Author’s response to reviews

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

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Author’s response to reviews:

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Jianping Liu
Section Editor, Clinical Research
BMC Complementary and Alternative Medicine

Dear Editor:

We wish to re-submit our manuscript titled “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.” The manuscript ID is BCAM-D-17-00855.
We thank you and the reviewers for your thoughtful suggestions and insights. The manuscript has benefited from these insightful suggestions. I look forward to working with you and the reviewers to move this manuscript closer to publication in BMC Complementary and Alternative Medicine.

The manuscript has been rechecked and the necessary changes have been made in accordance with the reviewers’ suggestions. These changes are indicated by red text in the manuscript file. The responses to all comments have been prepared and are given below.

Thank you for your consideration. We look forward to hearing from you.

Sincerely,

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Response to the Reviewer’s Comments

Reviewer 1

Comment: In general, the manuscript is of high quality and clear, however I believe it would be strengthened by more detail on Kampo medicines in the introduction.

This research will be read by an international audience who may not be familiar with the differences between Kampo and traditional Chinese medicine. It would be important to highlight these differences and to emphasise that (in contrast to other jurisdictions) Kampo medicines are both strictly standardised and regulated.

Response: Thank you for your constructive comments. We described the history of Kampo medicine and its use in Japanese modern medicine to some extent in the Background and Discussion sections of the original manuscript. We do not believe that further explanation will contribute to the main point of this paper. Therefore, we'd like to avoid adding further background information at this time. However, for clarity, we added the following sentence to the Background section: “In contrast to other jurisdictions, Kampo medicines are both strictly standardised and regulated in Japan.” (Page 6, Lines 13–15)

Background:

Line 4: reporting is mandatory for teaching hospitals but voluntary for others....

Why is this?

Also what proportion of hospitals are not teaching hospitals.

It would be good to know what the position is for ADE and ADR reporting in the non-hospital setting e.g. community setting...is this mandatory for General Practitioners / pharmacists?

Are the general public allowed/ encouraged to report?
It would be interesting to compare this to other systems e.g. Yellow card scheme (UK) etc.

Response: Thank you for your insightful questions. In the Background section of the manuscript, we cited a World Health Organization reference (WHO draft guidelines for adverse event reporting and learning systems: from information to action. World Health Organization, Geneva. 2005. (http://apps.who.int/iris/bitstream/10665/69797/1/WHO-EIP-SPO-QPS-05.3-eng.pdf). For more explanation, we revised the second paragraph of the Background section as follows: “Currently, incident reporting systems are widely used to collect information about patient safety incidents that occur in hospitals. Patient injuries, sometimes referred to as adverse events, are reported along with near-misses and equipment failures. In Japan, hospitals are mandated by the Ministry of Health, Labour and Welfare to have internal reporting systems. Any hospital or health facility can voluntarily report to an accreditation body, but there is a mandatory requirement to report to the Japan Council for Quality Health Care, which implemented a national reporting system in 2004. Reporting to this system is only mandatory for teaching hospitals, and voluntary for others. Information is reported electronically. The Japan Council for Quality Health Care analyses the facts and circumstances of the incident and provides feedback to the reporting entities. The data are classified and summary results are disseminated to healthcare providers and to the public. Cases deemed particularly important are evaluated individually. Otherwise, reports are aggregated for statistical analysis [2, 4]. In 2015, the total number of medical institutions (hospitals) that reported medical adverse events was 1,018; of those, 275 were teaching hospitals (i.e., having mandatory reporting), and 743 were non-teaching hospitals (i.e., having voluntary reporting) [4].” (Page 4, Line 24– Page 5, Line 17)

Line 6: I would include the definition here of what you mean as traditional medicines and differentiate this from conventional medicine.

Response: Thank you for your helpful suggestion.

Methods:
Line 22: if this is a healthcare professional then I would say that, as professional is unclear. Also I think a Figure to depict the flow of an error through the system would be a useful addition.

Response: Thank you for your valuable suggestions. In accordance with your comments, we clarified that it is a “health-care professional” who is involved in or has knowledge of an incident who submits the first report (Page 7, Lines 16–18). Additionally, we added a new figure that illustrates the flow of an error through the system (Figure 1. Flow chart of the incident reporting system) to the manuscript, and added the following sentence in the Methods section: “A flow chart illustrating the incident reporting system in the Toyama University Hospital is provided in Figure 1.” (Page 7, Line 23–Page 8, Line 1)

Line 7: In THE case of a major....

