PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	A review of evidence on the links between patient experience and clinical safety and effectiveness
AUTHORS	Lennox, Laura; Doyle, Cathal; Bell, Derek

VERSION 1 - REVIEW

REVIEWER	Dr Karen Luxford Director, Patient Based Care Clinical Excellence Commission Sydney, NSW, Australia
REVIEW RETURNED	31-Jul-2012

THE STUDY	No supplemental information that would be better in manuscript. Leave as is.
GENERAL COMMENTS	This is a very well written paper addressing a topical and important question. Increasingly around the world there is an interest in the relationship between patient care experience and clinical effectiveness, safety and operational outcomes. This paper is a marvellous synthesis of the evidence to date. Excellent work! Authors - please check 2nd paragraph in Results section to ensure Table and Figure numbers are correct.

REVIEWER	Professor Glenn Robert Chair in Healthcare Innovation & Quality King's College London United Kingdom There are no competing interests.
REVIEW RETURNED	01-Aug-2012

THE STUDY	The authors are clear that they are conceptualising patient experience in the very broadest terms from the outset of the paper but - importantly - do not describe or discuss how it has been conceptualised and measured in the studies included in the review. Are all the studies, for example, using patient satisfaction surveys as the sole measure of patient experience? Are some using qualitative data? Do the studies focus on one specific aspect of patient experience? Do different onceptualisations and measures of patient experience result in different associations? You could use the sub-themes under your relational and functional categories to help organise the data more clearly (as you have done in table 3 for the 'outcomes'). This is a somewhat complex area to be exploring for 'associations' but the authors could frame this more clearly at the start of the paper, included these details in table 4 and return to this issue in their discussion.

	A key point is that it is not clear (page 5) how the authors extracted the data from the papers that met their inclusion criteria, nor whether any form of quality appraisal was undertaken on the papers. The 'data collection process' (PRISMA) is not at all clear.
RESULTS & CONCLUSIONS	The authors raise the important distinction between (a) patient level and (b) organisational level studies but do not return to this in either their results or discussion sections. How many of the included studies fell into each category and what are implications for the overall findings? The authors state (page 7) that 'Not all studies demonstrated associations, but those showing associations between patient experience and the other two domains of quality outweigh those that don't', and on page 8 the authors then conclude that 'The moderate strength of associations ...'. But the paper does not provide any details to support these assertions and so the reader is left unsure as to the strength or weakness of the evidence-base underpinning the conclusions. This limitation also relates to the point made above that it appears that no quality appraisal of the included studies has been undertaken. If so, presumably, the (far fewer) studies showing no association could be of a much higher quality than those that do? Table 4 could include these details (this would then follow the PRISMA guidelines on 'Results of individual studies') as well as summarising how 'patient experience' was measured in each study (see point above). (For example, the authors themselves state (page 8) 'The suggested association between measures of patient experience ...' and later on same page 'patient experience data' but the paper does not explore what these measures/data were or the implications of using different measures for establishing whether there are associations with effectiveness and safety). Is there a difference between those studies that explored 'relational', 'functional' and/or 'relational/functional' aspects of patient experience? The authors state (page 7) that 'associations ... appear consistent across a range of disease areas, study designs, settings, population groups and outcome measures' but the way their results are currently presented does not make this clear. Given the 4,000 word limit of the journal there is sufficient scope to present the results in more detail. It seems that predominantly the associations reported are with clinical effectiveness (rather than patient safety)? This warrants a comment and discussion. Overall, the authors should take a more critical perspective to their presentation, analysis and discussion of the included studies and their findings.
REPORTING & ETHICS	Data collection process' and of the PRISMA checklist where further work and presentation of results are required.
GENERAL COMMENTS	This is a potentially important contribution to the field but feels like a bit of a missed opportunity as currently drafted. The paper raises several significant points but the way in which the resilts are currently presented and discussed means that they are insufficiently addressed. I also had a significant concern about the 'data collection process' stage of the review - see comments above.

	Overall, I was also unsure as to why the article was only 1853 words as the journal instructions allow a 4000 word limit. The paper is an important one and with revision would raise significant points which certainly warrant a more detailed presentation of your results and further discussion. I hope some of the points (and suggestions for where further elaboration is needed) made in my review are helpful in this regard. Minor point: top of page 6 makes cross-reference to 'table 2'. Presumably this should be 'table 4'?

