PEER REVIEW HISTORY

ARTICLE DETAILS

TITLE (PROVISIONAL)	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	Yardley, Sarah; Williams, Huw; Bowie, Paul; Edwards, Adrian; Noble, S; Donaldson, Liam; Carson-Stevens, A

VERSION 1 – REVIEW

REVIEWER	Hasson, Felicity Univ Ulster, Institute of Nursing and Health Research
REVIEW RETURNED	24-Jan-2021

GENERAL COMMENTS	The provision of out of hours palliative care is considered a national priority and this paper adds to the evidence base. It reports on the re-analyses of workshop data, to develop a middle range theory, using CMO and SEIPS to identify the human factors framework for improving out-of-hour palliative care. It provides a conceptual model and analytic tool from which to study this type of care. However, there are several areas which require review. Abstract: This is national (UK focused) study which requires the relevance to be broadened to the international readership. The abstract itself is not clear with regards its focus. Is the aim of the study to report on the perceptions and experiences of the key stakeholders? Or is this aim to re-analyze workshop data and scenario data to inform the development of a mid-range theory (based upon SEIPS and CMO configurations) guided by a realist evaluation? The data was then collected (?) and analyzed using an integrated approach of CMO categorization and SEIPS to connect issues. Design: information relating to the method i.e. workshops is not reported. In addition, the number of incident reports presented and categories (if available) should also be summarized for context. The results should mention how many CMOs emerged from the workshop and scenario data and classify the contributing factors using SEIPS. With differences and comparisons between the two and any differences in perceptions from the participants noted. The conclusion could then report on the importance of understanding the contextual factors to ensure effective service delivery. Please note, as a reviewer I only make suggestions, but I did find the abstract difficult to follow. Strengths and limitations: Please consider expanding the limitations to include, diversity of stakeholders and the end product from this paper only results in a theoretical framework which requires development and pilot testing not just with people but in context, systems, and differing cultures. Main Text: Background – For the international reader context on what OOH services equates and what it entails is recommended. The need for this study and the application of mid-range theories as a possible response also requires some explanation. Research question & objective: See comments above in abstract – I feel that some refinement of wording is required to clarify exactly what this paper is reporting upon.

	Methods: This section requires some attention to the flow. The methods are not outlined for the reader (i.e. workshops, how many, in what format, guided by what protocol, undertaken by whom, over how many hours/ days… etc.) Was a variation of the nominal group technique used, where participants were provided with information to reflect upon and then discuss – then to get agreement? Moreover, data relating to the scenarios are not presented (i.e., how were they selected, how many, presented etc.) Has the event objectives been reported elsewhere, as it may be an idea to reference earlier publications for the reader. It is reported that the paper is based on the first two of the events objectives, yet they seem disjointed from what has come prior. Recruitment and selection: It's unclear how many from each professional/ non- professional group were approached, how many in total and who acted as the gatekeeper (if applicable) for this recruitment. PPI: Do you mean that PPI were represented in the workshops, if so, why not state this? Data generation: This section suggests that participants in the workshops were asked to undertake several tasks for example to describe recent experiences… of using OOH services or of providing OOH services OR from the analysis of the incident reports? This section is not clear with regards alignment to the overall aim of the study and the methods adopted. Analysis: The approach to analysis is unclear. Was the data from the analysis subject to realist evaluation using the CMO configuration and SEIPS model to analyze or classify the contributing factors of incident reports and workshop qualitative data of experiences? Results: On reflection you are making the reader look for your workshop and incident report findings within the tables, rather than presenting these initially. Consider presenting the findings and then present these with a CMO and SEIPS lens, removing the discussion elements within this section. Discussion: If possible, please outline the key finding of this study at the start of this section and break down the configurations of CMO (linked to existing literature) and SEPIS model for the reader. Strengths and limitations: This section could be shortened to ensure room is available for the key findings and literature to be discussed. Implications for policy, practice, and further research: the application of your research to OOH palliative care needs to be made stronger.

REVIEWER	Campling, Natasha University of Southampton Faculty of Health Sciences
REVIEW RETURNED	22-Apr-2021

GENERAL COMMENTS	Thank you for the opportunity to read this paper. It reveals a comprehensive mid range theory of human factors issues in OOH community palliative care, grounded in the realities of clinical practice. I feel that it's strength lies in it's interesting approach to data analysis, which draws together the work processes at play in this area of complexity. It's an illuminating paper with recommendations/lessons for research, care provision and future interventions.

