership.[44] The PPI co-investigator was recruited to co-produce the study from inception. Two independent PPI representatives were consulted (pre- and post-funding award) in addition to sharing the study design with the Marie Curie Research Voices PPI group. A PPI engagement group (n=10) has been recruited. Consultation with stakeholders through our PPI and Steering Groups (clinical and methodology experts) will continue throughout study execution and dissemination.

Study dates

Initial searches were conducted July 2021 to develop the search strategy protocol (phase 1). The main study commences February 2022. The study end date is October 2023.

Phase 1: Scoping Review

This scoping review will use the nine-step Joanna Briggs Institute (JBI) framework methodology.[45,46,47,48]

Step 1: Review objectives

We seek to identify key definitions, concepts, characteristics and factors related to activities and outcomes of prescription medication use in palliative care for symptoms control. Specifically, the review objectives are to establish evidence for an idealised intended process for prescribing and medication use, documenting from whose perspectives, and what contexts this has been studied. We will also note any evidence of challenges in the process steps, and proposed solutions to these, to guide the empirical ethnography of phase 2.

Step 2: Aligning the inclusion criteria with objectives

Figure 1 demonstrates the relationship between the review objectives, questions and inclusion criteria. The Population (receiving palliative care), Concept (prescribing and medication use), Context (home, hospice, hospital) framework defines our inclusion criteria (Figure 1). Exclusions are shown in Box 1. We will include empirical research (quantitative and qualitative), review studies (if answering a novel question), policy documents, practice standard and guidelines, organisational flowcharts, and reports focusing on how the processes should occur or gaps between any benchmark and what does occur. No date limits, English language only.

Insert approx. here. Figure 1: Relationship between review objectives, questions and inclusion criteria

Box 1. Scoping review exclusion criteria

Box 1: Scoping review exclusion criteria

- Studies focussed on neonatal, paediatric or adolescent populations
- Studies on palliative care as a result of trauma or attempted suicide
- Studies focussed on medication prescribed for indications other than symptom control or generic medication use principles without application to palliative care.
- Ethical dilemmas associated with prescribing in palliative care.
- Opinion pieces, anecdotes, editorials, narratives or commentaries without reference to any form of intended process or practice (e.g. solely first person experience of

Step 3: Design for evidence searching, selection, data extraction, and presentation

Preliminary searches of Prospero, Medline (Ovid), CINAHL Plus (EBSCOhost), Embase (Ovid), Open Science Framework and JBI Evidence Synthesis (July 2021) established absence of an evidence-based understanding for prescribing and medication use in palliative care. This will therefore be followed by a comprehensive second search, reference and citation snowballing.[48] To gain an overview of the scope of evidence we will undertake an iterative mind-mapping exercise to extract descriptive data of process steps before using the richest sources of data to chart using an extraction form (supplementary file 2) and then build into a model illustrating how processes ideally occur, incorporating the multiple steps of typical episodes of prescribing and medication use for symptom control.

Step 4: Searching

The review will scope Medline Ovid, CINAHL (EBSCO) and Embase Ovid, Google Scholar and Google Images (seeking organisational flowcharts and policies). Keywords and index terms in relevant papers identified in the preliminary search together with stakeholder suggestions[49] form the comprehensive search strategy (see Supplementary file 3 for this in Medline Ovid). National Institute for Health and Care Excellence (NICE), Department of Health (DH), NHS England (also includes Wales), NHS Scotland, and other UK policy data policy database searches will be conducted. All identified citations will be uploaded into Endnote and de-duplicated. Reference and citation snowballing will be undertaken in Scopus for included full text sources. The reviewers will contact any relevant authors for additional information if required. Further searching for unpublished evidence will occur iteratively, following leads from the above and/or recommendations from local collaborators. This will enable us to contextualise our empirical data within a localised scoping of the intended processes.

Step 5: Selecting evidence

Titles and abstracts, then full texts will be independently screened by two independent reviewers (SY and SAF). Disagreements will be resolved by discussion, if required, with a third reviewer. The results of the search will be reported using Preferred Reporting Items for Systematic Reviews and Meta-analyses extension for scoping reviews (PRISMA-ScR).[50]

Step 6: Extracting evidence

Our data extraction is designed around a basic process framework of decision-making, prescribing, monitoring and supply, use (administration), stopping/disposal of medications and moving across healthcare contexts.

Following initial mapping by two researchers, one (SAF) will chart essential descriptive data: authors, year of publication, country of origin, main aim, study design, perspectives represented (context (home, hospital, hospice or transitions between these), process steps included, problems and challenges reported, potential solutions or workarounds suggested. Although we will not exclude studies on the basis of quality, we will use a 5-point 'strength score' to stratify evidence (Figure 2). A second researcher (SY) will verify charting for consistency and rigour. Interim findings will be discussed with the wider research team, steering and engagement groups to ensure focus remains on 'what matters most'. Any iterative modifications to the draft data charting tool will be detailed in the full report.

Insert approx. here: Figure 2. Strength score (Researcher-derived strength score descriptors adapted for use in quality assessment for secondary analysis[50])

Step 7: Analysis

We will draw on the model of the intended processes developed by Kajamaa et al[10] in their AT analysis of antibiotic prescribing, together with our own provisional model developed from stakeholder engagement in prescribing and using palliative medication.[49] Once we have established the range, methods and content of existing evidence we will consider if further analysis is likely to add new interpretations, such as using meta-ethnography techniques.[51]

Step 8: Presentation of results

The evidence will be presented as a model with accompanying descriptive summary representing all parts of the multi-step intended processes that have been studied, from each perspective and in which context. The model will expose problems, challenges and potential solutions or workarounds in existing sources, as well as help to identify evidence gaps.

Step 9: Summarizing, making conclusions and noting implications

We intend to refine and elaborate the model during the empirical ethnography of what happens in practice (Phase 2) by asking participants to 'think aloud' about the multistep processes, drawing on the intended model derived from the scoping review as a prompt on which to elaborate.

