

A Systematic Review of the Psychometric Properties of Patient Safety Culture Assessment Instruments

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Abstract: *Objective:* A comprehensive analysis of patient safety culture assessment tools for domestic and international patients was conducted to provide references for healthcare institutions in investigating safety culture and safety awareness, as well as for the development of related tools. *Methods:* A systematic search across nine databases, identified studies on tool development or validation. Data extraction was followed by methodological quality assessment using the COSMIN Risk of Bias checklist and evaluation of psychometric properties against updated criteria. *Results:* From 42 included studies (24 development, 18 validation), 24 distinct instruments were identified: 13 generic and 11 setting-specific. Commonly assessed dimensions were teamwork, communication openness, organizational learning, event reporting, staffing, and patient safety. *Conclusion:* Findings reveal a wide variety of instruments but no unified standard, underscoring the need for context-specific tools. It is recommended to develop concise, theoretically grounded localized instruments to support safety management. In China, independently developed tools remain limited. Future work should prioritize creating culturally adapted instruments with strong psychometric stability and applicability for the Chinese context.

Keywords: Patient safety; Patient safety culture; Measuring tools; Scoping review

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1. Introduction

As a core component of healthcare quality management, patient safety culture refers to the shared attitudes, beliefs, values, and behaviors among healthcare professionals in the process of ensuring patient safety^[1]. In 2010, Sammer et al. identified seven subcultures of patient safety culture: leadership, teamwork, evidence-based practice, communication, learning, justice, and patient-centeredness^[2]. The World Health Organization (WHO) emphasizes that establishing a positive patient safety culture is a strategic foundation for achieving healthcare safety goals, highlighting its role in fostering open communication, non-punitive

incident reporting, and continuous improvement mechanisms^[3]. Studies have demonstrated that a positive safety culture is associated with reduced incidences of adverse nursing events, such as pressure injuries, medication errors, and patient falls^[4,5]. However, as culture is an implicit and dynamic complex system, it cannot be directly assessed through subjective observation alone. Consequently, the development of scientifically sound and reliable measurement instruments has become a critical approach for quantitatively assessing safety culture levels and identifying organizational vulnerabilities. Patient safety culture assessment instruments enable the identification of latent safety risks within organizations and facilitate the implementation of targeted improvement strategies. To date, researchers worldwide have developed a variety of patient safety culture (PSC) assessment tools applicable to diverse healthcare settings, which have been widely used to evaluate the safety culture of hospitals and nursing institutions. These instruments are typically questionnaire-based and encompass multiple dimensions, including management commitment to safety, communication openness, teamwork, and incident reporting^[6]. At present, internationally recognized patient safety culture assessment instruments are primarily represented by the Hospital Survey on Patient Safety Culture (HSOPS) developed by the Agency for Healthcare Research and Quality (AHRQ) and the Safety Attitudes Questionnaire (SAQ)^[7,8]. These tools have evolved into multidimensional and standardized measurement instruments and have demonstrated progress in areas such as cross-cultural adaptation and intelligent data analysis. In China, existing studies have largely focused on the translation and cross-cultural adaptation of well-established international instruments. However, further evidence is still needed regarding the reliability and validity of these tools, as well as their practical applicability across diverse settings, including hospitals, long-term care facilities, and community healthcare environments^[9]. Currently, this field faces several challenges, including insufficient development of localized assessment instruments, a lack of dynamic monitoring and longitudinal intervention studies, unclear mechanisms linking assessment outcomes with clinical safety endpoints, and limited cross-institutional data comparability due to heterogeneity in measurement indicators. Therefore, a systematic synthesis of the content, structure, and psychometric performance of existing domestic and international PSC assessment instruments is warranted. In accordance with the PRISMA extension for scoping reviews (PRISMA-ScR) published by Andrea et al. in 2018, this study conducts a scoping review of patient safety culture assessment instruments to provide evidence-based references for future research and clinical practice^[10].