REVIEWER	Fee, Anne Ulster University - Jordanstown Campus, School of Nursing
REVIEW RETURNED	27-Apr-2021

GENERAL COMMENTS	1) In general: Some of the sentences are very long. This potentially makes an interesting paper (and very valid points) more arduous to read for readers who are unfamiliar with this approach/methodology. See below for an example (page 10):

	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 andrationales,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. 2) Abstract Line 10 – a spacing issue in the sentence ...'community tell us about potential underlying human'... 3) Introduction Authors may want to define 'out-of-hours' (within the UK) as variations in the provision of out-of-hours exist internationally: See: Johnston B, May P, McCauley R, et al. Out-of-hours specialist and generalist palliative care service provision: an evidence review. Dublin: Health Research Board 2019. 4) Methods (setting) Page 6: Some readers may not be familiar with QI, I suggest you write the words in full. 5) Recruitment, Selection and Participation Although you have included informal (family) carers in the results section (page 8), and discussion (page 9) there is no mention of their involvement in the stakeholder event. Can you please specify if they were included in the stakeholder event and if not, why not? 6) Strengths and Limitations Page 10, Line 26 – typo (comma instead of a full stop) Page 10, Line 60 – typo ('our of hours')

REVIEWER	Jeffries, Mark University of Manchester, School of Health Sciences
REVIEW RETURNED	09-May-2021

GENERAL COMMENTS	1) The authors are dealing with a complex issue using complex theory. I think this is really important and their conclusions around the use of human factors in this way are great. However, some readers are going to be less familiar with human factors, realist approaches and palliative care and therefore further and clearer explanations are needed to open the accessibility of the manuscript to a broader audience. 2)At times the paper is a little ragged in grammar and clarity and could do with a little tidy up. Specific minor comments: Abstract: 1. I don't feel the abstract stands alone – I felt I needed to go into the body of the manuscript to fully understand the abstract. 2. I think the source of the incident reports needs mentioning here. 3. In the results I think the past tense might serve better 4. The results feel like bullet points – whilst word count might be challenging here I think it might be better if they felt less list like. 5. This also applies to the conclusion here. 6. The first statement of the conclusion is a little disconnected from the results. Background 7. Paragraph 1 final sentence beginning "The extent to which risk and well-being is impacted…." Do you mean specifically to out-of-hours palliative care? If not I'd suggest there is a wide literature around risk , well-being and system wide human factors so am unsure of this claim here.

	8. In the second paragraph can you please give some specific challenges of care needs of palliative care. 9. Paragraph 4 – Socio-technical needs a full explanation in the way you do for human factors 10. The last sentence here nicely sums up the problem and justifies this research but why is this specifically important for palliative out of hours care? What here can be clearly linked to the specifics of palliative care as outlined earlier in the background. Methods 11. The description of realist approaches is really good but could useful draw back to the foundation of realist evaluations for instance the work of Pawson and Tilley. I also think some further explanation of what a mechanism actually is would help. I think when you talk about mid-range theory and mention “underlying changes in reasoning and behaviour” you do touch upon what mechanisms actually do but I think this a further explanation. The work of Dalkin might be useful here. 12. The first sentence of this paragraph (page 5 line 20) needs a citation. 13. In the second paragraph (page 5, starting line 33) ‘naturally occurring processes’ is in quotation marks, but you don’t give a citation for it. I personally think it would be fine without the quote marks but if you leave them in I think it needs a source. 14. In the methods here could you reflect upon and cite some empirical research that has utilised realist approaches or human factors in healthcare particularly around patient safety or palliative care. 15. Page 6 line 11. QI needs defining on first use. If this isn’t the first use - my apologies. 16. Could you please provide a little more detail on the coding of the data. Was a coding framework used? Was a software package used? What codes were identified and how did these then become interpreted as CMOs. A little bit more detail would just help the reader. Results 17. The results are outstanding and it is a remarkable achievement to deal with such complexity. I think it would have been so easy here to present some CMOs and leave it there but I think the interpretative analysis here expertly moves on from the simple and complicated CMOs to build to the more complex CMOs and bring those together with the underlying themes provides such a rich interpretation. 18. I found the tables and figures really useful. It is a bit challenging moving back and forward from the text but I suspect that will be easier when they are in line with the text that will be easier. However a little more explanation in the text would help. 19. I feel some parts of the results could be better placed in the discussion specifically the material in the paragraph starting line 37 page 8. 20. The paragraph starting line 9 on page 9 “The outcomes of the CMO configurations…..”. This paragraph feels a bit isolated. It’s a really important point but could usefully be moved, maybe earlier in the results. 21. The comments at the end of the results around socio-technical underline how useful it would be to have an explanation of what the authors mean by socio technical in the introduction. Discussion 22. This really brings the paper together. I think the implications section in particular is exceptional.

