Author's response to reviews

Title: Factors Associated with Use and Non-use of the Fecal Immunochemical Test (FIT) Kit for Colorectal Cancer Screening in Response to a 2012 Outreach Screening Program: a Survey Study

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Author's response to reviews: see over
19 May 2015

Re: BioMed Central Public Health ms # 8144685491601422 (Factors Associated with Use and Non-use of the Fecal Immunochemical Test (FIT) Kit for Colorectal Cancer Screening in Response to a 2012 Outreach Screening Program: a Survey Study)

Dear Editor:

We are re-submitting a revised version of our manuscript titled “Factors Associated with Use and Non-use of the Fecal Immunochemical Test (FIT) Kit for Colorectal Cancer Screening in Response to a 2012 Outreach Screening Program: a Survey Study.”

Per your request, we have moved 3 of the 4 figures into Additional files. We would like to keep one figure as part of the main body of the manuscript if possible (formerly Figure 4, now called Figure 1). Unlike the other figures, we don’t report any of the new Figure 1 statistics in the text, and we think it would be very unwieldy to do so. We hope that the format of the figures is now satisfactory. If not, please give me specific advice about the changes that need to be made.

Detailed responses to the recommended/required revisions or questions/concerns indicated by the two thoughtful and thorough reviewers are found below. The reviewer comments/questions are in boldface, our answers in regular font.

We want to thank the reviewers for their comments and suggestions. We hope that with these revisions you will now find the manuscript acceptable for publication.

Sincerely,

Nancy P. Gordon, ScD
Corresponding author

Reviewer Shahna Sultan:

Discretionary Revisions (Questions/Concerns): A “flow diagram” of sorts outlining the and how many individuals were sent surveys versus how many returned. Of those that returned, how many returned the survey after the initial mailing; for the nonuser group, how many phone calls were attempted and how many actually were reached and were willing to complete the telephone survey.

This study used a complex survey sample, specifically stratified random samples of three groups in the 2012 FIT Kit Outreach cohort (members who had completed FITs in all 3 years 2010-2012; members who completed a FIT in 2012 but not 2010-2011; and members who did not complete a FIT in any of those years). The strata used to sample for each group included 3 race-ethnic groups (nonHispanic Whites, Blacks, and Latinos) x 2 age groups (52-64, 65-76) x 2 gender groups. We sent everyone an initial mailing and then people who had not responded by a cut-off date were sent another mailing. However, some people’s response to the first mailing came in after we started preparations for the second mailing and we did not keep track of whether the questionnaire we received was from the first or second mailing. For
each Study Group, we generated race-ethnicity x age group response rates after two mailings. As noted in the text (Page 8, lines 153-154), for each Study Group, we found no significant differences in survey response rate by race-ethnicity x age group, but overall significant race-ethnic differences in response. Rather than a flow diagram, we have added the race-ethnic response rates for each Study Group (below) in Additional File 2. We hope this will satisfy the revision request.

<table>
<thead>
<tr>
<th></th>
<th>Continuers</th>
<th>Converts</th>
<th>Nonusers</th>
</tr>
</thead>
<tbody>
<tr>
<td>White</td>
<td>73.7%</td>
<td>41.3%</td>
<td>21.8%</td>
</tr>
<tr>
<td>Black</td>
<td>60.9%</td>
<td>32.4%</td>
<td>19.8%</td>
</tr>
<tr>
<td>Latino</td>
<td>68.0%</td>
<td>33.0%</td>
<td>21.8%</td>
</tr>
</tbody>
</table>

For the phone interviews with nonrespondents in the Nonuser group, we randomly selected 50 men and 50 women non-responders in each race-ethnic group (total groups = 6). Our research assistant was told to complete 15 interviews with people in each group. Some people were unreachable due to disconnected phone numbers, no way to leave a message, and language barrier (4 people in the Latino groups). Out of the people she actually spoke to, 7 White males, 1 White female, 1 Black male, 2 Black females, 1 Latino male, and 1 Latino female refused to participate in the survey. She did not pursue calling back people she had left messages with after completing the required number of interviews. We did not add any of this to the manuscript but report it to satisfy your concern.

Was there a difference between the Nonuser group answers that completed the initial survey versus the 100 additional telephone survey responses?

On the subset of items that were on both the print and phone interview survey, there were no significant differences between Nonusers.

This reviewer had some confusion about the following: Why were individuals with a family history receiving FIT cards for screening. FIT as a screening strategy is targeting average risk patients. Individuals with a family history (specifically a first degree relative before the age of 60 are considered high risk and) should be referred for a colonoscopy for screening (not FIT).

According to Dr. T.R. Levin, Medical Director for Kaiser Permanente Northern California’s Colorectal Cancer Screening program, individuals with a family history of CRC or at elevated risk for CRC based on other medical conditions are not excluded from the outreach group; however, in the letter everyone receives, people are told that if they have a family history of CRC they should let their doctor know so that a decision can be made as to whether they should have a colonoscopy instead. The family history information in our electronic medical record system is not very complete for most members as of yet (we are working on ways to improve completeness, and even for those with a family history of CRC, the electronic medical record is unlikely to have easily extractable data on the age at which the family member developed CRC.

In the discussion section focusing on efforts to improve use, the authors should discuss and provide detail about the degree and extent of outreach and inreach efforts (it seems that these efforts were pretty aggressive i.e. multiple reminders (?telephone, ?letters)
and despite that, a fair number of individuals fell into the nonuser category (and the convert category). This provides context for what interventions were tried and their degree of effectiveness and what additional efforts could boost further compliance.

