Author's response to reviews

Title: Quitline Referral vs. Self-help Manual for Tobacco Use Cessation in the Emergency Department: A Prospective Pilot Study

Authors:

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Author's response to reviews: see over
Dear Editors

We would like to thank the reviewers for the time they spent reviewing our manuscript and for their insightful and helpful comments which, we believe, significantly improve the manuscript. We would also like to thank you for the opportunity to provide these edits and resubmit. We have addressed all the concerns of the reviewers. The abstract section has been significantly rewritten and throughout the remainder of the manuscript we have noted changes addressing reviewer suggestions in **bold**.

Please do not hesitate to contact me with any questions.

Sincerely,

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**Editor**

1) **The reviewers have expressed concerns regarding the study's sample size, lack of comparison group, and the descriptive nature of the results.**

We understand the reviewers’ concerns and have attempted to address them in the “Limitations” section. The study was designed as a pilot and therefore not expected to be powered to be able to detect a difference in the treatment groups. Given the poor participation in outpatient intervention in other studies and our own clinical experience with poor outpatient follow-up for all clinical appointments we make for this population, we were looking to see if Emergency Department (ED) patients would participate at all in the Quitline intervention. We also planned to assess if the outcome follow-up planned was feasible and whether a larger trial with this specific design was warranted. As such the outcome of quitline intervention completion was planned as a descriptive result. The manuscript and abstract have been edited to clarify our objectives.

We believe our results are largely hypothesis-generating and agree that it would be interesting to see how compliance with a patient initiated quitline intervention would be compared to our proactive model. We have added this idea to our discussion section as well.

2) **Structure your abstract, ensuring that a background section is included**

We have made the changes.

3) **Trial registration number - Please submit the revised version of your manuscript with the NCT number included in the abstract.**
We have included trial number in abstract.

**Reviewer #1**

1) **Sample size limitation**

   We have clarified the goals and attempted to address the sample size issue as per the response to the Editors, Comment#1.

2) **Overall Design: Entire flowchart is relevant and should be included in Results section of text, including clarifying that it was 212 smokers that were assessed for eligibility.**

   We have added this information into the Results section of text.

   The most important descriptive result would be to know reasons for refusal in more detail.

   We agree that it would be helpful information to have collected this information and had considered it. However, the busy clinical setting in which this study took place and the acute nature of the presenting complaints limited our ability to ascertain the reason for refusal in detail. We have added what information we collected on reasons for refusal.

3) **Primary outcome is descriptive**

   We have clarified this with revisions to the abstract and manuscript as per the response to the Editors, Comment#1.

   Secondary outcome, completion rates for outcome calls at 3 and 6 months is not an obvious one for a tobacco treatment study and would benefit by more explanation and justification.

   We agree with the reviewer’s concern. This outcome was designed to assess feasibility of this study design in the ED population, not as an outcome for a tobacco treatment study. As such, we anticipated difficulty with follow-up, as our patients frequently are difficult to reach for follow-up of clinical issues, and often do not keep follow-up appointments we arrange. We have clarified this with revisions to the manuscript.

   Wouldn’t it have been more useful to compare use of services in the control to the QL group, or compare some other process measure rather than completion of follow-up calls?

   We agree that it may have been useful to compare the use of the services between the two groups. In the present study, we did not collect data on use of other services.
4) It would be helpful to document efficacy of quitlines, in general, in the introduction

We have included this in the manuscript (Introduction).

5) Define how “no plans to quit” was operationalized.

We have included in the manuscript (Methods, Study Setting & Selection of Participants).

6) Comment on higher number of cigarettes smoked in QL group compared to control group shown in Table 1.

We have included this in the manuscript (Results).

7) Qualify the term “acuity of illness.”

We have included this in the manuscript (Results).

8) Low enrollment rate is highlighted for the first time in Discussion, which seems late.

We have included this information in the Results section.

9) It would be interesting to speculate on a potential relationship between the cause for the ED visit and enrollment in tobacco treatment.

We did not collect data in a way that would allow us to evaluate this. It is an interesting idea, and likely would be worth investigating, particularly for stable chest pain patients as well as those with respiratory complaints. We have added this idea to the Discussion section of the manuscript.

Reviewer # 2

1) No inferential statistics are provided to compare quit rates between the two groups

We have included this in the manuscript (Results).

2) Did the USPHS manual contain the phone number of the national smoker’s quitline?

The manual did not contain this quitline number as we were attempting to assess feasibility of trial comparing a proactive quitline as a counseling intervention to a self-help manual only. Given the complete lack of participation in outpatient counseling in other ED studies and our own clinical experience with poor outpatient follow-up for all clinical appointments we make for this population, we chose the proactive model in the hopes that we could get at least some of this population to participate in a counseling intervention. As such, the outcome of quitline
intervention completion was planned as a descriptive result as part of a feasibility assessment.

The question of whether or not ED patients would utilize a patient initiated quitline was not addressed with our study, but is an interesting question. None of the patients randomized to the control arm, however, requested a phone number for a quitline even after the informed consent process which involved an explanation of what the quitline had to offer. Indeed, anecdotally, our experience was that most of the patients who declined to participate in the study did so because they did not want to spend time on any counseling, even though a previous survey at our ED indicated 27% of smokers (almost all who indicated they were considering smoking cessation in the next month) would be interested in receiving telephone-based counseling.

3) The abstract implies that the quit rates were the primary endpoint, not completion of quitline calls. Please clarify.

The abstract has been substantially revised to address this.

4) Please clarify when study personnel were available

We have included in the manuscript (Methods, Study Setting and Selection of Participants).

5) Was the study open to non-English speakers?

No, the quitline counseling was only available in English. This has been clarified in the manuscript (Methods, Study Setting and Selection of Participants).

6) Data is plural

Corrected in manuscript (Methods, Measurements).

7) Spell out terms such as UTI and DVT

Corrected in manuscript (Results).

8) Report non-normally distributed data as medians and interquartile ranges.

We have provided this information in Table 1. We elected to provide entire range for values such as number of call attempts as we felt this was more descriptive of the effort made to contact study participants for follow-up.

9) It is Wisconsin Center for Tobacco Research and Intervention, and Centers for Disease Control and Prevention.

Corrected in manuscript (Discussion).
10) **Expand Limitations section**

   We have expanded this section.

11) For the electronic references, please provide the dates you accessed them.

   Added to references.

12) **Table 1:** Correct title and report median/interquartile range rather than means.

   Corrected in table 1.

13) **Table 2:** Delete and comment only in manuscript on no differences.

   We have deleted table 2 and included a comment in the manuscript.