Response: Thank you for pointing out this error. In accordance with your suggestion, we changed “In a case of [...]” to “In the case of [...]” in the manuscript (Page 8, Line 5).

Line 9: professional (as above)

Response: Thank you for your suggestion. We have added the term “health-care” on Page 8, Line 8.

Study design:

Line 20: ward as opposed to site
Response: Thank you for your helpful suggestion. We have changed the term “site” to “ward or department” in the manuscript (Page 9, Line 20).

Line 21: profession (as above)

Response: In accordance with your suggestion, we added the term “health-care” to the relevant portion of text in the manuscript (Page 9, Line 20).

Line 22: need to be a little clearer on the process as up until now it was not clear to me that a person, other than the person involved in the error, could report this error.

Response: Thank you for your valuable comment. There are cases where the reporter and the person involved in the incident are actually different people. In “The patient safety incident reporting system” subsection of the Methods, we explained that “A health-care professional who is involved in or has knowledge of an incident submits the first report […]” (Page 7, Lines 16–18). We hope that this sufficiently clarifies this information.

Line 23: what is meant by steps of medication error?

Response: Thank you for your insightful comment. When discussing the steps of medication error, we are referring to when/at what stage of the process the error occurred, i.e., whether it was a prescribing error, dispensing error, or administering errors. To clarify this information, we changed “[…] classification of the incident (i.e., steps of medication error or adverse drug event) […]” to “[…] classification of the incident (i.e., the step/stage at which the medication error [prescribing error, dispensing error, or administering error] or adverse drug event occurred) […]” in the manuscript (Page 9, Line 23– Page 10, Line 1).
Results:

Line 22: ? use of redundant? Perhaps “inaccurately” may be better

Response: Thank you for your valuable comment. In this instance, we used the term “redundantly” to indicate that more than one report was filed, by different people, for the same incident. In other words, we meant that duplicate reports were submitted for a single incident. We do not believe that the term “inaccurately” should be used instead of “redundantly” because, technically, the duplicated reports were accurate; they were just reported more than once. To clarify this information in the manuscript, we made the following revision: “Of the 108 Kampo medicine-related incident reports, five cases were reported redundantly (i.e., duplicate reports were submitted for the same incident) […]” (Page 11, Lines 2–3). We hope that this revision sufficiently addresses your concern.

Line 1: Occurred ON the hospital wards

Response: Thank you for your helpful suggestion. In accordance with your comment, we changed “in” to “on” in the Results section of the manuscript (Page 11, Line 6).

Line 13-15: this could be clearer by the use of brackets and / or commas throughout

Response: Thank you for your suggestion. Accordingly, we changed “Of the 103 incidents, 99 (96.1%) were medication errors (77 [74.7%] administration errors, 15 [14.6%] dispensing errors, and seven [6.8%] prescribing errors) and four (3.9%) were adverse drug events (all adverse drug reactions; Figure 5)” to “Of the 103 incidents, 99 (96.1%) were medication errors and four (3.9%) were adverse drug events (all adverse drug reactions). Of the medication errors, 77 (74.7%) were administering errors, 15 (14.6%) were dispensing errors, and seven (6.8%) were prescribing errors (Figure 4).” (Page 11, Lines 18–21)
Line 19: would avoid use of < and > in text

Response: Thank you for your helpful suggestion. In accordance with your suggestion, we have changed “>” to “more than” and “<” to “less than” in the manuscript (Page 12, Lines 1–2).

Discussion:

Line 8: All OF THESE..

Response: Thank you for your suggestion. In accordance with your comment, we changed “All” to “All of these” (Page 13, Lines 18–19).

Line 12-13: you have given two explanations as to why the number of administration errors has decreased but I think it should be mentioned that it is only the number of reports that have decreased as it is not clear what the organisational level effects of reporting an error are; i.e. is there a blame culture, would it be that due to time constraints staff do not have the resources to report. What about feedback to staff? Has this been done, so that they know that these reports are important to help patients and fellow caregivers and to avoid mistakes... Is root-cause analysis conducted on these errors? It would seem that the majority of errors occurred in the administration of medication; either not at all or not on time... was any effort made to see why this is happening?

Response: Thank you for your valuable comments. Nurses in the Toyama University Hospital are eagerly working on medical safety. Feedback has been given to hospital staff regarding the importance of incident reporting for the safety of patients and prevention of errors in the hospital. Table 2 shows that the number of inpatients in the Department of Japanese Oriental Medicine (N of IPs in DJOM) has been decreased year by year. This is considered to be one of the reasons for the decrease in the number of administration errors associated with Kampo medicines. Therefore, we explained the two reasons as to why the number of administration errors has decreased (Page 13, Line 24–Page 14, Line 6). In the revised manuscript, we added the following sentence to the Discussion section: “, because feedback has been given to hospital staff regarding the importance
of incident reporting for the safety of patients and prevention of errors in the hospital” (Page 14, Line 1–3). We respectfully request that you take this into consideration.

