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.

This paper was submitted to the JECH but declined for publication following peer review. The authors addressed the reviewers’ comments and submitted the revised paper to BMJ Open. The paper was subsequently accepted for publication at BMJ Open.

ARTICLE DETAILS

| TITLE (PROVISIONAL) | How Context Affects Electronic Health Record-Based Test Result Follow-up: A Mixed-Methods Evaluation |
|---------------------|--------------------------------------------------------------------------------------------------|
| AUTHORS             | Singh, Hardeep; Menon, Shailaja; Smith, Michael; Sittig, Dean; Petersen, Nancy; Hysong, Sylvia; Espadas, Donna; Modi, Varsha |

REVIEWER

| REVIEWER       | Peter Cram |
|----------------|------------|
| University of Toronto |
| Toronto, Canada |

REVIEW RETURNED

| REVIEW RETURNED | 03-Aug-2014 |

GENERAL COMMENTS

1. This paper addresses an important topic: the role of organizational culture and context in explaining missed test results. The researchers provide important insights about how organizational differences may play a role in explaining differences in the frequency of missed test results. The differences are interesting given that the researchers work in (and studied) a fairly hierarchical and centralized health system (The VA).

2. The authors frequently used the terms “contextual” and “sociotechnical” but do not make it clear precisely what these terms mean. It would be useful to provide specific examples wherever possible and avoid jargon to the extent possible.

3. The authors spend much of the methods describing the process of facility selection and matching, but the description of the actual survey development is quite brief. I would suggest less description of the matching (or moving some of the detail to an Appendix), and more detail describing the actual survey. In particular: you might think about providing the conceptual model as a figure; it would be useful to make it clear how the various interview questions were mapped to the results in Tables 2 and 3 (as it stands, it isn’t always clear which questions your results were pulled from, or maybe include the actual interview guide as an Appendix).

4. The Analysis section could use additional details. As described above, it would be helpful for the reader to know which questions provided qualitative data and which provided quantitative data. Similarly, it appears that some of the closed ended questions were dichotomous (Yes/No) and others were categorical, this isn’t clear. Also, it would be useful to describe the process by which the
"Scenarios" were developed; right now, this isn't described in the methods section. Methods should describe techniques used to generate results; typically, all results have a corresponding description in the methods section.

Detailed comments
1) Abstract, Results: Not clear what is meant by "clinician designees." Please clarify.
2) Abstract, Conclusion: Could you be a bit bolder? What should hospitals consider doing in light of your findings?
3) Background, Line 42: Could you provide some specific examples of what "system factors" are important?
4) Background, final sentence: Could you provide a specific example of what "contextual factors" might be important?
5) Methods: You might consider presenting the actual conceptual model as a Figure or Table.
6) Methods, Setting, final sentence: Could you provide an example of the "policies and procedures" that facilities can implement to improve test management?
7) Methods: How do facilities decide which tests/results should be included on the "alert list?" Is this decided centrally or do hospitals have discretion? If hospitals do have discretion, how do they decide which test results are "critical" and which are not?
8) Methods: As mentioned previously, it would be helpful to make it more clear what quantitative data were collected. As written, it is a bit hard to see precisely which questions led to quantitative data and which questions provided qualitative results.
9) Methods: I did not see a clear statement of IRB approval (though assume that you had it). Also, it would be useful to know what statistical package was used for the quantitative analysis (SAS? STATA?).
10) Results: I found Tables 2 and 3 quite difficult to understand. Would it be possible to explain both tables a bit better? Also, it was a bit hard to see how the results in the Tables related back to the specific interview questions (Table 1).
11) Results, scenario 1: Could you clarify what you mean by "leaving the facility?" Does this mean leaving for the day or leaving on vacation? Or something else (leaving for a new position?)
12) Discussion, 1st sentence: While 5-10 years ago I do think that it would have been fair to say that there are few studies looking at missed test results in a health system with an EHR, today I don't think that this is quite accurate. There have been a number of good quality studies of missed test results. A few include:

- Callen J, Georgiou A, Li J, Westbrook JI. The safety implications of missed test results for hospitalised patients: a systematic review. BMJ Qual Saf. 2011 Feb;20(2):194-9. doi: 10.1136/bmjqs.2010.044339. Epub 2011 Feb 7. Review. PubMed PMID: 21300992; PubMed Central PMCID: PMC3038104.

- Callen J, Paoloni R, Georgiou A, Prgomet M, Westbrook J. The rate of missed test results in an emergency department: an evaluation using an electronic test order and results viewing system. Methods Inf Med. 2010;49(1):37-43. doi: 10.3414/ME09-01-0011. Epub 2009 Nov 5. PubMed PMID: 19893851.

