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: 31 Aug 2017

Reviewer: Laura Sahm

Reviewer's report:

Thank you for the opportunity to review this paper.

I have some general and specific comments

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.

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.

Line 6:

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

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.

Line 7: In THE case of a major….

Line 9: professional (as above)

Study design:

Line 20: ? ward as opposed to site

Line 21: profession (as above)

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.

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

Results:

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

Line 1 Occurred ON the hospital wards

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

Line 19: would avoid use of < and > in text

Discussion:

Line 8: All OF THESE..

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?
Line 24: are these discharge prescriptions?

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

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)

Line 12: Both of which were …

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

Table 2: OPS not Ops

Table 3: I think that the recommendations for practice should flow from here

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
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.

Unable to assess

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.

Not relevant to this manuscript

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

Needs some language corrections before being published

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