

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)	Engaging Patients Through Open Notes: An evaluation using mixed methods
AUTHORS	Esch, Tobias; Mejilla, Roanne; Anselmo, Melissa; Podtschaske, Beatrice; Delbanco, Tom; Walker, Jan

VERSION 1 - REVIEW

REVIEWER	Kim Nazi Department of Veterans Affairs, USA
REVIEW RETURNED	26-Oct-2015

GENERAL COMMENTS	<p>General Comments:</p> <p>The paper describes a mixed methods evaluation of OpenNotes users to further understand the experience of patients accessing their clinical visit notes. As a complement to previously reported quantitative findings, this primarily qualitative study has the potential to add depth and validate early findings. As such, the study findings are timely, relevant, and have the potential to be a contribution to the literature. However, several concerns suggest that a major revision is warranted.</p> <p>Specific comments =====</p> <p>Major comments -----</p> <ol style="list-style-type: none"> 1. The introduction section fails to adequately contextualize the study and its findings by 1) painting a broad picture of 'transparency' in medical records but then distracting with a gloss of "shifting care toward more integrated perspectives", 2) summarizing the most salient controversies as "discouraging some patients from seeing doctors when actually necessary" and "shifting important face to face visits to virtual encounters" rather than noting other well documented controversies in the literature, and 3) providing a too brief overview of survey findings noting "clinical benefits". A more focused introduction is needed to contextualize this work, especially focusing on the very specific aspect of enabling patient access to clinical notes, and the findings reported in the literature to date. 2. The methods section was challenging to follow and I found it necessary to re-read and rely on a detailed examination of the appendix and figures. Suggest that this needs to be more clearly written. 3. The methods section does not provide adequate information about the survey or data collection. If the quantitative findings from the survey were previously reported and this report included a full description, then the authors should reference that but repeat relevant details here as well. 4. The methods indicate that qualitative analysis of free text survey responses included both baseline surveys and post surveys;
-------------------------	--

	<p>however little distinction is made between themes at baseline versus after users had been reading their notes (Post survey). I would really question inclusion of baseline data—unless it is made distinct and fully represented as user’s perspectives BEFORE having the experience of reading their notes. Similarly, the post survey themes for a user who viewed their notes 0 times does not reflect the same sample as a more frequent user post survey. Are Figure 4 and Figure 5 also reflective of user’s perspectives who did not read their notes? or patients who did read their notes before they did so at baseline? This concern also applies to Appendix 4 which aims to characterize the themes by user characteristics but without distinguishing between read/didn’t read and before/after across variables.</p> <p>5. The authors note using quantitative descriptive analysis as a method, however do not provide any description or citations. A scan of the literature did not reveal use of this method for this kind of analysis—is this a valid method for the study design? It seems to have been used for consumer sensory product analysis but there is no description or justification for its use in qualitative content analysis.</p> <p>6. The authors use the term “member checking” loosely—how is the output from the pre-study immersion project member checked by the QIA?</p> <p>7. The authors introduce the PAM but then quickly discount the findings. A more thoughtful examination of the findings here is warranted.</p> <p>8. The themes resulting from the cross arm analysis benefit from the sample quotes, however there is at times overlap that introduces lack of clarity. For example, on page 7 the theme “sharing notes and withholding information” then states “Frequent users seemed eager to comment on notes or have parts corrected” which would seem to be more appropriate related to the theme above: “clarity, error detection, and correction.”</p> <p>9. In both the introduction and the discussion (as well as the information box), related work completed at the Department of Veteran Affairs appears to have been overlooked, even though the authors note on page 9 that their goal was to “both reflect and refer to the full body of existing literature and knowledge in the field”</p> <p>a. Nazi KM, Turvey CL, Klein DM, Hogan TP, Woods SS. VA OpenNotes: exploring the experiences of early patient adopters with access to clinical notes. J Am Med Inform Assoc 2014;0:1–7.</p> <p>b. Woods SS, Schwartz E, Tuepker A, Press NA, Nazi KM, Turvey CL, Nichol WP. Patient Experiences With Full Electronic Access to Health Records and Clinical Notes Through the My HealtheVet Personal Health Record Pilot: Qualitative Study. J Med Internet Res 2013;15(3):e65 doi: 10.2196/jmir.2356</p> <p>Minor comments: -----</p> <p>1. Typographical errors in reference #2, #28</p> <p>2. In figure 2 it is unclear what the footnote means “totals include only initial note and progress note”?</p> <p>3. On page 9, suggest qualifying “portals and electronic medical records cannot currently handle...” with “To our knowledge”</p> <p>4. The information box on page 12 discusses revisiting the original cohort and gather primary data from this expert panel. This is somewhat misleading unless the analysis focuses on post survey free text comments.</p>
--	--

