Reviewer’s report

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

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Reviewer: Janet Wale

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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.

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.

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.

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)

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

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.

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?

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.

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.

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.

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).
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.

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.

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

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

Abstract, Background (page 2), line 50: state that it is the United States Institute of Medicine.

lines 57/59: …compliance with …these standards.

Results (page 3), line 29: …public comment on draft guidelines;

Conclusions, line 38: …and practice within the United States,

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.

Methods, page 6, line 15: would read better as '…including organizations who rarely produce guidelines…'
Results, page 11, line 29: '…sometimes performed by an additional 2%…'

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

Line 58: '. developers reported involving…'

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An article of importance in its field

**Quality of written English**
Please indicate the quality of language in the manuscript:

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