## PEER REVIEW HISTORY



## ARTICLE DETAILS

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| **TITLE (PROVISIONAL)** | Measuring patient safety culture in maternal and child health institutions in China: a qualitative study |
| **AUTHORS** | Wang, Yuanyuan; Liu, Weiwei; Shi, Huifeng; Liu, Chaojie; Wang, Yan |

## VERSION 1 - REVIEW

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| **REVIEWER** | Mingming Zhang<br>Chinese Evidence-Based Medicine Centre<br>West China Hospital, Sichuan University |
| **REVIEW RETURNED** | 05-Jan-2017 |

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| **GENERAL COMMENTS** | 1.The title if this paper is interesting but background section did not provide anything new to the reader. I would encourage the authors to provide more information on what is the grounded theory and why they choose the grounded theory?<br>2.Could you please provide further information on how the 6 MCH institutions were selected for inclusion? As the information showed in Appendix Table 1, there is a significant gap on the staff and bed between in the 6 MCH institutions. I just wonder whether the sample size is representative<br>3.The authors should provider more statistical detail about the sample size calculation. |

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| **REVIEWER** | Hongbing Tao<br>School of Medicine & Health Management, Tongji Medical College, Huazhong University of Science & Technology |
| **REVIEW RETURNED** | 24-Jan-2017 |

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| **GENERAL COMMENTS** | It was still necessary to conduct such a grounded theory on PSC of MCH institutions in China and it is an important question to dig the concept of PSC in China. It was needed to fundamentally and theoretically dig the concept of PSC again and again, in order to nourish novel innovations and strategies for researchers and managers to pursue PS and quality improving.<br>1.The author could tell us what are the specific characteristics of PSC in MCH institutions and the differences between MCH institutions and other institutions. It is the important reason to decide the frameworks of culture in MCH institutions.<br>2. Stratified purposive sampling methods were used to recruit participants from six MCH institutions in two provinces. Why could the framework of PSC be applied both in MCH institutions and in other institutions? (Page 3 of 26 line 3-4)<br>3. Patient safety culture (PSC), defined as 'the shared values, beliefs, norms and procedures related to patient safety among |

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| | members of the organization', was a really relevant and important issue for PS highly concerned worldwide. climate provided a snapshot of medical staff' perceptions of culture; and attitudes referred to medical staff' attitudes and perceptions on PS.<br>Why were the participants investigated in this study, including patients? And in fact patients have no experiences in many practices such as management support, regulation and procedure, teamwork, openness to adverse events and working perception, and they could not decided the related perceptions of culture. (Appendix Table 5) |

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| **REVIEWER** | Reema Harrison<br>UNSW Australia |
| **REVIEW RETURNED** | 28-Feb-2017 |

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| **GENERAL COMMENTS** | I feel that the paper is fundamentally flawed in the question posed and approach taken. There are many well-known and widely validated frameworks for patient safety as a concept and patient safety culture specifically. The latter have been used in Chinese healthcare contexts. The case for undertaking a grounded theory approach that does not draw on any of this existing material is not made here. The study would be more appropriate if it had assessed this data against current frameworks to determine the suitability of current frameworks for the MCH setting in China. The link between PSC and MCH is also not clearly established - they are simply identified as important areas. The findings reinforce that for the most part, existing frameworks are relevant to the MCH context in China although the issue of 'public security' may be more pronounced - this features to some extent in existing frameworks. |

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| **REVIEWER** | Gulzar Shah<br>Jiann-Ping Hsu College of Public Health<br>Georgia Southern University<br>P.O. Box 8015<br>Statesboro, GA 30460<br>United States of America |
| **REVIEW RETURNED** | 13-Mar-2017 |

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| **GENERAL COMMENTS** | This study aimed to use a grounded theory approach, in order to provide a conceptual framework and code the results of qualitative responses from key informant interviews with MCH clinics staff. The study is innovative in it's application of the grounded theory principles for indepth analysis of patient safety culture.<br>There are several issues the authors may want to address before to make this study acceptable for MBJ. First, the grounded theory is much more than simply conducting qualitative interviews on pre-decided questions. Instead, it is iterative and concept forming evolves during or based on data collection. The authors do need to make a case foe how their study comprises a true grounded theory approach rather than a simple qualitative analysis of key informant interviews based on pre-constructed open ended questions. There is no mention of organizational culture with respect to patient safety observed during the study and included in the analysis (yet contextual observational information is essential component of the Grounded Theory Approach).<br><br>In the conceptualization (Page 4; results), the authors mention, "PS |