2. Materials and methods

2.1. Search strategy

This scoping review was conducted in accordance with the Joanna Briggs Institute (JBI) Manual for Evidence Synthesis: Chapter on Scoping Reviews^[11]. A comprehensive electronic search was performed in nine Chinese and international databases, including The Cochrane Library, PubMed, Web of Science, Embase, CINAHL, Wanfang Data, CNKI, VIP Database, and the Chinese Biomedical Literature Database (CBM). The search covered the period from database inception to August 26, 2025. In addition, manual searches of the reference lists of included studies were conducted to identify potentially relevant literature. A combination of controlled vocabulary terms and free-text keywords was used. Taking CNKI as an example for Chinese databases, the search strategy was as follows: SU% = ('Patient Safety Culture' OR 'Patient Safety Culture' OR 'Safety Culture' OR 'Safety Awareness' OR 'Safety Attitude' OR 'Safety Climate') AND

(‘Questionnaire’ OR ‘Survey’ OR ‘Scale’ OR ‘Measurement’ OR ‘Assessment’ OR ‘Tool’). For English databases, PubMed was used as an example, and the search strategy was: (“patient safety culture”[Title/Abstract]) OR (“patient safety climate”[Title/Abstract]) OR (“patients’ safety climate”[Title/Abstract]) OR (“patients safety culture”[Title/Abstract]) OR (“safety culture”[Title/Abstract]) OR (“safety climate”[Title/Abstract])) AND (“Questionnaire”[Text Word]) OR (“Scale”[Text Word]) OR (“Survey”[Text Word]) OR (“Assessment”[Text Word])).

2.2. Eligibility criteria

2.2.1. Inclusion criteria

Studies focusing on the development, validation, or Chinese translation and cross-cultural adaptation of patient safety culture assessment instruments.

2.2.2. Exclusion criteria

- (1) Studies published in languages other than Chinese or English;
- (2) Publication types such as reviews, study protocols, or conference abstracts; and
- (3) Studies for which the full text was unavailable.

2.3. Study selection and data extraction

All retrieved records were imported into EndNote 21 software for deduplication. Two members of the research team independently screened the literature. Initially, titles and abstracts were reviewed to exclude studies irrelevant to the research objectives. Subsequently, full-text screening was conducted for studies that met the inclusion and exclusion criteria. Any discrepancies were resolved through discussion between the two reviewers; if consensus could not be reached, a third reviewer was consulted for adjudication. Data were extracted from the included studies using a standardized form. Extracted information included the instrument name, authors, country of origin, year of publication, target population, scoring method, and primary assessment domains.

2.4. Quality assessment

Quality assessment was conducted in accordance with the Consensus-based Standards for the Selection of Health Measurement Instruments (COSMIN) guideline ^[12]. Two researchers independently evaluated the methodological quality and psychometric properties of the instruments and graded the level of evidence for each measurement property. Disagreements were resolved through discussion with a third researcher.

The COSMIN Risk of Bias checklist was applied, covering ten domains, including content validity, structural validity, and internal consistency ^[12]. For each domain, the overall rating was determined according to the lowest score assigned to any item within that domain. The rating options were “very good” “adequate” “doubtful” “inadequate” and “not applicable”.

3. Results

3.1. Literature search results

A total of 4,327 records were identified through database searches, including 2,683 English-language publications and 1,644 Chinese-language publications. After the screening process, 42 studies were

ultimately included in the review, comprising 38 English-language and 4 Chinese-language studies. The literature selection process is illustrated in **Figure 1**.

