Author's response to reviews

Title: Patient Involvement in Guidelines Remains Poor Five Years after Institute of Medicine Standards: Review of Guideline Methodologies

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Author’s response to reviews:

Reviewer #1: Overall

This paper is well written and the research uses strong, well established review methodologies.

The research question is highly relevant and well chosen. The terms used are defined very well.

RESPONSE: Thank you. No changes to be made.

I was very interested that the authors did not mention 'person/patient-centred health care' once in the entire paper. This may be an observation rather than a criticism but is also relevant to an aim of modern health care in many countries of the world.

RESPONSE: We have added the term “person-centered healthcare” to the discussion on page 13, where the bottom paragraph’s second sentence now reads, “While stated rationales for PPI are largely ethical ones – emphasizing patients’ autonomy and experiential knowledge in the context of person-centered healthcare, consumer rights, and/or democratic rights of citizens and taxpayers [4]…” (page 14 lines 4-5)

One hundred and one organisations were identified that met the criteria for inclusion - does this mean they all have a base in the United States? Is this the inference? It would be very helpful to know upfront if/that the current research is specifically for guideline developers in the US [and any 'contamination' discussed in terms of influence on findings]. The previous survey in 2008 was international, so we do not know if the US was on a par with other countries for patient and public involvement in guideline development then.

RESPONSE: We are aware of no prior work identifying the frequency with which U.S.-based guideline developers engage patients/consumers in the process. There is very little work on this at all, which is why the 2008 study is relevant even though it has international scope. The National Guideline Clearinghouse does not require that submissions be from U.S.-based developers, but the majority of participants in the NGC are from the U.S. We have added a sentence to clarify this in the methods (page 6, lines 16-17) which says, “The NGC permits
submissions by international guideline developers but contributors are primarily based in the United States.” In the results we have added the clarification (page 9, lines 15-17) “All included developers appeared to be based in the United States, though some organizations had North American or international scope.”

Title

Both the numeral '5' and the abbreviation 'IOM' are used in the title… Rather than to say 'remains' would it be more accurate to say 'is' (as no baseline data to support statement)

RESPONSE: We wrote out the numeral “five” and changed “IOM” to “Institute of Medicine.” We changed “remains” to “is” as requested.

It is important to not assume knowledge of the fact but to say the IOM is the: United States of America Institute of Medicine

RESPONSE: In the plain English summary, abstract, and background of the main manuscript, we have clarified that the Institute of Medicine is “United States-based.” Of note, the IOM is a nonprofit, non-governmental organization.

Text, Background: Would be useful to have a paragraph that outlines the purpose of the other IOM standards within the same report, and their role in making guidelines more trustworthy (eg addressing conflicts of interest of clinicians, more transparent processes), and why involving patients and the public is important in doing this. The understanding gained would make the conclusions of the paper even stronger.

RESPONSE: We do not want to distract from the central point of this manuscript by going too in-depth regarding the broader IOM report, but we have edited the background to address the reviewer’s suggestion. We have added a sentence to the background (sentence #2, page 4 lines 9-12) providing additional background on other IOM standards, “This report outlined eight standards of trustworthy clinical practice guidelines including transparency, managing conflicts of interest, use of systematic reviews, processes for recommendation development, and updating mechanisms.”

Present results

≥2 guidelines in the National Guideline Clearinghouse between March 2011 and November 2015 Publically available information extracted from guideline developers' websites, methodology manuals, and guidelines between November 2015 and December 2016:

Of 101 [north American?] organizations meeting inclusion criteria, only 8% require patient/public involvement on guideline development groups; 15% sometimes require it or describe it as optional. Only 24% always utilize public comment of draft guidelines; 13% engage patients/public in external review at least some of the time. Twenty percent of developers create patient-targeted guideline products.
- Are all 101 organisations US based? If not, a brief description of their base would be helpful. That is, is it right that the present findings specific to the US?