VERSION 1 – AUTHOR RESPONSE

Editor/Reviewer comment	Author response	Manuscript changes
Please revise the title of your manuscript to include the research question, study design and setting.	Our title has been revised so that it includes the key elements of: 1. The research question 2. Study Design: realist approaches (this was already included) and application of an established human factors framework to develop mid-range programme theory 3. Setting: out-of-hours community palliative care (this was already included) The content in the title is consistent with that in the main text/abstract but we have used expanded versions where this will add clarity for the reader.	Title rephrased to: Which human factors design issues are influencing system performance in out of hours community palliative care?: integration of realist approaches with an established human factors framework to develop mid-range programme theory
The provision of out of hours palliative care is considered a national priority and this paper adds to the evidence base. It reports on the re-analyses of workshop data, to develop a middle range theory, using CMO and SEIPS to identify the human factors framework for improving out-of-hour palliative care. It provides a conceptual model and analytic tool from which to study this type of care.	Thank you, we agree.	N/A
However, there are several areas which require review.	Please see below for responses to points raised.	See below
Abstract: This is national (UK focused) study which requires the relevance to be broadened to the international readership.	Explicit sentences added to main text and abstract to clarify that a mid-range theory is not itself context specific, rather it should be applied with consideration of context in new settings. We have also explained further how our work is relevant to similar modern health systems. Key to this is our mapping of the work to the SEIPS framework which is established in use internationally. In doing so, we demonstrate that the findings directly speak to elements in SEIPS and hence, these findings provide additional support to people seeking to apply the SEIPS framework in their own context by extending the definitions, concepts and	We have added the following to the discussion of strengths and limitations in the main text: Although our data is drawn from the United Kingdom, by developing a mid-range programme theory we have created a framework that is of international relevance by guiding quality improvement work in similar modern health systems. Using our theory will help

	themes they should be alert to within the SEIPS framework.	ensure attention is paid to both agency and structure in system (re)design. A shorter version is included in the abstract where we are limited by word count: Although set in the United Kingdom, 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. Minor edits to rest of abstract to remain within word count requirement.
The abstract itself is not clear with regards its focus. Is the aim of the study to report on the perceptions and experiences of the key stakeholders? Or is this aim to re-analyze workshop data and scenario data to inform the development of a mid-range theory (based upon SEIPS and CMO configurations) guided by a realist evaluation?	The answer to this question is both, as analysis of perceptions and experiences of key stakeholders is how we have developed a mid-range theory of these human factors issues. In order to clarify this, rather than giving the impression it is one or the other we have rephrased the research question and objective in both the abstract and the main text.	Abstract changes: 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 in palliative care These are replicated in the main text and consistent with the title.
The data was then collected (?) and analyzed using an	This is correct. We believe the changes documented above and below in response to other comments,	No further changes needed.

integrated approach of CMO categorization and SEIPS to connect issues.	including the sequencing of the analysis, have made this clearer.	
Design: information relating to the method i.e. workshops is not reported.	We have clarified this in the abstract. We note a later comment from one of the reviewer in respect to this issue in the main text, and so have addressed this issue more fully there as well – see later response.	Minor edits in addition to changes documented below – see tracked version.
In addition, the number of incident reports presented and categories (if available) should also be summarized for context.	We have added in the number of incidents (1072) that were subject to a separate study, and in the main text provided additional signposting to the reference of the full publication which described these as this is a separate study. We cannot do justice to the details of a whole other within the word count in the abstract. Furthermore, with respect to the main text, we think it would detract from the objectives of this paper to quote further details from another study here, particularly in the light of our clarifications (see responses below) that the development of a mid-range programme theory with our chosen methods is by definition to abstract from the singular details of particular incidents.	Abstract: After sharing experiences, event participants were presented with analyses of 1072 incident reports to discuss and consider potential priorities for change. Main Text: We wanted to use the learning from our prior analyses of 1072 incident reports from the national database to inform the improvement agenda for out-of-hours palliative care within a local health board. This analysis has since been published.[1,2]
The results should mention how many CMOs emerged from the workshop and scenario data and classify the contributing factors using SEIPS. With differences and comparisons between the two and any differences in perceptions from the participants noted.	The number of CMOs is already provided in Tables 2 and 3 together with the complex CMO configuration possibilities presented in Figure 2. We have added sentences to clarify and give total numbers in the text. The 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. We have added a sentence to better signpost readers to this.	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 summary, six CMO configurations that could be classified as simple/complicated (see Table 2) were identified. In addition six themes (see table 3) were identified and synthesised into the complex CMO configuration possibilities in Figure 2. By definition, as these are complex, the three contextual constraints, four external influences, six mechanisms (two of these subdivided in to 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 then presented in Figure 2 and critically examined using SEIPS (Figure 3). The 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.
The conclusion could then report on the importance of understanding the contextual factors to ensure effective service delivery.	We already include this in the strengths and limitations sections and reviewed the whole manuscript to ensure this message is emphasised as we agree it is important throughout.	No changes made.
Please note, as a reviewer I only make suggestions, but I did find the abstract difficult to follow.	Noted, thank you. We hope we have successful clarified in addressing the points above and below along with re-proof reading the text.	Minor text edits – see tracked version.
Strengths and limitations: Please consider expanding the limitations to include, diversity of stakeholders and the end product from this paper only results in a theoretical framework which requires development and pilot testing not just with people but in context, systems, and differing cultures.	We have revised the strengths and limitations section to take account of these points. In line with realist approaches and what a programme theory is we anticipate it functioning as a framework for critical thought about the issues in other contexts and cultures rather than something that is 'pilot tested' and then fixed.	We note the limited diversity of our participants. It remains, however, the case that the end product from this work results in a theoretical framework which requires further refinement through application in different contexts, and with different people across differing systems and cultures.
Main Text: Background – For the international reader context on what OOH services equates and what it entails is recommended.	We have added the definition of out-of-hours community care from our prior work as this was the definition that we used in the present study..	Text changes detailed in similar comment below.
The need for this study and the application of mid-range theories as a possible response also	We already explain the need for this study in the main text ("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	Changes incorporated to other responses.

