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Psychometric Evaluation of the Hospital Survey on Patient Safety Culture in Kuwaiti Healthcare

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ABSTRACT

Objective

As healthcare organisations endeavor to improve the quality and safety of their services, there is increasing recognition of the importance of building a culture of safety to promote patient safety and improve the outcomes of patient care. Surveys of safety culture/climate have not knowingly been conducted in Kuwait public hospitals, nor are valid or reliable survey instruments available for this context. This study aims to investigate the psychometric properties of the HSOPSC (Hospital Survey of Patient Safety Culture) tool in Kuwait public hospitals in addition to constructing an optimal model to assess the level of safety climate in this setting.

Design

cross-sectional study.

Setting

Three public hospitals in Kuwait.

Participants

About 1,317 healthcare professionals.

Main outcome measure

An adapted and contextualised version of HSOPSC was used to conduct psychometric evaluation including exploratory factor analysis, confirmatory factor analysis reliability and correlation analysis.

Results

1,317 questionnaires (87%) were returned. Psychometric evaluation, showed an optimal model of Eight factors and 22 safety climate items. All items have strong factor loadings (0.42-0.86) and are theoretically related. Reliability analysis showed satisfactory results ($\alpha > 0.60$).

Conclusions

This is the first validation study of a standardised safety climate measure in a Kuwaiti healthcare setting. An optimal model for assessing patient safety climate was produced that mirrors other international studies and which can be used for measuring the prevailing safety climate. More importance should be attached to the psychometric fidelity of safety climate questionnaires before extending their use in other healthcare culture and contexts internationally.

KEYWORDS: patient safety, safety culture, psychometrics, surveys, quality improvement.

STRENGTHS AND LIMITATIONS OF THIS STUDY:

- A rigorous and scientific psychometric approach was designed and executed based on recommended reporting practices with strengths of both EFA and CFA analytical techniques were used to test the original HSOPSC model and construct an optimal model.
- The large sample size (n=1280) allowed for the dataset to be split and for factor analysis to be undertaken with acceptable model fit indices.
- One limitation is the number of items per factor in the optimal model. Three factors contained only two items per factor in the final Eight-factor model.
- Another limitation is the exclusion of partially answered questionnaires. As a result, a subset of the total sample, with all items answered, was used for the validation of the psychometric properties of the HSOPSC.
- Lack of reporting of explicit psychometric data in some important studies used in the comparative analyses was another challenge faced in our study.

INTRODUCTION

Modern healthcare systems are concerned with improving the safety of patient care and attempting to build a strong organisational safety cultures. "Safety Culture" is identified as a key element of a healthcare organisation's ability to learn openly from safety incidents and reduce preventable harm to patients. The perceived importance of safety culture in improving patient safety and its impact on clinical outcomes has led to a growing interest in the assessment of safety culture in healthcare organisations. The use of survey questionnaires is one of the most popular methods for assessing safety culture. These surveys aim to measure healthcare workers' perceptions of the prevailing safety culture or "safety climate" in their organisations.

There are numerous definitions of safety culture and safety climate. Despite their distinctive terminologies, they are commonly used arbitrarily and interchangeably in the literature [1]. Safety culture has been described as a set of shared values, beliefs, norms, and attitudes that interact with an organisation's structure and control systems resulting in behavioural norms [2 3]. Safety climate provides a "snapshot" of the perceptions held by healthcare workers about visible, surface level features of safety culture at a given point in time [4]. It "*assesses workforce perceptions of procedures and behaviours in their work environment that indicate the priority given to safety relative to other organisational goals*" [5].

Assessing the status of the existing safety culture in a healthcare organisation is promoted as the first step for developing a strong and solid safety culture [6]. The resulting data potentially offers policymakers, healthcare providers, teams and managers a clear view of areas in need of attention to strengthen the prevailing safety climate, in addition to identifying specific challenges that impede progress in safety initiatives [7]. It can also be used for benchmarking and improving safety culture measures across time and between organisations on national and international levels [8 9].

A range of safety climate assessment tools have been developed for acute hospital settings, although the scientific rigour with which they were designed and tested is variable [5 10 11].

Multiple reviews of patient safety climate instruments have been published [5 10-16]. Most concluded that the Safety Attitudes Questionnaire (SAQ) and Hospital Survey on Patient Safety Culture

(HSOPSC) were the most appropriate tools available in terms of their psychometric properties, but also critiqued climate tools generally as many lack appropriate scale development, validation and evidence for their predictive validity. Over a decade ago, Flin, et al. [5] argued that it is essential that tools are developed with robust psychometric properties to enable valid interpretations of patient safety climate test scores to be made.

Despite this, many published studies are still limited in their reporting of the necessary psychometric properties of questionnaires [5 10 17 18]. It is argued that HSOPSC is one of the most rigorously tested instruments with good psychometric properties in addition to being tested on the necessary large sample sizes [5]. Psychometric analysis involves the use of established statistical assessment techniques to assess the psychometric properties of questionnaires and identify the underlying safety culture dimensions [11].

Repeated high-profile media coverage has drawn the attention of Kuwaiti politicians and the public to failings in healthcare delivery and patient safety, which has contributed to growing demands for a better quality of care [19-21]. Subsequent inquiries and reports have placed patient safety high on the Kuwait policy agenda. The Ministry of Health (MOH) responded by investing significantly in the improvement of healthcare services. Safety climate assessment is one of the latest approaches to be adopted by the MOH with the goal of evaluating and improving patient safety in Kuwaiti hospitals.

Surveys of safety climate have yet to be conducted at public hospitals in the state of Kuwait, nor are valid or reliable survey instruments available for this purpose. This study aims, therefore, to assess the psychometric properties of the HSOPSC tool in Kuwaiti public hospitals in addition to constructing an optimal model to assess the level of safety climate in this setting and to benchmark the data against other international studies.

METHOD

Instrument selection

HSOPSC is a 12-factor, 42 item survey questionnaire. It assesses ten climate dimensions of patient safety, with two outcome measures (overall perceptions of patient safety and frequency of event reporting). Two additional single-item outcome measure are included [22 23]. The HSOPSC tool was chosen for this study for several reasons. Firstly, a systematic review of tools designed for acute hospital settings concluded that HSOPSC had good overall methodological quality with good assessment of the tool's reported psychometric properties (Alsalem et al 2018). Secondly, HSOPSC was one of the most rigorously tested instruments at the time of selection, with extensive literature reporting its psychometric properties [5]. The tool has been extensively used in hospitals in the United States where it was originally developed [24], and validated for use in more than 60 countries and translated into 30 different languages [25-32]. Thirdly, HSOPSC is a comprehensive measure of safety climate as it assesses key aspects related to patient safety at multiple levels of analysis including the individual, unit and hospital levels (Box 1). Finally, the tool is freely available, uses clear language with a scale that is simple and easy to follow.

Instrument modification

The tool was pilot tested and modified for Kuwaiti healthcare in order to solve any technical and feasibility issues associated with its application [33 34]. Seven face-to-face interviews were conducted with a panel of healthcare staff from MOH (including doctors, nurses and risk and safety officers) to evaluate HSOPSC content and ensure the proper transfer of the intended meaning of the questionnaire items to the culture and language differences in the Kuwait context. The panel endorsed the HSOPSC content as being of high relevance to safety culture in Kuwaiti hospitals. All items were retained. However, wording was modified in eight items to clarify their meaning as some comments indicated potential ambiguity in items' interpretations.

Instrument testing

A stratified random sample was drawn from healthcare clinical staff in three public hospitals in Kuwait. To ensure that the sample size was adequate to satisfactorily undertake factor analysis (FA), sample size requirements (sample size of the study, ratio of the sample size to the number

of variables, ratio of the number of variables to the number of factors) were evaluated [35]. Tabachnick and Fidell [36] rule recommends having at least 300 cases to undertake FA. The Kaiser-Meyer-Olkin (KMO) coefficient was used as another measure of sampling adequacy. KMO coefficient values range between 0 and 1. Surveys of health professionals can be challenging and are characterised by declining response rates [37] with a significant downward trend in response rates from 1998 to 2008 [38]. Based on their findings, the predicted response rate for this study was 20% and it was estimated that the sample size should be a minimum of 1,500 of distributed questionnaires.

Data collection and management

Staff members were invited by letter to participate in the study. Questionnaires were distributed across different departments in the three public hospitals. The questionnaires were completed anonymously and returned to multiple collection boxes located within the hospitals. Data were coded and entered into an electronic data file using the Statistical Package for Social Science (SPSS 24). Negatively worded items were reverse coded. If less than one entire section of the survey was answered or less than half of the items throughout the entire survey (in different sections) were answered, or if every item was answered the same, these questionnaires were excluded [39]. Missing values were deleted in a listwise manner in order to minimise any possible biases [40].

Factor analysis (FA)

FA is a statistical method that "*explores the extent to which individual items in a questionnaire can be grouped together according to the correlations between the responses to them*", thus reducing the dimensionality of the data [41]. It can be applied as a data reduction or a structure detection method [42]. The two main techniques of FA are Exploratory Factor Analysis (EFA), and Confirmatory Factor Analysis (CFA), which are both recommended to test construct validity [43].

EFA allows the researcher to uncover the main dimensions to develop a theory, or model from a smaller number of latent constructs that are often represented by a larger set of measured variables [44,45]. CFA tests a pre-determined factor structure or a proposed theory [44,45]. This study combined both approaches to develop an optimal model, based on the original HSOPSC model, for

specifically assessing patient safety climate in Kuwaiti public hospitals. Due to the controversy associated with conducting EFA and CFA on the same data, a split-half validation technique is recommended [46 47]. Therefore, the Kuwaiti dataset was randomly split into to two independent datasets using SPSS 24. Each group contains a set of 640 (n=640) cases - the calibration half of the dataset was used for model construction and the validation half of the dataset was used for confirming the explored factor structure resulting from model construction.

Data analysis was based on three main phases. 1. To investigate whether the original HSOPSC 12-factor model is appropriate for the Kuwaiti data. Both CFA and reliability analysis were used at this step. 2. To examine whether an alternative factor model would fit the Kuwaiti data better. For model construction, EFA was carried out using the calibration half of the dataset (Sample A, n=640). 3. Undertaking CFA and reliability analysis using the validation half of the dataset, to test the fit of the resultant model from the previous phase (Sample B, n=640). Cronbach's alpha (α) was calculated for each factor to examine the internal consistency or reliability with the minimum criterion for acceptable reliability of at least $\alpha \geq 0.60$ as recommended for the majority of research purposes [48 49]. Factor correlations of the optimal model were performed in addition to comparisons between the CFA output of our optimal factor model and the outputs reported in previous studies.

RESULTS

Response rate and sample demographics

Of the 1,511 questionnaires distributed at the three hospitals, 1,317 questionnaires (87%) were returned. A KMO statistic of 0.88 was calculated , which indicates that the sample has a sufficient level of homogeneity [50 51]. Thirty-seven questionnaires were excluded. Appendix 1 summarizes the relevant demographics of survey respondents.

Instrument testing

Testing the original HSOPSC (12-factor) model

A CFA was performed, using AMOS software [52], to test the model fit of the original HSOPSC 12-factor structure using the Kuwaiti data. The global fit of our model was not consistently satisfactory for the Kuwaiti data. Three criteria measures did not indicate an acceptable fit with Comparitive

Fit Index (CFI) = 0.81 (CFI values ≥0.90 considered a good model fit [53]), Chi-squared statistic per one degree of freedom (x^2/DF) = 4.81 (x^2/DF value ≤2 for a good fit [54]), and TLI = 0.784 (TLI of > 0.90 indicates a good fit [53]) values indicate that the fit is not adequately good enough to confirm the proposed factor structure.

The internal consistency of the Kuwaiti data (n=1280) was ≥0.60 within nine dimensions. Three dimensions had internal consistencies less than 0.60. Additionally, two dimensions have a questionable internal consistency because their Cronbach's alpha value was 0.60 (Cronbach's α=0.604 for "Non-punitive Response to Errors" and Cronbach's α=0.601 for "communication openness". In summary, the results of the CFA and reliability analysis indicate that the original HSOPSC 12 Factor model is not a satisfactory fit when it is used for the Kuwaiti data. Therefore, an EFA was used for investigating an alternative factor structure which might be more appropriate for Kuwaiti data.

Construction of an optimal model

EFA consists of two basic stages. 1. Estimating the number of factors that should be extracted to represent the HSOPSC factor structure; and 2. Interpreting the meaning of the extracted factors and representing them in terms of theoretical structures that reflect the patient safety climate dimensions. EFA (principal axis factoring with varimax then oblique rotation) was performed on the calibration half of the dataset (n=640). Based on the Kaiser criterion of Eigenvalues greater than one (Eigenvalues > 1) [50] and Cattell scree plot [55], different numbers of factors (12,11,10,9,8,7 factors) were extracted and investigated to find the optimal alternative model.

Following the rotation of factors the factor pattern matrix was examined to decide on the acceptable level of loading for variables to define factors [56]. To reach a satisfactory solution, a number of points need to be taken into consideration including identifying items with low communalities, no or low loading, items with cross loadings and the theoretical structure of items. It should be noted that the decision on how many factors to retain based on the degree of comprehensibility and interpretability of the factor structure in the context of the research [57]. In addition, theoretical knowledge regarding the construct under study is more significant than a statistical measure and the items and factors should make conceptual sense and be theoretically related [56].

Final factor solution

An Eight-factor solution (all loadings ≥ 0.40) showed the best model fit to the Kuwaiti dataset. The Scree plot of the final EFA solution is shown in Figure 1. The structure and factor loadings of the final EFA solution are reported in Table 1. The final solution explains 50.2% of variance by eight extracted factors and represents 22 items from the safety climate questionnaire (20 items were excluded). All factor loadings are within the range of 0.428-0.864.

Table 1: Pattern matrix of the final EFA solution (Eight factors, 22 items)

Variable	Factor							
	1	2	3	4	5	6	7	8
(B1) My supervisor/manager says a good word when he/she sees a job done according to established patient safety procedures (SEA)	,822							
(B2) My supervisor/manager seriously considers staff suggestions for improving patient safety (SEA)	,623							
(E2) When a mistake is made, but has no potential to harm the patient, how often is this reported? (FER)		,864						
(E1) When a mistake is made, but is caught and corrected before affecting the patient, how often is this reported? (FER)		,776						
(E3) When a mistake is made that could harm the patient, but does not, how often is this reported? (FER)		,776						
(D5) Important patient care information is often lost during shift changes. (negatively worded) (HO)			-,662					
(D3) Things 'fall between the cracks' when transferring patients from one unit to another (negatively worded) (HO)			-,621					
(D6) It is often unpleasant to work with staff from other hospital units. (negatively worded) (TWAU)			-,495					
(D7) Problems often occur in the exchange of information across hospital units. (negatively worded) (HO)			-,428					
(A16) Staff worry that mistakes they make are kept in their personnel file. (negatively worded) (NRP)				,578				
(A8) Staff feel like their mistakes are held (used) against them. (negatively worded) (NPR)				,559				
(A12) When an incident is reported, it feels like the person is being reported, not the problem. (negatively worded) (NPR)				,531				

Variable	Factor							
	1	2	3	4	5	6	7	8
(D4) There is good cooperation among hospital units that need to work together (TWAU)					-,641			
(D2) Hospital units do not coordinate well with each other. (negatively worded) (TWAU)					-,522			
(A1) People support one another in this unit (TWWU)						,688		
(A3) When a lot of work needs to be done quickly, we work together as a team to get the work done (TWWU)						,605		
(A4) In this unit, people treat each other with respect (TWWU)						,556		
(C6) Staff are afraid to ask questions when something does not seem right. (negatively worded) (CO)							,615	
(C4) Staff feel free to question the decisions or actions of those with more authority (CO)							,600	
(C2) Staff will freely speak up if they see something that may negatively affect patient care (CO)							,524	
(D1) Hospital management provides a work climate that promotes patient safety (MS)								,677
(D8) The actions of hospital management show that patient safety is a top priority (MS)								,574

Extraction Method: Principal Axis Factoring. Rotation Method: Oblimin with Kaiser Normalization.
Rotation converged in 16 iterations. Supervisor/manager expectations and actions promoting safety (SMEA), Organisational learning—continuous improvement (OL),Teamwork within hospital units (TWWU), Teamwork across hospital units (TWAU), Communication openness (CO), Feedback and communication about error (FB), Non-punitive response to error (NPRE), Staffing (S), Hospital management support for patient safety (MS), Hospital handoffs and transitions (HO), Frequency of incident reporting (FER), Overall perceptions of patient safety (OPPS).

Five factors (Factor 2, Factor 3, Factor 4, Factor 6, and Factor 7) have three and more items with loading >0.4. Factor 1, Factor 5, and Factor 8 have two items with very high loading of >0.5 and the items in each factor are theoretically related (Table 2). There are no cross loaded items and there are no items with loading <0.4 and with communalities <0.3 in the solution. The solution is essentially consistent with all items within each factor theoretically related. Only D6 moved from "Teamwork across units" to "Handoffs and transitions."

Table 2: Structure, factors loadings and internal consistency of the final EFA solution (Eight factors, 22 items)

Number of Factor	Factor	Heavy loaded items (>0.4)	Number of items	Cronbach's Alpha
1	Supervisor/Manager Expectations and Actions Promoting Safety	B1-B2	2	0.776
2	Frequency of Events Reported	E1-E2-E3	3	0.858

Number of Factor	Factor	Heavy loaded items (>0.4)	Number of items	Cronbach's Alpha
3	Handoffs and Transitions	D3-D5-D6-D7	4	0.685
4	Non-punitive Response to Errors	A8-A12-A16	3	0.604
5	Teamwork Across Units	D2-D4	2	0.689
6	Teamwork Within Units	A1-A3-A4	3	0.705
7	Communication Openness	C2-C4-C6	3	0.601
8	Management Support for Patient Safety	D1-D8	2	0.724

Testing the final factor (Eight-factor) model

The optimal Eight-factor model was vigorously examined by conducting two confirmatory analyses initially using the validation half of the dataset (n=640), followed by the whole dataset (n=1280). All estimated parameters indicate a good model fit (Eight factors and 22 items) as reported in Table 3.