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| | was categorized into six hierarchical levels:"<br>[1] public security as other public places,<br>[2] medical safety in the whole process of medical services provided, privacy and information security,<br>[3] financial security prevented from unnecessary interventions,<br>[4] psychological safety whether unsafe events happened or not, and<br>[5] demands been met or problems be solved.<br>The authors need to cite relevant literature as to justify their "hierarchical" levels. As such the schema itself makes no particular sense. Particularly it is not clear how/why the authors thought the " public security as other public places" was at the top of the hierarchy. As a student of patient safety culture, I know that patient safety is primarily concerned mostly with what the authors state in their point 2.: "medical safety in the whole process of medical services provided.." If safety issues arise at public places other than the care provider (e.g. a hospital), that may have consequences for the care but is not directly a feature of organizational patient safety from care providers point of view.<br>Further, if the authors can justify the hierarchical levels of PS (consistent with the literature on patient safety), they should be encouraged to show the hierarchy in a diagram with explanation of proper connections across levels.<br>For this paper to be acceptable, the authors should not try to sell the new conceptual framework as the standard tested schema for measuring patient safety. Their thrust should be on their results based on thematic coding that made sense to them (which could be one of many ways to code the qualitative interviews on patient safety). They should reduce the emphasis on grounded theory and generation of a standard conceptual frame to be used by others in all relevant components of the article, including the title, the abstract, introduction and discussion.<br><br>Finally the authors may be asked to review the manuscript for readability and grammar. One particular aspect of the language is that authors uses the past tense throughout the article even when it was not appropriate. Some examples include:<br>Page 1: The authors say "Patient safety (PS) was a key principle in medical practice." Why the use of past tense? Is it not a key principle now? In fact it is more of a concern now than historically.<br><br>Page 2: again "patient safety culture ...was a really relevant and important issue for PS highly concerned worldwide." Again it is still the case; why use "was"?<br>The authors state "Maternal and child health (MCH) was another highly-concerned issue all over the world." Not sure when it ceased to be an issue! So why use past tense?<br>Methods: "This was a qualitative study based" ...<br><br>Limitation Section: The study is likely to have several limitations but the limitations section is obscure and incomplete. For instance the authors indicate "This study was conducted through a qualitative approach based on grounded theory, which more likely represented views from researchers themselves". If this in fact is true then the study should have very limited value. The authors should address/discuss this. |

**VERSION 1 – AUTHOR RESPONSE**

Reviewer: 1
Reviewer Name: Mingming Zhang
Institution and Country: Chinese Evidence-Based Medicine Centre, West China Hospital, Sichuan University
Please state any competing interests: None declared

1.The title if this paper is interesting but background section did not provide anything new to the reader. I would encourage the authors to provide more information on what is the grounded theory and why they choose the grounded theory?

Thanks for the advice. This study used both inductive (based on the existing PSC theory developed by the Agency for Healthcare Research and Quality) and deductive (open coding arising from data) approaches. The deductive approach followed the principles of grounded theory. It allows us to generate a new (or modified) PSC framework without necessarily being restricted to any existing theoretical framework. We have added some explanations in the method section. However, in line with advice from another reviewer, we have de-emphasized the grounded theory.
Details can be seen in Page 3, 4, 5.

2.Could you please provide further information on how the 6 MCH institutions were selected for inclusion? As the information showed in Appendix Table 1, there is a significant gap on the staff and bed between in the 6 MCH institutions. I just wonder whether the sample size is representative

We have included more details about the sampling. The six MCH institutions were purposively selected, considering diversities in staffing, resources (eg. beds), and scope and volume of services (eg. outpatient, inpatient and birth deliveries). This is why a significant gap in resources exists across the institutions (Page 4).

3.The authors should provider more statistical detail about the sample size calculation.

Thanks for the advice. We followed the principles of grounded theory. Data analyses took place concurrently with data collection. The final sample size was determined by saturation of information when no new theme emerged from coding. The saturation of information was deemed to be achieved when the entire research team (especially those who performed interviews and coding) reached consensus (Page 4).

Reviewer: 2
Reviewer Name: Hongbing Tao
Institution and Country: School of Medicine & Health Management, Tongji Medical College, Huazhong University of Science & Technology
Please state any competing interests: There is no any competing interests.

1.The author could tell us what are the specific characteristics of PSC in MCH institutions and the differences between MCH institutions and other institutions. It is the important reason to decide the frameworks of culture in MCH institutions.

