PEER REVIEW HISTORY

BMJ Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form (**http://bmjopen.bmj.com/site/about/resources/checklist.pdf**) and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below.

ARTICLE DETAILS

TITLE (PROVISIONAL)	Barriers and facilitators to implementation of non-medical independent prescribing in primary care in the United Kingdom: a qualitative systematic review.
AUTHORS	Edwards, Judith; Coward, Melaine; Carey, Nicola

VERSION 1 – REVIEW

REVIEWER	Ali Hindi The University of Manchester, Centre for Pharmacy Workforce Studies, Division of Pharmacy and Optometry
REVIEW RETURNED	10-Jul-2021

GENERAL COMMENTS	Overall remarks: This paper is well-written and focuses on implementation of IP within primary care. Whilst written to a high standard, this paper does not really add anything new to the evidence base. A recent systematic review conducted by Clark et al. (2019) used both qualitative and mixed methods to look at barriers and facilitators to IP and reached similar conclusions. It's hard to make an argument for another systematic review two years later given that things won't have changed/moved much from both a policy and research standpoint. Whilst the implementation theoretical lens/frameworks add some value and additional insights, I wonder if this is enough to justify publication of this systematic review. Another thing that doesn't come out clear in this study is how things have changed from one decade (2010) to another (2020) in terms of how IP is perceived by other HCPs and patients. Has anything changed since other medical professionals would have a bit more experience working with IPs over time? Also, the authors could draw out key differences (if any) between implementation facilitators and barriers to IP amongst different HCPs. Abstract: - Needs a bit more information in methods section (i.e. databases used, Quality appraisal tool). Methods: - I wonder why the authors did not consider using Scopus? - How were cut-off scores for classifying the quality of papers decided upon? Was the cut-off evidence-based or arbitrary? - "In order to expose methodological weaknesses in the literature(97, 98). studies were not excluded on the basis of quality assessment(84, 99)". I think another (stronger) reason/justification is that the scope of this review is to synthesis qualitative evidence so excluding papers based on quality is not necessary compared to

	RCTs. Results: - Themes 2.2 and 2.3 seem to conceptually overlap. Could they be merged? Discussion: - Whilst study is UK based, authors could make references/comparisons to international countries with similar IP advancements. I feel this would make the remit of the paper more broader and beneficial to international audience.

REVIEWER	Rosemary Lim University of Reading, Reading School of Pharmacy
REVIEW RETURNED	14-Jul-2021

GENERAL COMMENTS	Thank you for the opportunity to review the study entitled “Barriers and facilitators to implementation of non-medical independent prescribing in primary care: a qualitative systematic review.” Overall, I think this is an important area of research, within the context of primary care in the UK and thank you for conducting research in this area. I do, however, have some comments/concerns, please see them below: The title does not accurately reflect the main objectives and the reported findings. Abstract: - The study focuses on the UK context and it would be better to make that clear in the first couple of sentences. - Methods were unclear for a systematic review type study. What databases, eligibility criteria etc would have helped. - The results section could be made much clearer – does not seem to have fully addressed the objectives of the review “The objective of this qualitative systematic review was to identify barriers and facilitators to non-medical independent prescribing in UK primary care and explore their influence on adoption, implementation and sustainability.” - It was unclear how the conclusions were drawn from the presented results. - Does not seem to have been reported according to PRISMA statement? Introduction - Check accuracy of the term “long Covid-19”. Long COVID? - Second paragraph, first sentence – does this relate to England or UK as stated? Reference 18 refereed to ICS not PCN? There are non-medical staff who are already part of PCNs and worth highlighting its current existence rather than a projected figure of 20K by 2024. I suggest revisiting this paragraph for accuracy. - Healthcare administration is devolved in the 4 nations in the UK and it is worth commenting briefly on the implications on service delivery within the context of non-medical IP in primary care. Method - The use of relevant theory was important but it was unclear how it informed the design and conduct of the study. It was unclear how the Diffusion of Innovations theory and the Consolidated Framework for Implementation Research were used to inform the meta-synthesis process? Framework Analysis seemed to have been used