Table 3: CFA Results of Eight factor optimal model (validation sample and whole sample)

Eight-factors model	Chi-Square statistic (x^2)	DF	CMIN/DF (x^2/DF)	CFI	RMR	SRMR	RMSEA	TLI
Validation sample	424.9 good	181 good	2.3 acceptable	0.94 good	0.049 good	0.048 good	0.046 good	0.92 good
Whole sample	617.8 good	181 good	3.4 acceptable	0.946 good	0.041 good	0.038 good	0.043 good	0.931 good

Chi-square test statistic (x^2), Chi-squared statistic per one freedom degree (x^2/DF), the Comparative Fit Index (CFI), Root mean square residuals (RMR), the Standardised Root Mean Square Residual (SRMR), the Root Mean Square Error of Approximation (RMSEA), Tucker-Lewis Index (TLI)

The standardised path coefficients reflecting the strength of the relationship between items and dimensions [58] were found to be generally large (>0.50) and ranged from 0.46 (Communication openness) to 0.89 (Frequency of incidents reported) (see Appendix 2). Therefore, this model was accepted as the optimal model of HSOPSC for the Kuwaiti healthcare setting.

Reliability

Reliability analysis was performed using the whole sample with Cronbach's Alpha values reported to be ≥ 0.60 for all factors. Therefore, the internal consistency was acceptable for the Eight factors solution (Table 2). In order to test the construct validity of the HSOPSC instrument, inter-correlation coefficients with Pearson's ***r*** were calculated between the Eight factors in addition to the two single item outcome measures (patient safety grade and number of incidents reported). The Pearson's correlation coefficients between scale scores are reported in online appendix 3. Inter-correlation coefficients ranged between 0.08 and 0.72. All correlation coefficients are significant. The highest correlations were those between "Management support for patient safety" and "Teamwork across units" (r=0.722). All eight factors are interrelated to each other. Most of the correlation coefficients indicate a moderate correlation between dimensions. This indicates that no two factors are measuring the same construct.

Proposed optimal Eight factors model for Kuwaiti data

As shown in Table 4, the proposed optimal model structure includes 8 dimensions and 22 items.

Table 4: Proposed Eight factors optimal model for Kuwaiti data

Factor 1: Supervisor/Manager Expectations and Actions Promoting Patient Safety (2 items)
B1: My supervisor/manager says a good word when he/she sees a job done according to established patient safety procedures
B2: My supervisor/manager seriously considers staff suggestions for improving patient safety.
Factor 2: Frequency of Events Reported (3 items)
E1: When a mistake is made, but is caught and corrected before affecting the patient, how often is this reported?
E2: When a mistake is made, but has no potential to harm the patient, how often is this reported?
E3: When a mistake is made that could harm the patient, but does not, how often is this reported?
Factor 3: Handoffs and Transitions (4 items)
D3: Things "fall between the cracks" when transferring patients from one unit to another. (negatively worded)
D5: Important patient care information is often lost during shift changes. (negatively worded)
D6: It is often unpleasant to work with staff from other hospital units. (negatively worded)
D7: Problems often occur in the exchange of information across hospital units. (negatively worded)
Factor 4: Non-punitive Response to Errors (3 items)
A8: Staff feel like their mistakes are held (used) against them. (negatively worded)
A12: When an incident is reported, it feels like the person is being reported, not the problem. (negatively worded)
A16: Staff worry that mistakes they make are kept in their personnel file. (negatively worded)

Factor 5: Teamwork Across Units (2 items)
D2: Hospital units do not coordinate well with each other. (negatively worded)
D4: There is good cooperation among hospital units that need to work together.
Factor 6: Teamwork Within Units (3 items)
A1: People support one another in this unit.
A3: When a lot of work needs to be done quickly, we work together as a team to get the work done.
A4: In this unit, people treat each other with respect.
Factor 7: Communication Openness (3 items)
C2: Staff will freely speak up if they see something that may negatively affect patient care.
C4: Staff feel free to question the decisions or actions of those with more authority.
C6: Staff are afraid to ask questions when something does not seem right. (negatively worded)
Factor 8: Management Support for Patient Safety (2 items)
D1: Hospital management provides a work climate that promotes patient safety.
D8: The actions of hospital management show that patient safety is a top priority.

DISCUSSION

This psychometric evaluation is the first reported validation study of a standardised safety climate measure in a Kuwaiti healthcare setting. The psychometric properties of the HSOPSC questionnaire were assessed and an optimal model for assessing patient safety climate in Kuwaiti hospitals was constructed. The final questionnaire contains 22 safety climate items (variables) that measure eight safety climate factors. The optimal model's psychometric properties (including validity and reliability) were good with all items loading strongly (>0.40) onto one factor and all items, within each factor, were theoretically related.

Our results are in line with other studies investigating the psychometric properties of the original HSOPSC questionnaire. The suitability of the original HSOPSC model for Kuwaiti data was tested and results revealed an unsatisfactory fit [59]. Different international studies [27 31 60 61] reported similar findings. This finding is in contrast with other studies that assessed patient safety climate by using the original HSOPSC questionnaire [59] in hospitals without examining the reliability and validity of the questionnaire in a different context [62-68]

Various underlying factor structures were identified as optimal factor models. The original 12 factor model was replicated in Belgian [6], Portuguese [69] and Scottish data [70]. Other studies reported 11 factor models for Dutch [30], Arabic [61], Croatian [71] and Norwegian data [72]; 10 factor models for French [28], Turkish [26], Chinese [73] and Brazilian data [74]; 9 factor models for UK [31] and Slovene data

[75]; Eight factor models for Swiss [27], Saudi [60], Kosovo [76] and Kuwaiti data. This discrepancy in results could be attributed to differences in employing survey methods and psychometric analytical techniques, in addition to the various modifications made to adapt the original instrument to different healthcare settings [70]. Neglect of crucial elements, including context, processes and actors involved, when attempting to adapt an instrument in a different setting might lead to conflicting results and might weaken the validity of the instrument [77]. Thus, the original HSOPSC will clearly be limited when used in other contexts without proper assessment of its psychometric properties. The optimal model of our study is in line with other international studies [31 60]. Four dimensions were either dropped or merged with other factors into a single dimension. In our study, the same dimensions reported low reliability using the original HSOPSC in addition to other international studies [31 60 78]. The optimal model was confirmed using CFA with good model fit indices. This was consistent with the CFA results of the USA [59], Saudi Arabia [60], Palestine [61], UK [31] and Scotland [70] optimal models.

Considering all of this evidence, it seems that the original HSOPSC questionnaire [59] does not appear to perform well in different countries. Survey instruments that are designed for particular settings are tailored to meet the unique characteristics and contexts of the local setting and population. In the case of the HSOPSC, a number of the reported adaptations have performed less well than the original tool [28 31 72 73 79].

In a review of quantitative patient safety culture instruments, it was concluded that all of the surveys designed for general administration to hospital personnel addressed three common dimensions: management support and commitment to safety, communication openness and teamwork [11]. They suggested that these common dimensions might be considered “core dimensions” of patient safety culture. In addition, a number of dimensions seem to be common among optimal factor models across different countries.

Factor structure of the optimal model of our study compared with optimal models that were developed in Saudi Arabia, Palestine, England, Scotland, Netherlands, Turkey and Switzerland in addition to the original USA HSOPSC questionnaire [59] is shown in Online Appendix 4. This comparison is aimed at identifying a common set of patient safety culture dimensions across different countries.

Six studies reported different dimensions combined into one dimension. A significant degree of overlap in the content of the safety culture dimensions exists. As a result, included items in certain dimensions tend to load onto differently labeled dimensions. “Feedback and communication about error” and “Communication openness” were grouped into one dimension in the Palestinian, Swiss and Scottish studies respectively [27 61 78]. This result is expected as both dimensions are closely related. Feedback and communication with staff about errors and discussing ways to prevent them are linked to allowing staff to freely speak up, if they see something that might negatively affect patient care.

Cox and Flin [1] suggest that the nature of safety climate is “context-dependent.” Keiser [80] argues that since safety climate measures include both general and contextualized items, excluding contextual measures might provide a rather deficient evaluation of the underlying safety climate construct. Thus, research currently supports the idea of integrating both qualitative and quantitative methods in developing a culturally appropriate instrument as standard approaches that exclusively rely on translation and quantitative validation may not be sufficient to produce an instrument that is applicable to the local context [73]. As a result, the adopted tool will be able to reflect important safety climate themes that are specific to the local healthcare context.

A number of common dimensions that were emerging rather consistently across international settings despite the lack of confirmation of the original factor structure of the HSOPSC in numerous studies. Those dimensions include: management support for patient safety, supervisors' action promoting patient safety, teamwork within and across units, handoffs and transitions, non-punitive response to error, frequency of incidents reported, communication openness and organisational learning.

The item composition of each factor of the optimal model of our study was compared with optimal models that were developed in Saudi Arabia, Palestine, England, Netherlands, Turkey and Switzerland in addition to the original USA HSOPSC questionnaire [59]. This comparison is aimed at identifying a common set of patient safety climate items across different countries (Appendix 5). The different adaptations of the HSOPSC did not confirm the original factor structure of the HSOPSC [59]. Still, some dimensions corresponded to the ones proposed in the original HSOPSC model and items were repeated across the different studies. It should be noted that not all studies reported their optimum factor model structure. As a result, this created a difficulty in identifying the structure of the common dimensions across different countries.

STRENGTHS AND LIMITATIONS

A rigorous and scientific psychometric approach was designed and executed based on recommended reporting practices. Strengths of both EFA and CFA analytical techniques were used to test the original HSOPSC model and construct an optimal model. The large sample size (n=1280) allowed for the dataset to be split and for factor analysis to be undertaken with acceptable model fit indices.

One limitation is the number of items per factor in the optimal model. Three factors contained only two items per factor in the final Eight-factor model. This is less than the recommended minimum of three items per factor. However, the items reported high loadings with a strong theoretical linkage. Similar findings have been reported in the literature [31 60]. Another limitation is the exclusion of partially answered questionnaires. As a result, a subset of the total sample, with all items answered, was used for the validation of the psychometric properties of the HSOPSC. Lack of reporting of explicit psychometric data in some important studies used in the comparative analyses was another challenge faced in our study.

CONCLUSION

This is the first validation study of a patient safety climate questionnaire conducted in a Kuwaiti healthcare setting. The results clearly indicate the need for caution when using the original version of the HSOPSC questionnaire [59] and highlight the importance of appropriate validation of safety climate surveys before applying them to different populations and healthcare contexts than those in which they were originally developed. The study also shows the original composition of the HSOPSC dimensions was not confirmed in most studies. When compared to the USA, the HSOPSC questionnaire may be assessing different dimensions of safety culture across different countries including Kuwait [59]. More work is needed on cross-cultural investigations of differences in dimensionality to allow comparisons of healthcare safety climate results at an international level [27 41]. This study provided comparative data on the use of the HSOPSC questionnaire internationally and nine common dimensions and items were identified when comparing the different studies that reported their optimum models. The optimal factor model that was constructed in this study can be used as a basis for measuring patient safety climate in Kuwaiti hospitals and in evaluating changes in safety climate over time as part of patient safety improvement initiatives.

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GA, PB and JM made considerable contributions to conception and design of the psychometric evaluation.

GA completed the psychometric assessment and development of the final eight-factor model.

GA was involved in drafting the manuscript while JM and PB have done revising the drafts.

All authors have given final approval of the version to be published and agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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Box 1: HSOPSC patient safety culture dimensions and definitions [39]

Patient Safety Culture Composite	Definition: *The extent to which…*
Communication Openness	Staff freely speak up if they see something that may negatively affect a patient and feel free to question those with more authority.
Feedback and Communication About Error	Staff are informed about errors that happen, are given feedback about changes implemented, and discuss ways to prevent errors.
Frequency of Events Reported	Mistakes of the following types are reported: (1) mistakes caught and corrected before affecting the patient, (2) mistakes with no potential to harm the patient, and (3) mistakes that could harm the patient but do not.
Handoffs and Transitions	Important patient care information is transferred across hospital units and during shift changes.
Management Support for Patient Safety	Hospital management provides a work climate that promotes patient safety and shows that patient safety is a top priority.
Nonpunitive Response to Error	Staff feel that their mistakes and event reports are not held against them and that mistakes are not kept in their personnel file.
Organizational Learning—Continuous Improvement	Mistakes have led to positive changes and changes are evaluated for effectiveness.
Overall Perceptions of Patient Safety	Procedures and systems are good at preventing errors and there is a lack of patient safety problems.

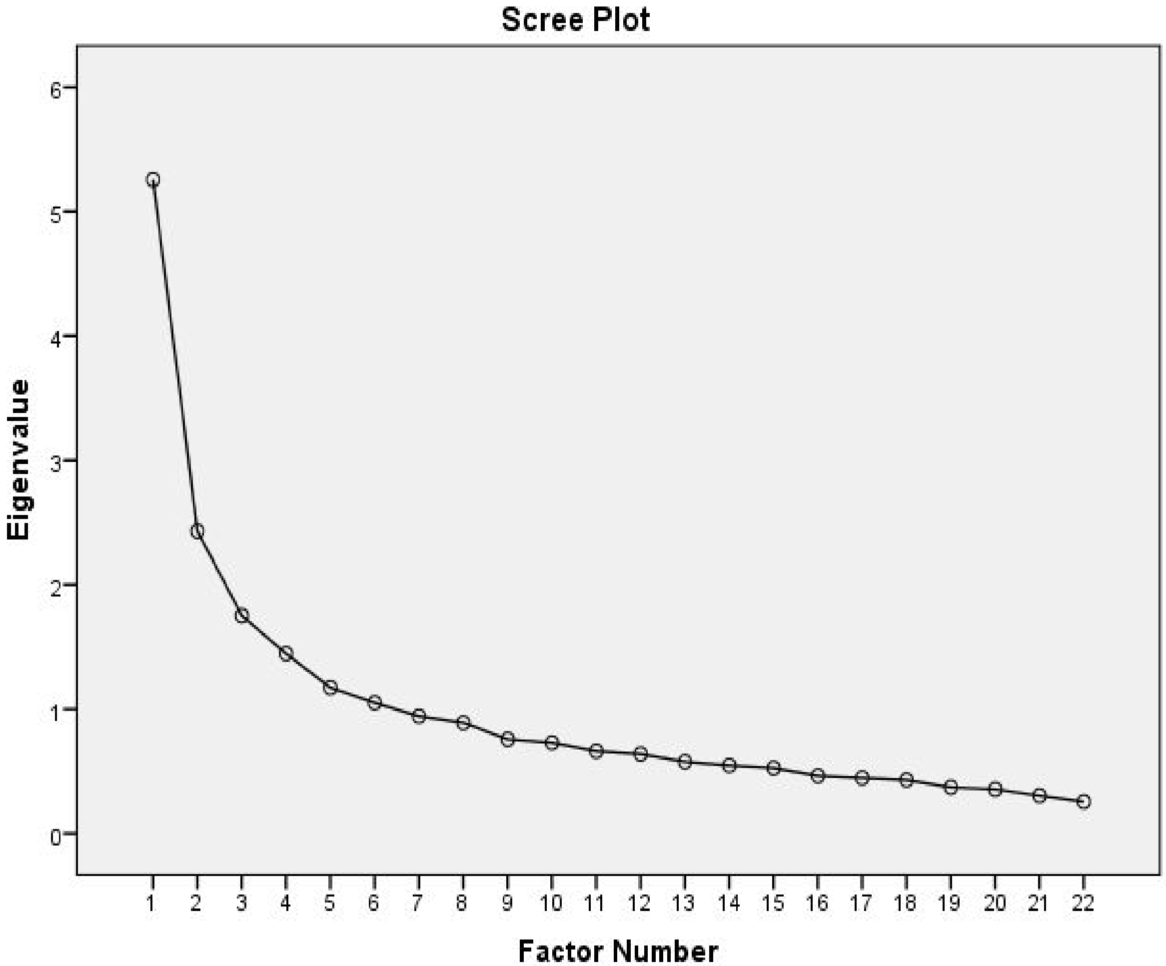
Patient Safety Culture Composite	Definition: *The extent to which…*
Staffing	There are enough staff to handle the workload and work hours are appropriate to provide the best care for patients.
Supervisor/Manager Expectations and Actions Promoting Patient Safety	Supervisors/managers consider staff suggestions for improving patient safety, praise staff for following patient safety procedures, and do not overlook patient safety problems.
Teamwork Across Units	Hospital units cooperate and coordinate with one another to provide the best care for patients.
Teamwork Within Units	Staff support each other, treat each other with respect, and work together as a team.

