

PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	Perceptions of patient safety culture among medical students: A cross-sectional investigation in Heilongjiang Province, China
AUTHORS	Liu, He; Li, Ying; Zhao, Siqi; Jiao, Mingli; Lu, Yan; Liu, Jinghua; Jiang, Kexin; Fang, Huiying; Sun, Peihang; Li, Peng; Wang, Yameng; Jia, Haonan; Wu, Yuming; Liu, Limin; Zhao, Yanming; Wu, Qunhong

VERSION 1 – REVIEW

REVIEWER	Professor Gilberto K.K. Leung Department of Surgery, LiKa Shing Faculty of Medicine, The University of Hong Kong, Hong Kong.
REVIEW RETURNED	27-Oct-2017

GENERAL COMMENTS	<p>This is an interesting and meaningful study of practical and educational value. The authors examined patient safety culture among a large cohort of students in China, and found differences within and among medical schools. As stated by the authors, patient safety education is an emerging theme in China and this paper should provide new and useful information in guiding its implementation. The study design is straightforward and the results are methodologically valid and well presented. Findings are discussed in a scholarly fashion under Discussion. The conclusions drawn are supported by the findings.</p> <p>There are several areas that require further attention:</p> <ol style="list-style-type: none">1. Under 'Strength and limitations of this study' - the authors reiterated their findings instead of appraising the actual methodological aspects of their study. This should be amended2. Any limitations of their study should also be discussed within the main text.3. The paper refers to the effect of 'hidden curriculum' on students' safety culture. This cannot be fully substantiated without basing on or referring to the prevailing norms and values of their teachers. This ought to be clarified4. How were students 'randomly selected'?5. Actual statistical findings are not presented in the text nor in the tables.6. The authors had helpfully contrasted their findings with those from other countries. It would be interesting if some, albeit hypothetical, explanations can be offered such as differences in cultural,
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	<p>socioeconomic or healthcare setting factors?</p> <p>7. One of the most interesting and unexpected findings is that more senior students appeared to have less positive perceptions. Any explanations offered?</p> <p>8. While the manuscript is generally well written in terms of its content and scholarly discussions, further assistance in English writing is indicated..</p>
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REVIEWER	Anna Byszewski Professor, Faculty of Medicine, University of Ottawa, Ottawa, Ontario, Canada
REVIEW RETURNED	29-Nov-2017

GENERAL COMMENTS	<p>This was a survey using APSQ-III which does not seem to have been tested sufficiently. It was used to survey the 5 year program cohorts of medical students at 4 medical schools in China. There is no current patient safety curriculum in these schools as it appears in the text, and if one exists it should be described. Yet students in great measure feel well prepared to address this issue, and indicate they would provide feedback if they see breaches, which is actually very challenging for most junior trainees without significant training and support, as well as established structures. This study does not inform the reader how should such a curriculum be developed and yet this is one of the major objectives as stated in abstract - identifying students' educational needs and how to promote patient safety. We only see that students answered throughout in very affirmative manner.</p> <p>The paper would need a major rewrite as the standard of English is very poor, many sentences do not make sense eg. Abstract line 38-43.</p> <p>Some reference is made to papers or studies without references cited. It is not clear how students were "randomly" selected, or were these percentages answering. Words/sentences are included throughout that do not make sense eg. page 10, line 41 "escape responsibility", without explanation.</p>
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VERSION 1 – AUTHOR RESPONSE

Response to the reviewer's comments:

Reviewer 1:

1. Under 'Strength and limitations' - the authors reiterated their findings instead of appraising the actual methodological aspects of their study. This should be amended

Response: Thanks for your comments and kind suggestions. We have revise and complete the section of 'Strength and limitations' of this study' as follows:

Strengths:

- This is the first use of the APSQ-III to compare patient safety in different schools and cohorts within a developing country (China)
- We covered almost all of the medical colleges within a rather large province
- This study provides the necessary evidence for educators to design future interventions and create a sense of focus on patient safety in medical education

Limitations:

- APSQ-III is a new instrument, the reliability and validity of which have not yet been retested

□ Our study is limited by the potential for non-response bias. Students who responded to the survey may have been more likely than their peers to be interested in patient safety, which may have led to inflation of the attitude ratings

We have supplemented and explained the limitation in the main text, details can be found in Line 65-76.

