JOURNAL OF EVIDENCE-BASED MEDICINE

Journal of Evidence-Based Medicine ISSN 1756-5391

REVIEW

Literature review regarding patient safety culture

Mao Xuanyue[1,*], Nie Yanli[1,*], Cui Hao[2], Jia Pengli[1] and Zhang Mingming[1]

[1] Chinese Evidence Based Medicine Centre, West China Hospital, Sichuan University, Chengdu, China
[2] School of Public Health, Sichuan University, Chengdu, China

Keywords
Medical error; organization culture; patient safety culture; safety climate.

Correspondence
Zhang Mingming, Chinese Evidence Based Medicine Centre, West China Hospital, Sichuan University, No. 37 Guoxue Xiang, Chengdu 610041, China.
Tel: +86-28-85422079;
Fax: +86-28-85422253;
Email: mingming-zhang@163.com

*These authors contributed equally to this work.

Received 31 December 2012; accepted for publication 5 January 2013.

doi: 10.1111/jebm.12020

Abstract

Background: Quite a number of articles on patient safety culture have been published in recent 10 years to assess the safety culture in hospitals using the Hospital Survey on Patient Safety Culture in many countries. However, until now there have been no relevant studies to investigate the quality of these, and their contribution to present-day thinking.
Objectives: The aim of this study was to explore the areas of theme, and the study design of published research on patient safety culture in literature published in English and Chinese language journals.
Methods: We searched the major databases, including MEDLINE, EMbase, Chinese Biomedical Literature Database, Chinese Journals Full-text Database, and to analyze the publication years, research themes, authors' affiliations and methodologies of articles published from January 2001 to December 2011. Quality and statistical method were only appraised by classification of study designs.
Results: The annual number of published articles on patient safety culture was increasing in the last decade, and the number of articles published in 2010 and 2011 reached its peak with 86 articles accounting for 44.6% of the decade's publication; patient safety culture scale dominated the included literature, accounting for 67.8% of all studies. Cross-sectional studies and commentary reviews were the most popular study designs which took up approximately 95.9% of the included studies with 66.9% (129 articles) and 29.0% (56 articles), respectively. All the included studies on patient safety culture were conducted in the following four institutions: hospitals, geracomium, Veterans Health Administration hospitals, and medical schools.
Conclusions: There is a growing change trend in the number of articles on patient safety culture research in recent 10 years, most of which are non-comparative studies. More methodologically rigorous designs are needed to improve research quality on patient safety culture.

Background

Patient safety is a fundamental principle of health care. Every point in the process of caregiving contains a certain degree of inherent unsafety. Adverse events may result from problems in practice, products, procedures, or systems (1–3). Patient safety improvements demand a complex system-wide effort, involving a wide range of actions in performance improvement, environmental safety and risk management, including infection control, safe use of medicines, equipment safety, safe clinical practice, and safe environment of care (4–6).

Patient safety in healthcare organization has received much attention following the Institute of Medicine (IOM) report 'To Error is Human: Building a Safer Health System' (7). The IOM states that if there is a safety culture where adverse events can be reported without people being blamed, they have the opportunity to learn from their mistakes and it is possible to make improvements in order to prevent future human and system errors, and thus promoting patient safety

(7). Therefore, if hospitals want to improve patient safety, it is important to know more about the culture regarding to patient safety.

Patient safety culture, which is also called patient safety climate, is an overall behavior of individuals and organizations, based on common beliefs and values (8, 9). Reduce possible harm of patient at the lowest level in the service procedure though hard efforts. Related research shows that: positive patient safety culture could promote patient safety (10) and could help to improve organization with safety behavior, including reporting little errors, self reporting errors, safety behaviors, safety audit rating, etc (11–15).

To date, many countries have initiated patient safety culture research, especially in developed countries (6, 8, 16–20). On a global basis, several international organizations have significantly contributed to the promotion of the culture of patient safety, such as the World Alliance for Patient Safety, the National Patient Safety Agency in the UK, and the Agency for Healthcare Research and Quality in USA, etc (21). Our recent initial literature searching on patient safety including Chinese Biomedical Literature Database and Chinese Journals Full-text Database has also yielded a total of 40,375 relevant studies (22).

Research on patient safety culture has been growing in recent years. However, there has been no objective and quantitative evaluation of the quality of these researches so far; thus, it is hard to tell to what extend these researches can be used to direct health-related policy decisions in this field. The objective of this study is to explore the current status of patient safety culture and the general quality of the resulting research articles.