Figure legends:

Figure 1 title: Scree plot of the final EFA solution (Eight factors, 22 items)

Box 1: HSOPSC patient safety culture dimensions and definitions 39

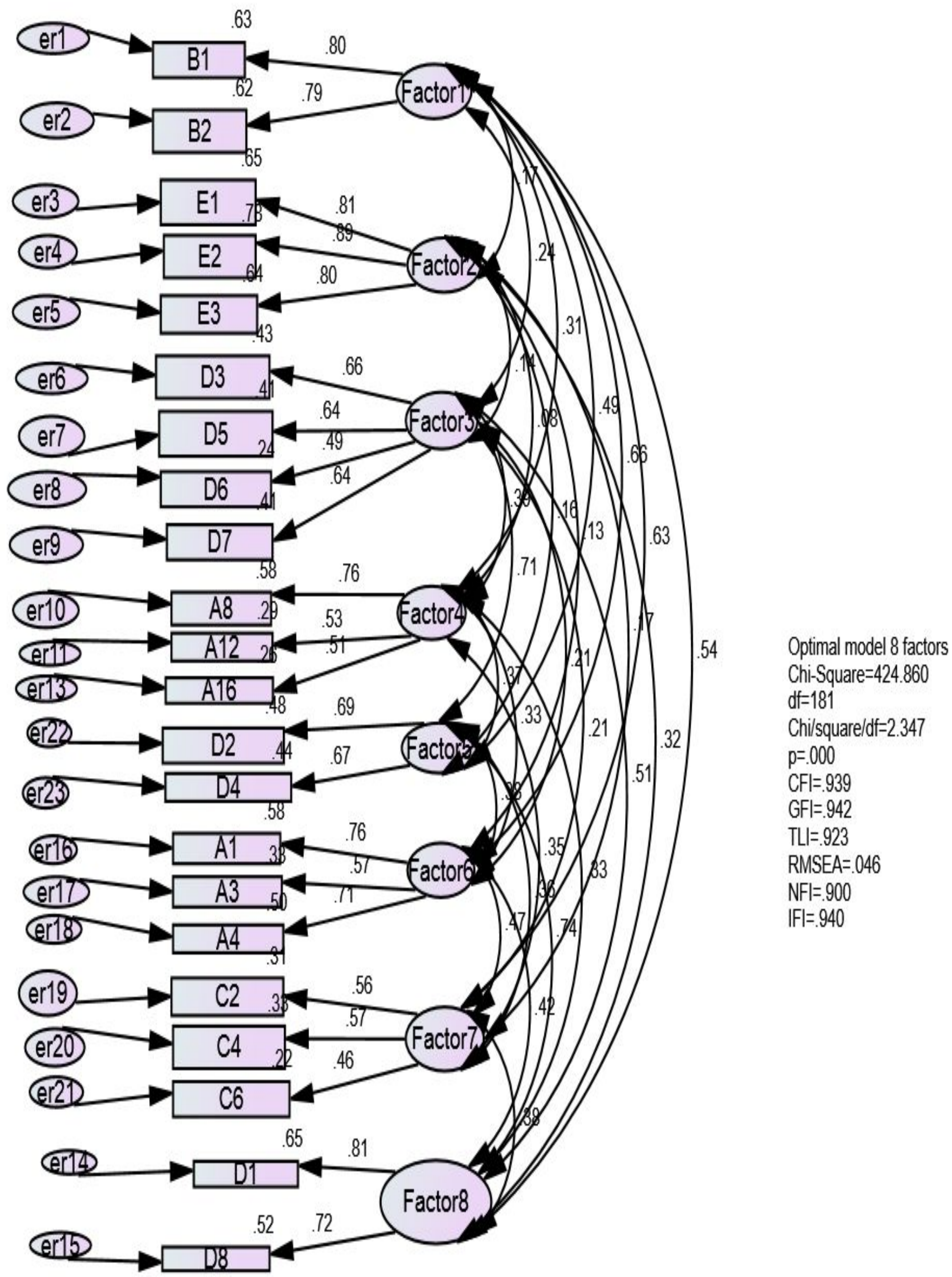
Figure.1: Scree plot of the final EFA solution (Eight factors, 22 items)



Appendix 1: Professional and personal characteristics of study respondents (n=1,310)

Variable	**Category**	**Frequency (n)**	**Percentage (%)**
Staff Position	Assistant Nurse	30	2.4
	Nurse	697	55.0
	Head nurse/Nurse manager	27	2.1
	Unit Assistant/Clerk	4	0.3
	Attending/Staff Physician	227	17.9
	Resident Physician/Physician in training	41	3.2
	Pharmacist	21	1.7
	Dietician	10	0.8
	Respiratory Therapist	3	0.2
	Physical, Occupational, or Speech Therapist	18	1.4
	Technician	176	13.9
	Management	13	1.0
Gender	Male	479	37.2
	Female	808	62.8
Direct Patient Contact	Yes	1112	88.5
	No	144	11.5

Appendix 2:
HSOPSC Eight factor model in Kuwait and individual item standardised path coefficients



Appendix 3: Inter-correlations between Eight factors (scales)

N	Scales	1	2	3	4	5	6	7
1	Supervisor/Manager Expectations and Actions Promoting Patient Safety	-						
2	Frequency of Events Reported	0,155***						
3	Handoffs and Transitions	0,286***	0,183***					
4	Non-punitive Response to Errors	0,339***	0,133***	0,371***				
5	Teamwork Across Units	0,51***	0,228***	0,64***	0,435***			
6	Teamwork Within Units	0,664***	0,105**	0,236***	0,356***	0,392***		
7	Communication Openness	0,614***	0,088*	0,259***	0,431***	0,404***	0,517***	
8	Management Support for Patient Safety	0,519***	0,311***	0,531***	0,322***	0,722***	0,432***	0,353***

*** p<0.001, ** p<0.01, *p<0.05

Appendix 4: Dimensions of HSOPSC for USA (US), Kuwait (KWT), Saudi Arabia (SA), Palestine (PAL), England (ENG), Scotland (SCO), Netherlands (NL), Switzerland (Swiss) and Turkey (TUR) factor models

HSOPSC Dimensions	US 59	KWT	SA 60	PAL 61	ENG 31	SCO 78	NL 30	TUR 26	SWISS 27
Supervisor/manager expectations and actions promoting safety	√	√	√	√	√	√	-	-	√
Organisational learning— continuous improvement	√	-	√	√	-	√	√	√	√ With Teamwork within units
Teamwork within hospital units	√	√	√	√	√	√	√	√	-
Communication openness	√	√	√	-	√	-	√	√	-
Feedback and communication about error	√	-	-	√ With Communication Openness	√	√ With Communication Openness	√ With Organisational learning— continuous improvement	√ With Supervisor expectations and actions promoting patient safety	√ With Communication Openness
Non-punitive response to error	√	√	√	√	√	√	√	√	√
Staffing	√	-	√	√	-	-	√	√	-
Hospital management support for patient safety	√	√	-	√	-	√	√	√ With Teamwork across units	√

HSOPSC Dimensions	US 59	KWT	SA 60	PAL 61	ENG 31	SCO 78	NL 30	TUR 26	SWISS 27
Teamwork across hospital units	√	√	-	√	√	√	√	-	-
Hospital handoffs and transitions	√	√	√	√	√	√	√	√	√ With Teamwork across units
Frequency of incident reporting	√	√	√	√	√	√	√	√	√
Overall perceptions of patient safety	√	-	-	√	√ With Staffing	√ With Staffing	√	√	√ With Staffing
Number of optimal model factors	12	8	8	11	9	10	11	10	8

Appendix 5: Item composition of dimensions of HSOPSC for USA (US), Kuwait (KWT), Saudi Arabia (SA), Palestine (PAL), England (ENG), Netherlands (NL), Switzerland (Swiss) and Turkey (TUR) factor models

HSOPSC Factors	USA 59	Kuwait	SA 60	ENG 31	PAL 61		SWISS 27	NL 30	TUR 26
Supervisor/Manager Expectations and Actions Promoting Patient Safety	B1-B2-B3-B4	B1-B2	B1-B2	B1-B2	B1-B2-B3-B4		B1-B2-B3-B4	B1-B2-B3-B4	‡
Frequency of Events Reported	E1-E2-E3*	E1-E2-E3	E1-E2-E3	E1-E2-E3	E1-E2-E3		E1-E2-E3	E1-E2-E3	E1-E2-E3
Handoffs and Transitions	D3-D5-D7-D11*	D3-D5-D7-D6**	D5- D7-D11-D6**	D3-D5-D7-D11	D3-D5-D7-D11		‡	D5 -D11	D3-D5-D7-D11
Non-punitive Response to Errors	A8-A12-A16	A8-A12-A16	A8-A12-A16	A8-A16	A8-A12-A16		A8-A12-A16	A8-A12-A16	A8-A12-A16
Teamwork Across Units	D2-D4-D6-D10*	D2-D4	-	D2-D4-D6-D10	D2-D4-D6-D10		D2-D4-D6-D10-D3**-D7**	D2-D4-D10-D3**-D7**	‡
Teamwork Within Units	A1-A3-A4-A11	A1-A3-A4	A1-A3-A4	A1-A3-A4	A1-A3-A4-A11		A1-A3-A4-A6-A9-A13‡	A1-A3-A4-A11	A1-A3-A4-A11
Communication Openness	C2-C4-C6	C2-C4-C6	C2-C4	C2-C4-C6	C2-C4-C3-C5‡		‡	C2-C4-C6	C2-C4-C6

HSOPSC Factors	**USA** 59	**Kuwait**	**SA** 60	**ENG** 31	**PAL** 61		**SWISS** 27	**NL** 30	**TUR** 26
Management Support for Patient Safety	D1-D8-D9*	D1-D8	-	-	D1-D8-D9		D1-D8-D9	D1-D8-D9	D1-D8-D9
Organisational learning—continuous improvement	A6-A9-A13	-	A6-A9-A13-D8**	-	A6-A9-A13		‡	‡	A6-A9-A13
Feedback and communication about error	C1-C3-C5	-	-	C1-C3-C5	‡		C1-C3-C5- C2-C4-C6‡	C1-C3-C5 A6-A9-A13	C1-C3-C5- B1-B2-B3-B4‡
Staffing	A2-A5-A7-A14	-	A5-A7	A2-A14-A10-A17‡	A2-A5-A14		A2-A5-A14 -A10-A17-A18‡	A2-A5-A7	A2-A5-A7-A14
Overall perceptions of safety	A10-A15-A17-A18	-	-	‡	A15-A17-A18		‡	A10-A17-A18-A14**	A10-A15-A17-A18
No of factors	12	8	8	9	11		8	11	10

*For comparison reasons, items with the letter F have been changed to letter D and items with the letter D have been changed to letter E as the modified version used in our study, ‡ denotes a merged dimension, ** denotes a moved item from a different dimension

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Hospital Survey on Patient Safety Culture: Psychometric evaluation in Kuwaiti Public Healthcare Settings

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ABSTRACT

Objective

As healthcare organisations endeavor to improve the quality and safety of their services, there is increasing recognition of the importance of building a culture of safety to promote patient safety and improve the outcomes of patient care. Surveys of safety culture/climate have not knowingly been conducted in Kuwait public hospitals, nor are valid or reliable survey instruments available for this context. This study aims to investigate the psychometric properties of the HSOPSC (Hospital Survey of Patient Safety Culture) tool in Kuwait public hospitals in addition to constructing an optimal model to assess the level of safety climate in this setting.

Design

cross-sectional study.

Setting

Three public hospitals in Kuwait.

Participants

About 1,317 healthcare professionals.

Main outcome measure

An adapted and contextualised version of HSOPSC was used to conduct psychometric evaluation including exploratory factor analysis, confirmatory factor analysis reliability and correlation analysis.

Results

1,317 questionnaires (87%) were returned. Psychometric evaluation, showed an optimal model of Eight factors and 22 safety climate items. All items have strong factor loadings (0.42-0.86) and are theoretically related. Reliability analysis showed satisfactory results ($\alpha > 0.60$).

Conclusions

This is the first validation study of a standardised safety climate measure in a Kuwaiti healthcare setting. An optimal model for assessing patient safety climate was produced that mirrors other international studies and which can be used for measuring the prevailing safety climate. More importance should be attached to the psychometric fidelity of safety climate questionnaires before extending their use in other healthcare culture and contexts internationally.

KEYWORDS: patient safety, safety culture, psychometrics, surveys, quality improvement.

STRENGTHS AND LIMITATIONS OF THIS STUDY:

- A rigorous and scientific psychometric approach was designed and executed based on recommended reporting practices with strengths of both EFA and CFA analytical techniques were used to test the original HSOPSC model and construct an optimal model.
- The large sample size (n=1280) allowed for the dataset to be split and for factor analysis to be undertaken with acceptable model fit indices.
- One limitation is the number of items per factor in the optimal model. Three factors contained only two items per factor in the final Eight-factor model.
- Another limitation is the exclusion of partially answered questionnaires. As a result, a subset of the total sample, with all items answered, was used for the validation of the psychometric properties of the HSOPSC.

INTRODUCTION

Modern healthcare systems are concerned with improving the safety of patient care and attempting to build a strong organisational safety cultures. "Safety Culture" is identified as a key element of a healthcare organisation's ability to learn openly from safety incidents and reduce preventable harm to patients. The perceived importance of safety culture in improving patient safety and its impact on clinical outcomes has led to a growing interest in the assessment of safety culture in healthcare organisations. The use of survey questionnaires is one of the most popular methods for assessing safety culture. These surveys aim to measure healthcare workers' perceptions of the prevailing safety culture or "safety climate" in their organisations.

There are numerous definitions of safety culture and safety climate. Despite their distinctive terminologies, they are commonly used arbitrarily and interchangeably in the literature [1]. Safety culture has been described as a set of shared values, beliefs, norms, and attitudes that interact with an organisation's structure and control systems resulting in behavioural norms [2 3]. Safety climate provides a "snapshot" of the perceptions held by healthcare workers about visible, surface level features of safety culture at a given point in time [4]. It "*assesses workforce perceptions of procedures and behaviours in their work environment that indicate the priority given to safety relative to other organisational goals*" [5].

Assessing the status of the existing safety climate in a healthcare organisation is promoted as the first step for developing a strong and solid safety culture [6]. The resulting data potentially offers policymakers, healthcare providers, teams and managers a clear view of areas in need of attention to strengthen the prevailing safety climate, in addition to identifying specific challenges that impede progress in safety initiatives [7]. It can also be used for benchmarking and improving safety climate measures across time and between organisations on national and international levels [8 9].

A range of safety climate assessment tools have been developed for acute hospital settings, although the scientific rigour with which they were designed and tested is variable [5 10 11].

Multiple reviews of patient safety climate instruments have been published [5 10-16]. Most concluded that the Safety Attitudes Questionnaire (SAQ) and Hospital Survey on Patient Safety Culture

(HSOPSC) were the most appropriate tools available in terms of their psychometric properties, but also critiqued climate tools generally as many lack appropriate scale development, validation and evidence for their predictive validity. Over a decade ago, Flin, et al. [5] argued that it is essential that tools are developed with robust psychometric properties to enable valid interpretations of patient safety climate test scores to be made.

Despite this, many published studies are still limited in their reporting of the necessary psychometric properties of questionnaires [5 10 17 18]. It is argued that HSOPSC is one of the most rigorously tested instruments with good psychometric properties in addition to being tested on the necessary large sample sizes [5]. Psychometric analysis involves the use of established statistical assessment techniques to assess the psychometric properties of questionnaires and identify the underlying safety culture dimensions [11].

Repeated high-profile media coverage has drawn the attention of Kuwaiti politicians and the public to failings in healthcare delivery and patient safety, which has contributed to growing demands for a better quality of care [19-21]. Subsequent inquiries and reports have placed patient safety high on the Kuwait policy agenda. The Ministry of Health (MOH) responded by investing significantly in the improvement of healthcare services. Safety climate assessment is one of the latest approaches to be adopted by the MOH with the goal of evaluating and improving patient safety in Kuwaiti hospitals.

Surveys of safety climate have yet to be conducted at public hospitals in the state of Kuwait, nor are valid or reliable survey instruments available for this purpose. This study aims, therefore, to assess the psychometric properties of the HSOPSC tool in Kuwaiti public hospitals in addition to constructing an optimal model to assess the level of safety climate in this setting and to benchmark the data against other international studies.

METHOD

Instrument selection

HSOPSC is a 12-factor, 42 item survey questionnaire. It assesses ten climate dimensions of patient safety, with two outcome measures (overall perceptions of patient safety and frequency of event reporting). Two additional single-item outcome measure are included [22 23]. The HSOPSC tool was chosen for this study for several reasons. Firstly, a systematic review of tools designed for acute hospital settings concluded that HSOPSC had good overall methodological quality with good assessment of the tool's reported psychometric properties (Alsalem et al 2018). Secondly, HSOPSC was one of the most rigorously tested instruments at the time of selection, with extensive literature reporting its psychometric properties [5]. The tool has been extensively used in hospitals in the United States where it was originally developed [24], and validated for use in more than 60 countries and translated into 30 different languages [25-32]. Thirdly, HSOPSC is a comprehensive measure of safety climate as it assesses key aspects related to patient safety at multiple levels of analysis including the individual, unit and hospital levels (Box 1). Finally, the tool is freely available, uses clear language with a scale that is simple and easy to follow.

Instrument modification

The English version of the tool was pilot tested and modified for Kuwaiti healthcare in order to solve any technical and feasibility issues associated with its application [33 34]. Seven face-to-face interviews were conducted with a panel of healthcare staff from MOH (including doctors, nurses and risk and safety officers) to evaluate HSOPSC content and ensure the proper transfer of the intended meaning of the questionnaire items to the culture and language differences in the Kuwait context. The panel endorsed the HSOPSC content as being of high relevance to safety culture in Kuwaiti hospitals. All items were retained. However, wording was modified in eight items to clarify their meaning as some comments indicated potential ambiguity in items' interpretations.

Instrument testing

A stratified random sample was drawn from healthcare clinical staff in three public hospitals in Kuwait. To ensure that the sample size was adequate to satisfactorily undertake factor analysis (FA), sample size requirements (sample size of the study, ratio of the sample size to the number

of variables, ratio of the number of variables to the number of factors) were evaluated [35]. Tabachnick and Fidell [36] rule recommends having at least 300 cases to undertake FA. The Kaiser-Meyer-Olkin (KMO) coefficient was used as another measure of sampling adequacy. KMO coefficient values range between 0 and 1. Surveys of health professionals can be challenging and are characterised by declining response rates [37] with a significant downward trend in response rates from 1998 to 2008 [38]. Based on their findings, the predicted response rate for this study was 20% and it was estimated that the sample size should be a minimum of 1,500 of distributed questionnaires.

Data collection and management

Staff members were invited by letter to participate in the study. Questionnaires were distributed across different departments in the three public hospitals. The questionnaires were completed anonymously and returned to multiple collection boxes located within the hospitals. Data were coded and entered into an electronic data file using the Statistical Package for Social Science (SPSS 24). Negatively worded items were reverse coded. If less than one entire section of the survey was answered or less than half of the items throughout the entire survey (in different sections) were answered, or if every item was answered the same, these questionnaires were excluded [39]. Missing values were deleted in a listwise manner in order to minimise any possible biases [40].