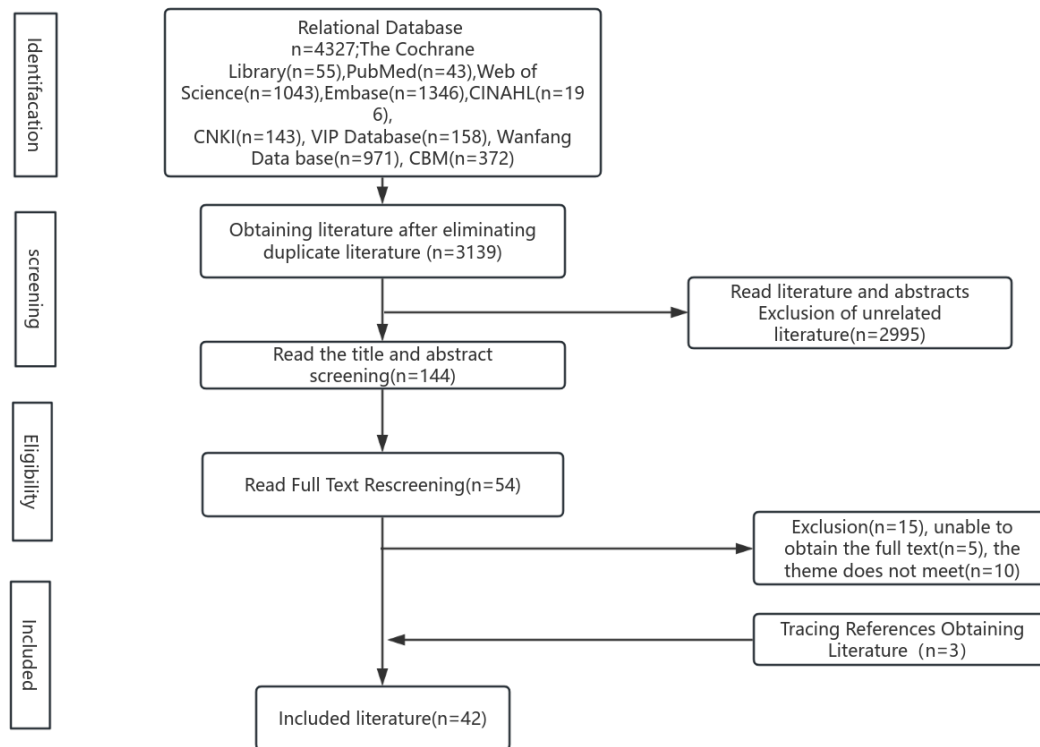


Figure 1. Flow chart of literature screening.

3.2. Characteristics and content summary of included studies

Among the included studies, 24 focused on instrument development and 18 on instrument validation. A total of 24 patient safety culture assessment instruments were identified, including 13 generic instruments and 11 setting-specific instruments [7,8,11,13–33]. Generic instruments were developed for use among all staff within comprehensive healthcare institutions, whereas setting-specific instruments targeted particular populations or healthcare settings. Of the setting-specific instruments, eight were designed for specific institutions or departments, including medical offices, nursing homes, community pharmacies, ambulatory surgery centers, radiology departments, dental hospitals, maternal and child healthcare institutions, and obstetric units [11,24–28,31,32]. The remaining three instruments were developed for specific populations, including healthcare administrators, medical students, and parents of pediatric patients [29,30,33]. The instruments were developed or validated in multiple countries, including the United States, the United Kingdom, Germany, the Netherlands, Indonesia, and Malaysia [7,11,13–15,18,19,21,24–27,29,32]. Six instruments were either developed by Chinese scholars or underwent Chinese translation and cross-cultural adaptation [17,20,22,23,31,33]. All included instruments were multidimensional scales administered through self-report questionnaires. Regarding the timeline of development, 11 instruments were developed between 1998 and 2010, 10 between 2011 and 2020, and 3 between 2021 and 2025. The basic characteristics of the included studies are presented in **Table 1**.

