PEER REVIEW HISTORY

ARTICLE DETAILS

TITLE (PROVISIONAL)	Safety Culture in Pharmacy Setting Using Pharmacy Survey on Patient Safety Culture: A Cross-sectional Study in China
AUTHORS	Jia, Pengli; Zhang, Longhao; Zhang, Mingmig; Zhang, Linli; Zhang, Chuan; Qin, Shengfang; Li, Xinli; Liu, Kexin

VERSION 1 - REVIEW

REVIEWER	Said Bodur Balikesir University Medical School Department of Public Health, Turkey
REVIEW RETURNED	03-Mar-2014

- The reviewer completed the checklist but made no further comments.

REVIEWER	Jason Etchegaray The University of Texas Medical School at Houston
REVIEW RETURNED	27-Mar-2014

GENERAL COMMENTS	The authors should be commended for attempting to extend the measurement of culture into another language. I have several concerns focused on the methodology and data analysis. Concerns: 1) The authors appeared to have translated the PSOPSC into a Chinese version but it does not appear that the authors used proper translation-back translation techniques. If they did, they did not explain that they did or how they accomplished this. Rather, it sounds like they translated the survey into Chinese and sought consensus internally about whether the translation was correct. 2) Given that the factor structure of the PSOPSC is known given previous research, why did the researchers not conduct a confirmatory factor analysis to examine their data? The exploratory factor analysis approach makes more sense when we do not know the likely factor structure. 3) The authors note differences between the Chinese and US versions of the PSOPSC and note that this caused them to only examine differences between some items but they do not explain what the differences are or why they existed (which is also related to my first concern above). 4) In Table 2, did the authors aggregate the results across all 20 pharmacies? If so, did they have justification to do so by looking at agreement indices? 5) I cannot see the survey items in Table 3, as they do not appear on the page. 6) Table 4 is interesting and leads me to wonder whether there is a

	positive correlation between dimensions on the PSOPSC and overall patient safety grade. Did the researchers find such a correlation? 7) I expected to see a discussion of CFA results in the validity section.....

REVIEWER	Annika Nordén-Hägg Faculty of Pharmacy, University of Uppsala
REVIEW RETURNED	27-Apr-2014

GENERAL COMMENTS	**Background** In the very end the authors choose to use the word “we” – I recommend a re-phrasing to avoid the use of this word in a scientific paper. **Methods** The self-administered survey was going on for 6 months – this is a very long time. Why? All pharmacy staff were included. What is pharmacy staff in China? Education? Hospital pharmacy in China – a brief description is needed. 20 hospital pharmacies were included – what was the number of staff in each pharmacy? **Results** The primary focus ought to be on the evaluation of the method, the survey which has been used. This is however not the case. The method and the validity of the survey ought to constitute the first part of the result section, not the findings of the survey. What is the difference between senior and junior pharmacist? What is a pharmacy intern? Cronbach alpha values are very low for some dimensions. **Discussion** Initially the method used and the validity of it, ought to be discussed. This is not the case. As far as I understand the statistics demonstrating the validity of the method is not clear-cut and need to be scrutinized by a statistician. The validity of the method has a ruling influence on the discussion that should follow, i.e. the results of the survey. This part of the discussion ought to be reviewed in total, in light of the validity of the method. In general this part of the discussion – the outcome of the survey – is in several parts not referring to the hospital pharmacies that are the object of the survey. And conclusions are drawn, that are impossible taken into account the items included in the survey. For instance it is concluded that the “pharmacy staff were delight in cooperating with others and well function relative to hospital departments” – this is not studied and therefore the conclusion is

	hard to understand. Also a relatively low positive response rate was noted in the dimension Patient Counseling which, in the discussion is said to reflect the problem poor doctor – patient communication. This conclusion is hard to understand as well – the study encompasses pharmacy staff – not doctors. Also the part about lawsuits refers to the medical profession, not pharmacists, as far as I understand.

VERSION 1 – AUTHOR RESPONSE

Reviewer: 1
Reviewer Name Said Bodur
Institution and Country Balikesir University Medical School Department of Public Health, Turkey
Please state any competing interests or state 'None declared': None declared
There are no comments.

Reviewer: 2
Reviewer Name Jason Etchegaray
Institution and Country The University of Texas Medical School at Houston
Please state any competing interests or state 'None declared': None declared

The authors should be commended for attempting to extend the measurement of culture into another language. I have several concerns focused on the methodology and data analysis.

Concerns:
1) The authors appeared to have translated the PSOPSC into a Chinese version but it does not appear that the authors used proper translation-back translation techniques. If they did, they did not explain that they did or how they accomplished this. Rather, it sounds like they translated the survey into Chinese and sought consensus internally about whether the translation was correct.