- Gordon JR, Wahls T, Carlos RC, Pipinos II, Rosenthal GE, Cram P. Failure to recognize newly identified aortic dilations in a health care system with an advanced electronic medical record. Ann Intern Med. 2009 Jul 7;151(1):21-7, W5. PubMed PMID: 19581643.
• Roy CL, Rothschild JM, Dighe AS, Schiff GD, Graydon-Baker E, Lenoci-Edwards J, Dwyer C, Khorasani R, Gandhi TK. An initiative to improve the management of clinically significant test results in a large health care network. Jt Comm J Qual Patient Saf. 2013 Nov;39(11):517-27. PubMed PMID: 24294680.

• Cram P, Rosenthal GE, Ohhsfeldt R, Wallace RB, Schlechte J, Schiff GD. Failure to recognize and act on abnormal test results: the case of screening bone densitometry. Jt Comm J Qual Patient Saf. 2005 Feb;31(2):90-7. Review. PubMed PMID: 15791768.

REVIEWER
Anuj K Dalal
Brigham and Women's Hospital, USA

REVIEW RETURNED
05-Aug-2014

GENERAL COMMENTS
This is a well written and informative manuscript that identifies and describes socio-technical contextual factors that are important for organizations to consider in mitigating the issue of missed test results. It is a meaningful contribution to current literature.

#1 Conceptual Model - Consider adding a figure or online supplement illustrating the conceptual model and how it informed the questions in the interview guide. It was not initially clear that the socio-technical dimensions mapped to the eight constructs of the conceptual model in Table 1.

#2 Methodology to characterize perceived vulnerability of facilities. This is a key assumption and limitation in the study. What was the PCP response rate to the survey for each facility? How many facilities had a response rate >60%? As the authors pointed out, the survey assessed perception of missed test results, not actual missed test results. What about non-PCP providers? Could they have a different perception of missed test results at the same facility? This is an important bias to address. Finally, was this methodology previously validated (i.e., did the authors previously correlate actual missed test results to perception of missed test results)?

#3 Methodology to prioritize facility pairs. Seems reasonable and appropriate, albeit a bit complex

#4 Analysis. A mixed-methods approach is very appropriate.

#5 Results. Quantitative data in Table 2 and 3 are detailed, consider summarizing more succinctly if possible. The authors assume that unread test results are synonymous with unacknowledged results; however, different providers may have different perceptions of what it means to "read" vs "acknowledge" a test result in the context of an electronic health record. A subtle but important distinction. Qualitative data re: high risk scenarios are excellent.

#6 Discussion. Seems appropriate and informative with regard to key findings. Consider adding emphasizing key limitations and assumptions highlighted in #2.

The authors should emphasize key limitations and assumptions in the discussion more carefully (i.e., subjective assessment of PCP perception of missed test results to assess perceived facility
Reviewer 1

General comments
1. This paper addresses an important topic: the role of organizational culture and context in explaining missed test results. The researchers provide important insights about how organizational differences may play a role in explaining differences in the frequency of missed test results. The differences are interesting given that the researchers work in (and studied) a fairly hierarchical and centralized health system (The VA).

Our Response: We thank the reviewer for these comments.

2. The authors frequently used the terms “contextual” and “sociotechnical” but do not make it clear precisely what these terms mean. It would be useful to provide specific examples wherever possible and avoid jargon to the extent possible.

Our Response: We have provided a description of the term sociotechnical factors and provided examples (Page 4, last paragraph). After the initial definition, we have consistently used the words sociotechnical factors throughout the paper.

3. The authors spend much of the methods describing the process of facility selection and matching, but the description of the actual survey development is quite brief.

Our Response: We used only two questions from the PCP survey to calculate perceived vulnerability (for facility selection). Thus, the description of the survey was brief. While the details of the PCP survey are published elsewhere (Reference #17), we have now added more text about survey development (Page 7, second paragraph). In this mixed-method study we conducted semi-structured interviews, and we have now added more information regarding development of the interview guide for interviews (page 9, second paragraph).

3-a. I would suggest less description of the matching (or moving some of the detail to an Appendix), and more detail describing the actual survey.

Our Response: We added details about the survey (Page 7, second paragraph) and reduced the length of text related to matching. We believe the methodology used to select the facilities is an important part of the study design, so we retained some important details of the facility selection in the main body of the manuscript.

