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A mid-range programme theory of human factors issues in out-of-hours community palliative care: lessons from a realist approach to analysis of stakeholder experiences

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Complete List of Authors:	Yardley, Sarah; University College London Marie Curie Palliative Care Research Department, Williams, Huw; Cardiff University Bowie, Paul; NHS Education for Scotland Edwards, Adrian; Cardiff University Noble, S; University of Cardiff, Marie Curie Research Centre Donaldson, Liam; London School of Hygiene and Tropical Medicine Carson-Stevens, A; Cardiff University
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Title: A mid-range programme theory of human factors issues in out-of-hours community palliative care: lessons from a realist approach to analysis of stakeholder experiences

Authors: Sarah Yardley,[1] Huw Williams,[2] Paul Bowie,[3] Adrian Edwards,[2] Simon Noble,[4] Liam Donaldson,[5] Andrew Carson-Stevens[2]*

1. Marie Curie Palliative Care Research Department, University College London; Palliative Care Service, Central & North London NHS Foundation Trust; The Health Improvement Studies (THIS) Institute Post-doctoral Fellow

2. Division of Population Medicine, Cardiff University, 8th floor, Neuadd Meirionnydd, Health Park, Cardiff CF14 4XN

3. Safety, Skills and Improvement Research Collaborative, NHS Education for Scotland, Edinburgh, UK; Institute of Health and Wellbeing, University of Glasgow, Glasgow, UK; School of Health and Social Care, Staffordshire University

4. Marie Curie Palliative Care Research Centre, Division of Population, Cardiff University, Cardiff, Wales, UK

5. Faculty of Epidemiology and Population Health, London School of Hygiene and Tropical Medicine, London, WC1E 7HT, UK

*Corresponding author: Dr A. Carson-Stevens carson-stevensap@cardiff.ac.uk

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Abstract

Background: In the UK around 30% of people receiving palliative care have contact with out-of-hours services. Interactions between emotions, cognition, tasks, technology and behaviours must be considered to improve safety.
Research question: What do perceptions and experiences of out-of-hours provision in the community tell us about potential underlying human factors design issues that might be influencing system performance for achieving desirable outcomes in palliative care?
Objective: To develop a mid-range theory accounting for human factors design issues in driving quality improvement in out-of-hours palliative care.
Setting: Local providers of out-of-hours palliative care were invited to a stakeholder event.
Participants: 17 stakeholders participated.
Design: After sharing their experiences, participants were presented with analyses of incident reports to discuss and consider potential priorities for change. Discussions were audio-recorded and transcribed verbatim by the study team. Event artefacts, e.g. sticky notes, were retained for analysis. Two researchers independently identified context-mechanism-outcome configurations using realist approaches before studying the interrelation of configurations to build a mid-range theory. This was critically considered using Systems Engineering Initiative for Patient Safety (SEIPS), an established human factors framework.
Results: Complex interacting configurations explain relational and experience-based human-mediated outcomes in out-of-hours care:1. Prioritisation; 2. Emotional labour; 3. Complicated/Complex systems; 4a. System inadequacies & 4b. Differential attention and weighing of risks by organisations; 5. Learning. Metacognition, emotional intelligence, prior experiences and learning will either overcome system limitations or overwhelm system safeguards. Underpinning all configurations were two further mechanisms: trust and access to expertise; and, isolation at night.
Conclusions: Cycles of thought and behaviour are refined and replicated according to prior experiences. Integration of human-centred co-design principles, and informal learning theory, into approaches for quality improvement may improve results.

Keywords

Palliative Care Medicine; Health Services, Community; After-Hours Care; Realist Theory; Social Theory; Human Factors Issues; Quality Improvement; Stakeholder Participation

Strengths and limitations of this study

- The study design provided a safe space to integrate multiple perspectives on safety and improvement initiatives in palliative care
- Cross-disciplinary expertise has been combined with stakeholder experiences of frontline care to develop new understandings of human factor issues in out-of-hours palliative care, and how these create mechanisms for desirable or undesirable outcomes
- Using SEIPS in combination with realist approaches is a novel methodological development for cross-disciplinary analysis that has promise for future research
- Further work is needed to explore the issues raised and mid-range theory generated in other contexts and with more people
- We were not able to address the issue of a false divide between out-of-hours and in-hours care in this study but this requires urgent attention as each impacts on the other

Main text

Background

Fragmented system design of out-of-hours palliative care creates high risk of patient safety incidents.[1,2] With a sub-optimal system design, human factor issues are highlighted as people seek to work-around, manage goal conflicts and resource constraints, and mitigate structural challenges 'to get the job done' safely and efficiently as possible. The extent to which risk and wellbeing is impacted because of system-wide human factors issues is unknown.

In the United Kingdom (U.K.), out-of-hours healthcare provision is complex due to the many different professionals, organisations and systems involved. Palliative care out-of-hours presents patient safety and professional performance challenges arising from both the nature of the care needs and generic risks commonly found in out-of-hours care.[1,2] The latter include problems with lack of prior knowledge about patients, reliance on remote consultations, lack of access to patient records and difficulties in service co-ordination.[1,2] Electronic Palliative Care Coordination Records have been designed to provide a systematic approach to information needs but are not universally available nor fully functional in practice.[3,4,5]

Around 30% of people receiving palliative care in their usual place of residence in the U.K. have contact with frontline out-of-hours services.[6] Patients and families can struggle to identify who to contact out-of-hours and may feel they have to trade-off between speed of response and relevant service/expertise of responders.[7] Most patients in the last phase of life are in their usual place of residence for the vast percentage of their remaining time (home or care home).[8] This means access to services for most out-of-hours palliative care is via community/primary care and emergency services. Acute hospitals are the second commonest place of care and most patients still die in hospital, with numbers of deaths and the proportion occurring in hospitals both projected to rise.[9,10] Addressing out-of-hours challenges has been identified as a key priority by patients and palliative care organisations.[11]

In this paper, we use the term 'system' to refer to the entirety of healthcare enterprise, that is both the structural (in various disciplines referred to as field, architecture, artefacts) and human factors issues. 'Human factors' (also known as ergonomics) is a scientific discipline that seeks to understand and optimise the interaction of people within the wider system in which they work. More specifically human factors have been used to consider the direct and indirect (humanly-mediated) impacts of socio-technical systems and environments on safety, risk and wellbeing.[12] The interactions between human emotion, cognition and behaviours and the influence of wider system elements have not however, always been fully considered. This is essential to better understand how to design environments and structural systems to guide humans into the best course of action, while still maintaining allowances for necessary adaptions in performance to 'get the job' done given care complexities, goal conflicts and resource constraints.

In previous work, NHS patient palliative care safety incident reports stored on national databases were analysed for underlying causes and contributing factors.[1,2] These findings were presented to stakeholders in out-of-hours palliative care in a half day research workshop which itself generated data for the current study. Analysis of the workshop data was conducted to further understand underlying desirable/wanted and undesirable/unwanted outcomes in community-based palliative care drawing on the concerns of those on the frontline. This study design was situated in a wider quality improvement project, which aimed to improve out-of-hours palliative care across a South Wales Health Board.

Research question

What do perceptions and experiences of out-of-hours provision in the community tell us about potential underlying human factors design issues that might be influencing system performance for achieving desirable outcomes in palliative care?

Objective

To develop a mid-range theory of change to account for human factors design issues in driving quality improvement in out-of-hours palliative care.[13]

Methods

Ethical approval was granted from Wales Research Ethics Committee 3 (17/WA/0222).

Theoretical orientation

Realist approaches seek to understand what works, for whom, under what circumstances and how, through the identification of context-mechanism-outcome (CMO) configurations. If outcomes (desired or not) are known, then analysis can trace back the mechanisms that led to those outcomes in particular contexts.[14] Once CMO configurations are identified, these can be drawn together into a mid-range programme theory of practice. Mid-range theories are concepts that explain CMOs within an overarching theory of how a process functions to produce particular outcomes in different circumstances i.e. as underlying changes in reasoning and behaviour are triggered by different types or qualities of interaction or context.[13,15] Whether in an intervention or routine frontline clinical practice, the routines in which people engage will be subject to different participants making choices, and these choices subject to social influences such as prior experience.

In this study we apply realist approaches to 'naturally occurring processes' of routine clinical practice. Our initial programme theory (i.e. what might be producing outcomes from a complex system with diverse participants and how) was derived from our knowledge of the existing literature and prior work analysing NHS patient safety incident reports. The process of conducting the workshop and the data generated from it permitted us to test and refine this initial programme theory by identifying CMO configurations. In doing so, we sought to develop a mid-range theory, that is a theory to explain what was happening and why that 'lie[s] between the minor but necessary working hypotheses that evolve in abundance during day-to-day research and the all-inclusive systematic efforts to develop a unified theory'.[16]

We chose to initially conduct an inductive data-driven analysis using realist principles to explore the possibility of generating new theories related to human factor issues which would be emergent from the data. Following this we critically considered our analysis, including the developed mid-range theory, using a deductive approach to compare and contrast our findings with the perspective of the Systems Engineering Initiative for Patient Safety (SEIPS) which is an established human factors framework.[17,18]

Setting

We wanted to use the learning from our prior analyses of incident reports from the national database to inform the improvement agenda for out-of-hours palliative care within a local health board.[1,2] This was undertaken within Aneurin Bevan University Health Board, the largest of the seven health boards in Wales, serving a population of 560,500 in South East Wales. In cooperation with the Board's Palliative Care Strategy Group, a stakeholder event was convened.

The event objectives were to:

1. Identify which issues in out-of-hours palliative care highlighted in national level analyses of patient safety incident reports were prevalent in the local out-of-hours service;
2. Identify which of these issues should be the priority area for improvement efforts within local services; and,
3. Identify a QI project group.

In this paper we present analysis of the first two of these objectives.

Recruitment, selection and participation

Local providers of out-of-hours palliative care were invited to participate in a stakeholder event via email. These invitations were disseminated to the local palliative care network, out-of-hours GP providers, GP cluster networks and the local Research and Development office. Further direct email invitations were sent by the study team to people in key roles including hospice providers, out-of-hours clinicians, palliative care consultants, GP leads and members of the public (including patients). All those who chose to attend the stakeholder event provided written informed consent for this study; hence it is based on a convenience sample of stakeholders who were engaged and interested in the subject.

Patient and public involvement

We are reporting analysis of data collected during an event to which the existing patient and public involvement contacts of Division of Population Medicine, Cardiff University were invited. Intrinsic to our methods is a collaborative approach as this study/the event were the mechanism for sharing prior research findings and seeking to bridge the gap between these and the experiences of all stakeholders in frontline clinical care.

Data generation

The stakeholder event was designed to first allow participants to have an open opportunity to share and reflect on their experiences of out-of-hours provision of palliative care. They were provided with the findings of our analyses of incident reports (we presented initial ideas for change in the form of a driver diagram, see Figure 1).[2] Event facilitators worked with stakeholders to compare experiences with reported incidents and discuss potential priorities for change. We drew on our prior experience of engagement exercises using quality improvement tools[19] to disseminate research findings.

Insert Figure 1 approx. here

Participants were asked to describe examples from recent experiences; discuss views on potential solutions to identified problems; and decide which problems would be most important and feasible to tackle locally. Discussions were audio-recorded and transcribed verbatim by the study team. Participants were also invited to record challenges to the provision of good care and their priorities via sticky notes and these were retained as data (hard copy plus photographs of collective arrangements made during the workshop).

Data analysis

We focused analysis on understanding:

1. the context of out-of-hours community palliative care, and what occurs (mechanisms) to produce desirable outcomes; the intended global outcome of interest was for patients to receive the right care by the right person at the right time in the right place; and,

2. what mechanisms were operating in the same context to produce deviations from desirable outcomes, and what undesirable outcomes consequentially occurred.

HW and SY independently identified individual CMO configurations in data transcripts before comparing to reach a consensus of their coding. This was refined with joint analysis of post-it notes and photographs of flipchart material plus handwritten notes generated in the course of the stakeholder event. We then studied the interrelation of the CMO configurations to identify themes and build a mid-range programme theory of the potential human factors in experiences of out-of-hours palliative care.

SY and PB led the critical comparison of our mid-range theory with the SEIPS framework by re-analysing the raw data, identified CMO configurations and themes during a cross-matching and mapping exercise using the SEIPS framework.

Results

The roles of event participants are listed in Table 1 below.

Insert Table 1 approx. here

Simple situations are defined by identification of straightforward solutions if necessary skills and techniques are mastered. In complicated situations an identifiable set of linked solution components which interact in predictable ways can still lead to definite outcomes.[20] During our analysis, it became rapidly evident that with exception of relatively few specific instances, it was not possible to disentangle independent simple, or even complicated, CMO configurations. Instead the analysis pointed to interacting complex CMO configurations as possible explanations for relational and experience-based human-mediated mechanisms and outcomes.

Tables 2&3 provide a summary of our analytic working as we developed the mid-range theory then presented in Figure 2 and critically examined it using SEIPS (Figure 3).

We first present the few simple and complicated CMO configurations that might be most amenable to technical/structural system change, gaining of skills or techniques for tasks or other component-by-component interventions in Table 2. This table demonstrates that contextual factors such as multiple care providers, including informal carers within a specialist-generalist advisory model where advance care planning was not well established triggered system breakdowns which were considered by participants in the stakeholder event to be amendable to systems-based change. Technological solutions and greater investment in care coordination services such as a single point of access/medication management models in tandem with greater public health assessment of population need were all anticipated to offer improvements. Hence, it can be seen from Table 2 that structural solutions are likely to provide part of the solution particularly if human factors issues are taken into consideration in any redesign.

Insert Table 2 approx. here

However, what we were identifying in most of the data was complex with several significant and concerning underlying themes contributing to multiple human-mediated mechanisms. The themes are presented in Table 3, with illustrative quotations from participants. Together these themes were identified to be influencing outcomes which were produced by mechanisms that co-evolved through interpersonal relationships and could not be explained by a straightforward analysis of parts. Furthermore, the outcomes and subsequent consequences resulting were both unpredictable and yet what mattered most.[20]

We present our overarching interpretive analysis, bringing together the underlying themes and complex CMOs (see Table 3 below and Figure 2 which follows). The interconnected mechanisms interact to form a system with adaptive capacity to change from experience as mediated by the people within it, and their experiential learning. At any point the mechanisms might come together to either overcome system limitations (a 'desirable' outcome) or to overwhelm system safeguards (an 'undesired' outcome).

Insert Table 3 and Figure 2 approx. here

In Figure 2, for each of the outcomes and mechanisms described, all the contextual elements listed were relevant. The themes of Table 3 also underpin all of these complex CMO configurations. The context of out-of-hours palliative care was one where multiple service providers are disconnected from each other, and so misunderstanding and miscommunication could occur very easily in addition to different professional cultures developing regarding risk (present by definition for most people needing palliative care as they have progressive irreversible illnesses) and uncertain outcomes.

The mechanisms numbered 1-5 (1.Prioritisation; 2.Emotional labour; 3.Complicated/Complex systems; 4a.System inadequacies & 4b.Differential attention and weighing of risks by organisations; 5.Learning) within Figure 2 all feed into and off each other. Underlying these mechanisms could be either 'Trust and access to expertise (6a)' which if strong enough could lead to desired outcomes in support of, or regardless of, mechanisms 1-5 through a positive cycle **or** 'Isolation at night (6b)' which could lead to the opposite effects and hence undesirable outcomes. 'Trust and access to expertise (6a)' is, therefore, 'interpersonal glue' that can stick the component parts together to reach desired outcomes.

This data suggest that seeking to focus on specific parts in isolation is unlikely to be successful. What needs to be generated is a positive cycle of learning with attention to all of the underlying themes and interacting human-mediated mechanisms identified. Depending on how human factors-based systems issues interact and function in a particular patient's care, there are alternative desirable or undesirable outcomes for patients that are intertwined with the same for professionals. When patients, informal carers or professionals seek help they are commonly weighing up priorities between speed of response and ability to meet a particular need. Emotional labour is a significant mechanism as being safe in a technical sense does not hold meaning if patients, informal carers or professionals do not feel safe in their location, decision-making, or actions. Furthermore, both prioritisation and emotional labour mechanisms feed into confusion about whom to call for what and when and mechanisms driven by organisational interests or system inadequacies which do not support, for example, individualised decision-making or use of professional judgement when in a situation that requires doing the 'least wrong' thing.

In out-of-hours palliative care, if underlying all of these mechanisms are those of trust and access to expertise then desired outcomes can still be achieved, but if instead the underlying mechanism is a sense of personal or professional isolation undesirable outcomes result. The commonest undesirable outcomes identified were unnecessary patient and informal carer distress, defaulting to admitting patients to acute hospital care and/or escalation of treatment interventions from which there was not a realistic possibility of patient benefit, and professional disempowerment – all of which would feed back into the mechanism cycle by triggering adverse learning that in turn would influence future help-seeking approaches. Positive learning could, however, be created as a result of achieving desired outcomes, as could best use of available resources, both in turn leading to human factors supporting the system.

The outcomes of the CMO configurations identified in this data impact on both system performance and human wellbeing, demonstrating how in out-of-hours palliative care these are not possible to fully disentangle.

In mapping the identified CMO configurations to the SEIPS model it is possible to see clearly how little of the complex person-level concerns from stakeholders regarding out-of-hours palliative care directly relate to technical rather than **socio-**technical in what should be a combination to optimise combined socio-technical system elements. External influences, organisation of work and person elements come to the fore, demonstrating what is filling design gaps in a system which has evolved piecemeal over time, with a striking absence of identified mechanisms related to human factors based design issues at individual, team, organisation and external levels. Furthermore, while it is possible to map relatively simple and complicated mechanisms (Table 2) to SEIPS elements, other than the person level this is not the case with the complex interacting mechanisms that are influencing broader system interaction issues and related performance and wellbeing outcomes (Table 3).

Insert Figure 3 approximately here

Discussion

Our key findings and recommendations are summarised in Table 4. We have drawn on realist and human factors theory to interpret the reality of day-to-day experiences of patients, informal carers and professionals as they are active agents in patient safety endeavours in out-of-hours palliative care. In doing so we demonstrate a small number of CMO configurations that may be amenable to structural change but more importantly why structural change alone will never be enough to ensure patients receive the right care by the right person at the right time in the right place. Our findings show human factors issues go beyond how people interact with each other and with their surroundings, or immediate environment. As people experience different events, socially constructed learning in the form of sense-, or meaning-making occur leading to cycles of thought and behaviour that are refined and replicated according to experiences in future events.

In demonstrating complexity, it is important to note that this means different approaches to mitigations and improvement interventions will be needed. Simple and complicated solutions can only take us so far. We suggest that better integration of human-centred co-design principles,[21] a fundamental approach of human factors, and informal learning theory into future attempts at improvement are needed to increase the likelihood of success. This is because our findings demonstrate that optimal care is dependent on 'interpersonal glue': often mediated by trust, empowerment and ability to tell whether a situation demands a standardised, customised or flexible response.[22] Optimal care and a holistic approach to safety in palliative care is seen to commonly require in-the-moment enacting of workaround strategies to manage risk in complex and adverse conditions.[23-26] Our findings provide evidence of not just what the problems are but how these are created, defined and constructed by people in ways that generate variable patient outcomes, experiential learning (desirable or otherwise) and consequences for future healthcare. The granularity of our findings provides a basis for selecting targeted interventions to influence the social mechanisms underlying safety issues in out-of-hours care.[27]

Insert Table 4 approx. here

This extends previous work analysing database incident reports[1,2,28] by deepening analysis of the human factors interaction issues which are an intrinsic part of the complexity of palliative care work in the community.[21] As a result we propose a mid-range programme theory of the influences on human factors in response to palliative care needs out-of-hours which can be used to guide future attempts to improve the design of care processes through recognition of implicit assumptions and rationales,[13] thereby increasing the chances of mitigating undesirable mechanisms and promoting desirable ones to create meaningful change for patients and increase professionals chance of success as they endeavour to provide safe care in difficult circumstances. We have applied this mid-range programme theory to our later analysis of incidents arising from advance care planning.[28] This identified that regardless of system based solutions to address creation and communication/accessibility of advance care planning these would not be enough; in 37% (26/70) of advance care planning incidents, the plan was not followed due to person-level issues such as poor higher-level meta-cognitive skills or emotional intelligence often in the context of lack of confidence or experience.

