Reviewer’s report

Title: A pragmatic, randomized, controlled study evaluating the impact of Access to Smoking Cessation Pharmacotherapy Coverage on the Proportion of Successful Quitters in a Canadian Population of Smokers Motivated to Quit (ACCESSATION)

Version: 3 Date: 24 January 2014

Reviewer: Sheila M Alessi

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Providing coverage for smoking cessation pharmacotherapy increases pharmacotherapy utilization. In this study, in collaboration with Pfizer, the authors examine the extent to which providing 26-week coverage versus no coverage increased self-reported 7-day point-prevalence abstinence (PPA) at week 26 (primary outcome). Participants were smokers motivated to quit but without insurance coverage and recruited from 58 sites in Canada. Results indicate increased PPA (per self-report and cotinine-verified self-report) at week 26 in the coverage versus no coverage group. Continuous abstinence through week 26 was not measured. Whether or not there were significant differences between groups on a number of secondary outcomes is unclear (see #1 below). Continuous abstinence week 26 through week 56 (post-coverage period) was assessed and did not differ between groups. Overall, this manuscript is well written, with a thoughtful presentation. The method is appropriate to the purpose, the results clearly laid out, and the Discussion on point and acknowledging study limitations. It appears that the authors have responded to previous reviewer’s comments (although I am not privy to those and cannot speak to comprehensiveness). Nevertheless, below are my questions and comments for the authors’ consideration.

Major Compulsory Revisions

1. Currently, only descriptive information is provided for the proportion of participants in each group who made at least one quit attempt, number of quit attempts, percentage dispensed at least one smoking cessation medication, and number of doses dispensed. Significance tests should be provided. Table 2 could be expanded to accommodate this information. The medication information in particular seems critical to drawing accurate conclusions, and the quit attempt outcomes highly valuable in terms of understanding process variables.

Minor Compulsory Revisions

1. The authors note that medication utilization was higher in this study than generally reported in the literature. One possible explanation is that the involvement of Pfizer in selecting the study recruitment sites could have resulted in bias towards locations that promoted medication initiation, maintenance of
medication, re-starting medication following a failed quit attempt, or other factors related to medication use. This possibility should be noted in the Discussion.

Discretionary

1. The authors might consider limiting p-values to the thousandths decimal place, as further out is arguably meaningless.

2. On page 7, there is a statement justifying the selection of the self-report only primary outcome by a finding in the literature that self-report and verified self-reported smoking status did not differ in a cross-sectional population-based survey conducted in Canada. However, that is somewhat difficult to reconcile with the findings herein that self-report only versus biochemically-verified abstinence rates did differ (although we do not know whether the difference is statistically different). The authors emphasis on pragmatism, however, is duly noted and seems appropriate.

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

**Quality of written English:** Acceptable

**Statistical review:** No, the manuscript does not need to be seen by a statistician.

**Declaration of competing interests:**

I declare that I have no competing interests.