VERSION 1 – AUTHOR RESPONSE

Tables 6 and 7 now describe in detail how each study conceptualised and measured patient experience and contains specifics of the methods used to measure both patient experience variables and safety and effectiveness variables. It makes it more explicit what data has been extracted from each study to enable us to draw our conclusions. We have explained in more detail the inclusion criteria and quality criteria, the steps taken to sift through the evidence and our inclusion and quality criteria.

For each study we count associations that either support or refute the hypothesis and this enables us to be more precise about the weight of evidence overall and compare the strength of evidence in different areas and suggest areas where more research is needed. In Table 4 we assess the weight of evidence categorised by type of safety and effectiveness measure. This enables us to assess the relative strength of the evidence in different areas, differentiating strong evidence (e.g. adherence and medication compliance) from those areas where more research is needed (e.g. safety, technical quality of care) and we now discuss these differences in more detail in the discussion section.

While we have kept the distinction between ‘relational’ and ‘functional’ in the section on framing our understanding of patient experience, it is less helpful when comparing evidence and we think the more detailed or granular analysis in Tables 4, 6 and 7 enables us to assess comparative strength of evidence and priorities for future research more clearly.

From Tables 6 and 7 it is now possible to see that there are only a few studies where the weight of evidence showing associations outweigh those that don’t and we make the point in the text that there is no indication that these stand out as methodologically superior to others.

The reference to ‘moderate strength of associations’ in the article in the first draft wasn’t well expressed. In this redraft we have explained that although all findings on associations are statistically significant it should be acknowledged that the strength of associations vary. Due to time constraints and heterogeneity of study designs and measures we did not attempt to stratify and systematically compare the strengths of associations in different studies, but we suggest this is potentially an area for further work.

The reviewer was correct that there is more evidence regarding clinical effectiveness rather than patient safety. We demonstrate this in the data in Table 4 and raise it in the discussion as a priority for future research.

VERSION 2 – REVIEW

REVIEWER	Professor Glenn Robert Chair in Healthcare Quality & Innovation National Nursing Research Unit King's College London

	No competing interests.
REVIEW RETURNED	02-Oct-2012

THE STUDY	Description of methods: (1) did you really 'snowball' all 5323 references or just the 55 you included? presumably the latter but even then it looks like a very small yield (n=35); need a little more description and clarity as to what form the 'snowballing' took and when you did it, (2) under 'study strengths and limitations' section you raise issue of statistical significance - this needs to come much earlier and be described in your 'methods' section (see other comments re positive/negative nature of associations which should also be addressed in methods section), (3) minor point but wouldn't 'mechanisms' be better than 'pathways' in first paragraph of 'methods'? Abstract/key messages: (1) abstract needs a close proof-read (e.g. use of brackets). (2) and final sentence in 'results' section of abstract needs clarifying - do you mean 'overall it was more common to find positive associations between patient experience and patient safety and clinical effectiveness than no association' Standard of writing: at places there are notes in the manuscript saying 'ADD REFS' - all needs very careful proof reading. Often the language to describe key concepts in the paper is inconsistent. References: (1) shouldn't the 'relational', 'functional' distinction be clearly referenced to Val Iles work (Iles V and Vaughan Smith J. Working in health care could be one of the most satisfying jobs in the world - why doesn't it feel like that? 2009 (available at http://www.reallylearning.com/)) or wherever you are drawing on this material? (2) References 9 and 10 in introduction seem to be in wrong order?
RESULTS & CONCLUSIONS	Presentation: (1) you seem to have lost the 'Results' section heading? (presumably just before paragraph above table 3?) (2) I couldn't make the various totals of associations add up - 556 in text, 378 in table 4 and 270 in table 5. Am sure there's a good reason but needs explaining to the reader Interpretation: (1) how many were US studies, you say 'most' but you must know the number/% of the 40 empirical studies at least, (2) 'patient-centred care' gets a mention for the very first time (I think) in the conclusion. Either make it more prominent in the introduction or don't use it at all - personally I don't think the paper needs it (3) the biggest issue re interpretation is that your findings can't support your conclusion that a good patient experience 'may result in important clinical benefits etc'; your findings relate to positive associations between 2 or 3 domains of quality, they don't actually indicate in what direction those links might be (i.e. safer care is positively associated with a better patient experience (not the other way around)). Need to be very careful with way you word your conclusions to make this clear - you have shown positive associations between 2/3 domains of quality not causality. Clarity: throughout the paper (1) suggest use 'patient experience', 'patient safety' and 'clinical effectiveness' as your three domains of quality. At various places (including the title and 'key messages') you use alternative (e.g. 'clinical safety', 'health outcomes', 'clinical outcomes); just be consistent, (2) you must be clear throughout