Methods

Inclusion and exclusion criteria

All included studies focused on patient safety culture/climate. The providers of health service system including clinicians, nurses, medical laboratory workers, hospital managers, or supervisors and medical students. Articles on patient safety culture element, patient safety culture scale/questionnaire, patient safety culture with medical error, patient safety culture with system were also included. However, studies only with hospital management, medical error, and culture innovation were excluded.

Search strategies

We conducted a comprehensive literature search databases including MEDLINE, EMbase, Chinese Biomedical Literature Database, and China National Knowledge Infrastructure, two of the largest biomedical abstract and full text literature databases in China. In addition, references identified from bibliographies of pertinent articles were also retrieved if needed. The search combination terms for the electronic databases were Medical Subject Headings (MeSHs), text words and word variants on 'hospital safety', 'culture of safety', 'safety culture', 'safety climate', 'patient safety culture', 'culture of patient safety', and 'organization culture'. We searched only for studies from January 2001 to December 2011. Search strategies were adjusted and run based on the characteristics of different databases, regardless of the publication status of the searched articles (Box 1).

Box 1: Search strategy for MEDLINE

#1 hospital safety

#2 culture of safety

#3 safety culture

#4 safety climate

#5 patient safety culture

#7 culture of patient safety

#8 organization culture

#9 #1 AND #2 AND #3 AND #4 AND #5 AND #6 AND #7 AND #8

,

Study selection

Two reviewers (YL Nieand H Cui) independently selected the studies, initially based on titles, key words, and abstracts of the retrieved records. Studies that did not meet the inclusion and exclusion criteria were discarded during the initial review. Then, the studies were cross-checked by two reviewers (XY Mao and PL Jia). When uncertainty existed, we retrieved and assessed the full text studies if they were available. Different opinions were resolved through discussion or by consulting a third reviewer (MM Zhang).

Data extraction

Two reviewers (YL Nie, H Cui) independently extracted information from the full texts of the included articles using a self-designed data extraction form. The items of this form included:

1. General information: titles, publication year, countries, authors' affiliation, journal names, etc.
2. Literature theme: each paper was classified as subculture elements (leadership, communication, report errors, team work, etc); patient safety culture scale/questionnaire/

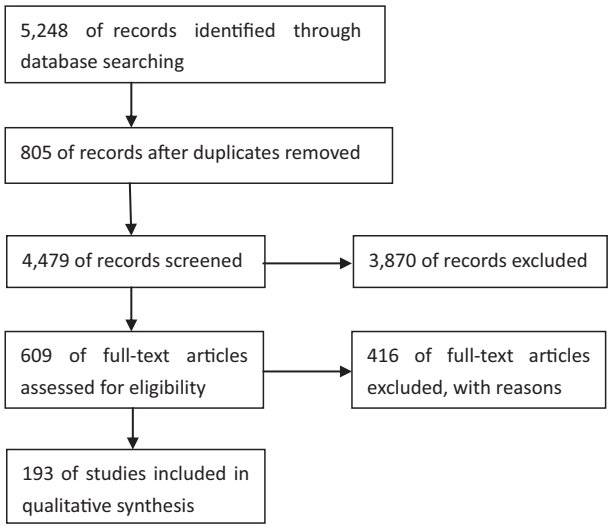

Figure 1 Flow chart of the included studies.

survey, patient safety culture with medical error and others.

3. Study design: randomized controlled trial, comparative studies, focus group, cross-section study, expert comment, and comment review (23, 24).

We developed data extraction form and trained four reviewers to independently extract and cross-check data. Thirty per cent of the extracted data were randomly rechecked to verify the accuracy of data extraction.

Data analysis

EndNote X3 (Thomson Corporation, US), SPSS 17 (SPSS Corporation, US), Microsoft Excel 2007 (Microsoft Corporation, US) were used for data analysis. General information, literature themes, and study designs were analyzed and expressed using percentage.

Results

Search results

Electronic searched yielded 5248 articles, but most were eliminated using the inclusion and exclusion criteria. Finally, a total of 193 articles were included in the analysis (Figure 1).

General information

A total of 193 articles were included in our study in recent 10 years. In 2010 and 2011, the number of articles reached its peak with 86 articles accounting for 44.6% of the decade's publication. The year of 2002 saw the least publication during the decade with only one article on patient safety culture published. In addition, there was an increasing trend during this period, and the most noteworthy increasing was recorded in the period between the years 2009 and 2011 when the number accounted for 62.2% (Figure 2).