Table 1. Basic characteristics of patient safety culture assessment tools

Tool name	Author(s)	Country	Year	Target population	Dimensions / items
VA PSCS (Department of Veterans Affairs Patient Safety Culture Survey) ^[13]	Shiner,B. et al.	USA	1998	Department of Veterans Affairs staff	14 dimensions / 65 items
HSOPSC 1.0 (Hospital Survey on Patient Safety Culture) ^[7]	Westat.et al.	USA	2004	Hospital staff	12 dimensions / 51 items
TSCS (Teamwork and Safety Climate Survey questionnaire) ^[14]	Allen, Hutchinson et al.	UK	2006	Healthcare institution staff	5 dimensions / 22 items
SAQ (Safety Attitudes Questionnaire) ^[8] ; AQ-SF ^[15]	Sexton, J.B. et al.	USA	2006	Hospital staff	6 domains / 60 items
PSCHO (Patient Safety Climate in Healthcare Organizations) ^[16] ; PSCHO-SF ^[17]	Sara Singer et al.	USA	2007	Healthcare institution staff	9 dimensions / 38 items
NHSOPSC (Nursing Home Survey on Patient Safety Culture) ^[18]	Westat et al.	USA	2008	Nursing home staff	12 dimensions / 42 items
MOSOPSC (Medical Office Survey on Patient Safety Culture) ^[19]	Westat et al.	USA	2008	Medical office staff	10 dimensions / 38 items
MaPSaF (Manchester Patient Safety Framework) ^[20]	Arker, D. et al.	UK	2009	Healthcare and medical staff	9 dimensions / items not reported
PSCAS (Patient Safety Culture Assessment Scale) ^[21]	Chen, Fanglei et al.	China	2009	Hospital nursing staff	5 dimensions / 24 items
APSQ (Attitudes to Patient Safety questionnaire) ^[22]	Carruthers et al.	UK	2009	Medical students	9 dimensions / 26 items
CAS (cultural assessment survey) ^[23]	Kenneth Milne J. et al.	UK	2010	Obstetricians and nurses	6 subscales / 124 items
SCOPE (safety culture questionnaire for general practice) ^[24]	Zwart, D.L. et al.	Netherlands	2011	Healthcare personnel	8 dimensions / 46 items
HSOPS_M (Hospital Surveyon Patient Safety Culture for hospital Management) ^[25]	Antje Hammer et al.	Germany	2011	Senior hospital management	12 dimensions / 43 items
CPSOPSC (Community Pharmacy Survey on Patient Safety Culture) ^[11]	Westat et al.	USA	2012	Community pharmacy staff	11 dimensions / 36 items
SCOPE-PC (safety culture questionnaire for Primary Care) ^[26]	Verbakel, N.J. et al.	Netherlands	2013	Primary healthcare personnel	7 dimensions / 41 items
PSCQ (Patient Safety Culture Questionnaire) ^[27]	Jiang, He et al.	China	2013	Hospital nursing staff	8 dimensions / 36 items
ASCOPSC (Ambulatory Surgery Center Survey on Patient Safety Culture) ^[28]	Westat et al.	USA	2015	Ambulatory surgery center staff	8 dimensions / 27 items
PSCS-MCHI (patient safety culture scale for maternal and child health institutions) ^[29]	Yuanyuan Wang et al.	China	2018	Maternal and child healthcare staff	10 dimensions / 37 items
HSOPSC 2.0 (Hospital Survey on Patient Safety Culture) ^[30]	Westat et al.	USA	2019	Hospital staff	10 dimensions / 40 items
PSCSCHI (Patient Safety Culture Scale of Community-Level Healthcare Institutions) ^[31]	Lu, Chuntao et al.	China	2019	Primary healthcare institution staff	7 dimensions / 32 items

PVHSOPSC (Parental Version of Hospital Survey on Patient Safety Culture) ^[32]	Zeng, Xin et al.	China	2019	Parents of pediatric patients	4 dimensions / 14 items
PSCS-PC (Patient Safety Culture Scale for Chinese Primary Health Care Institution) ^[33]	Siyu Cheng et al.	China	2021	Primary healthcare institution staff	7 dimensions / 32 items
DOSOPSC (Dental Office Survey on Patient Safety Culture) ^[22]	Kusuma Arbianti et al.	Indonesia	2023	Dental hospital staff	10 dimensions / 35 items
SAQMI (Safety Attitude Questionnaire for the medical imaging) ^[34]	Ravi Chanthriga Eturajulu et al.	Malaysia	2023	Hospital radiology department staff	5 dimensions / 22 items

3.3. High-frequency dimensions of patient safety culture assessments and variability across instruments

Among the included instruments, the most frequently assessed dimensions were teamwork (18 occurrences), communication openness (16 occurrences), organizational learning and continuous improvement (15 occurrences), event reporting (14 occurrences), staffing and work pressure (12 occurrences), and patient involvement (9 occurrences). In the past five years, several newly introduced dimensions have emerged, including openness of communication with parents, parents' overall perceptions of safety, patient involvement in safety, overall commitment to quality, open communication, patient safety improvement, quality commitment, safety and teamwork climate, working conditions, patient care tracking/follow-up, and standardization of office workflows. In contrast, dimensions related to negative emotions, such as shame and fear of blame, have become less prevalent in recent instruments.