Strengths and limitations

SEIPS is one of the most widely used human factors frameworks in healthcare[18,19] and the use of realist approaches in healthcare has grown significantly in recent decades, Using of both to develop a cross-disciplinary analysis to theory and empirical data is, we believe, a novel methodological development. In doing so we have been better placed to consider intersectionality between human factors issues and with structural elements in the context of a healthcare system. Our explicit use of realist principles in concert with SEIPS in our analysis provided us with the analytic means to make the familiar unfamiliar, and to consider multiple dimensions operating as interacting mechanisms in the real-world experiences of stakeholders. In doing so we have illuminated the space where structure meets agency, developing a mid-range programme theory through complex CMO configurations.[13] Further study is needed to develop how different paradigms can work together, including the usefulness of synthesising methods in this way for application in other contexts. While the use of the driver diagram (Figure 1) created as a result of our prior work remains a useful tool for organisations to evaluate their own local context, the addition of this study is to provide a similar contextualised framework for digging deeper into socially constructed concerns which may help or hinder process- and task-based interventions seeking better outcomes. This study used analyses of data summarised as driver diagrams as prompts to engage stakeholders in structured discussions that would help us better understand the differences between what happens 'on paper' and in reported incidents (knowing these are likely to be the tip of an iceberg) and what happens in day-to-day practice. It is not enough to consider out-of-hours palliative care to be a series of task-based processes. Professionals and patients/informal carers alike base choices and behaviours on 'grander' socially influenced learning from prior experiences and constructions of roles, responsibilities and accountability. We suggest that our approach is a helpful method for creating safe spaces to promote voices to build a richer and more meaningful construct of the challenges which need to be addressed through improvement initiatives.[29]

The study team included GPs (HW, ACS, AE) and Palliative Medicine Consultants (SN, SY) with interests in realist methodological, educational and socio-cultural expertise. In addition, the study team had expertise in human ergonomics (PB) and patient safety (ACS, LD). The stakeholder event also provided a starting point for a local quality improvement project in South East Wales (unpublished data, Williams H A Study to Improve the Quality of Out of Hours palliative care services for our of hours patients. RCGP MC-06-16). In this way we sought to create local impact alongside our research objectives.[13] We are aware, however, that our research data are necessarily contextualised and hence further work exploring the issues raised and theories generated in other contexts is needed. It is also worth noting that out-of-hours both makes up the majority of time in any given week, and what happens in-hours is bound to impact on out-of-hours care. Rethinking systems from a patient and informal carer perspective is needed to shift from considering in and out-of-hours as two distinct entities. Addressing this issue was outside the remit of our current study.

Implications for policy, practice and further research

We do not claim our programme theory to be more than mid-range and accept that it is based on a relatively small sample of people. It is not intended to be a definitive explanation of all out-of-hours palliative care: rather we would anticipate its usefulness being in providing a framework to guide quality improvement work that integrates person-level and other human factors-based systems thinking principles,[30] with specific studies. Throughout our work we accept that the meaning people derive from experiences influences future learning and actions.[31] Human agency inherently risks unintended and unanticipated consequences of actions as people seek to adapt to changing circumstances. Practical experience creates informal knowledge of how work can be done. There are often gaps between 'work-as-imagined' (i.e. designed and necessarily schematic) and work-as-done (i.e. on the ground practice).[32] Less attention has, perhaps been given in healthcare improvement to 'work-as-reimagined', that is how those on the ground learn informally to get work done, or not, based on prior experience, including when structural elements of a system are sub-optimal. It remains the case that there is a lack of empirical evidence to support many improvement interventions in out-of-hours palliative care that professionals believe in. In many instances this is due to an absence of high-quality studies rather than evidence against interventions. There is also a lack of human factors-based studies exploring system-wide complexities and adaptations that facilitate or inhibit good quality care. Further work is needed to support the design and redesign of improvement interventions to better suit the people in the system and develop meaningful ways for impact (effectiveness, efficiency, and value as well as patient benefit) to be assessed.

Figure Captions:

Figure 1. Driver diagram to show potential interventions to improve the safety of out of hours primary care for patients at the end of life

Figure 2. Complex CMO configurations

Figure 3. Care system of informal/formal work processes: Interactions and outcomes

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Authorship: The study team included GPs (HW, ACS, AE) and Palliative Medicine Consultants (SN, SY) with interests in realist methodological, educational and socio-cultural expertise. In addition, the study team had expertise in human ergonomics (PB) and patient safety (ACS, LD). All authors were involved in the conception and design of the work in addition to all authors contributing to the acquisition, analysis or interpretation of the data. HW, ACS & SN attended the event with HW facilitating and ensuring accurate data collection. SY led the analysis with HW (both independently identifying individual CMO configurations) SY drafted the first version of the full manuscript with input from ACS and PB. SY and PB led the critical comparison of our mid-range theory with the SEIPS framework by re-analysing the raw data, identified CMO configurations and themes during a cross-matching and mapping exercise using the SEIPS framework. All authors provided critical revisions and their own expertise to reach the final synthesis and interpretation. All authors agreed the final version.

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Data Sharing: We are not able to provide the raw dataset for this study to other parties because it is not possible to sufficiently anonymise the data to protect the identity of our participants. We are willing to discuss and provide further details of our methodological approach on request.

Competing interests:

Dr. Carson-Stevens reports grants from Royal College of General Practitioners Marie Curie Palliative Care Fellowship, during the conduct of the study. No specific funding was received by any author for the study reported in this paper.

No completing interests to declare for any other authors.

Tables

Table 1: Participants in Stakeholder event (n=17)

- Facilitator (HW), GP and Clinical Research Fellow
- Patient Participants x2
- Palliative Care Consultants x2
- Palliative Care Nurse specialist x2
- GP Macmillan lead
- District Nurse
- out-of-hours Nurse Practitioner
- NHS 111 GP lead
- NHS 111 Pharmacist
- Ambulance Service Paramedic
- Nurse lecturer - Interest in Palliative Care
- Professor of Primary Care
- Health Board Patient Safety Officer
- Health Board Palliative Care lead nurse

Table 2. Specific CMO configurations that might be amenable to simple or complicated interventions

CONTEXT	MECHANISMS	OUTCOMES	INTERVENTIONS SUGGESTED TO IMPROVE*	Exemplar quotations from stakeholder group	SEIPS mapping of mechanisms [subject specific examples given in square brackets]
Multiple care providers	Different information technology systems Uncertainty about who to contact for what	Lack of timely access to patient records Decisions made on incomplete information leading to sub-optimal care	Technological interfaces to improve access to live patient records in a timely manner need to be developed with a user-centred design approach Single point of access for out-of-hours care	“most of the time we’ll get everything that we need from the out-of-hours GP but it’s adding that extra time, for both us, for the patient and for the GP out-of-hours GP you know. If we knew the information in the first place it would be a lot easier” (Professional) “what do carer’s want? And the answer is a single point of communication… don’t think it matters what the single point is but I do think it’s absolutely essential for a carer to have that phone number they can, they can ring and say help I don’t know the answer to this” (Informal carer)	External influences [national policies] Organisation of work Technology and Tools
Advance care planning	Plans not created Plans not communicated / accessible when needed Unclear who is responsible for completing and updating advance care plans Lack of effective processes and tools for care coordination between hospital and community	Optimal care in line with patient preferences not delivered Deviations from preferred place of care or death Admissions to acute healthcare when patient not going to benefit from escalation in treatment interventions	Interpersonal solutions accounting for socially mediated factors to prompt advance care planning creation Technological interfaces to improve access to live patient records in a timely manner across all services including hospitals	“We looked at the volume of 999 to care homes pre ACP’s and post ACP’s and there’s a definite reduction it caused. ACP’s are empowering care homes nurses to not make that phone call.” (Professional) “how do you keep that up to date when we’ve got an electronic system that’s – but there’s lots of different electronic systems that we’re supposed to be putting the information on” (Professional) “because he’s not ambulant he can’t go through the usual turn up to clinic so he has to get brought in by ambulance so he has to go through the medical intake he’s there waiting you know for hours and hours and hours for that, then they do the DVT and they admit his through the process check his DVT – no, but then it took 3½ weeks to get him home, discharge planning all he came in for was a DVT to be ruled out and but the fact is he’s now in hospital unsafe discharge, la, la, la, la, la, you know everyone wanted him to be at home, he wanted to be at home, but the minute we ticked this system box of get him in we can’t get him out then” (Professional)	Organisation of work Technology and Tools Person [including dynamics between people – patient/informal carers/healthcare professionals; and, psychological, social and cognitive factors] Physical environment
Workload pressures due to volume of need in comparison to staff resources	Professionals focusing on crisis management Tendency to leave complex issues to ‘in hours’ care providers	Further crises due to lack of preventative / prophylactic measures Agency staff used – lack of local knowledge disadvantaging them in providing best care	Population-based needs assessment of resources to deliver agreed standards of care	“what we do is we normalise a lot of it we just say it’s part of our working day to go around correcting all the mistakes that the system has put in” (Professional) “how much extra work these mistakes cause us and literally every you know about a third of these is that somebody else has actually caused so yes we’ve had to do the extra paperwork. So, it builds inefficiency into our systems” (Professional) “actually, we could chuck in agency staff… absolutely yeah and that’s above their paid rate you know” (Professional)	Organisation of work Person [healthcare professionals - physical, cognitive and psychological capabilities]
Reliance on professionals outside specialist palliative care to deliver frontline services	Inexperience Lack of training Uncertainty about how to gain expert advice / advice not available	Default to admit patients to hospital Missed or delayed diagnosis of palliative care emergencies e.g. bowel obstruction, pathological	Additional specialist palliative care resources for direct patient care and/or training of others in frontline care: population-based needs assessments could guide quantification of this. Robust concurrent evaluations of effectiveness, and value of additional resources and new training interventions.	“we might have breathing difficulties… well breathing difficulties can be so many things so we’ve got to walk in and we’ve got to, we’ve got to determine first of all you know is this a reversible cause, you know is this an asthma, is this a chest infection or is it palliative care you know so…and then once we’ve decided okay perhaps it is palliative care, we don’t know at what stage” (Professional)	Organisation of work Person [healthcare professionals: team working, psychological and cognitive factors]

		fractures		“you’ve got the GP who doesn’t know the patient, they turn up its gonna take a lot more time to sort them out locally, it’s easier to get them admitted.” (Professional)	
Medication management	Complicated medication regimes Unfamiliarity of frontline staff with palliative care medications Myths and fears about symptom control medications Breakdown of practical systems for prescribing, supplying and administering medications	Delays in symptom control Increased risk of medication errors: wrong doses prescribed, dispensed or administered	End-to-end solutions for medication provision and management e.g. electronic prescribing, clarity about who could prescribe / alter dosing of existing medications / transcribe prescriptions out-of-hours Pharmacy support Increased anticipatory prescribing	“I saw people going out of hospital with complicated treatments regimes that gave the feeling that I don’t think there’s a chance in a million of those people taking the right drugs at the right time. “ (Informal carer) “tell me if I’m speaking out of turn, I think in the community out-of-hours GP’s, Primary care, some people are afraid of it and they’ll only prescribe it [oral morphine instant release liquid] every 4 hours whereas we didn’t have a problem in giving them every hour” (Professional) “and then when there’s artificial barriers put up so when for instance we can’t get the drugs in the community even if you call on-call pharmacy it’s really difficult to get the medicine from say the hospital because it’s a community patient and they want a hospital prescription and it’s always things like that it’s like an artificial barrier that’s put up for accessing the meds” (Professional) “we used to have dose ranges which were stopped so we would have 2.5 – 10 mg of midazolam written up but once that’s stopped the GP then writes 2.5mg 2 hourly, but if that patient then overnight an hour later is in excruciating pain the qualified nurses there can’t give anything, can’t take a verbal, has to wait for out-of-hours then to come which could take X,Y - 10 you know or however long, so that can be quite frustrating” (Professional)	Organisation of work Person [patient, informal carers, healthcare professionals: physical, psychological and cognitive factors]
Implicit reliance on informal carers	Inadequate support	Carer distress and breakdown	Investment in carer support: psychological, emotional and practical Adequate needs-based assessment of patient care	“I had a patient admitted a week last Friday who was in renal failure end of life, he preferred basically a death at his home we rang out-of-hours at quarter to eleven they arrived at 2am patient was severely agitated with retention of urine potentially they gave a stat that they didn’t catheterise patient an hour later became very, very agitated GP couldn’t go out the wife panicked and then rang 999 he was then admitted and died so.... I think if the reassurance that somebody was gonna go back, maybe the GP could visit then she may not have panicked and rung 999. However, she could’ve also rung me back, but she didn’t so it was a very sad situation really, because he was obviously extremely agitated, but he dipped very quickly… People react differently overnight as they might do during the day really don’t they? They often say long hours at night they see things differently, in the day there would’ve been a lot more people around… we see a lot of out-of-hours calls where people panic and ring 999 even though you’ve put everything in place” (Professional) “I was confused, my wife running a really high temperature with her being tired because I thought they visited on the weekend I didn’t take her temperature quite as often as I should” (Informal carer) “and I had a promise of support from Marie Curie which was very good for my peace of mind” (Informal carer)	Organisation of work Person [patient, informal carers: - physical, social, psychological and cognitive factors]

**as demonstrated in Figure 1 evidence to support these is variable: we report here the suggestions made during the stakeholder event. Our analysis demonstrated professional belief in these interventions regardless of the level of empirical evidence.*

Table 3: Complex person-level themes leading to interacting mechanisms that influence human factors issues in out-of-hours palliative care

Themes	Exemplar quotation	SEIPS mapping
Frontline professionals commonly feared that the consequences of not admitting a patient to hospital or escalating investigations or disease-focused treatment would be personal blame	"for the carer one of the critical questions is how will I know when they are actually about to die? Or what will I see, what will actually happen? And some cancers some conditions will manifest themselves in different ways, so for instance if I were to anticipate …I wouldn't want to manage that and that could be …and coping afterwards you know, because that would be very stressful… but I don't when people talk about preferred place of care they go into the A - the options, or that the hospitals sort've of thing or B – what each one then can offer, still so that they're aware" (Professional) "one area with clinical practice which has changed dramatically in the last 24 months is sepsis and it's not included in the advanced care plan it's gonna happen that you become sceptic and everyone is now saying that and in out-of-hours cos I've seen in happen oh well if they become septic well their preferred place of care is at home but when they're sceptic – call an ambulance" (Professional)	Person [Healthcare professionals: emotional intelligence, meta-cognition, workplace culture, learning from prior experiences]
Patients and informal carers were reported to be regularly facing an impossible choice due to enormous differentials in the speed of response times of different services i.e. people were choosing between having any professional present quickly over having someone with the right expertise. Who was called by patients and informal carers was also shaped by previous experiences of who was most likely to respond.	"we have a lot of calls because it's quicker to get through to us than it is we have I mean we've worked our 8 hours that day so we're doing an on-call and then doing another 8 hours literally we're working solid through for 2 days and we have many calls at 3am, 5am you know because we're quicker and that's not a good thing is it at all?" (Professional)	Person [Patients and informal carers: psychological, cognitive and social factors]
Neither patients/informal carers nor professionals felt safe or supported to take calculated risks in line with patient priorities for care in the community	"there's a lady who'd had a severe stroke who was actually bed-bound for about 4 years DNAR end of life drugs, she was deteriorating, we sent a driver up, he [patient's informal carer] still rang 999 and there was no way on earth that lady of ever being moved, she was hoist only, and she died in the ambulance – it's unavoidable on times isn't it?" (Professional)	Person [Patients, informal carers and healthcare professionals: psychological factors and learning from prior experiences]
The lack of pre-existing relationships between professionals within and across out-of-hours services meant there was a lack of trust, which in turn impinged on professional autonomy, giving and receiving advice, and lack of understanding of practical constraint on each others working practices	"it took a couple of hours for someone from out-of-hours to see them, we were going that's good! It's pretty damn good that 2 hours, but you know it all depends what the family were expecting and actually 2 hours, I'm dialling 999 cos no one's coming I'm on my own I don't know what's going on, they're looking terrible… So there's an issue of knowing what carer's needs are and what their expectations are, and actually whether we're able to meet them because otherwise the default will be 999. There were some issues around kind've expertise and knowledge and skills I don't think it was a big as one of the other issues and the other final one which I suppose is around equipment 2 major issues were around catheters, simple as that, someone with terminal agitation where a catheter would've sorted it, for various reasons it wasn't, and another where a patient had, had a catheter, it had come out at their request and then when it needed to go back in because it had been put in by frailty the DN service, there wasn't a catheter pack, so they couldn't do it. So once again, different systems not, not connecting…" (Professional)	Person [Healthcare professionals: psychological and social factors in team working]
Apart from some doctors professionals were uncertain of their authority to act on discussions around ceilings of care even in the presence of documented advance care plans, in part due to different policies and guidance in different organisations.	"we had a 40 year old lady who we'd discharged from nursing home who had a detailed advanced care plan and they still admitted her at 8 o'clock in the morning you know we just sat and managed then to turn her around the following day and get her back out. So that was really disappointing because she could've died on route or what have you, fortunately she made it back to the home it was all the distress around that so there's communication there around the nursing home and skills of the nursing staff and I think the knowledge and the understanding of the detail around the advanced care plan because when we looked into that they were saying oh we not everybody realised that the detail of that and therefore you know somebody like you say has probably panicked and thought oh my god we just need to send her in you know she was a little bit more short of breath, that was potentially imminently dying and it was just all very unfortunate" (Professional) "and that's gone to the NMC saying why didn't you start it? And she said well he was obviously dead it was not DNA CPR you have to go in and jump on his chest you cannot make that decision to say to stop it has to be a doctor" (Professional)	Person [Healthcare professionals: metacognition, lack of empowerment, workplace cultures, learning from prior experiences]
Many professionals lacked understanding of the law regarding mental capacity and advance care planning and viewed 'doing something' as being by definition more defensible than what they perceived to be 'doing nothing' even though the latter was often in fact not nothing but taking action to provide appropriate symptom control and basic care	"because they'll say oh yeah we've got a DNA ah, but it doesn't mean to say that they're not gonna be actively treated up to the point of arrest and the number of times when you're saying to people in nursing homes well are they for admission or are they treatment within their home? And they can't answer you most of the time and they're making calls in the middle of the night to relatives to ask then do you want them to go in or not? But we can't take that as a legal requirement because we, because nobody's had the discussion properly and put it in writing, so some of it is to do with the advanced planning really. It seems to be lacking…[]so by the time our GP's or our nurses are coming in the middle of the night you've got to follow with what's before you and half of the times when I've driven like say and I don't want to send this person in, but there is nothing there to stop me" (Professional) "the COPD's and the dementia's and things like that, because the disease trajectory is difficult to work out you can have somebody who's had a DNA and they are in place for 4 years but it's never been updated and therefore how can you make a decision on something that was put on 4 years ago. If it's not been updated on an electronic system or anything" (Professional)	Person [Healthcare professionals: cognitive and psychological factors]

Table 4: Key messages and recommendations	
Methodology & theory-building There is value in drawing on different perspectives and frameworks to explore the nature of problems before attempting to offer potential solutions.	Sharing findings from research methods applied to incident reporting directly with stakeholders is an effective prompt for discussing gaps between official accounts and day-to-day experiences. Synthesis of complementary approaches (e.g. the realist context-mechanism-outcome model with SEIPS) helps cross disciplinary boundaries and consider intersectionality between different perspectives.
Human factors issues Interventions can only be targeted at underlying mechanisms driving human factors issues when problems are studied in depth and in context.	As people experience different events, socially constructed learning in the form of sense-, or meaning-making occur leading to cycles of thought and behaviour that are refined and replicated according to experiences in future events. It is relatively rare that addressing knowledge gaps alone will make a difference in complex situations. Better integration of human-centred co-design principles and informal learning theory into future attempts at improvement are needed to increase the likelihood of success.
Safety in out-of-hours palliative care Problems are created, defined and constructed by people in ways that generate variable patient outcomes, experiential learning (desirable or otherwise) and consequences for future healthcare.	Optimal care is dependent on 'interpersonal glue': often mediated by trust, empowerment and ability to tell whether a situation demands a standardised, customised or flexible response. Optimal care and a holistic approach to safety in palliative care is seen to commonly require in-the-moment enacting of workaround strategies to manage risk in complex and adverse conditions.

