PEER REVIEW HISTORY

ARTICLE DETAILS

TITLE (PROVISIONAL)	Balancing student/trainee learning with the delivery of patient care in the healthcare workplace: protocol for realist synthesis
AUTHORS	Sholl, Sarah; Ajjawi, Rola; Allbutt, Helen; Butler, Jane; Jindal-Snape, Divya; Morrison, Jill; Rees, Charlotte

VERSION 1 - REVIEW

REVIEWER	Victor Mogre University for Development Studies School of Medicine and Health Sciences Department of Health Professions Education and Innovative Learning Tamale, Ghana
REVIEW RETURNED	02-Feb-2016

GENERAL COMMENTS	This is a nicely written realist review protocol intending to review the literature on balancing student/trainee learning with patient care. The evidence from this review will be very useful in the training of medical students especially at the clinical level. I have a few comments that could help improve the protocol further. I present them below. Abstract References should be included in the abstract. The introduction should be a bit more focus, describing the problem and the essence of the review. The first four lines of the methods section will be appropriate for the introduction section of the abstract. Authors could also mention here some of the databases they will be searching for evidence. Methods Realists reviews/synthesis are theory driven and the testing of candidate theories. However, authors have not made mention of any candidate theory that they intend to test in the review. The description of the search strategy is also too limited. Apart from searching the databases, it will be imperative to go through the reference list of included papers and also contact experts in the field. Given the fact this is a realist review, the search has to be broad. The databases as they are now are quite limited. Authors could include ERIC, Embase and Pyschinfo. A prisma flow chart of the searching and selection of studies will be helpful. Authors should also elaborate further on their inclusion and exclusion criteria including study designs, type of data that will be included, geographical boundaries, outcome measures, etc.

The description of how the quality of studies will be assessed is too limited. Authors should provide more information. Authors should bear in mind assessment of quality in a realist review is quite different from that of a traditional systematic review. papers may not be included based on their strength of evidence but based on how much they contribute to the programme theory.
Authors indicate that a certain percentage of papers will be assessed independently, however, they have not indicated how they intend to resolve any differences that may arise through this process.

Authors described how the data will be synthesised but have not indicated how the data will be analysed. Although analysis and synthesis are usually combined, analysis precedes synthesis. Authors should indicate in detail how the data will be analysed using realists concepts. The information provided for how synthesis will be done is too limited. Elaboration is needed.

REVIEWER	Jean Robson
	NHS Dumfries and Galloway, UK
REVIEW RETURNED	02-Feb-2016

| GENERAL COMMENTS | I have reviewed this as a clinician and educationalist not a researcher, and would recommend the next review is done by someone with specific expertise in research methodology.
1. The objects of the study are variously referred to as students / trainees - will an international audience understand which grades of doctor are involved? and Should separate research questions address the two groups since the challenges and opportunities are very different.
2. A strength is given as the multidisciplinary group involved, it would be interesting to understand the spread
3. I found the introduction a bit muddled, might it be more logical to start with the fact that 21 priorities were identified, and the top for stakeholders was...., explain that little information in this area exists, before discussing the themes
4. Will all readers understand the term 'grey literature'?
5. Research aims are given but research questions are not clearly defined
6. in Methods - the populations to be studied and timelines might be better discussed separately; will all readers know what MeSH means?; I am not clear that the method is specific enough to allow repeat
7. Why limit search to UK? Especially in PG education much of the most effective learning is 'in-practice' and publications from other developed countries have shown very useful methods to facilitate this.
8. In the paper 'E.G. protected learning time' is used a lot - is the focus to be how to facilitate protected time, or balancing learning.....?, the latter could well find that extending time for clinical encounters such as clinics and ward rounds to support better in-practice learning was the more effective strategy.Would making research questions more explicit help with this? |

VERSION 1 – AUTHOR RESPONSE

Reviewer 1: References should be included in the abstract.
Author response: We respectfully disagree with the reviewer on this point. The BMJ Open guidelines stipulate that "references should not be included in abstracts or summaries", and so we have not followed the reviewer's suggestion here.

