Portuguese cross-cultural adaptation and validation of the Hospital Survey on Patient Safety Culture 2.0

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Abstract

Background

As patient safety continues to be a global priority, it is crucial to emphasize the assessment and development of Patient Safety Culture to advance healthcare quality and safety initiatives worldwide. This study focused on the assessment of patient safety culture in Portuguese hospitals, specifically through the translation and cultural adaptation of the Hospital Survey on Patient Safety Culture 2.0 (HSOPSC 2.0) for the Portuguese context.

Methods

The research involved a two-phase study design, including translation, cultural adaptation, and psychometric analysis of the HSOPSC 2.0. The study sample comprised seven public hospitals from different regions in Portugal, ensuring a diverse representation within the Portuguese National Health System. Analysis of the data involved statistical methods such as Structural Equation Models, Exploratory Factor Analysis, Confirmatory Factor Analysis, and composite reliability analysis.

Results

The results showed that the translated version of HSOPSC 2.0 (PT-HSOPSC 2.0) had good internal consistency and construct validity. Therefore, the instrument is reliable and valid for assessing Patient Safety Culture in Portuguese healthcare settings. The analysis revealed both strengths and areas for improvement in the patient safety culture in Portuguese hospitals. Strengths included teamwork and management support for patient safety, while opportunities for improvement were related to open communication and hospital management.

Conclusion

This study contributes significantly to enhancing patient safety culture assessment in Portuguese healthcare settings by updating and validating the Portuguese version of HSOPSC 2.0.

Background

The concept of "safety culture" emerged in the aftermath of the 1988 Chernobyl nuclear disaster and has since been adopted by various industries and organizations to improve safety. In 1999, the Institute of Medicine report, To Err is Human, brought this concept to the healthcare sector. Since then, numerous studies have highlighted the importance of safety culture in improving healthcare safety (1).

Patient safety culture [PSC] in healthcare refers to the values, beliefs, norms, and capabilities of individuals and organizations that determine their commitment and actions towards patient safety (2). Promoting PSC and assessing it are essential for improving patient safety. PSC assessment has multiple uses, including raising awareness of patient safety among professionals; identifying strengths and opportunities for improvement; assessing the current state of PSC; evaluating the impact of actions and initiatives to be implemented in the development of PSC; analyzing the evolution of PSC; and comparing services within healthcare organization, or even national and international benchmarking between different healthcare organizations (3). Improved levels of PSC have also been linked to shorter hospital stays, fewer readmissions, and medication errors. This underscores the importance of maintaining a positive PSC to minimize errors and adverse events (4).

The World Health Organization's Global Patient Safety Action Plan 2021–2030 recommends that all countries promote and enhance a culture of patient safety in their healthcare systems. This includes conducting regular safety culture assessments and participating in international benchmarking initiatives. This approach allows healthcare systems to identify their strengths and areas for improvement regarding safety culture. Insights from other countries can be used to enhance patient safety and mitigate adverse events (5).

The most frequently used method for assessing the level of PSC in healthcare organizations is the quantitative approach. This involves administering anonymous surveys that measure various dimensions of PSC (1). These instruments are considered an efficient strategy and have been the focus of a large number of review studies that compare their general characteristics and examine their psychometric properties (6). The Hospital Survey on Patient Safety Culture [HSOPSC] of the Agency for Healthcare Research and Quality [AHRQ] is one of the most widely used tool internationally, with excellent psychometric properties and it has been subject to several translations and cultural adaptations (4, 6).

Portugal has shown its dedication to improving patient safety and healthcare quality through its PSC efforts. Legislative documents reflect the government's commitment to this goal (7, 8). Previous research by Eiras et al. investigated the validity and reliability of the first version of HSOPSC in Portuguese hospitals. The study provided foundational insights into the PSC landscape. Eiras et al. concluded that the dimensions of PSC present in HSOPS 1.0 were appropriate for the Portuguese population. The study also highlighted the importance of using hospital culture assessment tools to develop effective strategies and projects for patient safety in Portuguese healthcare organizations (9). Since then, the Portuguese version of HSOPS has been used to assess the patient safety culture of Portuguese hospitals, enabling national and international benchmarking and also identifying strengths and opportunities for improvement in Portuguese hospitals (10).

In 2019, AHRQ released HSOPS 2.0, incorporating feedback and suggestions from various countries that have implemented HSOPS 1.0. AHRQ stated that starting in 2020, the 1.0 benchmarks would no longer be updated and that direct comparison between the 1.0 and 2.0 surveys would not be possible. They recommended transitioning the research (11).

Considering that it is crucial to continue the international benchmarking of PSC in our Portuguese hospitals in the future, the present study aims to update the Portuguese version of HSOPS and to determine the psychometric properties of the Portuguese version of HSOPS 2.0, in order to continue assessing and characterizing PSC in Portuguese hospitals.