Figure 1. Driver diagram to show potential interventions to improve the safety of out of hours primary care for patients at the end of life.

Reproduced from : Williams H, Donaldson SL, Noble S, et al. Quality improvement priorities for safer out-of-hours palliative care: Lessons from a mixed-methods analysis of a national incident-reporting database. Palliative Medicine. 2019;33(3):346-356. doi:10.1177/0269216318817692 Article Copyright © 2018 Authors, Source DOI: 10.1177/0269216318817692.

Figure 1. Driver diagram to show potential interventions to improve the safety of out of hours primary care for patients at the end of life

101x76mm (300 x 300 DPI)

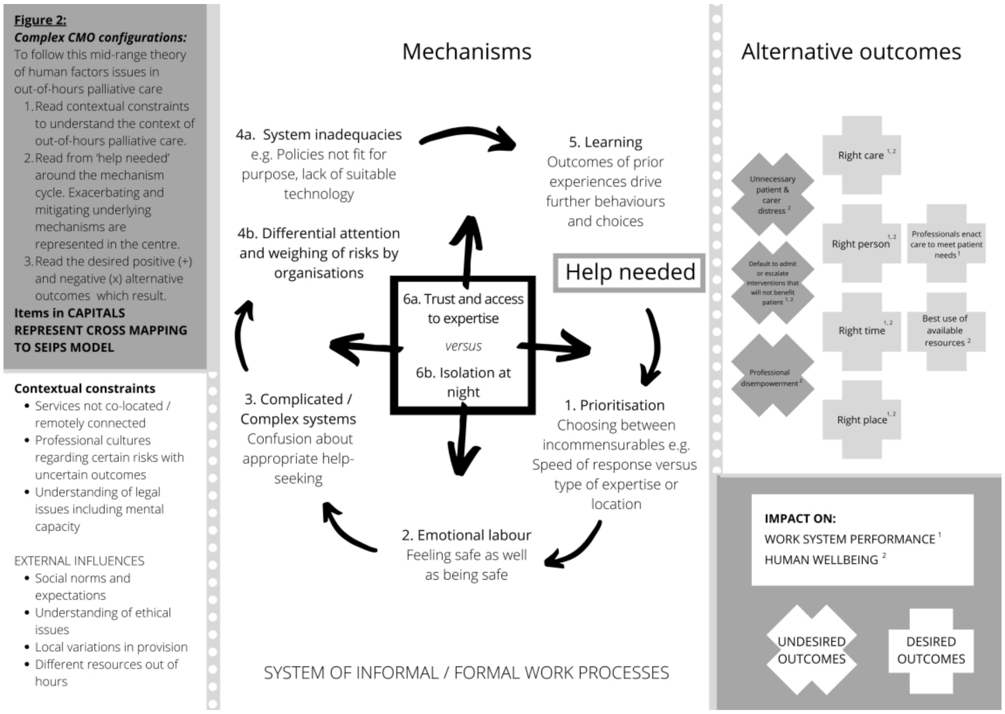
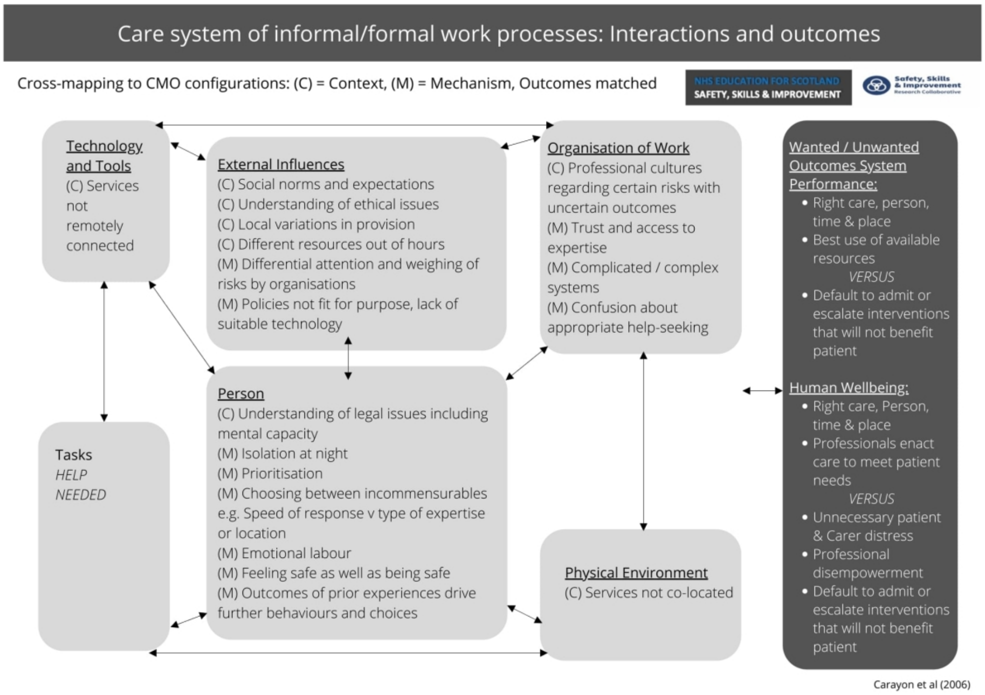


Figure 2. Complex CMO configurations

380x269mm (300 x 300 DPI)



Care system of informal/formal work processes: Interactions and outcomes

Cross-mapping to CMO configurations: (C) = Context, (M) = Mechanism, Outcomes matched

Technology and Tools
(C) Services not remotely connected

External Influences
(C) Social norms and expectations
(C) Understanding of ethical issues
(C) Local variations in provision
(C) Different resources out of hours
(M) Differential attention and weighing of risks by organisations
(M) Policies not fit for purpose, lack of suitable technology

Organisation of Work
(C) Professional cultures regarding certain risks with uncertain outcomes
(M) Trust and access to expertise
(M) Complicated / complex systems
(M) Confusion about appropriate help-seeking

Wanted / Unwanted Outcomes System Performance:

- Right care, person, time & place
- Best use of available resources

VERSUS

- Default to admit or escalate interventions that will not benefit patient

Human Wellbeing:

- Right care, Person, time & place
- Professionals enact care to meet patient needs

VERSUS

- Unnecessary patient & Carer distress
- Professional disempowerment
- Default to admit or escalate interventions that will not benefit patient

Tasks
HELP NEEDED

Person
(C) Understanding of legal issues including mental capacity
(M) Isolation at night
(M) Prioritisation
(M) Choosing between incommensurables e.g. Speed of response v type of expertise or location
(M) Emotional labour
(M) Feeling safe as well as being safe
(M) Outcomes of prior experiences drive further behaviours and choices

Physical Environment
(C) Services not co-located

Carayon et al (2006)

Figure 3. Care system of informal/formal work processes: Interactions and outcomes

176x121mm (300 x 300 DPI)

Dear Editors and Reviewers
Please find enclosed our manuscript entitled **A mid-range programme theory of human factors issues in out-of-hours community palliative care: lessons from a realist approach to analysis of stakeholder experiences**.

Given the novel integration of methods in this work we have not been able to complete a standard reporting checklist. Therefore, we have provided details on how our manuscript conforms to the relevant elements of RAMESES and COREQ which are the closest options.

Combined checklist – based on:

Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *International Journal for Quality in Health Care*. 2007. Volume 19, Number 6: pp. 349 – 357

Wong, G., Westhorp, G., Manzano, A. *et al.* RAMESES II reporting standards for realist evaluations. *BMC Med* **14,** 96 (2016). https://doi.org/10.1186/s12916-016-0643-1

Yours faithfully,

Dr Sarah Yardley
On behalf of all authors.

Item	**Description**	**Section**
Title	We have identified the use of a realist approach in the title in addition to stating that the manuscript presents a mid-range theory.	Title page
Abstract	A structured abstract is provided using the headings required by BMJ Quality & Safety. This includes our research question, objectives, research methods and a summary of the data used as well as further details on the analytic methods and approaches. Participant details are provided alongside key themes and subthemes. The implications of these are discussed.	Abstract
Rationale	The purpose of the study and the implications for its focus and design are explained.	Introduction
Programme theory	The initial programme theory that underpinned the study, and the evidence sources it was derived from are explained.	Introduction
Questions, objectives and focus	These are provided.	Introduction
Ethical approval	These details are provided at the start of the methods section.	Methods
Research team/characteristics and reflexivity	Details of the research team are provided with reflexive comment in the discussion. Prior to this the role of research team members who undertook the data analysis are provided in the methods.	Methods Results Discussion

	Research team members involved in data collection are named in the results along with other participants as this was a joint activity with the stakeholder participants.	
Methodological orientation and Theory	Details of our theoretical orientation are provided in the methods. This section includes explanation of how we applied realist approaches to 'naturally occurring processes' described in a stakeholder event. We also provide explanation of how we integrated these approaches with an established approach to analysing data for human factors issues. The setting of the work is described along with the stakeholder event itself. It should be noted that we are not reporting a QI intervention in this manuscript.	Methods
Sampling	Recruitment, selection and participation are all described. Included participants are listed in the results.	Methods Results
Data collection	The processes of data generation and collection during the stakeholder event are described. As all possible participants were included in the analysis it is not appropriate to refer to data saturation.	Methods
Data analysis	Details of the analytic processes are provided along with the focus.	Methods
Number of data coders	Included.	Methods
Derivation of themes	The initial inductive approach was supplemented by a deductive comparison with SEIPS. This is described in detail.	Methods
Reporting	Quotations from participants are included. Key findings are presented linking them to CMO configurations at various levels of analysis with the use of tables / figures to supplement main text. Major themes are drawn out further in the discussion.	Results Discussion.
Strengths, limitations and future directions	These are discussed along with comparison to existing literature before recommendations are provided.	Discussion.
Funding and conflict of interest	No specific funding for this piece of work was received.	N/A

BMJ Open

Which human factors design issues are influencing system performance in out-of-hours community palliative care? Integration of realist approaches with an established systems analysis framework to develop mid-range programme theory

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Secondary Subject Heading:	General practice / Family practice, Palliative care, Qualitative research
Keywords:	Adult palliative care < PALLIATIVE CARE, Organisation of health services < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, PRIMARY CARE

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Title: Which human factors design issues are influencing system performance in out-of-hours community palliative care? Integration of realist approaches with an established systems analysis framework to develop mid-range programme theory

Authors: Sarah Yardley,[1] Huw Williams,[2] Paul Bowie,[3] Adrian Edwards,[2] Simon Noble,[4] Liam Donaldson,[2,5] Andrew Carson-Stevens[2]*

1. Marie Curie Palliative Care Research Department, University College London; Palliative Care Service, Central & North London NHS Foundation Trust; The Health Improvement Studies (THIS) Institute Post-doctoral Fellow

2. Division of Population Medicine, Cardiff University, 8th floor, Neuadd Meirionnydd, Health Park, Cardiff CF14 4YS

3. Safety, Skills and Improvement Research Collaborative, NHS Education for Scotland, Edinburgh, UK; Institute of Health and Wellbeing, University of Glasgow, Glasgow, UK; School of Health and Social Care, Staffordshire University

4. Marie Curie Palliative Care Research Centre, Division of Population, Cardiff University, Cardiff, Wales, UK

5. Faculty of Epidemiology and Population Health, London School of Hygiene and Tropical Medicine, London, WC1E 7HT, UK

*Corresponding author: Dr A. Carson-Stevens carson-stevensap@cardiff.ac.uk

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Abstract

Objective:
To develop mid-range programme theory from perceptions and experiences of out-of-hours community palliative care, accounting for human factors design issues that might be influencing system performance for achieving desirable outcomes through quality improvement.
Setting: Community providers and users of out-of-hours palliative care.
Participants: 17 stakeholders participated in a workshop event.
Design: In the UK around 30% of people receiving palliative care have contact with out-of-hours services. Interactions between emotions, cognition, tasks, technology and behaviours must be considered to improve safety. After sharing experiences, participants were presented with analyses of 1072 National Reporting and Learning System incident reports. Discussion was orientated to consider priorities for change. Discussions were audio-recorded and transcribed verbatim by the study team. Event artefacts, e.g. sticky notes, flip chart lists, participant notes, were retained for analysis. Two researchers independently identified context-mechanism-outcome configurations using realist approaches before studying the interrelation of configurations to build a mid-range theory. This was critically appraised using Systems Engineering Initiative for Patient Safety (SEIPS), an established human factors framework.
Results: Complex interacting configurations explain relational human-mediated outcomes where cycles of thought and behaviour are refined and replicated according to prior experiences. Five such configurations were identified: 1.Prioritisation; 2.Emotional labour; 3.Complicated/Complex systems; 4a.System inadequacies & 4b.Differential attention and weighing of risks by organisations; 5.Learning. Underpinning all these configurations was a sixth: 6a.trust and access to expertise; and, 6b.isolation at night. By developing a mid-range programme theory, we have created a framework with international relevance for guiding quality improvement work in similar modern health systems.
Conclusions:. Metacognition, emotional intelligence, and informal learning will either overcome system limitations or overwhelm system safeguards. Integration of human-centred co-design principles, and informal learning theory, into quality improvement may improve results.

Keywords

Palliative Care Medicine; Health Services, Community; After-Hours Care; Realist Theory; Social Theory; Human Factors Issues; Quality Improvement; Stakeholder Participation

Strengths and limitations of this study

- The study design provided a safe space to integrate multiple perspectives on safety and improvement initiatives in palliative care.
- Cross-disciplinary expertise has been combined with stakeholder experiences of frontline care to develop new understandings of human factor issues in out-of-hours palliative care, and how these create mechanisms for desirable or undesirable outcomes.
- Using SEIPS in combination with realist approaches is a novel methodological development for cross-disciplinary analysis that has promise for future research.
- Further work is needed to explore the issues raised and mid-range theory generated in other contexts, different cultures and with more people.
- We were not able to address the issue of a false divide between out-of-hours and in-hours care in this study but this requires urgent attention as each impacts on the other.

Main text

Background

Palliative care seeks to improve the quality of life of patients and their families when they are facing challenges associated with life-threatening illness, whether physical, psychological, social or spiritual. Fragmented system design of out-of-hours palliative care creates high risk of patient safety incidents.[1,2] In a sub-optimally designed system, human factors issues are exposed as people seek to work-around, manage goal conflicts and resource constraints, and mitigate structural challenges 'to get the job done' as safely and efficiently as possible. The extent to which risk and wellbeing are impacted because of system-wide human factors issues in out-of-hours palliative care is unknown.

In the United Kingdom (U.K.), out-of-hours healthcare provision is complex due to the many different professionals, organisations and systems involved.[2] So-called 'out-of-hours' community healthcare services are responsible for providing care for two-thirds of the week (commonly 18:30 to 08:00 on weekdays, and all hours at weekends).[2] Out-of-hours palliative care provision presents patient safety and professional performance challenges arising from both the nature of the care needs (which are often unstable and/or unpredictable e.g. medications required to achieve and maintain symptom control) and generic risks commonly found in out-of-hours care.[1,2] The latter include problems with lack of prior knowledge about patients, reliance on remote consultations, lack of access to patient records and difficulties in service co-ordination.[1,2] Electronic Palliative Care Coordination Records have been designed to provide a systematic approach to information needs but are not universally available nor fully functional in practice.[3,4,5]

Around 30% of people receiving palliative care in their usual place of residence in the U.K. have contact with out-of-hours services.[6] Patients and families can struggle to identify who to contact out-of-hours and may feel they have to trade-off between speed of response and relevant service/expertise of responders.[7] Most patients in the last phase of life are in their usual place of residence for the majority of their remaining time (home or care home).[8] Access to services for most out-of-hours palliative care is via community/primary care and emergency services. Acute hospitals are the second commonest place of care and most patients still die in hospital, with both numbers of deaths and the proportion occurring in hospitals projected to rise.[9,10] Addressing out-of-hours challenges has been identified as a key priority by patients and palliative care organisations.[11]

In this study, we use the term 'system' to refer to the entirety of healthcare enterprise, that is both the structural (in various disciplines referred to as field, architecture, artefacts) and the human. 'Human factors' (also known as ergonomics) is a scientific discipline that seeks to understand and optimise the interaction of people within the wider system in which they work.[12] More specifically human factors have been used to consider the direct and indirect (humanly-mediated) impacts of socio-technical systems (i.e. systems intrinsically dependent on the interaction of human beings with structures, organisations and artefacts) and environments on safety, risk and wellbeing.[12] The interactions between human emotion, cognition and behaviours and the influence of wider system elements have not however, always been fully considered. This is essential to better understand how to design environments and structural systems to guide humans into the best course of action, while still maintaining allowances for necessary adaptions in performance to 'get the job' done given care complexities, goal conflicts and resource constraints. This is a priority for out-of-hours palliative care given the proportion of time covered by these services.

In previous work, NHS patient palliative care safety incident reports stored on national databases were analysed for underlying contributing factors.[1,2] These findings were presented to stakeholders in out-of-hours palliative care in a half-day research event which itself generated data for the current study. Separate analysis of the stakeholder event data, in this study, was conducted to further understand underlying desirable/wanted and undesirable/unwanted outcomes in community-based palliative care drawing on the concerns of those on the frontline. The study design was also situated in a wider quality improvement project, which aimed to improve out-of-hours palliative care across a South Wales Health Board.

Research question

Which human factors design issues are influencing system performance in out-of-hours community palliative care?

Objective

To develop mid-range programme theory from perceptions and experiences of out-of-hours community palliative care, accounting for human factors design issues that might be influencing system performance for achieving desirable outcomes through quality improvement.[13]

Methods

Ethical approval was granted from Wales Research Ethics Committee 3 (17/WA/0222).

Theoretical orientation

Realist approaches seek to understand what works, for whom, under what circumstances and how, through the identification of context-mechanism-outcome (CMO) configurations.[14] If outcomes (desired or not) are known, then analysis can trace back the mechanisms that led to those outcomes in particular contexts.[15] Once CMO configurations are identified, these can be drawn together into a mid-range programme theory of practice. Mid-range theories are concepts that explain CMOs within an overarching theory of how a process functions to produce particular outcomes in different circumstances i.e. as underlying changes in reasoning and behaviour are triggered by different types or qualities of interaction or context.[13,16]

Mechanisms almost always operate on a continuum of activation rather than as a discrete dichotomous on/off. Mechanisms are components of whole systems, (incorporating both agency and structure), that intervene in or otherwise moderate, the relationship with other components. A mechanism's functionality is dependent on combinations of human reasoning and available resource. When an intervention (such as a quality improvement initiative) is made, with the provision of additional or different resources then there is a complex interaction which occurs between resource, reasoning and context.[17] This means that in an intervention, or routine clinical practice, the activities people engage in will be subject to individual and group choices, and these choices subject to social influences such as prior experience.

In this study we apply realist approaches to the naturally occurring processes of routine clinical practice. Our initial ('rough') programme theory (i.e. what might be producing outcomes from a complex system with diverse participants and how) was derived from our knowledge of the existing literature and prior work analysing NHS patient safety incident reports. The process of conducting the workshop and the data generated from it permitted us to refine this initial programme theory by identifying CMO configurations. In doing so, we have developed a mid-range theory, to explain what was happening and why. As with all mid-range theories ours 'lie[s] between the minor but necessary working hypotheses that evolve in abundance during day-to-day research and the all-inclusive systematic efforts to develop a unified theory'.[18]

After initially conducting an inductive data-driven analysis using the realist approach described above, and in more detail in the methods section below we critically considered our analysis, including the developing mid-range theory, using a deductive approach to compare and contrast our findings with the perspective of the Systems Engineering Initiative for Patient Safety (SEIPS) framework.[19,20] SEIPS is a well-established, multi-functional human factors framework that can be applied holistically to map research findings (in this case, CMO configurations) across pre-defined elements of healthcare (work) systems such as the person, task, technology, and organisational factors that typically interact and give rise to both wanted and unwanted care outcomes.

