Author's response to reviews

Title: Prevalence of inappropriate medication using Beers criteria in Japanese long-term care facilities

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Author's response to reviews: see over
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Dear Dr. Newmark:

Thank you for your letter about our manuscript. Please find attached the revised manuscript.

Regarding the discussion of measured outcomes of hospitalizations and falls covered in one paragraph in the discussion, Referee 1 and 3 suggested that we delete, while Referee 2 suggested that we move to the result section. Since these suggestions conflict, we left them in the Discussion section. However, we are quite prepared to delete this portion (p5. l11~l13, p13. l2~p14. l7) if the editors concur with Referrer 1 and 3’s suggestion.

We look forward to your favorable consideration.

Sincerely, yours

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ANSWERS TO REFEREES’ COMMENTS

Reply to Referee 1

Thank you for your comments.

Major compulsory revisions

1. The first is to leave out the summary of regression analysis from the abstract. Without better understanding the variables included and the approach taken (as is accomplished later) the findings seem odd, as they are not really predictive variables. Indeed, even within the full discussion, the results are a bit odd because variables such as total cost are not particularly useful either clinically or for policy. The authors might discuss the significance and usefulness of the findings of their regression in such a light.

The description was deleted from the abstract as suggested.

2. The second issue is the discussion of measured outcomes of hospitalizations and falls covered in one paragraph in the discussion. Those results are not appropriately developed and seem tangential to the paper’s methods and purpose. I suggest removing this discussion. If the authors have enough information here, they should consider a separate paper on validation that would better explain the methods and results.

Within the limitation of our database, we tried to explore the outcomes of inappropriate medication which might contribute to the literature. However, since we do not think that the results merit a separate article, we have left it in the Discussion. We are quite prepared to delete this portion (p5. 111~13, p13. l2~p14. l7) if the editors concur with referrer 1’s suggestion.


**Reply to Referee 2**

Thank you for your comments. The English style was corrected throughout the paper as suggested.

**Major compulsory revisions**

1. The major weakness is the similarity of the results to other studies. The authors need to make a stronger argument that this is the first study to examine inappropriate use in LTC institutions in Japan.

We have rewritten the Background as suggested.

2. The authors need to address how terminal patients were handled in the database. If they were unable to separate them then this is an important limitation that deserves discussion.

There were 5 terminally ill patients in the sample, none of them having inappropriate medication prescribed. This point was added to the end of the first paragraph of the Discussion.

3. The background needs complete revision. What general problem will be discussed?, What specific issue within the problem will be addressed?, What is the LTC literature on inappropriate medication usage? What have others done to address the specific issue?, What still needs to be done, or what is still unknown? Why is it important to study Japanese LTC institutions? The purpose of the study should be incorporated in one or two sentences at the end of the background.

We rewrote the Background according as suggested. There have been no reports on inappropriate medication usage in Japan because data have been unavailable.

4. The methods need to describe how the LTC facilities were selected and what the universe was. Why were other facilities excluded? Were these only facilities in Tokyo and what are the implications, if so?

The sample of this study was a convenience sampling rather than a random sampling. However, the sample facilities were located throughout the country. We added more information on LTC facilities in Japan to the Background and we improved the description in the Sample (p5. l4).

5. The discussion section needs to include comment on the revised percentage of medication use after ticlopidine is removed. (first paragraph of the discussion section) This seems to indicate that Tokyo area LTC institutions may have lower rates than elsewhere which would be an important finding.
After ticlopidine were excluded from the analysis, prevalence of inappropriate medication use was still within the range of the previous studies in other countries. However, we rewrote the first paragraph of the Discussion as suggested.

6. Also, as mentioned above, while small, the validity work and adverse outcomes work is a major part of the results. As such, the parts of these paragraphs that should be in the results section should be moved there.

Within the limitation of our database, we tried to explore the outcomes of inappropriate medication which might contribute to the literature. However, we do not think that the results should be in the results section because the sample in this analysis is too small to make meaningful interpretations, and thus we have left it in the Discussion.

**Minor essential revisions**

7. Page numbers were not included which hampers feedback to the authors.

Page numbers had been already shown at the foot of each page.

8. Background: The first sentence in the Background section needs a reference.

A reference was added as suggested.

9. Background: The second sentence uses “etc.” which is a nonstandard abbreviation.

“etc.” has been deleted.

10. Methods: Measurements—the first paragraph on Beers criteria is too wordy and can be reduced to one sentence.

The paragraph was reduced as suggested.