Thanks for this point. Honestly speaking that we did not use "translation-back translation techniques". Yes, that "translation-back translation techniques" is a good approach for some languages especially for Latin language system, however we do not think it is one of the best approaches for the Chinese translation which is totally different language system. So before we did this translation, we had seek the advice from the language experts and gave up this approach.
The process we did for translation is as we explained in the method part. We translated and revised the English survey for over ten times and did the pilot test among 30 pharmacy staff and modified the translation, then back again to revise it with pharmacy staff, methodologists, and English teacher for the final Chinese version so as to fit for Chinese content.

2) Given that the factor structure of the PSOPSC is known given previous research, why did the researchers not conduct a confirmatory factor analysis to examine their data? The exploratory factor analysis approach makes more sense when we do not know the likely factor structure.

To conduct patient safety survey is somewhat very sensitive in Chinese hospitals and we came across many difficulties while we implemented this. Our initial design was to include over 1000 pharmacy staff for about 50 hospitals across China so that we thought there would be bigger sample size for us to conduct confirmatory factor analysis and exploratory factor analysis as well. However, with our hard efforts, there were only about 527 pharmacy staff from 20 hospitals included finally. We

were advised by our statistician that conducting confirmatory factor analysis with small number of people would not make much sense for this study. So in this case we only conduct an exploratory factor analysis, which might be a weak point for this research. But we would add this point both in the “limitation” and “discussion” part of our submitted manuscript.
In addition, unlike other similar studies published anywhere focused on tool evaluation or developing the survey tool, the primary objective of our study focused on “To explore the attitudes and perceptions of patient safety culture for pharmacy workers in China by using a Pharmacy Survey on Patient Safety Culture ” . We would like to learn more about the current situation in pharmacy of China rather than to learn the evaluation of the survey tool.
On the other hand, as far as we know, the PSOPSC was developed by AHRQ in 2012 on the purpose of pilot study and until now, only the Gronbach’s α and some baseline data were provided by the AHRQ, so the factor structure of the PSOPSC was not given in the previous research. In view of this and you mentioned above, the exploratory factor analysis approach may make more sense as we do not know the likely factor structure.

3) The authors note differences between the Chinese and US versions of the PSOPSC and note that this caused them to only examine differences between some items but they do not explain what the differences are or why they existed (which is also related to my first concern above).

Thanks for this point and we have explained the existence of the differences and interpreted the reasons for it in paragraph 1 of Methods.
Yes, the translation might be one of the reasons for this. However we think any translations approaches can not be perfect. The differences between the Chinese and US versions is: in the original version of U.S. PSOPSC, the A3:“Technicians in this pharmacy receive the training they need to do their jobs” and A10: “ Staff get enough training from this pharmacy” are seperate items, in our modified Chinese version, we combined the two items into a single item. The reason for this change was that the two items almost the same meaning in Chinese translation. We seek advice from the language experts and did the pilot test among 30 pharmacy staff then back again to revise it with pharmacy staff, methodologists, and English teacher for the final Chinese version so as to fit for Chinese content.

4) In Table 2, did the authors aggregate the results across all 20 pharmacies? If so, did they have justification to do so by looking at agreement indices?

Yes.

5) I cannot see the survey items in Table 3, as they do not appear on the page.

Sorry about this. We do not know how we can help with this. When we submitted, we have submitted the whole document with a complete tables including Table 3.

6) Table 4 is interesting and leads me to wonder whether there is a positive correlation between dimensions on the PSOPSC and overall patient safety grade. Did the researchers find such a correlation?

The primary purpose for Table 4 we hope is to explore if there was a statistical difference on “overall patient safety grade” in different qualification levels of Chinese pharmacies compared with that of US pharmacies. As you mentioned above, we have examined it again and found that there is a positive correlation between the 11 dimensions on the PSOPSC and overall patient safety grade and all correlations are significant at $P < 0.001$. The correlation coefficient ranged from 0.30 to 0.46. “Communication About Prescriptions Across Shifts” and “overall patient safety grade” ($r = 0.30$) was

least correlated, while “Teamwork” and “overall patient safety grade “(r = 0.46) was most correlated. Meanwhile, there is also a positive correlation between the scale and “overall patient safety grade”. The correlation coefficient was 0.43 and the correlation is also significant at P < 0.001.

7) I expected to see a discussion of CFA results in the validity section.....

We have revised this point both in the “limitation” and “discussion” part of our manuscript.

Much appreciated for your above constructive comments which will help us better improve our future research.

Reviewer: 3
Reviewer Name Annika Nordén-Hägg
Institution and Country Faculty of Pharmacy, University of Uppsala
Please state any competing interests or state ‘None declared’: none declared

I have some comments on this paper, which follows below.

The English language, in which the manuscript is written, is not satisfactorily.

Thanks for this point and we have asked a native English speaker to polish English again.

I also feel that there is a need to have a statistician scrutinize the statistics as presented in this study.