Reviewer 1: The introduction should be a bit more focus, describing the problem and the essence of the review.
Author response: We agree that the introduction could be more focused and logical. We have now restructured it so that it progresses much as Reviewer 2 suggested; namely:
-Outline of priority-setting exercise and identification of 21 areas, falling into 5 themes;
-Identification of top priority area for stakeholders;
-Scoping exercise revealing little information in this area;
-Choice of an appropriate type of review.

Reviewer 1: The first four lines of the methods section will be appropriate for the introduction section of the abstract. Authors could also mention here some of the databases they will be searching for evidence.
Author response: We agree that Pawson's five stages should be included in the abstract, although we respectfully point out that they are already mentioned in its methods section: "Pawson's five stages for undertaking a realist review underpin this protocol." In response to the reviewer's helpful comment, we have added the following text to the abstract: "These stages may progress in a non-linear fashion due to the iterative nature of the review process."

Reviewer 1: Realists reviews/synthesis are theory driven and the testing of candidate theories. However, authors have not made mention of any candidate theory that they intend to test in the review.
Author response: We agree, and we should perhaps have been more explicit about our intentions. Since we have not yet identified the interventions to be explored, we did not feel it appropriate to provide candidate theories at this stage. We have therefore inserted the following text: "A number of possible programme theories were considered when developing the protocol, and it was decided that it would be better to start reviewing the identified literature before developing specific candidate theories for testing."

Reviewer 1: The description of the search strategy is also too limited. Apart from searching the databases, it will be imperative to go through the reference list of included papers and also contact experts in the field. Given the fact this is a realist review, the search has to be broad. The databases as they are now are quite limited. Authors could include ERIC, Embase and Pyschinfo.
Author response: In response to these helpful suggestions, we have now inserted a box summarising the types of sources we will use, and have listed the databases we will search (see Box 1). We agree that ERIC, Embase and PsychInfo are useful, and we will include them accordingly.
We note that Embase includes Medline citations, and that Scopus includes all Embase citations from 1996 onwards; therefore a search of Scopus should yield citations from both Embase and Medline within our inclusion criteria. Consequently we have not listed Embase and Medline separately in the table, although Medline is referred to in the text.
We have also made explicit that we will check the reference lists of identified papers and contact authors where appropriate.

Reviewer 1: A prisma flow chart of the searching and selection of studies will be helpful.
Author response: Thank you for this suggestion. We have inserted a PRISMA diagram accordingly (see figure 2).

Reviewer 1: Authors should also elaborate further on their inclusion and exclusion criteria including study designs, type of data that will be included, geographical boundaries, outcome measures, etc.
Author response: Thank you for this suggestion. We have inserted a box to summarise the inclusion criteria (see Box 2). Boxes 1 and 2 together summarise the type of material, sources to be searched and other inclusion criteria. Since we are including non-research papers in our search, we have chosen not to include specific study designs or outcome measures at this stage, although we will bear these in mind as the study progresses.

Reviewer 1: The description of how the quality of studies will be assessed is too limited. Authors should provide more information. Authors should bear in mind assessment of quality in a realist review is quite different from that of a traditional systematic review. papers may not be included based on their strength of evidence but based on how much they contribute to the programme theory.
Author response: We agree that contribution to the development/refinement of programme theory is important here, and the assessment of relevance and rigour will be as per RAMESES publication standards, but we understand that we have not made this explicit. We have restructured this section to make our description and definitions clearer. It now reads:
"Literature will be assessed for relevance and rigour according to RAMESES publication standards [14].
Relevance – papers will be screened first for relevance, i.e. those which "provide data that inform programme theory development and refinement".[14,30]
Initial assessment of relevance will be carried out by reviewing abstracts using preliminary inclusion criteria. Any ambiguities at this stage will be checked by an additional researcher. Depending on the quantity of studies found, it is likely that a two-stage review process will be carried out; firstly to identify the main interventions that are relevant, and then to prioritise one or two interventions which will be the focus of the main study.
Double-checking will be carried out and discussed for 10-25% of the citations, along with a number of papers previously excluded (for quality control purposes).[30]
Rigour - assessment of rigour will follow the same process, this time employing a review of the whole paper, to determine "whether the methods used to generate the relevant data are credible and trustworthy".[30] Any differences will be resolved between the two analysts through negotiation and if this is not possible, then a third analyst will be brought in to adjudicate. The application of inclusion/exclusion criteria will be an iterative process, as will be the testing and refinement of programme theories that are generated during this stage. Figure 2 shows a summary of the searching and selection process."

