Author’s response to reviews

Title: Factors influencing national implementation of innovations within community pharmacy: a systematic review applying the Consolidated Framework for Implementation Research

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Author’s response to reviews:

Dear editor and reviewers,

Thank you for your comprehensive review of our systematic review manuscript. Please find our response to each of the comments and suggestions below.

Reviewer comments

Reviewer #1

1) This is a lot of work which gives a good overview of some of the contextual factors which can influence implementation of innovations within pharmacy practice. However, by its very nature the richness of the individuals studies is missing and this is also not a full typology of all the contextual factors which can influence implementation and their interdependent relationship. I feel the authors could make more of why this paper is important and what it can contribute to the community pharmacy literature.

   • We agree that the manuscript requires improving in that respect. See response to comment numbers 3 and 9 from Reviewer #1 for the specific amendments made to the paper in relation to this.

2) First sentence is poor and needs re-written.

   • This sentence has been rewritten (lines 58-61, page 3): “A strong primary care system underpins improvements in a nation’s population health [1, 2], therefore the primary care sector must continually adapt to meet emergent healthcare needs.”
3) There could be more in the introduction about why this review was needed, what they data can be used for.

   • We agree it has not been explicitly stated why this review is needed. Within the introduction before stating the aim, we have added in the following (lines 95-102, page 5):

   “Considering the evolving role of the community pharmacy setting, and the uniqueness of this context, further exploration is required to understand how innovations in this setting can be scaled up to affect nation-wide improvements in health. This systemic review addresses this to identify barriers and facilitators to the national implementation of community pharmacy innovations. By building upon the reviews previously conducted and overcoming their associated limitations [20, 21], this will allow for the development of a preliminary causal theory of how innovations become successfully implemented within community pharmacies at a national level.”

   • We have further elaborated on this within the discussion (see response to comment number 9).

4) Line 72 spelling mistake

   • This has been amended with the correction of the spelling of ‘however’ (line 87, page 4)

5) Exclusion criteria line 99 - not clear to me why they excluded studies about adoption. I think adoption can be argued to be the first stage of implementation. In the conclusion one of the key findings is about adoption "pharmacy staff engagement, including the perceptions of pharmacy staff and their belief that the innovation was beneficial.” I think the authors need to make their definition of implementation and make their rationale for not including adoption clear.

   • We agree that this is not clear within the manuscript. We have removed the bullet point “participants who chose not to adopt an innovation (as this reports on barriers to adoption and not implementation)” and instead clarified in the preceding text which studies were eligible for inclusion. In lines 116-121 (page 5-6), we have expanded what we mean by the eligibility criteria:

   “An innovation was considered a practice, object or idea perceived to be new to the setting in which it was implemented [18]. Implementation was considered the process by which an innovation was introduced and applied within the pharmacy setting [26, 27]. Studies solely focusing on views of adoption prior to the implementation of an innovation were outwith the scope of this review as this was considered the preliminary decision making process of the pharmacy staff to use an innovation [18], which was considered conceptually dissimilar to implementation.”

   • In lines 405-411 (page 17-18) we have amended the text to be clearer:
Three key thematic areas were identified: (1) pharmacy staff engagement with implemented innovations, including staff perceptions and beliefs regarding the innovation; (2) operationalisation of innovations, such as lack of resources; and (3) external engagement with implemented innovations, including perceived negative views of patients and other healthcare professionals.

- We have also alluded to the importance of further exploration of adoption within lines 431-434 (page 18-19) of the discussion:

  “Although exploring pre-implementation phases was outwith the scope of this review, exploring the cognitive processes underpinning decisions to implement innovations in light of financial and personal incentives, and how these weigh against patient-related benefits, would be an interesting area for future research [94].”

6) I'm not clear what type of studies are included? Are these interventions which have been successfully evaluated in a trial and then this includes studies of their implementation into practice. My assumption is that they are not previously developed or evaluated interventions.