2. Any limitations of their study should also be discussed within the main text.

Response: Thanks for your kind suggestion. One of the limitations of this study is a possible non-response bias. Students who agreed to respond to the survey may have been more likely than their non-responding peers to be interested in patient safety. This greater level of interest may have led to inflation of attitude ratings. Another limitation is that the study made use of a non-standardised survey instrument. Nevertheless, this is the first use of the APSQ-III to compare patient safety cultures in different schools and cohorts within mainland China. While the present sample was taken from only one region in China, we covered almost all of the medical colleges within a rather large province. Furthermore, we recruited a cohort of medical students across five years of their programs. Thus, the present study represents an important first step toward patient safety education research in China. We believe that our findings can help educators develop curricula for patient safety education. We have supplemented and explained the limitation in the main text, details can be found in Line 376-387.

3. The paper refers to the effect of 'hidden curriculum' on students' safety culture. This cannot be fully substantiated without basing on or referring to the prevailing norms and values of their teachers. This ought to be clarified

Response: Thanks for your kind comment. We did not properly address this expression and have clarified the statement in the revised paper:

“In conclusion, our study researched perceptions of patient safety culture among medical students in China.” details can be found in Line 388-389.

4. How were students 'randomly selected'?

Response: Thanks for your question. We indeed don't provide a complete introduction to this issue. Our supplement is as follows:

We used systematic random sampling to select 800 medical students from a roster of all medical undergraduates at each school. We provided these students with detailed explanations of the objective of this investigation; some students expressed interest in participating in the survey, while others declined to participate. Students who were willing to participate in the investigation were given two days to complete the questionnaire anonymously; they were asked to then return it to a box provided in the counselor's office. Respondents' names and other identifiers were not collected. Details can be found in Line 172-179.

5. Actual statistical findings are not presented in the text nor in the tables.

Response: Thanks for your comment. There was a significant difference ($p < 0.05$) between cohorts on responses to the factors 'patient safety training received', 'error reporting confidence', 'working hours as an error cause', 'error inevitability', 'team functioning', 'patient involvement in reducing errors', and 'importance of patient safety in the curriculum'. We have supplemented the statistical findings in the text and tables, details can be found in Table 3.

6. The authors had helpfully contrasted their findings with those from other countries. It would be interesting if some, albeit hypothetical, explanations can be offered such as differences in cultural, socioeconomic or healthcare setting factors?

Response: Thanks for your kind and construction suggestion.

In contrast with students in Hong Kong, mainland students responded positively to items relating to 'patient involvement in reducing errors'. A possible reason for this is that patients in Hong Kong must

follow the arrangements made by public medical institutions with regard to waiting lists, hospitalisation, and surgery, in accordance with the process established for their illness. They can't choose their doctors for themselves, but are generally trusting of doctors and hospitals. In mainland China, however, the patient's understanding of their diagnosis and treatment has been continuously improving, and the traditional medical model has gradually been replaced by active patient participation [1]. The process of medical decision-making is undertaken by the doctor and patient together, and the patient has the right to choose their doctor independently. In addition, medical staff often encourage patients and their families to participate in procedures relating to diagnosis and treatment [2]. This may include encouraging patients or family members to participate in examining the label on an infusion bottle for the name of the drug, reading drug information, and so on. Furthermore, previous work has shown that patient participation can reduce the occurrence of medical errors [3]. Therefore, Chinese medical students have positive attitudes on the item.

[1] Na Yuan, Chune Liu, Lei Yu. Study Process of Patients Involved in Treatment Decision – Making State Quo and Influencing Factors [J]. *Medicine and Society*, 2017, 30(3):58-61.

[2] FAN Xin, LIU Zhijian, SUN Rongrong, LI Yingyue, WANG Jing, HAN Guangshu. Discussion on the influence of patient safety Jculture to hospital safety management in China.[J]*Chinese Hospitals*. 2017,21(7):16-17

[3] Gongchun Lan, Wenguo Ying, Xiexin Qian, Songmei Fang, Lai Wei, Wei Xue. Effective observation on prevention for mismatched intravenous infusion by patients' participation in double-identity confirmation.[J]. *Chinese Journal of Modern Nursing*, 2012, 18(14):1657-1659.

7. One of the most interesting and unexpected findings is that more senior students appeared to have less positive perceptions. Any explanations offered?