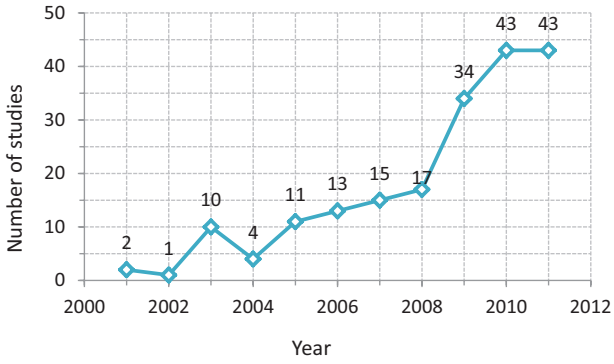

Figure 2 Studies published each year in recent 10 years.

Authors of the included articles were from 26 countries, most of which were from America (87), China (39) and the UK (13) followed by Canada (8), Germany (6). There were 15 countries with less than three articles published on patient safety culture. China was on the second position with 39 articles published, most of which were from eastern coastal cities.

All articles (193) were published in more than 50 journals. The top five English journals of publication on patient safety culture were *Quality & Safety in Health Care* (22 articles), *BMC Health Service Research* (15 articles), *BMJ Quality & Safety* (10 articles), *Health Services Research* (8 articles), and *Association of Operating Room Nurses* (7 articles). The top five Chinese medical journals of publication on patient safety culture were *Chinese Nursing Management* (eight articles), *Journal of Nursing Science* (seven articles), *Chinese Journal of Nursing* (five articles), *Nursing Journal of Chinese People's Liberation Army* (four articles), and *Contemporary Medicine* (three articles).

Study themes

We classified all the included articles into patient safety subculture elements (leadership, communication, report errors, team work, just culture, learning, non-punitive environment, etc) (25), patient safety culture scale/questionnaire, patient safety culture with medical error and others according to the themes that reported by the original articles (Table 1).

Table 1 indicated that patient safety culture scale dominated all the included articles, accounting for 67.8% of all articles. Moreover, 39 articles emphasized on patient safety culture elements of which 'leadership' was the most prevalent (nine articles), whereas 'evidence-based practice' was only with two articles.

Table 1 Theme classifications of 193 included articles published in journals

Theme	No. of articles [*n*, (%)]
Scale	129 (67.8)
Leadership	9 (4.7)
Communication	7 (3.6)
Report	6 (3.1)
Teamwork	5 (2.6)
Learning	4 (2.1)
Just culture	3 (1.6)
Evidence-based practice	3 (1.6)
Non-punitive environment	2 (1.0)
Others	25 (12.9)
Total	193 (100)

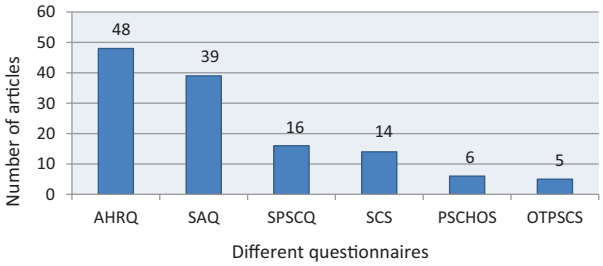

Figure 3 Scales used for assessing hospital patient safety culture. AHRQ: Hospital Survey on Patient Safety Culture; SAQ: Safety Attitudes Questionnaire; SPSCQ: Self designed patient safety culture questionnaire; PSCHOS: Patient Safety Climate in Healthcare Organizations Survey; OTPSCS: Other types of patient safety culture scale.

The theme of the included articles mainly focused on the assessment of questionnaire (129 articles), most of which were developed by Hospital Survey on Patient Safety Culture by Agency of Healthcare Research and Quality (AHRQ) in the USA in 2004 (26). In addition, some other questionnaires were also used for patient safety culture including Safety Attitudes Questionnaires (SAQ) developed by Texas University of USA in 2000 (27), Safety Climate Survey (SCS) developed by Zohar in Israel in 1980 (12), Patient Safety Climate in Healthcare Organization (PSCHO) developed by GaBa in USA in 2003 (28), and The Manchester Patient Safety Framework (NZ-MaPSaF) developed by Stanford University of USA in 2006 (29). The main purpose of the studies of these questionnaires was to assess their validity and reliability when they were applied in hospitals of different countries. The details were shown in Figure 3.