requires some explanation.	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.") and have made changes to explain more clearly how the development of a mid-range theory can help address current issues. We also note that other reviewers disagreed with this comment (in fact, one of them noted our background clearly ended with identified need), and so have not made further changes in addition to those above but are willing to discuss with the Editorial team further if helpful.	
Research question & objective: See comments above in abstract – I feel that some refinement of wording is required to clarify exactly what this paper is reporting upon.	We have addressed this in our response to the comments made on the abstract.	Abstract changes above mirrored in main text.
Methods: This section requires some attention to the flow.	We have reviewed this.	Minor edits made to improve flow. See tracked version.
The methods are not outlined for the reader (i.e. workshops, how many, in what format, guided by what protocol, undertaken by whom, over how many hours/ days… etc.) Was a variation of the nominal group technique used, where participants were provided with information to reflect upon and then discuss – then to get agreement? Moreover, data relating to the scenarios are not presented (i.e., how were they selected, how many, presented etc.)	We have clarified it was a single event and that it was a workshop format. We have added more detail to the description of data generation to make it a richer description of the flow of the workshop. We already explain it is a convenience sample and that combinations of event artefacts were retained for analysis. There was no formal nominal group technique but we have already explained participants were provided with information from a prior incident data analysis and literature review.	See tracked version for minor edits to address clarifications under setting / data generation sections.
Has the event objectives been reported elsewhere, as it may be an idea to reference earlier publications for the reader. It is reported that the paper is based on the first two of the events objectives, yet they seem	The event objectives have not been reported elsewhere formally but we have referenced the report which was written as a result for the study funders of HW who worked on this study as part of a fellowship programme). These are provided here under the subsection of 'setting' which we think will be clearer in a typeset manuscript and with the addition of additional information added into manuscript in response to the	See tracked version for minor edits to address clarifications under setting / data generation sections.

disjointed from what has come prior.	request for additional detail on the running of the workshops above. We do not think it would be helpful to add to the manuscript but for information there is a description of the subsequent Quality Improvement Project that arose out of objective three of the event currently in review with BMJ Quality Open.	
Recruitment and selection: It's unclear how many from each professional/ non-professional group were approached, how many in total and who acted as the gatekeeper (if applicable) for this recruitment.	We have edited the text to clarify in relation to this point. Table 1 provides the details of those who actually participated.	Local providers 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… …As we did not own the mailing lists used we are not able to speculate on the number of people approached.
PPI: Do you mean that PPI were represented in the workshops, if so, why not state this?	We have revised our statement on this to make it clearer.	We are reporting analysis of data collected during an event which included PPI attendees.
Data generation: This section suggests that participants in the workshops were asked to undertake several tasks for example to describe recent experiences… of using OOH services or of providing OOH services OR from the analysis of the incident reports? This section is not clear with regards alignment to the overall aim of the study and the methods adopted.	We have clarified what participants were asked to do in response to comments above by adding additional detail.	No additional changes needed to those above.
Analysis: The approach to analysis is unclear. Was the data from the analysis subject to realist evaluation using the CMO configuration and SEIPS model to analyze or classify the	The data was subject to analysis using CMO configurations as a framework first. Second the raw data (i.e. qualitative data from the workshops) CMO configurations were mapped to the SEIPS model. We have made edits to the text in response to other comments to clarify the study reported in this paper is an	This 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