Thanks for the important advice. We have re-written the results and discussion sections, with an emphasis on similarities and differences in PSC between MCH institutions and general hospitals (Page 12-13).

2. Stratified purposive sampling methods were used to recruit participants from six MCH institutions in

two provinces. Why could the framework of PSC be applied both in MCH institutions and in other institutions? (Page 3 of 26 line 3-4)

Sorry for the lack of clarity in the previous version. We have amended the writing. The PSC framework contains some common features similar to those in general hospitals, as well as some unique features specific to MCH institutions (Page 12-13).

3. Patient safety culture (PSC), defined as 'the shared values, beliefs, norms and procedures related to patient safety among members of the organization', was a really relevant and important issue for PS highly concerned worldwide. climate provided a snapshot of medical staff' perceptions of culture; and attitudes referred to medical staff' attitudes and perceptions on PS. Why were the participants investigated in this study, including patients? And in fact patients have no experiences in many practices such as management support, regulation and procedure, teamwork, openness to adverse events and working perception, and they could not decided the related perceptions of culture. (Appendix Table 5)

We agree that PSC is a concept applicable to health providers, and patients may not have direct observations on some aspects of PSC. Indeed, coding of data collected from patients does not cover all of the themes emerged in this study. The reason for including patients in this study is simply because the concept of PSC reflects the philosophy of patient-centered health care. In reality, concerns of health workers may not always be aligned with those of patients. There may exist cognitive conflicts and interest conflicts between health workers and patients. Involving patients in this study gives us a chance to examine potential conflicts between patients and health workers, which is often associated with PSC (Page 13).

Reviewer: 3
Reviewer Name: Reema Harrison
Institution and Country: UNSW Australia
Please state any competing interests: None declared

-I feel that the paper is fundamentally flawed in the question posed and approach taken. There are many well-known and widely validated frameworks for patient safety as a concept and patient safety culture specifically. The latter have been used in Chinese healthcare contexts. The case for undertaking a grounded theory approach that does not draw on any of this existing material is not made here. The study would be more appropriate if it had assessed this data against current frameworks to determine the suitability of current frameworks for the MCH setting in China.

We are sorry for the inadequate description of methods in the previous version. This study used both inductive (based on the existing PSC theory developed by the Agency for Healthcare Research and Quality) and deductive (open coding arising from data) approaches (Page 4-5). Thanks for the critical advice, which has helped us clarify such an important matter.

-The link between PSC and MCH is also not clearly established - they are simply identified as important areas. The findings reinforce that for the most part, existing frameworks are relevant to the MCH context in China although the issue of 'public security' may be more pronounced - this features to some extent in existing frameworks.

Thanks. We have realized the lack of clarity in the results and discussion sections. We have re-written those two sections completely, with an emphasis on the similarities and differences in PSC between MCH institutions and general hospitals. We have also discussed the reasons underpinning the special features of MCH institutions (Page 12-13).

Reviewer: 4
Reviewer Name: Gulzar Shah
Institution and Country: Jiann-Ping Hsu College of Public Health, Georgia Southern University, P.O. Box 8015 Statesboro, GA 30460, United States of America
Please state any competing interests: None declared

-This study aimed to use a grounded theory approach, in order to provide a conceptual framework and code the results of qualitative responses from key informant interviews with MCH clinics staff. The study is innovative in it's application of the grounded theory principles for indepth analysis of patient safety culture.

Thanks for the encouragement.

-There are several issues the authors may want to address before to make this study acceptable for MBJ. First, the grounded theory is much more than simply conducting qualitative interviews on pre-decided questions. Instead, it is iterative and concept forming evolves during or based on data collection. The authors do need to make a case foe how their study comprises a true grounded theory approach rather than a simple qualitative analysis of key informant interviews based on pre-constructed open ended questions. There is no mention of organizational culture with respect to patient safety observed during the study and included in the analysis (yet contextual observational information is essential component of the Grounded Theory Approach).

We totally agree with the comments. In the revised manuscript, we have added more details about the characteristics of MCH institutions and participators. We have also added more details about how the data were coded. We used both inductive (based on the existing PSC theory developed by the Agency for Healthcare Research and Quality) and deductive (open coding arising from data) approaches. It allows us to generate a new (or modified) PSC framework without being necessarily restricted to any existing theoretical framework. Data analyses took place concurrently with data collection. Coding was modified constantly by referring back to data. The sample size was determined by saturation of information where no new theme emerged from additional interview (Page 4-5).