3-b. In particular: you might think about providing the conceptual model as a figure; it would be useful to make it clear how the various interview questions were mapped to the results in Tables 2 and 3 (as it stands, it isn’t always clear which questions your results were pulled from, or maybe include the actual interview guide as an Appendix).

Our Response: We have included the eight-dimensional sociotechnical model in the paper as Figure 1 (Page 6). We have updated Table 2 and grouped the interview questions under the relevant sociotechnical dimension. We have added the actual interview guide to Appendix 1. However, some of the interview questions (demographics) were not included in Table 2.

4. The Analysis section could use additional details. As described above, it would be helpful for the reader to know which questions provided qualitative data and which provided quantitative data.

Our Response: In Appendix 1 we have provided a list of structured questions used for the quantitative analysis (results presented in Table 2).

Similarly, it appears that some of the closed ended questions were dichotomous (Yes/No) and others were categorical, this isn’t clear.

Our Response: Categorical variables are marked with an asterisk (*). A note to Table 2 explains how five continuous variables were categorized into dichotomous groups.

Also, it would be useful to describe the process by which the “scenarios” were developed; right now,
this isn’t described in the methods section. Methods should describe techniques used to generate results; typically, all results have a corresponding description in the methods section.

Our Response: We have provided a detailed description of the procedure involved in conducting qualitative content analysis. We did not use a separate methodology to develop the scenarios. A semi-structured format used for the interviews allowed the respondents to voice their concerns regarding a number of safety issues related to alert management. After initial code validation, researchers (SM, MS and SH) identified transcripts, with discussion about potentially high-risk situations. These transcripts were further analyzed to identify most salient high-risk scenarios.

Detailed comments:
1) Abstract, Results: Not clear what is meant by “clinician designees.” Please clarify.
Our Response: We changed this to surrogate to be consistent with the paper and explained in the paper that, before clinicians leave their offices for an extended period, they are expected to designate another clinician (surrogate) to receive their alert notifications.
2) Abstract, Conclusion: Could you be a bit bolder? What should hospitals consider doing in light of your findings?
Our Response: We added the following line to the conclusion:
“In addition to implementing provider-level strategies to prevent missed test results, healthcare organizations should consider implementing monitoring systems to track missed test results”.
3) Background, Line 42: Could you provide some specific examples of what “system factors” are important?
Our Response: We have provided example of system factors (page 4)
4) Background, final sentence: Could you provide a specific example of what “contextual factors” might be important?
Our Response: We have made a change in response to your concern.
5) Methods: You might consider presenting the actual conceptual model as a Figure or Table.
Our Response: Table 1 (pages 9 and 10) maps interview questions to the Eight-Dimensional Sociotechnical Model. We have included the model in our manuscript (page 6).
6) Methods, Setting, final sentence: Could you provide an example of the “policies and procedures” that facilities can implement to improve test management?
Our Response: We have provided an example of the “policies and procedures” (Page 7).
7) Methods: How do facilities decide which tests/results should be included on the “alert list?” Is this decided centrally or do hospitals have discretion? If hospitals do have discretion, how do they decide which test results are “critical” and which are not?
Our Response: We have explained this point on page 6 (last paragraph).
8) Methods: As mentioned previously, it would be helpful to make it more clear what quantitative data were collected. As written, it is a bit hard to see precisely which questions led to quantitative data and which questions provided qualitative results.
Our Response: We have added the interview guide to the Appendix. Open-ended questions were used for qualitative analysis. Close-ended/structured questions were used for quantitative analysis.
9) Methods: I did not see a clear statement of IRB approval (though assume that you had it). Also, it would be useful to know what statistical package was used for the quantitative analysis (SAS? STATA?).
Our Response: We have a statement regarding IRB approval (Page 5, end of last paragraph). Quantitative analyses were done using SAS® version 9 software (page 11).
10) Results: I found Tables 2 and 3 quite difficult to understand. Would it be possible to explain both tables a bit better? Also, it was a bit hard to see how the results in the Tables related back to the specific interview questions (Table 1).
Our Response: We have modified Table 2 to clearly group questions corresponding with sociotechnical dimensions.
11) Results, scenario 1: Could you clarify what you mean by “leaving the facility?” Does this mean leaving for the day or leaving on vacation? Or something else (leaving for a new position)?
Our Response: We have added clarification (Page 16, third paragraph).
12) Discussion, 1st sentence: While 5-10 years ago I do think that it would have been fair to say that there are few studies looking at missed test results in a health system with an EHR, today I don’t think that this is quite accurate. There have been a number of good quality studies of missed test results. A few include:

Our Response: We thank the reviewers for suggesting additional references. We have updated our references and changed statements regarding available evidence (Page 19, last paragraph).