- We did not restrict the inclusion of studies to those exploring innovations which had been successfully evaluated in a trial. The pilot implementation and development of the innovations explored were not always detailed within the studies, thus we cannot comment on the innovations’ prior development and evaluation. We have now amended the discussion to explicitly state this within line 474-481 (page 20):

  “In line with previous work, this review identified that adopted implementation strategies are poorly reported in the literature [14, 21], and the development of innovations was also poorly described. Future studies should explicitly report the implementation strategies adopted and greater details of the innovation being implemented, including its development, to allow for consideration of how these aspects may influence successful implementation [116, 117].”

7) Line 163 where or to what literature the CFIR is commonly applied would be useful.

- In line 188-191 (page 8), we have amended the sentence to read:

  “It is widely applied [40], commonly to explore healthcare practitioners’ experiences of implementing an innovation [41], which facilitates cross comparison of results [27].”

- We have also included a reference of a systematic review by Kirk et al on the use of the CFIR (reference number 41).

8) Line 311 spelling mistake

- This has been amended with the correction of ‘for’ to ‘from’ (line 346, page 15)
9) In the discussion I would like to see more about how these findings can be used to inform more research. I think these findings would be useful to inform intervention development as there are calls for implementation into practice to be considered at a much earlier stage.

• Considering your comments and those of Reviewer #2, we have amended the discussion to include a section entitled ‘Development of a preliminary theory and recommendations for future research’. Within this section we introduce a preliminary theory and suggest areas for future research (lines 461-474, pages 19-20):

“A critical output of this systematic review was the identification of the three overarching thematic areas (Table 4). Fig 3 presents a preliminary causal theory based upon this, where we propose that successful national implementation of an innovation requires: (1) the pharmacy staff to positively engage with an innovation; (2) the innovation to be easily operational within community pharmacies; and (3) positive external engagement of patients and other healthcare professionals. Further work is needed to understand the interaction between these three areas, and to consider how the influence of each may differ within varying contexts and settings. Once tested further, applying this theory at an early stage of an innovation’s implementation process could inform potential refinements to an innovation. As ‘External Engagement’, was an emergent theme, this exemplifies the impact of the surrounding outer context and indicates that the community pharmacy setting is not detached from the wider primary care setting. Wider exploration of the perspectives of other healthcare professionals and the public may strengthen this understanding.”

Fig 3. Preliminary theory of the influences affecting the national implementation of community pharmacy innovations

Reviewer #2

1) Thank you for this manuscript. I would like, first, to start by some general reflections: This is an article that could be of importance in its field because, by looking at the challenges of innovating in community pharmacy through the staff perception, challenges of the pharmacist sub system within the health systems could be highlighted. Unfortunately, the approach used to identify factors influencing these innovation implementations (a single rigorous systematic review) doesn't allow to come up with a strong discussion. The list of factors proposed could be, mostly, common to any innovation implementation process in any other field. One way to make reflect the added value of the author's work would be to use propose an initial hypothesis/causal theory of how innovations at community pharmacy level could work and, afterwards, to make sense of the factors they identified by redefining this initial hypothesis. In a way, the importance of this article may be to present these factors influencing at community pharmacy level as part of a health system and not as an isolated case.
This is a valid point, and we agree that the development of an initial hypothesis would have strengthened this piece of work. We feel that due to the characteristics and limitations of the previous reviews by Roberts et al and Shoemaker et al, developing an initial causal theory was not possible. We have since considered how our results could lead to the development of a causal theory. We have edited the introduction to explicitly state this (lines 98-101, pages 4-5):

“By building upon the reviews previously conducted and overcoming their associated limitations [20, 21], this will allow for the development of a preliminary causal theory of how innovations become successfully implemented within community pharmacies at a national level.”

We have included a specific objective for this (lines 106-107, page 5):

“3. Develop a causal theory of the factors influencing successful national implementation of community pharmacy innovations”

We believe the three thematic areas identified represent an initial theory. We have included the following text and figure within a new subsection entitled ‘Development of a preliminary theory and recommendations for future research’ (lines 461-474, pages 19-20):

“A critical output of this systematic review was the identification of the three overarching thematic areas (Table 4). Fig 3 presents a preliminary causal theory based upon this, where we propose that successful national implementation of an innovation requires: (1) the pharmacy staff to positively engage with an innovation; (2) the innovation to be easily operational within community pharmacies; and (3) positive external engagement of patients and other healthcare professionals. Further work is needed to understand the interaction between these three areas, and to consider how the influence of each may differ within varying contexts and settings. Once tested further, applying this theory at an early stage of an innovation’s implementation process could inform potential refinements to an innovation. As ‘External Engagement’, was an emergent theme, this exemplifies the impact of the surrounding outer context and indicates that the community pharmacy setting is not detached from the wider primary care setting. Wider exploration of the perspectives of other healthcare professionals and the public may strengthen this understanding.