-In the conceptualization (Page 4; results), the authors mention, "PS was categorized into six hierarchical levels:"
[1] public security as other public places,
[2] medical safety in the whole process of medical services provided, privacy and information security,
[3] financial security prevented from unnecessary interventions,
[4] psychological safety whether unsafe events happened or not, and
[5] demands been met or problems be solved.
The authors need to cite relevant literature as to justify their "hierarchical" levels. As such the schema itself makes no particular sense. Particularly it is not clear how/why the authors thought the " public security as other public places" was at the top of the hierarchy. As a student of patient safety culture, I know that patient safety is primarily concerned mostly with what the authors state in their point 2.: "medical safety in the whole process of medical services provided.." If safety issues arise at public places other than the care provider (e.g. a hospital), that may have consequences for the care but is not directly a feature of organizational patient safety from care providers point of view.
Further, if the authors can justify the hierarchical levels of PS (consistent with the literature on patient safety), they should be encouraged to show the hierarchy in a diagram with explanation of proper connections across levels.

Thanks for the advice. We admit that "hierarchical" is an inappropriate term. We have rephrased the sentences, with further explanations about the implications of the six aspects of patient safety issues

and their associations with patient safety culture revealed in this study. For example, “public security” was replaced with “safety and security of public spaces”. It describes “incidents that happen in public spaces, e.g., falls, fires, property loss and damage” (Table 1 in Page 7), which can result in harm to patients, or prevent patients from receiving needed interventions. In MCH settings, the concept of patient safety is linked to unwanted health outcomes, not necessarily adverse events as a result of medical interventions. The absence or shortage of wanted services became a safety concern because it can also lead to potential harm to patients.“Gap in services” can be caused by many reasons, including loss of property or overspending on unnecessary interventions (this is particularly true in resource-poor countries).
(Details can be seen in Page 5, 12)

-For this paper to be acceptable, the authors should not try to sell the new conceptual framework as the standard tested schema for measuring patient safety. Their thrust should be on their results based on thematic coding that made sense to them (which could be one of many ways to code the qualitative interviews on patient safety). They should reduce the emphasis on grounded theory and generation of a standard conceptual frame to be used by others in all relevant components of the article, including the title, the abstract, introduction and discussion.

Thanks for the advice. We have reduced emphasis on grounded theory and re-written the entire manuscript. We also took caution in discussing implications of the findings. This includes, but not limited to, using a COREQ check-list to improve reporting of this study and discussing limitations of this study.
Details can be seen in Page 3-5, 12-14.

-Finally the authors may be asked to review the manuscript for readability and grammar. One particular aspect of the language is that authors uses the past tense throughout the article even when it was not appropriate. Some examples include:
Page 1: The authors say "Patient safety (PS) was a key principle in medical practice." Why the use of past tense? Is it not a key principle now? In fact it is more of a concern now than historically.
Page 2: again "patient safety culture ...was a really relevant and important issue for PS highly concerned worldwide." Again it is still the case; why use “was”?
The authors state "Maternal and child health (MCH) was another highly-concerned issue all over the world." Not sure when it ceased to be an issue! So why use past tense?
Methods: "This was a qualitative study based" ...

Thanks for the detailed recommendations. The manuscript has now been revised by Prof. Chaojie Liu and proofread by a native English speaking colleague at La Trobe University.

-Limitation Section: The study is likely to have several limitations but the limitations section is obscure and incomplete. For instance the authors indicate “This study was conducted through a qualitative approach based on grounded theory, which more likely represented views from researchers themselves”. If this in fact is true then the study should have very limited value. The authors should address/discuss this.

We have re-written the limitation section. All studies have their strength and weakness. A qualitative study has strength in its rich data. The inappropriate claim was discarded. (Page13-14)

**VERSION 2 – REVIEW**

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| **REVIEWER** | Hongbing Tao<br>School of Medicine and Health Management of Tongji Medical College at Huazhong University of Science and Technology in China |
| **REVIEW RETURNED** | 08-May-2017 |