From a cross-national perspective, patient safety culture assessment instruments developed in Europe and the United States such as the HSOPS, SAQ, and PSCHO tend to emphasize management support, organizational learning, and a non-punitive culture, reflecting a strong focus on systematic improvement within healthcare systems ^[7,8,16]. The MaPSaF instrument places particular emphasis on commitment to quality, aligning with European healthcare quality accreditation frameworks ^[20]. In contrast, patient safety culture assessment instruments developed in China place greater emphasis on perceived punitive responses, resource allocation at the primary care level, and patient involvement, reflecting the complexity of doctor-patient relationships and constraints in primary healthcare resources. Notably, the maternal and child healthcare instrument PSCS-MCHI incorporates dimensions related to defensive medical practices, highlighting characteristics of clinical behavior in high-risk healthcare environments ^[29]. In developing countries, such as Indonesia, assessment instruments like DOSOPS focus on staff training and work pressure, reflecting challenges related to workforce shortages and occupational burnout ^[22].

From an institutional perspective, instruments developed for comprehensive hospitals, such as the HSOPS and SAQ, emphasize core dimensions including teamwork, handoffs and transitions, and interdepartmental collaboration. In contrast, instruments designed for primary care or community-based settings, such as the SCOPE-PC and PSCS-PC, focus on resource allocation, open communication, and patient safety training, reflecting the practical challenges of workforce and equipment shortages in primary healthcare settings ^[7,8,26,33]. Instruments developed for specialized institutions, including maternal and child healthcare facilities and dental hospitals, place greater emphasis on patient involvement and patient follow-up ^[22,29]. From the perspective of role-related power differentials, instruments targeting healthcare professionals such as the HSOPS and SAQ tend to emphasize work pressure, management support, and trust in technology

[7,8]. Instruments developed for medical students, such as the APSQ, include dimensions related to acceptance of patient safety training and attributions of error, aligning with competency development and educational objectives [30]. In contrast, instruments designed for patients or family members, such as the parent-version questionnaire, simplify dimensional structures and avoid technical terminology, thereby enhancing feasibility and usability [32].

3.4. Methodological quality and psychometric evaluation of patient safety culture assessment instruments

Regarding item development, nine instruments relied solely on literature review. Eleven instruments, including HSOPSC 2.0, incorporated interviews with target respondents [8,11,13,14,16,19–29]. Twelve instruments, such as SCOPE, employed the Delphi method, while eight instruments, including PSCS-MCHI, used all three methods in combination. With respect to sampling methods, sixteen instruments applied convenience sampling [7,11,15,17,19–34].

The methodological quality of instrument development was evaluated using the COSMIN Risk of Bias (RoB) checklist. For structural validity, thirteen instruments, including the SAQ, conducted both confirmatory and exploratory factor analyses, and were rated as very good in methodological quality [7,8,14,25–27,29–34]. Five instruments, such as PSCHO, performed exploratory factor analysis only and were rated as adequate [16,18,24,27,32]. For internal consistency, COSMIN recommends that each dimension be unidimensional and that Cronbach’s alpha be calculated for each dimension. Among the included instruments, 15 instruments tested unidimensionality and reported Cronbach’s alpha for each dimension, receiving a methodological quality rating of very good [7,16,18,19,25,27,29,30–34].

Regarding test-retest reliability, five instruments, including HSOPSC 1.0, calculated test-retest reliability using the Pearson correlation coefficient while accounting for systematic error, and were rated as very good [7,19,25,29,30]. Eight instruments, such as DOSOPS-C, calculated Pearson correlation coefficients without accounting for systematic error, resulting in a methodological quality rating of doubtful [14,18,21,22,26,27,32,33]. The psychometric properties of the instruments were further graded using the updated criteria for good measurement properties. Among the 13 instruments that assessed structural validity, seven instruments, including HSOPSC 1.0, met all criteria and were rated as sufficient [7,8,11,26,27,29,30]. For internal consistency, six instruments, including MOSOPSC, achieved a rating of sufficient [18,19,29,31–33]. Among the 14 instruments that assessed test-retest reliability, 11 instruments, such as DOSOPS-C, did not report intraclass correlation coefficients (ICCs) and were therefore rated as indeterminate [14,18,21–27,31–33]. Detailed information is provided in **Table 2**.