Materials and Methods

Study Design

This is a two-phase study. The first phase involved the translation and cultural adaptation of the HSOPS 2.0 into the Portuguese language and culture. The second phase of the study is a cross-sectional study and consisted of the implementation of the translated version of HSOPS 2.0, in order to assess the psychometric characteristics of the survey and to allow the PSC assessment of the participating hospitals.

Instrument

HSOPS 2.0 assesses some of the same areas of patient safety culture as HSOPS 1.0. However, AHRQ made significant changes to the new survey. The HSOPS 2.0 consists of 40 items, whereas the HSOPS 1.0 consists of 51 items.

In terms of changes to the survey items, five items from the HSOPS 1.0 survey remained unchanged in HSOPS 2.0, 21 items were dropped, 25 items from HSOPS 1.0 were reworded or had their response options changed, and 10 new items were added to the new HSOPS 2.0.

In terms of items, it is worth noting that, as in HSOPS 1.0, HSOPS 2.0 contains a mix of both positively and negatively worded items. HSOPS 2.0 includes a "Does not apply/Don’t know" response option, whereas in the previous version, participants could leave the question blank if they were faced with a situation to which they did not know how to respond or in which they did not fit.

The new HSOPS 2.0 assesses 10 composite measures of patient safety culture, while the previous version assesses 12 composite measures, and two of these composite measures have been eliminated (Overall Perceptions of Patient Safety and Teamwork Across Units). It was also noted that the names of some of the dimensions were changed to better reflect the content assessed in the survey.

Therefore, HSOPS 2.0 includes thirty-two items that inquire about the 10 composite measures that the survey assesses, distributed in groups of 3 to 4 items throughout the survey. Of these items, 13 are negative and 19 are positive; there are also two single-item measures, one of which asks how many patient safety events the respondent has reported, while the other asks for an overall patient safety rating of their service/unit. The HSOPS 2.0 also includes six items that ask for general and contextual information, including occupational category, service/unit, length of service, and patient contact. Table 1 lists the ten HSOPS 2.0 composites measures assessed in HSOPS 2.0 and their corresponding items.

Finally, AHRQ recommends that translations of the survey maintain the same number of items and dimensions and that no items be eliminated.

Table 1
– Composite Measures and Items of the HSOPS 2.0

Composite measures (Response options)		Item number	Item
1	**Teamwork** (Strongly Disagree, Disagree, Neither Agree nor Disagree, Agree, Strongly Agree, Does Not Apply or Don't Know)	A1	In this unit, we work together as an effective team.
		A8	During busy times, staff in this unit help each other.
		A9r*	There is a problem with disrespectful behavior by those working in this unit.
2	**Staffing and Work Pace** (Strongly Disagree, Disagree, Neither Agree nor Disagree, Agree, Strongly Agree, Does Not Apply or Don't Know)	A2	In this unit, we have enough staff to handle the workload.
		A3r*	Staff in this unit work longer hours than is best for patient care.
		A5r*	This unit relies too much on temporary, float, or PRN staff.
		A11r*	The work pace in this unit is so rushed that it negatively affects patient safety.
3	**Organizational Learning—Continuous Improvement** (Strongly Disagree, Disagree, Neither Agree nor Disagree, Agree, Strongly Agree, Does Not Apply or Don't Know)	A4	This unit regularly reviews work processes to determine if changes are needed to improve patient safety.
		A12	In this unit, changes to improve patient safety are evaluated to see how well they worked.
		A14r*	This unit lets the same patient safety problems keep happening.
4	**Response to Error** (Strongly Disagree, Disagree, Neither Agree nor Disagree, Agree, Strongly Agree, Does Not Apply or Don't Know)	A6r*	In this unit, staff feel like their mistakes are held against them.
		A7r*	When an event is reported in this unit, it feels like the person is being written up, not the problem.
		A10	When staff make errors, this unit focuses on learning rather than blaming individuals.
		A13r*	In this unit, there is a lack of support for staff involved in patient safety errors.
5	**Supervisor, Manager, or Clinical Leader Support for Patient Safety**	B1	My supervisor, manager, or clinical leader seriously considers staff suggestions for improving patient safety.

