Reviewer's report

Title: The changing patterns of dispensing branded and generic drugs for the treatment of gastroesophageal reflux disease between 2006 and 2011 in Japan: a retrospective cohort study

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Reviewer: Jie Chen

Reviewer's report:

This study examined the patterns of dispensing branded and generic drugs for the treatment of GERD in Japan. I have some suggestions to improve the study design.

1. Brand vs. generic drug utilizations have been studied well in the United States, the literature that I am familiar with. It is interesting to know more about the prescription drug dispensing pattern in Japan. I would expect to see more discussion on the health care market, such as health insurance, physician practice settings, of Japan in particular. What are the differences of health care delivery system in Japan, compared to systems in other countries? Does Japan have FDA to monitor the application of generic drugs? Are generic drugs bio-equivalent to brand name drugs? How long will a patent of brand name drug last in Japan?

2. First sentence: “Generic drugs can help reduce healthcare costs and patients’ co-payments.”. In the literature of US Pharmaceutical market, new drugs are effective in terms of improving health outcome, and probably can save cost in the long run. If authors believe generic drugs can reduce overall health care cost, please at least cite the evidence to support your statement

3. On page 6: authors list 7 exclusion criteria. Please justify. I am not clear about criteria 6 and 7. Also from criterion 4, it looks to me that people with different diseases might be exposed to different likelihood of receiving brand vs. generic drugs, right?

4. Analysis: overall, I think more rigorous analysis is required. For example, table 1 demonstrated the differences in age of populations who use brand vs. generic drugs (e.g. switch from brand to generic and vice versa: 47.3 vs. 43.9). Can the decreasing rates in brand name drugs reflect the older population, who prefer generics, over 5 years? Are the age differences or gender difference among the groups significant?

5. Authors have a rich data set. If age and gender, and chronic diseases are correlated with the likelihood of receiving brand vs. generic drugs, then multivariate regression will be more appropriate.

6. I need to be convinced more on the drugs selected in this study. For example, lafutidine did not have generic equivalent in the market. What is the market share of lafutidine? If lafutidine as large market share, then the lack of generic of
lafutidine may influence the results.
7. Discussion section is well written.

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

**Quality of written English:** Acceptable

**Statistical review:** Yes, and I have assessed the statistics in my report.

**Declaration of competing interests:**

'I declare that I have no competing interests.'