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The Patient Safety Culture Scale for Chinese Primary Health Care Institutions: Development, Validity and Reliability

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Background: Existing patient safety culture assessment tools are mostly developed in western countries and may not be suitable for Chinese primary health care institutions. Primary care plays an important role in China's medical system, and a targeted tool for its patient safety culture is urgently needed.

Objective: The aim of the study was to develop a dependable instrument to assess the patient safety culture in Chinese primary health care institutions.

Methods: Three phases were undertaken to develop the scale. The first phase developed a pilot scale by literature review, focus groups, and 2-round Delphi expert consultation. The second phase conducted a pilot survey. The third phase carried out a formal survey to test reliability and validity, involving 369 participants from 9 primary health care institutions.

Results: The final scale included 32 items under 7 dimensions. For reliability, the Cronbach α coefficients among dimensions varied from 0.754 to 0.926, and the Cronbach α for the scale was 0.940. For content validity, the corrected item-level content validity varied between 0.64 and 1, the scale-level content validity index/universal agreement was 0.625, and the scale-level content validity index/average was 0.93. For construct validity, the Spearman correlations of dimension-total score varied between 0.129 and 0.851, all Spearman correlations of the dimension-total score were greater than that of interdimensions and the Spearman correlations of item-total score ranged from 0.042 to 0.775. The results of the confirmatory factor analysis indicated that the model fitted well.

Conclusions: The Patient Safety Culture Scale for Chinese primary health care institutions demonstrated good reliability and acceptable validity; thus, it can be used as an assessment instrument for patient safety culture in Chinese primary health care institutions.

Key Words: patient safety culture, primary health care institutions, validity and reliability

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Since the Institution of Medicine reported *To Err Is Human: Building a Safer Health System,*[1] patient safety has become an important issue of global concern. Most researchers and activities are more focusing on hospitals, although more patients are treated in primary care institutions.[2] To raise awareness of primary care, the World Health Organization Patient Safety Program has initiated the "Safer Primary Care" project, being committed to protecting patients at primary care level.[3]

Many countries have begun to make great efforts in this field. The construction of patient safety culture was one of these positive attempts. The National Patient Safety Agency highlights the importance of "building a safety culture" as the first of 7 key steps for primary care organizations to protect patients.[4] Organizational culture refers to the beliefs, values, and norms shared by staff throughout the organization that influence their actions and behaviors. Patient safety culture is the extent to which these beliefs, values, and norms support and promote patient safety.[5]

Many organizations, such as the Joint Commission International and the National Patient Safety Agency, suggested that hospitals should conduct safety culture surveys for safety improvement regularly.[6] Assessing patient safety culture helps organizations detect areas for improvement and monitor changes over time.

A number of patient safety culture assessment tools had been developed for various kinds of medical institutions,[7] such as general hospitals,[8,9] pharmacy,[10] ambulatory surgery centers,[11] and nursing homes.[12] Among them, Hospital Survey on Patient Safety Culture (HSOPS) developed by the U.S. Agency for Healthcare Research and Quality is the most widely used evaluation tool for patient safety culture in general hospitals.

As for primary health care institutions, there are also several evaluation tools such as the Manchester Patient Safety Assessment Framework (MaPSaF),[13] the Medical Office Survey on Patient Safety Culture (MOSOPS),[14] the Primary Care Patient Measure of Safety (PC-PMOS),[15] the Systematic Culture inquiry On Patient Safety in Primary Care (SCOPE-PC),[16] and the Safety Climate Measure for Primary Care (PC-SafeQuest).[17] Each of these tools has advantages and disadvantages. As an early developed, widely recognized tool in the health sector, the MaPSaF offers a theory-based framework for assessing safety culture. It can not only diagnose the current status of patient safety culture but also provide targeted management suggestions.[18] However, as a qualitative tool, its convenience restricts the scope of application. The MOSOPS developed by the Agency for Healthcare Research and Quality is the most widely used evaluation tool for patient safety culture in primary care, but it has the lowest restriction on the size of the institution and the number of staff members been evaluated.[19] The PC-PMOS is the only tool that assesses patients' perception of the factors contributing to patient safety in primary care. Limited by a low response rate, it fails to demonstrate significant convergent validity and predictive validity.[20] The SCOPE-PC also has the limitation of a relatively low response rate.[21] The PC-SafeQuest is more targeted at safety climate. Although it is similar to the meaning of safety culture, some studies suggest that there are indeed differences between the 2 concepts.[22]

