Reviewer's report

Title: Preventing and Lessening Exacerbations of Asthma in School-age children Associated with a New Term (PLEASANT): Study protocol for a cluster randomised control trial

Version: 4 Date: 23 April 2013

Reviewer: Lynn Gerald

Reviewer's report:

Major Compulsory Revisions

This manuscript describes the design of a cluster randomized trial of 140 general practices which will include approximately 100 children aged 4-16 with a diagnosis of asthma. The major concern with the manuscript is that there is very limited information on the intervention. The abstract has no mention of the intervention and just states that “a simple intervention” sent from the GP will be evaluated. Within the methods, the authors describe the intervention as a “brief postal intervention (letter)”. If this is the extent of the intervention, then the text of the letter should be included. Given that the intervention is simply a reminder letter, the authors should better justify why this would be expected to work. This is quite a large trial with no preliminary data or even theoretical justification as to why such a limited intervention would reduce asthma exacerbations and unscheduled medical contacts in school aged children. Such justification is necessary.

The authors provide a nice sample size calculation; however, it is unclear why a decrease in unscheduled medical contacts from 30% to 25% is considered clinically significant. Justification for this effect size as relevant should be included. Furthermore, the authors mention that they expect some practices not to follow the protocol (i.e. send out the reminder letter). These estimates should be justified (10/70 = 14%).

The authors state that “a detailed description of the statistical analysis of efficacy and safety outcomes will be written in the trial Statistical Analysis Plan which will be finalized prior to receiving post-intervention data from CPRD.” This statement should be deleted as it seems unnecessary and suggests that the authors do not know how they will analyze their data. The analysis plan presented is sufficient. It is unclear how QALYs will be assessed in these children for the economic evaluation.

Minor Essential Revisions

1. Clarify the intervention within the abstract.
2. Clarify the 4-16 year age group. I believe “school age” is conceptualized differently in Europe than in the United States so clarification would be useful (i.e. why is the upper age limit 16?). Also, the abstract states “4-16” while the
methods section ages “5-16” in several places and “4-16” in others. This needs to be consistent throughout the manuscript.

3. The methods states that “patients aged <5 will be analyzed separately to these”; however, it is unclear that these children are actually included in the study.

4. Clarify the school year start and end dates.

5. The “randomization plan” is referred to under the randomization section but it is unclear what this plan actually is.

6. In the abstract, last paragraph, “….we would hope that this is could be adopted as part of routine…..” The word “is” should be deleted.

7. In the background, 4th paragraph, “It could therefore be argued that July and August is a good time…..” The word “is” should be “are”.

8. In the background, 4th paragraph, “….the pollen season is in the main over, school age children are not…..” “In the main” could be changed to “primarily” or “almost”. The word “and” should be inserted between “over” and “school”

9. Most of the interpretation paragraph after “Insert Figure 2 here” should be deleted as readers should know how to interpret that number.

**Level of interest:** An article of limited interest

**Quality of written English:** Acceptable

**Statistical review:** Yes, but I do not feel adequately qualified to assess the statistics.

**Declaration of competing interests:**

I declare that I have no competing interests.