RESPONSE: We now clarify in the methods (participants section, page 6, lines 16-17) that, “The NGC permits submissions by international guideline developers but contributors are primarily based in the United States.” We re-reviewed the included developers’ websites and all appear to be U.S.-based. We have added a sentence to the results (page 9, lines 15-17) that reads, “All included developers appeared to be based in the United States, though some organizations had North American or international scope.”

For the post hoc analysis of GIN North America members and non-members, clarity on geographical spread is also important. It would be good to state explicitly in the paper why or how GIN membership is a factor for patient and public involvement in guideline development, and so why the analysis was done.

RESPONSE: The reason for the post-hoc analysis is described in the analysis section of the methods (page 8, lines 21-25): “Given the low identified frequency of PPI practices and the fact that an aim of G-I-N North America is to “improve the effectiveness, rigor and efficiency of guideline development” in the North American community [6], a post hoc analysis compared differences in PPI practices between developers who were and were not G-I-N North America members to inform potential trends in guideline development.”

The Discussion begins with a good summary of the results.

The statement on page 12, line 54: "These low numbers represent a discouraging lack of progress of PPI since publication of the IOM report" would appear to have no basis for direct comparison as PPI was not determined in the same population of guideline developers before the IOM report - so this needs rephrasing. In doing so, the number of guidelines involving patients and public is low and so the impact of the finding is not reduced in any way.

RESPONSE: The sentence has been rephrased to read, “These numbers are discouragingly low, particularly since five years have passed since publication of the IOM report” (page 13 lines 17-18).

This is where the comparison with an international group of guideline developers is stated, but there is no measure of the current level of participation in this population to say if it has increased or decreased over time.

RESPONSE: We have made the suggested edit as above. We agree that we do not know whether the international rate of PPI has increased or decreased since the 2008 survey, but as that is the only other identified research in the area, believe the inclusion of those results is still important.

The statement that 'rationales for PPI are largely ethical ones' (page 13, line 25) does not read as entirely true when for example experiential knowledge is included. It is the experiential knowledge that means patients and caregivers can contribute in the number of ways then listed (lines 31 to 36).
RESPONSE: We have edited the sentence slightly to read, “While stated rationales for PPI are largely ethical ones…” (page 14 lines 3-5). This sentence references the G-I-N PUBLIC manual, which emphasizes the rationales outlined. We agree with the reviewers’ point that experiential knowledge contributes, reflected in the conclusion of the cited sentence, “…increasing evidence suggests that patients and the public make meaningful contributions to guideline development.”

Line 40 to 43: Important to make clear whether these factors are from the patient and/or provider perspective, that they may differ between the two, and how they would be addressed if patients were not involved in the process of developing recommendations - and therefore to the relevance of the resulting guidelines….

RESPONSE: The references cited in the barriers section are varied and include reports from experiences at NICE (where they interviewed patients/consumers and professional committee members) and knowledge syntheses/systematic reviews (eg Legare 2011). To investigate professional vs patient barriers at length is outside the scope of this discussion, but we agree with the reviewer that these are likely to be different.

When discussing the barriers (page 13, line 56 to page 14, line 11), I think this can be summed up as a lack of commitment to involving patients/patient advocates. There are other areas of health care and medicine in the US where patients/patient advocates are successfully involved (eg in the FDA, research), showing it is possible. Measuring impact may actually be more feasible with guidelines than in other areas, at least in theory.

RESPONSE: We agree that there is a lack of commitment to involving patients/patient advocates, though we believe that there is value in outlining the barriers that developers need to overcome to respect a commitment to involving patients. We have heard many developers describe their concerns regarding costs, lack of experience, time, recruitment difficulties, etc. We believe these barriers are overcome-able for those who are committed to involving patients, but they are still known/published barriers that guideline developers describe.