The primary health care institutions serve as "health gatekeepers" in China, including community health service centers, urban health centers, township health institutions, village clinics, and so on. However, in the last decades, primary health care institutions had been gradually neglected in Chinese health reform. Because the hierarchical medical system had been adopted, the

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government re-emphasized the importance of primary health care and tried to return to a greater reliance on primary health care services.[23] According to the China Health Statistical Yearbook 2018, the number of primary health care institutions was more than 930,000 in China, increasing with time. Those institutions served more than half of the total number of patients. On average, doctors in primary health care institutions provide diagnostic and therapeutic services to 10 patients per day, even more than general hospitals. It is clear that the significance of primary health care institutions is continuously being strengthened in China. At the same time, faced with such a large number of patients, patient safety has become an issue that cannot be ignored.

In China, researches on patient safety culture started later than western countries. The HSOPS has been developed into different Chinese versions, which have been widely used in hospitals.[24] However, at present, the evaluation of patient safety culture in China is mainly concentrated in third-tier and second-tier general hospitals. Primary health care institutions are ignored in the field of patient safety culture assessment again, which we do not want to see. According to our literature review, there was only one study that investigated the patient safety culture in primary care but using HSOPS. The result showed that the overall patient safety culture was at a relatively low level.[25] Meanwhile, most of these researches only included medical staff as respondents but ignored that there are indeed some differences in the perceptions of patient safety culture among people in different positions.[26] The measurement of patient safety culture in primary health care institutions has not received enough attention, and there is not yet a targeted evaluation tool.

Current assessment tools are mainly developed in western countries and cannot be directly applied to China because of different health system structures and local cultures. Studies in different countries suggest that translated versions of the HSOPS have shown lower internal consistency reliability than the original version[27–29] and indicate the need for caution when applying the original version of the HSOPS to different populations.[30] Moreover, research has proved that there are indeed differences between Chinese and American in patient safety culture, suggesting that cultural uniqueness should be taken into consideration whenever safety culture measurement tools are applied in different countries.[31] When implemented in other countries, some dimensions of the original version of the MOSOPS show high nonresponse rate and nonapplicability.[2] Although the Chinese version of the MOSOPS has been launched, it has not been applied nor tested for psychometric properties and adaptability. Developed in recent years, the PC-PMOS, SCOPE-PC, and PC-SafeQuest have few applications in China so far, and no corresponding Chinese version has been launched. As an early developed tool, through translation and back translation, as well as expert consultation, the MaPSaF has been developed into a Chinese version and has proved to have good reliability, effectiveness, and operability after cross-cultural adaptation.[32] That is the reason why we choose the MaPSaF as the initial theoretical framework of this study.

With regard to the patient safety of primary care, we decided to develop the Patient Safety Culture Scale for Chinese Primary Health Care Institutions (PSCS-PC) with good reliability and validity, thereby filling a gap in this aspect in China. The scale can scientifically identify the problem of patient safety culture in primary health care institutions and deliver the knowledge base to create a safer medical environment.

METHODS

Study Design

For the development of the scale, there were 3 phases: (1) formed the pilot scale through literature review, focus group discussion, and 2 rounds of Delphi expert consultation; (2) conducted the pilot survey in 2018 and modified items and dimensions to form the PSCS-PC according to the result of the pilot survey; and (3) carried out a formal questionnaire survey in 2019 to assess the reliability and validity of the scale.

