Reviewer's report

Title: Medicaid prescription limits: policy trends and comparative impact on utilization

Version: 2

Date: 20 February 2014

Reviewer: Federica Angeli

Reviewer's report:

The manuscript investigates the effect of prescription caps on drug utilization using US state-level aggregated data between 2001 and 2010.

I enjoyed reading your manuscript. The language is clear and concise, the topic relevant, the analysis valuable and the results very interesting. Particularly insightful are the differentiation between overall cap and brand caps on the policy side and between preventive essential and symptomatic essential medications on the outcome side. However, I have some major and minor observations regarding your research. I will highlight them below in bullet points, and group them into major and minor issues.

Major compulsory revisions

1. The analyses consider the trend of drug utilization before and after the implementation of prescription cap policy and test the statistical significance of the change in prescription utilization. My concern is that the implemented policies – although they can all be generally labelled as prescription caps – present quite different characteristics across states. A reference cited in this regard is the paper by Fischer et al (2002). However, it seems to me that the policy intervention studied in that paper was much more homogeneous. Here instead states in the sample have implemented overall caps only or only brand caps or even a combination of both, which make it difficult to discern isolated effects. Moreover, the maximum number of prescriptions per month imposed by the policies greatly varies, 3-15 per month for overall caps and 2-5 per month for brand caps. Cap levels also seem to vary over time in addition to across states. I would expect states with a larger number of cap-allowed prescriptions per month to display a lesser decrease of drug utilization. How were these differences accounted for in the model? And what are the possible biases and threats to internal validity that these differences can generate?

2. Somewhat related to the previous point, could you please elaborate on the statistical power of the model? Separate analyses are run for the introduction of overall caps and brand caps between 2001 and 2010. However, N=3 for overall caps and 6 for brand caps, while the control group is formed by 19 states (as specified in the text, although table 2 seems to be suggesting differently). How robust are your estimates, given the small sample?

3. In your conclusion you state that ‘when faced with caps, patients are willing to
forgo medications with little symptomatic benefit to maintain the use of those that provide short-term benefits’. It is an interesting interpretation, but since your aggregated analyses do not test for physician or patient behaviour, such claim lacks corroboration. Moreover, no theory is presented about the effect of cap policies on physician and patient behaviour, therefore such interpretations unfortunately sound not well-grounded.

I think your work would greatly benefit from more theoretical insights on the effect of cap policies on patient and physician and on possible interactions between the two. These insights would provide a much richer platform for discussion. First, in the introduction you could explain how cap policies are implemented. For example you could clarify whether a maximum of 4 prescriptions a month is applied at physician level, health practice level, patient level? Building on this, you could highlight how such policies are argued to influence physician choice but also patient discrimination between different medications, and thus prescription utilization. In addition to that, I would like to know more about how these behaviours are predicted to be different in the peculiar patient base represented by Medicaid, although this point could be added to your limitation section, in addition to the considerations you already mention about Medicaid patients. In sum, I think more theoretical elaboration is very much needed to infuse meaning to your results.

4. Systematic differences between control states and sample states may indeed harm the soundness of your analyses, as you rightly point out. The trends in Figure 1 and 2 clearly show a systematic difference between the prescription use in control vs cap states. Could you run t-test on various demographics of the states and/or to isolate possible sources of differences and to check for the statistical significance of these differences?

Minor essential revisions

1. I would suggest organizing your results clearly around the tables that you aim to include in the printed version of your article. Right now many references are to online resources, while the connection between the results that are being discussed and the pertinent table is less straightforward.

2. You mention 19 control states with no caps. However, Table 2 seems to report different numbers (36 in 2001 and 30 in 2010). Please explain.

3. I would shift the first paragraph under the headline ‘Impact of cap policy implementation on prescription use’ (Results section, bottom pg 9) under the headline ‘data collection’ (in the methods section), since this paragraph clearly describes your sample.

I hope you will find my comments worthwhile and useful. Best of luck with further developing the study!

**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 that I have no competing interests