For person/patient-centered care could be added to the very last sentence of the Discussion (page 15, line 31)

RESPONSE: Reference to person-centered healthcare added on page 14 (lines 4-5) as above

Detailed corrections:

Plain language summary (page 2), 1st sentence, line 10: State that the Institute of Medicine standards are for the United States.

line 12: …standards …recommend ie tense agreement

RESPONSE: We have rewritten the first sentence of the plain language summary to read, “The 2011 standards for trustworthy development of healthcare guidelines published by the United States-based Institute of Medicine recommends…” We feel this wording clarifies the location of
the IOM without implying that the standards don’t have relevance for other guideline developers. The IOM standards overlap with those outlined by G-I-N and AGREE2 and have international relevance even though published in the U.S. We have changed “recommends” to “recommend” (page 2 line 8).

Abstract, Background (page 2), line 50: state that it is the United States Institute of Medicine…. lines 57/59: …compliance with …these standards….

RESPONSE: We have rewritten the first sentence of the abstract to read, “The United States-based Institute of Medicine 2011 standards for trustworthy clinical practice guidelines…”

Results (page 3), line 29: …public comment on draft guidelines; Conclusions, line 38: …and practice within the United States,

RESPONSE: Changed “of” to “on.” Added “in the United States” (abstract conclusion, page 3 line 23).

Main text, Background, page 3, line 53: make clear it is the United States Institute of Medicine Page 4, line 7: explain ‘CPG’

Line 20: make clear that these are international organizations…. Page 5, line 18: reported

Line 29: I would suggest this is 'have taken up or increased….'

Line 40: this is in terms of involving patients, patient advocates and the public to increase transparency of guideline development - as the standards cover more than patient and public involvement….

RESPONSE: Added “United States-based” as mentioned above (page 4, line 8). Added “[clinical practice guideline]” after use of “CPG” within a quote (note that “CPG” is only used in this manuscript in this single instance, where it is part of a quote, thus it is defined in brackets rather than changing the quote). It seems redundant to say that the Guidelines-International-Network is international, so this change was not made. AGREE-2 is driven by Canadian investigators but is applied internationally; it is not clear that this level of detail is necessary here, particularly with a link to the AGREE II manuscript. Changed “reporting” to “reported” (page 5 line 20). Reworded sentence to read “No studies investigate… whether U.S. guideline developers are including PPI as recommended by the 2011 IOM report.” We cannot get our lines to match those of the reviewer and are uncertain of the changes suggested in the reference to “Line 40.” The goal of patient engagement is not to increase transparency (transparency is Standard 1 of the IOM report, but this is separate from patient engagement.)

Methods, page 6, line 15: would read better as '…including organizations who rarely produce guidelines…'
RESPONSE: Change made (page 6, line 22).

Results, page 11, line 29: '…sometimes performed by an additional 2%…'

RESPONSE: Change made ("and" to "an") (page 12, line 7)

Discussion, page 12, line 51: '…preparing patient guidelines or summaries…'

Line 58: '..developers reported involving…'

RESPONSE: Changes made (page 13 lines 16, 20)

Reviewer #2: A useful study. As the authors state their methodology may result in an under estimate of PPI in guideline development. This is unlikely however to be very very significant and the study importantly draws attention to the lack of congruence between the prevailing PPI narrative and actual practice. The study points to the important benefits of PPI to guideline development and the failings in current practice to operationalise these benefits. This is the first study that I am aware of that has attempted to explore this area. Publication should promote further interest in this area which in turn may contribute to improvements in practice.

RESPONSE: Thank you. No changes needed.

Reviewer #3 (Diego Villalón): [Discussion reviewed but not copied and pasted here as it did not require edits.] I have only one change to propose to authors. I think that discrepancies between the views of patients and physicians must not be considered in the article as a barrier (this is said in page 13). PPI in guidelines development implies potential discrepancies between them because both represent different perspectives of the disease and may be have different perceptions and expectations. Therefore, in mi opinion, these must be understood as a consequence and a result of the review, not as barrier for PPI. To examples: If scientific community feels this is a barrier, probably it is because of their own resistances. And if these discrepancies are consequence of a lack of knowledge of patient about this process, the barrier would be the lack of training of patients.

