**Author's response to reviews**

**Title:** Development of a Prototype Clinical Decision Support Tool for Osteoporosis Disease Management: A Qualitative Study of Focus Groups

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**Author's response to reviews:** see over
Response to Reviewers
Development of a Prototype Clinical Decision Support Tool for Osteoporosis Disease Management: A Qualitative Study of Focus Groups

Dear Editor:

Thank you very much for the opportunity to publish our work in your journal. We have carefully considered all comments and have revised the manuscript accordingly. We addressed the reviewers’ questions and comments below (highlighted in blue), and have also amended the manuscript accordingly (please see both marked and unmarked versions attached).

Editor Comments

1. Please adhere to the RATS guidelines for reporting qualitative studies

Response: We carefully examined the RATS guidelines to ensure that we adhered to all factors.

2. Provide a copy of the questionnaire administered in your study as an additional file to your submission

Response: We attached an electronic copy of the focus group questionnaire guide.

3. Provide a copy of the support tool developed for your study as an additional file to your submission

Response: Figures 1-3 of the original submission represent the 3 components of the osteoporosis tool:
- Component 1 = risk assessment questionnaire (RAQ);
- Component 2 = best practice recommendation prompt (BestPROMPT);
- Component 3 = customized osteoporosis education (COPE)

However, we also attached 3 additional electronic files that show the evolution from conceptual design to post-focus group version of the RAQ (Figure 8), BestPROMPT sheet for physicians (Figure 9), and the COPE sheet for patients (Figure 10). We also added a sentence about this in the “Discussion” section of the manuscript (pg. 16-17).
Reviewer 1 Comments:

Major revisions

1. A major limitation is the small sample size. We know little about the practices of the doctors in the focus groups. Do they treat OP or refer? What percent of their practice treats patients at risk for osteoporosis (age 50+ in women)?

   **Response:** Unfortunately we did not assess these factors in our focus group study. We are currently evaluating the osteoporosis tool in 3 family practice settings (in Hamilton Ontario), and found that approximately 30-40% of the patient population of the 5 participating family physicians consists of people aged ≥ 65 (men) and ≥ 50 (women), who represent those at risk for osteoporosis.

Minor revisions

2. Define ORAI

   **Response:** We defined ORAI on pg. 14 of the manuscript (i.e., osteoporosis risk assessment instrument).

3. Discuss the generalizability of the findings to other clinical decision support tools such as FRAX

   **Response:** The osteoporosis tool developed in the current study is unique from other osteoporosis tools such as FRAX in several ways. FRAX is an instrument designed to assess the percentage 10-year probability of a fracture based on major risk factors (and it also calculates BMI). Our osteoporosis tool is based on the same risk factors but our tool goes beyond by addressing all aspects of disease management (risk, diagnosis, and treatment). Our osteoporosis tool is designed not only to assess risk for osteoporosis and fractures but also provides customized recommendations for initiating diagnostic testing (i.e. bone mineral density testing) and initiating appropriate treatment (e.g. bisphosphonates) at the point of care. Our tool also involves patients in the risk assessment process at the point of care (thus the tool incorporates a patient self-management aspect). Furthermore, the tool also generates customized education for patients that they can take with them after the visit. We included more detail about the tool on pg. 5 of the manuscript to highlight these points, and we added a sentence about the FRAX tool (also on pg. 5).

4. The authors note that doctors find it time consuming to find BMD results. Could the decision support tool be completed by the bone density technologist to help the doctor?

   **Response:** This is a great idea, and in future studies, we will consider other health care professionals such as bone density technologists and nurses as other potential targets for the tool.
Reviewer 2 Comments:

Minor essential revisions

1. Pg 2 and 3 – the numbers (under 10) should be spelled out I believe

   **Response:** We are not aware of this rule, but happy to correct if the journal requires it.

2. Pg 3, abstract (under results) would use semicolons for more clarity that these are distinct points

   **Response:** We placed semicolons between the points in the first sentence of the Results in the abstract (pg 3 of the manuscript).

