Reviewer's report

Title: Impact of a direct-to-consumer information campaign on prescription patterns for overactive bladder

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Reviewer: Aukje Mantel-Teeuwisse

Reviewer's report:

This manuscript assesses the impact of a direct-to-consumer campaign targeted at increasing awareness of the possibility to treat overactive bladder with medicines on medicines use in Japan. There is little evidence of unbranded advertising of prescription medicines on relevant outcomes such as health services use and costs. As such, the current paper is a welcome addition to the medical literature.

My main concern, however, is that the chosen design does not answer the research question, at least not in the most optimal way. First, the authors established a cohort of participants with an overactive bladder before start of the study. I assume that the campaign was also or even especially targeted at those who did not seek help or treatment before and may therefore not yet have a diagnosis. My impression is that the data from the Japan Medical Data Center would allow for an analysis of diagnosis for overactive bladder during the study period. In addition, it would be more interesting if the proportion of people with a new diagnosis starting treatment would be assessed than start of treatment in a small cohort with a previous diagnosis. And potentially, the authors could estimate the incidence of use of medicines for overactive bladder, again over time during the study period.

In addition, the chosen methodology could be strengthened. I had difficulties interpreting the data as currently presented. It is clear by visual inspection that something triggered an increase in use of treatment in this cohort in periods 4-6, but can this really be attributed to the campaign so many weeks earlier? In their discussion (page 11, lines 27-33) the authors suggest that this delay may be caused by the advice to start with behavioural therapy during a 3 months period. However, since all of the patients in the cohort were already diagnosed with overactive bladder, I would assume that this advice had already been given at time of (registration of) diagnosis.
A better design to study the impact of an event such as a campaign during a short period of time is the interrupted time series analysis. This methodology accounts for longer term underlying trends and is able to estimate both a direct impact (level change) as well as longer term impact (slope change). I would suggest the author use this methodology for this research question.

Minor comments:
* Disease awareness campaigns is an often used synonym for DTCl campaigns. I would suggest to mention this term in the introduction and add it to the selected key words.
* Abstract methods: reference period is not mentioned (but see comment above on choosing different methodology)
* Methods, page 7, lines 17-18: age and comorbidity were time varying variables, but only assessed at the beginning of each year. Why not per period, especially because in the results it is stated that distributions changed during the analysis period?
* Did you observe any effect of the introduction of mirabegron in September 2011? This approximately coincides with period 8 in the pre-campaign year I suppose. The authors rightly point out in the discussion section that campaigns such as the one under study are usually accompanied by promotion targeted at health care professionals. This may also explain the large increase seen in the current study. In my view, this can be strengthened in the paper.

Are the methods appropriate and well described?
If not, please specify what is required in your comments to the authors.
No

Does the work include the necessary controls?
If not, please specify which controls are required in your comments to the authors.
Yes

Are the conclusions drawn adequately supported by the data shown?
If not, please explain in your comments to the authors.
No
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