RESPONSE: We thank the reviewer for his detailed reading of the manuscript and his suggestions for further research. We agree with the need for the research he has highlighted and hope that this manuscript may serve as background for such investigations. With regards to his one proposed change, the description of “discrepancies between the views of patients and physicians [13]” as a barrier is not the opinion of the authors but rather the reflection of that reference. The referenced paper states, “Notably, a discrepancy between the perspectives of experts and patients/the public was the most frequently reported barrier (8/71)” (page E51 of the cited reference PDF). We have tried to emphasize this fact further by adding the phrase “(the most commonly identified barrier in a knowledge synthesis)” to the paragraph (page 14, lines 25-26). We hope this will direct the reader to the reference – an excellent review – to read further
about what was characterized under this barrier (it reflects both developer and patient perspectives).

Reviewer #4: The paper covers an important topic i.e. the identification that the involvement of patients in guidelines remains poor. There is clearly variability in the US and this needs to be improved, which is the essence of the paper. However, there are a number of elements that need to be addressed to ensure this message is clearly conveyed as at present, sections are unclear to the reader. For ease, I have outlined the areas that need attention by section.

1. The abstract: the background section needs editing for clarity; the sentence "disagreements were resolved by discussion" is not explanatory. Suggest changing to "where the researchers differed in opinion on ... discussion was held for resolution" (this sentence is later repeated in the main document, further expansion can be given here). The background notes that it is US guideline developers but this is not restated in the rest of the abstract. As practice varies internationally, please state in all sections that this pertains to US guideline developers.

RESPONSE: As suggested by the reviewer, we left the abstract unchanged but clarified the methods by rewriting the sentence to read, “When reviewers completed spreadsheet cells differently, websites were re-reviewed and discussed to achieve consensus.” The U.S.-based nature of this work is now emphasized throughout, including the fact that the IOM is U.S.-based, that most contributors to the NGC are from the U.S., and that the 101 included developers all appear U.S. based (see pages and quotes in response to Reviewer #1, who voiced similar concerns).

2. Background: second paragraph: unclear why reference is made to only these 3 organisations. If a systematic review was carried out, please identify. Internationally other organisations do involve patients in guideline development such as the National Institute for Health and Care Excellence (NICE).

RESPONSE: There was no systematic review for the background for this paper. The background refers to three organizations that advise on guideline development (page 4, lines 22-23), not independent guideline developers. There is no doubt that NICE is an excellent example of how guideline developers engage patients thoroughly and well, but they are not an organization that advises others on guideline development and thus are not mentioned here.

Identify when referring to IOM

RESPONSE: The meaning of this suggestion is unclear. “Institute of Medicine” is written out in the patient summary and the abstract and in the main text, is defined in the first sentence of the background before proceeding to use the abbreviation “IOM.”

fifth paragraph; a reference re the consensus is needed. Identification of how many guideline developers were surveyed should be provided in order to contextualise the percentages. The following overview of percentages of the study lacks clarity.
RESPONSE: The sentence about consensus reflects the many preceding references including the G-I-N standards, the G-I-N PUBLIC toolkit, the AGREE-2 instrument, etc. It would be somewhat disingenuous to cite a single reference here, though we could cite the G-I-N reference if desired. With regards to the Lavis survey publication, we have edited the sentence to read, “where 39% of 31 guideline developers…” (page 5 lines 19-20).

3. Methods: Please state what IRB is. Reporting of participants is confusing between what is an organisational guideline developer and what is an independant guideline developer. Unsure as to what a producer of a 'rare guideline' is. Does this mean an organisation that does not frequently produce guidelines? The methodology used is not stated.

