Author's response to reviews

Title: A Multilevel Intervention to Promote Colorectal Cancer Screening among Community Health Center Patients: Results of a Pilot Study

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RE: Manuscript #197777901235341 – “Patient Navigation to Promote Colorectal Cancer Screening among Community Health Center Patients: Results of a Pilot Study”

Dear Editors:

Thanks to you and the reviewers for thoughtful comments on our manuscript. The revised manuscript is 3373 words. Below I address each of the reviewers’ comments:

Referee #1’s Comments:

1) Regarding the concern that the methods included 2 forms of intervention, a letter and patient navigation:

We have changed the title of the manuscript to “A Multilevel Intervention to Promote Colorectal Cancer Screening among Community Health Center Patients: Results of a Pilot Study.” We have also changed the conclusions section of the abstract to include the following sentence: “A patient navigator-based intervention, in combination with a letter from the patient’s
primary care provider, was associated with an increased rate of colorectal cancer screening at one health center as compared to a demographically similar control health center.”

2) Regarding the request for a better understanding of the number of charts reviewed to arrive at 93 intervention patients, as well as how the control cases were identified:

We have added language to the manuscript to clarify these points:

“Because the electronic data system did not capture diagnostic tests performed outside of the health center network, one investigator (KEL) reviewed the medical records of all patients at both the intervention and control health centers who appeared unscreened in the data report to confirm that they were, in fact, unscreened. After reviewing 196 medical records at the intervention center and 191 medical records at the intervention center, we identified 93 intervention patients and 90 control patients who had not received colorectal cancer screening according to the criteria specified above.” (page 6, lines 6-12)

8) Regarding the concern that the title and abstract do not accurately convey the findings of the study:

Please see response to concern #1, above.

Specific Essential Revisions

1) Regarding the concern that the title is misleading:

Please see response to concern #1, above.

2) Regarding the request for more updated information on colorectal cancer and screening guidelines in the first paragraph:

We have checked with the American Cancer Society, and the figures presented in the following sentence have not been updated yet: “In 2008, an estimated 148,810 people will be diagnosed with colorectal cancer, and it is estimated that 49,960 will die of the disease. [1]” (page 3, lines 2-3) We have edited the reference to reflect that this website was checked in February 2009. We have added the following sentence to the first paragraph: “Current guidelines from the U.S. Preventive Services Task Force1 recommend screening individuals age 50 until age 75 with one of the following tests: flexible sigmoidoscopy every 5 years, colonoscopy every 10 years, or fecal occult blood test (FOBT) every year.” (page 3, lines 4-7)

3) Regarding the request that we clarify where the prior qualitative study took place, and the concern about PCP bias:

We have edited the first sentence of the second paragraph to specify that the study took place at Cambridge Health Alliance. (page 3, lines 13-14) We have added the following language to the discussion section: “A further potential source of bias is the fact that our qualitative study of barriers to colorectal cancer
screening included one PCP from the intervention site, and no PCPs from the control site. We doubt that a one-hour interview conducted with a PCP in 2005 would have significantly affected his colorectal cancer screening practices.

4) Regarding the concern that patient navigators are not always lay people:

We have edited the text to reflect this distinction:

“Patient navigators are people selected from the community who are trained to guide patients through the health care system to receive appropriate services.”

5) Regarding the suggestion that we add an additional reference to the background section:

We appreciate this suggestion and have added the Nash et al reference accordingly.

6) Regarding a request for clarification of age 52 instead of 50 used as the lower age limit for screening:

We have added the following language to the methods section:

“We chose to begin at age 52 instead of age 50 (the age at which guidelines suggest that screening begin), because we sought consistency with the Healthcare Effectiveness Data and Information Set (HEDIS) measure on colorectal cancer screening. [24] The unscreened patient report used in our study also served as the basis for our ambulatory quality improvement colorectal cancer screening measure.”

7) Regarding the request for information on screening rates prior to this study, the number of charts reviewed to identify intervention and control cases, and the reason why 14 patients were deemed ineligible for outreach due to insurance status:

We have added the following information to the methods section: “Using this definition, 47% of eligible patients in our network of community health centers received colorectal cancer screening in the year 2006. Since the data report did not capture tests performed outside of Cambridge Health Alliance, or FOBT cards that were not billed, we suspect that the true screening rate was higher than 47%.”

Please see response to concern #2 (in first section of responses) above regarding the number of charts reviewed.