Fig 3. Preliminary theory of the influences affecting the national implementation of community pharmacy innovations

We have amended the conclusion of the manuscript to reflect this change. We have removed the text in lines 576-580 and inserted the following text in lines 569-572 (page24):

“Key findings led to the development of a preliminary theory where it is proposed that successful national implementation of community pharmacy innovations requires innovations which are
easy to operate, alongside positively engaged patients, pharmacy staff, and other healthcare professionals such as GPs.”

- We have amended the abstract’s conclusion to reflect these changes. We have removed some text and inserted the following text in lines 47-80 (pages 2-3):

“A preliminary theory of how salient factors influence national implementation in the community pharmacy setting has been developed, with further research necessary to understand how the influence of these factors may differ within varying contexts.”

- In response to the reviewer’s comments about presenting these factors as part of a health system and not as an isolated case, we believe Fig 3 exemplifies the influence of the outer context. We have stressed this and the necessity to explore the wider context with the inclusion of the following text (lines 470-473, page 20):

“As ‘External Engagement’, was an emergent theme, this exemplifies the impact of the surrounding outer context and indicates that the community pharmacy setting is not detached from the wider primary care setting. Wider exploration of the perspectives of other healthcare professionals and the public may strengthen this understanding.”

2)  Line 185: Among the study characteristics, did the authors include papers from all over the world?

- Studies from any country were considered eligible for inclusion. The paper has been amended to explicitly state this within line 124 (page 6):

“Studies from any country were considered eligible for inclusion.”

3)  Line 189: Among the 4 categories concerning the innovation types, there is one labelled as the 'legislative changes'. Later in the paper there are not referring to any legislative example. Can the authors describe a bit better which kind of innovations are included there?

- We agree it was not made clear what legislative change means. We have provided examples within the manuscript when this is first mentioned (lines 216-218, page 9):

“The innovation types can be categorised into four subtypes: Clinical Service (n=21); Pharmacovigilance (n=6); e-Technology (n=2); and Legislative Change (n=10) such as policy changes and reclassification of medicines.”

4)  Line 272: The title here is 'External policy and incentives' but the development of this paragraph is almost all focused on incentives. Again, can the authors justify to which examples of 'external policy' they refer to?
We have restructured this section to first focus on external policy and then to focus on incentives (lines 304-313, pages 13-4):

“In relation to external policy, reported barriers included the innovation not being aligned with policy [64]. Studies suggested hypothetical facilitators including extending the scope of innovations [6, 51, 64], and making participation in pharmacovigilance innovations compulsory [50, 57, 59, 84]. In relation to external incentives, lack of/insufficient funding [6, 82] or remuneration [49, 75, 78] were reported barriers. Suggestions of incentives which could facilitate implementation were primarily financial [49-51, 59, 64, 71, 75, 84], but also included the provision of awards, certifications, journal subscription, conference attendance [59] or penalising other healthcare professionals for lack of co-operation [49].”

5) Line 273-Line 289: Which is the difference between 'incentives' used in the title of line 272 and 'organisational incentives' used in the title of line 289?

- We agree it was not made clear how these differ. Under the heading External Policy and Incentives the initial text has been amended to read (line 303, page 13):

“This construct relates to policy and incentives originating from government or other central entities [93].”

- Under the heading Organizational Incentives and Rewards, the text has been amended as follows (lines 315-316, page 14):

“This CFIR construct relates to incentives and rewards originating from specific pharmacy organisations, as well personal incentives of the community pharmacy staff [93]. One study cited negative perceptions of target-setting within the pharmacy, which were perceived as income-focused rather than patient-focused [86].”