Phase 1: Forming the Pilot Scale

We first developed the item pool based on the MaPSaF and other patient safety culture evaluation tools, mainly through literature review. We did not directly translate the indexes, which came from foreign patient safety culture evaluation tools into Chinese, because we found that even indexes with similar meaning have different expressions in different tools. Instead, we organized a focus group to conduct group discussions toward the item pool. We refined the core ideas of the indexes and made them better integrate with the current status of Chinese primary health care institutions; thus, these developed our original items. A number of unique items were also proposed and involved according to the current status of primary care in China. A total of 9 dimensions with 55 items were generated from the item pool through rounds of group discussions, forming the index system framework of the scale.

Delphi method was used to modify the items and dimensions further. A total of 18 experts with different working years from various fields such as teaching and scientific research (n = 5), clinical medical practice (n = 11), and primary health care institution management (n = 2) were invited to the consultation. Relevant information was provided to experts, including a brief introduction to the research theme and the current dimensions and items. Experts were asked to rate the importance of each item and dimension from 1 to 5 (1 for very unimportant, 5 for very important). Experts can also propose other amendments that they felt necessary, especially for verbal expression. For each response, experts were also asked to provide comments or justifications for their response. We developed a consultation questionnaire, which contains the previous information and requirements. The questionnaires were sent to the experts in person and by e-mail, and they were urged to give feedback within the prescribed time. The filter of the dimensions, items, and the adjustment of language expressions were performed after their suggestions.

After the first round of expert consultation, the original 9 dimensions were merged into 7 dimensions, and the order was adjusted. At the same time, according to expert opinions, 12 items were merged into 6 items, 14 items were deleted, and 6 new items were added. Thus, the scale was adjusted to 7 dimensions and 41 items, and language expression had also been extensively improved to be more precise. After the second round of expert consultation, there was no change in dimensions, but 5 items were deleted, 2 items were merged into one and 3 were added. In addition, the language expression and description of 5 other items had been further optimized. After 2 rounds of consultation, the opinions of the experts tend to be consistent, indicating that the filtering of dimensions and items and cross-cultural language adaptation to Chinese have been completed.

The final pilot scale included 7 dimensions and 38 items and was compiled into a questionnaire form. The response format used a 5-point Likert scale to calculate scores. The investigate results of each item (except D1 and D2 were adverse scoring items) were scored from 1 to 5, 1 was assigned for “disagree completely,” 2 for “disagree,” 3 for “fair,” 4 for “agree,” and 5 for “agree completely.” Each respondent chose a score based on their own experiences and the current status of their institutions.

Phase 2: Conducting the Pilot Survey and Forming the PSCS-PC

Following the cluster sampling method, we selected 7 primary health care institutions including community health service centers and township health institutions. The participants included physicians, nurses, medical technicians, pharmacists, logistics personnels, and managers. A total of 343 questionnaires were sent, and 242 valid questionnaires were obtained.

Items were scientifically refined based on the following methods: frequency distribution analysis, critical ratio method, variation coefficient (CV) method, Cronbach α coefficient method, correlation analysis, and exploratory factor analysis.