Phase 2: Empirical ethnography

A rapid, focused ethnography will be conducted using a cross-sectional approach.[52]

Setting

An English local health economy functioning as a meta-system of palliative care provision incorporating NHS and voluntary sector services. Within this, the contexts of hospital, hospice and 'home' function as three interacting systems. Previous work on prescribing experiences identified greater differences within each context studied than across different contexts.[10]

We will use a minimum of one acute hospital, one community palliative care team and one hospice as study sites. We anticipate also using additional sites such as general practices and community pharmacy services. We have defined 'home' as a person's usual place of residence within a community setting: this might be a private home, supported living, care home or other dwelling.

Recruitment and selection

The study population groups are defined in Box 2. We will work with a lead local clinical collaborator at each site to identify potential participants. Recruitment strategies include poster advertising, presentations and provision of study materials for dissemination to professionals/patients/carers. Participants will be purposively selected by role and site for interviews as shown in Table 1. A similar range of participants will be sought to participate in observation work. Exclusion criteria are:

- Not employed within, sharing care with or receiving care from the services under study.
- Clinical grounds/concern relating to psychological distress flagged by healthcare teams.

Box 2: Study population groups

Box 2: Study population groups

1. **Patients**: the person receiving palliative care, including either direct or indirect care from a specialist team.
   Inclusion criteria:
   - The 'last phase of life' is defined as having potentially life-limiting irreversible or progressive conditions requiring general or specialist palliative care. Patients may have prognoses between weeks and short years.
   - Receiving one or more prescription medications for symptom control. The study remit includes all medications used by patient when this criterion is met.
   - Over the age of 18 years.
2. **Carers:** anyone identified by the patient as having a role supporting them in their healthcare needs or illness who is not doing so because they are employed to do so. Carers can include family, friends, neighbours and/or anyone else who is important to the patient. Paid carers who are employed by a health or social care agency or other organisation are not included in this definition as medication use is usually explicitly excluded from their employment remit.
3. **Ward doctors/nurses/pharmacists:** professionals working in inpatient wards of hospices or hospitals.
4. **Clinical Nurse Specialists in Palliative Care:** Clinical Nurse Specialists in Palliative Care working within either hospital or community specialist palliative care services.
5. **Palliative Medicine Doctors:** Speciality Trainees and Consultants working within either hospital or community specialist palliative care services.
6. **Non-medical prescribers**: professionals who are not doctors but who are qualified to prescribe medications for symptom control. May include nurses, pharmacists or other professionals.
7. **Community Pharmacists:** may include pharmacists employed by NHS Trusts, Clinical Commissioning Groups, General Practice or independent Pharmacists (running their own business or employed in the private sector to provide high street pharmacy services).
8. **GPs:** General practitioners
9. **District Nurses:** community nurses providing care to people at home.

Table 1. Purposive sampling strategy for interviews

Hospital	Hospice	'Home' (usual place of residence)	Total
Patients (n=5)	Patients (n=5)	Patients (n=5)	15
Informal carer (e.g. relative, friend) (n=5)	Informal carer (n=5)	Informal carer (n=5)	15

Ward doctors (n=2)	Ward doctors, not specialising in palliative care (n=2)	GPs (n=4 individuals from at least 2 different practices)	8
Ward nurses (n=3)	Ward nurses (n=3)	District Nurses (n=3)	9
Clinical Nurse Specialists(CNS) in Palliative Care (prescribers and non-prescribers) (n=4)	Any non-medical prescribers available and willing to participate (n=2)	CNS Palliative Care (prescribers and non-prescribers) (n=4)	10
Palliative medicine doctors (n=2)	Palliative medicine doctors (n=2)	Palliative Medicine Doctors (n=2)	6
Ward pharmacists (n=2 or all willing to participate if fewer than 2 working in this field)	Hospice pharmacist (n=1)	Community Pharmacists (n=3) Community NHS Trust Pharmacist / Outreach Pharmacist (n=1 if post filled and willing to participate)	7

Data generation

Direct observations (n= 15 whole day equivalents) of everyday work and practices, plus informal conversations around the acts of prescribing and medication use, will be undertaken. We are seeking 'typical' process examples and so will not be selecting sites in the expectation of particularly positive or negative experiences. Doctors, nurses and pharmacists will be shadowed, and asked to describe processes, giving examples of decisions, practices and significant events. The researcher will engage patients, and if present, informal carers in informal conversations during the observations. For example, while the researcher is shadowing a professional who visits a patient, the patient and/or others in the household might be asked to show the researcher anything they use to help them remember or manage their medications, or how they store their medication, and the researcher will make note of any items around the room or house that may be contributing to medication practices.

Following these, semi-structured interviews will be conducted with a purposive sample of patients, informal carers and professionals in which we will explicitly discuss our model (see supplementary file 4).

Data collection methods will include field notes, including pictorial representations of processes, during observations and video/audio-recording of interviews. In addition the research team will keep reflective diaries and notes of team discussions.

Contingency plans have been made to transfer the ethnography to a remote working design in the event of further COVID-19 restrictions.

Data analysis

Reflexive analysis concurrent with data collection will allow iterative exploration of the data within the AT framework. Constant comparative thematic coding of activities/work/effort related to prescribing and medication use will be undertaken. The presence or absence of reference to each model step will be coded, identifying volume of talk: 'hot spots' – memorable examples and stories related to incidents, disturbances, learning experiences; and 'cold spots' - areas that are not talked about (but may still be problematic)

Disturbances in the process will be analysed to categorise types and identify underlying themes and contributing factors. The precedent study using this methodology in antibiotic use identified five categories: consultation challenges, lack of overview, process variation, challenges of handover, loss of the object (goal).[10] We will specifically seek these while remaining alert to new and alternative categories. Attention will be paid to normal and out-of-hours care, different contexts and points of transition.