contributing factors of incident reports and workshop qualitative data of experiences?	analysis of the workshops as data; at no point do we say that the qualitative data of experiences derived from holding the workshop was analysed in any other way. Nor do we say that we were analysing incident reports in this study – instead we describe how incident report analysis from *prior* work was used as prompts within the workshop.	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.
	We have added a sentence to emphasise how SEIPS was used in addition to making minor edits throughout to clarify the sequencing of the analysis and its content: some of these changes have been made in response to other review comments – see comments on CMO analysis.	First, HW and SY independently identified individual CMO configurations in data transcripts before comparing to reach a consensus of their line-by-line coding (by context, mechanisms and outcomes) and annotating these to form provisional configurations. 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. Second, SY and PB led the critical comparison of our mid-range theory, built from CMO configurations with the SEIPS framework by re-analysing the raw data to map it to the SEIPs framework elements as well as mapping the, identified CMO configurations and themes during a cross-matching and mapping exercise using the SEIPS framework. Other minor text edits – see tracked version

Results: On reflection you are making the reader look for your workshop and incident report findings within the tables, rather than presenting these initially. Consider presenting the findings and then present these with a CMO and SEIPS lens, removing the discussion elements within this section.	As explained above the incident report findings are not the focus of this paper and are fully presented elsewhere (referenced peer reviewed publication of this is included). The incident reports findings are not contained with the tables. We believe that the table labelling does actually make this clear although we have revised it slightly to be really explicit about this. We have also clarified this in the text in response to a comment above. Similarly there are no separate workshop findings as the analysis of the workshop data was only through a CMO and SEIPS lens as one would expect for a study using realist approaches. We wonder if this reviewer thinks we also conducted some other alternative analysis so we have reviewed the manuscript to ensure that is not the impression given. We disagree that 'discussion elements' within the results should be moved as the placement of the prose in our result section is consistent with both realist approaches and more generally qualitative research. In particular when the product of a study is a mid-range theory this is usually presented as a figure with supporting explanatory prose. In addition, we think that presenting the products of our study in tabulated form and then describing these in the text is more accessible to readers than it would be if we were to attempt to present the contents of the tables as prose. We also consider this prose in our results section to be a narrative description of the results, rather than an interpretation for discussion.	Edits to clarify made throughout – see tracked version.
Discussion: If possible, please outline the key finding of this study at the start of this section and break down the configurations of CMO (linked to existing literature) and SEPIS model for the reader.	The key findings are presented in Table 4 because we believe this will be easier for readers to grasp in this format. This is a complex study and so it is not appropriate to breakdown the configurations of the CMOs and SEIPS model in a non-tabulated form (to attempt this would equate to asking authors of quantitative study to describe the contents of their results tables in prose). We have, however, revised the first paragraph of the discussion to address this in more detail.	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. Ultimately, 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.

Strengths and limitations: This section could be shortened to ensure room is available for the key findings and literature to be discussed.	We are not sure what the reviewer specifically thinks is missing from our discussion of key findings and literature, and hope that we will have addressed this concern with our changes made in response to other comments. We have reviewed the strengths and limitations section and do not now consider there to be surplus information there given that this study is reporting novel methodology and methods as well as advancing theory and adding to the evidence base on patient safety in palliative care. It is important that we consider the strengths and limitations on all three of these fronts. We also note other reviewers asked for additions to this section which we have made.	Minor text edits – see tracked version.
Implications for policy, practice, and further research: the application of your research to OOH palliative care needs to be made stronger.	We note that one of the other reviewers referred to our implications section as 'exceptional' and are a little puzzled as to how our study could be interpreted as anything other than for application to out of hours palliative care given this is its whole focus. We have, however, made edits throughout this section to emphasise the application of our findings should be to out of hours palliative care.	Minor text edits – see tracked version
Thank you for the opportunity to read this paper. It reveals a comprehensive mid range theory of human factors issues in OOH community palliative care, grounded in the realities of clinical practice. I feel that it's strength lies in it's interesting approach to data analysis, which draws together the work processes at play in this area of complexity. It's an illuminating paper with recommendations/lessons for research, care provision and future interventions.	Thank you.	N/A
Thank-you for the opportunity to review this paper. The study highlights underlying human factors design issues that might be influencing system performance for achieving desirable	Thank you	N/A

outcomes in out-of-hours palliative care. This paper makes a valuable and timely contribution to existing literature about out-of-hours community-based palliative care. It uses novel methodology to advance important work in this area.		
I have just minor points to raise: 1) In general: Some of the sentences are very long. This potentially makes an interesting paper (and very valid points) more arduous to read for readers who are unfamiliar with this approach/methodology. See below for an example (page 10): 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 andrationales,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 reviewed the length of sentences and when possible split these.	See tracked version.
2) Abstract Line 10 – a spacing issue in the sentence ...'community tell us about potential underlying human'...	This has been superseded by other changes	No further change needed.