Factor analysis (FA)

FA is a statistical method that "*explores the extent to which individual items in a questionnaire can be grouped together according to the correlations between the responses to them*", thus reducing the dimensionality of the data [41]. It can be applied as a data reduction or a structure detection method [42]. The two main techniques of FA are Exploratory Factor Analysis (EFA), and Confirmatory Factor Analysis (CFA), which are both recommended to test construct validity [43].

EFA allows the researcher to uncover the main dimensions to develop a theory, or model from a smaller number of latent constructs that are often represented by a larger set of measured variables [44 45]. CFA tests a pre-determined factor structure or a proposed theory [44 45]. This study combined both approaches to develop an optimal model, based on the original HSOPSC model, for

specifically assessing patient safety climate in Kuwaiti public hospitals. Due to the controversy associated with conducting EFA and CFA on the same data, a split-half validation technique is recommended [46 47]. Therefore, the Kuwaiti dataset was randomly split into to two independent datasets using SPSS 24. Each group contains a set of 640 (n=640) cases - the calibration half of the dataset was used for model construction and the validation half of the dataset was used for confirming the explored factor structure resulting from model construction.

Data analysis was based on three main phases. 1. To investigate whether the original HSOPSC 12-factor model is appropriate for the Kuwaiti data. Both CFA and reliability analysis were used at this step. 2. To examine whether an alternative factor model would fit the Kuwaiti data better. For model construction, EFA was carried out using the calibration half of the dataset (Sample A, n=640). 3. Undertaking CFA and reliability analysis using the validation half of the dataset, to test the fit of the resultant model from the previous phase (Sample B, n=640). Cronbach's alpha (α) was calculated for each factor to examine the internal consistency or reliability with the minimum criterion for acceptable reliability of at least $\alpha \geq 0.60$ as recommended for the majority of research purposes [48 49]. Factor correlations of the optimal model were performed in addition to comparisons between the CFA output of our optimal factor model and the outputs reported in previous studies.

Patient and public involvement statement

Patient and public were not involved in the analysis of this study.

RESULTS

Response rate and sample demographics

Of the 1,511 questionnaires distributed at the three hospitals, 1,317 questionnaires (87%) were returned. A KMO statistic of 0.88 was calculated , which indicates that the sample has a sufficient level of homogeneity [50 51]. Thirty-seven questionnaires were excluded. Appendix 1 summarizes the relevant demographics of survey respondents.

Instrument testing

Following the deletion of missing values, one thousand, two hundred and eighty questionnaires (n=1280) were considered eligible and this number of completed questionnaires (n=1280) was sufficient to undertake FA.

Testing the original HSOPSC (12-factor) model

A CFA was performed, using AMOS software [52], to test the model fit of the original HSOPSC 12-factor structure using the Kuwaiti data (n=1280). The global fit of our model was not consistently satisfactory for the Kuwaiti data. Three criteria measures did not indicate an acceptable fit with Comparitive Fit Index (CFI) = 0.81 (CFI values ≥0.90 considered a good model fit [53]), Chi-squared statistic per one degree of freedom (x^2/DF) = 4.81 (x^2/DF value ≤2 for a good fit [54]), and TLI = 0.784 (TLI of > 0.90 indicates a good fit [53]) values indicate that the fit is not adequately good enough to confirm the proposed factor structure.

The internal consistency of the Kuwaiti data (n=1280) was ≥0.60 within nine dimensions. Three dimensions had internal consistencies less than 0.60. Additionally, two dimensions have a questionable internal consistency because their Cronbach's alpha value was 0.60 (Cronbach's α=0.604 for "Non-punitive Response to Errors" and Cronbach's α=0.601 for "communication openness". In summary, the results of the CFA and reliability analysis indicate that the original HSOPSC 12 Factor model is not a satisfactory fit when it is used for the Kuwaiti data. Therefore, an EFA was used for investigating an alternative factor structure which might be more appropriate for Kuwaiti data.

Construction of an optimal model

EFA consists of two basic stages. 1. Estimating the number of factors that should be extracted to represent the HSOPSC factor structure; and 2. Interpreting the meaning of the extracted factors and representing them in terms of theoretical structures that reflect the patient safety climate dimensions. EFA (principal axis factoring with varimax then oblique rotation) was performed on the calibration half of the dataset (n=640). Based on the Kaiser criterion of Eigenvalues greater than one (Eigenvalues > 1) [50] and Cattell scree plot [55], different numbers of factors (12,11,10,9,8,7 factors) were extracted and investigated to find the optimal alternative model (see Appendix 2).

Following the rotation of factors the factor pattern matrix was examined to decide on the acceptable level of loading for variables to define factors [56]. To reach a satisfactory solution, a number of points need to be taken into consideration including identifying items with low communalities (<0.3), no or low loading (<0.4), items with cross loadings (>0.30) and the theoretical structure of items. It should be noted that the decision on how many factors to retain based on the degree of comprehensibility and interpretability of the factor structure in the context of the research [57]. In addition, theoretical knowledge regarding the construct under study is more significant than a statistical measure and the items and factors should make conceptual sense and be theoretically related [56].

Final factor solution

An Eight-factor solution (all loadings ≥ 0.40) showed the best model fit to the Kuwaiti dataset. The Scree plot of the final EFA solution is shown in Figure 1. The structure and factor loadings of the final EFA solution are reported in Table 1. The final solution explains 50.2% of variance by eight extracted factors and represents 22 items from the safety climate questionnaire (20 items were excluded). All factor loadings are within the range of 0.428-0.864.

Table 1: Pattern matrix of the final EFA solution (Eight factors, 22 items)

Variable	Factor							
	1	2	3	4	5	6	7	8
(B1) My supervisor/manager says a good word when he/she sees a job done according to established patient safety procedures (SEA)	,822							
(B2) My supervisor/manager seriously considers staff suggestions for improving patient safety (SEA)	,623							
(E2) When a mistake is made, but has no potential to harm the patient, how often is this reported? (FER)		,864						
(E1) When a mistake is made, but is caught and corrected before affecting the patient, how often is this reported? (FER)		,776						
(E3) When a mistake is made that could harm the patient, but does not, how often is this reported? (FER)		,776						
(D5) Important patient care information is often lost during shift changes. (negatively worded) (HO)			-,662					

Variable	Factor							
	1	2	3	4	5	6	7	8
(D3) Things 'fall between the cracks' when transferring patients from one unit to another (negatively worded) (HO)			-,621					
(D6) It is often unpleasant to work with staff from other hospital units. (negatively worded) (TWAU)			-,495					
(D7) Problems often occur in the exchange of information across hospital units. (negatively worded) (HO)			-,428					
(A16) Staff worry that mistakes they make are kept in their personnel file. (negatively worded) (NRP)				,578				
(A8) Staff feel like their mistakes are held (used) against them. (negatively worded) (NPR)				,559				
(A12) When an incident is reported, it feels like the person is being reported, not the problem. (negatively worded) (NPR)				,531				
(D4) There is good cooperation among hospital units that need to work together (TWAU)					-,641			
(D2) Hospital units do not coordinate well with each other. (negatively worded) (TWAU)					-,522			
(A1) People support one another in this unit (TWWU)						,688		
(A3) When a lot of work needs to be done quickly, we work together as a team to get the work done (TWWU)						,605		
(A4) In this unit, people treat each other with respect (TWWU)						,556		
(C6) Staff are afraid to ask questions when something does not seem right. (negatively worded) (CO)							,615	
(C4) Staff feel free to question the decisions or actions of those with more authority (CO)							,600	
(C2) Staff will freely speak up if they see something that may negatively affect patient care (CO)							,524	
(D1) Hospital management provides a work climate that promotes patient safety (MS)								,677
(D8) The actions of hospital management show that patient safety is a top priority (MS)								,574

Extraction Method: Principal Axis Factoring. Rotation Method: Oblimin with Kaiser Normalization.
Rotation converged in 16 iterations. Supervisor/manager expectations and actions promoting safety (SMEA), Organisational learning—continuous improvement (OL),Teamwork within hospital units (TWWU), Teamwork across hospital units (TWAU), Communication openness (CO), Feedback and communication about error (FB), Non-punitive response to error (NPRE), Staffing (S), Hospital management support for patient safety (MS), Hospital handoffs and transitions (HO), Frequency of incident reporting (FER), Overall perceptions of patient safety (OPPS).

Five factors (Factor 2, Factor 3, Factor 4, Factor 6, and Factor 7) have three and more items with loading >0.4. Factor 1, Factor 5, and Factor 8 have two items with very high loading of >0.5 and the items in each factor are theoretically related (Table 2). There are no cross loaded items and there are no items with loading <0.4 and with communalities <0.3 in the solution. The solution is essentially consistent with all items within each factor theoretically related. Only D6 moved from "Teamwork across units" to "Handoffs and transitions."

Table 2: Structure, factors loadings and internal consistency of the final EFA solution (Eight factors, 22 items)

Number of Factor	Factor	Heavy loaded items (>0.4)	Number of items	Cronbach's Alpha
1	Supervisor/Manager Expectations and Actions Promoting Safety	B1-B2	2	0.776
2	Frequency of Events Reported	E1-E2-E3	3	0.858
3	Handoffs and Transitions	D3-D5-D6-D7	4	0.685
4	Non-punitive Response to Errors	A8-A12-A16	3	0.604
5	Teamwork Across Units	D2-D4	2	0.689
6	Teamwork Within Units	A1-A3-A4	3	0.705
7	Communication Openness	C2-C4-C6	3	0.601
8	Management Support for Patient Safety	D1-D8	2	0.724

Testing the final factor (Eight-factor) model

The optimal Eight-factor model was vigorously examined by conducting two confirmatory analyses initially using the validation half of the dataset (n=640), followed by the whole dataset (n=1280). All estimated parameters indicate a good model fit (Eight factors and 22 items) as reported in Table 3.

Table 3: CFA Results of Eight factor optimal model (validation sample and whole sample)

Eight-factors model	Chi-Square statistic (x^2)	DF	CMIN/DF (x^2/DF)	CFI	RMR	SRMR	RMSEA	TLI
Validation sample	424.9 good	181 good	2.3 acceptable	0.94 good	0.049 good	0.048 good	0.046 good	0.92 good
Whole sample	617.8 good	181 good	3.4 acceptable	0.946 good	0.041 good	0.038 good	0.043 good	0.931 good

Chi-square test statistic (x^2), Chi-squared statistic per one freedom degree (x^2/DF), the Comparative Fit Index (CFI), Root mean square residuals (RMR), the Standardised Root Mean Square Residual (SRMR), the Root Mean Square Error of Approximation (RMSEA), Tucker-Lewis Index (TLI)

The standardised path coefficients reflecting the strength of the relationship between items and dimensions [58] were found to be generally large (>0.50) and ranged from 0.46 (Communication openness) to 0.89 (Frequency of incidents reported) (see Appendix 3). Therefore, this model was accepted as the optimal model of HSOPSC for the Kuwaiti healthcare setting.

Reliability

Reliability analysis was performed using the whole sample with Cronbach's Alpha values reported to be ≥ 0.60 for all factors. Therefore, the internal consistency was acceptable for the Eight factors solution (Table 2). In order to test the construct validity of the HSOPSC instrument, inter-correlation coefficients with Pearson's ***r*** were calculated between the Eight factors in addition to the two single item outcome measures (patient safety grade and number of incidents reported). The Pearson's correlation coefficients between scale scores are reported in online appendix 4. Inter-correlation coefficients ranged between 0.08 and 0.72. All correlation coefficients are significant. The highest correlations were those between "Management support for patient safety" and "Teamwork across units" (r=0.722). All eight factors are interrelated to each other. Most of the correlation coefficients indicate a moderate correlation between dimensions. This indicates that no two factors are measuring the same construct.

Proposed optimal Eight factors model for Kuwaiti data

As shown in Table 4, the proposed optimal model structure includes 8 dimensions and 22 items.

Table 4: Proposed Eight factors optimal model for Kuwaiti data

Factor 1: Supervisor/Manager Expectations and Actions Promoting Patient Safety (2 items)
B1: My supervisor/manager says a good word when he/she sees a job done according to established patient safety procedures
B2: My supervisor/manager seriously considers staff suggestions for improving patient safety.
Factor 2: Frequency of Events Reported (3 items)
E1: When a mistake is made, but is caught and corrected before affecting the patient, how often is this reported?
E2: When a mistake is made, but has no potential to harm the patient, how often is this reported?
E3: When a mistake is made that could harm the patient, but does not, how often is this reported?
Factor 3: Handoffs and Transitions (4 items)
D3: Things "fall between the cracks" when transferring patients from one unit to another. (negatively worded)

D5: Important patient care information is often lost during shift changes. (negatively worded)
D6: It is often unpleasant to work with staff from other hospital units. (negatively worded)
D7: Problems often occur in the exchange of information across hospital units. (negatively worded)
Factor 4: Non-punitive Response to Errors (3 items)
A8: Staff feel like their mistakes are held (used) against them. (negatively worded)
A12: When an incident is reported, it feels like the person is being reported, not the problem. (negatively worded)
A16: Staff worry that mistakes they make are kept in their personnel file. (negatively worded)
Factor 5: Teamwork Across Units (2 items)
D2: Hospital units do not coordinate well with each other. (negatively worded)
D4: There is good cooperation among hospital units that need to work together.
Factor 6: Teamwork Within Units (3 items)
A1: People support one another in this unit.
A3: When a lot of work needs to be done quickly, we work together as a team to get the work done.
A4: In this unit, people treat each other with respect.
Factor 7: Communication Openness (3 items)
C2: Staff will freely speak up if they see something that may negatively affect patient care.
C4: Staff feel free to question the decisions or actions of those with more authority.
C6: Staff are afraid to ask questions when something does not seem right. (negatively worded)
Factor 8: Management Support for Patient Safety (2 items)
D1: Hospital management provides a work climate that promotes patient safety.
D8: The actions of hospital management show that patient safety is a top priority.

DISCUSSION

This psychometric evaluation is the first reported validation study of a standardised safety climate measure in a Kuwaiti healthcare setting. The psychometric properties of the HSOPSC questionnaire were assessed and an optimal model for assessing patient safety climate in Kuwaiti hospitals was constructed. The final questionnaire contains 22 safety climate items (variables) that measure eight safety climate factors. The optimal model's psychometric properties (including validity and reliability) were good with all items loading strongly (>0.40) onto one factor and all items, within each factor, were theoretically related.

Our results are in line with other studies investigating the psychometric properties of the original HSOPSC questionnaire. The suitability of the original HSOPSC model for Kuwaiti data was tested and results revealed an unsatisfactory fit [59]. Different international studies [27 31 60 61] reported similar findings. This finding is in contrast with other studies that assessed patient safety climate by using the original HSOPSC questionnaire [59] in hospitals without examining the reliability and validity of the questionnaire in a different context [62-68]

Various underlying factor structures were identified as optimal factor models. The original 12 factor model was replicated in Belgian [6], Portuguese [69] Brazilian[70] and Scottish data [71]. Other studies reported 11 factor models for Dutch [30], Arabic [61], Croatian [72] and Norwegian data [73]; 10 factor models for French [28], Turkish [26], Chinese [74] and Brazilian data [75]; 9 factor models for UK [31] and Slovene data [76]; Eight factor models for Swiss [27], Saudi [60], Kosovo [77] and Kuwaiti data. This discrepancy in results could be attributed to differences in employing survey methods and psychometric analytical techniques, in addition to the various modifications made to adapt the original instrument to different healthcare settings [71]. Neglect of crucial elements, including context, processes and actors involved, when attempting to adapt an instrument in a different setting might lead to conflicting results and might weaken the validity of the instrument [78]. Thus, the original HSOPSC will clearly be limited when used in other contexts without proper assessment of its psychometric properties.

The optimal model of our study is in line with other international studies [31 60]. Four dimensions were either dropped or merged with other factors into a single dimension. In our study, the same dimensions reported low reliability using the original HSOPSC in addition to other international studies [31 60 79]. The optimal model was confirmed using CFA with good model fit indices. This was consistent with the CFA results of the USA [59], Saudi Arabia [60], Palestine [61], UK [31] and Scotland [71] optimal models.

Considering all of this evidence, it seems that the original HSOPSC questionnaire [59] does not appear to perform well in different countries. Survey instruments that are designed for particular settings are tailored to meet the unique characteristics and contexts of the local setting and population. In the case of the HSOPSC, a number of the reported adaptations have performed less well than the original tool [28 31 73 74 80]. This might be due to the contextual specificity of the construct of safety culture [81]. Other factors include unique country characteristics, types of health systems and settings, staff groups, and cultural differences [27 82]. Hedsköld, et al. [78] pointed out that such differences might weaken the validity of the instrument.

In a review of quantitative patient safety culture instruments, it was concluded that all of the surveys designed for general administration to hospital personnel addressed three common dimensions: management support and commitment to safety, communication openness and teamwork Singla, et al. [11]. They suggested that these common dimensions might be considered "core dimensions" of patient safety culture. In addition, a number of dimensions seem to be common among optimal factor models across different countries.

Factor structure of the optimal model of our study compared with optimal models that were developed in Saudi Arabia, Palestine, England, Scotland, Netherlands, Turkey and Switzerland in addition to the original USA HSOPSC questionnaire [59] is shown in online appendix 5. This comparison is aimed at identifying a common set of patient safety culture dimensions across different countries.

Six studies reported different dimensions combined into one dimension. A significant degree of overlap in the content of the safety culture dimensions exists. As a result, included items in certain dimensions tend to load onto differently labeled dimensions. "Feedback and communication about error" and "Communication openness" were grouped into one dimension in the Palestinian, Swiss and Scottish studies respectively [27 61 79]. This result is expected as both dimensions are closely related. Feedback and communication with staff about errors and discussing ways to prevent them are linked to allowing staff to freely speak up, if they see something that might negatively affect patient care.

