Author's response to reviews

Title: Impact of a web-assisted tobacco quality improvement intervention of subsequent patient tobacco product use: A National Dental PBRN Study

Authors:

Thomas K Houston II (thomas.houston@umassmed.edu)
Kathryn L DeLaughter (kathryn.delaughter@umassmed.edu)
Midge N. Ray (midgeray@uab.edu)
Gregg H. Gilbert (ghg@umassmed.edu)
Jeroan J. Allison (jeroan.allison@umassmed.edu)
Catarina I. Kiefe (catarina.kiefe@umassmed.edu)
Julie E. Volkman (julie.volkman@va.gov)

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BMC Oral Health
BioMed Central
Floor 6, 236 Gray’s Inn Road
London
WC1X 8HB
United Kingdom

RE: Reviewer comments

Dear Editors,

Thank you for the additional review of our paper. We appreciated the positive comments of the reviewers and the directive critiques. Below, we address each critique in order, and reference the changes in the paper.

Referee 1:
Major compulsory revisions

1. I pointed out in the last review that the authors had written what looks like a misleading abstract. I was shocked to see this come back in much the same state as previously. I cannot make this point strongly enough. The main thing that will be read in this paper is the abstract and it is grossly misleading. First, in my view and in standard statistical theory the statement 'Tobacco use quit rate approached significance (p = .088) between the Intervention and Control groups.' is always wrong. In this instance doubly so. The implication of this sentence in the context of the whole abstract is that there was some evidence the intervention was effective, when in fact the quit rate in the control group was quite a bit higher than the intervention group. It is important in abstracts that the authors give numerical information about the main outcome in the abstract ie quit rates in each group. Please do so here. Second, the conclusion is inappropriate. The conclusion as written states 'Follow-up surveys suggest that the advice giving through dental practices work, yet repeated interventions may be needed to produce a significant increase of self-reported tobacco use quit rates.' There are several errors. First and most important this is not a conclusion that follows from the data in the study. It’s a conclusion about some other studies. Second, I am not sure what a follow-up survey is- do you mean cohort studies? Third, there is no evidence at all that repeated interventions may be needed to support cessation. What is needed is a conclusion about the study in hand. I suggest the following accurately describes the findings; This study shows no evidence that brief advice by dentists increases long-term abstinence in smokers. However, low follow-up rates in the study reduced the ability to detect a difference in cessation'. ....

We apologize, apparently our revised abstract was not submitted with the manuscript. Clearly, this created confusion.

As background: There are two levels of outcomes in this trial. The first is the change in the practice performance. We have demonstrated in a prior publication (Houston et al, JMIR) that we were successful in increasing rates of smoking advice provided by dentists.
In this report, we focus on the subsequent effect on patients. As we report, the practice-level outcome was positive, but the patient-level was negative. There was no difference in rates of smoking cessation comparing the intervention and control in our final adjusted analysis.

However, we disagree slightly with the reviewer about the lack of importance of the unadjusted analysis. There a suggestion of a difference, just not favoring the Intervention. As the reviewer notes, the borderline significant difference favors the control.

In my view, there are two interesting aspects to this report. The first is the overall results of the practice-level intervention on smoking cessation (a negative but valuable result).

The second issue that is valuable is that this is a cluster-randomized trial, a less common study design in the dental literature. This article is an opportunity to demonstrate, in a small way, one the major challenges of a cluster-randomized trial. Namely, that there can be unbalance at levels lower than the cluster (in our case, the patient).

In traditional patient-level randomization trials, the primary analysis is presented unadjusted, as patient characteristics are balanced by randomization.

What we did find is that, in unadjusted analysis, the CONTROL cessation rate was higher than the intervention, and this bordered on statistical significance (p = 0.088), as p = 0.05 is an arbitrary cutoff, we find this interesting although counter to our hypothesis. Not reporting this feels to me like burying an interesting finding.

A simple interpretation of this result, that the INTERVENTION came close to HURTING smoking cessation rates.

However, as we demonstrate, patient characteristics were not balanced (as is common in cluster randomization), and after adjustment, this was a negative study.

We acknowledge that this interesting and uncommon nuance related to study design is far too complex to be conveyed in the abstract. The new abstract reflects the overall negative nature of the study.

However, we have left the full interpretation in the discussion section. Again, I think this would be a valuable addition to the journal and of interest to your readership. If the editors and reviewers wish for us to simply report the negative study without the further detail above, we can remove from the discussion.

We completely agree with the reviewer that the conclusion of the abstract was incorrect, and was the result of a residual typo that stems from the two levels (practice and patient) of this study.

2. The study does not follow the consort statement. Many details are missing.

We apologize for not being comprehensive with the consort statement. Note that this reports one outcome of our trial that has both a dental practice component intervention, and patient follow-up. Thus, not all components of a consort checklist directly relate to this study (ie: randomization was not at the patient level). We agree that more detail is needed in this report. We have tried to balance the
detail in this manuscript with prevention redundancy with the practice-level report we previously published. We have now completed additional sections in the consort statement checklist (see included checklist). In particular, we have included details of the intervention and usual care as described in question #3. Page numbers have been added to the consort statement checklist of the areas where content was added. There are three areas not reported and are not described in this manuscript; these specific areas were 1. Any changes to trial outcomes after the trial commenced; 2. Explanation of interim analyses; and 3. All important harms or unintended effects in each group. Our focus in this manuscript did not touch on these three areas defined in the consort statements; these have been described in prior published manuscripts. If the reviewers and editors wish us to provide more detail on the provider-level intervention or further refine the description of the components of the checklist directly related to this manuscript, we are happy to do so.