Table 2. Evaluation of the methodological and measurement properties of the PSC evaluation tool development study

Tool	Item development method	Sample			Structural validity		Internal consistency		Test-retest reliability	
		Sampling method	Sample size	Sample characteristics	MQ	QM	MQ	QM	MQ	QM
VA PSCS [13]	Literature review	Convenience sampling	28	Department of Veterans Affairs staff	-	-	-	-	Adequate	Sufficient

HSOPSC 1.0 ^[7]	Literature review + Interviews with target population	Convenience sampling	50513	Hospital staff	Very good	Sufficient	Very good	Indeterminate (0.62–0.85)	Very good	Sufficient
TSCS ^[14]	Literature review	Random sampling	897	Patient-contact healthcare staff	Very good	Insufficient	Problematic	Indeterminate (>0.69)	Problematic	Indeterminate
SAQ ^[8]	Literature review	Random sampling	16184	Clinical staff	Very good	Sufficient	-	-	-	-
PSCHO ^[16]	Literature review	Random sampling	42249	Hospital staff	Adequate	Indeterminate	Very good	Indeterminate	-	-
NHS OPSC ^[18]	Literature review + Interviews + Delphi method	Convenience sampling	306	Nursing home staff	Adequate	Indeterminate	Very good	Sufficient (0.94)	Problematic	Indeterminate
MOS OPSC ^[19]	Literature review + Interviews + Delphi method	Convenience sampling	4100	Medical office staff	Very good	Sufficient	Very good	Sufficient	Very good	Sufficient
MaPSaF ^[20]	Literature review + Interviews	-	-	Primary healthcare organization staff	-	-	-	-	-	-
Patient Safety Culture Questionnaire ^[21]	Literature review + Delphi method	Convenience sampling	236	Nurses	Very good	Indeterminate	Very good	Sufficient (0.8861)	Problematic	Indeterminate
APSQ ^[22]	Literature review	Convenience sampling	721	Medical students and their supervisors	Very good	Indeterminate	Problematic	Indeterminate (0.73)	-	-
CAS ^[23]	Literature review + Interviews + Delphi method	Convenience sampling	350	Obstetricians and nurses	-	-	-	-	-	-
SCOPE ^[24]	Literature review + Delphi method	Convenience sampling	331	Healthcare workers	Adequate	Indeterminate	Very good	Indeterminate (0.64–0.85)	Adequate	Indeterminate
HSOPS_M ^[25]	Literature review	Convenience sampling	551	Hospital management personnel	Very good	Indeterminate	Very good	Indeterminate (0.61–0.87)	Very good	Indeterminate
CPSO PSC ^[11]	Literature review + Interviews + Delphi method	Convenience sampling	630	Pharmacy staff	-	-	Problematic	Indeterminate (0.89)	Adequate	Sufficient
SCOPE-PC ^[26]	Literature review	Random sampling	615	Primary healthcare personnel	Very good	Sufficient	Very good	Indeterminate (0.58–0.86)	Problematic	Indeterminate

Patient Safety Culture Questionnaire ^[27]	Literature review + Interviews + Delphi method	Random sampling	580	Nursing staff	Adequate	Indeterminate	Very good	Indeterminate (0.658–0.890)	Problematic	Indeterminate
ASC OPSC ^[28]	Literature review + Interviews + Delphi method	Convenience sampling	59 ASCs	Ambulatory surgery center staff	-	-	-	-	-	-
PSCS-MCHI ^[29]	Literature review + Interviews + Delphi method	Convenience sampling	1256	Maternal and child healthcare staff	Very good	Sufficient	Very good	Indeterminate (0.89)	Very good	Sufficient
HSOP SC2.0 ^[30]	Literature review + Interviews + Delphi method	Convenience sampling	1300	Nurses	Very good	Sufficient	Very good	Indeterminate (0.68–0.93)	Very good	Sufficient
Primary Healthcare Patient Safety Culture Scale ^[31]	Literature review + Delphi method	Random sampling	343	Primary healthcare institution staff	Very good	Insufficient	Very good	Sufficient (0.940)	Inadequate	Indeterminate
Parent Version Hospital Safety Culture Questionnaire ^[32]	Literature review + Delphi method	Convenience sampling	562	Parents of pediatric patients	Adequate	Indeterminate	Very good	Sufficient (0.893)	Problematic	Indeterminate
PSCS-PC ^[33]	Literature review + Focus group discussions + Delphi method	Random sampling	369	Healthcare staff	Very good	Insufficient	Very good	Sufficient (0.940)	Problematic	Indeterminate
DOSOPSC ^[22]	Literature review	Convenience sampling	123	Dental hospital staff	-	-	Problematic	Indeterminate (>0.7)	Problematic	Indeterminate
SAQ-MI ^[34]	Literature review	Convenience sampling	300	Hospital radiology department staff	Very good	Sufficient	Very good	Indeterminate (0.921)	-	-