We have no information, nor could we obtain information, about the number of inreach and outreach contacts individual members had to get them to complete the FIT. We only know whether they received the standard outreach during calendar year 2012 ("PCP" heads up letter, FIT kit, followup reminder robo call, second mailing of kit). There was no formal protocol for inreach in 2012 or prior years.

The question of perceived risk of developing CRC (Figure 1) why was a 5 point Likert scale used (is there prior validation for this?).

This was a questionnaire item used in a colorectal cancer screening study conducted by researchers in Kaiser Permanente’s Northwest Region. The resulting publication was Liles EG, Perrin n, Rosales AG, Feldstein AC, Smith DH, Mosen DM, Schneider JL. Change to FIT increased CRC screening rates: Evaluation of a US screening outreach program. Am J Manag Care. 2012; 18(10): 588-95. However, they did not report on the results of that specific question in their article.

30% of nonusers had no interest in using FIT (but less than 10% said they had no interest in getting screened). The authors reference Duncan. In that same paragraph, perhaps the authors could expand the discussion about having choices or options for screening and matching patients values and preferences for different screening tests (invasive versus noninvasive) which has been shown to increase overall compliance with CRC screening.

This is discussed a little further on (Pages 18-19, lines 417-427 in the revised manuscript).

Prior CRC screening history and prior experience with different tests may have helped to put some of the survey responses into broader context. For example, how many had had prior colonoscopies (especially in the older group). Also, what percentage of the nonusers (described as those who did not complete FIT in 2010-2012) had never had CRC screening tests at all?

We do not have information about prior CRC screening history and prior experience with different screening tests, and it is doubtful that the health plan would have accurate information as many members aged 65+ join the health plan at time of enrolling in Medicare, and the health plan would have very limited information on the CRC screening history of these members. The only information we have is from our survey of NonUsers, reported on Page 14, line 296-297: 41% [of Non-Users] indicated that they had been screened for CRC in the past (21% with a FOBT). This suggests that the majority had never been screened.

Finally, in the nonuser group, it might be that these patients appropriately did not complete the FIT test (because of overall limited life expectancy or co-morbid conditions). Was this accounted for in determining who was even eligible for getting a mailed FIT card? If these patients had limited life expectancy, it was appropriate that they did not complete the Fit screening. The authors should comment on this.

Again, we had limited information about these patients. Personal physicians can remove patients from future FIT kit and CRC screening outreach if they feel that CRC screening is not...
appropriate for the patient or after the patient and physicians have discussed CRC screening, the patient makes it clear that he/she does not want to be bothered by any further outreach.

Reviewer: Harvey Murff

Major Compulsory Revisions:
The paper notes that individuals where targeted based on their being due for CRC screening yet almost 40% of nonusers reported a prior CRC screening. This would suggest the algorithm to identify individuals who needed CRC was not very successful. Was any other attempt made to validate how well the algorithm developed to identify individuals due for CRC screening worked? How was this determined?

Validating the algorithm to identify people who needed CRC was not in the scope of this study. Our Regional Quality and Operations Support department that runs the FIT Kit Outreach program gave us a dataset of health plan members who were in the 2012 FIT kit outreach cohort. We linked this 2012 cohort to their 2010 and 2011 FIT kit outreach datasets to determine which members had been in both of these previous outreach cohorts, and to our electronic health record database to determine which individuals had completed FIT tests after receiving those outreaches. Anyone whose electronic medical record indicated having had a colonoscopy in the 9 years prior to 2012 or sigmoidoscopy in the 4 years prior to 2012 would have been excluded from the 2012 FIT Kit outreach because they would still be up to date for CRC screening. If they had CRC screening outside the health plan or they had CRC screening using an FOBT or FIT in the health plan but over a year before, they would have been due for CRC screening again. One of the findings of our Nonuser survey was that some had been screened with a colonoscopy outside of the health plan (e.g., by the Veterans Administration) but this had not been noted in their electronic health record. The health plan is now trying to make it easier for members and/or clinical staff to document that the person’s CRC screening is up to date based on receiving screening from an outside source. We hope the reviewer will accept our explanation of why we did not and cannot validate the algorithm used to identify individuals due for CRC screening.

Were responses different in the nonusers based on those who responded to the mailings and those who were contacted by phone? Were the same questions used in both instruments?

There were no significant differences between responses of NonUsers who completed questionnaires or participated in the structured phone interview (nonrespondents). The phone interview contained a subset of the questions included in the print version. For the most part, the questions and structured responses were identically worded. However, for certain questions, e.g., reason for not using the FIT, the question in the phone interview was asked as an open-ended question, and then the interviewer probed extensively for other reasons, then recoded the reasons to match the response categories in the print version. When reported results for NonUsers are based only on those who responded by questionnaire, we’ve indicated that in the text and tables.
Minor Essential Revisions

Please comment on whether the strategic enhancements to encourage the use of the kits was similar in all three study years.

I posed this question to Dr. Theodore R. Levin, Medical Director for Kaiser Permanente Northern California’s CRC Screening Program, and whose article was cited in the section describing the CRC Screening Program including the FIT kit outreach. He said that prior to 2013, there was a great deal of variability in facility-based “outreach” and “inreach” (i.e., at clinic visits). The basic Regional FIT Kit Outreach program was the same all three years, although over the years, there were slight changes made to the letters and content of the follow-up calls. After 2012, there were more formal recommendations for facility “inreach” efforts; revised instructions accompanying the kit that included more pictures; and a Kaiser Permanente produced video on why and how to use the FIT kit posted on a website. We did not make any changes to the manuscript about strategic enhancements.

Discretionary Revisions
Page 4, Line 59. An enema is not the usual bowel prep for colonoscopy and would recommend changing "an enema" to "a colonoscopy bowel preparation".

Change made in text using your recommended wording (now Page 4, line 44-45).

cc: Beverly B. Green