*negatively worded

Composite measures (Response options)		Item number	Item
	(Strongly Disagree, Disagree, Neither Agree nor Disagree, Agree, Strongly Agree, Does Not Apply or Don't Know)	B2r*	My supervisor, manager, or clinical leader wants us to work faster during busy times, even if it means taking shortcuts.
		B3	My supervisor, manager, or clinical leader takes action to address patient safety concerns that are brought to their attention.
6	**Communication About Error** (Never, Rarely, Sometimes, Most of the time, Always, Does Not Apply or Don't Know)	C1	We are informed about errors that happen in this unit.
		C2	When errors happen in this unit, we discuss ways to prevent them from happening again.
		C3	In this unit, we are informed about changes that are made based on event reports.
7	**Communication Openness** (Never, Rarely, Sometimes, Most of the time, Always, Does Not Apply or Don't Know)	C4	In this unit, staff speak up if they see something that may negatively affect patient care.
		C5	When staff in this unit see someone with more authority doing something unsafe for patients, they speak up.
		C6	When staff in this unit speak up, those with more authority are open to their patient safety concerns.
		C7r*	In this unit, staff are afraid to ask questions when something does not seem right.
8	**Reporting Patient Safety Events** (Never, Rarely, Sometimes, Most of the time, Always, Does Not Apply or Don't Know)	D1	When a mistake is caught and corrected before reaching the patient, how often is this reported?
		D2	When a mistake reaches the patient and could have harmed the patient, but did not, how often is this reported?
9	**Hospital Management Support for Patient Safety** (Strongly Disagree, Disagree, Neither Agree nor Disagree, Agree, Strongly Agree, Does Not Apply or Don't Know)	F1	The actions of hospital management show that patient safety is a top priority.
		F2	Hospital management provides adequate resources to improve patient safety.

*negatively worded

Composite measures (Response options)		Item number	Item
		F3r*	Hospital management seems interested in patient safety only after an adverse event happens.
10	**Handoffs and Information Exchange** (Strongly Disagree, Disagree, Neither Agree nor Disagree, Agree, Strongly Agree, Does Not Apply or Don't Know)	F4r*	When transferring patients from one unit to another, important information is often left out.
		F5r*	During shift changes, important patient care information is often left out.
		F6	During shift changes, there is adequate time to exchange all key patient care information.
Number of Events Reported (None, 1 to 2, 3 to 5, 6 to 10, 11 or more)		D3	In the past 12 months, how many patient safety events have you reported?
Patient Safety Rating (Poor, Fair, Good, Very Good, Excellent)		E1	How would you rate your unit/work area on patient safety?
*negatively worded			

Translation

The translation process began after approval for the Portuguese translation and cultural adaptation of the HSOPS was obtained through email correspondence with AHRQ. International guidelines were carefully followed to ensure linguistic and cross-cultural equivalence and included the following steps: forward translation, synthesis of translations, reverse translation, expert panel assessment, pre-test, and final version development. The process began with two translations of the survey by two bilingual translators. The translations were then compared for clarity, cultural relevance, and appropriateness. Differences were resolved in consultation with the translators, resulting in the creation of a single version of the survey in Portuguese. This was then back-translated into English by a native English translator and compared to the original version. The aim of the back-translation process was to capture the conceptual meaning. The translations were reviewed by a group of seven experts, consisting of bilingual academics and professionals with experience in quality and patient safety. This group of experts identified inappropriate expressions in the translation, linguistic inconsistencies, assessed the semantic, cultural, and conceptual equivalence of the survey translations and suggested some minor adjustments to the wording of the items to fit the Portuguese context, and unanimously concluded that each item was appropriate in terms of readability, comprehension, and cultural relevance of the translated items, response options, and survey instructions, resulting in the construction of the Portuguese version of the HSOPSC 2.0 [PT-HSOPSC 2.0].

A pre-test was then conducted on a convenience sample of 10 hospital staff to assess comprehensibility, pertinence, cultural relevance, accessibility of the survey on different electronic devices or different web browsers, and functionality. The final version resulting from this phase was then used in the cross-sectional phase to assess measurement equivalence through psychometric analyses, focusing on the reliability and validity of the instrument.

Settings, sample and data collection

All hospitals included in the sample are part of the Portuguese National Health System, which integrates the public sector. Seven public hospitals participated in the study, geographically distributed throughout the national territory, ensuring representation from each of the five Regional Health Administrations in Portugal. One of the participating hospitals had a minimum total bed capacity of 85, while the remaining hospitals had a bed capacity ranging from 200 to 450. In terms of human resources, the participating hospitals employed approximately 400 to 2500 staff members.

The data collection method used in this study was convenience sampling. Hospital selection was based on participation in the study, while staff selection followed a voluntary response sampling approach, which is a non-probabilistic convenience sampling method. Every staff member present in the participating hospitals during the data collection period was included in the study, including all professional categories, regardless of direct patient interaction. Inclusion criteria in this study were working in one of the participating hospitals and being on actual duty during the data collection period, excluding professionals who were absent from work at the time. Completion of the questionnaire was considered an indicator of consent to voluntary participation in the study.

Regarding the sample size, since an instrument validation study should contain a minimum of ten respondents per item in validity and reliability studies (12), for the present study, it was defined that a minimum total sample of 400 respondents would be required, since the survey comprises 40 items.