	whether you are discussing 'positive associations' (i.e. a better patient experience is associated with safer/more effective care), 'negative' associations (a better patient experience is associated with less safe/ effective care or vice versa) or no associations at all. At the moment the paper implicitly suggests you are referring to 'positive associations' throughout - just need to be clear about this in the methods section and review wording elsewhere. Use 'positive associations' throughout (including tables) if this is what you mean (3) in final paragraph you use term 'measures' when really you mean 'dimensions of quality'
GENERAL COMMENTS	This is a frustrating paper to review!! There is a good and helpful paper here - and the revisions already made have improved it - but it still needs considerable tightening up in places. I hope the authors will persevere and that they can make the suggested amendments to the paper - partly I suspect the remaining shortcomings in the paper are a function of the work being a 'time-limited' review but there are also aspects of the paper that just need better drafting and a little more thought (rather than requiring the authors having to go back and revisit their methods and results). It does require further revisions along lines suggested before being acceptable for publication. You may want to acknowledge in limitations that simple counts of studies (or associations in this case) is the weakest form of 'synthesis' but the time-limited nature of your review meant this was all you could do - it's clearly a weakness not to have formally appraised the quality of the 55 included studies and taken these into account in your synthesis and I think you should be up front about this. There's still plenty if the paper of interest as a starting point to think about these links.

VERSION 2 – AUTHOR RESPONSE

Reviewer comment: Description of methods: (1) did you really 'snowball' all 5323 references or just the 55 you included? presumably the latter but even then it looks like a very small yield (n=35); need a little more description and clarity as to what form the 'snowballing' took and when you did it

Response: We have expanded the description a bit as follows and redesigned the graphic to clarify. ‘Given concerns about the sole use of protocol-driven search strategies for complex evidence, for the full text articles retrieved for review, we used a ‘snowballing’ approach to identify further studies. This involved sourcing further articles in these studies for assessment and using the ‘related articles’ function in the PubMED database. We repeated this for new articles identified until the approach ceased to identify new studies. ‘

Reviewer comment: (2) under 'study strengths and limitations' section you raise issue of statistical significance - this needs to come much earlier and be described in your 'methods' section (see other comments re positive/negative nature of associations which should also be addressed in methods section)

Response: We refer to statistical significance in the methods section in the following sentence. ‘Associations refer to cases where one measure of patient experience (typically an overall rating of patient experience for a care provider) has a statistically significant association with one or more effectiveness or safety variable.’ We also now specify in the methods section that we checked for both negative and positive associations and that a negligible number of negative associations were found.

Reviewer comment: minor point but wouldn't 'mechanisms' be better than 'pathways' in first paragraph

of 'methods'?

Response: Agree and change made

Reviewer comment: Abstract/key messages: (1) abstract needs a close proof-read (e.g. use of brackets). (2) and final sentence in 'results' section of abstract needs clarifying - do you mean 'overall it was more common to find positive associations between patient experience and patient safety and clinical effectiveness than no association' .

Response: We agree this is a better wording and we have used it. The article has been closely proof-read.

Reviewer comment: References (1) shouldn't the 'relational', 'functional' distinction be clearly referenced to Val Iles work (Iles V and Vaughan Smith J. Working in health care could be one of the most satisfying jobs in the world - why doesn't it feel like that? 2009 (available at http://www.reallylearning.com/)) or wherever you are drawing on this material? (2) References 9 and 10 in introduction seem to be in wrong order?

Response: This was something that came via Angela Coulter's work and if that came via Iles's work we missed it so thanks for pointing it out. We have now included as a reference.

Reviewer comment: …you seem to have lost the 'Results' section heading? (presumably just before paragraph above table 3?)

Response: Rectified.

Reviewer comment: I couldn't make the various totals of associations add up - 556 in text, 378 in table 4 and 270 in table 5. Am sure there's a good reason but needs explaining to the reader

Response: We have adjusted the text to explain that in both tables we are referring to subsets of cases where sufficient information was available to make these categorisations.