Study design

Study designs in the included articles were mostly cross-sectional studies and commentary reviews which took up approximately 95.9% of the included articles, with 66.9% (129 articles) and 29.0% (56 articles), respectively. Only one comparative study published in the US (30). This study was compared patient safety climate of US hospitals with that of Veterans Health Administration hospitals (Table 2).

Table 2 Study designs of 193 included articles published in journals

Study design	No. of articles [*n*, (%)]
Comparative study	1 (0.5)
Cross-section study	129 (66.9)
Focus group	1 (0.5)
Expert comment	6 (3.1)
Commentary Review	56 (29.0)
Total	193 (100)

Authors' affiliations of the published studies

The included 193 studies on patient safety culture were conducted in the following four institutions: hospitals (including teaching hospitals, general hospitals, and specialized hospitals, with 179 articles), geracomium (9 articles), Veterans Health Administration hospitals (4 articles), and medical schools (1 article). In China, all of the included 39 studies were conducted in hospitals including 27 in the teaching hospitals, 10 in the general hospitals, and 2 in the specialized hospitals.

Discussion

In this study, we reviewed the literature on patient safety culture published from January 2001 to December 2011 in English and Chinese language journals. We hope to find out the distribution of articles published over the last decade in terms of theme, study designs, and authors' affiliations and assess the general quality of identified articles. Meanwhile, we also hoped that through this study it will be able to provide insight into the current status of patient safety culture research in China and ways in which it can be advanced and guided.

Our study found that the annual number of articles published was increased by years especially between the years 2010 and 2011. Most articles on patient safety culture were published in *Quality & Safety in Health Care* (22 articles), *BMC Health Service Research* (15 articles), and *BMJ Quality & Safety* (10 articles). The reason for this we assumed is that these journals are much relevant to health quality and patient safety. While most articles on patient safety culture published in Chinese medical journals are much relevant to the nursing field. We did a further investigation to find that most of the content for the publication in Chinese medical journals focused on the assessment of validity and reliability

of the questionnaire developed by AHRQ which is in accordance with the results published in other studies (31–33). There are also some other self made surveys (34) on nurses for their knowledge and attitudes to patient safety culture. The results might imply that more attention to patient safety has been paid in nursing field than that of other medical fields in China in past 10 years. An increase in the number of articles addressing patient safety culture is encouraging. This suggests that patient safety is an important component of healthcare quality. The past 10 years witnessed an increasing interest in safety and quality issue in health care. However, there are still some problems, such as most of publications are still from developed countries.

Our study shows that the most popular theme for patient safety culture research was the assessment of questionnaire (129 articles) including 'Hospital Survey on Patient Safety Culture and Safety Attitudes Questionnaires', followed by patient safety subculture elements of leadership commitment, management communication, learning errors, and error report (43 articles) and introduction to patient safety culture (21 articles). This trend accords with that found in other studies, for example the study by Guldenmund shows that most of the safety culture research reported in his study would yield some scores on certain dimensions (35). On the other hand, we found it was not very easy for us to classify the theme of the included articles while reviewing the included 193 articles addressing different themes, so the criteria for this we based mostly on the study of 'What is patient safety culture? a review of literature' by Sammer in 2010 (25).

More knowledge and better use of that knowledge are essential for improving patient safety. However, patient safety research is still in its infancy (36). Our results show that at present, patient safety culture research was at the initial stage. Non-comparative studies accounted for the majority (99.5%) of the included literature and commentary review was the most commonly publication for raising awareness of patient safety culture. Comparative studies and systematic reviews that are considered of better quality in design were very rare in all the included articles. Our findings were similar to those in other patient safety study (21). More rigorously designed methodologies have been generally encouraged in patient safety research in recent days by WHO Patient Safety Program (36) addressing that it is based on the principle that effective improvement requires sound local evidence about the nature and extent of existing problems and risks including producing high-quality patient safety research by selecting and implementing the most appropriate methods. In this study, we found that the cross-sectional studies mainly focused on the evaluation and analysis of reliability and validity questionnaire, while commentary review mainly focused on patient safety subculture contents.

Patient safety in hospital is of global concern, especially for developing countries like China. No large empirical studies have demonstrated the severity of extent of medical errors in China; nevertheless, Chinese Hospital Association (CHA) estimated that adverse events affect 1.6 to 7.6 million hospitalizations annually in Chinese hospitals (37). In response to the challenges, the Ministry of Health of China has established the 'Department of Health Quality and Patient Safety' to help to promote patient safety activities in China since 2010. Quite a number of studies have suggested that an organizational culture that supports safety is associated with fewer errors (38–40). So the results of this study might be used as basic information for us to help think about if we hope to promote patient safety in China, we should foster patient safety culture in the whole organization, especially, in the hospital leadership level instead of only in nursing field.