Synthesis of Phases 1 and 2

Activity Theory provides a framework to make sense of data, building a rich multivoiced picture of work and effort. Ethnographic findings will be integrated with the initial process model to develop it into an experience/practice-based model for practices to ensure people with palliative care needs receive the right medications and with the right support at the right time. We will identify how symptom control can best be effective when processes are distributed across roles and contexts as well as using the final model to identify safety concerns with a focus on understanding underlying themes and contributing factors so that these can become targets for intervention and improvement.

Ethics and dissemination

NHS Regional Ethics Committee approval has been obtained. A multi-professional/expert steering group is supporting the research team. We have consulted widely to consider ethical issues. We recognise that participants may find discussing care and service provision distressing if this prompts reflection on examples where all did not go well. Equally, some participants may find the research encounters therapeutic or useful for reflexive professional practice. We will develop a support protocol for this with each local site / clinical team and will signpost to, or facilitate, referral to additional services as necessary. Both the research fellow (registered pharmacist) and the CI (doctor) are experienced in working in clinical settings and adhering to the standards of confidentiality required.

Anticipated outcomes

Understanding the effort and work practices required day-to-day in the use of prescription medications, and the underlying themes and contributing factors in disruptions is crucial to designing, testing and implementing more efficient care models. This study will produce:

- A theoretically informed, empirically evidenced, model of how prescribing and medication use, as a complex multi-step process involving multiple people, occurs in a 'typical' English local healthcare economy
- Understanding of underlying themes and contributing factors to challenges in the system
- Identification of forms of collaborative action in prescribing and medication use
- Recommendations for system quality indicators
- A toolkit for patients and carers to empower them in conversations with professionals, and for professionals to assess the current processes for prescription medications in their local context. Scrutinising prescribing and medication use practices by applying our model may reduce the need for unanticipated care provision and decrease patient/carer burdens.

Dissemination

Findings will be disseminated through academic publications, a stakeholder dissemination event and a Plain English report circulated to policymakers, commissioners, clinicians, researchers and the public. We will seek informed consent for data archiving and use for secondary research purposes including sharing anonymised data with other researchers.

Figure Legends:

Figure 1: Relationship between review objectives, questions and inclusion criteria
Figure 2: Strength score (Researcher-derived strength score descriptors adapted for use in quality assessment for secondary analysis[51])

Authors' contributions: BDF, MEO, AK and KM co-produced the study design from inception led by SY, making substantive contributions to gaining funding, ethical approval, and writing this protocol. SAF was recruited to join the research team once funding was secured, making substantive contributions to refining the study design and writing this protocol. All authors have approved the final version.

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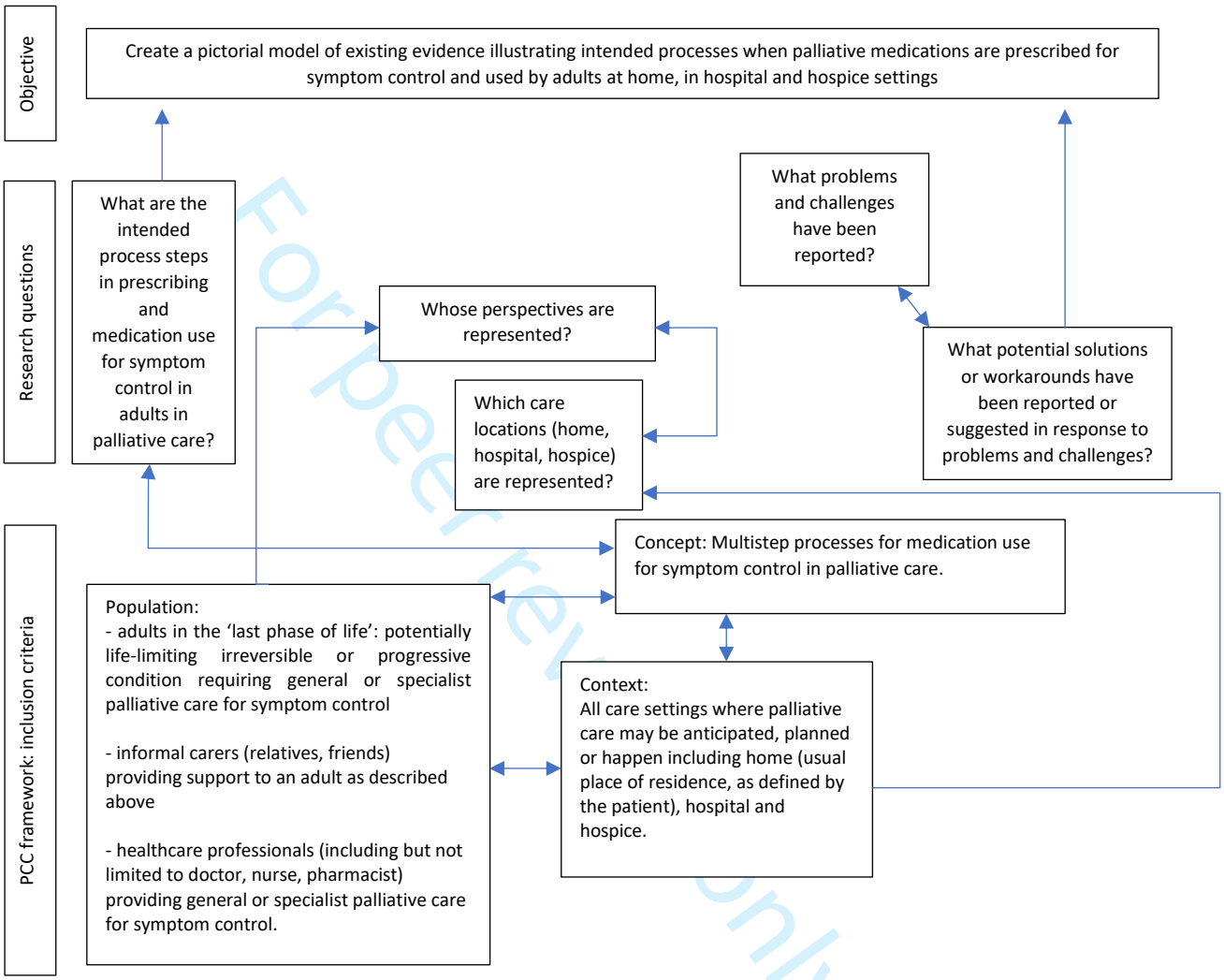