The survey was conducted electronically from January 18 to February 8, 2023, and was administered via email within the participating institutions after obtaining approval from the Ethics Committees and authorizations from institution’s leaders. The online survey was created using SurveyMonkey software, and an exclusive survey link was provided to each hospital to access the survey. All survey items were mandatory except for the open-ended question. Each survey was anonymous, making it impossible to track respondents. The administration of the web survey included the following steps: sending a pre-notification to publicize the study, sending the invitation to participate in the study, and sending weekly reminders to communicate the importance of participation and the time frame for participation in the study. Throughout the data collection process, leaders received weekly updates on response rates, enabling them to improve local initiatives to increase engagement and instrument participation. Preliminary response rates were calculated on a weekly basis to track response progress.

Variables

As recommended by AHRQ, the Portuguese version of HSOPS 2.0 maintains the original structure to ensure comparability of results with the original instrument, keeping the same number of composite measures and items. Consequently, the variables in this study correspond to the composite measures and items derived from the translation process of the survey, as previously shown in Table 1.

Data analysis

Following AHRQ's recommendation, the negative category was created by combining the two lowest response categories (Strongly Disagree/Disagree and Never/Rarely) before proceeding with data analysis. Similarly, the positive category was created by grouping the two highest response categories (Strongly Agree/Agree and Most of the Time/Always). When calculating the response frequency for each survey item, we considered the midpoints of the scales (Neither and Sometime) to be in the Neutral category.

The data was analyzed with IBM SPSS Statistics V.26 to assess the instrument's reliability. The survey's validity was determined using Structural Equation Models, specifically the Exploratory Factor Analysis and the Confirmatory Factor Analysis with IBM®'s SPSS AMOS software version 26.

The measurement of the instrument's reliability was determined through composite reliability analysis to evaluate the internal consistency of items within each composite measure, utilizing Cronbach's alpha statistics. Cronbach's alpha values between 0.7 and 0.9 indicate higher internal consistency, while values of 0.5 are considered reasonable (13).

Factorial reliability analysis was employed to examine the consistency of the factor structure identified by exploratory factor analysis. Exploratory factor analysis is based on the principle that the covariance (or correlation) among a set of observed variables is caused by the existence of latent variables common to these observed variables (factors or theoretical dimensions of the instrument).

The exploratory factor analysis utilized the maximum likelihood extraction method and the Varimax orthogonal rotation method with Kaiser normalization (eigenvalues greater than 1). Communalities (the proportion of total variance explained by the extracted components) exceeding 0.30 were ensured. The Kaiser-Meyer-Olkin [KMO] measure of sampling adequacy validated the analysis, with a value closer to 1 indicating better data suitability for analysis and a clearer underlying structure. A KMO value of 0.7 or higher is acceptable for proceeding with factor analysis, while values above 0.8 are considered good (14).

The significant result (p-value < α) of Bartlett's sphericity test allowed us to reject the null hypothesis that the correlation matrix is equal to the identity matrix, thus validating the factor analysis (14).

Concerning the validity of the instrument, factorial validity (via confirmatory factor analysis), convergent validity (via average extracted variance), and divergent validity (via Pearson correlation coefficient) were all examined.

We evaluated factorial validity using confirmatory factor analysis applied to the construct resulting from the exploratory factor analysis. Confirmatory factor analysis was conducted using the maximum likelihood estimation method, which is commonly used in structural equation analysis, assuming that the joint distribution of observed variables is multivariate normal.

The assumptions of structural equation analysis were met, including the absence of outliers, a multivariate normal distribution (with skewness and kurtosis values around zero), and the absence of multicollinearity (with VIF < 5 and Tolerance > 0.1) (13).

To rate the quality of fit of the measurement model, the chi-squared test of goodness of fit and different fit indices (absolute, relative, parsimonious and population discrepancy) were analyzed (13, 15).

The chi-square test (X^2) measures the difference between observed and expected covariance matrices. A smaller X^2 value indicates a better model fit, as the difference between covariance matrices decreases. Fit indices are used to evaluate the quality of a model's fit in comparison to the saturated or baseline model.

Absolute fit indices assess the model's fit without comparing it to another model. The X^2/df ratio corrects the chi-square goodness-of-fit statistic by its degrees of freedom (df). A ratio close to 1 indicates a perfect fit, while a ratio below 3 is considered good, between 3 and 5 is acceptable, and above 5 is unacceptable.

Relative fit indices compare the estimated model with the baseline model. The Goodness Fit Index [GFI] measures absolute fit, with values below 0.90 indicating poor fit, 0.90 to 0.95 indicating good fit, and above 0.95 indicating very good fit. The Normed Fit Index [NFI] assesses how much the estimated model's fit improves compared to the null model, with values equal to or above 0.95 indicating a very good fit.