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| **GENERAL COMMENTS** | 1. This paper studied the connotation of patient safety culture in MCH. The background of this article briefly describes the definition of patient safety culture, the situation and responsibilities of MCH, and the importance of assessing patient safety culture. The application of the rooting theory added innovation to this research. However, the background part didn't introduce the research situation of patient safety culture connotation internationally, and the characteristics of patient safety culture in MCH. Similarly, this paper also lacks the introduction of concrete connotation of the rooted theoretical method, and the application of rooted theoretical method in patient safety culture field. Therefore, the omissive information described above should be added into this article.<br><br>2. The writers extracted key term words through NVivo 8.0 software to define the connotation of patient safety and patient safety culture and the related factors of patient safety culture. However, the patient safety culture connotation and the patient safety culture's assessment dimensions are two different concepts. It is recommended to introduce the difference between the connotation of the patient safety culture and the assessment dimensions of patient safety culture to prevent confusion.<br><br>3. The discussion section discusses the extension of the patient safety culture, the characteristics of the safety culture in MCH, and the challenge of fostering patient safety culture. The discussion part and the results part have too many repetitive places (need to mark the number of rows), and the discussion part lacks comparison with the relevant research results. At the same time, it is also necessary to discuss the reasons and relevant factors of the results to improve this paper from the whole.<br><br>4. The language of this paper requires an English native to modify and polish. |

## VERSION 2 – AUTHOR RESPONSE

Reviewer: 2
Reviewer Name: Hongbing Tao
Institution and Country: School of Medicine and Health Management of Tongji Medical College at Huazhong University of Science and Technology in China

1. This paper studied the connotation of patient safety culture in MCH. The background of this article briefly describes the definition of patient safety culture, the situation and responsibilities of MCH, and the importance of assessing patient safety culture. The application of the rooting theory added innovation to this research. However, the background part didn't introduce the research situation of patient safety culture connotation internationally, and the characteristics of patient safety culture in MCH. Similarly, this paper also lacks the introduction of concrete connotation of the rooted theoretical method, and the application of rooted theoretical method in patient safety culture field. Therefore, the omissive information described above should be added into this article.

Thanks for the advice. We have added an overview of PSC elements.
The commonly accepted PSC elements cover a wide range of domains, including, but not limited to, leadership, communication, teamwork, error reporting, continuous learning, evidence-based practice, and non-punitive environment.

Internationally, there is a dearth of literature that examines PSC in MCH institutions. But due to the unique features of MCH services, PSC components that need to be addressed in MCH institutions could be different from those in general hospitals.
Instead of presenting details of PSC, this study intended to provide a high level classification of patient safety and PSC for the MCH institutions in China. (Page 3)
We have explained the methodological design of this study:
This study used both inductive (based on the existing PSC theory developed by the Agency for Healthcare Research and Quality) and deductive (open coding arising from data) approaches. The deductive approach followed the principles of grounded theory. It allows us to generate a new (or modified) PSC framework without necessarily being restricted to any existing theoretical framework. (page 3)
While the inductive approach tested the fitness of data into the existing PSC theories, the deductive approach guided by the grounded theory allowed the researchers to keep mind open and generate new theories through the data. (page 4)
Further details about how we follow the principles of grounded theory can be found in the description of coding and data analyses (Page 5). However, in line with advice from the other reviewers, we have de-emphasized the grounded theory because we used mixed methods, with the inductive approach playing an important role.

2. The writers extracted key term words through NVivo 8.0 software to define the connotation of patient safety and patient safety culture and the related factors of patient safety culture. However, the patient safety culture connotation and the patient safety culture's assessment dimensions are two different concepts. It is recommended to introduce the difference between the connotation of the patient safety culture and the assessment dimensions of patient safety culture to prevent confusion.
Thanks for the comment. We have now made it clear that:
Instead of presenting details of PSC, this study intended to provide a high level classification of patient safety and PSC for the MCH institutions in China. (Page 3)

3. The discussion section discusses the extension of the patient safety culture, the characteristics of the safety culture in MCH, and the challenge of fostering patient safety culture. The discussion part and the results part have too many repetitive places (need to mark the number of rows), and the discussion part lacks comparison with the relevant research results. At the same time, it is also necessary to discuss the reasons and relevant factors of the results to improve this paper from the whole.

Thanks for the suggestion. We have reviewed the discussion section, deleted unnecessary repetitions, compared our findings with the results of other relevant studies, and added explanations on our findings. However, as is indicated in the introduction section: “Internationally, there is a dearth of literature that examines PSC in MCH institutions. Due to the unique features of MCH services, PSC components that need to be addressed in MCH institutions could be different from those in general hospitals” (Page 3)

4. The language of this paper requires an English native to modify and polish.

The manuscript has been revised by Prof. Chaojie Liu and proofread by a native English speaking colleague from La Trobe University, Australia.