The frequency distribution analysis of each item calculated the rate of each option. If the chosen rate of one option was greater than 85% or less than 15%, the existence of the ceiling or floor effect should be taken into consideration.[33] The critical ratio method sorted the total scores of each respondent from high to low. The highest 27% were divided as a high-score group and the lowest 27% as a low-score group, and *t* test was used to identify the difference in means of each item for the 2 groups. If a *P* value is greater than 0.05, the item could not identify different subjects and should be deleted. The CV is the ratio of standard deviation and mean, greater coefficient of variation indicates higher sensitivity of the item, and if the CV of the item is less than 15%, the item was excluded. The coefficient of Cronbach α stands for the stability of items. First, the Cronbach α coefficient of the whole scale was calculated, then an item was deleted, and the Cronbach α coefficient of the residual scale with left items was calculated again. If the Cronbach α coefficient of the residual scale was higher than the whole scale, the item should be removed. The correlation analysis first calculated the correlation coefficient between each item and its belonging dimension; if greater than 0.6, the item was included. Then, it calculated the correlation coefficient between each item and other dimensions; if less than 0.5, the item was included. Kaiser–Meyer–Olkin (KMO) measure and the Bartlett test of sphericity were used to determine the appropriateness of factor analysis. The result (KMO = 0.892, Bartlett significance = $P < 0.000$) indicated perfect appropriateness to conduct exploratory factor analysis. If the factor loading of the item was less than 0.4, the item should be excluded.

Considering the previous 6 methods comprehensively, if an item was excluded by 2 or more methods, the item would be deleted from the scale. Finally, the PSCS-PC with 7 dimensions and 32 items was developed.

Phase 3: Testing the Validity and Reliability of the PSCS-PC

Participants

The formal survey was carried out in 9 primary health care institutions in the Hubei Province in China. Those institutions were randomly selected by cluster sampling, including both community health service centers and township health institutions. The respondents included not only doctors and nurses but also managers, logistics personnels, pharmacists, and medical technicians. This formal survey mainly sent the questionnaires to the leaders of the institutions, who were responsible for the distribution and recovery of the questionnaires. Finally, a total of 369 valid questionnaires were obtained. Because the exact number of questionnaires which had been distributed was unknown, the response rate was unobtainable for the study.

Statistical Analysis

EpiData Entry 3.1 (The EpiData Association, Odense, Denmark) was used to build and manage the database. To ensure the data accuracy, double-entry input pattern was performed. The scoring of the scale was to calculate the sum of each item. Statistical analyses were performed with IBM SPSS Statistics 22.0 (IBM Corp, Armonk, NY) and IBM SPSS AMOS 17.0 (IBM Corp, Armonk, NY).

The psychometric properties of 32 items were tested for reliability and validity. Reliability refers to the consistency and stability of test results. Generally, reliability is indicated by internal consistency and estimated using Cronbach α coefficients and split-half reliability coefficient. Validity refers to the degree to which a measurement tool can accurately measure what needs to be measured, including content validity and construct validity. Content validity refers to the degree to which an assessment instrument is representative of the targeted content which is designed to measure and is often verified with content validity index (CVI). Construct validity is generally tested by correlation analysis and factor analysis.

Reliability

Cronbach α coefficients of the whole scale and each dimension were calculated to assess the internal consistency. Cronbach α coefficients vary between 0 and 1, and greater than 0.70 could be acceptable. As for the split-half reliability coefficient, the items were divided into 2 groups based on the parity of the item number. Then, the correlation coefficient between the 2 groups was calculated, and the Spearman-Brown formula was applied to estimate the reliability of the whole scale. It is agreed that the split-half reliability coefficient should be greater than 0.70 to reach an acceptable level.

Content Validity

The test of content validity was applied by CVI, using ratings of item relevance by expert consultation. Experts were asked to rate the correlation between each item and its belonging dimension from 1 to 4 (1 for no relevance, 4 for strong relevance). For item-level CVI (I-CVI), which is the number of experts who rated 3 or 4 in correlation evaluation for each item divided by the total number of experts, it generally required to be greater than 0.78 if the total number of experts is more than 6. Considering the randomness of the experts' scoring, random consistency formula should be used to obtain the corrected I-CVI. If the corrected I-CVI were greater than 0.74, it could be considered as an excellent degree, and greater than 0.6 could be admitted as acceptable. For scale-level CVI (S-CVI), the scale-level content validity index/universal agreement (S-CVI/UA) should be greater than 0.8,[34] and the scale-level content validity index/average (S-CVI/Ave) should be greater than 0.9 to reach an excellent level.[35]