Reviewer 1: Authors indicate that a certain percentage of papers will be assessed independently, however, they have not indicated how they intend to resolve any differences that may arise through this process.
Author response: Thank you for this comment. We have inserted the following into the text: "Any differences will be resolved between the two analysts through negotiation and if this is not possible, then a third analyst will be brought in to adjudicate."

Reviewer 1: Authors described how the data will be synthesised but have not indicated how the data will be analysed. Although analysis and synthesis are usually combined, analysis precedes synthesis. Authors should indicate in detail how the data will be analysed using realists concepts. The information provided for how synthesis will be done is too limited. Elaboration is needed.
Author response: We understand that more detail is needed here regarding the proposed data analysis, and have amended a section of the study design accordingly. Section 4 now reads:
"Realist review data is characterised by annotation rather than list extraction,[14,30] and a thematic approach will be adopted here. The process of analysis will pursue the following iterative progression: (1) Reading a sample of the data to identify codes for contexts, mechanisms and outcomes; (2) Developing a coding framework including descriptive elements and more analytic C-M-O

configurations; (3) Applying the coding framework to the rest of the data; and (4) Interrogating the codes using ATLAS.ti software in order to look for patterns and organise codes. Discussion of the data between researchers allows continuation of the testing and refinement of programme theories at this stage."

Reviewer 2: The objects of the study are variously referred to as students / trainees - will an international audience understand which grades of doctor are involved? and Should separate research questions address the two groups since the challenges and opportunities are very different.
Author response: We agree that we should be more explicit about what we mean by "student/trainee". We have therefore added the following text: "These populations include students (i.e. those who have not yet gained their initial qualification but who undergo some of their training as part of a team in the healthcare workplace) and trainees (i.e. individuals post-qualification but not yet at the end of their training)." Since both students and trainees are part of the team in question, we think it appropriate to consider them together rather than separately.

Reviewer 2: A strength is given as the multidisciplinary group involved, it would be interesting to understand the spread
Author response: We have added text at the end of section 5 to read:
"The research team is multidisciplinary in background, including clinically-qualified individuals, social scientists, healthcare education researchers and managers. We anticipate that this broad range of experience will lend itself to a more comprehensive interpretation of the data."

Reviewer 2: I found the introduction a bit muddled, might it be more logical to start with the fact that 21 priorities were identified, and the top for stakeholders was...., explain that little information in this area exists, before discussing the themes
Author response: Please see the above response to Reviewer 1 detailing changes we have made to the introduction section.

Reviewer 2: Will all readers understand the term 'grey literature'?
Author response: We have altered the text to read: "grey literature (i.e. that which lies outside academic or commercial publication)".

Reviewer 2: Research aims are given but research questions are not clearly defined
Author response: Thank you for pointing this out. We have amended the paragraph to make our questions clearer. It now reads:
"The research questions arising from the scoping exercise were as follows:
How can the delivery of service to patients and of training be simultaneously facilitated in the healthcare workplace?
What are the key complex interventions which are designed to help achieve/maintain this balance?
In what ways do successful interventions enable this balance within the healthcare workplace?
Our study therefore aims to address the ways in which identified interventions enable balanced patient care-trainee learning within the healthcare workplace, for whom, why and under what circumstances."