Response: Thanks for your kind suggestion. In mainland China, the medical education system stipulates that basic course is conducted in the first to third years of medical schools and clinical practice is conducted in the forth to fifth years of medical schools. Medical students at this stage have come into contact with clinical practice, and even started to participate in clinical activities. At this stage, they are easily affected by the environment. As seen in Table 3, more senior students appeared to have less positive perceptions of 'error reporting confidence' and 'the importance of patient safety in the curriculum'. Possible reasons include their experience of working in strong clinical hierarchies, which is known to have a negative influence on error reporting and disclosure of medical errors [1]. It is likely that this decrease in medical error disclosure emerges as result of the increasing awareness and more realistic self-assessment that students develop during the process of medical education [2]. It could also be the result of inadequate training and preparation of young doctors. Additionally, more senior students appeared to have less positive perceptions of 'the importance of patient safety in the curriculum'. A possible reason for this is that from the first grade to the fifth grade in the university, with the increasing number of courses and pressure of examinations, students do not want to add new courses to the curriculum. However, the underlying reason for this state remains to be established.

Based on the above, we supplement the revision manuscript. Details can be found in Line 363-375.

[1] Tallentire V R, Smith S E, Skinner J, et al. Understanding the behaviour of newly qualified doctors in acute care contexts[J]. *Medical Education*, 2011, 45(10):995-1005.

[2] Kiesewetter J, Kager M, Lux R, et al. German undergraduate medical students' attitudes and needs regarding medical errors and patient safety--a national survey in Germany.[J]. *Medical Teacher*, 2014, 36(6):505-10.

8. While the manuscript is generally well written in terms of its content and scholarly discussions, further assistance in English writing is indicated.

Response: Thanks for your suggestion. The academic writing of English has been edited by the company of Editage to make clear of grammar and English language.

Reviewer 2:

1. This was a survey using APSQ-III which does not seem to have been tested sufficiently. It was used to survey the 5 year program cohorts of medical students at 4 medical schools in China. There is no current patient safety curriculum in these schools as it appears in the text, and if one exists it should be described. Yet students in great measure feel well prepared to address this issue, and indicate they would provide feedback if they see breaches, which is actually very challenging for most junior trainees without significant training and support, as well as established structures. This study does not inform the reader how should such a curriculum be developed and yet this is one of the major objectives as stated in abstract - identifying students' educational needs and how to promote patient safety. We only see that students answered throughout in very affirmative manner.

Response: Thanks for your comment. The questionnaire was chosen because it is validated for students and may serve as an instrument for monitoring development of the patient safety culture. We used the English version of the questionnaire to investigate. Other scholars also used unverified English version of the APSQ-III in their study and usually write the shortcoming in the limitation [1-3]. We have supplemented the limitation in the manuscript. Details can be found in Line 379-380.

(Some schools offered courses in doctor-patient relations and evidence-based medicine, but there was no dedicated and systematic patient safety course. None of the students had received any prior formal teaching on patient safety, enabling a baseline assessment of safety culture among these students.) Details can be found in Line 169-172.

And we indeed made the inaccurate formulation in the abstract. We have made a revision to the abstract. Details can be found in Line 41-43 (The present study aimed to assess medical students' perceptions on patient safety culture. And the goal of this assessment was also to identify the educational needs of these students and provide the evidence for the curriculum of patient safety.) .

And in order to make the article easier to understand, we used English editing company to compile the text. Furthermore, as we all know, the development of patient safety courses is challenging. It involves the change of culture. Although we do not have a structural framework including course settings, teachers, and assessment methods right now, we have started the work and thinking of building a patient safety training framework suitable for China: Our research ideas are basing a 6-step approach to medical curriculum development [4]

Step 1: Problem Identification and General Needs Assessment

Step 2: Needs Assessment of Targeted Learners

Step 3: Goal and Specific Measurable Objectives

Step 4: Educational Strategies

Step 5: Implementation

Step 6: Evaluation and Feedback

Until now, we are just consider and study the first two steps. The following steps will be progressively carried out in further research. But according to the current research, we have made clear the direction of the next step.

[1] Leung G K, Ang S B, Lau T C, et al. Patient safety culture among medical students in Singapore and Hong Kong.[J]. Singapore Medical Journal, 2013, 54(9):501-505.

[2] Leung G K, Patil N G. Patient safety in the undergraduate curriculum: medical students' perception.[J]. Hong Kong medical journal = Xianggang yixuezazhi/ Hong Kong Academy of Medicine, 2010, 16(2):101-5.

[3] Kow A W C, Ang B L S, Chong C S, et al. Innovative Patient Safety Curriculum Using iPad Game (PASSED) Improved Patient Safety Concepts in Undergraduate Medical Students[J]. World Journal of Surgery, 2016, 40(11):1-10.