Construct Validity

The test of construct validity was applied with correlation analysis and confirmatory factor analysis (CFA). If the Spearman correlations of the dimension-total score were between 0.3 and 0.8, the dimension intercorrelations were less than 0.8, and if the Spearman correlations of the item-total score were in the range of 0.3 to 0.8, it could be inferred that the scale has good relevance and discrimination.[36] Bartlett test of sphericity scores less than 0.05 and a KMO score of sampling adequacy greater than 0.70 and close to 1 were considered appropriate for factor analysis.[37] As for CFA, model fit indices such as χ^2/df, root mean square error of approximation (RMSEA), comparative fit index (CFI), goodness-of-fit index (GFI), Tucker-Lewis index (TLI), and root mean square residual (RMR) were used to evaluate the model fit. In general, if $\chi^2/df < 3$, RMSEA < 0.08, CFI > 0.90, GFI > 0.90, TLI > 0.90, and RMR < 0.09, it indicates that the goodness-of-fit index is reasonable and acceptable.[38,39]

RESULTS

Respondent Characteristics

In total, 369 questionnaires were analyzed. The descriptive statistics of the respondent characteristics are shown in Table 1 hereinafter.

As the table shows, there were 78 males and 291 females participated. Most of the participants were younger than 60 years, and only 9 participants were older than 60 years. According to the China Health Statistical Yearbook 2018, the sex ratio and the age level of respondents in this study were basically consistent with the characteristics of primary health care workers in the last 2 years. Therefore, the respondents could be considered to be representative.

TABLE 1. Characteristics of Respondents (N = 369)

Characteristics	Frequency	Percentage
Sex		
Male	78	21.14
Female	291	78.86
Age, y		
≤29	91	24.66
30–44	175	47.43
45–59	94	25.47
≥60	9	2.44
Education level		
Master's degree or above	24	6.50
Bachelor's degree	205	55.56
College's degree or below	140	37.94
Profession		
Doctor	116	31.44
Nurse	159	43.09
Medical technician	31	8.40
Pharmacist	9	2.44
Manager or logistics personnel	36	9.76
Others	18	4.87
Working years		
≤5	84	22.77
6–10	108	29.27
11–15	56	15.17
16–20	30	8.13
≥21	91	24.66
Professional title		
None	51	13.82
Primary title	179	48.51
Intermediate title	120	32.52
Senior title	19	5.15
Participate in patient safety training		
Yes	334	90.51
No	35	9.49
Contact with patients directly		
Yes	316	85.64
No	53	14.36
Working hours per week		
≤40	219	59.35
41–60	136	36.86
≥61	14	3.79

Reliability

(1) *Cronbach α coefficient*: Cronbach α coefficient of the whole scale reached 0.940, indicating that the scale had reasonable structure, and it can measure the concept of patient safety culture reliably and effectively. Cronbach α coefficients of the dimensions ranged from 0.754 to 0.926, all greater than 0.70, which proved that the scale had good internal consistency reliability.

(2) *Split-half reliability*: The correlation coefficient of the 2 groups was 0.943; thus, the split-half reliability coefficient (Spearman-Brown coefficient) was 0.970, which also reflected good internal reliability of the scale.

Content Validity

As for the corrected I-CVI (Table 2), except A5 and E4, other items all achieved an excellent level of content validity. For S-CVI, the S-CVI/UA was 0.625 and the S-CVI/Ave was 0.93 (>0.9). Although the S-CVI/UA was lower than 0.8, research indicates that as the number of experts increases, the value of S-CVI/UA will decrease. For this reason, the true overall content validity of the scale may be somewhere between the S-CVI/UA and S-CVI/Ave, which could be considered as an acceptable level.