Reviewer: 2
Reviewer Name: Anuj K Dalal
Institution and Country: Brigham and Women’s Hospital, USA. Please state any competing interests or state ‘None declared’: None declared

This is a well written and informative manuscript that identifies and describes sociotechnical contextual factors that are important for organizations to consider in mitigating the issue of missed test results. It is a meaningful contribution to current literature.

Our Response: We thank the reviewer for these comments.

#1 Conceptual Model - Consider adding a figure or online supplement illustrating the conceptual model and how it informed the questions in the interview guide. It was not initially clear that the sociotechnical dimensions mapped to the eight constructs of the conceptual model in Table 1.

Our Response: This point was raised by the other reviewer, and we have added the Eight-Dimensional Sociotechnical Model to the paper and explained how it informed questions. (See Table 1 and Figure 1.)

#2 Methodology to characterize perceived vulnerability of facilities. This is a key assumption and limitation in the study. What was the PCP response rate to the survey for each facility? How many facilities had a response rate >60%? As the authors pointed out, the survey assessed perception of missed test results, not actual missed test results.

Our Response: We agree and have acknowledged this limitation. Only two facilities had more than a 60% response rate. The lowest was 42%.

What about non-PCP providers? Could they have a different perception of missed test results at the same facility? This is an important bias to address.

Our Response: We agree with the reviewers and added this to limitations of the study on Page 21. We have used perceptions of the PCPs to characterize perceived vulnerability of facilities. Non-PCPs perhaps may have a different perception about vulnerability of facilities. However, in the VA PCPs play a key coordination role, receive most alert notifications and are most often responsible for follow-up action. Thus, using perceptions of the PCPs seems to be a reasonable approach.

Finally, was this methodology previously validated (i.e., did the authors previously correlate actual missed test results to perception of missed test results)?

Our Response: While this methodology is not validated to ensure actual missed test results correspond to perception of missed test results, two findings from the survey suggest that PCP perceptions of test-results issues might be fairly accurate. One, self-reported number of alerts, in the survey was 63; and this is fairly similar to results of a quantitative study that found this to be 58 (Reference #25). Second, about 29.8% of PCPs reported missed results (reference # 13), which is comparable to other surveys, including 37% reported by Wahls (reference # 3) and 22.2% reported by and Giardina (see reference below).

1. Giardina, T.D., Callen, J., Georgiou, A., Westbrook, J.I., Greisinger, A., Esquivel, A., Forjuoh, S.N., Parrish, D., Singh, H. Releasing Test Results Directly to Patients: A Multisite Survey of Physician Perspectives. 2014. Under Review at Patient Education and Counseling

#3 Methodology to prioritize facility pairs. Seems reasonable and appropriate, albeit a bit complex.

Our Response: We removed some complex details, as suggested by Reviewer 1.

#4 Analysis. A mixed-methods approach is very appropriate.

Our Response: Thank you for the comment.

Results. Quantitative data in Table 2 and 3 are detailed; consider summarizing more succinctly if possible.

Our Response: We have made some modifications to the format of the tables and removed Table 3
from the manuscript. We agree with the reviewer regarding the details presented in the tables. We have presented data on a range of sociotechnical factors related to test-result management to give others an idea of what we studied; thus, the tables are lengthy.

The authors assume that unread test results are synonymous with unacknowledged results; however, different providers may have different perceptions of what it means to "read" vs "acknowledge" a test result in the context of an electronic health record. A subtle but important distinction.

Our Response: We agree that different providers may have different perceptions of what it means to "read" vs "acknowledge" a test result in the context of an electronic health record. However, for this paper we did not use PCP survey data related to "acknowledged" test results. The data presented here are based on our interview with CACs and PCPs.

Qualitative data re: high risk scenarios are excellent.

Our Response: Thank you for the comment.

#6 Discussion. Seems appropriate and informative with regard to key findings. Consider adding emphasizing key limitations and assumptions highlighted in #2.

Our Response: We have discussed the issue of perceptions regarding missed test results (limitations and assumptions highlighted in #2) in the limitations. We have also discussed the possibility of bias because non-PCPs were not included.

The authors should emphasize key limitations and assumptions in the discussion more carefully (i.e., subjective assessment of PCP perception of missed test results to assess perceived facility vulnerability; possibility that PCP response rate was variable by facility; lack of other providers in the original surveys and potential for bias, etc.).

Our Response: We have added the points raised by the reviewer to limitations of the study (Page 21).