	instead? Or perhaps I had misunderstood the relevant theories driving the meta-synthesis ie used also as an analytical framework rather than inductive analysis of data using methods akin to framework analysis as described. PPI - Unclear how the service user/carers group were involved in the reported study. Please clarify further. Result - I found it difficult to follow Table 4. For example, what does analytical theme 1 relate to – barrier or facilitator? More context to the quotes provided would have been useful. E.g analytical theme 1, theme 1.3, quote from ref 131 – what was the context was this a dr? "Maximising and sustaining" as a title for "analytical theme" does not help the reader understand what it relates to? Referring to Supplementary File 4 – there was little context as to what aspects of how "impact on workload" (Analytical theme 4, theme 4.1) was both a barrier and facilitator. There was also inconsistency in reporting of themes – here it is "maximising and developing IP" but in the manuscript it was "maximising and sustaining". - I may have missed this as it was difficult to follow the results of the analytical themes – it is not clear how the DOI and CFIR informed the results. - I was also unclear from reading the results, how the aims of the study were answered? What were the barriers and facilitators to non-medical independent prescribing in UK primary care? And how did they then influence on adoption, implementation and sustainability? I suspect the answers are somewhere in the results and perhaps restructuring its presentation can make it clearer for the reader to understand and interpret the findings. - Were there any differences in the barriers and facilitators and hence influence on adoption, implementation and sustainability across the 4 nations, that was noteworthy? Discussion - Following previous comments about theory, I am unclear how the findings are theory based (as stated in the strengths and limitations section. Conclusion - "…identified barriers at four key stages of implementation including initial organisational preparation, selection and support of practitioners during training, transition of prescribing into practice and long-term development and sustainability" This was not reported in the results section so unclear how the conclusion was derived?

REVIEWER	T McIntosh Robert Gordon University, Pharmacy and Life Sciences
REVIEW RETURNED	20-Jul-2021

GENERAL COMMENTS	Thank you for submitting this paper which I have read with great interest. It addresses an important issue, particularly given the number of non-medical prescribers who are not prescribing, and also as you identify, a growing demand for healthcare which cannot be met only by medical prescribers. It adds greatly to the knowledge base in this area and is likely to be interesting and very useful for all involved in NMP and particularly for those providing policy-level and organisational support for implementation including transition. I hope you will find my comments on the script and in a separate document

	helpful. These will address my 'No' responses. The reviewer provided a marked copy with additional comments. Please contact the publisher for full details.

VERSION 1 – AUTHOR RESPONSE

Reviewer 1:

1) This review differs from that published by Graham-Clarke et al (2018) by specifically addressing primary health care contexts, synthesising only IP literature (and not studies including a mix of supplementary and independent prescribers) and adding a novel approach to barrier/facilitator identification by linking them to stages of implementation that emerged during meta-synthesis. This has provided a temporal order to the challenges faced when implementing IP rather than a "list" type review of barriers and facilitators.
2) Themes now highlight the repetition/persistence of barriers over the review decade, with this finding included in the discussion. It was not possible to draw out how/whether HCP attitudes to IP had changed over time, as few studies included team members/other stakeholders, and there was insufficient data from prescribing participants (the main participant group overall) that made reference to other team members' other than those relating to managers/doctors.
3) **Abstract**: The methods section in the abstract has been amended accordingly to reflect databases searched, the quality appraisal tool used etc in line with 2020 PRISMA checklist for abstracts.
4) **Methods:**
    a. Six major/recommended databases were searched. As the number of databases necessary is arguable (Lefebvre et al, 2021) and the number of duplicates identified (n=4062) suggested that saturation had been reached, it was not felt necessary to additionally search Scopus.
    b. The mean QATSDD score overall has been presented and arbitrary "cut off" scores classifying *low, medium, high* quality removed. Attributes/strengths of high/low scoring studies according to the QATSDD have been presented.
    c. "*Studies were not excluded on the basis of quality assessment*" – the authors acknowledge the suggestion that selection based on quality is unnecessary for the scope of a meta-synthesis and this has been amended.
5) **Results:** Themes 2.2 and 2.3 have been amalgamated for conceptual clarity/overlap as recommended.
6) **Conclusion:** Reference to the increased interest/legislation of non-medical IP internationally has been made in the conclusion as suggested.