Note:

QM: Quality of measurement properties; refers to the quality of the measurement attributes.

MQ: Methodological quality; refers to the methodological rigor of the tool development and validation process.

“-” indicates information not reported.

4. Discussion

4.1. General characteristics of patient safety culture assessment instruments

Healthcare institutions of different types and levels vary in management models and work practices;

therefore, patient safety culture assessment instruments need to be developed and adapted according to the specific characteristics of healthcare services in each setting. Among all instruments, those developed for hospital environments are the most numerous. Of the 24 instruments included in this study, ten were specifically developed for hospital settings ^[7,16,18,20–22,25,29,30,32]. Among them, the HSOPSC has been the most widely applied and has been used in multiple countries to assess hospital safety culture ^[7]. It has been validated across different languages and cultural contexts, demonstrating good stability. The SAQ measures patient safety culture through healthcare professionals' safety attitudes and perceptions and has also been validated for use in community hospitals, showing satisfactory psychometric properties ^[8,36].

In terms of assessed domains, 11 instruments included ten or more dimensions, covering areas such as communication, teamwork, organizational support, and event reporting ^[7,11,16–18,19–21,29,30]. Core dimensions were highly consistent across instruments, with teamwork, communication openness, and organizational learning occurring in 15 or more instruments, indicating that safety culture fundamentally depends on collaboration, transparency, and continuous improvement mechanisms. Content analysis further revealed cross-national differences: instruments developed in Europe and the United States are generally oriented toward market-driven and systematized improvements, emphasizing open communication and individual accountability, whereas instruments developed in East Asian countries, including China, tend to prioritize collective coordination and risk avoidance, often reflecting local healthcare policies and the push for localized tool development. Regarding scoring methods, the APSQ uses a 7-point Likert scale, while the remaining 23 instruments employ a 5-point Likert scale, all based on self-report ^[22]. Several instruments, including the SAQ, VA PSCS, HSOPS_M, SCOPE-PC, and CAS, contain more than 40 items, which can lead to lengthy assessment times ^[8,13,23–25]. Some instruments have been simplified or updated to improve feasibility, such as the SAQ-SF and PSCHO-SF ^[15,17]. Future efforts should aim to maintain comprehensive coverage of assessment domains while enhancing brevity to improve efficiency.

4.2. Trends toward simplification and differentiation in the development of patient safety culture assessment instruments

Among the instruments developed under the Surveys on Patient Safety Culture ® (SOPS®) initiative led by the U.S. Agency for Healthcare Research and Quality (AHRQ), five instruments HSOPSC, NHSOPSC, MOSOPSC, CPSOPSC, and ASCOPSC represent the most widely applied patient safety culture assessment tools internationally and have undergone localization in multiple countries. Notably, the HSOPSC was revised in 2019, reducing the original 12 dimensions and 51 items to 10 dimensions and 40 items in version 2.0, while retaining psychometric properties comparable to the original version, with Cronbach's α coefficients ranging from 0.67 to 0.89 ^[7,30]. In China, Yin et al conducted a cross-cultural adaptation of the HSOPSC 2.0 in 2023 ^[9]. After merging two dimensions, the instrument still demonstrated strong psychometric properties (Cronbach's $\alpha = 0.952$; test-retest reliability = 0.924). In addition, due to differences in work environments across healthcare institutions and departments, researchers in various countries have adapted existing generic instruments to specific populations or settings, resulting in specialized assessment tools. For example, Ravi et al. developed the SAQ MI based on the SAQ to address potential biases in specialized clinical environments, achieving a Cronbach's α of 0.921 ^[16]. The proliferation of specialized instruments, however, may hinder cross-institutional and cross-population comparability, limiting the ability to evaluate patient safety culture at a system-wide level or establish national benchmarks. Therefore, a hybrid

development model combining core modules with optional specialty- or institution-specific modules is recommended, allowing differentiation while maintaining comparability of essential dimensions.