Setting

We wanted to use the learning from prior analyses of 1072 incident reports from the National Reporting and Learning System (NRLS) in England and Wales to inform improvement agendas for out-of-hours palliative care. The NRLS analysis itself was a separate study, also published,[2] which was used as a prompt to participants in this study. This study was set within the Aneurin Bevan University Health Board, one of the largest of the seven health boards in Wales, serving a population of 560,500 in South East Wales. In cooperation with the Board's Palliative Care Strategy Group, a single stakeholder event (workshop format) was convened, combining our research objectives with local objectives to develop quality improvement planning in this area.

The event objectives were to:

1. Identify which issues in out-of-hours palliative care highlighted in national level analyses of patient safety incident reports were prevalent in the local out-of-hours service (this fed into our study objective);
2. Identify which of these issues should be the priority area for improvement efforts within local services (shared objective); and,
3. Create an opportunity for participants to identify a local quality improvement project group (local objective, unpublished data, Williams, H. A. Study to Improve the Quality of Out of Hours palliative care services for out of hours patients. Grant: RCGP MC-06-16).[21]

In this paper we present analysis of the first two of these objectives as these relate to our overarching research question and objective for this study. The third was not a specific objective of this study but something we wanted to support participants in, should they choose to do so.

Recruitment, selection and participation

Local providers and service users of out-of-hours palliative care were invited to participate in a stakeholder event via email. The palliative care network in South East Wales and Gwent Palliative Care Strategy Board agreed to facilitate this. Invitations were disseminated to the local palliative care network, out-of-hours GP providers, GP clusters and the local Research and Development office asking them to circulate details to their networks/membership. Further direct email invitations were sent by the study team to people in key roles including hospice providers, out-of-hours clinicians, palliative care consultants, GP leads and members of the public (including informal carers and patients). Potential participants were told they were being invited to a stakeholder event to identify priority areas in out-of-hours palliative care and that their participation would be used to inform a wider research programme. This led to a convenience sample of stakeholders who were engaged and interested in the subject. All those who chose to attend the stakeholder event provided written informed consent for this study.. As we did not own the mailing lists used, we do not know the total number of people approached.

Patient and public involvement (PPI)

Two informal carers attended the event in addition to the other stakeholders. Intrinsic to our methods is a collaborative approach as this study/the event were the mechanism for sharing prior research findings and seeking to bridge the gap between these and the experiences of all stakeholders in frontline clinical care.

Data generation

The event was approximately six hours long, with participants working in a mixture of small groups (five to six) and the whole group of 17. We drew on our prior experience of engagement exercises using quality improvement principles and tools[22] to structure our dissemination of our previous analyses of safety incident reports during the event.

The stakeholder event was designed to first allow participants an opportunity to share and reflect on their experiences of out-of-hours provision of palliative care ("Tell us what could have gone better in the last month whilst delivering palliative care in your role"). They were then provided with our analyses of incident reports (three examples used to provide stories behind a summary of incident types by severity of harm, contributory factors, and patient outcomes). Event facilitators next worked with stakeholders to compare experiences with reported incidents and discuss potential priorities for change ("which of the issues identified thus far should be a priority and why?"). The facilitators then shared a summary of existing literature for improvement (we presented initial ideas for change in the form of a driver diagram, see Figure 1).[2] Participants were next asked to expand on examples from recent experiences with a focus on potential solutions to identified problems; and decide which problems would be most important and feasible to tackle locally ("Ask yourself 'What's feasible in our service and why? Where next?'").

All event discussions were audio-recorded and transcribed verbatim by the study team. Participants were also invited to record challenges to the provision of good care and their priorities via sticky notes, flip chart lists, and participant notes and these were retained as data (hard copy plus photographs of collective arrangements (e.g. group ordering of priorities) made during the event).

Insert Figure 1 approx. here

Data analysis

We focused analysis on understanding:

1. the context of out-of-hours community palliative care, and what occurs (mechanisms) to produce desirable outcomes; the intended global outcome of interest was for patients to receive the right care by the right person at the right time in the right place; and,

2. what mechanisms were operating in the same context to produce deviations from desirable outcomes, and what undesirable outcomes consequentially occurred.

First, HW and SY independently identified individual CMO configurations in data transcripts before comparing to reach a consensus of their line-by-line coding (using the framework of context, mechanisms and outcomes) and annotating these to form provisional configurations. This was refined with joint analysis of sticky notes and photographs of flipchart material plus handwritten field notes generated in the course of the stakeholder event. We then studied the interrelation of the CMO configurations to identify themes and build a mid-range programme theory of the potential human factors design issues in out-of-hours palliative care.

Second, SY and PB led the critical comparison of our mid-range theory, built from CMO configurations with the SEIPS framework. This was achieved by re-analysing the raw data described above, notably complex themes and identified CMO configurations (simple, complicated and complex), to map all data to the SEIPs framework elements. This provided us with a second analytic lens from which to consider underlying contributing factors across the spectrum of CMO configurations.

Results

The roles of event participants are listed in Table 1 below.

Insert Table 1 approx. here

The outcomes of the CMO configurations identified in these data impact on both system performance and human wellbeing, demonstrating how it is not possible to fully disentangle these in out-of-hours palliative care. In summary, six CMO configurations that could be classified as simple/complicated (see Table 2) were identified. In addition, six complex themes (see table 3) were identified and synthesised into the complex CMO configuration possibilities in Figure 2. By definition, as these are complex, the resulting three contextual constraints, four external influences, six mechanisms (two of these subdivided into parts a) and b) and nine alternative outcomes identified in Figure 2 cannot be simplified into individual CMOs. However, Tables 2&3 provide a summary of our analytic working as we developed the mid-range theory that is then presented in Figure 2 and critically examined using SEIPS (Figure 3). Underlying contributing factors, as well as mechanisms and outcomes are classified using SEIPS. This is demonstrated in Figure 3, and the right-hand columns of both Tables 2 and 3.

Simple situations are defined by identification of straightforward solutions if necessary skills and techniques are mastered. In complicated situations, an identifiable set of linked solution components which interact in predictable ways can still lead to definite outcomes.[23] During our analysis, it became evident that with exception of relatively few specific instances (provided in Table 2), it was not possible to disentangle independent simple, or even complicated, CMO configurations. Instead, the analysis pointed to interacting complex CMO configurations as possible explanations for relational and experience-based human-mediated mechanisms and outcomes (Table 3 and Figure 3).

Therefore, we first present the few simple and complicated CMO configurations that might be most amenable to technical/structural system change, gaining of skills or techniques for tasks or other component-by-component interventions in Table 2. This table demonstrates that contextual factors such as multiple care providers, including informal carers within a specialist-generalist advisory model where advance care planning was not well established, triggered system breakdowns which were considered by participants in the stakeholder event to be amendable to systems-based change. Technological solutions and greater investment in care coordination services such as a single point of access/medication management models in tandem with greater public health assessment of population need were all anticipated to offer improvements. Hence, it can be seen from Table 2 that structural solutions are likely to provide part, but not all, of the solution particularly if human factors issues are taken into consideration in any redesign.

Insert Table 2 approx. here

However, as indicated above, what we were identifying in most of the data was complex with several significant and concerning underlying themes contributing to multiple human-mediated mechanisms. The themes are presented in Table 3, with illustrative quotations from participants to demonstrate how these themes are supported by analysis of the raw data. Together these themes were identified to be influencing outcomes which were produced by mechanisms that co-evolved through interpersonal relationships. Such mechanisms could not be explained by a straightforward analysis of parts. Furthermore, the outcomes and subsequent consequences resulting were both unpredictable and yet what mattered most.[23]

Our overarching interpretive analysis, bringing together the underlying themes and complex CMOs is presented in Figure 2 (our mid-range theory). The interconnected mechanisms interact to form a system with adaptive capacity to change from experience as mediated by the people within it, and their experiential learning. At any point the mechanisms might come together to either overcome system limitations (a 'desirable' outcome) or to overwhelm system safeguards (an 'undesired' outcome).

Insert Table 3 and Figure 2 approx. here

In Figure 2, for each of the outcomes and mechanisms described, all the contextual elements listed were relevant. The themes of Table 3 also underpin all these complex CMO configurations. The context of out-of-hours palliative care was one where multiple service providers are disconnected from each other, and so misunderstanding and miscommunication could occur very easily in addition to different professional cultures developing regarding risk and uncertain outcomes.

The mechanisms numbered 1-5 (1.Prioritisation; 2.Emotional labour; 3.Complicated/Complex systems; 4a.System inadequacies & 4b.Differential attention and weighing of risks by organisations; 5.Learning) within Figure 2 all feed into and off each other. Underlying these mechanisms could be either 'Trust and access to expertise (6a)' which if strong enough could lead to desired outcomes in support of, or regardless of, mechanisms 1-5 through a positive cycle **or** 'Isolation at night (6b)' which could lead to the opposite effects and hence undesirable outcomes. 'Trust and access to expertise (6a)' is, therefore, 'interpersonal glue' that can stick the component parts together to reach desired outcomes. We have labelled 6a and 6b as such as these are components on a continuum.

The data suggest that seeking to focus on specific parts of these complex CMO configurations in isolation is unlikely to be successful. What needs to be generated is a positive cycle of learning with attention to all the underlying themes and interacting human-mediated mechanisms identified. Depending on how human factors-based systems issues interact and function in a particular patient's care, there are alternative desirable or undesirable outcomes for patients that are intertwined with the same for professionals. When patients, informal carers or professionals seek help they are commonly weighing up priorities between speed of response and ability to meet a particular need. Emotional labour is a significant mechanism. Being safe in a technical sense does not hold meaning if patients, informal carers, or professionals do not feel safe in their location, decision-making, or actions. Furthermore, both prioritisation and emotional labour mechanisms feed into confusion about whom to call for what and when. Mechanisms driven by organisational interests or system inadequacies which do not support, for example, individualised decision-making or use of professional judgement when in a situation that requires doing the 'least wrong' thing are unhelpful.

In out-of-hours palliative care, if trust is achieved and access to expertise is available then desired outcomes can be achieved, but if instead the underlying mechanism is a sense of personal or professional isolation, undesirable outcomes result. The commonest undesirable outcomes identified were unnecessary patient and carer distress, defaulting to admitting patients to acute hospital care and/or escalation of treatment interventions from which there was not a realistic possibility of patient benefit, and professional disempowerment – all of which would feed back into the mechanism cycle by triggering adverse learning that in turn would influence future help-seeking approaches. Positive learning could, however, be created by achieving desired outcomes, as could best use of available resources, both in turn leading to human factors supporting the system.

In mapping the identified CMO configurations to the SEIPS model (Figure 3), it is possible to see more clearly how little of the complex person-level concerns from stakeholders regarding out-of-hours palliative care directly relate exclusively to technical factors. Instead, the inter-relationships between socio **and** technical factors warrant greater attention to optimise the system. External influences, organisation of work and person elements come to the fore, demonstrating what is filling design gaps in a system which has evolved piecemeal over time, with a striking absence of identified mechanisms related to human factors-based design issues at individual, team, organisation and external levels. Furthermore, while it is possible to map relatively simple and complicated mechanisms (Table 2) to SEIPS elements, other than the person level this is not the case with the complex interacting mechanisms that are influencing broader system interaction issues and related performance and wellbeing outcomes (Table 3).

Insert Figure 3 approximately here

Discussion

Our work demonstrates that optimal care is dependent on 'interpersonal glue': often mediated by trust, empowerment and ability to tell whether a situation demands a standardised, customised or flexible response. This study contributes to the existing literature on three fronts: methodology and theory-building; human factors issues, and; safety in out-of-hours palliative care. The key messages and recommendations for each are summarised in Table 4.

Insert Table 4 approx. here

We have drawn on realist and human factors theory to interpret the reality of day-to-day experiences of patients, informal carers and professionals as they are active agents in patient safety endeavours in out-of-hours palliative care. In doing so we demonstrate a small number of CMO configurations that may be amenable to structural change but more importantly why structural change alone will seldom be enough to ensure patients receive the right care by the right person at the right time in the right place. Our findings show human factors issues go beyond how people interact with each other and with their surroundings, or immediate environment. As people experience different events, socially constructed learning in the form of sense-, or meaning-making occur leading to cycles of thought and behaviour that are refined and replicated according to experiences in future events.

In demonstrating complexity, it is important to note that this means different approaches to the planning and testing of improvement interventions will be needed. Simple and complicated solutions can only take us so far. We suggest that better integration of human-centred co-design principles,[24] a fundamental approach of human factors, and informal learning theory into future attempts at improvement are needed to increase the likelihood of success. This is because our findings demonstrate that optimal care is dependent on 'interpersonal glue': often mediated by trust, empowerment and ability to tell whether a situation demands a standardised, customised or flexible response.[25] Optimal care and a holistic approach to safety in palliative care is seen to commonly require in-the-moment enacting of workaround strategies to manage risk in complex and adverse conditions.[26-29] Our findings provide evidence of not just what the problems are but how these are created, defined and constructed by people in ways that generate variable patient outcomes, experiential learning (desirable or otherwise) and consequences for future healthcare. Our data provide a basis for selecting targeted interventions to influence the social mechanisms underlying safety issues in out-of-hours care.[30]

This extends previous work analysing patient safety incident reports[1,2,31] by deepening analysis of the human factors interaction issues which are an intrinsic part of the complexity of palliative care work in the community.[24] As a result we propose a mid-range programme theory of the influences on human factors in response to palliative care needs out-of-hours. This can be used to guide future attempts to improve the design of care processes through recognition of implicit assumptions and rationales,[13] thereby increasing the chances of mitigating undesirable mechanisms and promoting desirable ones. Doing so should help to create meaningful change for patients and increase professionals chance of success as they endeavour to provide safe care in difficult circumstances. We have already applied this mid-range programme theory to our later analysis of incidents arising from advance care planning.[31] This identified structure-based solutions to ensure patients receive timely and robust advance care planning would not be enough; in 37% (26/70) of advance care planning incidents, the plan was not followed due to person-level issues such as poor higher-level meta-cognitive skills or emotional intelligence often in the context of lack of confidence or experience.

Strengths and limitations

SEIPS is one of the most widely used human factors frameworks in healthcare[20,22] and the use of realist approaches in healthcare has grown significantly in recent decades. Using both to develop a cross-disciplinary analysis to theory and empirical data is, we believe, a novel methodological development. In doing so we have been better placed to consider intersectionality between human factors issues and structural elements in the context of a healthcare system. Our explicit use of realist principles in concert with SEIPS provided us with the analytic means to consider multiple dimensions operating as interacting mechanisms in the real-world experiences of stakeholders. In doing so we have illuminated the space where structure meets agency, developing a mid-range programme theory through complex CMO configurations.[13] Although our data are drawn from the United Kingdom, by developing a mid-range programme theory and integrating SEIPS we have created a framework that is of international relevance through its potential to guide quality improvement work in similar modern health systems. Using our theory will help ensure attention is paid to both agency and structure in system (re)design. Nevertheless, the end product from this work results in a theoretical framework which requires further refinement and testing through application in different contexts, and with different people across differing systems and cultures.

While the use of the driver diagram (Figure 1) created in our prior work remains a useful tool for organisations to evaluate their own local context, the addition of this study is to provide a similar contextualised framework for digging deeper into socially constructed concerns which may help or hinder process- and task-based interventions seeking better outcomes. This study used analyses of data summarised as driver diagrams as prompts to engage stakeholders in structured discussions that would help us better understand the differences between what happens 'on paper' and in reported incidents (knowing these are likely to be the tip of an iceberg) and what happens in day-to-day practice. It is not enough to consider out-of-hours palliative care to be a series of task-based processes. Professionals and patients/informal carers alike base choices and behaviours on 'grander' socially influenced learning from prior experiences and constructions of roles, responsibilities and accountability. We suggest that our approach is a helpful method for creating safe spaces to promote voices to build a richer and more meaningful construct of the challenges which need to be addressed through improvement initiatives.[32]

The study team included GPs (HW, ACS, AE) and Palliative Medicine Consultants (SN, SY) with interests in realist methodological, educational and socio-cultural expertise. In addition, the study team had expertise in human ergonomics (PB) and patient safety (ACS, LD). The stakeholder event also provided a starting point for a local quality improvement project in South East Wales (unpublished data, Williams H, A Study to Improve the Quality of Out of Hours palliative care services for out-of-hours patients. RCGP MC-06-16). In this way we sought to create local impact alongside our research objectives.[13] We are aware, however, that our research data are necessarily contextualised and hence further work exploring the issues raised and theories generated in other contexts is needed. For example, we note the limited diversity of our participants. It is also worth noting that out-of-hours both makes up the majority of time in any given week, and what happens in-hours is bound to impact on out-of-hours care. Rethinking systems from a patient and informal carer perspective is needed to shift from considering in and out-of-hours as two distinct entities. Addressing this issue was outside the remit of our current study.

Implications for policy, practice and further research

We do not claim our programme theory to be more than mid-range and accept that it is based on a relatively small sample of people. It is not intended to be a definitive explanation of all out-of-hours palliative care: rather we anticipate its usefulness being in providing a framework to guide quality improvement work that integrates person-level and other human factors-based systems thinking principles.[33] We expect, for example, this will help to support future attempts to improve out-of-hours palliative care, thereby increasing the likelihood of meaningful constructive change. This is because our mid-range theory highlights areas that are often overlooked in whole systems re-design. Throughout our work we accept that the meaning people derive from experiences influences future learning and actions.[34] Human agency inherently risks unintended and unanticipated consequences of actions as people seek to adapt to changing circumstances. Practical experience creates informal knowledge of how work can be done. There are often gaps between work-as-imagined (i.e. designed and necessarily schematic) and work-as-done (i.e. on the ground practice).[35] As we identified the sense of isolation experienced in out-of-hours work exacerbates these challenges.

Less attention has, perhaps been given in healthcare improvement to work-as-reimagined, that is how those on the ground learn informally to get work done, or not, based on prior experience, including when structural elements of a system are sub-optimal. It remains the case that there is a lack of empirical evidence to support many improvement interventions in out-of-hours palliative care that professionals believe in. In many instances this is due to an absence of high-quality studies rather than evidence against interventions. There is also a lack of human factors-based studies exploring system-wide complexities and adaptations that facilitate or inhibit good quality care. Further work is needed to support the design and redesign of improvement interventions to better suit the people in the system and develop meaningful ways for impact (effectiveness, efficiency, and value as well as patient benefit) to be assessed.

Figure Captions:

Figure 1. Driver diagram to show potential interventions to improve the safety of out of hours primary care for patients at the end of life

Figure 2. Complex CMO configurations

Figure 3. Care system of informal/formal work processes: Interactions and outcomes

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Contributorship Statement: The study team included GPs (HW, ACS, AE) and Palliative Medicine Consultants (SN, SY) with interests in realist methodological, educational and socio-cultural expertise. In addition, the study team had expertise in human ergonomics (PB) and patient safety (ACS, LD). All authors were involved in the conception and design of the work in addition to all authors contributing to the acquisition, analysis or interpretation of the data. HW, ACS & SN attended the event with HW facilitating and ensuring accurate data collection. SY led the analysis with HW (both independently identifying individual CMO configurations) SY drafted the first version of the full manuscript with input from ACS and PB. SY and PB led the critical comparison of our mid-range theory with the SEIPS framework by re-analysing the raw data, identified CMO configurations and themes during a cross-matching and mapping exercise using the SEIPS framework. All authors provided critical revisions and their own expertise to reach the final synthesis and interpretation. All authors agreed the final version.

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Data Sharing: We are not able to provide the raw dataset for this study to other parties because it is not possible to sufficiently anonymise the data to protect the identity of our participants. We are willing to discuss and provide further details of our methodological approach on request.

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Competing interests:

Dr Carson-Stevens was Senior Mentor to Dr Huw Williams as recipient of a Royal College of General Practitioners Marie Curie Palliative Care Fellowship.

No competing interests to declare for any other authors.