Construct Validity

(1) *Correlation analysis*: The Spearman correlations of the dimension-total score varied between 0.129 and 0.851. Although the correlation coefficient between dimension D and total score was less than 0.3, it is mainly because all items in this dimension were reverse scoring items. The absolute value of Spearman correlations of interdimension ranged from 0.125 to 0.656 (Table 3); the relevant coefficients among dimension A, B, and C were beyond 0.6 but less than 0.8, which indicated that the dimension intercorrelation degree had reached an acceptable level. Moreover, all Spearman correlations of the dimension-total score were greater than that of interdimensions. The Spearman correlations of item-total score ranged from 0.042 to 0.775 (Table 2). All correlations of item-total score were higher than 0.3 except D1 and D2, which was because those two items were scored in reverse, indicating a good item-total score correlation.

(2) *Confirmatory factor analysis*: The Bartlett test of sphericity scores and KMO were used to determine the appropriateness of factor analysis. The result (KMO = 0.926, Bartlett significance = $P < 0.000$) indicated perfect appropriateness to conduct confirmatory factor analysis. For CFA, the model fit indices were $\chi^2/df = 2.993$ (<3), RMSEA = 0.078 (<0.08), CFI = 0.925 (>0.90), GFI = 0.904 (>0.90), TLI = 0.709 (did not reach the level of 0.9), and RMR = 0.068 (<0.09). As these indices showed, the construct validity of the scale had reached an acceptable degree.

DISCUSSION

Combining qualitative and quantitative methods, we developed the PSCS-PC with good validity and reliability, which means that it could be considered as a dependable and valid instrument for the assessment of patient safety culture in Chinese primary health care institutions. The final version of the PSCS-PC contains altogether 32 items under the following 7 dimensions: priority given to patient safety, training about patient safety, perception and reporting of patient safety events, punitive feeling, patient safety improvement, communication openness, and overall commitment to quality.

Based on the MaPSaF, which consists of 9 dimensions, our study retained 2 original dimensions (priority given to patient safety and overall commitment to quality). To better adapt to the Chinese environment, 3 original dimensions had undergone linguistic adjustment. "Staff education and training about safety issues" had been changed into "training about patient safety"; "perceptions of the causes of patient safety incidents and their

TABLE 2. Corrected I-CVI and Spearman Correlations of Item-Total Score

Dimensions/Items	Corrected I-CVI	Item-Total Score Correlations
A. Priority given to patient safety		
A1. The behaviors of leaders indicate that patient safety is a priority for our institution	1	0.517
A2. Patient safety has been put in the first place in our institution	1	0.526
A3. When there is a disagreement on treatment in our department, our decisions are usually based on the perspective of patient safety	1	0.644
A4. We will analyze and reflect on the causes of patient safety events from the perspective of medical staff, institutional treatment process and so on	0.79	0.678
A5. We will organize all staff to learn and discuss on patient safety events occurring in our institution	0.64	0.743
B. Training about patient safety		
B1. New employees in our institution will attend a series of training on patient safety before entry	0.92	0.678
B2. When we introduce new processes or new approaches to treatment, we will attend a series of training	1	0.711
B3. Our institution will continuously review our operation and treatment process	1	0.693
B4. Our staff training reduces the frequency of patient safety events	0.79	0.702
B5. The department will not ask us to do any untrained work	0.92	0.610
C. Perception and reporting of patient safety events		
C1. When we find potential patient safety issues, we will take the initiative to report them to the relevant departments and personnels in time	1	0.658
C2. I know the reporting process of patient safety events (such as drop bed, prescription error, wrong medication, etc.)	1	0.631
C3. When a patient safety event occurs, we will report it even if there is no harm done to the patient	1	0.673
D. Punitive feeling		
D1. I'm worried that when I report a patient safety event, the person involved will be punished	1	0.042*
D2. For fear that patient safety events will be recorded in the file, I will choose not to report patient safety events caused by myself	1	0.159*
E. Patient safety improvement		
E1. Our institution will provide follow-up care for patients who need to be monitored	1	0.662
E2. We will remind the patient when to proceed with the next step of treatment	0.79	0.606
E3. Our institution will disclose patient safety events (such as in-house work groups, in-hospital bulletin boards)	0.79	0.564
E4. We will receive feedback about patient safety events from the relevant departments in our institution	0.64	0.775
E5. When the institution is reforming, we will assess whether these reforms are helpful for patient safety	1	0.586
F. Communication openness		
F1. In our institution, we can freely doubt the treatment decisions made by authoritative people	1	0.467
F2. In our institution, staff with different titles can communicate patient safety events openly	0.92	0.579
F3. Our institution encourages employees to express different views on patient safety events	1	0.700
G. Overall commitment to quality		
G1. There is a standardized handover process between our medical staff	0.86	0.655
G2. When patients need referrals, we can contact and transmit patient information promptly	0.92	0.680
G3. Our institution has enough workforce to complete the work	1	0.488
G4. Patient visiting process in our institution can prevent patient safety events	1	0.612
G5. We will complete the work according to the standardized medical treatment procedures (such as hand hygiene, aseptic operation, etc.)	1	0.771
G6. The environment of all departments of our institution is clean and tidy	0.92	0.688
G7. We check medical equipment regularly to ensure that they work properly	1	0.718
G8. I think our institution has invested enough resources to ensure patient safety	1	0.429
G9. Our medical quality management system guarantees patient safety	1	0.711