[4] Thompson D D A, Cowan M J, Holzmueller M C, et al. Planning and Implementing a Systems-Based Patient Safety Curriculum in Medical Education[J]. American Journal of Medical Quality the Official Journal of the American College of Medical Quality, 2008, 23(4):271.

2. The paper would need a major rewrite as the standard of English is very poor, many sentences do not make sense eg. Abstract line 38-43.

Response: Thanks for your kind suggestion. We used the English language editing service (Editage) to improve the English language.

3. Some reference is made to papers or studies without references cited.

Response: Thank you for your reminding, we have joined the reference in the corresponding position in the text.

4. It is not clear how students were "randomly" selected, or were these percentages answering.

Response: Thank you for your question, and we do have a lack of explanation in our manuscript. Our supplement is as follows:

We used systematic random sampling to select 800 medical students from a roster of all medical undergraduates at each school. We provided these students with detailed explanations of the objective of this investigation; some students expressed interest in participating in the survey, while others declined to participate. Students who were willing to participate in the investigation were given two days to complete the questionnaire anonymously; they were asked to then return it to a box provided in the counselor's office. Respondents' names and other identifiers were not collected. Using this procedure, we obtained 2489 valid questionnaires (total response rate: 78.1%). Of the students who participated, 726 (response rate: 90.8%) came from Harbin Medical University, 631 (78.9%) from Qiqihar Medical University, 459 (57.4%) from Mudanjiang Medical University, and 682 (85.3%) from the Medical College of Jiamusi University.

Details can be found in Line 172-184.

5. Words/sentences are included throughout that do not make sense eg. page 10, line 41 "escape responsibility", without explanation.

Response : Thank you for your comment. The good training evaluation on the subject in our study may be due to a common psychological phenomenon of "escape responsibility" of student in China, which refers to the notion that students in this culture are struggling to cope with and protect themselves in an intensely hierarchical environment. This means that not only are they afraid to tell the truth, but they also fear the effects of doing so on teachers' evaluations of them. Details can be found in Line 272-275.

VERSION 2 – REVIEW

REVIEWER	Gilberto K K Leung University of Hong Kong
REVIEW RETURNED	12-Jan-2018

GENERAL COMMENTS	The revision has adequately addressed issues previously raised by me. I would recommend publication.
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REVIEWER	Anna Byszewski University of Ottawa, Ottawa, Ontario, Canada
REVIEW RETURNED	25-Jan-2018

GENERAL COMMENTS	This is a much improved version. I remain concerned about the low standard of English/medical terminology eg. "promotion of human safety" line 81 should be "patient safety". line 88 replace "resulted" with developed...the list goes on, I have circled changes on just about every page when reviewing. Need to elaborate on some statements, eg. line 135 for reference
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	<p>15, same for line 129.</p> <p>I am also still concerned with the fact that the results are skewed - such a high percentage feel they have an understanding - yet the formal curriculum lacks content on patient safety. The discussion is well done on that point but this should be highlighted somehow in the abstract and in the limitations. I am not sure this paper really answers what knowledge is lacking as the students felt they were well informed.... The objective may be more to overcome the reluctance to speak up in this culture.</p> <p>Please also clarify what was the denominator for each school on choosing 800 students, ie what was the representative sample at each school.</p> <p>Also clarify line 157 : 3813 thousand people - this does not make sense.</p> <p>Tables are hard to understand - maybe a formatting issue.</p>
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VERSION 2 – AUTHOR RESPONSE

Response to the reviewer's comments:

Reviewer 1:

The revision has adequately addressed issues previously raised by me. I would recommend publication.

Response: Thank you for the time and energy that you spend on our manuscript. And thank you for your thoughtful suggestions and insights, which have enriched the manuscript and produced a more balanced and better account of the research.

Reviewer 2:

1、 I remain concerned about the low standard of English/medical terminology eg. "promotion of human safety" line 81 should be "patient safety". line 88 replace "resulted" with developed...the list goes on, I have circled changes on just about every page when reviewing.

Response: Thank you for your careful modification. In the manuscript, the grammar, format, content and other errors have been improved. And we will use the English language editing service (Editage) for a new round of revision to improve the quality of the English throughout the manuscript.

2、 Need to elaborate on some statements, eg. line 135 for reference 15, same for line 129.

Response: Thank you for your suggestion. We indeed didn't provide a complete introduction to line 129 and line 135. Our supplement is as follows:

For line 129, we change as follows:

However the study only surveyed two cohorts of second-year medical students, and it did not consider students in different year of medical school. Details can be found in line 128-130.