Tables

Table 1: Participants in Stakeholder event (n=17)

- Facilitator (HW), GP and Clinical Research Fellow
- Patient and Public Involvement Participants x2 (both informal carers)
- Palliative Care Consultants x2
- Palliative Care Nurse specialist x2
- GP Macmillan lead
- District Nurse
- out-of-hours Nurse Practitioner
- NHS 111 GP lead
- NHS 111 Pharmacist
- Ambulance Service Paramedic
- Nurse lecturer - Interest in Palliative Care
- Professor of Primary Care
- Health Board Patient Safety Officer
- Health Board Palliative Care lead nurse

Table 2. Specific CMO configurations that might be amenable to simple or complicated interventions

CONTEXT	MECHANISMS	OUTCOMES	INTERVENTIONS SUGGESTED TO IMPROVE*	Exemplar quotations from stakeholder group to support the CMO configurations created	SEIPS mapping of mechanisms [subject specific examples given in square brackets]
Multiple care providers	Different information technology systems Uncertainty about who to contact for what	Lack of timely access to patient records Decisions made on incomplete information leading to sub-optimal care	Technological interfaces to improve access to live patient records in a timely manner need to be developed with a user-centred design approach Single point of access for out-of-hours care	“most of the time we’ll get everything that we need from the out-of-hours GP but it’s adding that extra time, for both us, for the patient and for the GP out-of-hours GP you know. If we knew the information in the first place it would be a lot easier” (Professional) “what do carer’s want? And the answer is a single point of communication… don’t think it matters what the single point is but I do think it’s absolutely essential for a carer to have that phone number they can, they can ring and say help I don’t know the answer to this” (Informal carer)	External influences [national policies] Organisation of work Technology and Tools
Advance care planning	Plans not created Plans not communicated / accessible when needed Unclear who is responsible for completing and updating advance care plans Lack of effective processes and tools for care coordination between hospital and community	Optimal care in line with patient preferences not delivered Deviations from preferred place of care or death Admissions to acute healthcare when patient not going to benefit from escalation in treatment interventions	Interpersonal solutions accounting for socially mediated factors to prompt advance care planning creation Technological interfaces to improve access to live patient records in a timely manner across all services including hospitals	“We looked at the volume of 999 to care homes pre ACP’s and post ACP’s and there’s a definite reduction it caused. ACP’s are empowering care homes nurses to not make that phone call.” (Professional) “how do you keep that up to date when we’ve got an electronic system that’s – but there’s lots of different electronic systems that we’re supposed to be putting the information on” (Professional) “because he’s not ambulant he can’t go through the usual turn up to clinic so he has to get brought in by ambulance so he has to go through the medical intake he’s there waiting you know for hours and hours and hours for that, then they do the DVT and they admit his through the process check his DVT – no, but then it took 3½ weeks to get him home, discharge planning all he came in for was a DVT to be ruled out and but the fact is he’s now in hospital unsafe discharge, la, la, la, la, la, you know everyone wanted him to be at home, he wanted to be at home, but the minute we ticked this system box of get him in we can’t get him out then” (Professional)	Organisation of work Technology and Tools Person [including dynamics between people – patient/informal carers/healthcare professionals; and, psychological, social and cognitive factors] Physical environment
Workload pressures due to volume of need in comparison to staff resources	Professionals focusing on crisis management Tendency to leave complex issues to ‘in hours’ care providers	Further crises due to lack of preventative / prophylactic measures Agency staff used – lack of local knowledge disadvantaging them in providing best care	Population-based needs assessment of resources to deliver agreed standards of care	“what we do is we normalise a lot of it we just say it’s part of our working day to go around correcting all the mistakes that the system has put in” (Professional) “how much extra work these mistakes cause us and literally every you know about a third of these is that somebody else has actually caused so yes we’ve had to do the extra paperwork. So, it builds inefficiency into our systems” (Professional) “actually, we could chuck in agency staff… absolutely yeah and that’s above their paid rate you know” (Professional)	Organisation of work Person [healthcare professionals - physical, cognitive and psychological capabilities]
Reliance on professionals outside specialist palliative care to deliver frontline services	Inexperience Lack of training Uncertainty about how to gain expert advice / advice not available	Default to admit patients to hospital Missed or delayed diagnosis of palliative care emergencies e.g. bowel obstruction, pathological	Additional specialist palliative care resources for direct patient care and/or training of others in frontline care: population-based needs assessments could guide quantification of this. Robust concurrent evaluations of effectiveness, and value of additional resources and new training interventions.	“we might have breathing difficulties… well breathing difficulties can be so many things so we’ve got to walk in and we’ve got to, we’ve got to determine first of all you know is this a reversible cause, you know is this an asthma, is this a chest infection or is it palliative care you know so…and then once we’ve decided okay perhaps it is palliative care, we don’t know at what stage” (Professional)	Organisation of work Person [healthcare professionals: team working, psychological and cognitive factors]

		fractures		"you've got the GP who doesn't know the patient, they turn up its gonna take a lot more time to sort them out locally, it's easier to get them admitted." (Professional)	
Medication management	Complicated medication regimes Unfamiliarity of frontline staff with palliative care medications Myths and fears about symptom control medications Breakdown of practical systems for prescribing, supplying and administering medications	Delays in symptom control Increased risk of medication errors: wrong doses prescribed, dispensed or administered	End-to-end solutions for medication provision and management e.g. electronic prescribing, clarity about who could prescribe / alter dosing of existing medications / transcribe prescriptions out-of-hours Pharmacy support Increased anticipatory prescribing	"I saw people going out of hospital with complicated treatments regimes that gave the feeling that I don't think there's a chance in a million of those people taking the right drugs at the right time. " (Informal carer) "tell me if I'm speaking out of turn, I think in the community out-of-hours GP's, Primary care, some people are afraid of it and they'll only prescribe it [oral morphine instant release liquid] every 4 hours whereas we didn't have a problem in giving them every hour" (Professional) "and then when there's artificial barriers put up so when for instance we can't get the drugs in the community even if you call on-call pharmacy it's really difficult to get the medicine from say the hospital because it's a community patient and they want a hospital prescription and it's always things like that it's like an artificial barrier that's put up for accessing the meds" (Professional) "we used to have dose ranges which were stopped so we would have 2.5 – 10 mg of midazolam written up but once that's stopped the GP then writes 2.5mg 2 hourly, but if that patient then overnight an hour later is in excruciating pain the qualified nurses there can't give anything, can't take a verbal, has to wait for out-of-hours then to come which could take X,Y - 10 you know or however long, so that can be quite frustrating" (Professional)	Organisation of work Person [patient, informal carers, healthcare professionals: physical, psychological and cognitive factors]
Implicit reliance on informal carers	Inadequate support	Carer distress and breakdown	Investment in carer support: psychological, emotional and practical Adequate needs-based assessment of patient care	"I had a patient admitted a week last Friday who was in renal failure end of life, he preferred basically a death at his home we rang out-of-hours at quarter to eleven they arrived at 2am patient was severely agitated with retention of urine potentially they gave a stat that they didn't catheterise patient an hour later became very, very agitated GP couldn't go out the wife panicked and then rang 999 he was then admitted and died so.... I think if the reassurance that somebody was gonna go back, maybe the GP could visit then she may not have panicked and rung 999. However, she could've also rung me back, but she didn't so it was a very sad situation really, because he was obviously extremely agitated, but he dipped very quickly… People react differently overnight as they might do during the day really don't they? They often say long hours at night they see things differently, in the day there would've been a lot more people around… we see a lot of out-of-hours calls where people panic and ring 999 even though you've put everything in place" (Professional) "I was confused, my wife running a really high temperature with her being tired because I thought they visited on the weekend I didn't take her temperature quite as often as I should" (Informal carer) "and I had a promise of support from Marie Curie which was very good for my peace of mind" (Informal carer)	Organisation of work Person [patient, informal carers: - physical, social, psychological and cognitive factors]

**as demonstrated in Figure 1 evidence to support these is variable: we report here the suggestions made during the stakeholder event. Our analysis demonstrated professional belief in these interventions regardless of the level of empirical evidence.*

Table 3: Complex person-level themes leading to interacting mechanisms that influence human factors issues in out-of-hours palliative care

Themes	Exemplar quotations to support themes identified	SEIPS mapping
Frontline professionals commonly feared that the consequences of not admitting a patient to hospital or escalating investigations or disease-focused treatment would be personal blame	"for the carer one of the critical questions is how will I know when they are actually about to die? Or what will I see, what will actually happen? And some cancers some conditions will manifest themselves in different ways, so for instance if I were to anticipate …I wouldn't want to manage that and that could be …and coping afterwards you know, because that would be very stressful… but I don't when people talk about preferred place of care they go into the A - the options, or that the hospitals sort've of thing or B – what each one then can offer, still so that they're aware" (Professional) "one area with clinical practice which has changed dramatically in the last 24 months is sepsis and it's not included in the advanced care plan it's gonna happen that you become sceptic and everyone is now saying that and in out-of-hours cos I've seen in happen oh well if they become septic well their preferred place of care is at home but when they're sceptic – call an ambulance" (Professional)	Person [Healthcare professionals: emotional intelligence, meta-cognition, workplace culture, learning from prior experiences]
Patients and informal carers were reported to be regularly facing an impossible choice due to enormous differentials in the speed of response times of different services i.e. people were choosing between having any professional present quickly over having someone with the right expertise. Who was called by patients and informal carers was also shaped by previous experiences of who was most likely to respond.	"we have a lot of calls because it's quicker to get through to us than it is we have I mean we've worked our 8 hours that day so we're doing an on-call and then doing another 8 hours literally we're working solid through for 2 days and we have many calls at 3am, 5am you know because we're quicker and that's not a good thing is it at all?" (Professional)	Person [Patients and informal carers: psychological, cognitive and social factors]
Neither patients/informal carers nor professionals felt safe or supported to take calculated risks in line with patient priorities for care in the community	"there's a lady who'd had a severe stroke who was actually bed-bound for about 4 years DNAR end of life drugs, she was deteriorating, we sent a driver up, he [patient's informal carer] still rang 999 and there was no way on earth that lady of ever being moved, she was hoist only, and she died in the ambulance – it's unavoidable on times isn't it?" (Professional)	Person [Patients, informal carers and healthcare professionals: psychological factors and learning from prior experiences]
The lack of pre-existing relationships between professionals within and across out-of-hours services meant there was a lack of trust, which in turn impinged on professional autonomy, giving and receiving advice, and lack of understanding of practical constraint on each others working practices	"it took a couple of hours for someone from out-of-hours to see them, we were going that's good! It's pretty damn good that 2 hours, but you know it all depends what the family were expecting and actually 2 hours, I'm dialling 999 cos no one's coming I'm on my own I don't know what's going on, they're looking terrible… So there's an issue of knowing what carer's needs are and what their expectations are, and actually whether we're able to meet them because otherwise the default will be 999. There were some issues around kind've expertise and knowledge and skills I don't think it was a big as one of the other issues and the other final one which I suppose is around equipment 2 major issues were around catheters, simple as that, someone with terminal agitation where a catheter would've sorted it, for various reasons it wasn't, and another where a patient had, had a catheter, it had come out at their request and then when it needed to go back in because it had been put in by frailty the DN service, there wasn't a catheter pack, so they couldn't do it. So once again, different systems not, not connecting…" (Professional)	Person [Healthcare professionals: psychological and social factors in team working]
Apart from some doctors professionals were uncertain of their authority to act on discussions around ceilings of care even in the presence of documented advance care plans, in part due to different policies and guidance in different organisations.	"we had a 40 year old lady who we'd discharged from nursing home who had a detailed advanced care plan and they still admitted her at 8 o'clock in the morning you know we just sat and managed then to turn her around the following day and get her back out. So that was really disappointing because she could've died on route or what have you, fortunately she made it back to the home it was all the distress around that so there's communication there around the nursing home and skills of the nursing staff and I think the knowledge and the understanding of the detail around the advanced care plan because when we looked into that they were saying oh we not everybody realised that the detail of that and therefore you know somebody like you say has probably panicked and thought oh my god we just need to send her in you know she was a little bit more short of breath, that was potentially imminently dying and it was just all very unfortunate" (Professional) "and that's gone to the NMC saying why didn't you start it? And she said well he was obviously dead it was not DNA CPR you have to go in and jump on his chest you cannot make that decision to say to stop it has to be a doctor" (Professional)	Person [Healthcare professionals: metacognition, lack of empowerment, workplace cultures, learning from prior experiences]
Many professionals lacked understanding of the law regarding mental capacity and advance care planning and viewed 'doing something' as being by definition more defensible than what they perceived to be 'doing nothing' even though the latter was often in fact not nothing but taking action to provide appropriate symptom control and basic care	"because they'll say oh yeah we've got a DNA ah, but it doesn't mean to say that they're not gonna be actively treated up to the point of arrest and the number of times when you're saying to people in nursing homes well are they for admission or are they treatment within their home? And they can't answer you most of the time and they're making calls in the middle of the night to relatives to ask then do you want them to go in or not? But we can't take that as a legal requirement because we, because nobody's had the discussion properly and put it in writing, so some of it is to do with the advanced planning really. It seems to be lacking…[]so by the time our GP's or our nurses are coming in the middle of the night you've got to follow with what's before you and half of the times when I've driven like say and I don't want to send this person in, but there is nothing there to stop me" (Professional) "the COPD's and the dementia's and things like that, because the disease trajectory is difficult to work out you can have somebody who's had a DNA and they are in place for 4 years but it's never been updated and therefore how can you make a decision on something that was put on 4 years ago. If it's not been updated on an electronic system or anything" (Professional)	Person [Healthcare professionals: cognitive and psychological factors]

Table 4: Key messages and recommendations	
Methodology & theory-building There is value in drawing on different perspectives and frameworks to explore the nature of problems before attempting to offer potential solutions.	Sharing findings from analysis of patient safety incident reports directly with stakeholders is an effective prompt for discussing gaps between official accounts and day-to-day experiences. Synthesis of complementary approaches (e.g. the realist context-mechanism-outcome model with SEIPS) helps cross disciplinary boundaries and consider intersectionality between different perspectives.
Human factors issues Interventions can only be targeted at underlying mechanisms driving human factors issues when problems are studied in depth and in context.	As people experience different events, socially constructed learning in the form of sense-, or meaning-making occur leading to cycles of thought and behaviour that are refined and replicated according to experiences in future events. It is relatively rare that addressing knowledge gaps alone will make a difference in complex situations. Better integration of human-centred co-design principles and informal learning theory into future attempts at improvement are needed to increase the likelihood of success.
Safety in out-of-hours palliative care Problems are created, defined and constructed by people in ways that generate variable patient outcomes, experiential learning (desirable or otherwise) and consequences for future healthcare.	Optimal care is dependent on 'interpersonal glue': often mediated by trust, empowerment and ability to tell whether a situation demands a standardised, customised or flexible response. Optimal care and a holistic approach to safety in palliative care is seen to commonly require in-the-moment enacting of workaround strategies to manage risk in complex and adverse conditions.

Secondary drivers	Strength as per USDVA classification[30]	Current evidence of efficacy
Single point of access for OOH palliative care advice and care	Strong	No
E-documentation (including discharge summaries, referrals and other communications between healthcare professionals) with forcing functions and contractually mandated, timely delivery	Strong	Yes[43]
Standardised electronic records available between care settings which could be patient controlled	Strong	Limited
Increased conversations, documentation and communication of advanced care planning decisions and preferences	Weak	Yes [44 - 46]
Communication system between OOH providers for message handling	Intermediate	No
Increased anticipatory prescribing of key medications	Intermediate	Limited
Electronic prescribing systems with remote prescribing	Strong	No
Drug charts with usual dosages and opiate conversions included for end of life medications	Strong	No
New skill mix during OOH including specialist pharmacists and nurse specialist prescribers	Intermediate	No
Improved access to specialist palliative care advice in the OOH	Intermediate	No
Increased confidence of OOH staff in dealing with palliative care problems	Weak	Limited
Agreed local protocols for common procedures (catheterisation, nasogastric tube) to be delivered by OOH services	Intermediate	No
Ensure OOH teams carry sufficient equipment for common procedures e.g. catheters, leg bags, NG tubes	Intermediate	No
Basic minimum skill set for OOH practitioners	Intermediate	No

Figure 1. Driver diagram to show potential interventions to improve the safety of out of hours primary care for patients at the end of life.

Reproduced from : Williams H, Donaldson SL, Noble S, et al. Quality improvement priorities for safer out-of-hours palliative care: Lessons from a mixed-methods analysis of a national incident-reporting database. Palliative Medicine. 2019;33(3):346-356. doi:10.1177/0269216318817692 Article Copyright © 2018 Authors, Source DOI: 10.1177/0269216318817692.

Figure 1. Driver diagram to show potential interventions to improve the safety of out of hours primary care for patients at the end of life

81x60mm (300 x 300 DPI)

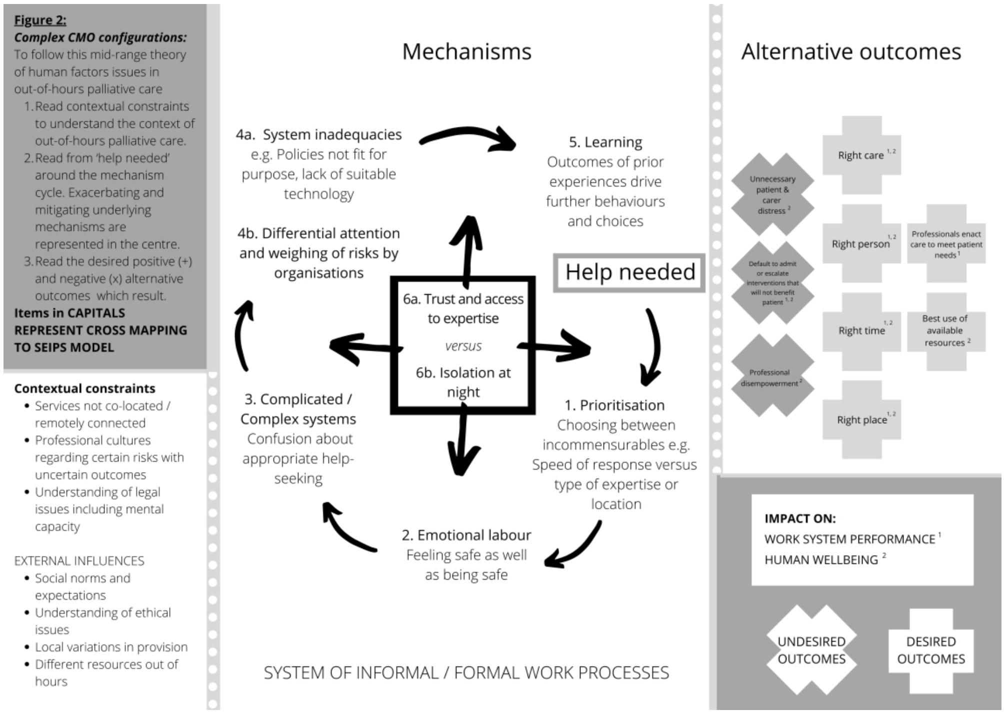
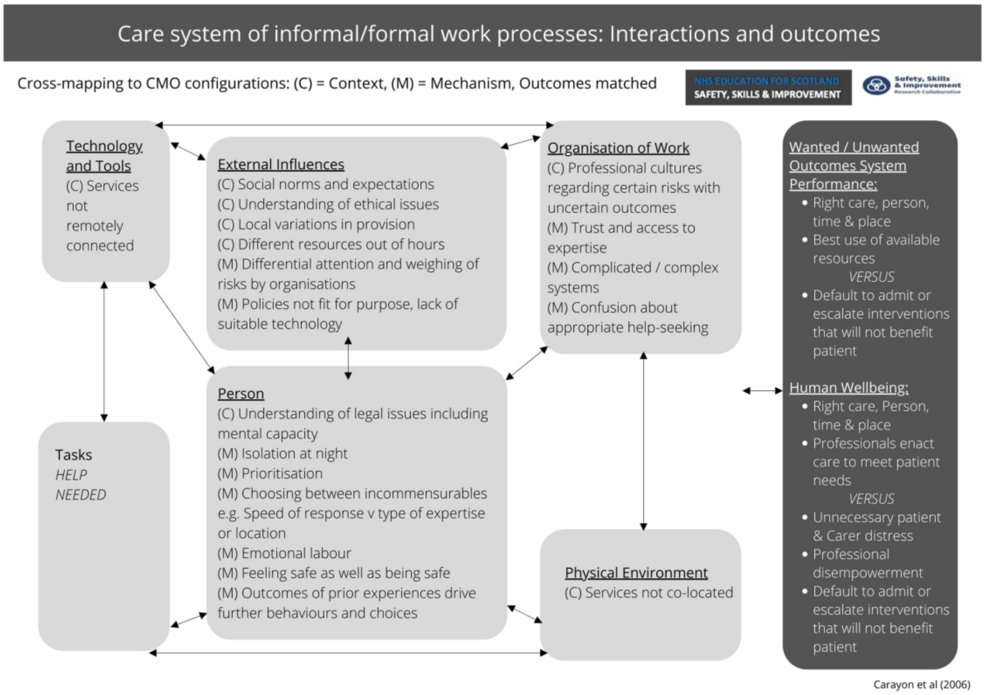


Figure 2. Complex CMO configurations

380x269mm (300 x 300 DPI)



Care system of informal/formal work processes: Interactions and outcomes

Cross-mapping to CMO configurations: (C) = Context, (M) = Mechanism, Outcomes matched

NHS EDUCATION FOR SCOTLAND
SAFETY, SKILLS & IMPROVEMENT

Safety, Skills & Improvement Research Collaborative

Technology and Tools
(C) Services not remotely connected

External Influences
(C) Social norms and expectations
(C) Understanding of ethical issues
(C) Local variations in provision
(C) Different resources out of hours
(M) Differential attention and weighing of risks by organisations
(M) Policies not fit for purpose, lack of suitable technology

Organisation of Work
(C) Professional cultures regarding certain risks with uncertain outcomes
(M) Trust and access to expertise
(M) Complicated / complex systems
(M) Confusion about appropriate help-seeking

Wanted / Unwanted Outcomes System Performance:
- Right care, person, time & place
- Best use of available resources

VERSUS
- Default to admit or escalate interventions that will not benefit patient

Human Wellbeing:
- Right care, Person, time & place
- Professionals enact care to meet patient needs

VERSUS
- Unnecessary patient & Carer distress
- Professional disempowerment
- Default to admit or escalate interventions that will not benefit patient

Tasks
HELP NEEDED

Person
(C) Understanding of legal issues including mental capacity
(M) Isolation at night
(M) Prioritisation
(M) Choosing between incommensurables e.g. Speed of response v type of expertise or location
(M) Emotional labour
(M) Feeling safe as well as being safe
(M) Outcomes of prior experiences drive further behaviours and choices

Physical Environment
(C) Services not co-located

Carayon et al (2006)

Figure 3. Care system of informal/formal work processes: Interactions and outcomes

176x121mm (300 x 300 DPI)

Dear Editors and Reviewers
Please find enclosed our manuscript entitled **A mid-range programme theory of human factors issues in out-of-hours community palliative care: lessons from a realist approach to analysis of stakeholder experiences**.

