Reviewer's report

Title: Nicotine patches and quitline counseling to help hospitalized smokers stay quit: A factorial design

Version: 1 Date: 17 November 2011

Reviewer: Charlie Goldsmith

Reviewer's report:

The following issues are offered in an attempt to improve this protocol and study. It is great that you are planning to use a factorial design. This should be done more often, as few health care interventions consist of a single factor. Thank you for numbering the pages.

1. Page 3, paragraph 1, line 6. Since [or] logically includes [and], suggest dropping [and/]. Also page 17, paragraph 2, line 10. Also page 22, paragraph 5, line 7.

2. Page 3, paragraph 2, line 1. Replace [N] by [n] and insert a space on either side of the [=] sign to read [n = 1640].

3. Page 4, paragraph 3, line 1. Include the date of registration and the date the first patient was randomized if that has happened.

4. Page 5, paragraph 2, line 2. Replace [recent] by [2007]. The word becomes less relevant with time while the date does not.

5. Page 5, paragraph 2, lines 3 and 4. Delete [in order] in front of [to] as the words are redundant in English.


7. Page 6, paragraph 1, line 1. Delete [only] as it implies an unstated expectation. Page 21, paragraph 2, line 8.

8. Page 6, paragraph 3, line 5. Rewrite as [p < 0.01].

9. Page 6, paragraphs 3 to 7. Can this be referenced?

10. Page 6, paragraph 4, line 1. Replace [significant] by [important]. Reserve significant for a statistical context.

11. Page 8, paragraph 1, line 5. Suggest that the block size NOT be listed as this provides those who make decisions about eligibility of patients with information to anticipate the next allocation. This has been shown to create bias. The block size does not need to be published until the study is being written for final publication. The fact of blocking is desirable.

12. Page 9, paragraph 4. This sample size assumes an additive model. If there is any interaction it likely will not be detectable unless it is much larger that the main effects. This feature should be mentioned. Are the 7% effects actually clear as what can be seen in the literature? It would be good to R(eference) them.

13. Page 10, paragraph 1, line 1. Is there evidence that the variance inflation for clustering is around 10% for these two factors? Provide a R if you can. What software was
used to calculate the sample sizes?

14. P 10, p 1, l 3. Suggest including how big the effects need to be in this subgroup to show they will be clinically important as well as statistically significant.


16. P 12, p 1, l 3. Provide a R.

17. P 12, p 2. Provide a R for the system used.

18. P 13, p 2, l 13. Are the number of calls recorded and will they be used for exploratory analyses?

19. P 13, p 3, l 4. Try to make your language gender neutral by replacing [his/her] by [their] or some other neutral phrase.

20. P 14, p 4, l 2. Rewrite as [< 10].

21. P 15, p 2, l 6. Provide a R to CHART measures. This R could also be used on P 16, p 1, l 1 and p 3, l 1.

22. P 15, p 2, l 7. Replace [is] by [are] since data is a plural word and it is used correctly on the same P.

23. P 17, p 3, l 1 and 2. Delete [(this issue)].

24. P 17, p 3, l 3. Include the name of the company and its location in PA. What is known about the reliability of the cotinine analyses for this company?

25. P 19, p 1 and 2. Provide the software that you plan to use for the overall analysis and the handling of missing data.

26. P 19, p 1, l 4 and 5. Since your study is not powered to detect an interaction, this should be mentioned here as well in the discussion.

27. P 19, p 2, l 6. Provide a R for the sensitivity analyses being proposed.

28. P 20, p 1, l 2 and 3. Since this subgroup is smaller than the sample size for the entire trial, this effect will not likely be detectable statistically unless it is synergistic and much larger rather than moderating.

29. P 20, p 2, l 8. No measure of utility has been proposed so far in the paper, so how will you compute the utilities to get the QALYs? Provide a R for this. Also the comparison of each active group vs control does not take advantage of the hidden replication in the design and they are correlated so should use some variant of Dunnett’s test in their analysis. Alternatively the 3 estimable contrasts could be used in the economic analysis, although the effect of the interaction is likely not going to be detectable statistically.

31. P 21, p 3, l 3. Delete [significantly]. Significance is a statement about a question, not part of it. Also P 22, p 1, l 3 and p 2, l 2 and p 3, l 1.

32. P 21, p 3, l 2 to 4. The viewpoint of the economic assessment has not been mentioned and should be.

33. P 23, p 1, l 2. Replace [efficient] by [effective]. No methods are provided to measure efficiency.

34. P 23, p 2, l 4. No mention has been made about the DSMB structure, membership, data access and reporting and should be.

A random sample of 10 Rs was selected and checked for accuracy of citation. This reviewer also likes to use issue numbers as they make the finding of articles easier on most websites.

35. P 25, R 2, l 3. Insert [(5) after [25].

36. P 25, R 3, l 2. Insert [(5)] after [10].


38. P 25, R 5, l 3. Insert [(1)] after [93].

39. P 26, R 13 appears to be correct.

40. P 26, R 14. Insert the date of last access for online documents as they can change.

41. P 26, R 19 appears to be correct.

42. P 27, R 24, l 3. Insert [(5)] after [36].


45. P 27, R 28, l 1. This is the second edition and replace [Jersey] by [York].

46. P 27, R 29, l 2. Insert [(421)] after [88].

47. P 28, R 30 appears to be correct.

48. P 28. Somewhere the paper should note that the reporting of the trial should follow the CONSORT guidelines and reference them.