Strength score	Adapted score descriptors used for secondary analysis	Outcome
S1	No clear methods leading to results and conclusions; not significant	Exclude paper
S2	Methods lack detail, although results may suggest a trend (e.g. article covers something unique)	Include paper
S3	Methods appropriate for our research question (population, data generated, data presented)	Include paper
S4	Methods are very clear and very likely to yield important data	Include and consider as key paper
S5	Methods have produced data that are unequivocal	Include and consider as key paper

Supplementary Files

Supplementary file 1

Supplementary Table 1: Activity Theory Concepts and Definitions

Supplementary Figure 1: Applied representation for this study

Supplementary file 2

Data extraction form

Supplementary file 3

Scoping review search strategy in Medline Ovid

Supplementary file 4

Interview guide

Supplementary file 1

Supplementary Table 1: Activity Theory Concepts and Definitions

Key concept	Definition	**Application in prescribing and medication use**	**Explanatory notes**
Activity	The work and effort undertaken by people to achieve an object (see below). Always collective, activities include ambiguity, surprise and sensemaking, all of which are considered to generate the potential for change, i.e. expansion of the object, and/or new ways of achieving it.	Processes, work, and efforts undertaken by patients, informal carers and healthcare professionals in prescribing and medication use for symptom control.	At its very simplest the task of getting the right medication to the right patient at the right time requires six broad steps: 1. Recognition of need, clinical assessment and decision-making 2. Agreeing a prescription (choice of medication, formulation, route of administration) and ensuring this is completed by an appropriately qualified and competent professional 3. Transfer of the prescription to a pharmacy for dispensing of medication 4. Delivery of the medication back to the patient 5. Administration either by the patient or by an appropriate person according to prescribing instructions 6. Monitoring for clinical effects and side-effects as well as levels of supply and repeat requests and the disposal of medications no longer required A commonly overlooked additional step when patients die at home is the management of medications during the post-death bereavement period. These steps demonstrate that to view prescribing and medication use as the activity of an individual is a flawed approach[1] and greater understanding is needed of how each is achieved, by whom if we are to understand the sources of frustration in prescribing and medication use for patients, carers and professionals then identify potential improvement targets that are meaningful to them.
Activity System	Historically evolving systems within organisations/contexts where activities take place.	For this study we have centred our focus on the patient. Therefore, our unit of analysis is patients' activity system incorporating the whole multi-step task of getting the right medication at the right time, and we will consider how their activity system has interacted with each context in their narratives of experiences at home, in hospice and in hospital and when moving between these.	Increasingly in healthcare the boundaries between activity systems are blurred. With respect to prescribing and medication use, each context of home, hospice and hospital might each be considered as a separate activity system. However, the object of prescribing and medication use within each activity system can also be conceptualised as shared activities, within any setting in a local health economy where people with palliative care needs might be found. This is because the whole multi-step task of prescribing and medication use encompasses everything from identifying a palliative care need that requires medication to deciding what to prescribe, prescribing, dispensing and delivering supply to patients and administration in the context of providing holistic symptom control for people according to need, and regardless of diagnosis or location.