Given the novel integration of methods in this work we have not been able to complete a standard reporting checklist. Therefore, we have provided details on how our manuscript conforms to the relevant elements of RAMESES and COREQ which are the closest options.

Combined checklist – based on:

Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *International Journal for Quality in Health Care*. 2007. Volume 19, Number 6: pp. 349 – 357

Wong, G., Westhorp, G., Manzano, A. *et al.* RAMESES II reporting standards for realist evaluations. *BMC Med* **14,** 96 (2016). https://doi.org/10.1186/s12916-016-0643-1

Yours faithfully,

Dr Sarah Yardley
On behalf of all authors.

Item	Description	Section
Title	We have identified the use of a realist approach in the title in addition to stating that the manuscript presents a mid-range theory.	Title page
Abstract	A structured abstract is provided using the headings required by BMJ Quality & Safety. This includes our research question, objectives, research methods and a summary of the data used as well as further details on the analytic methods and approaches. Participant details are provided alongside key themes and subthemes. The implications of these are discussed.	Abstract
Rationale	The purpose of the study and the implications for its focus and design are explained.	Introduction
Programme theory	The initial programme theory that underpinned the study, and the evidence sources it was derived from are explained.	Introduction
Questions, objectives and focus	These are provided.	Introduction
Ethical approval	These details are provided at the start of the methods section.	Methods
Research team/characteristics and reflexivity	Details of the research team are provided with reflexive comment in the discussion. Prior to this the role of research team members who undertook the data analysis are provided in the methods.	Methods Results Discussion

	Research team members involved in data collection are named in the results along with other participants as this was a joint activity with the stakeholder participants.	
Methodological orientation and Theory	Details of our theoretical orientation are provided in the methods. This section includes explanation of how we applied realist approaches to 'naturally occurring processes' described in a stakeholder event. We also provide explanation of how we integrated these approaches with an established approach to analysing data for human factors issues. The setting of the work is described along with the stakeholder event itself. It should be noted that we are not reporting a QI intervention in this manuscript.	Methods
Sampling	Recruitment, selection and participation are all described. Included participants are listed in the results.	Methods Results
Data collection	The processes of data generation and collection during the stakeholder event are described. As all possible participants were included in the analysis it is not appropriate to refer to data saturation.	Methods
Data analysis	Details of the analytic processes are provided along with the focus.	Methods
Number of data coders	Included.	Methods
Derivation of themes	The initial inductive approach was supplemented by a deductive comparison with SEIPS. This is described in detail.	Methods
Reporting	Quotations from participants are included. Key findings are presented linking them to CMO configurations at various levels of analysis with the use of tables / figures to supplement main text. Major themes are drawn out further in the discussion.	Results Discussion.
Strengths, limitations and future directions	These are discussed along with comparison to existing literature before recommendations are provided.	Discussion.
Funding and conflict of interest	No specific funding for this piece of work was received.	N/A

BMJ Open

Which human factors design issues are influencing system performance in out-of-hours community palliative care? Integration of realist approaches with an established systems analysis framework to develop mid-range programme theory

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Keywords:	Adult palliative care < PALLIATIVE CARE, Organisation of health services < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, PRIMARY CARE

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Title: Which human factors design issues are influencing system performance in out-of-hours community palliative care? Integration of realist approaches with an established systems analysis framework to develop mid-range programme theory

Authors: Sarah Yardley,[1] Huw Williams,[2] Paul Bowie,[3] Adrian Edwards,[2] Simon Noble,[4] Liam Donaldson,[2,5] Andrew Carson-Stevens[2]*

1. Marie Curie Palliative Care Research Department, University College London; Palliative Care Service, Central & North London NHS Foundation Trust; The Health Improvement Studies (THIS) Institute Post-doctoral Fellow

2. Division of Population Medicine, Cardiff University, 8th floor, Neuadd Meirionnydd, Health Park, Cardiff CF14 4YS

3. Safety, Skills and Improvement Research Collaborative, NHS Education for Scotland, Edinburgh, UK; Institute of Health and Wellbeing, University of Glasgow, Glasgow, UK; School of Health and Social Care, Staffordshire University

4. Marie Curie Palliative Care Research Centre, Division of Population, Cardiff University, Cardiff, Wales, UK

5. Faculty of Epidemiology and Population Health, London School of Hygiene and Tropical Medicine, London, WC1E 7HT, UK

*Corresponding author: Dr A. Carson-Stevens carson-stevensap@cardiff.ac.uk

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Abstract

Objective: To develop mid-range programme theory from perceptions and experiences of out-of-hours community palliative care, accounting for human factors design issues that might be influencing system performance for achieving desirable outcomes through quality improvement.
Setting: Community providers and users of out-of-hours palliative care.
Participants: 17 stakeholders participated in a workshop event.
Design: In the UK around 30% of people receiving palliative care have contact with out-of-hours services. Interactions between emotions, cognition, tasks, technology and behaviours must be considered to improve safety. After sharing experiences, participants were presented with analyses of 1072 National Reporting and Learning System incident reports. Discussion was orientated to consider priorities for change. Discussions were audio-recorded and transcribed verbatim by the study team. Event artefacts, e.g. sticky notes, flip chart lists, participant notes, were retained for analysis. Two researchers independently identified context-mechanism-outcome configurations using realist approaches before studying the interrelation of configurations to build a mid-range theory. This was critically appraised using Systems Engineering Initiative for Patient Safety (SEIPS), an established human factors framework.
Results: Complex interacting configurations explain relational human-mediated outcomes where cycles of thought and behaviour are refined and replicated according to prior experiences. Five such configurations were identified: 1.Prioritisation; 2.Emotional labour; 3.Complicated/Complex systems; 4a.System inadequacies & 4b.Differential attention and weighing of risks by organisations; 5.Learning. Underpinning all these configurations was a sixth: 6a.trust and access to expertise; and, 6b.isolation at night. By developing a mid-range programme theory, we have created a framework with international relevance for guiding quality improvement work in similar modern health systems.
Conclusions:. Metacognition, emotional intelligence, and informal learning will either overcome system limitations or overwhelm system safeguards. Integration of human-centred co-design principles, and informal learning theory, into quality improvement may improve results.

Keywords

Palliative Care Medicine; Health Services, Community; After-Hours Care; Realist Theory; Social Theory; Human Factors Issues; Quality Improvement; Stakeholder Participation

Strengths and limitations of this study

- The study design provided a safe space to integrate multiple perspectives on safety and improvement initiatives in palliative care.
- Cross-disciplinary expertise has been combined with stakeholder experiences of frontline care to develop new understandings of human factor issues in out-of-hours palliative care, and how these create mechanisms for desirable or undesirable outcomes.
- Using SEIPS in combination with realist approaches is a novel methodological development for cross-disciplinary analysis that has promise for future research.
- Further work is needed to explore the issues raised and mid-range theory generated in other contexts, different cultures and with more people.
- We were not able to address the issue of a false divide between out-of-hours and in-hours care in this study but this requires urgent attention as each impacts on the other.

Main text

Background

Palliative care seeks to improve the quality of life of patients and their families when they are facing challenges associated with life-threatening illness, whether physical, psychological, social or spiritual. Fragmented system design of out-of-hours palliative care creates high risk of patient safety incidents.[1,2] In a sub-optimally designed system, human factors issues are exposed as people seek to work-around, manage goal conflicts and resource constraints, and mitigate structural challenges 'to get the job done' as safely and efficiently as possible. The extent to which risk and wellbeing are impacted because of system-wide human factors issues in out-of-hours palliative care is unknown.

In the United Kingdom (U.K.), out-of-hours healthcare provision is complex due to the many different professionals, organisations and systems involved.[2] So-called 'out-of-hours' community healthcare services are responsible for providing care for two-thirds of the week (commonly 18:30 to 08:00 on weekdays, and all hours at weekends).[2] Out-of-hours palliative care provision presents patient safety and professional performance challenges arising from both the nature of the care needs (which are often unstable and/or unpredictable e.g. medications required to achieve and maintain symptom control) and generic risks commonly found in out-of-hours care.[1,2] The latter include problems with lack of prior knowledge about patients, reliance on remote consultations, lack of access to patient records and difficulties in service co-ordination.[1,2] Electronic Palliative Care Coordination Records have been designed to provide a systematic approach to information needs but are not universally available nor fully functional in practice.[3,4,5]

Around 30% of people receiving palliative care in their usual place of residence in the U.K. have contact with out-of-hours services.[6] Patients and families can struggle to identify who to contact out-of-hours and may feel they have to trade-off between speed of response and relevant service/expertise of responders.[7] Most patients in the last phase of life are in their usual place of residence for the majority of their remaining time (home or care home).[8] Access to services for most out-of-hours palliative care is via community/primary care and emergency services. Acute hospitals are the second commonest place of care and most patients still die in hospital, with both numbers of deaths and the proportion occurring in hospitals projected to rise.[9,10] Addressing out-of-hours challenges has been identified as a key priority by patients and palliative care organisations.[11]

In this study, we use the term 'system' to refer to the entirety of healthcare enterprise, that is both the structural (in various disciplines referred to as field, architecture, artefacts) and the human. 'Human factors' (also known as ergonomics) is a scientific discipline that seeks to understand and optimise the interaction of people within the wider system in which they work.[12] More specifically human factors have been used to consider the direct and indirect (humanly-mediated) impacts of socio-technical systems (i.e. systems intrinsically dependent on the interaction of human beings with structures, organisations and artefacts) and environments on safety, risk and wellbeing.[12] The interactions between human emotion, cognition and behaviours and the influence of wider system elements have not however, always been fully considered. This is essential to better understand how to design environments and structural systems to guide humans into the best course of action, while still maintaining allowances for necessary adaptions in performance to 'get the job' done given care complexities, goal conflicts and resource constraints. This is a priority for out-of-hours palliative care given the proportion of time covered by these services.

In previous work, NHS patient palliative care safety incident reports stored on national databases were analysed for underlying contributing factors.[1,2] These findings were presented to stakeholders in out-of-hours palliative care in a half-day research event which itself generated data for the current study. Separate analysis of the stakeholder event data, in this study, was conducted to further understand underlying desirable/wanted and undesirable/unwanted outcomes in community-based palliative care drawing on the concerns of those on the frontline. The study design was also situated in a wider quality improvement project, which aimed to improve out-of-hours palliative care across a South Wales Health Board.

Research question

Which human factors design issues are influencing system performance in out-of-hours community palliative care?

Objective

To develop mid-range programme theory from perceptions and experiences of out-of-hours community palliative care, accounting for human factors design issues that might be influencing system performance for achieving desirable outcomes through quality improvement.[13]

Methods

Ethical approval was granted from Wales Research Ethics Committee 3 (17/WA/0222).

Theoretical orientation

Realist approaches seek to understand what works, for whom, under what circumstances and how, through the identification of context-mechanism-outcome (CMO) configurations.[14] If outcomes (desired or not) are known, then analysis can trace back the mechanisms that led to those outcomes in particular contexts.[15] Once CMO configurations are identified, these can be drawn together into a mid-range programme theory of practice. Mid-range theories are concepts that explain CMOs within an overarching theory of how a process functions to produce particular outcomes in different circumstances i.e. as underlying changes in reasoning and behaviour are triggered by different types or qualities of interaction or context.[13,16]

Mechanisms almost always operate on a continuum of activation rather than as a discrete dichotomous on/off. Mechanisms are components of whole systems, (incorporating both agency and structure), that intervene in or otherwise moderate, the relationship with other components. A mechanism's functionality is dependent on combinations of human reasoning and available resource. When an intervention (such as a quality improvement initiative) is made, with the provision of additional or different resources then there is a complex interaction which occurs between resource, reasoning and context.[17] This means that in an intervention, or routine clinical practice, the activities people engage in will be subject to individual and group choices, and these choices subject to social influences such as prior experience.

In this study we apply realist approaches to the naturally occurring processes of routine clinical practice. Our initial ('rough') programme theory (i.e. what might be producing outcomes from a complex system with diverse participants and how) was derived from our knowledge of the existing literature and prior work analysing NHS patient safety incident reports. The process of conducting the workshop and the data generated from it permitted us to refine this initial programme theory by identifying CMO configurations. In doing so, we have developed a mid-range theory, to explain what was happening and why. As with all mid-range theories ours 'lie[s] between the minor but necessary working hypotheses that evolve in abundance during day-to-day research and the all-inclusive systematic efforts to develop a unified theory'.[18]

After initially conducting an inductive data-driven analysis using the realist approach described above, and in more detail in the methods section below we critically considered our analysis, including the developing mid-range theory, using a deductive approach to compare and contrast our findings with the perspective of the Systems Engineering Initiative for Patient Safety (SEIPS) framework.[19,20] SEIPS is a well-established, multi-functional human factors framework that can be applied holistically to map research findings (in this case, CMO configurations) across pre-defined elements of healthcare (work) systems such as the person, task, technology, and organisational factors that typically interact and give rise to both wanted and unwanted care outcomes.

Setting

We wanted to use the learning from prior analyses of 1072 incident reports from the National Reporting and Learning System (NRLS) in England and Wales to inform improvement agendas for out-of-hours palliative care. The NRLS analysis itself was a separate study, also published,[2] which was used as a prompt to participants in this study. This study was set within the Aneurin Bevan University Health Board, one of the largest of the seven health boards in Wales, serving a population of 560,500 in South East Wales. In cooperation with the Board's Palliative Care Strategy Group, a single stakeholder event (workshop format) was convened, combining our research objective, (i.e. a mid-range programme theory of out-of-hours community palliative care)with local goals for develop quality improvement planning in this area.

The local goals were to:

1. Identify which issues in out-of-hours palliative care highlighted in national level analyses of patient safety incident reports were prevalent in the local out-of-hours service (perceptions and experiences discussed also fed into our research objective);
2. Identify which of these issues should be the priority area for improvement efforts within local services (shared goal/objective); and,
3. Create an opportunity for participants to identify a local quality improvement project group (local goal, unpublished data, Williams, H. A. Study to Improve the Quality of Out of Hours palliative care services for out of hours patients. Grant: RCGP MC-06-16).[21]

In this paper we present analysis related to our overarching research question and research objective for this study. The third local goal was not an objective of the research but something we wanted to support participants in, should they choose to do so.

Recruitment, selection and participation

Local providers and service users of out-of-hours palliative care were invited to participate in a stakeholder event via email. The palliative care network in South East Wales and Gwent Palliative Care Strategy Board agreed to facilitate this. Invitations were disseminated to the local palliative care network, out-of-hours GP providers, GP clusters and the local Research and Development office asking them to circulate details to their networks/membership. Further direct email invitations were sent by the study team to people in key roles including hospice providers, out-of-hours clinicians, palliative care consultants, GP leads and members of the public (including informal carers and patients). Potential participants were told they were being invited to a stakeholder event to identify priority areas in out-of-hours palliative care and that their participation would be used to inform a wider research programme. This led to a convenience sample of stakeholders who were engaged and interested in the subject. All those who chose to attend the stakeholder event provided written informed consent for this study.. As we did not own the mailing lists used, we do not know the total number of people approached.

Patient and public involvement (PPI)

Two informal carers attended the event in addition to the other stakeholders. Intrinsic to our methods is a collaborative approach as this study/the event were the mechanism for sharing prior research findings and seeking to bridge the gap between these and the experiences of all stakeholders in frontline clinical care.

Data generation

The event was approximately six hours long, with participants working in a mixture of small groups (five to six) and the whole group of 17. We drew on our prior experience of engagement exercises using quality improvement principles and tools[22] to structure our dissemination of our previous analyses of safety incident reports during the event.

The stakeholder event was designed to first allow participants an opportunity to share and reflect on their experiences of out-of-hours provision of palliative care (“Tell us what could have gone better in the last month whilst delivering palliative care in your role”). They were then provided with our analyses of incident reports (three examples used to provide stories behind a summary of incident types by severity of harm, contributory factors, and patient outcomes). Event facilitators next worked with stakeholders to compare experiences with reported incidents and discuss potential priorities for change (“which of the issues identified thus far should be a priority and why?”). The facilitators then shared a summary of existing literature for improvement (we presented initial ideas for change in the form of a driver diagram, see Figure 1).[2] Participants were next asked to expand on examples from recent experiences with a focus on potential solutions to identified problems; and decide which problems would be most important and feasible to tackle locally (“Ask yourself ‘What’s feasible in our service and why? Where next?’”).

All event discussions were audio-recorded and transcribed verbatim by the study team. Participants were also invited to record challenges to the provision of good care and their priorities via sticky notes, flip chart lists, and participant notes and these were retained as data (hard copy plus photographs of collective arrangements (e.g. group ordering of priorities) made during the event).

Insert Figure 1 approx. here

Data analysis

We focused analysis on understanding:

1. the context of out-of-hours community palliative care, and what occurs (mechanisms) to produce desirable outcomes; the intended global outcome of interest was for patients to receive the right care by the right person at the right time in the right place; and,

2. what mechanisms were operating in the same context to produce deviations from desirable outcomes, and what undesirable outcomes consequentially occurred.

First, HW and SY independently identified individual CMO configurations in data transcripts before comparing to reach a consensus of their line-by-line coding (using the framework of context, mechanisms and outcomes) and annotating these to form provisional configurations. This was refined with joint analysis of sticky notes and photographs of flipchart material plus handwritten field notes generated in the course of the stakeholder event. We then studied the interrelation of the CMO configurations to identify themes and build a mid-range programme theory of the potential human factors design issues in out-of-hours palliative care.

Second, SY and PB led the critical comparison of our mid-range theory, built from CMO configurations with the SEIPS framework. This was achieved by re-analysing the raw data described above, notably complex themes and identified CMO configurations (simple, complicated and complex), to map all data to the SEIPs framework elements. This provided us with a second analytic lens from which to consider underlying contributing factors across the spectrum of CMO configurations.