	5. On page 7, does better clarity of health information mean that users found notes to result in better clarity, or that notes need better clarity?
--	---

REVIEWER	Dale Rose, DHA, MS, RN, CENP University of Maryland Medical Center USA
REVIEW RETURNED	28-Oct-2015

GENERAL COMMENTS	Very relevant topic to current health care environment with patient engagement and population health. Excellent use of mixed methods. Clearly written article that adds to body of knowledge. Study appears to have been done with fairly high literacy/education level population (only measurement with or without college.) This is an additional limitation- would like to see future open notes study with lower literacy population.
-------------------------	--

VERSION 1 – AUTHOR RESPONSE

Reviewer 1

1. The introduction section fails to adequately contextualize the study and its findings by

1) painting a broad picture of ‘transparency’ in medical records but then distracting with a gloss of “shifting care toward more integrated perspectives”,

2) summarizing the most salient controversies as “discouraging some patients from seeing doctors when actually necessary” and “shifting important face to face visits to virtual encounters” rather than noting other well documented controversies in the literature, and

3) providing a too brief overview of survey findings noting “clinical benefits”. A more focused introduction is needed to contextualize this work, especially focusing on the very specific aspect of enabling patient access to clinical notes, and the findings reported in the literature to date.

Response: ✓

We re-wrote the introduction section.

2. The methods section was challenging to follow and I found it necessary to re-read and rely on a detailed examination of the appendix and figures. Suggest that this needs to be more clearly written.

Response: ✓

We re-wrote the methods section.

3. The methods section does not provide adequate information about the survey or data collection. If the quantitative findings from the survey were previously reported and this report included a full description, then the authors should reference that but repeat relevant details here as well.

Response: ✓

A new paragraph about the original survey and data collection was added.

4. The methods indicate that qualitative analysis of free text survey responses included both baseline surveys and post surveys; however little distinction is made between themes at baseline versus after users had been reading their notes (Post survey). I would really question inclusion of baseline data—unless it is made distinct and fully represented as user's perspectives BEFORE having the experience of reading their notes. Similarly, the post survey themes for a user who viewed their notes 0 times does not reflect the same sample as a more frequent user post survey. Are Figure 4 and Figure 5 also reflective of user's perspectives who did not read their notes? or patients who did read their notes before they did so at baseline? This concern also applies to Appendix 4 which aims to characterize the themes by user characteristics but without distinguishing between read/didn't read and before/after across variables.

Response: ✓

- i) For a clearer and more specific distinction between baseline data and post-intervention data we added a new paragraph (also see no. 3).
- ii) For a more detailed description about our procedures and how we dealt with baseline versus post data, we additionally provided information (added another paragraph).

5. The authors note using quantitative descriptive analysis as a method, however do not provide any description or citations. A scan of the literature did not reveal use of this method for this kind of analysis—is this a valid method for the study design? It seems to have been used for consumer sensory product analysis but there is no description or justification for its use in qualitative content analysis.

Response: ✓

This term refers to the quantitative part of our mixed methods evaluation (i.e., the quantitative analysis of our primary data – theme/code counts and code frequencies), using Atlas.ti analysis software for technical support. Since this (◊analytic induction, by applying the codebook that iteratively evolved over the various analytic cycles, and then counting codes with referral to characteristics of the study population, or the time of survey – pre to post) can only be done descriptively, not inferentially, we speak of quantitative-descriptive analysis, saying that it is a description of the 'secondary quantification' of our primary/qualitative data...; please see also our response to no. 4.