Reviewer 2: in Methods - the populations to be studied and timelines might be better discussed separately; will all readers know what MeSH means?; I am not clear that the method is specific enough to allow repeat
Author response: We have altered the text to read: "Terminology will initially be refined using Medical Subject Headings (MeSH)"

Reviewer 2: Why limit search to UK? Especially in PG education much of the most effective learning is 'in-practice' and publications from other developed countries have shown very useful methods to

facilitate this.

Author response: We have explained in our paper that "Whilst the findings may have relevance to other national health systems, studies involving them will be excluded from this review as different health systems may be influenced by different contextual factors such as healthcare funding and educational pathways." Since a key part of the realist review is to identify context-mechanism-outcome configurations, we feel that our aim is better focused on the UK. The reviewer makes a good point here, so we have added the following text: "This is not to say that mechanisms identified in other countries would not be helpful to those in the UK healthcare workplace, however; they may indeed be transferable in this context."

Reviewer 2: In the paper 'E.G. protected learning time' is used a lot - is the focus to be how to facilitate protected time, or balancing learning.....?, the latter could well find that extending time for clinical encounters such as clinics and ward rounds to support better in-practice learning was the more effective strategy.Would making research questions more explicit help with this?

Author response: Thank you for this observation. Protected learning time is an exemplar of an intervention and it is not our intention to attribute more significance to one intervention than to another; we have therefore reduced the number of times PLT is mentioned as an example.

VERSION 2 – REVIEW

REVIEWER	Victor Mogre University for Development Studies, School of Medicine and Health Sciences, Tamale, Ghana
REVIEW RETURNED	04-Apr-2016

GENERAL COMMENTS	I will like to commend the authors for a good work done. The current state of the manuscript is now much improved than previously. I however have a few comments to make. 1. **Reviewer 1: References should be included in the abstract**. This has been addressed. Going by the authors assertion, the sentence that begins the introduction section of the abstract has a reference (i.e. Dennis et al.,). This should be revised. 2. **Reviewer 1: The first four lines of the methods section will be appropriate for the introduction section of the abstract. Authors could also mention here some of the databases they will be searching for evidence.** This comment has not been adequately addressed by the authors. Authors made mention of the inclusion of Pawson's five stages of realist synthesis to address this comment. However, the comment has nothing to do with Pawson's five stages of realist synthesis. It refers to the first four lines of the methods section of the abstract which will be appropriate for the introduction section of the abstract. The second part of the comment refers to the including the identified databases into the methods section of the abstract. Authors should either revise the manuscript appropriately or justify why a revision is not needed. 3. **Reviewer 1: The introduction should be a bit more**

focus, describing the problem and the essence of the review.

This comment has been adequately addressed.

4. **Reviewer 1: Realists reviews/synthesis are theory driven and the testing of candidate theories. However, authors have not made mention of any candidate theory that they intend to test in the review.**

Although I agree with authors that it is difficult to come out with a programme theory at this stage of the review, I think it is imperative to have a kind of a 'guess theory' or a candidate theory. As the name implies a candidate theory is an initial rough theory informed by little evidence. This candidate or initial rough theory can be refuted, refined or confirmed during the review as more evidence is brought on board. The initial rough or candidate theory guides the review; it plays an important role during quality assessment. During quality assessment some studies may be included based on how relevant they are to the initial rough or candidate theory but not necessarily methodological rigour. In a closely related issue, authors have clearly indicated in the quality assessment section of lines of 47-48 of the revised version which reads" Relevance – papers will be screened first for relevance, i.e. those which "provide data that inform programme theory development and refinement".[14,30]". How do authors expect to undertake this exercise if they do not have an initial rough theory or candidate theory (also referred to as programme theory)?

5. **Reviewer 1: The description of the search strategy is also too limited. Apart from searching the databases, it will be imperative to go through the reference list of included papers and also contact experts in the field. Given the fact this is a realist review, the search has to be broad. The databases as they are now are quite limited. Authors could include ERIC, Embase and Pyschinfo.**

This comment has been adequately addressed

6. **Reviewer 1: A prisma flow chart of the searching and selection of studies will be helpful.**

This has been adequately addressed.