Cox and Flin [1] suggest that the nature of safety climate is "context-dependent." Keiser [83] argues that since safety climate measures include both general and contextualized items, excluding contextual measures might provide a rather deficient evaluation of the underlying safety climate construct. Thus, research currently supports the idea of integrating both qualitative and quantitative methods in developing a culturally appropriate instrument as standard approaches that exclusively rely on translation and quantitative validation may not be sufficient to produce an instrument that is applicable to the local context [74]. As a result, the adopted tool will be able to reflect important safety climate themes that are specific to the local healthcare context.

A number of common dimensions that were emerging rather consistently across international settings despite the lack of confirmation of the original factor structure of the HSOPSC in numerous studies. Those dimensions include: management support for patient safety, supervisors' action promoting patient safety, teamwork within and across units, handoffs and transitions, non-punitive response to error, frequency of incidents reported, communication openness and organisational learning.

The item composition of each factor of the optimal model of our study was compared with optimal models that were developed in Saudi Arabia, Palestine, England, Netherlands, Turkey and Switzerland in addition to the original USA HSOPSC questionnaire [59]. This comparison is aimed at identifying a common set of patient safety climate items across different countries (see Appendix 6). The different adaptations of the HSOPSC did not confirm the original factor structure of the HSOPSC [59]. Still, some dimensions corresponded to the ones proposed in the original HSOPSC model and items were repeated across the different studies. It should be noted that not all studies reported their optimum factor model structure. As a result, this created a difficulty in identifying the structure of the common dimensions across different countries.

CONCLUSION

This is the first validation study of a patient safety climate questionnaire conducted in a Kuwaiti healthcare setting. The results clearly indicate the need for caution when using the original version of the HSOPSC questionnaire [59] and highlight the importance of appropriate validation of safety climate surveys before applying them to different populations and healthcare contexts than those in which they were originally developed. The study also shows the original composition of the HSOPSC dimensions was not confirmed in most studies. When compared to the USA, the HSOPSC questionnaire may be assessing different dimensions of safety culture across different countries including Kuwait [59]. More work is needed on cross-cultural investigations of differences in dimensionality to allow comparisons of healthcare safety climate results at an international level [27 41]. This study provided comparative data on the use of the HSOPSC questionnaire internationally and nine common dimensions and items were identified when comparing the different studies that reported their optimum models. The optimal factor model that was constructed in this study can be used as a basis for measuring patient safety climate in Kuwaiti hospitals and in evaluating changes in safety climate over time as part of patient safety improvement initiatives.

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Authors' contributions:

GA, PB and JM made considerable contributions to conception and design of the psychometric evaluation.

GA completed the psychometric assessment and development of the final eight-factor model.

GA was involved in drafting the manuscript while JM and PB have done revising the drafts.

All authors have given final approval of the version to be published and agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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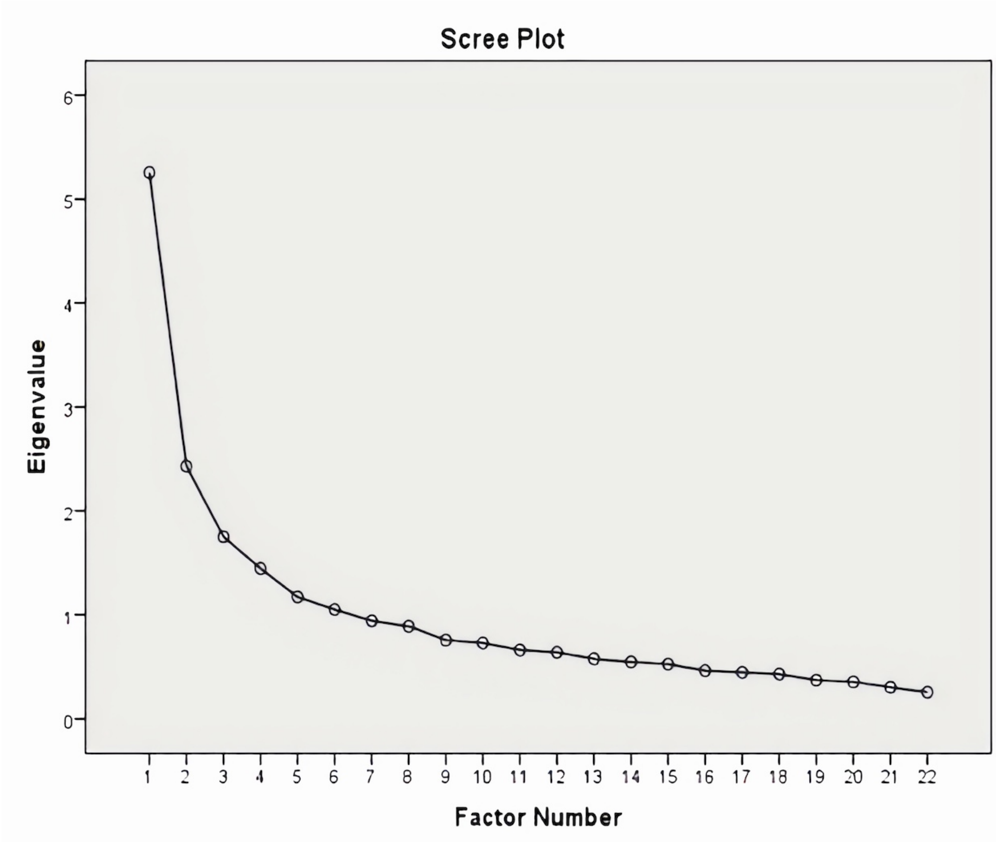
Box 1: HSOPSC patient safety culture dimensions and definitions [39]

Patient Safety Culture Composite	Definition: The extent to which...
Communication Openness	Staff freely speak up if they see something that may negatively affect a patient and feel free to question those with more authority.
Feedback and Communication About Error	Staff are informed about errors that happen, are given feedback about changes implemented, and discuss ways to prevent errors.
Frequency of Events Reported	Mistakes of the following types are reported: (1) mistakes caught and corrected before affecting the patient, (2) mistakes with no potential to harm the patient, and (3) mistakes that could harm the patient but do not.
Handoffs and Transitions	Important patient care information is transferred across hospital units and during shift changes.
Management Support for Patient Safety	Hospital management provides a work climate that promotes patient safety and shows that patient safety is a top priority.
Non-punitive Response to Error	Staff feel that their mistakes and event reports are not held against them and that mistakes are not kept in their personnel file.
Organizational Learning—Continuous Improvement	Mistakes have led to positive changes and changes are evaluated for effectiveness.
Overall Perceptions of Patient Safety	Procedures and systems are good at preventing errors and there is a lack of patient safety problems.
Staffing	There are enough staff to handle the workload and work hours are appropriate to provide the best care for patients.
Supervisor/Manager Expectations and Actions Promoting Patient Safety	Supervisors/managers consider staff suggestions for improving patient safety, praise staff for following patient safety procedures, and do not overlook patient safety problems.
Teamwork Across Units	Hospital units cooperate and coordinate with one another to provide the best care for patients.
Teamwork Within Units	Staff support each other, treat each other with respect, and work together as a team.

Figure legends:

Figure 1 title: Scree plot of the final EFA solution (Eight factors, 22 items)

Box 1: HSOPSC patient safety culture dimensions and definitions 39



Scree plot of the final EFA solution (Eight factors, 22 items)

105x90mm (300 x 300 DPI)

Appendix 1: Professional and personal characteristics of study respondents (n=1,310)

Variable	Category	Frequency (n)	Percentage (%)
Staff Position	Assistant Nurse	30	2.4
	Nurse	697	55.0
	Head nurse/Nurse manager	27	2.1
	Unit Assistant/Clerk	4	0.3
	Attending/Staff Physician	227	17.9
	Resident Physician/Physician in training	41	3.2
	Pharmacist	21	1.7
	Dietician	10	0.8
	Respiratory Therapist	3	0.2
	Physical, Occupational, or Speech Therapist	18	1.4
	Technician	176	13.9
	Management	13	1.0
Gender	Male	479	37.2
	Female	808	62.8
Direct Patient Contact	Yes	1112	88.5
	No	144	11.5

Appendix 2:
Conclusion from the solutions with different numbers of the factors (12- 9-8-7-10-11)

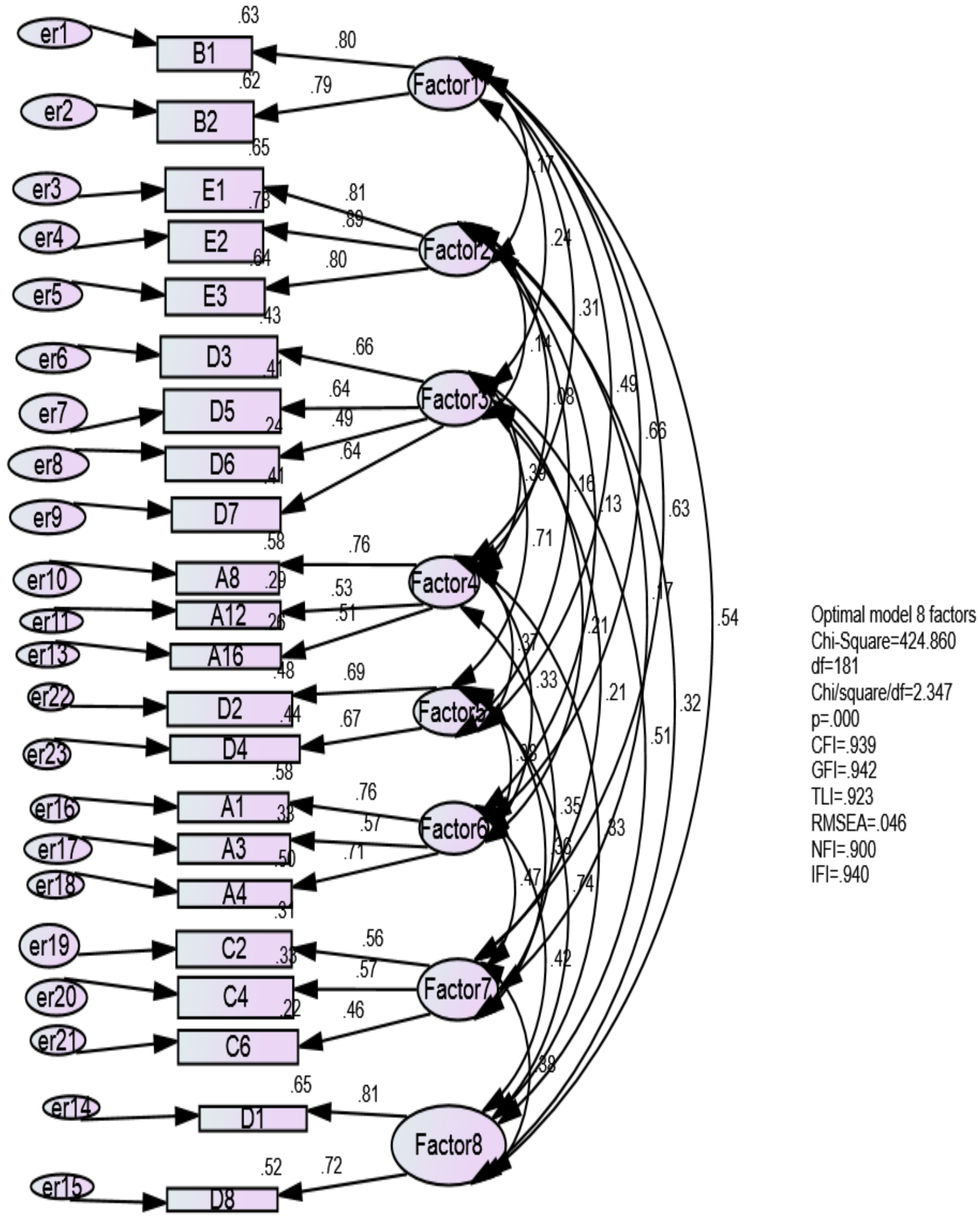
Step	**Number of extracted factors**	**Number of the satisfactory factors**	**Total variance explained by extracted factors**	**Items not loading**	**Items which have low communalities (<0.3)**	**Items which have low loadings (<0.4)**
1	**12**	**8**	**45**	**A5- A11- A15- A17**	**A5-A7-A9-A10-A11-A15-A17**	**A13- B3-D9- A6-C1-C5- A10- A7-D11- A18- C3**
4	9	7	41.0	A5 - A9- A15-A17-A7	A2-A5-A7-A9-A10-A15-A17	D9- B3- C5- A10-A2-A11
5	8	6	39.2	A5-A15-A17-A9	A2 - A5- A7- A9-A10- A11-A15-A17	A13-D9- C5-A6-B3- A10-A7- A2-A11
6	7	5	37.4	A11-A5-A7-A9-A15- A17	A2 - A5- A7- A9-A10 - A11- A15-A17- B3 -C3-D6	C3-A18-A13- C1-A2- B4-B3-A10
7	11	9	43.8	A5-A7- A17	A5- A7- A9- A10-A11- A15- A17-D6	B3-D9- A6- A10-A9-A13- C5- A7-A11
8	10	9	42.6	A5-A7- A17 A9	A5 - A7- A9- A10 - A11- A15- A17-D6	A13-D9- C5-A10- A11

An investigation of five possible solutions was undertaken in steps 4-8 to explore the number of factors that could be extracted. The initial solution with 12 factors demonstrates that 8 factors could fit the 42 safety climate items. The 9 Factors solution demonstrates that 7 factors could fit the 42 safety climate items. The 8 Factors solution demonstrates that 6 factors could fit the 42 safety climate items. The 11 Factors solution demonstrates that 9 factors could fit the 42 safety climate items. The 10 Factors solution demonstrates that 9 factors fit the 42 safety climate items. The summary results of the six solutions including the initial solution are displayed in the above table. The comparison of the different solutions suggests that the 8 Factors solution is most appropriate (four items without loadings, the initial solution with 12 factors indicates that 8 factors is satisfactory, only one factor is without strongly loaded items).

The optimal model is an Eight Factor model with 22 safety climate questionnaire items (20 items were excluded) that explains about 50.2% of the total variance. All factor loadings are within the range of 0.426-0.866. Five factors (Factor 2, Factor 3, Factor 4, Factor 6, and Factor 7) have three or more items with loadings >0.40. Factor 1, Factor 5, and Factor 8 have two items with very high loading >0.50 and acceptable theoretical basis. There are no cross loaded items and there are no items with loadings <0.40 in the solution. The solution is essentially consistent with the theoretical pattern. All factors consist of two to four items and all items within each factor are theoretically related. Only D6 moved from "Teamwork across units" into "Handoffs and Transitions." It should be noted that "Overall perceptions of patient safety", "Organisational learning—Continuous improvement", "Staffing" and "Feedback and communication about error" have no items in the final 8 factor solution.

In summary, the optimal Eight Factor model shows good psychometric properties with no cross loaded items and there are no items with loadings <0.40 in the solution. All factors consist of two to four items and all items within each factor are theoretically related. The optimal model of our study was confirmed by using CFA.

Appendix 3:
HSOPSC Eight factor model in Kuwait and individual item standardised path coefficients



Appendix 4: Inter-correlations between Eight factors (scales)

N	Scales	1	2	3	4	5	6	7
1	Supervisor/Manager Expectations and Actions Promoting Patient Safety	-						
2	Frequency of Events Reported	0,155***						
3	Handoffs and Transitions	0,286***	0,183***					
4	Non-punitive Response to Errors	0,339***	0,133***	0,371***				
5	Teamwork Across Units	0,51***	0,228***	0,64***	0,435***			
6	Teamwork Within Units	0,664***	0,105**	0,236***	0,356***	0,392***		
7	Communication Openness	0,614***	0,088*	0,259***	0,431***	0,404***	0,517***	
8	Management Support for Patient Safety	0,519***	0,311***	0,531***	0,322***	0,722***	0,432***	0,353***

*** p<0.001, ** p<0.01, *p<0.05

Appendix 5: Dimensions of HSOPSC for USA (US), Kuwait (KWT), Saudi Arabia (SA), Palestine (PAL), England (ENG), Scotland (SCO), Netherlands (NL), Turkey (TUR) and Switzerland (Swiss) factor models

HSOPSC Dimensions	US 59	KWT	SA 60	PAL 61	ENG 31	SCO 78	NL 30	TUR 26	SWISS 27
Supervisor/manager expectations and actions promoting safety	√	√	√	√	√	√	-	-	√
Organisational learning— continuous improvement	√	-	√	√	-	√	√	√	√ With Teamwork within units
Teamwork within hospital units	√	√	√	√	√	√	√	√	-
Communication openness	√	√	√	-	√	-	√	√	-
Feedback and communication about error	√	-	-	√ With Communication Openness	√	√ With Communication Openness	√ With Organisational learning— continuous improvement	√ With Supervisor expectations and actions promoting patient safety	√ With Communication Openness
Non-punitive response to error	√	√	√	√	√	√	√	√	√
Staffing	√	-	√	√	-	-	√	√	-
Hospital management support for patient safety	√	√	-	√	-	√	√	√ With Teamwork across units	√

HSOPSC Dimensions	US [59]	KWT	SA [60]	PAL [61]	ENG [31]	SCO [78]	NL [30]	TUR [26]	SWISS [27]
Teamwork across hospital units	√	√	-	√	√	√	√	-	-
Hospital handoffs and transitions	√	√	√	√	√	√	√	√	√ With Teamwork across units
Frequency of incident reporting	√	√	√	√	√	√	√	√	√
Overall perceptions of patient safety	√	-	-	√	√ With Staffing	√ With Staffing	√	√	√ With Staffing
Number of optimal model factors	12	8	8	11	9	10	11	10	8

Appendix 6: Item composition of dimensions of HSOPSC for USA (US), Kuwait (KWT), Saudi Arabia (SA), England (ENG), Palestine (PAL), Switzerland (Swiss), Netherlands (NL), and Turkey (TUR) factor models