11. Results: The second paragraph describes communication with Dr. Beers which can be deleted from the paper. Exclusion of external preparations is intuitively acceptable.

We think the exclusion of external preparations would have a great impact on this analysis. For example, 28 patients (1.7%) used indomethacin in the study and 27 of them used it as external preparations. Similarly, 24 patients (1.4%) used diphenhydramine and all of them used it as external preparations. Therefore, we think the exclusion of them should be stated in the paper. However, we deleted the sentence describing communications with Dr. Beers as suggested.

12. Limitations: The authors talk about higher quality facilities in the first paragraph. How did they
reach this conclusion?

The facilities were there that used the MDS which indicates they were more committed to improving quality. We added this fact in the Limitations.

13. Limitations: The third sentence talks about racial differences which should either be referenced or deleted.

Two references were added as mentioned.

14. Conclusions: Need to be rewritten to emphasize the importance of this manuscript. As it reads it is an argument of “sameness”.

We rewrote the Conclusions as suggested.

Discretionary Revisions

15. If the LTC universe studied is Tokyo-area only then the title should be changed to reflect that.

See reply to comment#4.
Reply to Referee 3

Thank you for your comments.
The English style was corrected throughout the paper as suggested.

**Major compulsory revisions**

1. The 2003 Beers Criteria were applied in this study to data from 2002. However, practitioners would not have had access to the 2003 criteria in 2002; rather, the 1998 criteria would have been the most recent available version. The authors should explain why they choose the 2003 version, and to what extent their findings might or might not have been influenced by differences in newly included drugs in the 2003 version.

We applied the 2003 Beers criteria because we think more recent knowledge should be reflected in identifying inappropriate medication use. Very few physicians are familiar with the Beers criteria in Japan, and we concluded that the differences between the versions would have little impact. We mentioned this fact in the Measurement (p6. l16-21).

2. Readers outside Japan will need a better understanding of the characteristics of HP, HFE, and NH settings which appear to be all categorized as long term care facilities which collected MDS data. Specifically, the hospital (HP) setting accounted for nearly half of the subjects. Is this a chronic care hospital rather than acute care? More information about long term care options in Japan would be helpful.

We rewrote the Background as suggested.

3. Are MDS assessments mandatory or voluntary in these settings?

They are voluntary. We added this fact to the Background (p4. l10).

4. Is there any form of mandated medication review by consultant pharmacists for nursing home residents as there is in the US? If so, are these pharmacy reviews the same for NP, HFE, and NH facilities, or do these processes of care differ by facility type?

No. We added these facts to the Background (p4. l4).

5. How were these facilities selected to be included in the study? Were the 17 participating facilities that collected MDS data sampled randomly from all similar facilities, or was this a convenience sampling from available facilities?

The sample of this study was a convenience sampling rather than a random sampling. However, the sample facilities were located throughout the country. This explanation has been added to the last
paragraph of the Background and the Sample (p5. l4).

6. On page 8, under Measurements, in the top two paragraphs, please specify which medications and which diseases or conditions were excluded from analysis.

We added a new table (Table 1) and showed which medications were excluded from the analysis as suggested.

7. Page 13, you have concluded that 8 patient characteristics and 3 facility characteristics were not associated with inappropriate medication use because they were not selected in the regression analysis. I think it is possible that number of medications used per day is so confounded with other measures of health status such as comorbidity, that that model is somewhat over-controlled. It is difficult to interpret this because you do not give any information about the bivariate association between each of the variables and the use of inappropriate medications, and you only report the multivariable model results.

As you mentioned, we added the bivariate association coefficients for each of the variables and the use of inappropriate medications in Table5 to show that there was no inconsistency.

8. Page 14: the description of adverse outcomes on the small sample in which you had prior 3 months data should be eliminated. It is not described in the methods or results sections, and as you point out, the number of subjects is too small in this analysis to make meaningful interpretations.

Within the limitation of our database, we tried to explore the outcomes of inappropriate medication which might contribute to the literature. However, we are quite prepared to delete this portion (p5. l11~13, p13. l2~p14. l7) if the editors concur with Referee 3’s suggestion.

Minor essential revisions

9. Under Results, it would be helpful to clarify that these rates of use of inappropriate medication use were for any use of any duration (is that correct?--Jan to July only?) over a 6 month period, rather than during a year.

Each assessment was cross-sectional so that the duration was not an issue.

10. I would suggest you use the plural 'medications' rather than 'medication' in all the phrases 'number of medication' throughout the paper.

We corrected all the phrases as suggested.