The Comparative Fit Index [CFI] is an incremental fit measure that requires a value of 0.90 or higher for a very good model fit. The Tucker-Lewis Index [TLI], or Non-Normed Fit Index [NNFI], indicates a good model fit with a TLI above 0.90.

Parsimony indices determine the impact of adding parameters to the model, including the Parsimony Comparative Fit Index [PCFI], which applies a penalty factor to CFI, and the Parsimony Goodness Fit Index [PGFI], which applies a penalty factor to GFI.

The Root Mean Square Error of Approximation [RMSEA] reflects the discrepancy between the estimated covariance matrix and the population covariance matrix, with values below 0.08 indicating good model fit.

Convergent validity refers to the extent to which items within the same construct or model are related as predicted by the underlying theory. It was measured through the Average Extracted Variance [AEV], with values above 0.5 or 0.6 considered suitable for demonstrating convergent validity.

Divergent validity examines the ability of a measure to correlate more strongly with its theoretical dimension, while correlating less strongly with other dimensions. This was evaluated using the Pearson correlation coefficient between study dimensions (or latent factors). The correlation is considered weak when $|r| < 0.25$, moderate when $0.25 \leq |r| < 0.5$, strong when $0.5 \leq |r| < 0.75$, and very strong when $|r| \geq 0.75$ (14).

In conclusion, divergent validity is established when the correlation between factors is lower than the value of the Average Extracted Variance expressing convergent validity.

A significance level of 5% was considered.

Results

Sample and Socio-demographic characteristics

The study had an overall average response rate of 32%, with a total of 2604 valid surveys. Participation rates varied between individual hospitals, ranging from 2–55% (Table 2).

Table 2
– Participation rates between individual hospitals

Hospital	Response Rate (%)
A	12
B	42
C	38
D	55
E	19
F	2
G	54
Mean	**32**

The distribution of professional categories among respondents (Table 3) highlighted the predominance of nurses, who comprised 46% of the study cohort. Other clinical staff, such as dietitians, pharmacists, psychologists, social workers, technicians, therapists, or clinical auxiliaries (24.5%), physicians (11.5%), and support staff, such as unit clerks, office staff, informatics, catering, cleaning, maintenance, or infrastructure staff (16.8%) and management staff (1.2%) were also represented.

Table 3
– Respondent distribution by Professional categories (n = 2604)

Total number of participants	n	%
Physicians	299	11.5
Nurses	1197	46
Other clinical staff	638	24.5
Support staff	438	16.8
Management	32	1.2

Looking at the results provided in the background information section of the survey (Table 4), 61% of participants reported having worked in the same hospital for 11 or more years, with 41% of respondents having worked in the same work area/unit for 11 or more years. It was also found that 78% of respondents reported working between 30 and 40 hours per week, and 83% of respondents reported frequent or direct patient interaction.

Table 4
– Demographics characteristics of study respondents (n = 2604)

Time working at that hospital:	**n**	**%**
Less than 1 year	88	3
1 to 5 years	588	23
6 to 10 years	333	13
11 or more years	1595	61
Time working in the current unit/work area:		
Less than 1 year	185	7
1 to 5 years	901	35
6 to 10 years	451	17
11 or more years	1067	41
Hours working per week, typically:		
Less than 30 hours per week	33	1
30 to 40 hours per week	2035	78
More than 40 hours per week	536	21
Direct interaction or contact with patients:		
Typically, yes	2156	83
Typically, no	448	17

Reliability analysis

The reliability of the adapted instrument was examined by calculating Cronbach's alpha coefficients for each composite measure. Table 5 shows Cronbach's alpha coefficients and composite reliability for each composite measure of the Portuguese version of the HSOPS 2.0.

Cronbach's alpha (α) coefficients ranged from 0.626 to 0.872. Except for the composite measures "Staffing and Work Pace" (α = 0.626) and Handoffs and Information Exchange (α = 0.669), all of the Cronbach's alpha values for the other composite measures were above 0.70.

Table 5
– PT-HSOPSC 2.0 Internal consistency reliability analysis

Composite Measures	Cronbach's alpha	Composite reliability
Teamwork	0.756	0.851
Staffing and Work Pace	0.626	0.726
Organizational learning – continuous improvement	0.800	0.846
Response to error	0.825	0.866
Supervisor, Manager, or Clinical Leader Support for Patient Safety	0.815	0.893
Communication About Error	0.872	0.925
Communication Openness	0.776	0.796
Reporting patient safety events	0.878	0.931
Hospital Management Support for Patient Safety	0.815	0.889
Handoffs and information exchange	0.669	0.800

Table 6 presents a comparative analysis of the internal consistency reliability, as measured by Cronbach's alpha coefficients, between the Portuguese version [PT-HSOPSC 2.0] and the original version of the Hospital Survey on Patient Safety Culture 2.0 [HSOPS 2.0].

