Reviewer's report

Title: Adherence with tobramycin inhaled solution and health care utilization

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Reviewer: Kevin Southern

Reviewer's report:

The authors have examined adherence to an inhaled antibiotic therapy for people with CF. To do this, they have utilised a US database that records insurance claims for healthcare. This system has been used extensively in the past for similar studies. The results are interesting, confirm other work in this area and provide some new findings (namely that poor adherence is associated with an increased risk of hospitalization). The paper is well written and the results presented clearly and fairly.

I have a few comments

Major comments (compulsory),

1) The methods are clear but for the non-US reader some further explanation of the healthcare system is required. Are these insurance claims from the employer or from the employee? (i.e., what does self-insure mean?) Is this a standard procedure in the states (i.e., might a patient move employer and then not be included)

2) Some more information about TSI is needed in the introduction. Particularly why was a one month on- one month off regimen decided on. This is a fairly unique regimen for a longterm suppressive antibiotic therapy. Could it be that this unusual regimen is a factor in these poor levels of adherence (i.e., the families never settle into a routine?). This might be considered in the discussion.

3) To highlight the poor levels in this study the authors should include data from studies that have used electronic data capturing (considered by most as the gold standard measure of adherence). For example, our study demonstrated mean adherence levels over 60% (McNamara, Journal of CF, 2009) to different inhaled CF regimens.

4) Although numbers are good for this study, a concern is the relatively low number of patients (54) in the high utilization, 14 of whom were hospitalized. I think the authors should highlight these numbers with some caution when describing their main finding.

Minor comments (essential)

5) In Background, I would rather have active than aggressive

6) Methods, how do you know the patients were on TSI for the whole of the year chosen? (for example if a physician stops TSI, would their prescription be pulled immediately (that doesn’t happen in this country but we have a different system)

7) Discussion para 2, what is “national rate of use” and how did the CFF measure
it? (why is the range up to 100% in 2006?)

8) Para 3, as above need to be more equivocal about the finding supporting Ramsey et al. Are you simply identifying all round good adherers. Cannot assume that it is TSI alone (you need to be particularly careful here not to overegg your findings as the company have provided some support for this study)

9) Last para of discussion, quite a number of off-license drugs are prescribed to children, I don’t think the authors should make too much of this, shame it is the last sentence, much more important is to highlight the appalling overall levels of adherence to this therapy and possibly suggest some interventions to improve.

Kevin Southern, 3rd October 2010

**Level of interest:** An article of importance in its field

**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 I have no competing interests