Reviewer 2:

1) **Title**: the title has been changed to reflect the main objective and findings.
2) **Abstract**:
    a. The UK context of the review has been made clear
    b. Methods: the methods are consistent with a qualitative meta-synthesis, with databases, eligibility criteria added in line with the 2020 PRISMA checklist.
    c. Results: now address the (amended) objective of the review and are presented in line with the PRISMA 2020 abstract checklist.
3) **Introduction:**
    a. Thank you for highlighting the inaccuracy of the "long COVID-19" statement – it has been amended and re-referenced in relation to evidence for COVID-19 on primary care, not Long COVID.
    b. Second paragraph, first sentence as previously "*To address workforce and service sustainability".* The introduction has been changed to make clear where England's primary

care models are referred to and has aimed to make the tone less England centric without detailing all devolved nation arrangements/models of primary care.

4) **Methods:** The DOI and CFIR were not used as a framework for analysis but rather as a theoretical lens/anchor for identifying barriers and facilitators during thematic analysis. The subsequent text on the models in the "Theoretical perspective" section have been removed/clarified.
5) **PPI:** this section has been amended to reflect that while PPI were involved in the design/methods of the PhD research, the review's focus on challenges to implementation and not patient-reported outcomes meant their input was not appropriate.
6) **Results:**
   a. In the "Data analysis and synthesis" section of the methods, a statement has been added ("*The aim of thematic analysis was to develop a coherent synthesis of barriers and facilitators that influenced IP across stages of the implementation continuum")* to clarify the intent to identify factors across the implementation "journey". Analytical themes have been accordingly renamed to reflect the stages of implementation that emerged during synthesis. Tables 3 and 4 have been revised to clarify a) the actual barriers and facilitators identified from included studies and b) how the analytical, descriptive and data themes emerged and their summative findings.
   b. Supplementary file 3 now includes indicative quotations and how they informed /are linked to the barriers and facilitators. This table also includes the link of themes to the Diffusion of Innovations theory and Consolidated Framework for Implementation research which was made post inductive thematic analysis (and not a priori as in framework analysis). To prevent an exhaustive table, quotes have been kept to the minimum necessary to exemplify key barriers and facilitators.
   c. It was not possible to deduce differences in barriers/facilitators in the 4 implementation stages across the devolved nations because of insufficient data representing Northern Ireland and Wales (noted in "*Study characteristics*"), and a predominance of studies conducted in England and mixed geographical settings. This has been noted in the "*Identification of barriers and facilitators and key stages of implementation*" section.

7) **Discussion:** reference has been made to theory "guiding" the study findings rather than "informing" them.
8) **Conclusion:** The conclusion has been amended to reflect the main findings.

<u>Reviewer 3</u>:

Thank you for the very thorough and instructive comments added to the main manuscript and supplementary files. Changes have been made in response to each, which can be found in side comment boxes added to the *MainDocumentV2.0_MarkedCopy_19112021FINAL.*
Particular attention has been paid to tenses/indefinite and definite articles; and the use of the word "included". The need to reduce word count had altered the readability and comprehension of some sections/sentences and this has been addressed. The review search time frame has been updated to September 2021 (adding n=1 extra paper) as recommended.

This re-submission has undergone major revision in response to reviewer comments, which has improved and strengthened the quality and clarity of the work. In order to address issues of comprehension imposed by former attempts to reduce the overall word count, an additional 425 words have been added. The manuscript length is now 5754 words with references, which reflects the nature and depth of synthesis undertaken.

The meta-synthesis represents a novel approach to the synthesis of stage based barriers and facilitators to non-medical IP implementation in UK primary care settings, the findings of which can be used to guide

future implementation endeavours in the UK and in countries considering/exploring the implementation of this important skill.

VERSION 2 – REVIEW

REVIEWER	T McIntosh Robert Gordon University, Pharmacy and Life Sciences
REVIEW RETURNED	15-Dec-2021

GENERAL COMMENTS	Thank you for reviewing this manuscript based on my suggestions and those of the other reviewer/s. It reads very well and will make a valuable contribution to understanding and hopefully to practice in this important area. Congratulations. The reviewer provided a marked copy with additional comments. Please contact the publisher for full details.