6. The authors use the term “member checking” loosely—how is the output from the pre-study immersion project member checked by the QIA?

Response: ✓

We decreased and specified the use of the term throughout the text.

7. The authors introduce the PAM but then quickly discount the findings. A more thoughtful examination of the findings here is warranted.

Response: ✓

We added information/a more critical viewpoint (◊reference) in the discussion section.

8. The themes resulting from the cross arm analysis benefit from the sample quotes, however there is at times overlap that introduces lack of clarity. For example, on page 7 the theme “sharing notes and withholding information” then states “Frequent users seemed eager to comment on notes or have

parts corrected” which would seem to be more appropriate related to the theme above: “clarity, error detection, and correction.”

Response: ✓

We modified the theme (headline) in this rubric to now include ‘commenting/co-authoring of notes’; in addition to that, we specified what was meant with “corrected” – thus the overlap could now be avoided and clarity should be restored.

9. In both the introduction and the discussion (as well as the information box), related work completed at the Department of Veteran Affairs appears to have been overlooked, even though the authors note on page 9 that their goal was to “both reflect and refer to the full body of existing literature and knowledge in the field”

Response: ✓

We added said references (at various points – where applicable) and also updated our literature search with some more recent studies retrieved and then, in parts, added (studies that we might have overlooked due to their actuality).

a. Nazi KM, Turvey CL, Klein DM, Hogan TP, Woods SS. VA OpenNotes: exploring the experiences of early patient adopters with access to clinical notes. J Am Med Inform Assoc 2014;0:1–7.

b. Woods SS, Schwartz E, Tuepker A, Press NA, Nazi KM, Turvey CL, Nichol WP. Patient Experiences With Full Electronic Access to Health Records and Clinical Notes Through the My HealtheVet Personal Health Record Pilot: Qualitative Study. J Med Internet Res 2013;15(3):e65 doi: 10.2196/jmir.2356

Minor comments:

1. Typographical errors in reference #2, #28

Response: ✓ (corrected)

2. In figure 2 it is unclear what the footnote means “totals include only initial note and progress note”?

Response: ✓ (footnote specified)

3. On page 9, suggest qualifying “portals and electronic medical records cannot currently handle...” with “To our knowledge”

Response: ✓ (“To our knowledge” added)

4. The information box on page 12 discusses revisiting the original cohort and gather primary data from this expert panel. This is somewhat misleading unless the analysis focuses on post survey free text comments.

Response: ✓ (specified)

5. On page 7, does better clarity of health information mean that users found notes to result in better clarity, or that notes need better clarity?

Response: ✓ (specified)

Reviewer: 2

Please leave your comments for the authors below Very relevant topic to current health care environment with patient engagement and population health. Excellent use of mixed methods. Clearly written article that adds to body of knowledge. Study appears to have been done with fairly high literacy/education level population (only measurement with or without college.) This is an additional limitation- would like to see future open notes study with lower literacy population.

Response: ✓

We addressed this issue and possible additional biases in the discussion section.

VERSION 2 – REVIEW

REVIEWER	Kim Nazi Department of Veterans Affairs, USA
REVIEW RETURNED	23-Nov-2015

GENERAL COMMENTS	The authors revisions in response to reviewer comments have strengthened the paper and addressed previously noted concerns.
-------------------------	---

REVIEWER	Dale Rose University of Maryland Medical Center USA
REVIEW RETURNED	25-Nov-2015

GENERAL COMMENTS	Improved clarity of writing objectives and participant definition. Introduction is stronger and draws greater reader interest. . Improved background with OpenNotes follow-up findings. This version of the article has a more detailed description of the researchers' methods, including eligibility requirements, data collection, and data analysis. In the discussion, the addition of Mosen et al. strengthens the authors' point. Some clarity is added in the area of privacy and the need for future research. Good addition of the Institute of Medicine recommendation of adoption of OpenNotes.
-------------------------	--