6) Line 319-320: In this paragraph 'complex operationalisation of the innovation' is mentioned and 'complex remuneration or reporting processes' as well. I would tend to say that the second sentence is part of the first. What the actors referred to by 'complex operationalisation of the innovation'?

- We agree that the second statement is part of the first. We have reworded to state (lines 354-357, page 15):

“Difficulty of an innovation [49, 55, 56, 62, 73, 77] and the complexity of its operationalisation was reported [60, 78], with the latter most commonly relating to the complexity of the remuneration or reporting processes [6, 50, 55, 58, 73, 84].”

7) Line 339: The title here is 'cosmopolitanism' but the paragraph is following points out about dysfunction of communication and coordination between health professionals. If we refer to the Alma-Ata and primary health care principles, the problems of communication and coordination not necessary appear because of the cosmopolitanism
but because of the health system organisation weaknesses and its pillars. Instead to accept this 'new concept' I would suggest to look into the literature to better describe and refer to this phenomenon.

- We agree with Reviewer #2 that the cosmopolitan issues presented in the studies may be related to limitations of the organizational set up of healthcare systems. Unfortunately the data emergent from the included studies did not pertain to how the infrastructure of organisations may have influenced cosmopolitanism, thus we have not be able to conceptualise this link within the current systematic review.

- We also agree that the cosmopolitan construct defined by the authors of the CFIR requires further elaboration and conceptualisation, particularly as it centres on networking. We have further elaborated on this limitation of the CFIR in this discussion as per the insights of Reviewer #2, and have amended this section to read (lines 529-531, page 22):

“The “Cosmopolitanism” construct overlooks the impact of external healthcare professional’s engagement as it centres on networking with external organisations, and further exploration of how cosmopolitanism may be influenced by the infrastructure of healthcare systems is required.”

Editor comments

1) This is a well conducted systematic review. Both reviewers have identified the need to explore contextual factors more. I think the use of CFIR is good but it would be good to consider what might be missing - or what else the studies described.

- We agree that this systematic review does not cover everything described within the included studies. Within the discussion, we have acknowledged that the implementation strategies applied for each of the innovations were rarely reported within the studies and thus due to the heterogeneity of the data available on this it has not been reported. This is acknowledged in lines 475-481 (page 20), and following the comment by Reviewer #1 (point 6), we have additionally mentioned that the development of the innovations evaluated within the studies was poorly reported. This meant a meaningful consideration of the implementation strategies used and the development process of the innovations could not be conducted. Instead we have stated that we recommend future primary studies explicitly describe this, and have explicitly rationalised why (lines 478-481, page 20):

“Future studies should explicitly report the implementation strategies adopted and greater details of the innovation being implemented, including its development, to allow for consideration of how these aspects may influence successful implementation [116, 117].”

2) I note the need to use different quality assessment tools. It might be useful to comment on this in your discussion - did this present some challenges?
This is an important point, and we have since considered what the challenges were, and have included the following text in lines 516-521 (page22):

“The inclusion of qualitative, quantitative and mixed methods studies ensured wide exploration of the barriers and facilitators in this context, which meant that different quality assessment tools were applied. Although tools of similar depth were selected, it is notable that the CASP and BGQC tools covered different aspects of quality [33, 35]. For example, the BGQC tool does not explore the relationship between participants and researchers unlike the CASP tool. Therefore, to what extent the quality assessment results are truly comparable between study types is unknown.”

3) The quality assessment is described in the methods but not referred to again. How was this used in your analysis?

- The text has been edited to make it clearer how the quality assessments results were used in the analysis (lines 563-267, pages 11-12):

“When removing studies with a quality assessment score of <50% (n=12, 41%), no changes were identified to the most commonly reported CFIR constructs amongst the barriers, facilitators and hypothetical facilitators. Likewise, when categorising results by innovation and not study, the most commonly reported CFIR constructs remained the same. Therefore, for completeness all studies were retained within the analysis.”

4) There are also some minor typos which should be corrected with a close read-through.

- We have closely read the manuscript and have amended typos.

Other edits made:

For brevity we have removed text throughout the manuscript which was not deemed necessary. The exclusion criteria has also been developed as a figure (Fig 1) and has been reworded slightly.