In addition, in our study, unlike most previous studies, the students include not only second-year medical students, but also students of other grades. This is one of the advantages of our study.

For line 135 when we comb through the literature, we made a few mistakes in the order of references. And we made corresponding amendments to the references.

Then we make the following changes:

While a few reports have explored safety education content and teaching methods in China, patient safety education has not been fully implemented within curricula and clinical practice. Ensuring the safety of patients is the primary task of medical staff. Medical students should have the capacity to ensure the safety of patients in the process of pursuing a medical career in the future. Patient safety education for medical students is to curb or reduce medical errors from the source and to promote patient safety.

Details can be found in line 135-138.

3、 I am also still concerned with the fact that the results are skewed - such a high percentage feel they have an understanding - yet the formal curriculum lacks content on patient safety. The discussion is well done on that point but this should be highlighted somehow in the abstract and in the limitations. I am not sure this paper really answers what knowledge is lacking as the students felt they were well informed.... The objective may be more to overcome the reluctance to speak up in this

Response: Thank you for your kind comment and useful suggestion. In our study, we find that although none of students had received any formal teaching on patient safety, students were more likely feel they have an understanding about patient safety. This finding is similar with a previous study by Gilberto Ka Kit Leung from Hong Kong [1], they analysis that the result could be due to the students' misunderstanding or an inability to distinguish teaching from what had been leaned from the public media. We believe that the high percentage may be due to non-response bias, the psychological phenomenon of escaping responsibility and the reluctance to speak up in our culture. And what should be worth emphasized is that the APSQ-III addresses students' self-assessment of patient safety culture rather than the actual teachings given. Thus, the results of the present study should not be taken as indicators of the students' actual skills and knowledge.

We added some contents in the abstract and the limitations: Details can be found in line 58-60 of the abstract; line 386-389 of the limitations; and other changes can be found in line 273-276, 282-283.

[1] Leung G K, Ang S B, Lau T C, et al. Patient safety culture among medical students in Singapore and Hong Kong[J]. Singapore Medical Journal, 2013, 54(9):501-505.

4、 Please also clarify what was the denominator for each school on choosing 800 students, ie what was the representative sample at each school.

Response: Thank you for your question. In 2014, there are about 2610 clinical medical students in Harbin Medical University; 3480 clinical medical students in Qiqihar Medical University; 3320 clinical medical students in Mudanjiang Medical University; 2520 clinical medical students in Medical College of Jiamusi University.

In China, the number of students enrolled at each school is approved by the Ministry of education in accordance with the conditions of the school. The school sets the number of classes based on the number of enrolment. However, the major of clinical medicine students are taught in large classes and

the number of students in each class is about 150 to 170, so we choose a class size as the sample base. According to the clinical medicine five-year training programs, we selected samples from five grades, and finalized the sample size of 800 students per university to ensure the representative of our samples. We then disrupted the student ID of clinical medicine students in all five grades, and used systematic random sampling to select 800 clinical medical students in each university.

Yet the results from the sample can't represent other institutions and other regions. So we add the following content: Extrapolation of the findings to other medical colleges should be done with caution. Details can be found in the limitations. Line 389-390.

5、 Also clarify line 157 : 3813 thousand people - this does not make sense.

Response: Thanks for your question. We are sorry that our study did not elaborate on the relationship between 3813 thousand people and our study.

We write this sentence to introduce the research background. And what we want to convey is that, medical schools provide medical and health service personnel training for a province of more than 30 million people.

In order to make it easier to understand, we tried to change the sentence. Details can be found in line 154-163.

In addition, the reason why we write 3813 thousand people is that we made the following considerations in our study:

During the initial phase of patient Safety Course development, it is often necessary to prioritize areas of learning according to the faculties' experiences and expertise. Students from different backgrounds may also differ in their knowledge, skills and educational needs. So, choosing which area to survey is one of the things we need to consider in our research. At the same time, we also take into account the conditions of time and resources. As the sixth largest province in China, Heilongjiang has the characteristics of a large population and a wide range of medical services. The medical students as the future medical workers trained by the medical schools in the region need to bear some pressure and mission. However, there are few studies on patient safety culture of medical students. Understanding their baseline patient safety cultures, and identifying important and urgent educational needs are factors critical for the develop medical and health services of Heilongjiang province.

6、 Tables are hard to understand - maybe a formatting issue.

Response: Thanks for your question. In order to make the tables easier to understand, we have made a proper adjustment to the tables.

Details can be found in page 19-25.