3. Pg 3/4, references in the Background section seem out-dated, and too many are web-sites. Not sure where the 32.5 billion estimate off the OC website is from (it was last accessed in 2007), should find an actual publication based on

   **Response:** Unfortunately most of the prevalence and cost data have not been updated since this study, particularly for Canadian data. Most data come from the Osteoporosis Canada website, which other authors of publications also site. We provided another reference to support the $32.5 billion estimate (see pg. 3 of the manuscript).

4. Pg 4 – 2nd paragraph, “Findings indicated that few…” awkward sentence, suggest re-wordings

   **Response:** We re-worded this sentence to clarify (see pg. 4 of the manuscript).

5. Pg 4 – last sentence 2nd paragraph, who was the multi-component intervention carried out on (physicians)?

   **Response:** The multi-component intervention in the Cranney et al study (2008) is targeted to both family physicians and patients. We indicated this in the manuscript (see pg. 4-5).

6. Pg 5 – the description of the 3 components is wordy and could be made more clear and concise

   **Response:** We included more detail about the 3 components of the tool to clarify (see pg. 5 of the manuscript).

7. Methods – were there any incentives offered for participating – mainpro credits, financial, etc?
Response: Focus group participants were offered a compensation of $200 for their time and participation in the study.

8. Pg 8, Results section 1st paragraph, 1/3 is not a small proportion”
   Response: We deleted “small” from this sentence (pg 8 of the manuscript).

9. Pg 10 – Under Theme 5, add sentence that linke relevance of this theme to CDSS (you discuss relevance in discussion on Pg 18)
   Response: We would prefer to state only the findings under the “Results” section so that it is consistent with the way other results are presented. We believe that discussion around linking theme 5 to CDSSs makes most sense in the “Discussion” section of the paper.

10. Pg 13 – two typos under 1st paragraph – possible “damage” and participants “were”
    Response: We corrected these on page 13 of the manuscript.

11. Table 1 – there is a star in the title – which doesn’t make sense – it should probably be starred under the row with CPOE and EMR
    Response: The asterisk in the title was used as a convention to refer to abbreviations used within the table (and which are defined in the footnote).

12. Also pertaining to comment #11 – there is an inconsistency as it says EMR in the row, and EHR in the table footnote
    Response: We corrected this (i.e. EMR was changed to EHR – pg. 27 in the manuscript).

13. Figure 2 – there is mention of t-score in the Risk Assessment Questionnaire Summary provided to the physicians – where will this come from, as in the paper you discuss how it’s infeasible for either patient, nursing or admin staff to enter this information
    Response: Figure 2 represents the “conceptual” design of what this output may look like, which includes t-score information in the risk assessment questionnaire summary. Following the focus group study, this output was changed to reflect the problems around clinic staff or physicians having to enter this information. Please see attached, additional figures depicting the evolution of changes that were made before and after the focus groups (please see attached Figures 8-10).

14. Avoid short forms like RAQ, COPE, if possible (just spell it out), was confusing, particularly since they are not standard terms
Response: We agree that using abbreviations is not ideal, but we feel that it is necessary in this case since they are used frequently throughout the manuscript and would be very long and repetitive if all cases were spelled out.

15. The interview guide should be included as an Appendix – there is also no mention of the interview guide was developed, based on what etc?

Response: We included the interview guide as an Appendix (see pg. 6 of the manuscript. We also attached the document to the re-submission.

The interview guide was developed based on our research questions, and pilot tested with physicians for clarity – pilot testing led to some modifications to the guide that was subsequently used for the focus groups. We added a sentence to reflect this (pg. 6 of the manuscript).

16. Under data collection and analysis there are other point of care tools used for other disease groups, should acknowledge any other studies on this – furthermore under results, it is not mentioned if prior exposure to other point of care tools was assessed, as many physicians may have used for diabetes, high cholesterol, etc

Response: We are not clear what the reviewer is asking in the first part of this question, i.e.: “Under data collection and analysis there are other point of care tools used for other disease groups, should acknowledge any other studies on this”.

In response to the second part of the question, prior exposure to point of care tools was not assessed quantitatively since this was a major question we wanted to explore qualitatively. One set of interview guide questions was dedicated to finding out whether participants would use a CDSS/tool in their practice (including those they’re already using), why/why not, how it might be used in their practice, what barriers they might foresee in implementing it, and how such a system would work if it were available at the point of care.