Results

The roles of event participants are listed in Table 1 below.

Insert Table 1 approx. here

The outcomes of the CMO configurations identified in these data impact on both system performance and human wellbeing, demonstrating how it is not possible to disentangle these in out-of-hours palliative care. In summary, six CMO configurations that could be classified as simple/complicated (see Table 2) were identified. In addition, six complex themes (see table 3) were identified and synthesised into the complex CMO configuration possibilities in Figure 2. By definition, as these are complex, the resulting three contextual constraints, four external influences, six mechanisms (two of these subdivided into parts a) and b) and nine alternative outcomes identified in Figure 2 cannot be simplified into individual CMOs. However, Tables 2&3 provide a summary of our analytic working as we developed the mid-range theory that is then presented in Figure 2 and critically examined using SEIPS (Figure 3). Underlying contributing factors, as well as mechanisms and outcomes are classified using SEIPS. This is demonstrated in Figure 3, and the right-hand columns of both Tables 2 and 3.

Simple situations are defined by identification of straightforward solutions if necessary skills and techniques are mastered. In complicated situations, an identifiable set of linked solution components which interact in predictable ways can still lead to definite outcomes.[23] As described above, during our analysis, it became evident that with exception of relatively few specific instances (provided in Table 2), it was not possible to disentangle independent simple, or even complicated, CMO configurations. Instead, the analysis pointed to interacting complex CMO configurations as possible explanations for relational and experience-based human-mediated mechanisms and outcomes (Table 3 and Figure 3).

Therefore, we first present the few simple and complicated CMO configurations that might be most amenable to technical/structural system change, gaining of skills or techniques for tasks or other component-by-component interventions in Table 2. This table demonstrates that contextual factors such as multiple care providers, including informal carers within a specialist-generalist advisory model where advance care planning was not well established, triggered system breakdowns which were considered by participants in the stakeholder event to be amendable to systems-based change. Technological solutions and greater investment in care coordination services such as a single point of access/medication management models in tandem with greater public health assessment of population need were all anticipated to offer improvements. Hence, it can be seen from Table 2 that structural solutions are likely to provide part, but not all, of the solution particularly if human factors issues are taken into consideration in any redesign.

Insert Table 2 approx. here

However, as indicated above, what we were identifying in most of the data was complex with several significant and concerning underlying themes contributing to multiple human-mediated mechanisms. The themes are presented in Table 3, with illustrative quotations from participants to demonstrate how these themes are supported by analysis of the raw data. Together these themes were identified to be influencing outcomes which were produced by mechanisms that co-evolved through interpersonal relationships. Such mechanisms could not be explained by a straightforward analysis of parts. Furthermore, the outcomes and subsequent consequences resulting were both unpredictable and yet what mattered most.[23]

Our overarching interpretive analysis, bringing together the underlying themes and complex CMOs is presented in Figure 2 (our mid-range theory). The interconnected mechanisms interact to form a system with adaptive capacity to change from experience as mediated by the people within it, and their experiential learning. At any point the mechanisms might come together to either overcome system limitations (a 'desirable' outcome) or to overwhelm system safeguards (an 'undesired' outcome).

Insert Table 3 and Figure 2 approx. here

In Figure 2, for each of the outcomes and mechanisms described, all the contextual elements listed were relevant. The themes of Table 3 also underpin all these complex CMO configurations. The context of out-of-hours palliative care was one where multiple service providers are disconnected from each other, and so misunderstanding and miscommunication could occur very easily in addition to different professional cultures developing regarding risk and uncertain outcomes.

The mechanisms numbered 1-5 (1.Prioritisation; 2.Emotional labour; 3.Complicated/Complex systems; 4a.System inadequacies & 4b.Differential attention and weighing of risks by organisations; 5.Learning) within Figure 2 all feed into and off each other. Underlying these mechanisms could be either 'Trust and access to expertise (6a)' which if strong enough could lead to desired outcomes in support of, or regardless of, mechanisms 1-5 through a positive cycle **or** 'Isolation at night (6b)' which could lead to the opposite effects and hence undesirable outcomes. 'Trust and access to expertise (6a)' is, therefore, 'interpersonal glue' that can stick the component parts together to reach desired outcomes. We have labelled 6a and 6b as such as these are components on a continuum.

The data suggest that seeking to focus on specific parts of these complex CMO configurations in isolation is unlikely to be successful. What needs to be generated is a positive cycle of learning with attention to all the underlying themes and interacting human-mediated mechanisms identified. Depending on how human factors-based systems issues interact and function in a particular patient's care, there are alternative desirable or undesirable outcomes for patients that are intertwined with the same for professionals. When patients, informal carers or professionals seek help they are commonly weighing up priorities between speed of response and ability to meet a particular need. Emotional labour is a significant mechanism. Being safe in a technical sense does not hold meaning if patients, informal carers, or professionals do not feel safe in their location, decision-making, or actions. Furthermore, both prioritisation and emotional labour mechanisms feed into confusion about whom to call for what and when. Mechanisms driven by organisational interests or system inadequacies which do not support, for example, individualised decision-making or use of professional judgement when in a situation that requires doing the 'least wrong' thing are unhelpful.

In out-of-hours palliative care, if trust is achieved and access to expertise is available then desired outcomes can be achieved, but if instead the underlying mechanism is a sense of personal or professional isolation, undesirable outcomes result. The commonest undesirable outcomes identified were unnecessary patient and carer distress, defaulting to admitting patients to acute hospital care and/or escalation of treatment interventions from which there was not a realistic possibility of patient benefit, and professional disempowerment – all of which would feed back into the mechanism cycle by triggering adverse learning that in turn would influence future help-seeking approaches. Positive learning could, however, be created by achieving desired outcomes, as could best use of available resources, both in turn leading to human factors supporting the system.

In mapping the identified CMO configurations to the SEIPS model (Figure 3), it is possible to see more clearly how little of the complex person-level concerns from stakeholders regarding out-of-hours palliative care directly relate exclusively to technical factors. Instead, the inter-relationships between socio **and** technical factors warrant greater attention to optimise the system. External influences, organisation of work and person elements come to the fore, demonstrating what is filling design gaps in a system which has evolved piecemeal over time, with a striking absence of identified mechanisms related to human factors-based design issues at individual, team, organisation and external levels. Furthermore, while it is possible to map relatively simple and complicated mechanisms (Table 2) to SEIPS elements, other than the person level this is not the case with the complex interacting mechanisms that are influencing broader system interaction issues and related performance and wellbeing outcomes (Table 3).

Insert Figure 3 approximately here

Discussion

Our work demonstrates that optimal care is dependent on 'interpersonal glue': often mediated by trust, empowerment and ability to tell whether a situation demands a standardised, customised or flexible response. This study contributes to the existing literature on three fronts: methodology and theory-building; human factors issues, and; safety in out-of-hours palliative care. The key messages and recommendations for each are summarised in Table 4.

Insert Table 4 approx. here

We have drawn on realist and human factors theory to interpret the reality of day-to-day experiences of patients, informal carers and professionals as they are active agents in patient safety endeavours in out-of-hours palliative care. In doing so we demonstrate a small number of CMO configurations that may be amenable to structural change but more importantly why structural change alone will seldom be enough to ensure patients receive the right care by the right person at the right time in the right place. Our findings show human factors issues go beyond how people interact with each other and with their surroundings, or immediate environment. As people experience different events, socially constructed learning in the form of sense-, or meaning-making occur leading to cycles of thought and behaviour that are refined and replicated according to experiences in future events.

In demonstrating complexity, it is important to note that this means different approaches to the planning and testing of improvement interventions will be needed. Simple and complicated solutions can only take us so far. We suggest that better integration of human-centred co-design principles,[24] a fundamental approach of human factors, and informal learning theory into future attempts at improvement are needed to increase the likelihood of success. This is because our findings demonstrate that optimal care is dependent on 'interpersonal glue': often mediated by trust, empowerment and ability to tell whether a situation demands a standardised, customised or flexible response.[25] Optimal care and a holistic approach to safety in palliative care is seen to commonly require in-the-moment enacting of workaround strategies to manage risk in complex and adverse conditions.[26-29] Our findings provide evidence of not just what the problems are but how these are created, defined and constructed by people in ways that generate variable patient outcomes, experiential learning (desirable or otherwise) and consequences for future healthcare. Our data provide a basis for selecting targeted interventions to influence the social mechanisms underlying safety issues in out-of-hours care.[30]

This extends previous work analysing patient safety incident reports[1,2,31] by deepening analysis of the human factors interaction issues which are an intrinsic part of the complexity of palliative care work in the community.[24] As a result we propose a mid-range programme theory of the influences on human factors in response to palliative care needs out-of-hours. This can be used to guide future attempts to improve the design of care processes through recognition of implicit assumptions and rationales,[13] thereby increasing the chances of mitigating undesirable mechanisms and promoting desirable ones. Doing so should help to create meaningful change for patients and increase professionals chance of success as they endeavour to provide safe care in difficult circumstances. We have already applied this mid-range programme theory to our later analysis of incidents arising from advance care planning.[31] This identified structure-based solutions to ensure patients receive timely and robust advance care planning would not be enough; in 37% (26/70) of advance care planning incidents, the plan was not followed due to person-level issues such as poor higher-level meta-cognitive skills or emotional intelligence often in the context of lack of confidence or experience.

Strengths and limitations

SEIPS is one of the most widely used human factors frameworks in healthcare[,20,22] and the use of realist approaches in healthcare has grown significantly in recent decades. Using both to develop a cross-disciplinary analysis to theory and empirical data is, we believe, a novel methodological development. In doing so we have been better placed to consider intersectionality between human factors issues and structural elements in the context of a healthcare system. Our explicit use of realist principles in concert with SEIPS provided us with the analytic means to consider multiple dimensions operating as interacting mechanisms in the real-world experiences of stakeholders. In doing so we have illuminated the space where structure meets agency, developing a mid-range programme theory through complex CMO configurations.[13] Although our data are drawn from the United Kingdom, by developing a mid-range programme theory and integrating SEIPS we have created a framework that is of international relevance through its potential to guide quality improvement work in similar modern health systems. Using our theory will help ensure attention is paid to both agency and structure in system (re)design. Nevertheless, the end product from this work results in a theoretical framework which requires further refinement and testing through application in different contexts, and with different people across differing systems and cultures.

While the use of the driver diagram (Figure 1) created in our prior work remains a useful tool for organisations to evaluate their own local context, the addition of this study is to provide a similar contextualised framework for digging deeper into socially constructed concerns which may help or hinder process- and task-based interventions seeking better outcomes. This study used analyses of data summarised as driver diagrams as prompts to engage stakeholders in structured discussions that would help us better understand the differences between what happens ‘on paper’ and in reported incidents (knowing these are likely to be the tip of an iceberg) and what happens in day-to-day practice. It is not enough to consider out-of-hours palliative care to be a series of task-based processes. Professionals and patients/informal carers alike base choices and behaviours on ‘grander’ socially influenced learning from prior experiences and constructions of roles, responsibilities and accountability. We suggest that our approach is a helpful method for creating safe spaces to promote voices to build a richer and more meaningful construct of the challenges which need to be addressed through improvement initiatives.[32]

The study team included GPs (HW, ACS, AE) and Palliative Medicine Consultants (SN, SY) with interests in realist methodological, educational and socio-cultural expertise. In addition, the study team had expertise in human ergonomics (PB) and patient safety (ACS, LD). The stakeholder event also provided a starting point for a local quality improvement project in South East Wales (unpublished data, Williams H, A Study to Improve the Quality of Out of Hours palliative care services for out-of-hours patients. RCGP MC-06-16). In this way we sought to create local impact alongside our research objectives.[13] We are aware, however, that our research data are necessarily contextualised and hence further work exploring the issues raised and theories generated in other contexts is needed. For example, we note the limited diversity of our participants. It is also worth noting that out-of-hours both makes up the majority of time in any given week, and what happens in-hours is bound to impact on out-of-hours care. Rethinking systems from a patient and informal carer perspective is needed to shift from considering in and out-of-hours as two distinct entities. Addressing this issue was outside the remit of our current study.

Implications for policy, practice and further research

We do not claim our programme theory to be more than mid-range and accept that it is based on a relatively small sample of people. It is not intended to be a definitive explanation of all out-of-hours palliative care: rather we anticipate its usefulness being in providing a framework to guide quality improvement work that integrates person-level and other human factors-based systems thinking principles.[33] We expect, for example, this will help to support future attempts to improve out-of-hours palliative care, thereby increasing the likelihood of meaningful constructive change. This is because our mid-range theory highlights areas that are often overlooked in whole systems re-design. Throughout our work we accept that the meaning people derive from experiences influences future learning and actions.[34] Human agency inherently risks unintended and unanticipated consequences of actions as people seek to adapt to changing circumstances. Practical experience creates informal knowledge of how work can be done. There are often gaps between work-as-imagined (i.e. designed and necessarily schematic) and work-as-done (i.e. on the ground practice).[35] As we identified a sense of isolation experienced in out-of-hours work exacerbates these challenges and is an underlying mechanism driving all the other CMO configurations. Addressing this through systems that facilitate ready access to expertise and interpersonal trust instead should be a priority.

Less attention has, perhaps been given in healthcare improvement to work-as-reimagined, that is how those on the ground learn informally to get work done, or not, based on prior experience, including when structural elements of a system are sub-optimal. It remains the case that there is a lack of empirical evidence to support many improvement interventions in out-of-hours palliative care that professionals believe in. In many instances this is due to an absence of high-quality studies rather than evidence against interventions. There is also a lack of human factors-based studies exploring system-wide complexities and adaptations that facilitate or inhibit good quality care. Further work is needed to support the design and redesign of improvement interventions to better suit the people in the system and develop meaningful ways for impact (effectiveness, efficiency, and value as well as patient benefit) to be assessed.

Figure Captions:

Figure 1. Driver diagram to show potential interventions to improve the safety of out of hours primary care for patients at the end of life

Figure 2. Complex CMO configurations

Figure 3. Care system of informal/formal work processes: Interactions and outcomes

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Contributorship Statement: The study team included GPs (HW, ACS, AE) and Palliative Medicine Consultants (SN, SY) with interests in realist methodological, educational and socio-cultural expertise. In addition, the study team had expertise in human ergonomics (PB) and patient safety (ACS, LD). All authors were involved in the conception and design of the work in addition to all authors contributing to the acquisition, analysis or interpretation of the data. HW, ACS & SN attended the event with HW facilitating and ensuring accurate data collection. SY led the analysis with HW (both independently identifying individual CMO configurations) SY drafted the first version of the full manuscript with input from ACS and PB. SY and PB led the critical comparison of our mid-range theory with the SEIPS framework by re-analysing the raw data, identified CMO configurations and themes during a cross-matching and mapping exercise using the SEIPS framework. All authors provided critical revisions and their own expertise to reach the final synthesis and interpretation. All authors agreed the final version.

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Data Sharing: We are not able to provide the raw dataset for this study to other parties because it is not possible to sufficiently anonymise the data to protect the identity of our participants. We are willing to discuss and provide further details of our methodological approach on request.

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Competing interests:

Dr Carson-Stevens was Senior Mentor to Dr Huw Williams as recipient of a Royal College of General Practitioners Marie Curie Palliative Care Fellowship.

No competing interests to declare for any other authors.

Tables

Table 1: Participants in Stakeholder event (n=17)

- Facilitator (HW), GP and Clinical Research Fellow
- Patient and Public Involvement Participants x2 (both informal carers)
- Palliative Care Consultants x2
- Palliative Care Nurse specialist x2
- GP Macmillan lead
- District Nurse
- out-of-hours Nurse Practitioner
- NHS 111 GP lead
- NHS 111 Pharmacist
- Ambulance Service Paramedic
- Nurse lecturer - Interest in Palliative Care
- Professor of Primary Care
- Health Board Patient Safety Officer
- Health Board Palliative Care lead nurse

Table 2. Specific CMO configurations that might be amenable to simple or complicated interventions

CONTEXT	MECHANISMS	OUTCOMES	INTERVENTIONS SUGGESTED TO IMPROVE*	Exemplar quotations from stakeholder group to support the CMO configurations created	SEIPS mapping of mechanisms [subject specific examples given in square brackets]
Multiple care providers	Different information technology systems Uncertainty about who to contact for what	Lack of timely access to patient records Decisions made on incomplete information leading to sub-optimal care	Technological interfaces to improve access to live patient records in a timely manner need to be developed with a user-centred design approach Single point of access for out-of-hours care	"most of the time we'll get everything that we need from the out-of-hours GP but it's adding that extra time, for both us, for the patient and for the GP out-of-hours GP you know. If we knew the information in the first place it would be a lot easier" (Professional) "what do carer's want? And the answer is a single point of communication... don't think it matters what the single point is but I do think it's absolutely essential for a carer to have that phone number they can, they can ring and say help I don't know the answer to this" (Informal carer)	External influences [national policies] Organisation of work Technology and Tools
Advance care planning	Plans not created Plans not communicated / accessible when needed Unclear who is responsible for completing and updating advance care plans Lack of effective processes and tools for care coordination between hospital and community	Optimal care in line with patient preferences not delivered Deviations from preferred place of care or death Admissions to acute healthcare when patient not going to benefit from escalation in treatment interventions	Interpersonal solutions accounting for socially mediated factors to prompt advance care planning creation Technological interfaces to improve access to live patient records in a timely manner across all services including hospitals	"We looked at the volume of 999 to care homes pre ACP's and post ACP's and there's a definite reduction it caused. ACP's are empowering care homes nurses to not make that phone call." (Professional) "how do you keep that up to date when we've got an electronic system that's – but there's lots of different electronic systems that we're supposed to be putting the information on" (Professional) "because he's not ambulant he can't go through the usual turn up to clinic so he has to get brought in by ambulance so he has to go through the medical intake he's there waiting you know for hours and hours and hours for that, then they do the DVT and they admit his through the process check his DVT – no, but then it took 3½ weeks to get him home, discharge planning all he came in for was a DVT to be ruled out and but the fact is he's now in hospital unsafe discharge, la, la, la, la, la, you know everyone wanted him to be at home, he wanted to be at home, but the minute we ticked this system box of get him in we can't get him out then" (Professional)	Organisation of work Technology and Tools Person [including dynamics between people – patient/informal carers/healthcare professionals; and, psychological, social and cognitive factors] Physical environment
Workload pressures due to volume of need in comparison to staff resources	Professionals focusing on crisis management Tendency to leave complex issues to 'in hours' care providers	Further crises due to lack of preventative / prophylactic measures Agency staff used – lack of local knowledge disadvantaging them in providing best care	Population-based needs assessment of resources to deliver agreed standards of care	"what we do is we normalise a lot of it we just say it's part of our working day to go around correcting all the mistakes that the system has put in" (Professional) "how much extra work these mistakes cause us and literally every you know about a third of these is that somebody else has actually caused so yes we've had to do the extra paperwork. So, it builds inefficiency into our systems" (Professional) "actually, we could chuck in agency staff... absolutely yeah and that's above their paid rate you know" (Professional)	Organisation of work Person [healthcare professionals - physical, cognitive and psychological capabilities]
Reliance on professionals outside specialist palliative care to deliver frontline services	Inexperience Lack of training Uncertainty about how to gain expert advice / advice not available	Default to admit patients to hospital Missed or delayed diagnosis of palliative care emergencies e.g. bowel obstruction, pathological	Additional specialist palliative care resources for direct patient care and/or training of others in frontline care: population-based needs assessments could guide quantification of this. Robust concurrent evaluations of effectiveness, and value of additional resources and new training interventions.	"we might have breathing difficulties... well breathing difficulties can be so many things so we've got to walk in and we've got to, we've got to determine first of all you know is this a reversible cause, you know is this an asthma, is this a chest infection or is it palliative care you know so...and then once we've decided okay perhaps it is palliative care, we don't know at what stage" (Professional)	Organisation of work Person [healthcare professionals: team working, psychological and cognitive factors]

		fractures		"you've got the GP who doesn't know the patient, they turn up its gonna take a lot more time to sort them out locally, it's easier to get them admitted." (Professional)	
Medication management	Complicated medication regimes Unfamiliarity of frontline staff with palliative care medications Myths and fears about symptom control medications Breakdown of practical systems for prescribing, supplying and administering medications	Delays in symptom control Increased risk of medication errors: wrong doses prescribed, dispensed or administered	End-to-end solutions for medication provision and management e.g. electronic prescribing, clarity about who could prescribe / alter dosing of existing medications / transcribe prescriptions out-of-hours Pharmacy support Increased anticipatory prescribing	"I saw people going out of hospital with complicated treatments regimes that gave the feeling that I don't think there's a chance in a million of those people taking the right drugs at the right time. " (Informal carer) "tell me if I'm speaking out of turn, I think in the community out-of-hours GP's, Primary care, some people are afraid of it and they'll only prescribe it [oral morphine instant release liquid] every 4 hours whereas we didn't have a problem in giving them every hour" (Professional) "and then when there's artificial barriers put up so when for instance we can't get the drugs in the community even if you call on-call pharmacy it's really difficult to get the medicine from say the hospital because it's a community patient and they want a hospital prescription and it's always things like that it's like an artificial barrier that's put up for accessing the meds" (Professional) "we used to have dose ranges which were stopped so we would have 2.5 – 10 mg of midazolam written up but once that's stopped the GP then writes 2.5mg 2 hourly, but if that patient then overnight an hour later is in excruciating pain the qualified nurses there can't give anything, can't take a verbal, has to wait for out-of-hours then to come which could take X,Y - 10 you know or however long, so that can be quite frustrating" (Professional)	Organisation of work Person [patient, informal carers, healthcare professionals: physical, psychological and cognitive factors]
Implicit reliance on informal carers	Inadequate support	Carer distress and breakdown	Investment in carer support: psychological, emotional and practical Adequate needs-based assessment of patient care	"I had a patient admitted a week last Friday who was in renal failure end of life, he preferred basically a death at his home we rang out-of-hours at quarter to eleven they arrived at 2am patient was severely agitated with retention of urine potentially they gave a stat that they didn't catheterise patient an hour later became very, very agitated GP couldn't go out the wife panicked and then rang 999 he was then admitted and died so.... I think if the reassurance that somebody was gonna go back, maybe the GP could visit then she may not have panicked and rung 999. However, she could've also rung me back, but she didn't so it was a very sad situation really, because he was obviously extremely agitated, but he dipped very quickly… People react differently overnight as they might do during the day really don't they? They often say long hours at night they see things differently, in the day there would've been a lot more people around… we see a lot of out-of-hours calls where people panic and ring 999 even though you've put everything in place" (Professional) "I was confused, my wife running a really high temperature with her being tired because I thought they visited on the weekend I didn't take her temperature quite as often as I should" (Informal carer) "and I had a promise of support from Marie Curie which was very good for my peace of mind" (Informal carer)	Organisation of work Person [patient, informal carers: - physical, social, psychological and cognitive factors]