4.3. Methodological quality and psychometric properties of patient safety culture assessment instruments require further exploration and refinement

Evaluation based on the COSMIN Risk of Bias checklist and the updated criteria for good measurement properties indicates that the development and validation processes of existing patient safety culture assessment instruments remain insufficiently rigorous. Some instruments relied solely on literature review during the item development phase, which may compromise the comprehensiveness and applicability of the tools. Future studies should integrate multiple data sources such as literature review, semi-structured interviews, and expert consultation to ensure thorough item construction. Over one-third (9/24) of instruments, including the APSQ and PSCHO, relied exclusively on literature review in the initial item development phase, without direct interviews or focus group discussions with target populations, such as healthcare professionals, patients, or administrators^[16,22]. This single-method approach may fail to capture the unique understanding and core concerns of specific cultural contexts, institutional types, or populations (e.g., primary healthcare institutions in China, medical students, parents of pediatric patients), potentially resulting in item content that does not reflect participants' actual experiences and undermining both face and content validity. Future instrument development should rigorously follow COSMIN guidelines, employing an integrated approach that combines literature review, semi-structured interviews/focus groups with target populations, and expert consultation (e.g., Delphi method) to systematically construct conceptual frameworks and generate item pools, thereby ensuring that the assessment content accurately reflects the patient safety culture in the target environment and strengthens content validity. During validation, some instruments exhibited unclear factor interpretations. For example, in the APSQ, certain factors such as team functioning demonstrated cross-loadings, indicating that even instruments using both exploratory and confirmatory factor analyses (EFA and CFA) may have ambiguities in factor definitions or insufficient discrimination among constructs, which can compromise interpretability and diagnostic value. Future studies should prioritize CFA to test pre-specified models or combine EFA and CFA in a cross-validation approach during the exploratory phase. Furthermore, methodological quality regarding instrument stability was limited. Among the included instruments, only the HSOPSC 2.0 and VA PSCS achieved a sufficient rating for test-retest reliability; other instruments either did not report test-retest reliability or provided unclear interpretations^[13,30]. It is recommended that stability assessments be conducted following the COSMIN-RoB checklist to ensure structural consistency. In summary, future research should ensure a rigorous, multi-stage instrument development and validation process guided by COSMIN standards, particularly for the development of localized instruments in China. Large-scale validation across different levels and types of healthcare institutions is necessary to establish reliable normative data and to explore the relationship between assessment results and clinical safety outcomes, such as adverse event rates.

5. Conclusion

This study systematically identified a total of 24 PSC assessment instruments and synthesized their characteristics, providing recommendations for future research:

- (1) Development of concise yet comprehensive instruments that fully reflect the diversity of healthcare

environments is warranted. Further rigorous studies such as stepped-wedge cluster randomized trials or interrupted time series analyses are encouraged to evaluate the causal effects of integrated safety improvement programs that incorporate PSC assessment as a diagnostic and monitoring tool on safety culture perception, safety-related behaviors, and clinical safety outcomes.

- (2) Future instrument development should be guided by robust theoretical frameworks and sound methodological principles to ensure accurate quantification of patient safety culture. This will provide reliable data to support the construction of safety culture, the design of interventions, and the formulation of management policies.
- (3) Chinese researchers are encouraged to develop more precise, culturally adapted PSC instruments under the guidance of the COSMIN-RoB checklist, and to validate these instruments across different levels of healthcare institutions to establish normative data.

This study has several limitations. First, the original literature primarily focused on instrument development and validation rather than intervention applications, resulting in a limited quantity and variable quality of effectiveness evidence, most of which were observational or descriptive. Second, although the COSMIN-RoB checklist was used for methodological quality assessment, some items in COSMIN-RoB are inherently subjective, which may introduce potential bias in the evaluation results.

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