17. Even though someone actually said this, under results, the quote on patients lying is not very positive or appropriate, recommend using another quote here

Response: We mean no disrespect by including this quote, we only indicated what the participant said verbatim. We included this quote because it had a large impact on how the “Alcohol” and “Caffeine” questions on the risk assessment questionnaire were subsequently changed.

18. The paragraph just above next steps in the conclusion, seems more appropriate in the methods section

Response: We included this statement under “Limitations” because it directly relates to how we dealt with threats to validity. However, we added a sentence
about pilot testing the focus group questions in the methods as per the reviewer’s question #15 above, which will reiterate this point.

19. What was the funding source – what paid for the focus groups – this should be spelled out?

   **Response:** We added a statement after “Competing interests” to state that this study was funded by a CIHR operating grant (pg. 20 of the manuscript).

Major Essential Revisions

1. Methods: There is very little description of the recruitment process – yet in the discussion it is mentioned under limitations i.e. problems with recruitment and a change in strategy. This needs to be outlined clearly and transparently in the methods section.

   **Response:** We included a sentence to describe the recruitment process further (page 7 of the manuscript).

2. In the methods or results section, it is required to mention how many people were actually approached, how many declined, etc.

   **Response:** We included a few sentences to provide more detail on the number of physicians invited and number that attended (pg. 7 of the manuscript).

3. Methods section – it needs to be better described how it was determined that physicians involved in the care of patients with osteoporosis were selected – was this an assumption or was some other method used to determine this such as billing codes?

   **Response:** We were interested in the perceptions of family physicians (who regularly see patients at risk for or with osteoporosis) as well as specialists who were involved in the care of patients with osteoporosis. We wanted to exclude specialists not involved in the care of patients with osteoporosis from the focus groups as the discussion would not be relevant for them. We clarified this point on page 6 of the manuscript.

Discretionary Revisions

1. There is very little discussion of the actual risk assessment tool etc. that constitutes the components. It should be given a couple of sentences at least, or make reference if you have another paper where you discuss the tool development more and how and why various questions and risk assessment items were included. Also, how does yours fit in light of the other tools that are out there, CAROC in Canada, and FRAX. Presumably the 10-year graph referred to a couple of times is from the CAROC.
model (Canadian Association of Radiologists and Osteoporosis Canada, denoted as CAROC)?

**Response:** The osteoporosis tool developed in the current study is unique from other osteoporosis tools such as FRAX in several ways. FRAX is an instrument designed to assess the percentage 10-year probability of a fracture based on major risk factors (and it also calculates BMI). Our osteoporosis tool is based on the same risk factors but our tool goes beyond by addressing all aspects of disease management (risk, diagnosis, and treatment). Our osteoporosis tool is designed not only to assess risk for osteoporosis and fractures but also provides customized recommendations for initiating diagnostic testing (i.e. bone mineral density testing) and initiating appropriate treatment (e.g. bisphosphonates) at the point of care. Our tool also involves patients in the risk assessment process at the point of care (thus the tool incorporates a patient self-management aspect). Furthermore, the tool also generates customized education for patients that they can take with them after the visit.

We included more detail about the tool on pg. 5 of the manuscript to highlight these points, and we added a sentence about the FRAX tool (also on pg. 5).

The 10-year fracture risk graph in our osteoporosis tool was adapted from the work done by Siminoski K, et al (see pg. 24 references), which outlines recommendations for bone mineral density reporting in Canada, and the shift to absolute fracture risk assessment.

There are new Canadian guidelines currently being reviewed and will be out shortly – so there should be some consideration of the consistency with these.

**Response:** The tool developed in the current study used the most recent version of the Canadian osteoporosis practice guidelines (2002) for programming the decision algorithm. However, we are aware of the new guidelines that are soon to be published and are planning to incorporate relevant changes from these guidelines in the tool’s decision algorithm.

2. Last paragraph before methods is where it first comes up – it may not just be a sheet given to patients at end of “physician visit” as there are many practices where a nurse practitioner or other health care professional could be interacting with the patient, instead of just the physician

**Response:** We agree, the provision of the COPE sheet to patients can be done by anyone at a clinic, but will depend on a workflow analysis of the clinic to determine the best route for this (and the BestPROMPT) sheets to be administered and by whom.