*Reverse scoring items.

identification" had been changed into "perception and reporting of patient safety events"; and "communication about safety issues" had been changed into "communication openness." Meanwhile, 4 original dimensions were deleted, and 2 new dimensions (punitive feeling and patient safety improvement) were included.

"Priority given to patient safety" emphasizes that patient safety is a priority in all aspects of management. The construction and

TABLE 3. Spearman Correlations of Interdimension and Dimension-Total Score

		Dimensions						
Dimensions	**Items Included in Dimensions**	**A**	**B**	**C**	**D**	**E**	**F**	**G**
A. Priority given to patient safety	5	1						
B. Training about patient safety	5	0.604*	1					
C. Perception and reporting of patient safety events	3	0.656*	0.651*	1				
D. Punitive feeling	2	0.125	0.155	−0.141	1			
E. Patient safety improvement	5	0.584	0.616*	0.523	−0.144	1		
F. Communication openness	3	0.355	0.507	0.522	−0.278	0.485	1	
G. Overall commitment to quality	9	0.362	0.506	0.459	−0.169	0.429	0.593	1
Total score	32	0.705	0.851	0.714	0.129	0.736	0.649	0.709

*Spearman correlations of interdimension were greater than 0.6.

maintaining of patient safety culture require sustained support and improvement measures from the leaders.[40,41] As Halligan and Zecevic[42] summarized, the expectation and behavior of leaders are important ways to create a more positive patient safety culture. The instruction of patient safety culture also needs the corresponding material conditions and system support. Compared with other tools, the dimension of "commitment to quality" pays more attention to the importance of equipment safety, environment safety, and human resources. For all types of medical institutions, including primary health care, these 2 dimensions are essential.

"Training about patient safety" is one of the important measures to form a dependable patient safety culture. The Nuclear Energy Agency, which initially proposed the concept of safety culture,[43] pointed out that the characteristics of the safety culture should include "learning to ensure safety." As the "health gatekeeper," primary health care institutions must ensure that medical service providers can get enough training and promote the patient safety culture as a "learning culture."

Studies find that errors in primary care can also have serious consequences,[44] although few published studies directly address patient safety events in primary care.[45] Anonymous reporting has been widely regarded as an effective way to reduce patient safety events and to find out the root cause.[46] "Perception and reporting of patient safety events" emphasizes the perception of patient safety events from the source and the reporting after the occurrence. Both leaders and staff must recognize that every patient safety event, no matter how serious the harm is, must be reported. One of Joint Commission International's principles on patient safety culture is "to use a transparent, nonpunitive approach to reporting and learning disabilities."[47] Thus, we included "punitive feeling" in the PSCS-PC to signify the importance of constructing a culture of fairness and justice, to convince medical staff that they will not be punished for reporting patient safety events.

