Reviewer’s report

Title: Patient safety incident reports related to traditional Japanese Kampo medicines: medication errors and adverse drug events in a university hospital for a ten-year period

Version: 0 Date: 07 Oct 2017

Reviewer: Heather Boon

Reviewer's report:

Thank you for the opportunity to review this paper. The paper is well-written and the study is clearly explained. I have a few suggestions for relatively minor revisions that I believe would strengthen the paper further:

1. Methods - pp 6-7. Please clarify if reporting to the patient safety incident reporting system of the hospital is mandatory or voluntary.

2. Discussion - p 14. The last paragraph of the discussion seems completely out of place and provides new data. I recommend removing this from the paper. Alternatively, the methods could be revised to explain how incidents regarding acupuncture were included in the data collection and then these findings should be included in the results section.

3. Conclusions: I did not find the conclusion to the paper or the abstract very strong. In my opinion, one of the most important findings of the study was the very low rate of safety issues associated with Kampo medicine and thus, I would recommend this be included in the conclusion. I am not sure I agree with the final sentence of the conclusion. The findings suggest to me that the more focus should be on administration errors which constitute by far the largest percentage of the safety incidents. Of course, those with the greatest impact (the adverse drug reactions) should also be a focus.

4. Figures: Overall, I think there are too many figures. I recommend omitting Figure 2 and Figure 7 as they do not add any additional information to the what is reported in the text.

Overall, this was a well-executed and reported study.
Are the methods appropriate and well described?
If not, please specify what is required in your comments to the authors.

Yes

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.

Yes

Are you able to assess any statistics in the manuscript or would you recommend an additional statistical review?
If an additional statistical review is recommended, please specify what aspects require further assessment in your comments to the editors.

I am able to assess the statistics

Quality of written English
Please indicate the quality of language in the manuscript:

Acceptable

Declaration of competing interests
Please complete a declaration of competing interests, considering the following questions:

1. Have you in the past five years received reimbursements, fees, funding, or salary from an organisation that may in any way gain or lose financially from the publication of this manuscript, either now or in the future?

2. Do you hold any stocks or shares in an organisation that may in any way gain or lose financially from the publication of this manuscript, either now or in the future?

3. Do you hold or are you currently applying for any patents relating to the content of the manuscript?

4. Have you received reimbursements, fees, funding, or salary from an organization that holds or has applied for patents relating to the content of the manuscript?

5. Do you have any other financial competing interests?
6. Do you have any non-financial competing interests in relation to this paper?

If you can answer no to all of the above, write 'I declare that I have no competing interests' below. If your reply is yes to any, please give details below.

'I declare that I have no competing interests'

I agree to the open peer review policy of the journal. I understand that my name will be included on my report to the authors and, if the manuscript is accepted for publication, my named report including any attachments I upload will be posted on the website along with the authors' responses. I agree for my report to be made available under an Open Access Creative Commons CC-BY license ([http://creativecommons.org/licenses/by/4.0/](http://creativecommons.org/licenses/by/4.0/)). I understand that any comments which I do not wish to be included in my named report can be included as confidential comments to the editors, which will not be published.

I agree to the open peer review policy of the journal