Dear Dr. McCormick


Thank you for sending us the revised paper. Our statistical consultant still has several concerns about the study, and before we make a final decision we would like to hear your responses to these concerns. We hope very much that you will be willing and able to address these issues so that we will be in a better position to understand your study and to decide whether The BMJ is the right journal for it.

Many thanks again. We look forward to seeing your revised article within one month and, we hope, to reaching a decision.

Yours sincerely

Jose Merino
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Reviewer: 1

Comments:
BMJ.2014.022293.R1 Statistical Review

I have reviewed the revised manuscript and the responses from the authors.

Whilst the analysis in the manuscript is statistically sound, appropriately extensive and well reported, I have serious concerns about the design and interpretation of this study. There are two key issues which cannot be rectified that undermine the validity of the study:

1) The intervention and control regions are poor matches for each other. Table 2 reports the characteristics in the regions, which show large significant differences in race (12% black vs 28% black) and smaller differences in other key variables. Similarly Figure 1 shows that the outcome rates in the two regions differ significantly throughout the timeframe of the study.

Although the difference in difference analysis looks at changes rather than absolute values (and thus adjusts for differences in baseline outcomes), and is adjusted for characteristics, I have significant residual concerns that the regions being compared are so unalike that the differences are beyond correction in any statistical model.

2) The study has failed to show impact of the intervention. There is an important difference between claiming evidence of absence of an effect, and absence of evidence. Whilst the study authors have been very careful to use appropriate words stating "no effects were observed", I cannot see that the study would have been able to detect large effects even if they had existed.

For example, Table 1 indicated that only 8.8% of the population were uninsured at baseline which decreased to 4.9% after the intervention. Thus, the intervention would only have affected 4% of the population, which places limits on the possible associated change in the event rates. The confidence intervals for the width of the effects are 5.7 percentage points wide for the overall composite ACSC and 6.5 and 7.6 percentage points wide for the acute and chronic ACSCs (Table 3) – these are all wider than the expected effect. For the impact on ethnic disparities the confidence intervals are 20 percentage points wide overall, and 21 and 26 percentage points for the chronic and acute (Table 4) – far too wide to be able to detect any likely effect. Thus it does not appear that the study did not have the statistical power to detect even the largest perceived possible effects if they had existed.

The authors briefly acknowledge this issue in their discussion. Whilst they could include a post hoc power calculation to demonstrate the ability of their study to detect possible effects, I find it hard to believe that it would show that the study could ever have detected anything likely to have
occurred.

Additional Questions:
Please enter your name: Jon Deeks
Job Title: Professor of Biostatistics
Institution: University of Birmingham
Reimbursement for attending a symposium?: No
A fee for speaking?: No
A fee for organising education?: No
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