According to related research, "communication openness" has proved to be an effective way to promote the formation of patient safety culture.[48] Achieving this aim not only requires the open communication between all staffs about patient safety events but also encourages equal doctor-patient and nurse-patient communication. Compared with general hospitals, primary health care institutions have a more relaxing atmosphere for patients and doctors to get along with each other. Therefore, primary care institutions are better suited to this responsibility of promoting patient safety culture.

In recent years, China has paid more attention to the important role of primary care in the health system and tried to establish a hierarchical medical system, aiming to strengthen the medical service capabilities of primary health care.[24] Under this background, the functions of primary health care institutions have been further expanded. In addition to implementing the diagnosis and treatment of basic diseases, it is also necessary for them to abide by the principles of 2-way referral and ensure the continuity of care. Therefore, we have integrated these core functions into the items of the PSCS-PC and added the dimension of "patient safety improvement," bringing them closer to the actual situation in China.

As a qualitative instrument, the MaPSaF is usually performed by the interview method. Although more information can be obtained, its convenience limits the scope of application. Based on the framework, our study changed the way of evaluation into a more quantitative method, greatly increasing the convenience of assessment.

Compared with the adapted Chinese version of the HSOPS, whose internal consistency ranged from 0.40 to 0.64 and whose Cronbach α value was 0.84, which was less than that of the original U.S. scale,[24] the PSCS-PC has significantly better reliability (the Cronbach α coefficient of the total scale was 0.940, and the internal consistency varied from 0.754 to 0.926). Research suggests that when applied to China, some items of the Chinese version of the HSOPS should be eliminated because of lack of sensitivity or semantic ambiguity,[49] which means that the application of the HSOPS in China is worth considering. Especially for primary health care institutions, there is no evidence of its applicability. Therefore, the development of PSCS-PC is of great significance to the evaluation of patient safety culture in Chinese primary health care institutions and thereby fills the gap in this field.

Limitations

We have done our best to ensure the authenticity and scientific of the study, but there are still some insurmountable limitations.

Firstly, the related methods of classical test theory were used in item selection in this study, and the estimated parameters could be affected by samples, which means that the process of item deletion could have some deviations.

Secondly, the pilot survey and the formal survey were both conducted in Hubei Province. Hubei Province is located in the central region of China, which represents the average level of China's development and has certain representativeness. To ensure the universality of the scale, different kinds of institutions such as community health service centers and township health centers were included. However, because of the vast territory, the sampling is challenging to cover all parts of China and all kinds of primary health care institutions. Therefore, the sample may be affected to some extent.

In addition, the leaders of participating primary health care institutions were responsible for the distribution and recovery of the questionnaires, and the scale was carried out through self-evaluation. Thus, the responses may be influenced by the potential impact of the leaders, resulting in a decrease of data veracity.

As a prospect, based on reflection and summary of the limitations, we will focus on the promotion and application of the PSCS-PC to a broader range of areas. In addition to community health service centers and township health centers, other types of institutions will also be included in the survey in subsequent research, such as urban health centers and village clinics. Through the wider application, we believe that the applicability of the scale in different environments will be effectively improved. At the same time, well-trained professional investigators will be responsible for the distribution and recovery of the questionnaire to ensure the reliability of the data to the greatest extent.

CONCLUSIONS

The study constructs the first quantitative evaluation scale for patient safety culture in China, which focuses on primary health care institutions. With 7 dimensions and 32 items, the PSCS-PC has proved to have good reliability and validity and can thus be an effective tool for the investigation of the present situation of patient safety culture. It can also help uncover patient safety risks, develop targeted improvement measures, ensure medical quality, and build a safer environment for Chinese primary health care institutions.

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