We also have asked the statistician in our Center to look at the part of data analysis again

Background
In the very end the authors choose to use the word “we” – I recommend a re-phrasing to avoid the use of this word in ascientific paper.

We have revised this. Thanks for pointing out.

Methods
The self-administered survey was going on for 6 months – this is a very long time. Why?

Although patient safety activity is getting recognized in China, we understand that there have still many challenges and difficulties in implementation this activity. E,g, to conduct this survey, the hospitals where we investigated were very sensitive and they did not want to “open” their ‘data’ or they were concerned whether this will influence the reputation of hospitals. Therefore, each time, we needed to negotiate and explain our purpose to get the approval from relative responsible person which is very time consuming experience and which was also the reason why our sample size is not big. Please understand this.

All pharmacy staff were included. What is pharmacy staff in China? Education?

Pharmacy staff including senior and junior pharmacists and pharmacy interns (their education background explained below in results part) working in the pharmacy area where prescriptions were dropped off, filled, dispensed, and picked up or prepared for delivery and with at least three years university education.

Hospital pharmacy in China – a brief description is needed.

Thanks for pointing out.We have revised this and added the description in the manuscript in paragraph 1 of Sample.
In China, hospital pharmacy is a very close unit within the hospitals which may not like the western countries. It is affiliated with the hospital and is one of the departments of the hospital.

20 hospital pharmacies were included – what was the number of staff in each pharmacy?

We have revised this and added the number in the manuscript in paragraph 1 of Sample.
The pharmacy workers ranging from 30 to 60 in each hospital

Results
The primary focus ought to be on the evaluation of the method, the survey which has been used. This is however not the case. The method and the validity of the survey ought to constitute the first part of the result section, not the findings of the survey.

Yes, we agree with this point. However, unlike other similar studies published anywhere focused on tool evaluation or develop the survey tool, the primary objective of our study focused on “To explore the attitudes and perceptions of patient safety culture for pharmacy workers in China by using a Pharmacy Survey on Patient Safety Culture” . We would like to learn more about the current situation in pharmacy of China rather than to learn the evaluation of the survey tool. Hence our results followed our objective which we focused on.

What is the difference between senior and junior pharmacist? What is a pharmacy intern?

Junior pharmacist with at least three years university education whose working time is less than 9 years in the pharmacy. Senior pharmacist also with at least three years university education but the working time must more than 9 years in the pharmacy. Pharmacy intern is someone who is still undergraduate and just work in a pharmacy in spare time.

Cronbach alpha values are very low for some dimensions.

Thanks for pointing out. And we have talked this problem in the Reliability and validity section of Discussion.

Discussion
Initially the method used and the validity of it, ought to be discussed. This is not the case. As far as I understand the statistics demonstrating the validity of the method is not clear-cut and need to be scrutinized by a statistician. The validity of the method has a ruling influence on the discussion that should follow, i.e. the results of the survey. This part of the discussion ought to be reviewed in total, in light of the validity of the method.

Thanks for this point and we agree with that “The validity of the method has a ruling influence on the discussion”. As we mentioned above in results part that unlike other similar published studies focusing on the tool evaluation or developing survey tool, our study primary objective is “To explore the attitudes and perceptions of patient safety culture for pharmacy workers in China by using a Pharmacy Survey on Patient Safety Culture ” rather than evaluation of the tool. So we focused much on the attitudes and perceptions of pharmacy in China by this pilot survey which is what we want to learn about. There is indeed a weak point that the statistics demonstrating the validity of the method. We would like to add this point to our “limitation” and ‘discussion’ part.

In general this part of the discussion – the outcome of the survey – is in several parts not referring to

the hospital pharmacies that are the object of the survey. And conclusions are drawn, that are impossible taken into account the items included in the survey. For instance it is concluded that the “pharmacy staff were delight in cooperating with others and well function relative to hospital departments” – this is not studied and therefore the conclusion is hard to understand.

Yes, we agree with your view. We deleted the conclusion.

Also a relatively low positive response rate was noted in the dimension Patient Counseling which, in the discussion is said to reflect the problem poor doctor – patient communication. This conclusion is hard to understand as well – the study encompasses pharmacy staff – not doctors. Also the part about lawsuits refers to the medical profession, not pharmacists, as far as I understand.

Sorry to cause confusing. We will try our best to revise this part and make it more clear. The Chinese pharmacies are a very close unit within the hospitals which may not like the western countries. The health professionals in China include hospital pharmacy workers. So many lawsuits also refer to hospital pharmacy workers because of their careless or lack of sense of patient safety culture to make medical errors happen. “Patient Counseling” is indeed the most weakest point in hospital either for medical doctors or for pharmacy workers in China that patients complain so munch.

Much appreciated for your above constructive comments which will help us better improve our future research.