3) Introduction Authors may want to define 'out-of-hours' (within the UK) as variations in the provision of out-of-hours exist internationally: See: Johnston B, May P, McCauley R, et al. Out-of-hours specialist and generalist palliative care service provision: an evidence review. Dublin: Health Research Board 2019.	We have addressed this in our response to a similar comment above.	No further change needed.
4) Methods (setting) Page 6: Some readers may not be familiar with QI, I suggest you write the words in full.	Thank you for spotting this, we have changed.	Written in full.
5) Recruitment, Selection and Participation Although you have included informal (family) carers in the results section (page 8), and discussion (page 9) there is no mention of their involvement in the stakeholder event. Can you please specify if they were included in the stakeholder event and if not, why not?	Table 1 provides the details of those who actually participated including the informal carers who were our patient and public involvement attendees. Details of how these people were invited are already in the methods.	Details already present. We have made minor edits to clarify – see tracked version.
6) Strengths and Limitations Page 10, Line 26 – typo (comma instead of a full stop) Page 10, Line 60 – typo ('our of hours')	Thank you. We have corrected these.	Minor edits – see tracked version.
Thank you for the opportunity to review this paper. I found it really interesting, intellectually stimulating and it will I'm sure be an exceptional contribution to the field. I offer a few minor suggestions below to make some improvements to the manuscript. I hope these help.	Thank you, we have responded to the minor comments below.	See below

General comments: 1)The authors are dealing with a complex issue using complex theory. I think this is really important and their conclusions around the use of human factors in this way are great.	Thank you	N/A
However, some readers are going to be less familiar with human factors, realist approaches and palliative care and therefore further and clearer explanations are needed to open the accessibility of the manuscript to a broader audience.	We note other reviewers complimented us on our explanation of realist approaches. We believe we have provided definitions and explanations of: • Human factors (already present) – see background • Realist approaches (already present) – see methods, also an increasingly well known methodology In both these instances we are using the definitions and explanations of established reference documents. We have also added additional explanation of SEIPs in response to another comment above. We have added a sentence defining palliative care.	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.
2)At times the paper is a little ragged in grammar and clarity and could do with a little tidy up.	We have reviewed this and made minor edits to improve it.	Minor edits – see tracked version.
Specific minor comments: Abstract: 1. I don't feel the abstract stands alone – I felt I needed to go into the body of the manuscript to fully understand the abstract.	Noted, we believe we have addressed this in addressing the comments of other reviewers on the abstract.	See above responses.
2. I think the source of the incident reports needs mentioning here.	We have added this into the abstract.	National Reporting and Learning System
3. In the results I think the past tense might serve better	We prefer to keep this in an active tense as written but are happy to review if the editors require it.	No changes made.
4. The results feel like bullet points – whilst word count might be challenging here I think it might be better if they felt less list like.	We understand this point but do not feel we can improve within the confines of the abstract word count while also adding in the additional information requested. We would be happy to discuss with the editors but note we cannot submit an abstract exceeding 300 words in the system.	No changes made.
5. This also applies to the conclusion here.	See response above.	No changes made.

6. The first statement of the conclusion is a little disconnected from the results.	Thank you. We have revised the results and conclusion sections of the abstract to reorder the statements to a better flow.	Reordering of statements to improve flow – see tracked version.
Background 7. Paragraph 1 final sentence beginning "The extent to which risk and well-being is impacted…." Do you mean specifically to out-of-hours palliative care? If not I'd suggest there is a wide literature around risk , well-being and system wide human factors so am unsure of this claim here.	Thank you. We have clarified that we do mean specifically in out-of-hours palliative care.	The extent to which risk and wellbeing is impacted because of system-wide human factors issues in out-of-hours palliative care is unknown.
8. In the second paragraph can you please give some specific challenges of care needs of palliative care.	We have updated the sentence to add this.	Now reads: Palliative care out-of-hours 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
9. Paragraph 4 – Socio-technical needs a full explanation in the way you do for human factors	We have provided a definition.	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.
10. The last sentence here nicely sums up the problem and justifies this research but why is this specifically important for palliative out of hours care? What here can be clearly linked to the specifics of palliative care as outlined earlier in the background.	Thank you. We have added a sentence here to make this clearer (in addition to adding a definition of out-of-hours care in response to another comment).	So-called 'Out-of-hours' community healthcare services are responsible for providing care for two-thirds of the working week (18:30 to 08:00 on weekdays, and all hours)… …This is a priority for out-of-hours palliative care