Line 24: are these discharge prescriptions?

Response: Thank you for your insightful question. “Out-of-hospital prescriptions” are not “discharge prescriptions”. In Japanese hospitals, there are “in-hospital prescriptions” and “out-of-hospital prescriptions” for outpatients; the latter (prescribed by doctors but dispensed by community pharmacies) are recommended by national policy, and have been increasingly prescribed in recent years.

Line 5: instead of out-of-hospital pharmacies, could we say "community" pharmacies?

Response: Thank you for your helpful suggestion. However, instead of changing “out-of-hospital pharmacies” to “community pharmacies” in the manuscript, we clarified this information in parentheses: “out-of-hospital pharmacies (i.e., community pharmacies)” (Page 14, Lines 20–21).

Line 8: erroneous names similar to those of correct medicines, this may not just be a knowledge question but rather errors can be attributed to sound-alike drug names (at least in English...SALAD)

Response: Thank you for your insightful comments. We agree with your opinion. For modern medicines, a fundamental systematic approach may be necessary. However, the names of traditional Japanese Kampo medicines cannot be changed; therefore, there is, in fact, an issue regarding lack of knowledge. We hope you understand our view regarding this matter.
Line 12: Both of which were ...

Response: Thank you for your comment. In accordance with your suggestion, we changed “all” to “both of which” in the manuscript (Page 15, Line 5).

Line 5-10: not sure that this is relevant to the aim of the paper or its thrust which is focusing on Kampo medicines.

Response: Thank you for your valuable comment. In accordance with your comment, we removed the last paragraph (pertaining to acupuncture) of the Discussion in the revised manuscript.

Tables:

Table 2: OPS not Ops
Table 3: I think that the recommendations for practice should flow from here

Response: Thank you for your pertinent comments. We changed “Ops” to “OPs” in Table 2. Additionally, based on your recommendation, we omitted the original Figure 1, and replaced it with a flow chart illustrating the incident reporting system in the Toyama University Hospital.

Figures:

Figure 1: Not sure this is necessary
Figure 2: Not sure this is necessary
Figure 3: labelling of axes unclear also the link between years of practice and incidents is not clear

Figure 4: Not sure this is necessary

Figure 5: Not sure this is necessary

Figure 6: Administration error

Figure 7: Not sure this is necessary

Response: Thank you for your valuable comments. In accordance with your suggestions, we omitted the original versions of Figures 1, 2, and 7 in the revised manuscript, and clarified the labelling of the axes in Figures 3 and 4 (now Figures 2 and 3 in the revised manuscript). In addition, we changed “administering error” to “Administration error” in Figure 4 (i.e., the original Figure 5) as the reviewer suggested.
Reviewer 2

Comment: 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:

Response: Thank you for your constructive and encouraging comments.

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

Response: Thank you for your pertinent suggestion. Reporting to the patient safety incident reporting system is mandatory for health-care professionals in the hospital. Therefore, we added the following sentence to the Methods section of the manuscript to clarify this information: “Reporting to the patient safety incident reporting system is mandatory for health-care professionals in the hospital.” (Page 7, Line 15–16)

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.

Response: Thank you for your valuable comments and suggestions. In accordance with your recommendation, we removed the last paragraph (pertaining to acupuncture) from the Discussion.
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.

Response: Thank you for your insightful comments. In accordance with your comments, we changed the following portions of text to the Abstract (Page 4, Lines 7–9) and the Conclusions section (Page 16, Lines 8–10), respectively: “There are many patient safety issues related to Kampo medicines. Patient safety awareness should be raised to prevent medication errors, especially administration errors, and adverse drug events in Kampo medicine.” and “These findings suggest that patient safety should be promoted to prevent medication errors, especially administration errors, and adverse drug events related to Kampo medicines.”

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.

Response: Thank you for your helpful suggestions. In accordance with your recommendation, we omitted Figures 2 and 7 from revised manuscript. Additionally, based on Reviewer 1’s recommendation, we omitted the original Figure 1, and replaced it with a flow chart illustrating the incident reporting system in the Toyama University Hospital.

Overall, this was a well-executed and reported study.

Response: Thank you for your kind and encouraging comments.