3. The authors have not addressed my comments about giving any detail of the intervention. The only statement we have about it is 'and had the opportunity for advanced tobacco use cessation advice.' What was the nature of the advice that dentists were trained to give. I assume you have no data on what advice was actually given, but you surely must report what you think dentists were supposed to do.

We apologize that our detail of the intervention was inadequate. In our previous version, we had added some description of the Intervention in the Introduction:

“One such web-assisted tobacco control quality improvement program for dental practice was delivered using oralcancerprevention.org. This multi-state community-based intervention targeted dentists and dental staff (hygienists and dental assistants) in 140 dental practices. Oralcancerprevention.org included case-based education to train dental providers on how to provide quit tobacco product advice at the point of care, individualized practice improvement planning, workflow support materials, and patient education quit materials. In previous publications from this NIH-funded study, we demonstrated that this web-assisted multi-component intervention resulted in an 11% increase in tobacco use cessation advice in dental practices, significantly greater improvement than control (p < 0.04).”

Because we focus on the patient outcomes, we had previously not provided detail on the provider intervention. A report of the provider intervention has been previously published (See Houston et al JMIIR 2009).

In this new version, the description of the intervention, we have included additional details about what the dental providers were exposed to that they may have then utilized in cessation advice (5As and 5Rs) in the Methods. (Page 7)

4. It is important to understand what the control patients received also and you know, but are not telling us. You say 'Tobacco users in control practices received usual dental care and services. Usual care for tobacco use cessation in the control dental practices was reported in baseline data collection from providers and patients in the practice.' That's great stuff for us to know- please tell us!...
We apologize. Again, this data was reported in our prior paper (Houston et al JMIR 2009), and thus we focused on the novel patient data in this article. However, we agree that this is important context for this paper. Information about pre-intervention “usual care” data reported from practices have been added to methods and results sections. (Pages 7 & 10-11)

5. The results could do with some rewriting. There's a section about the main outcome then something about quit attempts then a re-analysis of the main outcome again....

We have clarified in the main outcome section by reporting the main outcomes all together, and then reporting quit attempts. Adding quit attempts was requested in a prior review. (Pages 10-13)

6. It's almost impossible to follow the 'flow' of this trial in the way it is described. There were 143 practices randomized- how many in each arm? It appears but is not stated that the 100 cards were given out to all attendees, not just smokers, and only the smokers followed up. Please describe this process more clearly and state how many smokers were identified. It should have been the case that 14,300 cards were given out but it appears that only 10% were smokers. You should describe the baseline data on all smokers and those who consented to follow up as well by trial arm. It's not clear why the numbers in the table do not total the number of participants- I assume because of refusal to answer the question.

We apologize for the confusion. Appendix D describes the patients included in this report. In the practice-level analysis (previously reported in Houston, JMIR, 2009), there were two waves of patient exit cards (pre-intervention and post-intervention) 100 cards provided to each practice. As stated in our prior publication, the post-intervention the exit-card response rate was 81.6% (11,678/14,300), with 22% (2,571/11,678) reporting they were smokers. We have now added this to the methods.

7. Did the cards have any data on whether or not the dentist had talked about smoking? I find it hard to believe that this was not included so it should be included in the report.

The exit cards included the questions if they were asked about smoking and if any advice was given on quitting. This data is now in Table 2.

Referee 2:
Major Essential Revision
The paper has been considerably improved by the revisions submitted by the authors.

The outstanding issue is the limited discussion of the results of the study in the context of the literature.....

We had reviewed some of the relevant literature in the introduction. This trial is unique in its approach to intervening with Dental providers through technology, and looking for the impact on patients. We have now added an additional paragraph in the discussion to provide additional context. If the editor or reviewer has specific suggestions, we would be happy to add.
Referee 3:
[Minor Essential Revisions]
2-1. [Abstract] Results and Conclusions are ambiguous. In the present study, the intervention increased the patients’ opportunity to be advised, but did not change patients’ behavior. This result should be more clearly stated in the abstract. Abstract has been revised

2-2. [Page 11, 2nd para.] “p=25” -> “p=0.25”?…. Corrected

2-3. [Page 11, Discussion, 1st para. last sentence] I could not understand the sentence “Our evaluation adds …”. Do you mean that the program changed providers’ behavior but could not change patients’ behavior?… This sentence has been revised.

2-4. [Table 2] “Gave advice to quit tobacco use” -> “Gave advice to quit tobacco use”?… Corrected.

Sincerely,

Thomas Houston, MD, MPH
Professor and Chief Division of Health Informatics
University of Massachusetts Medical School
55 Lake Avenue North
Worcester, MA 01655