RESPONSE: We have now written out “institutional review board” instead of using the IRB abbreviation (page 6, line 13). An “organizational member of G-I-N North America” is an organization that is a member of G-I-N North America (as opposed to a person who is an individual member). An “independent guideline developer” is explained in the last sentence of the paragraph: “G-I-N North America organizational members that help societies develop guidelines but do not have internal methodologies of their own were excluded, as were organizations in the NGC that only adapt guidelines or collaborate on others’ guidelines with no independent guideline process” (page 6, lines 23-26). The second half of the relevant sentence describes the meaning of rare guidelines. Based on recommendations from a prior reviewer, this sentence now reads, “Because the intent was to identify practices of active guideline developers (so as not to artificially lower estimated PPI frequency by including organizations who rarely produce guidelines), organizations with only one guideline in the NGC since 2011 were excluded” (page 6, lines 20-23).

4. Data extraction: second paragraph, third sentence is unclear and confuses the process.

RESPONSE: We rewrote the sentence in question to now read, “Because the most recently published guideline was not easily identifiable for all developers, in cases where methodology was assessed by reviewing a published guideline, each reviewer noted the guideline that he or she used for this purpose. Knowing the guideline used to assess methodology assisted in reconciling differences in data extraction (page 7, lines 5-7).

56. Results: the use of the term ‘at least sometimes’ is very ambiguous. How is this quantified? There is an assumption that the term 'post' is clear, expand to state posted online / on their website. When making statements such as 'only half of US guidelines developers ...' please refer this back to the research 'only half of US guideline developers in this study...' The last sentence of the results section is confusing; this new information was subsequent to what? Consideration should be given to whether this should be in the results section of in the discussion. This section would benefit from clearer reporting.

RESPONSE: “At least sometimes” is the term used to state when there is evidence that developers do the activity in question at least some but not all of the time. This was a response option during data extraction which used drop-down menus within Excel for consistency (Additional file 1), so this cannot be altered at this stage in the project. The word “post” has been removed (page 9 line 8) and now the sentence reads, “The NGC search for organizations
publishing guidelines between March 1, 2011 and November 25, 2015…” (page 9, lines 7-9). The phrase “in this study” was not added to the results as the context is clear that the results presented in this section refer to the US guideline developers within the study, which, given the methods used, should reflect most regular guideline developers in the United States. The “subsequently” in the last sentence of results refers to the preceding sentence (now slightly rephrased based on another reviewers’ comments): “During conduct of the study conduct there was no identified evidence that any developer creating patient versions engaged patients or the public in that process” (page 12 line 27 to page 13 line 2).

7. Discussion: second paragraph again the number of organisations participating in the 2008 survey need to be stated. Fifth paragraph discusses known barrier to use of PPI, yet this was not outlined as an aim of the study. If it was it should be included. If not, then this paragraph may sit better in the background section.

RESPONSE: We have added the number of organizations in the 2008 survey to the discussion, where the sentence now reads, “…where 39% of 31 guideline developers reported involving consumers…” (page 13, line 19). Identifying barriers was not an aim of the study, nor was it part of the study (none of the results pertain to barriers). We believe that the paragraph on barriers to patient engagement in guidelines is an important part of the discussion because part of the job of the discussion is to put the results into context. In this case, the barriers help explain why patient engagement in guidelines may be so low.