We made an a priori decision not to outreach patients if their PCPs felt that they were not good candidates for outreach. We assumed that if a PCP felt that insurance status was a barrier to screening, then the patient was not eligible for free care and that our patient navigators would be unable to provide further assistance to the patients. This assumption may be false, and we may have
underestimated the potential impact of patient navigation. We have added the following sentence to the discussion section: “By excluding these patients, we may have underestimated the potential impact of patient navigation.” (page 14, lines 5-6)

8) Regarding the request for more information on patient navigator age and gender:

We have added the following sentence to the methods: All of the navigators were women, and were age 47, 42, and 37, respectively.” (page 8, lines 1-2)

9) Regarding the request for an explanation of the rationale for choosing 6 months as the point in time to determine screening status following the intervention, and for information on the wait time for a colonoscopy:

We added the following language to the methods section:

“We chose to analyze the data at six months because the wait for a screening colonoscopy at the time of the study was on the order of weeks, and we assumed that patients would have had sufficient time to complete their colonoscopy during the six-month period.” (page 11, lines 9-12)

10) Regarding the request that we consider including more details about race and language in table 1:

Due to small numbers in each race and language category, we are not able to include further details in this table (the table is primarily a presentation of statistical analyses comparing the demographics at the control and intervention health centers). We could add more details about race and language to the text if needed, but again we would caution the interpretation of such details due to small numbers.

11) Regarding the question of what percent of letters were returned as undeliverable, and what was the effect of each of the components of the intervention (letters and navigation), and what were the results of subgroup analyses (race, gender, language, insurance status):

We did not receive any letters returned to sender as undeliverable, though this may reflect a dysfunctional hospital mail system.

We were not able to analyze the individual effects of the different components of the intervention, nor were we able to analyze effects in different subgroups, due to small numbers of patients in the pilot study. We intend to perform these analyses in a forthcoming randomized control trail with a substantially larger sample size. We have added the following language to the discussion:

“Our study is also limited by small sample size, which precluded us from examining the individual effects of different components of the intervention (letter versus navigation) and from performing exploratory subgroup analyses.” (page 14, lines 6-9)
12) Regarding the request to clarify which intervention was associated with an increased rate of screening, and the request for information about the number of immigrants, and of those, the number of undocumented immigrants:

Due to small numbers of patients in the study, we were unable to identify which part of the intervention was associated with an increased rate of screening. We do not have information about the number of immigrants in the study, and have deleted the language about undocumented immigrants in the discussion section.

Referee #2’s Comments:

Major Compulsory Revisions

1) Regarding the question of why medical records of control participants were not reviewed:

We did review the charts of the control patients, and have added language to the manuscript to clarify this point:

“Because the electronic data system did not capture diagnostic tests performed outside of the health center network, one investigator (KEL) reviewed the medical records of all patients at both the intervention and control health centers who appeared unscreened in the data report to confirm that they were, in fact, unscreened. After reviewing 196 medical records at the intervention center and 191 medical records at the intervention center, we identified 93 intervention patients and 90 control patients who had not received colorectal cancer screening according to the criteria specified above.” (page 6, lines 6-12)

2) Regarding the concern that the removal from the intervention group of those patients whom the PCPs reported to have previously refused screening may have biased our study:

We did not remove these patients from the intervention group—we analyzed them as though they had received the intervention (the intention to treat analysis). We are not sure what additional language is needed to clarify this point—we would be happy to speak to the editor about this issue.

3) Regarding the request for a figure:

We attach a figure, and would be happy to work with the journal graphic design staff to make further changes.

Minor Essential Revisions

1) Regarding the request to clarify the PCP’s criteria for removing names from the eligible list:

The text of the manuscript reflects the exact communication with the PCPs. We edited the following section to promote clarity: “the patient will be out of the country continuously for at least three months during the period of navigation.” The purpose of this criterion was to prevent wasting navigator resources on
patients who were out of the country (i.e. not engaged in primary care) during the navigation pilot study. (page 6, lines 17-18)

2) Regarding the request to clarify the apparent conflict between the PCPs excluding patients without insurance from receiving navigation (n=4) and the next sentence saying 14 were uninsured:

In this section we are identifying the reason the PCP felt the patient was not eligible for navigation (one possible reason was lack of insurance) and the numbers of such patients who were uninsured. It is possible that a PCP deemed a patient ineligible for navigation for one reason (for example, they had a long history of refusing) and they also happened to be uninsured, but the insurance status was not the reason the PCP excluded them.

3) Regarding the request to clarify whether all patient calls were audited, or only a subset:

We have edited the text as follows: “During the study implementation, the project manager (who also attended the training sessions) audited between one and five patient calls by each navigator for adherence to a calling script and for motivational interviewing techniques.” (page 8, lines 13-15)

Discretionary Revisions

1) Regarding the request that we consider adding a discussion about the generalizability of our findings:

We believe that a discussion of generalizability is beyond the scope of our paper. We sought to determine the feasibility of the intervention in our patent population, and are now performing a randomized controlled trial of the intervention. We feel that a discussion of generalizability would be more appropriate in the discussion of the results of a randomized control trial, which is a more definitive methodology.

I apologize for the length of this letter, but hope that we have adequately addressed your and the reviewers’ concerns regarding our analyses and interpretation.

Thank you for considering our manuscript for publication in BMC Family Practice.

Please note that my institutional affiliation will be changing in March 2009, and I will need to add my new contact information to the manuscript in the future.

Sincerely,

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