HSOPSC Factors	**USA** [59]	**Kuwait**	**SA** [60]	**ENG** [31]	**PAL** [61]	**SWISS** [27]	**NL** [30]	**TUR** [26]
Supervisor/Manager Expectations and Actions Promoting Patient Safety	B1-B2-B3-B4	B1-B2	B1-B2	B1-B2	B1-B2-B3-B4	B1-B2-B3-B4	B1-B2-B3-B4	‡
Frequency of Events Reported	E1-E2-E3*	E1-E2-E3	E1-E2-E3	E1-E2-E3	E1-E2-E3	E1-E2-E3	E1-E2-E3	E1-E2-E3
Handoffs and Transitions	D3-D5-D7-D11*	D3-D5-D7-D6**	D5- D7-D11-D6**	D3-D5-D7-D11	D3-D5-D7-D11	‡	D5 -D11	D3-D5-D7-D11
Non-punitive Response to Errors	A8-A12-A16	A8-A12-A16	A8-A12-A16	A8-A16	A8-A12-A16	A8-A12-A16	A8-A12-A16	A8-A12-A16
Teamwork Across Units	D2-D4-D6-D10*	D2-D4	-	D2-D4-D6-D10	D2-D4-D6-D10	D2-D4-D6-D10-D3**-D7**	D2-D4-D10-D3**-D7**	‡
Teamwork Within Units	A1-A3-A4-A11	A1-A3-A4	A1-A3-A4	A1-A3-A4	A1-A3-A4-A11	A1-A3-A4-A6-A9-A13‡	A1-A3-A4-A11	A1-A3-A4-A11
Communication Openness	C2-C4-C6	C2-C4-C6	C2-C4	C2-C4-C6	C2-C4-C3-C5‡	‡	C2-C4-C6	C2-C4-C6

HSOPSC Factors	USA 59	Kuwait	SA 60	ENG 31	PAL 61	SWISS 27	NL 30	TUR 26
Management Support for Patient Safety	D1-D8-D9*	D1-D8	-	-	D1-D8-D9	D1-D8-D9	D1-D8-D9	D1-D8-D9
Organisational learning—continuous improvement	A6-A9-A13	-	A6-A9-A13-D8**	-	A6-A9-A13	‡	‡	A6-A9-A13
Feedback and communication about error	C1-C3-C5	-	-	C1-C3-C5	‡	C1-C3-C5- C2-C4-C6‡	C1-C3-C5 A6-A9-A13	C1-C3-C5- B1-B2-B3-B4‡
Staffing	A2-A5-A7-A14	-	A5-A7	A2-A14-A10-A17‡	A2-A5-A14	A2-A5-A14 -A10-A17-A18‡	A2-A5-A7	A2-A5-A7-A14
Overall perceptions of safety	A10-A15-A17-A18	-	-	‡	A15-A17-A18	‡	A10-A17-A18-A14**	A10-A15-A17-A18
No of factors	12	8	8	9	11	8	11	10

*For comparison reasons, items with the letter F have been changed to letter D and items with the letter D have been changed to letter E as the modified version used in our study, ‡ denotes a merged dimension, ** denotes a moved item from a different dimension

STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of *cross-sectional studies*

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	5
Objectives	3	State specific objectives, including any prespecified hypotheses	6
Methods			
Study design	4	Present key elements of study design early in the paper	7
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	7
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants	8
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	-
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	8
Bias	9	Describe any efforts to address potential sources of bias	8
Study size	10	Explain how the study size was arrived at	7,8
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	7,8,9
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	-
		(*b*) Describe any methods used to examine subgroups and interactions	8,9
		(*c*) Explain how missing data were addressed	8
		(*d*) If applicable, describe analytical methods taking account of sampling strategy	8,9
		(*e*) Describe any sensitivity analyses	-
Results			

Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	9
		(b) Give reasons for non-participation at each stage	9
		(c) Consider use of a flow diagram	-
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	Appendix 1
		(b) Indicate number of participants with missing data for each variable of interest	9
Outcome data	15*	Report numbers of outcome events or summary measures	-
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	9
		(*b*) Report category boundaries when continuous variables were categorized	-
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	-
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	Appendix 2
Discussion			
Key results	18	Summarise key results with reference to study objectives	15
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	4
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	15,16
Generalisability	21	Discuss the generalisability (external validity) of the study results	15,16,17,18
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	N/A

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

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Hospital Survey on Patient Safety Culture: Psychometric evaluation in Kuwaiti Public Healthcare Settings

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Hospital Survey on Patient Safety Culture: Psychometric evaluation in Kuwaiti Public Healthcare Settings

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ABSTRACT

Objective

As healthcare organisations endeavor to improve the quality and safety of their services, there is increasing recognition of the importance of building a culture of safety to promote patient safety and improve the outcomes of patient care. Surveys of safety culture/climate have not knowingly been conducted in Kuwait public hospitals, nor are valid or reliable survey instruments available for this context. This study aims to investigate the psychometric properties of the HSOPSC (Hospital Survey of Patient Safety Culture) tool in Kuwait public hospitals in addition to constructing an optimal model to assess the level of safety climate in this setting.

Design

cross-sectional study.

Setting

Three public hospitals in Kuwait.

Participants

About 1,317 healthcare professionals.

Main outcome measure

An adapted and contextualised version of HSOPSC was used to conduct psychometric evaluation including exploratory factor analysis, confirmatory factor analysis reliability and correlation analysis.

Results

1,317 questionnaires (87%) were returned. Psychometric evaluation, showed an optimal model of Eight factors and 22 safety climate items. All items have strong factor loadings (0.42-0.86) and are theoretically related. Reliability analysis showed satisfactory results ($\alpha > 0.60$).

Conclusions

This is the first validation study of a standardised safety climate measure in a Kuwaiti healthcare setting. An optimal model for assessing patient safety climate was produced that mirrors other international studies and which can be used for measuring the prevailing safety climate. More importance should be attached to the psychometric fidelity of safety climate questionnaires before extending their use in other healthcare culture and contexts internationally.

KEYWORDS: patient safety, safety culture, psychometrics, surveys, quality improvement.

STRENGTHS AND LIMITATIONS OF THIS STUDY:

- A rigorous and scientific psychometric approach was designed and executed based on recommended reporting practices to test the original HSOPSC model and construct an optimal model.
- The large sample size (n=1280) allowed for the dataset to be split and for factor analysis to be undertaken with acceptable model fit indices.
- One limitation is the number of items per factor in the optimal model. Three factors contained only two items per factor in the final Eight-factor model.
- Another limitation is the exclusion of partially answered questionnaires. As a result, a subset of the total sample, with all items answered, was used for the validation of the psychometric properties of the HSOPSC.

INTRODUCTION

Modern healthcare systems are concerned with improving the safety of patient care and attempting to build a strong organisational safety cultures. "Safety Culture" is identified as a key element of a healthcare organisation's ability to learn openly from safety incidents and reduce preventable harm to patients. The perceived importance of safety culture in improving patient safety and its impact on clinical outcomes has led to a growing interest in the assessment of safety culture in healthcare organisations. The use of survey questionnaires is one of the most popular methods for assessing safety culture. These surveys aim to measure healthcare workers' perceptions of the prevailing safety culture or "safety climate" in their organisations.

There are numerous definitions of safety culture and safety climate. Despite their distinctive terminologies, they are commonly used arbitrarily and interchangeably in the literature [1]. Safety culture has been described as a set of shared values, beliefs, norms, and attitudes that interact with an organisation's structure and control systems resulting in behavioural norms [2 3]. Safety climate provides a "snapshot" of the perceptions held by healthcare workers about visible, surface level features of safety culture at a given point in time [4]. It "*assesses workforce perceptions of procedures and behaviours in their work environment that indicate the priority given to safety relative to other organisational goals*" [5].

Assessing the status of the existing safety climate in a healthcare organisation is promoted as the first step for developing a strong and solid safety culture [6]. The resulting data potentially offers policymakers, healthcare providers, teams and managers a clear view of areas in need of attention to strengthen the prevailing safety climate, in addition to identifying specific challenges that impede progress in safety initiatives [7]. It can also be used for benchmarking and improving safety climate measures across time and between organisations on national and international levels [8 9].

A range of safety climate assessment tools have been developed for acute hospital settings, although the scientific rigour with which they were designed and tested is variable [5 10 11].

Multiple reviews of patient safety climate instruments have been published [5 10-16]. Most concluded that the Safety Attitudes Questionnaire (SAQ) and Hospital Survey on Patient Safety Culture

(HSOPSC) were the most appropriate tools available in terms of their psychometric properties, but also critiqued climate tools generally as many lack appropriate scale development, validation and evidence for their predictive validity. Over a decade ago, Flin, et al. [5] argued that it is essential that tools are developed with robust psychometric properties to enable valid interpretations of patient safety climate test scores to be made.

Despite this, many published studies are still limited in their reporting of the necessary psychometric properties of questionnaires [5 10 17 18]. It is argued that HSOPSC is one of the most rigorously tested instruments with good psychometric properties in addition to being tested on the necessary large sample sizes [5]. Psychometric analysis involves the use of established statistical assessment techniques to assess the psychometric properties of questionnaires and identify the underlying safety culture dimensions [11].

Repeated high-profile media coverage has drawn the attention of Kuwaiti politicians and the public to failings in healthcare delivery and patient safety, which has contributed to growing demands for a better quality of care [19-21]. Subsequent inquiries and reports have placed patient safety high on the Kuwait policy agenda. The Ministry of Health (MOH) responded by investing significantly in the improvement of healthcare services. Safety climate assessment is one of the latest approaches to be adopted by the MOH with the goal of evaluating and improving patient safety in Kuwaiti hospitals.

Surveys of safety climate have yet to be conducted at public hospitals in the state of Kuwait, nor are valid or reliable survey instruments available for this purpose. This study aims, therefore, to assess the psychometric properties of the HSOPSC tool in Kuwaiti public hospitals in addition to constructing an optimal model to assess the level of safety climate in this setting and to benchmark the data against other international studies.

METHOD

Instrument selection

HSOPSC is a 12-factor, 42 item survey questionnaire. It assesses ten climate dimensions of patient safety, with two outcome measures (overall perceptions of patient safety and frequency of event reporting). Two additional single-item outcome measure are included [22 23]. The HSOPSC tool was chosen for this study for several reasons. Firstly, a systematic review of tools designed for acute hospital settings concluded that HSOPSC had good overall methodological quality with good assessment of the tool's reported psychometric properties (Alsalem et al 2018). Secondly, HSOPSC was one of the most rigorously tested instruments at the time of selection, with extensive literature reporting its psychometric properties [5]. The tool has been extensively used in hospitals in the United States where it was originally developed [24], and validated for use in more than 60 countries and translated into 30 different languages [25-32]. Thirdly, HSOPSC is a comprehensive measure of safety climate as it assesses key aspects related to patient safety at multiple levels of analysis including the individual, unit and hospital levels (Box 1). Finally, the tool is freely available, uses clear language with a scale that is simple and easy to follow.

Instrument modification

The English version of the tool was pilot tested and modified for Kuwaiti healthcare in order to solve any technical and feasibility issues associated with its application [33 34]. Seven face-to-face interviews were conducted with a panel of healthcare staff from MOH (including doctors, nurses and risk and safety officers) to evaluate HSOPSC content and ensure the proper transfer of the intended meaning of the questionnaire items to the culture and language differences in the Kuwait context. The panel endorsed the HSOPSC content as being of high relevance to safety culture in Kuwaiti hospitals. All items were retained. However, wording was modified in eight items to clarify their meaning as some comments indicated potential ambiguity in items' interpretations.

Instrument testing

A stratified random sample was drawn from healthcare clinical staff in three public hospitals in Kuwait. To ensure that the sample size was adequate to satisfactorily undertake factor analysis (FA), sample size requirements (sample size of the study, ratio of the sample size to the number

of variables, ratio of the number of variables to the number of factors) were evaluated [35]. Tabachnick and Fidell [36] rule recommends having at least 300 cases to undertake FA. The Kaiser-Meyer-Olkin (KMO) coefficient was used as another measure of sampling adequacy. KMO coefficient values range between 0 and 1. Surveys of health professionals can be challenging and are characterised by declining response rates [37] with a significant downward trend in response rates from 1998 to 2008 [38]. Based on their findings, the predicted response rate for this study was 20% and it was estimated that the sample size should be a minimum of 1,500 of distributed questionnaires.

Data collection and management

Staff members were invited by letter to participate in the study. Questionnaires were distributed across different departments in the three public hospitals. The questionnaires were completed anonymously and returned to multiple collection boxes located within the hospitals. Data were coded and entered into an electronic data file using the Statistical Package for Social Science (SPSS 24). Negatively worded items were reverse coded. If less than one entire section of the survey was answered or less than half of the items throughout the entire survey (in different sections) were answered, or if every item was answered the same, these questionnaires were excluded [39]. Missing values were deleted in a listwise manner in order to minimise any possible biases [40].

Factor analysis (FA)

FA is a statistical method that "*explores the extent to which individual items in a questionnaire can be grouped together according to the correlations between the responses to them*", thus reducing the dimensionality of the data [41]. It can be applied as a data reduction or a structure detection method [42]. The two main techniques of FA are Exploratory Factor Analysis (EFA), and Confirmatory Factor Analysis (CFA), which are both recommended to test construct validity [43].

EFA allows the researcher to uncover the main dimensions to develop a theory, or model from a smaller number of latent constructs that are often represented by a larger set of measured variables [44 45]. CFA tests a pre-determined factor structure or a proposed theory [44 45]. This study combined both approaches to develop an optimal model, based on the original HSOPSC model, for

specifically assessing patient safety climate in Kuwaiti public hospitals. Due to the controversy associated with conducting EFA and CFA on the same data, a split-half validation technique is recommended [46 47]. Therefore, the Kuwaiti dataset was randomly split into to two independent datasets using SPSS 24. Each group contains a set of 640 (n=640) cases - the calibration half of the dataset was used for model construction and the validation half of the dataset was used for confirming the explored factor structure resulting from model construction.

Data analysis was based on three main phases. 1. To investigate whether the original HSOPSC 12-factor model is appropriate for the Kuwaiti data. Both CFA and reliability analysis were used at this step. 2. To examine whether an alternative factor model would fit the Kuwaiti data better. For model construction, EFA was carried out using the calibration half of the dataset (Sample A, n=640). 3. Undertaking CFA and reliability analysis using the validation half of the dataset, to test the fit of the resultant model from the previous phase (Sample B, n=640). Cronbach's alpha (α) was calculated for each factor to examine the internal consistency or reliability with the minimum criterion for acceptable reliability of at least $\alpha \geq 0.60$ as recommended for the majority of research purposes [48 49]. Factor correlations of the optimal model were performed in addition to comparisons between the CFA output of our optimal factor model and the outputs reported in previous studies.

Patient and public involvement statement

Patient and public were not involved in the design, planning or the analysis of the study.

RESULTS

Response rate and sample demographics

Of the 1,511 questionnaires distributed at the three hospitals, 1,317 questionnaires (87%) were returned. A KMO statistic of 0.88 was calculated , which indicates that the sample has a sufficient level of homogeneity [50 51]. Thirty-seven questionnaires were excluded. Appendix 1 summarizes the relevant demographics of survey respondents.

Instrument testing

Following the deletion of missing values, one thousand, two hundred and eighty questionnaires (n=1280) were considered eligible and this number of completed questionnaires (n=1280) was sufficient to undertake FA.

Testing the original HSOPSC (12-factor) model

A CFA was performed, using AMOS software [52], to test the model fit of the original HSOPSC 12-factor structure using the Kuwaiti data (n=1280). The global fit of our model was not consistently satisfactory for the Kuwaiti data. Three criteria measures did not indicate an acceptable fit with Comparitive Fit Index (CFI) = 0.81 (CFI values ≥0.90 considered a good model fit [53]), Chi-squared statistic per one degree of freedom (x^2/DF) = 4.81 (x^2/DF value ≤2 for a good fit [54]), and TLI = 0.784 (TLI of > 0.90 indicates a good fit [53]) values indicate that the fit is not adequately good enough to confirm the proposed factor structure.

The internal consistency of the Kuwaiti data (n=1280) was ≥0.60 within nine dimensions. Three dimensions had internal consistencies less than 0.60. Additionally, two dimensions have a questionable internal consistency because their Cronbach's alpha value was 0.60 (Cronbach's α=0.604 for "Non-punitive Response to Errors" and Cronbach's α=0.601 for "communication openness". In summary, the results of the CFA and reliability analysis indicate that the original HSOPSC 12 Factor model is not a satisfactory fit when it is used for the Kuwaiti data. Therefore, an EFA was used for investigating an alternative factor structure which might be more appropriate for Kuwaiti data.

Construction of an optimal model

EFA consists of two basic stages. 1. Estimating the number of factors that should be extracted to represent the HSOPSC factor structure; and 2. Interpreting the meaning of the extracted factors and representing them in terms of theoretical structures that reflect the patient safety climate dimensions. EFA (principal axis factoring with varimax then oblique rotation) was performed on the calibration half of the dataset (n=640). Based on the Kaiser criterion of Eigenvalues greater than one (Eigenvalues > 1) [50] and Cattell scree plot [55], different numbers of factors (12,11,10,9,8,7 factors) were extracted and investigated to find the optimal alternative model (see Appendix 2).

Following the rotation of factors the factor pattern matrix was examined to decide on the acceptable level of loading for variables to define factors [56]. To reach a satisfactory solution, a number of points need to be taken into consideration including identifying items with low communalities (<0.3), no or low loading (<0.4), items with cross loadings (>0.30) and the theoretical structure of items. It should be noted that the decision on how many factors to retain based on the degree of comprehensibility and interpretability of the factor structure in the context of the research [57]. In addition, theoretical knowledge regarding the construct under study is more significant than a statistical measure and the items and factors should make conceptual sense and be theoretically related [56].

Final factor solution

An Eight-factor solution (all loadings ≥ 0.40) showed the best model fit to the Kuwaiti dataset. The Scree plot of the final EFA solution is shown in Figure 1. The structure and factor loadings of the final EFA solution are reported in Table 1. The final solution explains 50.2% of variance by eight extracted factors and represents 22 items from the safety climate questionnaire (20 items were excluded). All factor loadings are within the range of 0.428-0.864.