The comparative analysis reveals notable similarities in the internal consistency reliability between the two versions. For composite measures such as “Teamwork” and “Response to error”, both versions demonstrate the same reliability and the composite measure Communication About Error also demonstrates high reliability in both versions, with alpha coefficients exceeding 0.8.

Table 6
– Comparative analysis of the internal consistency reliability between the Portuguese version and the original HSOPSC 2.0

Composites Measures	***Cronbach's alpha*** **PT_HSOPSC 2.0**	***Cronbach's alpha*** **HSOPS 2.0**
Teamwork	0.76	0.76
Staffing and Work Pace	0.63	0.67
Organizational Learning—Continuous Improvement	0.80	0.76
Response to Error	0.83	0.83
Supervisor, Manager, or Clinical Leader Support for Patient Safety	0.82	0.77
Communication About Error	0.87	0.89
Communication Openness	0.78	0.83
Reporting Patient Safety Events	0.88	0.75
Hospital Management Support for Patient Safety	0.82	0.77
Handoffs and Information Exchange	0.67	0.72

Construct validity

Figure 1 shows the results of the confirmatory factor analysis model. According to the obtained fit indices ($X^2/df = 4.64$, RMSEA = 0.05, CFI = 0.93, GFI = 0.90, TLI = 0.91, PCFI = 0.78, PGFI = 0.71), we can now state that the scale in question has adequate construct validity.

Table 7 displays the weight of each item's dimension. The results indicate that most items have a satisfactory factorial saturation (> 0.40), except for item A5 (this unit relies too much on temporary workers), which has a lower factorial load (0.329) due to its dimension. However, item A5 was retained because it still represents an acceptable value that does not compromise the construct validity.

Table 7
– PT-HSOPSC 2.0: factor loading

Item/dimension ratio			*Loading*
A9	<---	Teamwork (F1)	0,623
A8	<---	Teamwork (F1)	0,744
A1	<---	Teamwork (F1)	0,808
A11	<---	Staffing and work pace (F2)	0,732
A5	<---	Staffing and work pace (F2)	0,329
A3	<---	Staffing and work pace (F2)	0,470
A2	<---	Staffing and work pace (F2)	0,661
A14	<---	Organizational learning – continuous improvement (F3)	0,738
A12	<---	Organizational learning – continuous improvement (F3)	0,702
A4	<---	Organizational learning – continuous improvement (F3)	0,718
A13	<---	Response to error (F4)	0,712
A10	<---	Response to error (F4)	0,716
A7	<---	Response to error (F4)	0,673
A6	<---	Response to error (F4)	0,692
B3	<---	Supervisor, Manager, or Clinical Leader Support for Patient Safety (F5)	0,885
B2	<---	Supervisor, Manager, or Clinical Leader Support for Patient Safety (F5)	0,597
B1	<---	Supervisor, Manager, or Clinical Leader Support for Patient Safety (F5)	0,861
C1	<---	Communication About Error (F6)	0,796
C2	<---	Communication About Error (F6)	0,879
C3	<---	Communication About Error (F6)	0,824
C4	<---	Communication Openness (F7)	0,598
C5	<---	Communication Openness (F7)	0,583
C6	<---	Communication Openness (F7)	0,808
C7	<---	Communication Openness (F7)	0,627
D1	<---	Reporting patient safety events (F8)	0,901
D2	<---	Reporting patient safety events (F8)	0,868
F1	<---	Hospital Management Support for Patient Safety (F9)	0,879

Item/dimension ratio			*Loading*
F2	<---	Hospital Management Support for Patient Safety (F9)	0,825
F3	<---	Hospital Management Support for Patient Safety (F9)	0,624
F4	<---	Handoffs and information exchange (F10)	0,768
F5	<---	Handoffs and information exchange (F10)	0,823
F6	<---	Handoffs and information exchange (F10)	0,410

Convergent validity

The mean extracted variance [MEV] values indicate adequate convergent validity for all composite measures except for “Staffing and Work Pace”, which still exhibits a reasonably/acceptably convergent validity measure and should not be excluded from the construct (see Table 8).