From a presentation perspective, the following needs to be addressed; a grammar and spelling check is needed; there is a confusion of tenses, with the past being used and then the present when reporting results; abbreviations should only be used once the term has been written in full (IOM, CPG); consider using Institute of Medicine in the title for clarity; there is a confusion of terms such as public friendly or patient friendly; definitions would be more easily accessible if listed

RESPONSE: We have written out “IOM” now in the title. IOM is used within the text only after the full term is written out. The abbreviation “CPG” was only used in the context of a quote (limiting the ability to edit its appearance) but we have now added “[clinical practice guideline]” within the quote (see also Reviewer 1). There was a list of abbreviations in the manuscript with submission; this is located on page 17. We have reviewed references to patient- and public-facing guideline materials and have edited most of these to read “patient- and public-facing” or to use the term “patient/public.” This is indeed a challenge in the field. It is difficult to know in this and similar contexts whether the correct phrase is “patient,” “consumer,” “public,” or some variation; we have tried to use the terms where most appropriate in any given context. We have re-reviewed the document and edited tense for consistency. There are areas of the document that use present tense and others that use past tense, but we see the reviewer’s point about varied tenses within paragraphs in the results section and have edited the results section to make tenses consistent.
Reviewer #5: This study is a useful addition to the literature on patient and public involvement (PPI) in developing clinical practice guidelines. It effectively highlights the gap between PPI standards and practice in the U.S. and the need for substantial improvement.

The rationales for PPI in guideline development are helpfully outlined in your discussion section. These rationales are important and so I suggest including very brief reference to them in the abstract and plain English summary. In addition to the articles you have referenced, I suggest also referring to: 'Patient and Public Involvement in the Development of Healthcare Guidance: An Overview of Current Methods and Future Challenges' - Rashid A, Thomas V, Shaw T & Leng G. in The Patient: Patient Centred Outcomes Research, ISSN 1178-1653, 2016, Vol 9, No 5.

RESPONSE: We added the following sentence to the plain English summary (page 2, lines 21-25): “This is a missed opportunity, as patient and public contributions to guideline development include assessing guideline priorities, introducing new topics, identifying important populations and outcomes, suggesting whether findings are meaningful, prompting holistic approaches to care, assessing how recommendations interact with patient values, and writing plain-language guideline versions.” A similar sentence has been added to the abstract, “This is a missed opportunity, as patient and public contributions to guideline development include assessing guideline priorities, introducing new topics, identifying key populations and outcomes, informing whether findings are meaningful, prompting holistic approaches to care, assessing how recommendations interact with patient values, and writing plain-language guideline versions.” We appreciate the suggestion of another related reference. We looked up this article and unfortunately, it is not freely available and so we are unable to read it to determine if/where this should be referenced in the current manuscript. The references cited in the article (available on the journal page) overlap heavily with the references in the current manuscript and the references cited in the current manuscript, so we believe the same information is largely covered with the current cited references.

Although your study focuses on the U.S., it is good to see reference to the international consensus on the importance of PPI in guideline development including the work of the Guidelines International Network (G-I-N).

RESPONSE: Thank you, and we agree that G-I-N does important work in this area.

Page 2, line 57 - Typo - I think this should read 'Compliance with these standards'

RESPONSE: Added “with” (page 3, line 6)

Page 5, line 58 - Please spell out IRB in full Page 7, lines 20-58 - I suggest including these definitions in a glossary not in the main text, providing this fits in with the format for this publication.

RESPONSE: IRB is spelled out. The glossary is at the end of the manuscript as specified in the submission instructions.
Page 9, line 58 - Please clarify what you mean by 'protocols for guideline development', e.g. do you mean the protocols for each review question, as described in line 4, p.10 as 'draft research plan'?

RESPONSE: We have rephrased this sentence to read, “Only 6 developers post guideline development protocols for public comment prior to project initiation at least sometimes (Table 2)” (page 10, lines 10-11).

Page 11, line 29 - Please clarify what you mean by 'mandatory' public comment.

RESPONSE: Rephrased to read, “There is no difference in the number of guideline developers requiring public comment for all guidelines between G-I-N North America members and contributors to the NGC…” (page 12, lines 7-8).

Page 12, lines 17/18 - Typo - I think this should be 'During the conduct of the study'

RESPONSE: We are uncertain of the distinction between “during study conduct” and “during the conduct of the study” but we have made the suggested change.