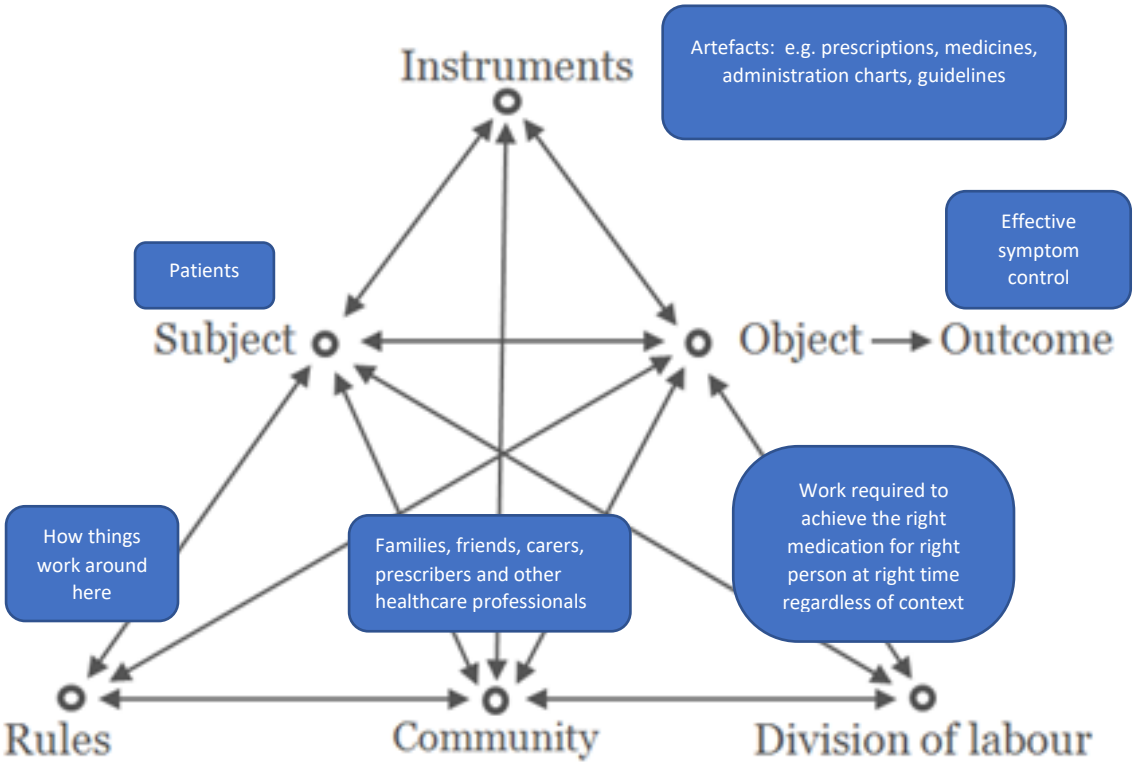
Community	People around the subject who are engaged in activities to achieve the object.	Achieving the object requires collective action of a large community of professionals together with patients and their informal network of carers (such as family and friends).	Multiple relations should be analysed while seeking to also analyse the systemic whole. Further complexities arise from societal myths and misconceptions about the purpose of palliative care and intended outcomes of using medications. The emotionally charged nature of interactions within palliative care may place particular demands on patients, those significant to them and professionals, with implications for their wellbeing.
Contradictions	Contradictions occur within and between activity systems on several levels: Primary contradictions occur when there are internal contradictions within the elements of the activity system, e.g. use value vs. exchange value in the object. Secondary contradictions occur between different elements of the system e.g. subject vs rules. Tertiary contradictions occur when there is difference between the object of the prevailing activity and a new activity through resistance to change. Quaternary contradictions arise in parallel with the generalization of the new activity between the new activity and its neighboring activities (conflicts with others).	We will explore contradictions as a cause of disturbances in the study. Contradictions and disturbances in activity processes do create problems – such as the daily hassles of prescribing and medication use reported by patients, carers and healthcare staff alike – but also offer targets for new collectively generated solutions: "*The distance between the present everyday actions of the individuals and the historically new form of the societal activity that can be collectively generated as a solution to the double bind potentially embedded in everyday actions*"[2]	Examples of each type will be sought. These might include things such as who should be prescribing and following up medication use, how different contexts permit different levels of patient choice in medication use or when an expert may choose to deviate from usual practice for specific reasons but this is not clearly communicated to others. Equally from a patient perspective, contradictions may arise between different priorities e.g. achieving good pain control versus beliefs about the use of strong analgesia such as opioids. Contradictions may also arise in different perceptions and assumptions about whose role or responsibility it is to contribute what activity within and when a patient moves between settings. Rather than viewing contradictions negatively within activity theory these will be viewed as sources of disturbance that hold the key to change and potential for improvement and learning.
Disturbances/ Deviations (used interchangeably in Activity Theory literature)	These are: *"deviations from the normal scripted course of events in the work process, normal being defined by plans, explicit rules and instructions, or tacitly assumed traditions. A disturbance may occur between*	The concept of disturbance will be used to explore prescribing and medication use processes, presented as chronological patient experiences and in our study, are treated as important tools for rethinking and developing healthcare processes.	Activity systems (of patients, carers and professionals within and during transitions between home, hospital and hospice) are interdependent and at the same time potentially tension-laden relationships with each other, generating disturbances. Disturbances in care processes and may hinder holistic management of patient care. However, instead of being viewed as error-causing phenomena, we view disturbances as an inherent feature of work processes and as drivers for change and development.[4,5,6,7] Deviations may occur because of competing pressures or priorities. For example, while effective symptom control may be the intended

	people and their instruments, or between two or more people. Disturbances appear in the form of an obstacle, difficulty, failure, disagreement, or conflict"[3]		object of activity competing objects such as the desire to please or avoid confrontation may cause disturbances in the process as may system failures or guidelines/protocols that are not practical to apply.
Divisions of labour	The divisions of labour describe how different individuals / roles act on the object of the activity.	Who is responsible to enact and ensure safety in each step of the process describes the division of labour. In reality this may not be clear or straightforward in all situations.	Divisions of labour tend to occur through use of implicit as well as explicitly developed norms (i.e. how we do things around here as well as officially promoted ways of how things should be done). Power is an important consideration in divisions of labour as inequalities in power will alter how divisions occur and are understood. Divisions may also evolve over time but will be influenced by what has historically been in place.
Expansive learning	In activity theory positive evolution and development of practice is framed as 'expansive learning' – that is learning which occurs through people interacting each other and co-producing new ways of working that better suit the goal to which they are working.	In order to understand how this can be achieved and where system breakdowns, barriers and facilitators or problems lie study of the existing practice and workplace context in which a particular goal, such as prescribing safety and effectively, is needed. In doing so it is important to pay attention to anything that creates a disturbance from ideal/intended/what happens on paper practice.	This type of learning can often start as in-situ 'work-arounds' that people develop informally. Research attempts to capture this so that it can be utilised further, bringing frontline innovations and initiatives into improvement strategies.
Mediating artefacts	The use of artefacts (tools and instruments) ideally driven by collective object-related motives to mediate actions between subjects and objects in the context of work.	Examples include: Using pathway protocols to standardize care procedures Medication administration / Drug charts Prescriptions (known as FP10s) Equipment for medication use	People both use inanimate mediating artefacts in their interactions with each other and assign these artefacts a place in the system. Understanding when an artefact has 'taken on a life of its own' i.e. is being used beyond its original intent or in novel ways to achieve / disrupt achievement of an object is important in understanding the dynamics of the community.
Object (goal)	Essentially what the subject needs and what the system and community should be trying to achieve. The object includes a collective motive (goal/outcome) and	The object of prescribing and medication use in palliative and end-of-life care is to achieve the best possible symptom control by delivering the right medication to the right person in a timely manner.	The sense and meaning of actions are attached to the object of an activity. Best possible symptom control is a collective object which enables a wider understanding of patient care and 'patient centredness' than the various specific potentially competing objects held by the many people involved in the process (i.e. professionals and carers as well as patients may also have other objects they pursue simultaneously, for example seeking to contain risks from potential side effects, or seeking to either share in or opt-out of prescribing decisions)