Table 1: Pattern matrix of the final EFA solution (Eight factors, 22 items)

Variable	Factor							
	1	2	3	4	5	6	7	8
(B1) My supervisor/manager says a good word when he/she sees a job done according to established patient safety procedures (SEA)	,822							
(B2) My supervisor/manager seriously considers staff suggestions for improving patient safety (SEA)	,623							
(E2) When a mistake is made, but has no potential to harm the patient, how often is this reported? (FER)		,864						
(E1) When a mistake is made, but is caught and corrected before affecting the patient, how often is this reported? (FER)		,776						
(E3) When a mistake is made that could harm the patient, but does not, how often is this reported? (FER)		,776						
(D5) Important patient care information is often lost during shift changes. (negatively worded) (HO)			-,662					

Variable	Factor							
	1	2	3	4	5	6	7	8
(D3) Things 'fall between the cracks' when transferring patients from one unit to another (negatively worded) (HO)			-,621					
(D6) It is often unpleasant to work with staff from other hospital units. (negatively worded) (TWAU)			-,495					
(D7) Problems often occur in the exchange of information across hospital units. (negatively worded) (HO)			-,428					
(A16) Staff worry that mistakes they make are kept in their personnel file. (negatively worded) (NRP)				,578				
(A8) Staff feel like their mistakes are held (used) against them. (negatively worded) (NPR)				,559				
(A12) When an incident is reported, it feels like the person is being reported, not the problem. (negatively worded) (NPR)				,531				
(D4) There is good cooperation among hospital units that need to work together (TWAU)					-,641			
(D2) Hospital units do not coordinate well with each other. (negatively worded) (TWAU)					-,522			
(A1) People support one another in this unit (TWWU)						,688		
(A3) When a lot of work needs to be done quickly, we work together as a team to get the work done (TWWU)						,605		
(A4) In this unit, people treat each other with respect (TWWU)						,556		
(C6) Staff are afraid to ask questions when something does not seem right. (negatively worded) (CO)							,615	
(C4) Staff feel free to question the decisions or actions of those with more authority (CO)							,600	
(C2) Staff will freely speak up if they see something that may negatively affect patient care (CO)							,524	
(D1) Hospital management provides a work climate that promotes patient safety (MS)								,677
(D8) The actions of hospital management show that patient safety is a top priority (MS)								,574

Extraction Method: Principal Axis Factoring. Rotation Method: Oblimin with Kaiser Normalization.
Rotation converged in 16 iterations. Supervisor/manager expectations and actions promoting safety (SMEA), Organisational learning—continuous improvement (OL),Teamwork within hospital units (TWWU), Teamwork across hospital units (TWAU), Communication openness (CO), Feedback and communication about error (FB), Non-punitive response to error (NPRE), Staffing (S), Hospital management support for patient safety (MS), Hospital handoffs and transitions (HO), Frequency of incident reporting (FER), Overall perceptions of patient safety (OPPS).

Five factors (Factor 2, Factor 3, Factor 4, Factor 6, and Factor 7) have three and more items with loading >0.4. Factor 1, Factor 5, and Factor 8 have two items with very high loading of >0.5 and the items in each factor are theoretically related (Table 2). There are no cross loaded items and there are no items with loading <0.4 and with communalities <0.3 in the solution. The solution is essentially consistent with all items within each factor theoretically related. Only D6 moved from "Teamwork across units" to "Handoffs and transitions."

Table 2: Structure, factors loadings and internal consistency of the final EFA solution (Eight factors, 22 items)

Number of Factor	Factor	Heavy loaded items (>0.4)	Number of items	Cronbach's Alpha
1	Supervisor/Manager Expectations and Actions Promoting Safety	B1-B2	2	0.776
2	Frequency of Events Reported	E1-E2-E3	3	0.858
3	Handoffs and Transitions	D3-D5-D6-D7	4	0.685
4	Non-punitive Response to Errors	A8-A12-A16	3	0.604
5	Teamwork Across Units	D2-D4	2	0.689
6	Teamwork Within Units	A1-A3-A4	3	0.705
7	Communication Openness	C2-C4-C6	3	0.601
8	Management Support for Patient Safety	D1-D8	2	0.724

Testing the final factor (Eight-factor) model

The optimal Eight-factor model was vigorously examined by conducting two confirmatory analyses initially using the validation half of the dataset (n=640), followed by the whole dataset (n=1280). All estimated parameters indicate a good model fit (Eight factors and 22 items) as reported in Table 3.

Table 3: CFA Results of Eight factor optimal model (validation sample and whole sample)

Eight-factors model	Chi-Square statistic (x^2)	DF	CMIN/DF (x^2/DF)	CFI	RMR	SRMR	RMSEA	TLI
Validation sample	424.9 good	181 good	2.3 acceptable	0.94 good	0.049 good	0.048 good	0.046 good	0.92 good
Whole sample	617.8 good	181 good	3.4 acceptable	0.946 good	0.041 good	0.038 good	0.043 good	0.931 good

Chi-square test statistic (x^2), Chi-squared statistic per one freedom degree (x^2/DF), the Comparative Fit Index (CFI), Root mean square residuals (RMR), the Standardised Root Mean Square Residual (SRMR), the Root Mean Square Error of Approximation (RMSEA), Tucker-Lewis Index (TLI)

The standardised path coefficients reflecting the strength of the relationship between items and dimensions [58] were found to be generally large (>0.50) and ranged from 0.46 (Communication openness) to 0.89 (Frequency of incidents reported) (see Appendix 3). Therefore, this model was accepted as the optimal model of HSOPSC for the Kuwaiti healthcare setting.

Reliability

Reliability analysis was performed using the whole sample with Cronbach's Alpha values reported to be ≥ 0.60 for all factors. Therefore, the internal consistency was acceptable for the Eight factors solution (Table 2). In order to test the construct validity of the HSOPSC instrument, inter-correlation coefficients with Pearson's ***r*** were calculated between the Eight factors in addition to the two single item outcome measures (patient safety grade and number of incidents reported). The Pearson's correlation coefficients between scale scores are reported in online appendix 4. Inter-correlation coefficients ranged between 0.08 and 0.72. All correlation coefficients are significant. The highest correlations were those between "Management support for patient safety" and "Teamwork across units" (r=0.722). All eight factors are interrelated to each other. Most of the correlation coefficients indicate a moderate correlation between dimensions. This indicates that no two factors are measuring the same construct.

Proposed optimal Eight factors model for Kuwaiti data

As shown in Table 4, the proposed optimal model structure includes 8 dimensions and 22 items.

Table 4: Proposed Eight factors optimal model for Kuwaiti data

Factor 1: Supervisor/Manager Expectations and Actions Promoting Patient Safety (2 items)
B1: My supervisor/manager says a good word when he/she sees a job done according to established patient safety procedures
B2: My supervisor/manager seriously considers staff suggestions for improving patient safety.
Factor 2: Frequency of Events Reported (3 items)
E1: When a mistake is made, but is caught and corrected before affecting the patient, how often is this reported?
E2: When a mistake is made, but has no potential to harm the patient, how often is this reported?
E3: When a mistake is made that could harm the patient, but does not, how often is this reported?
Factor 3: Handoffs and Transitions (4 items)
D3: Things "fall between the cracks" when transferring patients from one unit to another. (negatively worded)

D5: Important patient care information is often lost during shift changes. (negatively worded)
D6: It is often unpleasant to work with staff from other hospital units. (negatively worded)
D7: Problems often occur in the exchange of information across hospital units. (negatively worded)
Factor 4: Non-punitive Response to Errors (3 items)
A8: Staff feel like their mistakes are held (used) against them. (negatively worded)
A12: When an incident is reported, it feels like the person is being reported, not the problem. (negatively worded)
A16: Staff worry that mistakes they make are kept in their personnel file. (negatively worded)
Factor 5: Teamwork Across Units (2 items)
D2: Hospital units do not coordinate well with each other. (negatively worded)
D4: There is good cooperation among hospital units that need to work together.
Factor 6: Teamwork Within Units (3 items)
A1: People support one another in this unit.
A3: When a lot of work needs to be done quickly, we work together as a team to get the work done.
A4: In this unit, people treat each other with respect.
Factor 7: Communication Openness (3 items)
C2: Staff will freely speak up if they see something that may negatively affect patient care.
C4: Staff feel free to question the decisions or actions of those with more authority.
C6: Staff are afraid to ask questions when something does not seem right. (negatively worded)
Factor 8: Management Support for Patient Safety (2 items)
D1: Hospital management provides a work climate that promotes patient safety.
D8: The actions of hospital management show that patient safety is a top priority.

DISCUSSION

This psychometric evaluation is the first reported validation study of a standardised safety climate measure in a Kuwaiti healthcare setting. The psychometric properties of the HSOPSC questionnaire were assessed and an optimal model for assessing patient safety climate in Kuwaiti hospitals was constructed. The final questionnaire contains 22 safety climate items (variables) that measure eight safety climate factors. The optimal model's psychometric properties (including validity and reliability) were good with all items loading strongly (>0.40) onto one factor and all items, within each factor, were theoretically related.

Our results are in line with other studies investigating the psychometric properties of the original HSOPSC questionnaire. The suitability of the original HSOPSC model for Kuwaiti data was tested and results revealed an unsatisfactory fit [59]. Different international studies [27 31 60 61] reported similar findings. This finding is in contrast with other studies that assessed patient safety climate by using the original HSOPSC questionnaire [59] in hospitals without examining the reliability and validity of the questionnaire in a different context [62-68]

Various underlying factor structures were identified as optimal factor models. The original 12 factor model was replicated in Belgian [6], Portuguese [69] Brazilian[70] and Scottish data [71]. Other studies reported 11 factor models for Dutch [30], Arabic [61], Croatian [72] and Norwegian data [73]; 10 factor models for French [28], Turkish [26], Chinese [74] and Brazilian data [75]; 9 factor models for UK [31] and Slovene data [76]; Eight factor models for Swiss [27], Saudi [60], Kosovo [77] and Kuwaiti data. This discrepancy in results could be attributed to differences in employing survey methods and psychometric analytical techniques, in addition to the various modifications made to adapt the original instrument to different healthcare settings [71]. Neglect of crucial elements, including context, processes and actors involved, when attempting to adapt an instrument in a different setting might lead to conflicting results and might weaken the validity of the instrument [78]. Thus, the original HSOPSC will clearly be limited when used in other contexts without proper assessment of its psychometric properties.

The optimal model of our study is in line with other international studies [31 60]. Four dimensions were either dropped or merged with other factors into a single dimension. In our study, the same dimensions reported low reliability using the original HSOPSC in addition to other international studies [31 60 79]. The optimal model was confirmed using CFA with good model fit indices. This was consistent with the CFA results of the USA [59], Saudi Arabia [60], Palestine [61], UK [31] and Scotland [71] optimal models.

Considering all of this evidence, it seems that the original HSOPSC questionnaire [59] does not appear to perform well in different countries. Survey instruments that are designed for particular settings are tailored to meet the unique characteristics and contexts of the local setting and population. In the case of the HSOPSC, a number of the reported adaptations have performed less well than the original tool [28 31 73 74 80]. This might be due to the contextual specificity of the construct of safety culture [81]. Other factors include unique country characteristics, types of health systems and settings, staff groups, and cultural differences [27 82]. Hedsköld, et al. [78] pointed out that such differences might weaken the validity of the instrument.

In a review of quantitative patient safety culture instruments, it was concluded that all of the surveys designed for general administration to hospital personnel addressed three common dimensions: management support and commitment to safety, communication openness and teamwork Singla, et al. [11]. They suggested that these common dimensions might be considered "core dimensions" of patient safety culture. In addition, a number of dimensions seem to be common among optimal factor models across different countries.

Factor structure of the optimal model of our study compared with optimal models that were developed in Saudi Arabia, Palestine, England, Scotland, Netherlands, Turkey and Switzerland in addition to the original USA HSOPSC questionnaire [59] is shown in online appendix 5. This comparison is aimed at identifying a common set of patient safety culture dimensions across different countries.

Six studies reported different dimensions combined into one dimension. A significant degree of overlap in the content of the safety culture dimensions exists. As a result, included items in certain dimensions tend to load onto differently labeled dimensions. "Feedback and communication about error" and "Communication openness" were grouped into one dimension in the Palestinian, Swiss and Scottish studies respectively [27 61 79]. This result is expected as both dimensions are closely related. Feedback and communication with staff about errors and discussing ways to prevent them are linked to allowing staff to freely speak up, if they see something that might negatively affect patient care.

Cox and Flin [1] suggest that the nature of safety climate is "context-dependent." Keiser [83] argues that since safety climate measures include both general and contextualized items, excluding contextual measures might provide a rather deficient evaluation of the underlying safety climate construct. Thus, research currently supports the idea of integrating both qualitative and quantitative methods in developing a culturally appropriate instrument as standard approaches that exclusively rely on translation and quantitative validation may not be sufficient to produce an instrument that is applicable to the local context [74]. As a result, the adopted tool will be able to reflect important safety climate themes that are specific to the local healthcare context.

A number of common dimensions that were emerging rather consistently across international settings despite the lack of confirmation of the original factor structure of the HSOPSC in numerous studies. Those dimensions include: management support for patient safety, supervisors' action promoting patient safety, teamwork within and across units, handoffs and transitions, non-punitive response to error, frequency of incidents reported, communication openness and organisational learning.

The item composition of each factor of the optimal model of our study was compared with optimal models that were developed in Saudi Arabia, Palestine, England, Netherlands, Turkey and Switzerland in addition to the original USA HSOPSC questionnaire [59]. This comparison is aimed at identifying a common set of patient safety climate items across different countries (see Appendix 6). The different adaptations of the HSOPSC did not confirm the original factor structure of the HSOPSC [59]. Still, some dimensions corresponded to the ones proposed in the original HSOPSC model and items were repeated across the different studies. It should be noted that not all studies reported their optimum factor model structure. As a result, this created a difficulty in identifying the structure of the common dimensions across different countries.

STRENGTHS AND LIMITATIONS

This is the first validation study of a standardised safety climate measure in a Kuwaiti healthcare setting. The study assessed the psychometric properties of the HSOPSC questionnaire and constructed an optimal model for assessing patient safety climate in Kuwaiti hospitals. To examine the psychometric properties of the HSOPSC, a rigorous and scientific psychometric approach was designed and executed based on recommended reporting practices. Furthermore, strengths of both EFA and CFA analytical techniques were used to test the original HSOPSC model and construct an optimal model. Additionally, the researcher attempted to report all parameter estimates required for the reader to make valid interpretations of the results. Also, a large sample size (n=1280) allowed for the dataset to be split and for factor analysis, including EFA and CFA, to be undertaken with acceptable model fit indices.

One limitation of this study is the number of items per factor in the optimal model. Three factors contained only two items per factor in the final Eight factor model. This is less than the recommended minimum of three items per factor. However, the items reported high loadings with strong theoretical sense. Also, similar findings were reported in the literature.

Another limitation is the exclusion of partially answered questionnaires. As a result, a subset of the total sample, with all items answered, was used for the validation of the psychometric properties of the HSOPSC. Data imputation techniques were avoided due to their potential impact on the tool's reliability and construct validity estimates and in order to minimise any possible biases. This led to a more uniform sample.

CONCLUSION

This is the first validation study of a patient safety climate questionnaire conducted in a Kuwaiti healthcare setting. The results clearly indicate the need for caution when using the original version of the HSOPSC questionnaire [59] and highlight the importance of appropriate validation of safety climate surveys before applying them to different populations and healthcare contexts than those in which they were originally developed. The study also shows the original composition of the HSOPSC dimensions was not confirmed in most studies. When compared to the USA, the HSOPSC questionnaire may be assessing different dimensions of safety culture across different countries including Kuwait [59]. More work is needed on cross-cultural investigations of differences in dimensionality to allow comparisons of healthcare safety climate results at an international level [27 41]. This study provided comparative data on the use of the HSOPSC questionnaire internationally and nine common dimensions and items were identified when comparing the different studies that reported their optimum models. The optimal factor model that was constructed in this study can be used as a basis for measuring patient safety climate in Kuwaiti hospitals and in evaluating changes in safety climate over time as part of patient safety improvement initiatives.

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GA, PB and JM made considerable contributions to conception and design of the psychometric evaluation.

GA completed the psychometric assessment and development of the final eight-factor model.

GA was involved in drafting the manuscript while JM and PB have done revising the drafts.

