Reviewer's report

Title: Study protocol: Evaluating the effectiveness of GP endorsement on increasing participation in the NHS Bowel Cancer Screening Programme: a feasibility trial

Version: 1 Date: 5 January 2012

Reviewer: Carolyn Rutter

Reviewer's report:

MAJOR COMPULSORY REVISIONS
None

ESSENTIAL REVISIONS

The feasibility trial described in the submitted manuscript will examine the effectiveness of GP endorsed reminder to increase FOBT screening. Overall, the methods are well described, though these could be improved by adding clarifications noted below as essential revisions.

1. Describe the type of FOBT used: a guiac-based or immunochemical test?
2. Describe how the planned study differs from prior studies showing improved patient compliance to bowel cancer screening with GP involvement.
3. Note that the NHSBCSP sample is already a select group.
4. Describe the feasibility aspect of this study. Would the definitive study take place in the general population (rather than the NHSBCSP sample)?
5. Add plans to describe non-participating practices, especially in terms of their compliance rates and ideally also including information about how their patient lists differ from participating practices. Specific GP characteristics, if available, would also be beneficial. This would all shed light on potential selection bias and confounders. Such information would assist in execution of a subsequent study.
6. Clarify “completion”, does this means all three slides are completed? Or at least one?
7. Provide a better link between planned decision analyses and the analytic approach used to examine uptake. See suggestion 3, below. Are subgroup analyses suggested to align with development of decision trees? Could a model-based approach also work?
8. Describe the average GP list size. Is the assumed list size (2750) reasonable? Similarly, is there any information about the age distribution to support the assumed 11.8% of patients in the target age range?
9. Provide more a complete description of power calculations. What statistical analysis are these based on (eg, two-sample t-test? logistic regression?) and does the assumed approach take into account nesting of patients within GPs?
Power calculations should account for this nesting and should also state the assumed within-provider correlation.

10. Clarify the sentence “The proposed sample size will be sufficient to estimate the uptake of screening with a precision of at least 3.25% in each group.” Do you mean that for any degree of uptake, the resulting precision of estimated uptake in both the control and intervention groups would be plus or minus 0.0325? Is this based on a normal approximation to the binomial assuming the worst case (50% uptake)? Because point estimation is not the focus of the proposed study, it may be best to focus on the power for detecting differences between groups.

11. Please be more specific about the analyses that will be used. The manuscript states that a non-linear mixed effects model will be used. Do investigators plan to use a model for dichotomous outcomes? If either a logit or probit model are planned, then say so and use this assumption in power calculations.

DISCRETIONARY REVISIONS

In addition, I have the following suggestions about proposed analyses, which are discretionary. If these are incorporated, these changes should be noted in the manuscript:

1. It might be useful to examine whether prior contact with the GP has any impact on the effectiveness of the reminder. The idea is that contact with the GP is an imperfect proxy measure of the degree of connectedness between GP and patient.

2. Why are patients excluded only if they’ve had colonoscopy in the last 2 years? After colonoscopy, patients are not eligible for re-screening for another 10 years (if results for negative). In the US, if colonoscopy results are positive, patients are recommended for re-examination with colonoscopy in the next 1 to 5 years. In light of this, it seems patients with colonoscopy in the last 10 years should be excluded.

3. The planned analysis focuses on subgroup analyses. I suggest using a model-based approach that would allow direct comparison of uptake across groups of interest. For example, by include a gender effect and appropriate interaction terms, investigators could test for differences in uptake and differential effects of intervention for men and women.

Level of interest: An article whose findings are important to those with closely related research interests

Quality of written English: Acceptable

Statistical review: Yes, and I have assessed the statistics in my report.

Declaration of competing interests:

I declare that I have no competing interests