	connects actions of individuals to larger systems.		The concept of ***object*** can potentially widen our understanding of why disturbances take place. The existence of the multiple, specific and sometimes competing objects typically causes disturbances in care processes. The flexible aligning of the different and competing objects calls for the collective reflection, negotiation and reconceptualization of the object to enhance collaboration in the provision of patient care.[8]
Rules	The parameters within which activities take place.	These can be implicit (how things work around here) or explicit (e.g. legal regulations).	Due to the medications used there are complex and variable systems for prescribing, dispensing and administering in different settings and perspectives on division of labour to achieve this vary. The rules by which different people in the system are guided and constrained also vary and members of the community of professionals may or may not be party to understanding the context and capabilities of others.
Subject	The person who the object should serve.	In this case the patient.	
While we note that objects, rules, community and division of labour can be unclear, implicit and/or fluctuating this table provides an overview of these and other key concepts in Activity Theory. Understanding different perspectives on the specifics of the listed concepts is an essential part of using Activity Theory as a guiding framework for research. We have given a brief definition for each, followed by its potential application in our study of prescribing and medication use, and provided further explanatory notes to help those unfamiliar with this sociocultural theoretical approach. These have been modified from previous work studying antibiotic prescribing by members of the research team.[9]			

Supplementary Figure 1: Applied representation for this study[10]

Activity Theory is our methodological framework for understanding the processes and practices occurring from point of clinical decision that medication is needed to patient administration.



Using this framework we can place the patient and prescriber as subjects within a wider community of families, friends, carers and healthcare professionals between whom interactions will occur and the work of achieving the goal of symptom control through provision of the right medication at the right time regardless of setting requires a functional division of labour that meets everyone's understanding of the rules of 'how things work around here'.

The upper part of the diagram represents individual and group actions embedded in a collective system. The subject is whoever the activity (work, effort) is designed to benefit, for example patients. The instruments (tools, signs, artefacts) are the things used to achieve the benefit (for example a written prescription). The object is the goal of the activity (for example, medication for pain control) and the outcome is both the impact of the activity (does the patient get the medication when they need it and does it relieve them of pain) and the sense or meaning created by the patient and others about the activity.

The bottom part of the diagram provides a collective focus on the patient's environment, relationships and context. The community represents others around them (for example informal carers, healthcare professionals). The rules describe how formal systems and informal practices shape the activity – these may be written in policies (for example prescribing guidelines) or unwritten accepted norms (for example local preferences for one sort of medication over another for pain). The division of labour represents the differing roles and responsibilities of everyone involved in the activity. Divisions of labour are commonly characterised by ambiguity, interpretation and potential for change in complex systems involving many different people.

Supplementary file 2

Data extraction form

Reference: Authors and year of publication	Country of origin	Main study aim	Study design	Perspectives represented (e.g. doctor, nurse, pharmacist, patient, carer)	Context: home, hospital, hospice or transitions between these	Steps in processes included in study	Problems and challenges reported	Potential solutions or workarounds reported or suggested	Other key findings that relate to the scoping review question/s	Strength score

Supplementary file 3

Scoping review search strategy

Medline (Ovid)
Search conducted 14 July 2021

Search	Query	Records retrieved
S1	exp Patients/ OR exp Caregivers/ OR exp Spouses/ OR exp Family/ OR exp Friends/ OR Partner*.mp. OR carer*.mp. OR care giv*.mp. OR caregiv*.mp.	660,455
S2	Nurs*.mp. OR pharmacist*.mp. OR clinician*.mp. OR doctor*.mp.	1,142,041
S3	S1 OR S2	1,705,544
S4	exp medication therapy management/ OR prescri*.mp. OR exp Pharmacy Service, Hospital/ OR medic* management.mp. OR medic* reconcil*.mp. OR medic* safety.mp. OR medic* treatment.mp. OR exp Medication Errors/ OR medic* error.mp. OR exp Inappropriate Prescribing/ OR Inappropriate prescrib*.mp. OR suboptimal prescribe*.mp. OR exp Patient Safety/ OR patient safety.mp. OR side effect.mp. OR drug related side effects.mp. OR adverse drug reaction.mp. OR exp "Drug-Related Side Effects and Adverse Reactions"/ OR prescrip* appropriate*.mp. OR drug prescriptions.mp. OR exp Drug Prescriptions/ OR prescription appropriateness.mp. OR medic* review.mp. OR drug related problems.mp. OR Drug Interactions/ OR (drug adj1 safety).mp. OR patient harm.mp. OR Patient Harm/ OR exp Medication Systems/ OR exp Drug Utilization/ OR drug utilisation review.mp. OR exp "Drug Utilization Review"/ OR (utiliz* OR utilis* OR dispens*).mp. OR exp Patient-Centered Care/ OR patient centred care.mp. OR exp Pharmaceutical Preparations/ OR exp Drug Dosage Calculations/ OR exp Drug Prescriptions/ OR exp Polypharmacy/ OR self administration.mp. OR exp Self Administration/ OR exp Prescription Drugs/ OR exp "Off-Label Use"/ OR exp Infusion Pumps/ OR exp Infusions, Subcutaneous/ OR exp Injections, Subcutaneous/ OR medication*.mp. OR medicine*.mp.	3,299,100
S5	exp after-hours care/ OR exp "delivery of health care, integrated"/ OR exp practice patterns, pharmacists'/ OR exp practice patterns, nurses'/ OR exp practice patterns, physicians'/ OR exp professional practice gaps/ OR exp patient care team/ OR exp nursing, team/	149, 956
S6	S4 OR S5	3,396,358
S7	exp Terminally Ill/ OR exp Terminal Care/ OR exp Palliative Care/ OR (Hospice and palliative care nursing).mp. OR exp Hospice Care/ OR exp Palliative Medicine/ OR palliat*.mp. OR CSCI.mp. OR Continuous subcutaneous infusion.mp. OR Just in case medic*.mp. OR symptom control.mp. OR syringe pump.mp. OR syringe driver.mp. OR McKinley.mp.	150,547
S8	S6 AND S7	29, 153
S9	S3 AND S8	9, 537

Supplementary file 4

Interview guide

Interviews with be conducted using a semi-structured approach with:

- *Patients and informal carers (if carer interviewed separately tailor questions to ask about their perspective on the person they care for)*
- *Professionals*

1. **Experiences of medications for symptom control in palliative care**
    a. Ask participant to describe their experiences as a patient/carer/professional
    b. Prompt for specific examples and explanations
        i. What was happening?
        ii. Who was involved?
        iii. What needed to be done before/during/after each event or activity?
        iv. What was good / worked well?
        v. What wasn't good / didn't work?
        vi. What could have made a difference?
    c. Probe for detail on each step of the process (i.e each unit of analysis in the process) and the links/breakdowns between steps
        i. Decision-making/Starting a medication
        ii. Discussion of risks and benefits
        iii. Prescribing /Taking/Adding a medication
        iv. Monitoring and supply / Reviewing a medication
        v. Administration
        vi. Repurposing medications
        vii. Addressing new concerns
        viii. Stopping medications
        ix. Moving across healthcare contexts
    d. Ask about objects/tools mentioned and how these are used e.g. lists, prescriptions, medication boxes, reminders etc.
    e. Ask who is responsible for what in each part of the process?
    f. Ask how decisions are made?
    g. Ask about 'how things work around here?' – what are the informal ways of working / getting things done? Are there 'rules' or understandings of things that 'are just how it is done'
2. **Differences between settings**
    a. How do things work at home v hospice v hospital (as applicable to each participants experience)?
    b. What happens when people move between settings
        i. Admissions and discharges
3. **Discussion of AT framework:**
    a. Explain framework (as shown in figure 1) to participant and seek their feedback on how use of medication for symptom control in palliative care plays out within the system
        i. Thinking about the system from different perspectives – ask participants how they think others see the system: patients/carers/professionals and how the system is viewed from hospice/hospital to home and vice versa?
        ii. Where are there contradictions or breakdowns in the system?
4. **Anything else the participant would like to add?**

References

1. Noble C, Billett S. Learning to prescribe through co-working: junior doctors, pharmacists and consultants. Medical Education 2017;51:1365-2923.
2. Engeström, Y. Learning by expanding: An activity-theoretical approach to developmental research. Helsinki, Orienta-Konsultit. p174
3. Engeström Y. From teams to knots: Activity-theoretical studies of collaboration and learning at work. Cambridge: CUP; 2008.
4. Engeström, Y, Kajamaa, A, Kerosuo, H, Laurila P. Process Enhancement Versus Community Building: Transcending the Dichotomy through Expansive Learning. In K. Yamazumi (Ed.) Activity Theory and Fostering Learning: Developmental interventions in education and work. Osaka: Center for Human Activity Theory, Kansai University; 2010. pp. 1–28.
5. Public Involvement Standards Development Partnership. UK standards for Public Involvement. National Standard 3: Support & learning. Available at https://sites.google.com/nihr.ac.uk/pi-standards/home [accessed 17.06.19].
6. O'Brien H, Kiely F, Carmichael A. Doctor-related medication safety incidents on a specialist palliative medicine inpatient unit: A retrospective analysis of three years of voluntary reporting. Journal of Pain and Palliative Care Pharmacotherapy. 2017;1-8.
7. Casarett D., Spence C., Clark M., Shield R., Teno J. Defining patient safety in hospice: Principles to guide measurement and public reporting. *Journal of Palliative Medicine* 2012;15:1120-3.
8. Larsen D P, Wesevich A, Lichtenfeld J, Artino A R, Brydges R, Varpio L. Tying knots: an activity theory analysis of student learning goals in clinical education. *Medical Education* 2017;51:687‐98.
9. Kajamaa A, Mattick K, Parker H, Hilli A, Rees C. Trainee doctors' experiences of common problems in the antibiotic prescribing process: an activity theory analysis of narrative data from UK hospitals BMJ Open 2019;9:e028733. doi: 10.1136/bmjopen-2018-028733.
10. Adapted from Engeström, Y. Learning by expanding: An activity-theoretical approach to developmental research. Helsinki, Orienta-Konsultit. p78.

Integrated checklist drawing on relevant sections of checklists by choice of method: Getting palliative medications right across the contexts of homes, hospitals, and hospices: protocol to synthesise scoping review and ethnographic methods in an Activity Theory analysis

1. Scoping review We have used the Joanna Briggs Institute Manual for Evidence Synthesis with particular reference to Chapter 2: Systematic reviews of qualitative evidence and Chapter 11: Scoping reviews as the standard to inform design of our scoping review and qualitative meta-ethnography to synthesise the data. We have cross checked this against the JBI recommended SUMARI_Protocol_Template_Scoping_Reviews. Aromataris E, Munn Z (Editors). *JBI Manual for Evidence Synthesis.* JBI, 2020. Available from https://synthesismanual.jbi.global. https://doi.org/10.46658/JBIMES-20-01

2. **Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) Checklist**

SECTION	ITEM	PRISMA-ScR CHECKLIST ITEM	REPORTED ON PAGE #
TITLE			
Title	1	Identify the report as a scoping review.	Title page (1)
ABSTRACT			
Structured summary	2	Provide a structured summary that includes (as applicable): background, objectives, eligibility criteria, sources of evidence, charting methods, results, and conclusions that relate to the review questions and objectives.	Abstract page (2)
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known. Explain why the review questions/objectives lend themselves to a scoping review approach.	5
Objectives	4	Provide an explicit statement of the questions and objectives being addressed with reference to their key elements (e.g., population or participants, concepts, and context) or other relevant key elements used to conceptualize the review questions and/or objectives.	5-6
METHODS			
Protocol and registration	5	Indicate whether a review protocol exists; state if and where it can be accessed (e.g., a Web address); and if available, provide registration information, including the registration number.	Not applicable
Eligibility criteria	6	Specify characteristics of the sources of evidence used as eligibility criteria (e.g., years considered, language, and publication status), and provide a rationale.	7
Information sources*	7	Describe all information sources in the search (e.g., databases with dates of coverage and contact with authors to identify additional sources), as well as the date the most recent search was executed.	7-8
Search	8	Present the full electronic search strategy for at least 1 database, including any limits used, such that it could be repeated.	Supplementary file 3
Selection of sources of evidence†	9	State the process for selecting sources of evidence (i.e., screening and eligibility) included in the scoping review.	7-8
Data charting process‡	10	Describe the methods of charting data from the included sources of evidence (e.g., calibrated forms or forms that have been tested by the team before their use, and whether data charting was done independently	8 and supplementary file 2