Page 12, line 54 - I agree there does seem to have been a lack of progress in the U.S. since the IOM standards were published in 2011. Do you have evidence to back up this statement in reference to any baseline U.S. data prior to the publication of the IOM standards?

RESPONSE: We have changed the phrasing of this; please see response to Reviewer #1’s similar comment for details.

Reviewer #6: Great work. Important and good to see. A couple of minor comments:

p5, Line 49 - please specify if 'communication' is one of the IOM standards. If not perhaps highlight why it was selected

RESPONSE: Communication is not one of the IOM standards. We have now further outlined the IOM standards (page 4). On page 5, we describe that the patient engagement mechanisms suggested by the IOM “reflect two of the three described strategies for PPI in guidelines…” (line 9). At the end of the introduction, we explain how/why we used both the IOM and the G-I-N PUBLIC framework as framing mechanisms: “We considered both the IOM standards and G-I-N PUBLIC toolkit as framing mechanisms, looking at active PPI in guideline development groups (Standard 3, participation), external review and public comment (Standard 7, consultation), and the production of patient- and public-targeted guideline products (communication)” (page 6, lines 6-9).

p5, Line 58 - please define IRB p6, Line 11 - please define 'independent guideline developer'. it's a sub-category in the analysis but here it is a pre-requisite for inclusion
RESPONSE: Independent guideline developer is further clarified in the last sentence of the participants paragraph: “G-I-N North America organizational members that help societies develop guidelines but do not have internal methodologies of their own were excluded, as were organizations in the NGC that only adapt guidelines or collaborate on others’ guidelines with no independent guideline process (page 6, lines 23-26). The only place where the term “independent guideline developer” is a subcategory in the analysis is in Table 1 and we have renamed that row “unaffiliated guideline developer” for clarity. Thank you for pointing this out.

p8, Line 27 - please reference 'Wilson's method'

RESPONSE: Wilson’s method is simply a standard statistical approach to calculating confidence intervals, like doing an ANOVA or a t-test, which are not typically referenced.

p14, Line 9-10 - discrepancies between patient and physician views are not necessarily barriers, but are precisely the reason you want patients in the room!

RESPONSE: As noted above, the description of “discrepancies between the views of patients and physicians [13]” as a barrier is not the opinion of the authors but rather the reflection of the provided reference. The referenced paper states, “Notably, a discrepancy between the perspectives of experts and patients/the public was the most frequently reported barrier (8/71)” (page E51 of the cited reference PDF). We have tried to emphasize this fact further by adding the phrase “(the most commonly identified barrier in a knowledge synthesis)” to the paragraph (page 14, lines 25-26). We hope this will direct the reader to the reference – an excellent review – to read further about what was characterized under this barrier (it reflects both developer and patient perspectives).

p15, Line 15 - slightly misleading. the study looked at the PPI approaches of guideline developers. The way it's phrased implies a systematic assessment of PPI methodologies as a concept whereas this was a more practical examination of how individual developer organisations put these concepts into practice.

RESPONSE: The page numbers in our draft do not match those of the reviewer, but we think the reviewer is referencing the beginning of the last paragraph of the discussion. We have rephrased this sentence to use the suggested “approaches” rather than “strategies” (page 15, line 22).

p15, line 31 - alongside trustworthiness there's also the issue of credibility and implementability if patients haven't been included in developing recommendations P15, lines 38 onwards. It might also be interesting to reflect on how North American compares with other GIN members. Maybe the next project!

RESPONSE: We agree that PPI is likely to impact implementability, though to our knowledge, this has not yet been demonstrated in guideline implementation research. We hint at this throughout the manuscript, but mostly end up focusing on educational materials as one implementation tool (eg page 15 lines 14-21), only one small component of implementability. Without studies showing that guidelines are more implementable when they involve patients,
though, our ability to make this case is limited. We completely agree that it would be interesting to look at PPI across G-I-N and survey-based approach to this is in development.