**as demonstrated in Figure 1 evidence to support these is variable: we report here the suggestions made during the stakeholder event. Our analysis demonstrated professional belief in these interventions regardless of the level of empirical evidence.*

Table 3: Complex person-level themes leading to interacting mechanisms that influence human factors issues in out-of-hours palliative care

Themes	Exemplar quotations to support themes identified	SEIPS mapping
Frontline professionals commonly feared that the consequences of not admitting a patient to hospital or escalating investigations or disease-focused treatment would be personal blame	"for the carer one of the critical questions is how will I know when they are actually about to die? Or what will I see, what will actually happen? And some cancers some conditions will manifest themselves in different ways, so for instance if I were to anticipate …I wouldn't want to manage that and that could be …and coping afterwards you know, because that would be very stressful… but I don't when people talk about preferred place of care they go into the A - the options, or that the hospitals sort've of thing or B – what each one then can offer, still so that they're aware" (Professional) "one area with clinical practice which has changed dramatically in the last 24 months is sepsis and it's not included in the advanced care plan it's gonna happen that you become sceptic and everyone is now saying that and in out-of-hours cos I've seen in happen oh well if they become septic well their preferred place of care is at home but when they're sceptic – call an ambulance" (Professional)	Person [Healthcare professionals: emotional intelligence, meta-cognition, workplace culture, learning from prior experiences]
Patients and informal carers were reported to be regularly facing an impossible choice due to enormous differentials in the speed of response times of different services i.e. people were choosing between having any professional present quickly over having someone with the right expertise. Who was called by patients and informal carers was also shaped by previous experiences of who was most likely to respond.	"we have a lot of calls because it's quicker to get through to us than it is we have I mean we've worked our 8 hours that day so we're doing an on-call and then doing another 8 hours literally we're working solid through for 2 days and we have many calls at 3am, 5am you know because we're quicker and that's not a good thing is it at all?" (Professional)	Person [Patients and informal carers: psychological, cognitive and social factors]
Neither patients/informal carers nor professionals felt safe or supported to take calculated risks in line with patient priorities for care in the community	"there's a lady who'd had a severe stroke who was actually bed-bound for about 4 years DNAR end of life drugs, she was deteriorating, we sent a driver up, he [patient's informal carer] still rang 999 and there was no way on earth that lady of ever being moved, she was hoist only, and she died in the ambulance – it's unavoidable on times isn't it?" (Professional)	Person [Patients, informal carers and healthcare professionals: psychological factors and learning from prior experiences]
The lack of pre-existing relationships between professionals within and across out-of-hours services meant there was a lack of trust, which in turn impinged on professional autonomy, giving and receiving advice, and lack of understanding of practical constraint on each others working practices	"it took a couple of hours for someone from out-of-hours to see them, we were going that's good! It's pretty damn good that 2 hours, but you know it all depends what the family were expecting and actually 2 hours, I'm dialling 999 cos no one's coming I'm on my own I don't know what's going on, they're looking terrible… So there's an issue of knowing what carer's needs are and what their expectations are, and actually whether we're able to meet them because otherwise the default will be 999. There were some issues around kind've expertise and knowledge and skills I don't think it was a big as one of the other issues and the other final one which I suppose is around equipment 2 major issues were around catheters, simple as that, someone with terminal agitation where a catheter would've sorted it, for various reasons it wasn't, and another where a patient had, had a catheter, it had come out at their request and then when it needed to go back in because it had been put in by frailty the DN service, there wasn't a catheter pack, so they couldn't do it. So once again, different systems not, not connecting…" (Professional)	Person [Healthcare professionals: psychological and social factors in team working]
Apart from some doctors professionals were uncertain of their authority to act on discussions around ceilings of care even in the presence of documented advance care plans, in part due to different policies and guidance in different organisations.	"we had a 40 year old lady who we'd discharged from nursing home who had a detailed advanced care plan and they still admitted her at 8 o'clock in the morning you know we just sat and managed then to turn her around the following day and get her back out. So that was really disappointing because she could've died on route or what have you, fortunately she made it back to the home it was all the distress around that so there's communication there around the nursing home and skills of the nursing staff and I think the knowledge and the understanding of the detail around the advanced care plan because when we looked into that they were saying oh we not everybody realised that the detail of that and therefore you know somebody like you say has probably panicked and thought oh my god we just need to send her in you know she was a little bit more short of breath, that was potentially imminently dying and it was just all very unfortunate" (Professional) "and that's gone to the NMC saying why didn't you start it? And she said well he was obviously dead it was not DNA CPR you have to go in and jump on his chest you cannot make that decision to say to stop it has to be a doctor" (Professional)	Person [Healthcare professionals: metacognition, lack of empowerment, workplace cultures, learning from prior experiences]
Many professionals lacked understanding of the law regarding mental capacity and advance care planning and viewed 'doing something' as being by definition more defensible than what they perceived to be 'doing nothing' even though the latter was often in fact not nothing but taking action to provide appropriate symptom control and basic care	"because they'll say oh yeah we've got a DNA ah, but it doesn't mean to say that they're not gonna be actively treated up to the point of arrest and the number of times when you're saying to people in nursing homes well are they for admission or are they treatment within their home? And they can't answer you most of the time and they're making calls in the middle of the night to relatives to ask then do you want them to go in or not? But we can't take that as a legal requirement because we, because nobody's had the discussion properly and put it in writing, so some of it is to do with the advanced planning really. It seems to be lacking…[]so by the time our GP's or our nurses are coming in the middle of the night you've got to follow with what's before you and half of the times when I've driven like say and I don't want to send this person in, but there is nothing there to stop me" (Professional) "the COPD's and the dementia's and things like that, because the disease trajectory is difficult to work out you can have somebody who's had a DNA and they are in place for 4 years but it's never been updated and therefore how can you make a decision on something that was put on 4 years ago. If it's not been updated on an electronic system or anything" (Professional)	Person [Healthcare professionals: cognitive and psychological factors]

Table 4: Key messages and recommendations	
Methodology & theory-building There is value in drawing on different perspectives and frameworks to explore the nature of problems before attempting to offer potential solutions.	Sharing findings from analysis of patient safety incident reports directly with stakeholders is an effective prompt for discussing gaps between official accounts and day-to-day experiences. Synthesis of complementary approaches (e.g. the realist context-mechanism-outcome model with SEIPS) helps cross disciplinary boundaries and consider intersectionality between different perspectives.
Human factors issues Interventions can only be targeted at underlying mechanisms driving human factors issues when problems are studied in depth and in context.	As people experience different events, socially constructed learning in the form of sense-, or meaning-making occur leading to cycles of thought and behaviour that are refined and replicated according to experiences in future events. It is relatively rare that addressing knowledge gaps alone will make a difference in complex situations. Better integration of human-centred co-design principles and informal learning theory into future attempts at improvement are needed to increase the likelihood of success.
Safety in out-of-hours palliative care Problems are created, defined and constructed by people in ways that generate variable patient outcomes, experiential learning (desirable or otherwise) and consequences for future healthcare.	Optimal care is dependent on 'interpersonal glue': often mediated by trust, empowerment and ability to tell whether a situation demands a standardised, customised or flexible response. Optimal care and a holistic approach to safety in palliative care is seen to commonly require in-the-moment enacting of workaround strategies to manage risk in complex and adverse conditions.

Secondary drivers	Strength as per USDVA classification[30]	Current evidence of efficacy
Single point of access for OOH palliative care advice and care	Strong	No
E-documentation (including discharge summaries, referrals and other communications between healthcare professionals) with forcing functions and contractually mandated, timely delivery	Strong	Yes[43]
Standardised electronic records available between care settings which could be patient controlled	Strong	Limited
Increased conversations, documentation and communication of advanced care planning decisions and preferences	Weak	Yes [44-46]
Communication system between OOH providers for message handling	Intermediate	No
Increased anticipatory prescribing of key medications	Intermediate	Limited
Electronic prescribing systems with remote prescribing	Strong	No
Drug charts with usual dosages and opiate conversions included for end of life medications	Strong	No
New skill mix during OOH including specialist pharmacists and nurse specialist prescribers	Intermediate	No
Improved access to specialist palliative care advice in the OOH	Intermediate	No
Increased confidence of OOH staff in dealing with palliative care problems	Weak	Limited
Agreed local protocols for common procedures (catheterisation, nasogastric tube) to be delivered by OOH services	Intermediate	No
Ensure OOH teams carry sufficient equipment for common procedures e.g. catheters, leg bags, NG tubes	Intermediate	No
Basic minimum skill set for OOH practitioners	Intermediate	No

Figure 1. Driver diagram to show potential interventions to improve the safety of out of hours primary care for patients at the end of life.

Reproduced from : Williams H, Donaldson SL, Noble S, et al. Quality improvement priorities for safer out-of-hours palliative care: Lessons from a mixed-methods analysis of a national incident-reporting database. Palliative Medicine. 2019;33(3):346-356. doi:10.1177/0269216318817692 Article Copyright © 2018 Authors, Source DOI: 10.1177/0269216318817692.

Figure 1. Driver diagram to show potential interventions to improve the safety of out of hours primary care for patients at the end of life

81x60mm (300 x 300 DPI)

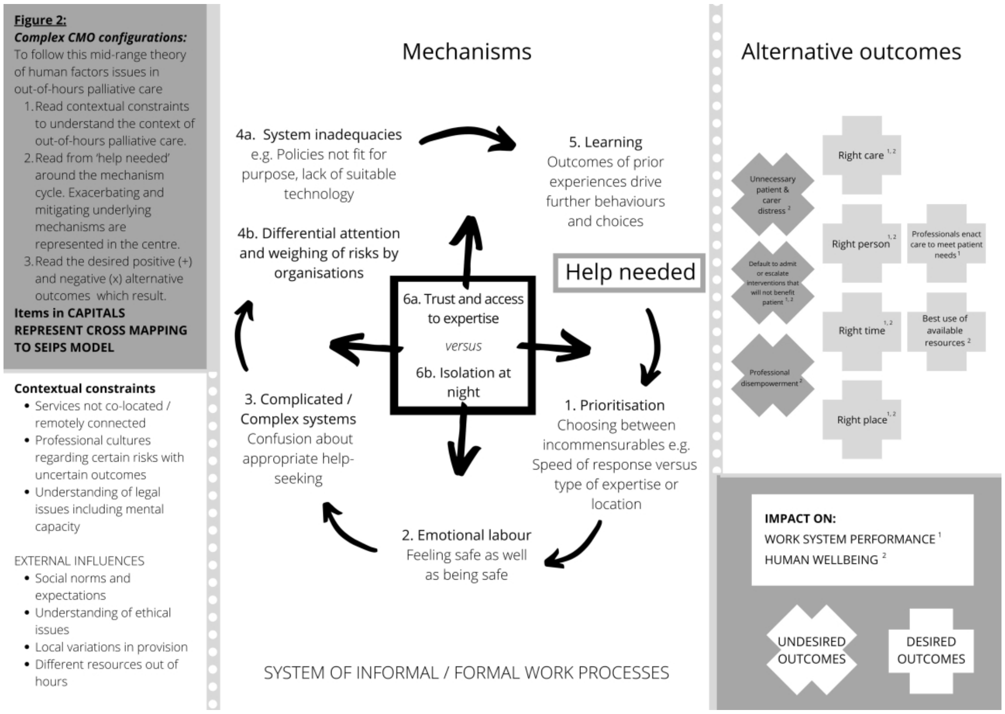

Figure 2:
Complex CMO configurations:
To follow this mid-range theory of human factors issues in out-of-hours palliative care

1. Read contextual constraints to understand the context of out-of-hours palliative care.
2. Read from 'help needed' around the mechanism cycle. Exacerbating and mitigating underlying mechanisms are represented in the centre.
3. Read the desired positive (+) and negative (x) alternative outcomes which result.

Items in CAPITALS REPRESENT CROSS MAPPING TO SEIPS MODEL

Contextual constraints
- Services not co-located / remotely connected
- Professional cultures regarding certain risks with uncertain outcomes
- Understanding of legal issues including mental capacity

EXTERNAL INFLUENCES
- Social norms and expectations
- Understanding of ethical issues
- Local variations in provision
- Different resources out of hours

Figure 2. Complex CMO configurations

380x269mm (300 x 300 DPI)

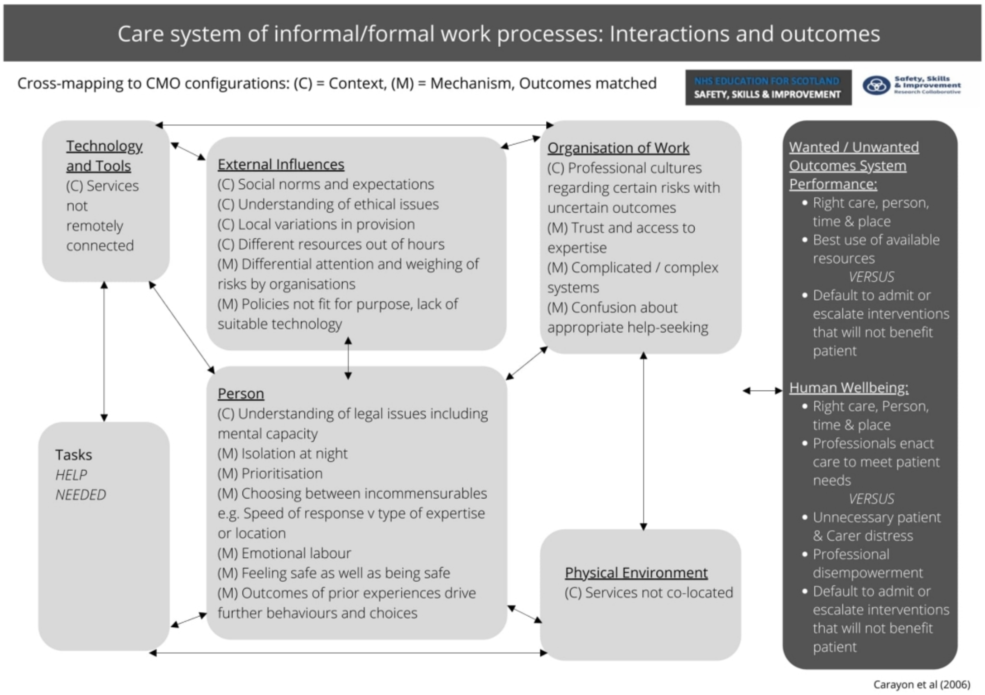

Figure 3. Care system of informal/formal work processes: Interactions and outcomes

176x121mm (300 x 300 DPI)

Dear Editors and Reviewers
Please find enclosed our manuscript entitled **A mid-range programme theory of human factors issues in out-of-hours community palliative care: lessons from a realist approach to analysis of stakeholder experiences**.

Given the novel integration of methods in this work we have not been able to complete a standard reporting checklist. Therefore, we have provided details on how our manuscript conforms to the relevant elements of RAMESES and COREQ which are the closest options.

Combined checklist – based on:

Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *International Journal for Quality in Health Care*. 2007. Volume 19, Number 6: pp. 349 – 357

Wong, G., Westhorp, G., Manzano, A. *et al.* RAMESES II reporting standards for realist evaluations. *BMC Med* **14,** 96 (2016). https://doi.org/10.1186/s12916-016-0643-1

Yours faithfully,

Dr Sarah Yardley
On behalf of all authors.

Item	**Description**	**Section**
Title	We have identified the use of a realist approach in the title in addition to stating that the manuscript presents a mid-range theory.	Title page
Abstract	A structured abstract is provided using the headings required by BMJ Quality & Safety. This includes our research question, objectives, research methods and a summary of the data used as well as further details on the analytic methods and approaches. Participant details are provided alongside key themes and subthemes. The implications of these are discussed.	Abstract
Rationale	The purpose of the study and the implications for its focus and design are explained.	Introduction
Programme theory	The initial programme theory that underpinned the study, and the evidence sources it was derived from are explained.	Introduction
Questions, objectives and focus	These are provided.	Introduction
Ethical approval	These details are provided at the start of the methods section.	Methods
Research team/characteristics and reflexivity	Details of the research team are provided with reflexive comment in the discussion. Prior to this the role of research team members who undertook the data analysis are provided in the methods.	Methods Results Discussion

	Research team members involved in data collection are named in the results along with other participants as this was a joint activity with the stakeholder participants.	
Methodological orientation and Theory	Details of our theoretical orientation are provided in the methods. This section includes explanation of how we applied realist approaches to 'naturally occurring processes' described in a stakeholder event. We also provide explanation of how we integrated these approaches with an established approach to analysing data for human factors issues. The setting of the work is described along with the stakeholder event itself. It should be noted that we are not reporting a QI intervention in this manuscript.	Methods
Sampling	Recruitment, selection and participation are all described. Included participants are listed in the results.	Methods Results
Data collection	The processes of data generation and collection during the stakeholder event are described. As all possible participants were included in the analysis it is not appropriate to refer to data saturation.	Methods
Data analysis	Details of the analytic processes are provided along with the focus.	Methods
Number of data coders	Included.	Methods
Derivation of themes	The initial inductive approach was supplemented by a deductive comparison with SEIPS. This is described in detail.	Methods
Reporting	Quotations from participants are included. Key findings are presented linking them to CMO configurations at various levels of analysis with the use of tables / figures to supplement main text. Major themes are drawn out further in the discussion.	Results Discussion.
Strengths, limitations and future directions	These are discussed along with comparison to existing literature before recommendations are provided.	Discussion.
Funding and conflict of interest	No specific funding for this piece of work was received.	N/A