		given the extent of time covered by these services.
Methods 11. The description of realist approaches is really good but could useful draw back to the foundation of realist evaluations for instance the work of Pawson and Tilley. I also think some further explanation of what a mechanism actually is would help. I think when you talk about mid-range theory and mention "underlying changes in reasoning and behaviour" you do touch upon what mechanisms actually do but I think this a further explanation. The work of Dalkin might be useful here.	Thank you for this comment and the suggestion of drawing on the work of Dalkin et al., which we are happy to reference as this aligns well with our approach to realist methodology. We have added some additional explanatory text regarding reasoning and behaviour drawing on this. We have also added a reference to Pawson and Tilley's original work so that readers who wish to understand more about the methodology are easily able to trace this.	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 and/or different resources then there is a complex interaction which occurs between resource, reasoning and context. References added Pawson R, Tilley N. Realistic evaluation. London: SAGE; 1997. Dalkin, S.M., Greenhalgh, J., Jones, D. *et al.* What's in a mechanism? Development of a key concept in realist evaluation. *Implementation Sci* **10,** 49 (2015). https://doi.org/10.1186/s13012-015-0237-x
12. The first sentence of this paragraph (page 5 line 20) needs a citation.	We have added a citation.	Citation added – see marked version.
13. In the second paragraph (page 5, starting line 33) 'naturally occurring processes' is in quotation marks, but you don't give a citation for it.	Thank you, we have removed quotation marks.	Quotation marks removed – see marked version.

I personally think it would be fine without the quote marks but if you leave them in I think it needs a source.		
14. In the methods here could you reflect upon and cite some empirical research that has utilised realist approaches or human factors in healthcare particularly around patient safety or palliative care.	As we state in our paper we have been unable (despite extensive searching) to identify any other work that has combined realist approaches, SEIPS or similar human factor issues analysis in palliative care previously. We also know from our wider research programmes (including two other studies in progress by members of our research group that have sought to systematically review evidence across academic databases regarding patient safety in palliative care) that patient safety research in palliative care is in its infancy. A google scholar title search (27.07.21) of 'realist' AND 'palliative' returns 16 records, none of which were focused on patient safety or human factors issues, although one was the PhD of Dalkin whose subsequent peer reviewed publication we have now added in, as per the reviewer suggestion about regarding expanding our explanation of mechanisms in realist theory. If the reviewer or editors have other specific suggestions in mind they would like us to consider we would be pleased to do so. Aside from this we think it would be too expansive within the limits of a single paper to describe here literature that is limited to one of the topics we address here (palliative care *or* patient safety) or is solely about one of the methods we integrate in other contexts.	No changes made.
15. Page 6 line 11. QI needs defining on first use. If this isn't the first use - my apologies.	We have now written this out in full as it is elsewhere in the paper.	QI changed to Quality Improvement
16. Could you please provide a little more detail on the coding of the data. Was a coding framework used? Was a software package used? What codes were identified and how did these then become interpreted as CMOs. A little bit more detail would just help the reader.	We have clarified this was line by line coding (and that C/M/O was the coding framework used) of the data transcripts which we annotated into configurations. We did not use a software package. There was no separate coding process prior to this. We hope the edits made now clarify appropriately.	HW and SY independently identified individual CMO configurations in data transcripts before comparing to reach a consensus of their line-by-line coding (by context, mechanisms and outcomes) and annotating these to form provisional configurations
Results 17. The results are outstanding and it is a remarkable achievement to deal with such complexity. I think it would have been so easy here to present some CMOs and leave it there	Thank you	N/A

but I think the interpretative analysis here expertly moves on from the simple and complicated CMOs to build to the more complex CMOs and bring those together with the underlying themes provides such a rich interpretation.		
18. I found the tables and figures really useful. It is a bit challenging moving back and forward from the text but I suspect that will be easier when they are in line with the text that will be easier. However a little more explanation in the text would help.	Thank you. We agree that in a typeset version this would be easier. We have considered the comment on more explanation but feel it conflicts with other comments made by reviewers so rather than adding explanation into the text we have checked the signposting.	Minor edits in tracked version.
19. I feel some parts of the results could be better placed in the discussion specifically the material in the paragraph starting line 37 page 8.	The paragraph referred to describes our initial programme theory. It is best practice to provide this in the methods for a realist approach when it was not derived from the empirical study as described by the RAMESES guidelines (https://bmcmedicine.biomedcentral.com/articles/10.1186/1741-7015-11-21/tables/1)	No change made.
20. The paragraph starting line 9 on page 9 "The outcomes of the CMO configurations…..". This paragraph feels a bit isolated. It's a really important point but could usefully be moved, maybe earlier in the results.	Thank you for this suggestion. We have moved this to the start of the results section, immediately after the reporting of the demographics of our participants.	See tracked version for move.
21. The comments at the end of the results around socio-technical underline how useful it would be to have an explanation of what the authors mean by socio technical in the introduction.	Noted.	Please see response to linked comment requesting this above.
Discussion 22. This really brings the paper together. I think	Thank you.	N/A

the implications section in particular is exceptional.		