All authors have given final approval of the version to be published and agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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Box 1: HSOPSC patient safety culture dimensions and definitions [39]

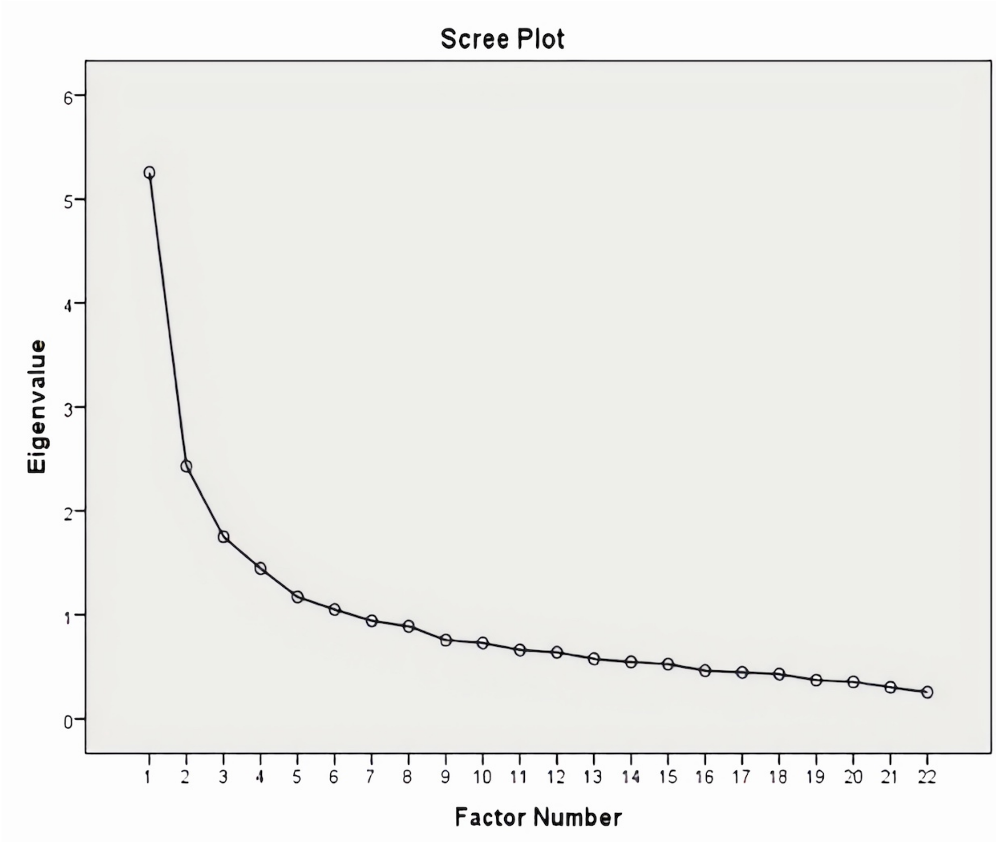
Patient Safety Culture Composite	**Definition: The extent to which...**
Communication Openness	Staff freely speak up if they see something that may negatively affect a patient and feel free to question those with more authority.
Feedback and Communication About Error	Staff are informed about errors that happen, are given feedback about changes implemented, and discuss ways to prevent errors.
Frequency of Events Reported	Mistakes of the following types are reported: (1) mistakes caught and corrected before affecting the patient, (2) mistakes with no potential to harm the

	patient, and (3) mistakes that could harm the patient but do not.
Handoffs and Transitions	Important patient care information is transferred across hospital units and during shift changes.
Management Support for Patient Safety	Hospital management provides a work climate that promotes patient safety and shows that patient safety is a top priority.
Non-punitive Response to Error	Staff feel that their mistakes and event reports are not held against them and that mistakes are not kept in their personnel file.
Organizational Learning—Continuous Improvement	Mistakes have led to positive changes and changes are evaluated for effectiveness.
Overall Perceptions of Patient Safety	Procedures and systems are good at preventing errors and there is a lack of patient safety problems.
Staffing	There are enough staff to handle the workload and work hours are appropriate to provide the best care for patients.
Supervisor/Manager Expectations and Actions Promoting Patient Safety	Supervisors/managers consider staff suggestions for improving patient safety, praise staff for following patient safety procedures, and do not overlook patient safety problems.
Teamwork Across Units	Hospital units cooperate and coordinate with one another to provide the best care for patients.
Teamwork Within Units	Staff support each other, treat each other with respect, and work together as a team.

Figure legends:

Figure 1 title: Scree plot of the final EFA solution (Eight factors, 22 items)

Box 1: HSOPSC patient safety culture dimensions and definitions 39



Scree plot of the final EFA solution (Eight factors, 22 items)

105x90mm (300 x 300 DPI)

Appendix 1: Professional and personal characteristics of study respondents (n=1,310)

Variable	Category	Frequency (n)	Percentage (%)
Staff Position	Assistant Nurse	30	2.4
	Nurse	697	55.0
	Head nurse/Nurse manager	27	2.1
	Unit Assistant/Clerk	4	0.3
	Attending/Staff Physician	227	17.9
	Resident Physician/Physician in training	41	3.2
	Pharmacist	21	1.7
	Dietician	10	0.8
	Respiratory Therapist	3	0.2
	Physical, Occupational, or Speech Therapist	18	1.4
	Technician	176	13.9
	Management	13	1.0
Gender	Male	479	37.2
	Female	808	62.8
Direct Patient Contact	Yes	1112	88.5
	No	144	11.5

Appendix 2:
Conclusion from the solutions with different numbers of the factors (12- 9-8-7-10-11)

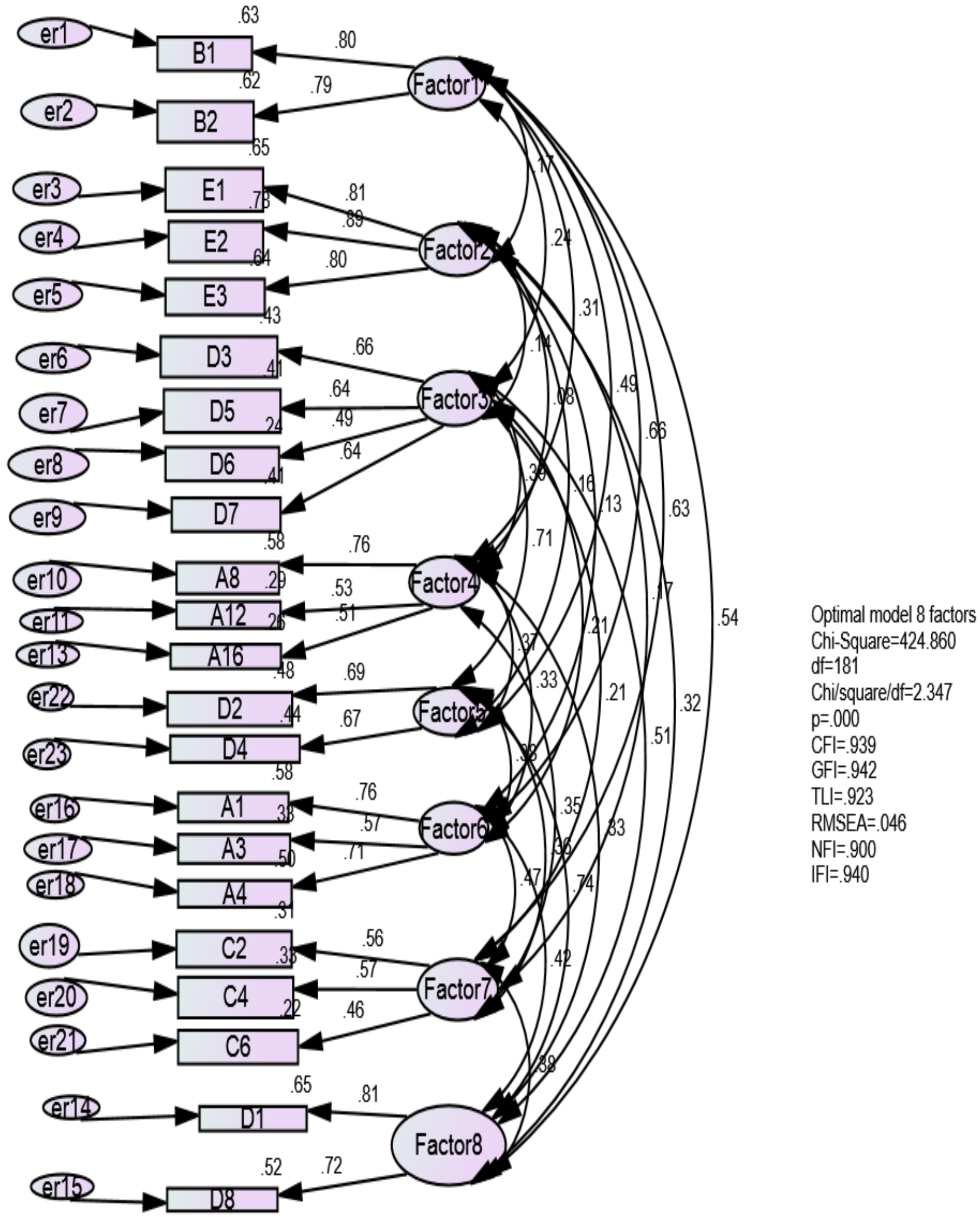
Step	**Number of extracted factors**	**Number of the satisfactory factors**	**Total variance explained by extracted factors**	**Items not loading**	**Items which have low communalities (<0.3)**	**Items which have low loadings (<0.4)**
1	**12**	**8**	**45**	**A5- A11- A15- A17**	**A5-A7-A9-A10-A11-A15-A17**	**A13- B3-D9- A6-C1-C5- A10- A7-D11- A18- C3**
4	9	7	41.0	A5 - A9- A15-A17-A7	A2-A5-A7-A9-A10-A15-A17	D9- B3- C5- A10-A2-A11
5	8	6	39.2	A5-A15-A17-A9	A2 - A5- A7- A9-A10- A11-A15-A17	A13-D9- C5-A6-B3- A10-A7- A2-A11
6	7	5	37.4	A11-A5-A7-A9-A15- A17	A2 - A5- A7- A9-A10 - A11- A15-A17- B3 -C3-D6	C3-A18-A13- C1-A2- B4-B3-A10
7	11	9	43.8	A5-A7- A17	A5- A7- A9- A10-A11- A15- A17-D6	B3-D9- A6- A10-A9-A13- C5- A7-A11
8	10	9	42.6	A5-A7- A17 A9	A5 - A7- A9- A10 - A11- A15- A17-D6	A13-D9- C5-A10- A11

An investigation of five possible solutions was undertaken in steps 4-8 to explore the number of factors that could be extracted. The initial solution with 12 factors demonstrates that 8 factors could fit the 42 safety climate items. The 9 Factors solution demonstrates that 7 factors could fit the 42 safety climate items. The 8 Factors solution demonstrates that 6 factors could fit the 42 safety climate items. The 11 Factors solution demonstrates that 9 factors could fit the 42 safety climate items. The 10 Factors solution demonstrates that 9 factors fit the 42 safety climate items. The summary results of the six solutions including the initial solution are displayed in the above table. The comparison of the different solutions suggests that the 8 Factors solution is most appropriate (four items without loadings, the initial solution with 12 factors indicates that 8 factors is satisfactory, only one factor is without strongly loaded items).

The optimal model is an Eight Factor model with 22 safety climate questionnaire items (20 items were excluded) that explains about 50.2% of the total variance. All factor loadings are within the range of 0.426-0.866. Five factors (Factor 2, Factor 3, Factor 4, Factor 6, and Factor 7) have three or more items with loadings >0.40. Factor 1, Factor 5, and Factor 8 have two items with very high loading >0.50 and acceptable theoretical basis. There are no cross loaded items and there are no items with loadings <0.40 in the solution. The solution is essentially consistent with the theoretical pattern. All factors consist of two to four items and all items within each factor are theoretically related. Only D6 moved from "Teamwork across units" into "Handoffs and Transitions." It should be noted that "Overall perceptions of patient safety", "Organisational learning—Continuous improvement", "Staffing" and "Feedback and communication about error" have no items in the final 8 factor solution.

In summary, the optimal Eight Factor model shows good psychometric properties with no cross loaded items and there are no items with loadings <0.40 in the solution. All factors consist of two to four items and all items within each factor are theoretically related. The optimal model of our study was confirmed by using CFA.

Appendix 3:
HSOPSC Eight factor model in Kuwait and individual item standardised path coefficients



Appendix 4: Inter-correlations between Eight factors (scales)

N	Scales	1	2	3	4	5	6	7
1	Supervisor/Manager Expectations and Actions Promoting Patient Safety	-						
2	Frequency of Events Reported	0,155***						
3	Handoffs and Transitions	0,286***	0,183***					
4	Non-punitive Response to Errors	0,339***	0,133***	0,371***				
5	Teamwork Across Units	0,51***	0,228***	0,64***	0,435***			
6	Teamwork Within Units	0,664***	0,105**	0,236***	0,356***	0,392***		
7	Communication Openness	0,614***	0,088*	0,259***	0,431***	0,404***	0,517***	
8	Management Support for Patient Safety	0,519***	0,311***	0,531***	0,322***	0,722***	0,432***	0,353***

*** p<0.001, ** p<0.01, *p<0.05

Appendix 5: Dimensions of HSOPSC for USA (US), Kuwait (KWT), Saudi Arabia (SA), Palestine (PAL), England (ENG), Scotland (SCO), Netherlands (NL), Turkey (TUR) and Switzerland (Swiss) factor models

HSOPSC Dimensions	US 59	KWT	SA 60	PAL 61	ENG 31	SCO 78	NL 30	TUR 26	SWISS 27
Supervisor/manager expectations and actions promoting safety	√	√	√	√	√	√	-	-	√
Organisational learning— continuous improvement	√	-	√	√	-	√	√	√	√ With Teamwork within units
Teamwork within hospital units	√	√	√	√	√	√	√	√	-
Communication openness	√	√	√	-	√	-	√	√	-
Feedback and communication about error	√	-	-	√ With Communication Openness	√	√ With Communication Openness	√ With Organisational learning— continuous improvement	√ With Supervisor expectations and actions promoting patient safety	√ With Communication Openness
Non-punitive response to error	√	√	√	√	√	√	√	√	√
Staffing	√	-	√	√	-	-	√	√	-
Hospital management support for patient safety	√	√	-	√	-	√	√	√ With Teamwork across units	√

HSOPSC Dimensions	US 59	KWT	SA 60	PAL 61	ENG 31	SCO 78	NL 30	TUR 26	SWISS 27
Teamwork across hospital units	√	√	-	√	√	√	√	-	-
Hospital handoffs and transitions	√	√	√	√	√	√	√	√	√ With Teamwork across units
Frequency of incident reporting	√	√	√	√	√	√	√	√	√
Overall perceptions of patient safety	√	-	-	√	√ With Staffing	√ With Staffing	√	√	√ With Staffing
Number of optimal model factors	12	8	8	11	9	10	11	10	8

Appendix 6: Item composition of dimensions of HSOPSC for USA (US), Kuwait (KWT), Saudi Arabia (SA), England (ENG), Palestine (PAL), Switzerland (Swiss), Netherlands (NL), and Turkey (TUR) factor models

HSOPSC Factors	USA 59	Kuwait	SA 60	ENG 31	PAL 61	SWISS 27	NL 30	TUR 26
Supervisor/Manager Expectations and Actions Promoting Patient Safety	B1-B2-B3-B4	B1-B2	B1-B2	B1-B2	B1-B2-B3-B4	B1-B2-B3-B4	B1-B2-B3-B4	‡
Frequency of Events Reported	E1-E2-E3*	E1-E2-E3	E1-E2-E3	E1-E2-E3	E1-E2-E3	E1-E2-E3	E1-E2-E3	E1-E2-E3
Handoffs and Transitions	D3-D5-D7-D11*	D3-D5-D7-D6**	D5- D7-D11-D6**	D3-D5-D7-D11	D3-D5-D7-D11	‡	D5 -D11	D3-D5-D7-D11
Non-punitive Response to Errors	A8-A12-A16	A8-A12-A16	A8-A12-A16	A8-A16	A8-A12-A16	A8-A12-A16	A8-A12-A16	A8-A12-A16
Teamwork Across Units	D2-D4-D6-D10*	D2-D4	-	D2-D4-D6-D10	D2-D4-D6-D10	D2-D4-D6-D10-D3**-D7**	D2-D4-D10-D3**-D7**	‡
Teamwork Within Units	A1-A3-A4-A11	A1-A3-A4	A1-A3-A4	A1-A3-A4	A1-A3-A4-A11	A1-A3-A4-A6-A9-A13‡	A1-A3-A4-A11	A1-A3-A4-A11
Communication Openness	C2-C4-C6	C2-C4-C6	C2-C4	C2-C4-C6	C2-C4-C3-C5‡	‡	C2-C4-C6	C2-C4-C6

HSOPSC Factors	USA 59	Kuwait	SA 60	ENG 31	PAL 61	SWISS 27	NL 30	TUR 26
Management Support for Patient Safety	D1-D8-D9*	D1-D8	-	-	D1-D8-D9	D1-D8-D9	D1-D8-D9	D1-D8-D9
Organisational learning—continuous improvement	A6-A9-A13	-	A6-A9-A13-D8**	-	A6-A9-A13	‡	‡	A6-A9-A13
Feedback and communication about error	C1-C3-C5	-	-	C1-C3-C5	‡	C1-C3-C5-C2-C4-C6‡	C1-C3-C5 A6-A9-A13	C1-C3-C5-B1-B2-B3-B4‡
Staffing	A2-A5-A7-A14	-	A5-A7	A2-A14-A10-A17‡	A2-A5-A14	A2-A5-A14-A10-A17-A18‡	A2-A5-A7	A2-A5-A7-A14
Overall perceptions of safety	A10-A15-A17-A18	-	-	‡	A15-A17-A18	‡	A10-A17-A18-A14**	A10-A15-A17-A18
No of factors	12	8	8	9	11	8	11	10

*For comparison reasons, items with the letter F have been changed to letter D and items with the letter D have been changed to letter E as the modified version used in our study, ‡ denotes a merged dimension, ** denotes a moved item from a different dimension

STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of *cross-sectional studies*

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	5
Objectives	3	State specific objectives, including any prespecified hypotheses	6
Methods			
Study design	4	Present key elements of study design early in the paper	7
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	7
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants	8
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	-
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	8
Bias	9	Describe any efforts to address potential sources of bias	8
Study size	10	Explain how the study size was arrived at	7,8
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	7,8,9
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	-
		(*b*) Describe any methods used to examine subgroups and interactions	8,9
		(*c*) Explain how missing data were addressed	8
		(*d*) If applicable, describe analytical methods taking account of sampling strategy	8,9
		(*e*) Describe any sensitivity analyses	-
Results			

Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	9
		(b) Give reasons for non-participation at each stage	9
		(c) Consider use of a flow diagram	-
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	Appendix 1
		(b) Indicate number of participants with missing data for each variable of interest	9
Outcome data	15*	Report numbers of outcome events or summary measures	-
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	9
		(*b*) Report category boundaries when continuous variables were categorized	-
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	-
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	Appendix 2
Discussion			
Key results	18	Summarise key results with reference to study objectives	15
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	4
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	15,16
Generalisability	21	Discuss the generalisability (external validity) of the study results	15,16,17,18
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	N/A

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.