7. **Reviewer 1: Authors should also elaborate further on their inclusion and exclusion criteria including study designs, type of data that will be included, geographical boundaries, outcome measures, etc.**

This has been adequately addressed.

8. **Reviewer 1: The description of how the quality of studies will be assessed is too limited. Authors should provide more information. Authors should bear in mind assessment of quality in a realist review is quite different from that of a traditional systematic review. papers may not be included based on their strength of evidence but based on how much they contribute to the programme theory.**

This has been adequately addressed

9. **Reviewer 1: Authors indicate that a certain percentage of papers will be assessed independently, however, they have not indicated how they intend to resolve any differences that may arise through this process.**
   This has been adequately addressed. However, in the revised version that reads ""Any differences will be resolved between the two analysts through negotiation". Authors should replace "negotiation" with "discussion".

10. **Reviewer 1: Authors described how the data will be synthesised but have not indicated how the data will be analysed. Although analysis and synthesis are usually combined, analysis precedes synthesis. Authors should indicate in detail how the data will be analysed using realists concepts. The information provided for how synthesis will be done is too limited. Elaboration is needed.**
    This has been adequately addressed

VERSION 2 – AUTHOR RESPONSE

Reviewer 1: References should be included in the abstract.
This has been addressed. Going by the authors assertion, the sentence that begins the introduction section of the abstract has a reference (i.e. Dennis et al.,). This should be revised.
Author response: We have altered the first sentence to read: "A national survey was recently conducted to explore medical education research priorities in Scotland."

Reviewer 1: The first four lines of the methods section will be appropriate for the introduction section of the abstract. Authors could also mention here some of the databases they will be searching for evidence.
This comment has not been adequately addressed by the authors. Authors made mention of the inclusion of Pawson's five stages of realist synthesis to address this comment. However, the comment has nothing to do with Pawson's five stages of realist synthesis. It refers to the first four lines of the methods section of the abstract which will be appropriate for the introduction section of the abstract. The second part of the comment refers to the including the identified databases into the methods section of the abstract. Authors should either revise the manuscript appropriately or justify why a revision is not needed.
Author response: Thank you for clarifying your previous comment. We have moved the first four lines of the methods section of the abstract up into the introduction section of the abstract.
We have added text to point (2) of the methods section of the abstract so that it now reads:
"(2) search journal articles and grey literature for empirical evidence from 1998 (introduction of the European Working Time Directive) on UK multidisciplinary team working concerning these interventions, theories and outcomes, using databases such as ERIC, Scopus, CINAHL, Web of Science, and PsychInfo;"

Reviewer 1: Realists reviews/synthesis are theory driven and the testing of candidate theories. However, authors have not made mention of any candidate theory that they intend to test in the review.
Although I agree with authors that it is difficult to come out with a programme theory at this stage of

the review, I think it is imperative to have a kind of a 'guess theory' or a candidate theory. As the name implies a candidate theory is an initial rough theory informed by little evidence. This candidate or initial rough theory can be refuted, refined or confirmed during the review as more evidence is brought on board. The initial rough or candidate theory guides the review; it plays an important role during quality assessment. During quality assessment some studies may be included based on how relevant they are to the initial rough or candidate theory but not necessarily methodological rigour.

Author response: The last sentence of stage 1 of the study design now reads as follows:

"A number of possible programme theories were considered when developing the protocol, and based on the scoping exercise a speculative candidate theory was identified as follows: protected learning time can be an effective intervention for postgraduate medical trainee in the hospital setting in the quest to balance the requirements of service delivery and of training depending on logistical pressures, learner motivation and attitude and the social environment. The mechanism is possibly due to access to education and perceived valuing/leadership."

Reviewer 1: Authors indicate that a certain percentage of papers will be assessed independently, however, they have not indicated how they intend to resolve any differences that may arise through this process.

This has been adequately addressed. However, in the revised version that reads ""Any differences will be resolved between the two analysts through negotiation". Authors should replace "negotiation" with "discussion".

Author response: We have replaced "negotiation" with "discussion" as suggested.