Table 8
– PT-HSOPSC 2.0 Mean Extracted Variance

Composite Measures - Portuguese version of HSOPSC 2.0	**MEV**
Teamwork	0.659
Staffing and Work Pace	0.418
Organizational learning – continuous improvement	0.648
Response to error	0.620
Supervisor, Manager, or Clinical Leader Support for Patient Safety	0.741
Communication About Error	0.806
Communication Openness	0.571
Reporting patient safety events	0.559
Hospital Management Support for Patient Safety	0.732
Handoffs and information exchange	0.589

Divergent validity

As can be seen from Table 9, the composite measure "Teamwork" has sufficient divergent validity. The composite measure "Staffing and Work Pace" does not have divergent validity in relation to the composite measure "Organizational Learning - Continuous Improvement" and the composite measure "Response to error". The composite measure "Organizational Learning - Continuous Improvement" does not have divergent validity in relation to these composite measures: "Response to Error", "Supervisor, Manager, or Clinical Leader Support for Patient Safety", "Communication about Error", and "Openness of Communication". The composite measure "Response to Error" does not have divergent validity in relation

to these composite measures: "Teamwork", "Organizational Learning - Continuous Improvement", "Supervisor, Manager, or Clinical Leader Support for Patient Safety", and "Communication Openness".

The composite measure "Supervisor, Manager, or Clinical Leader Support for Patient Safety" has no divergent validity with respect to the composite measure "Organizational Learning - Continuous Improvement". The composite measure "Communication about errors" has sufficient divergent validity. The composite measure "Openness in communication" does not have sufficient divergent validity in relation to these composite measures: "Organizational Learning - Continuous Improvement", "Response to Error", "Supervisor, Manager or Clinical Leader Support for Patient Safety", and "Communication about Error". The composite measure "Reporting Patient Safety Events" has adequate divergent validity. The composite measure "Hospital Management Support for Patient Safety" has adequate divergent validity. The composite measure "Handoffs and Information Exchange" has adequate divergent validity.

Table 9
– PT-HSOPSC 2.0 divergent validity

Composite Measures	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10
F1	**0.659**									
F2	0.230	**0.418**								
F3	0.585	0.454	**0.648**							
F4	0.622	0.435	0.877	**0.620**						
F5	0.450	0.304	0.749	0.636	**0.741**					
F6	0.381	0.212	0.664	0.538	0.512	**0.806**				
F7	0.499	0.249	0.680	0.669	0.670	0.715	**0.571**			
F8	0.158	0.104	0.372	0.268	0.247	0.410	0.342	**0.559**		
F9	0.243	0.416	0.501	0.412	0.358	0.281	0.336	0.207	**0.732**	
F10	0.168	0.146	0.209	0.194	0.146	0.114	0.210	0.078	0.108	**0.589**

Note: Mean Extracted Variance (MEV) values are shown in bold.

Patient Safety Culture Assessment

In general, the composite measures considered most positive by the majority of healthcare professionals were "Teamwork" (72%); followed by " Supervisor, Manager, or Clinical Leader Support for Patient Safety " (67%); and "Handoffs and Information Exchange" (61%), which represent the strengths of the patient safety culture assessment. On the other hand, opportunities for improvement relate to the composite measure with the lowest percentage of positive responses, such as "Reporting Patient Safety Events" (38%) and "Hospital Management Support for Patient Safety" (39%), as shown in Table 10.

When professionals were asked to indicate the number of reports made in the last 12 months, it seems that there is no culture of reporting in all hospitals, where 78% of the professionals surveyed said that they had not made any reports in the last year.

Table 10
– Patient Safety Assessment

Composite measures	Average of Positive Responses PT-HSOPSC 2.0 (%)
Teamwork	72
Staffing and Work Pace	45
Organizational Learning—Continuous Improvement	52
Response to Error	45
Supervisor, Manager, or Clinical Leader Support for Patient Safety	67
Communication About Error	47
Communication Openness	58
Reporting Patient Safety Events	38
Hospital Management Support for Patient Safety	39
Handoffs and Information Exchange	61

Discussion

The Portuguese version of the Hospital Survey on Patient Safety Culture 2.0 (PT-HSOPSC 2.0) was meticulously translated and culturally adapted, and then rigorously evaluated. Since AHRQ provides guidelines for the translation of its surveys and does not foresee retroversion or analysis by a panel of experts, it was decided to follow the process of translation and adaptation of instruments described by Vilelas (2020), which follows the international guidelines for translation and adaptation of research instruments (12).

Following the methodological process of translation and evaluation of cultural and conceptual semantic equivalence of the survey, which included a panel of experts, it was concluded that all items were relevant and applicable to the Portuguese hospital context and none of the items were removed, in a similar manner to China, Brazil, Turkish and Indonesia (4, 16, 17, 18). However, item A5 was removed from the Korean version of HSOPS 2.0 (19). Therefore, Portuguese version maintained the original structure of HSOPS 2.0 to facilitate comparability with the original instrument, emphasizing the importance of maintaining consistency in composite measures and items. Maintaining fidelity to the original structure ensures comparability of results (11).