SECTION	ITEM	PRISMA-ScR CHECKLIST ITEM	REPORTED ON PAGE #
		or in duplicate) and any processes for obtaining and confirming data from investigators.	
Data items	11	List and define all variables for which data were sought and any assumptions and simplifications made.	8
Critical appraisal of individual sources of evidence§	12	If done, provide a rationale for conducting a critical appraisal of included sources of evidence; describe the methods used and how this information was used in any data synthesis (if appropriate).	8
Synthesis of results	13	Describe the methods of handling and summarizing the data that were charted.	8-9
RESULTS			
Selection of sources of evidence	14	Give numbers of sources of evidence screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally using a flow diagram.	N/A at protocol stage
Characteristics of sources of evidence	15	For each source of evidence, present characteristics for which data were charted and provide the citations.	N/A at protocol stage
Critical appraisal within sources of evidence	16	If done, present data on critical appraisal of included sources of evidence (see item 12).	N/A at protocol stage
Results of individual sources of evidence	17	For each included source of evidence, present the relevant data that were charted that relate to the review questions and objectives.	N/A at protocol stage
Synthesis of results	18	Summarize and/or present the charting results as they relate to the review questions and objectives.	N/A at protocol stage
DISCUSSION			
Summary of evidence	19	Summarize the main results (including an overview of concepts, themes, and types of evidence available), link to the review questions and objectives, and consider the relevance to key groups.	N/A at protocol stage
Limitations	20	Discuss the limitations of the scoping review process.	N/A at protocol stage
Conclusions	21	Provide a general interpretation of the results with respect to the review questions and objectives, as well as potential implications and/or next steps.	N/A at protocol stage
FUNDING			
Funding	22	Describe sources of funding for the included sources of evidence, as well as sources of funding for the scoping review. Describe the role of the funders of the scoping review.	11

JBI = Joanna Briggs Institute; PRISMA-ScR = Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews.

* Where *sources of evidence* (see second footnote) are compiled from, such as bibliographic databases, social media platforms, and Web sites.

† A more inclusive/heterogeneous term used to account for the different types of evidence or data sources (e.g., quantitative and/or qualitative research, expert opinion, and policy documents) that may be eligible in a scoping review as opposed to only studies. This is not to be confused with *information sources* (see first footnote).

‡ The frameworks by Arksey and O'Malley (6) and Levac and colleagues (7) and the JBI guidance (4, 5) refer to the process of data extraction in a scoping review as data charting.

§ The process of systematically examining research evidence to assess its validity, results, and relevance before using it to inform a decision. This term is used for items 12 and 19 instead of "risk of bias" (which is more applicable to systematic reviews of interventions) to include and acknowledge the various sources of evidence

that may be used in a scoping review (e.g., quantitative and/or qualitative research, expert opinion, and policy document).*From:* Tricco AC, Lillie E, Zarin W, O'Brien KK, Colquhoun H, Levac D, et al. PRISMA Extension for Scoping Reviews (PRISMAScR): Checklist and Explanation. Ann Intern Med. 2018;169:467–473. doi: 10.7326/M18-0850.

3. Sections of GRIPP2 applicable to study protocols regarding PPI

Section and topic	Item	Reported on page No
Section 1: Abstract of paper		
1a: Aim	Report the aim of the study	2
1b: Methods	Describe the methods used by which patients and the public were involved	2
1e: Keywords	Include PPI, "patient and public involvement," or alternative terms as keywords	Not appropriate as not a study of PPI per se
Section 2: Background to paper		
2a: Definition	Report the definition of PPI used in the study and how it links to comparable studies	7
2b: Theoretical underpinnings	Report the theoretical rationale and any theoretical influences relating to PPI in the study	6-7
2c: Concepts and theory development	Report any conceptual models or influences used in the study	6-7
Section 3: Aims of paper		
3: Aim	Report the aim of the study	5
Section 4: Methods of paper		
4a: Design	Provide a clear description of methods by which patients and the public were involved	7
4b: People involved	Provide a description of patients, carers, and the public involved with the PPI activity in the study	7
4c: Stages of involvement	Report on how PPI is used at different stages of the study	7
4d: Level or nature of involvement	Report the level or nature of PPI used at various stages of the study	7

4. SRQR: Standards for Reporting Qualitative Research: A Synthesis of Recommendations

O'Brien, Bridget C.; Harris, Ilene B.; Beckman, Thomas J.; Reed, Darcy A.; Cook, David A. Academic Medicine89(9):1245-1251, September 2014. doi: 10.1097/ACM.0000000000000388

Item	Page no.
Title and abstract	
Title	1
Abstract	2
Introduction	
Problem formulation	5
Purpose or research question	5-6
Methods	
Qualitative approach and research paradigm	6
Researcher characteristics and reflexivity	11

Context	9
Sampling strategy	9 and Box 2, Table 2
Ethical issues pertaining to human subjects	11
Data collection methods	9-10
Data collection instruments and technologies	9-10 and Supplementary file 4
Units of study	Not applicable at protocol stage
Data processing	Available on request. Not standard to include in protocol papers.
Data analysis	10
Techniques to enhance trustworthiness	6
Results/Findings	
Synthesis and interpretation	Not applicable at protocol stage
Links to empirical data	Not applicable at protocol stage
Discussion	
Integration with prior work, implications, transferability and contributions to the field	Not applicable at protocol stage
Limitations	See strengths and limitations summary p4. Additional discussion will be provided with the results papers
Other	
Conflicts of interest	11
Funding	11