Author's response to reviews

Title: The impact of generic-only drug benefits on patients' use of inhaled corticosteroids in a Medicare population with asthma

Authors:

Vicki Fung (Vicki.Fung@kp.org)
Ira B Tager (ibt@berkeley.edu)
Richard Brand (ribrand@sbcglobal.net)
Joseph P Newhouse (newhouse@hcp.med.harvard.edu)
John Hsu (jth@dor.kaiser.org)

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Author's response to reviews: see over
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Re: BMC Health Services Research MS: 5669410241726232 (R2)

Dear Editors,

Thank you for the additional suggestions for our manuscript, “The impact of generic-only drug benefits on patients’ use of inhaled corticosteroids in a Medicare population with asthma”. We are submitting a revised manuscript that addresses the remaining concern raised by the reviewer. Our detailed response is below.

Please do not hesitate to contact me if you have any further questions.

Sincerely,

Vicki Fung, Ph.D.
Kaiser Permanente - Division of Research
Tel: 510-282-3526
Email: Vicki.Fung@kp.org
In terms of the other comment, the breakdown by disease severity summarized in Table 5 is helpful. It is intriguing that the changes in days of supply are basically the same regardless of disease severity. It would be helpful to present the absolute days of supply number in that table (the table is small and the data could fit in there). We should expect to see a much higher days-of-supply in the high-risk group. This will be helpful in two ways:

1. If those patients have much higher baseline use, the relative reduction will be smaller than that for more moderate users, although still differential across benefit design, which would change the clinical interpretation, though only slightly.

2. If for some reason the higher-risk patients do not have a high days-of-supply, I would be worried about whether there have been problems with ascertainment of either disease state or medication use.

If the authors are confident in the result in Table 5, they could be more expansive in the points they make at the beginning of the third paragraph of the Discussion. If this kind of coverage scheme serves as an undifferentiated "speed bump" regardless of the clinical severity of the patient's condition and their corresponding need for medication, that is concerning.

We now include the baseline levels of ICS use in 2003 in Table 5. As expected, levels of ICS use are higher in the higher-risk asthma groups as compared with the corresponding lower-risk asthma group with similar types of drug coverage. However, differences in 2003 ICS use by severity level are relatively smaller among patients with restricted coverage (11.6 days of supply), likely due to the presence of the annual benefit cap. As a result, the relative reductions in ICS use are similar across severity level.

We expanded the third paragraph of the Discussion section to present possible explanations for the finding within the higher-risk asthma group, as well as the potential implications:

Patients who were taking higher-cost ICS drugs at baseline exhibited greater asthma severity compared with lower-cost ICS users, as indicated by several medication and diagnoses measures shown in Table 3. In addition, in analyses stratified by asthma severity level (Table 5), loss of brand-name drug coverage was associated with reductions in ICS use, even among those with a strong clinical indication for the drug therapy (i.e., higher-risk asthma patients). Decreases in ICS use in the high-risk asthma group may reflect greater increases in drug costs associated with the loss of coverage, due to higher average daily doses. Alternatively, the high-risk asthma flag indicates a prior history of frequent or serious exacerbations, which may be associated with worse self-management of asthma symptoms. These findings raise important questions about potential adverse clinical consequences of reduced ICS use due to restrictive drug coverage policies, particularly for patients with greater clinical need for ICS therapy. Studies in non-elderly asthma populations have found that lower levels of ICS use are associated with greater hospitalizations, emergency department visits, and oral steroid use [6, 13, 14]. In addition, evidence suggests that increases in drug costs associated with ICS use are off-set by decreases in other direct medical costs [15-19]. Research is needed to assess clinical outcomes associated with these drug coverage policies, as well as to determine the impact on total medical costs.