Reviewer comment: How many were US studies, you say 'most' but you must know the number/% of the 40 empirical studies at least

Response: 28/40 – text changed

Reviewer comment: (2) 'patient-centred care' gets a mention for the very first time (I think) in the conclusion. Either make it more prominent in the introduction or don't use it at all - personally I don't think the paper needs it (3)
Response: Agree it's not needed. Has been removed.

Reviewer comment: The biggest issue re interpretation is that your findings can't support your conclusion that a good patient experience 'may result in important clinical benefits etc'; your findings relate to positive associations between 2 or 3 domains of quality, they don't actually indicate in what direction those links might be (i.e. safer care is positively associated with a better patient experience (not the other way around)). Need to be very careful with way you word your conclusions to make this clear - you have shown positive associations between 2/3 domains of quality not causality.

Response: We did say in the original submission and the resubmission that association does not entail causality and used tentative language such as 'may', 'suggest' etc to avoid misleading conclusions but we accept that may not have been sufficient. Therefore we have reworded the last 3

paragraphs as follows:
‘The inclusion of patient experience as one of the pillars of quality is partly justified on the grounds that patient experience data, robustly collected and analyzed, may help highlight strengths and weaknesses in effectiveness and safety and that focusing on improving patient experience will increase the likelihood of improvements in the other two domains.

The evidence collated in this study demonstrates positive associations between patient experience and the other two domains of quality. Because associations do not entail causality, this does not necessarily prove that improvements in patient experience will cause improvements in the other two domains.

However, the weight of evidence across different areas of healthcare indicates that patient experience is clinically important. There is also some evidence to suggest that patients can be used as partners in identifying poor and unsafe practice and help enhance effectiveness and safety. This supports the argument that the three dimensions of quality should be looked at as a group and not in isolation. Clinicians should resist sidelining patient experience measures as too subjective or mood-orientated, divorced from the ‘real’ clinical work of measuring and delivering safety and effectiveness.

Reviewer comment: Clarity throughout the paper (1) suggest use 'patient experience', 'patient safety' and 'clinical effectiveness' as your three domains of quality. At various places (including the title and 'key messages') you use alternative (e.g. 'clinical safety', 'health outcomes', 'clinical outcomes); just be consistent

Response: The document has been reviewed to ensure more consistent terminology. On a few occasions we use the terms ‘effectiveness’ and ‘safety’ as short hand to prevent the text becoming too repetitive.

Reviewer comment: you must be clear throughout whether you are discussing 'positive associations' (i.e. a better patient experience is associated with safer/more effective care), 'negative' associations (a better patient experience is associated with less safe/ effective care or vice versa) or no associations at all. At the moment the paper implicitly suggests you are referring to 'positive associations' throughout - just need to be clear about this in the methods section and review wording elsewhere. Use 'positive associations' throughout (including tables) if this is what you mean (3) in final paragraph you use term 'measures' when really you mean 'dimensions of quality'

Response: We have now clarified and made more explicit in the text that we searched for all 3. Negative associations were only found in one of the 40 individual studies. We have added this text. Negative associations were rare. Of the 40 individual studies assessed in Table 6 negative associations (between patient experience of clinical team interactions and continuity of care and separate assessment of the quality of clinical care) were found in only one study.

Reviewer comment: You may want to acknowledge in limitations that simple counts of studies (or associations in this case) is the weakest form of 'synthesis' but the time-limited nature of your review meant this was all you could do

Response: Extracting the data to get a sense of what the evidence was telling us certainly wasn’t simple but we acknowledge there may be scope for meta analysis in some areas. We’ve added the following sentence in strengths and limitations section.
‘There may also be scope to explore whether future research in this area could go beyond the counting of associations in this study through, for example, meta-analysis.

Reviewer comment: It's clearly a weakness not to have formally appraised the quality of the 55 included studies and taken these into account in your synthesis and I think you should be up front about this. There's still plenty if the paper of interest as a starting point to think about these links.

Response: We do not want to give the impression we did not consider the quality of studies included but acknowledge the point. We have added this text to strengths and limitations.
While we used some quality criteria to filter studies (including the use of validated tools to measure experience, safety and effectiveness outcomes and sample size), with more time a more detailed formal quality assessment may have added value to the study.