Limitations

The study also has several limitations. First, the research about patient safety culture has been conducted for over 10 years (41). However, our searching was limited in recent 10 years (from 2001 to 2011). Thus, the results may not fully reflect the whole picture of publication status on patient safety culture. Next, we only explored the study designs of published literature, but we did not assess the overall quality of research being conducted. Finally, patient safety culture encompass different subculture elements, so the classification of research theme may be not detailed enough to identify the most popular theme and active topics. Despite of these limitations, our findings in this study may provide preliminary evidence for current status of patient safety culture.

Conclusions

In summary, our study provided important insight into current status of patient safety culture research in recent 10 years regarding to its theme, study design, and publication trend in recent 10 years. However, there is a need for patient safety research to use more methodologically rigorous designs and interdisciplinary, multi-institutional approaches to ensure research quality. The need for each country for patient safety culture is urgent and compelling.

Competing Interests

None.

Authors' Contributions

XY Mao and YL Nie contributed equally to this study. MM Zhang conceptualized and designed the study. YL Nie and H Cui did the search and data extraction. XY Mao and PL

Jia checked the extracted data. YL Nie performed the data analysis and XY Mao contributed to the interpretation of the data. MM Zhang and XY Mao contributed to and revised the manuscript critically for intellectual content. All authors read and approved the final draft.

Acknowledgements

This project was supported by National Natural Science Foundation (No. 70973083).