VERSION 2 – REVIEW

REVIEWER	Hasson, Felicity Univ Ulster, Institute of Nursing and Health Research
REVIEW RETURNED	07-Sep-2021

GENERAL COMMENTS	The authors have responded to the majority of the comments, my only concern is the results are somewhat unclear and places an onus on the reader to unpick them. Moreover there is repetition in this section that also warrants attention. What are the prevalent issues from the national level analyses (objective 1)and what are the priority areas (objective 2) of the results? I appreciate many of the mechanisms are interconnected and the system is complex and multifaceted but answering the two objectives could be made clearer.

REVIEWER	Fee, Anne Ulster University - Jordanstown Campus, School of Nursing
REVIEW RETURNED	27-Aug-2021

GENERAL COMMENTS	Well done to authors for a timely and insightful paper using a novel approach. This will undoubtedly contribute to future research on the provision of out-of-hours palliative care. Thank-you.

REVIEWER	Jeffries, Mark University of Manchester, School of Health Sciences
REVIEW RETURNED	26-Aug-2021

GENERAL COMMENTS	Thank you for your detailed response to the points in my first review. I have no further comments to add and recommend this be accepted for publication.

VERSION 2 – AUTHOR RESPONSE

Reviewer comment	Authors response	Manuscript changes
Thank you for your detailed response to the points in my first review. I have no further comments to add and recommend this be accepted for publication.	Thank you.	N/A
Well done to authors for a timely and insightful paper using a novel approach. This will undoubtedly contribute to future research on the provision of out-of-	Thank you.	N/A

hours palliative care. Thank-you.		
The authors have responded to the majority of the comments, my only concern is the results are somewhat unclear and places an onus on the reader to unpick them.	We hope this part of the reviewer's comment is addressed by our clarification of the research study objective as separate to the local goals of stakeholders (see below) and our response to the next section of the comment re repetition. We have also reviewed the results section and consider it to be as clear as it is possible to be when describing complexity.	See responses to sections below.
Moreover there is repetition in this section that also warrants attention.	We have reviewed the results section and do not think there is any redundant repetition. The prose of the results section provides an overview followed by a more detailed walk through for the reader of each table and figure that form the essence of our results.	Minor edits made to emphasise where we are signposting between sections of the manuscript; the repetition in these was deliberately introduced in response to previous reviewer comments which asked us to help the reader link and cross-reference.
What are the prevalent issues from the national level analyses (objective 1)and what are the priority areas (objective 2) of the results?	The reviewer appears to have misread our study objectives, confusing these with the local objectives (goals) for quality improvement held by stakeholders themselves. We appreciate our use of 'objective' for both may have led to this. To improve clarity we have changed the word 'objective' when referring to the local clinician and other stakeholders desires to 'goals'.	See track changes in marked copy. 'Objective' changed to 'goals' when referring to local desire to develop quality improvement. Other minor changes made to emphasise the difference between the study objectives and local goals and clarify where these could result in a shared agenda. These changes are within the section on 'Setting' which now reads:
	We do also clearly state in our abstract and main text that the research study objective, and hence the objective of this manuscript is: "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	"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[1,2] which was used as a prompt to participants in this study. This study was set within the Aneurin Bevan University Health

	performance for achieving desirable outcomes through quality improvement." It would not be appropriate to duplicate the already published, and in this manuscript referenced study of prevalent issues form the national level analyses. We think the above changes make this clearer and we had already stated: "The NRLS analysis itself was a separate study, also published[1,2] which was used as a prompt to participants in this study." so readers can find this information. We have also made minor changes to the implications section to emphasise the priority for change arising from our results.	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." To emphasise the priority area for change arising from our results we have also expanded this sentence in the 'implications' section of the discussion to read:

		“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.”
I appreciate many of the mechanisms are interconnected and the system is complex and multifaceted but answering the two objectives could be made clearer.	This part of the reviewer’s comment appears to follow from the above misunderstanding of the study objective which we have clarified in our response above.	See above changes.