References

1. Bates DW, Cullen DJ, Laird N, et al. Incidence of adverse drug events and potential adverse drug events. Implications for prevention. ADE Prevention Study Group. *JAMA* 1995; 274(1): 29−34.
2. Leape LL, Bates DW, Cullen DJ, et al. Systems analysis of adverse drug events. ADE Prevention Study Group. *JAMA* 1995; 274(1): 35−43.
3. Reason J. Human error: models and management. *BMJ* 2000; 320(7237): 768−70.
4. Reid PP, Compton WD, Grossman JH, Fanjiang G, et al. Building a better delivery system: a new engineering/health care partnership. National Academy Press, 2005.
5. Hughes RG. Clancy CM. Working conditions that support patient safety. *J Nurs Care Qual* 2005; 20(4): 289−92.
6. Smits M, Christiaans-Dingelhoff I, Wagner C, Wal Gvd, Groenewegen PP. The psychometric properties of the 'Hospital Survey on Patient Safety Culture' in Dutch hospitals. *BMC Health Serv Res* 2008; 8: 230–239b.
7. Kohn LT, Corrigan JM, Donaldson MS. *To Err is Human: Building a Safer Health System*. Washington, DC: National Academy Press, 1999.
8. Ronald GS. Developing and operationalizing a culture of safety. *Chin Hosp* 2005; 9(12): 7−8.
9. Nieva VF, Sorra J. Safety culture assessment: a tool for improving patient safety in healthcare organizations. *Qual Saf Health Care* 2003; 12: 17−23.
10. Hellings J, Schrooten W, Klazinga N, Vleugels A. Challenging patient safety culture: survey results. *Int J Health Care Qual Assur* 2007; 20(7): 620−32.
11. Clarke S. Perceptions of organizational safety: implications for the development of safety culture. *J Organ Behav* 1999; 20(2): 185−98.
12. Zohar D. Safety climate in industrial organizations: theoretical and applied implications. *J Appl Psychol* 1980; 65(1): 96−102.
13. Zohar D. A group-level model of safety climate: testing the effect of group climate on microaccidents in manufacturing jobs. *J Appl Psychol* 2000; 85(4): 587−96.
14. Mearns K, Flin R, Gordon R, Fleming M. Human and organizational factors in offshore safety. *Work Stress* 2001; 15(2): 144−60.
15. Lee T. Assessment of safety culture at a nuclear reprocessing plant. *Work Stress* 1998; 12(3): 217−37.
16. Hammer A, Ernstmann N, Ommen O, Wirtz M, Manser T, Pfeiffer Y, et al. Psychometric properties of the Hospital Survey on Patient Safety Culture for hospital management (HSOPS_M). *BMC Health Serv Res* 2011; 11: 165–175.
17. Bagnasco A, Tibaldi L, Chirone P, et al. Patient safety culture: an Italian experience. *J Clin Nurs* 2010; 20(7–8): 1188–95.
18. Haugen AS, Softeland E, Eide GE, Nortvedt MW, Aase K, Harthug S. Patient safety in surgical environments: cross-countries comparison of psychometric properties and results of the Norwegian version of the Hospital Survey on Patient Safety. *BMC Health Serv Res* 2010; 10: 279–307.
19. Ito S, Seto K, Kigawa M, Fujita S, Hasegawa T, Hasegawa T. Development and applicability of Hospital Survey on Patient Safety Culture (HSOPS) in Japan. *BMC Health Serv Res* 2011; 11: 28–35.
20. Sorra JS, Dyer N. Multilevel psychometric properties of the AHRQ hospital survey on patient safety culture. *BMC Health Serv Res* 2010; 10: 199–212.
21. Nie YL, Li YL, Ning JP, Hou YL, Huang Y, Zhang MM. Patient Safety Research in China: a literature review. *J Evid-Based Med* 2011; 4(2): 66−72.
22. Manasse HR Jr, Eturnbull J, Diamond LH. Patient safety: review of the contemporary American experience. *Singapore Med J* 2002; 43(5): 254−62.
23. Harden RM, Grant J, Buckley G, Hart IRR. Beme guide no. 1: best evidence medical education. *Med Teach* 1999; 21(6): 553−62.
24. Tight MP. *Researching Higher Education*. Maidenhead: Open University Press, 2003.
25. Sammer CE, Lykens K, Singh KP, Mains DA, Lackan NA. What is patient safety culture? a review of the literature. *J Nurs Scholarsh* 2010; 42(2): 156−65.
26. Sorra J, Nieva VF. *Hospital Survey on Patient Safety Culture*. (AHRQ publication No 04-0041). Rockville, MD: Agency for Healthcare Research and Quality, 2007.
27. Helmreich RL, Merritt AC, Sherman PJ, Gergorich SE, Wiener EL. *The Flight Management Attitudes Questionnaire (FMAQ)*. University of Texas Press, 2012.
28. Gaba DM, Singer SJ, Sinaiko AD, Bowen JD, Ciavarelli AP. Differences in safety climate between hospital personnel and naval aviators. *Hum Factors* 2003; 45(2): 173−85.
29. National Patient Safety Agency. Manchester Patient Safety Framework (MaPSaF). 2006. Available at http://www.nrls.npsa.nhs.uk/resources/?EntryId45=59796.
30. Singer SJ, Hartmann CW, Hanchate A, et al. Comparing safety climate between two populations of hospitals in the United States. *Health Serv Res* 2009; 44(5 Pt 1): 1563−83.
31. Hellings J, Schrooten W, Klazinga N, Vleugels A. Challenging patient safety culture: survey results. *Int J Health Care Qual Assur* 2007; 20(7): 620−32.
32. Singer SJ, Gaba DM, Geppert JJ, Sinaiko AD, Howard SK, Park KC. The culture of safety: results of an organization-wide survey in 15 California hospitals. *Qual Saf Health Care* 2003; 12(2): 112−8.

33. Kho ME, Carbone JM, Lucas J, Cook DJ. Safety Climate Survey: reliability of results from a multicenter ICU survey. *Qual Saf Health Care* 2005; 14(4): 273−8.
34. Chen FL, Zhou L. Patient safety culture assessment scale: design and establishment. *Nurs J Chin People Liberation Army* 2009; 26(1): 1−4.
35. Guldenmund FW. The nature of safety culture: a review of theory and research. *Saf Sci* 2000; 34: 215−57.
36. World Health Organization (WHO). World Alliance for Patient Safety. Forward Program 2008. 2008. Available at www.who.int/patientsafety.
37. Cao RG. Medical quality and patient safety in China. *Chin Hosp* 2007; 11(11): 1−4.
38. Association of periOperative Registered N. AORN guidance statement: creating a patient safety culture. *AORN J* 2006; 83(4): 936−42.
39. Singer SJ, Falwell A, Gaba DM, Meterko M, Rosen A, Hartmann CW, et al. Identifying organizational cultures that promote patient safety. *Health Care Manage Rev* 2009; 34(4): 300−11.
40. Singer SJ, Meterko M, Baker L, Gaba D, Falwell A, Rosen A. Workforce perceptions of hospital safety culture: development and validation of the patient safety climate in healthcare organizations survey. *Health Serv Res.* 2007; 42(5): 1999−2021.
41. Llin R. Measuring safety culture in healthcare: a case for accurate diagnosis. *Saf Sci* 2007; 45: 653−67.