In general, the results of the analysis of the psychometric properties of the Portuguese version of HSOPSC 2.0 were positive, demonstrating good internal consistency and construct validity, as shown by the reliability estimates and model fit indices. Based on the Cronbach's alpha and composite reliability values obtained, these results indicate satisfactory internal consistency reliability. Notably, composite measures such as “Response to Error”, “Supervisor, Manager, or Clinical Leader Support for Patient Safety”, “Communication About Error”, “Reporting Patient Safety Events”, and “Hospital Management Support for Patient Safety” demonstrated particularly high reliability, with alpha coefficients exceeding 0.8, signifying robust consistency within the respective constructs. However, the Composite Measures "Staffing and Work Pace" and "Handoffs and Information Exchange" show lower reliability, but still reasonable since these composite measures where above 0.50 (13). Comparing these data with the results obtained with the original American version, it can be seen that the results overlap and that in the same dimensions "Staffing and Work Pace" and "Handoffs and Information Exchange", the Americans also showed lower reliability values.

Although an attempt was made to ensure the representativeness of the population through the participation of at least one hospital from each of the Regional Health Administration of mainland Portugal, the first limitation of the study is the use of convenience sampling.

Another limitation is the response rate obtained in the application of the questionnaire. Although the response rate in the United States of America was 48%, in the present study the response rates ranged from 2.29–55.98%, obtaining an average of 32.45%, which represents a very low adherence rate, especially if we consider Pronovost (2005). Future research should attempt to achieve higher adherence rates (20).

The role of patient safety culture in promoting the delivery of safe healthcare has become increasingly prominent and a priority in the Organization for Economic Co-operation and Development [OECD] countries and around the world. Interest in the relationship between the PSC and health outcomes is growing, and there is already some scientific evidence demonstrating the correlation between patient safety culture and improved health outcomes (5). PSC provides invaluable information about how patient safety is perceived within a healthcare organization. The study of seven Portuguese hospitals revealed that the dimensions with the highest positive percentages were “Teamwork” and “Supervisor, Manager, or Clinical Leader Support for Patient Safety”.

The future research directions suggested by this study include several key areas for further investigation.

HSOPSC complementary items: To improve patient safety and promote a healthier work environment for healthcare professionals, it is recommended to continue refining and validating PSC assessment tools. This includes incorporating complementary items such as those addressing Hospital Workplace Safety provided by AHRQ. Creating a healthy work environment for healthcare workers and improving the quality and safety of care are two mutually reinforcing areas.

Enhancing Reporting Culture: Given the low percentage of professionals reporting patient safety events in the last 12 months (78% reported no reports), future research could focus on strategies to improve and promote a culture of reporting within healthcare settings.

Exploring Organizational Support: Further studies could delve into how hospital management can better support patient safety initiatives beyond reactive responses to adverse events, as indicated by the findings that hospital management support for patient safety received a relatively low percentage of positive responses (39%).

Examining Communication Practices: Research focusing on communication aspects, such as openness, error communication, and information exchange during handoffs, could provide insights into how these factors influence patient safety culture within healthcare organizations.

Comparative Studies: Conducting comparative studies with other countries that have translated and adapted the HSOPSC 2.0, like China, Brazil, Turkey, and Indonesia, could offer cross-cultural insights into patient safety culture assessment methodologies and outcomes.

Longitudinal Studies: Longitudinal studies tracking changes in patient safety culture over time within hospitals could provide valuable information on the effectiveness of interventions and initiatives aimed at improving patient safety practices.

These future research directions aim to advance understanding, practices, and interventions related to patient safety culture within healthcare institutions based on the findings and implications of the current scientific work.

Conclusion

This study conducted a comprehensive assessment of patient safety culture in Portuguese hospitals by translating and adapting the HSOPS 2.0 survey to the Portuguese context and it highlights the importance of assessing patient safety culture in healthcare organizations.

Therefore, this study contributes significantly to enhancing patient safety culture assessment in Portuguese healthcare settings by updating and validating the Portuguese version of HSOPS 2.0. The findings from this study are crucial for ongoing efforts to improve patient safety practices, benchmarking initiatives, and quality enhancement strategies in Portuguese hospitals.

Abbreviations

AEV: Average Extracted Variance; AHRQ: Agency for Healthcare Research and Quality; AMOS: Analysis of Moment Structures; CFI: Comparative fit Index; DF: Degrees of freedom; GFI: Goodness Fit Index; HSOPSC: Hospital Survey on Patient Safety; IBM: International Business Machines Corporation; KMO: Kaiser-Meyer Olkin; NFI: Normed Fit Index; NNFI: Non Normed Fit Index; OECD: Organization for Economic Cooperatives and Development; PCFI: Parsimony Comparative Fit Index; PGFI: Parsimony

Goodness Fit Index; PSC: Patient Safety Culture; PT-HSOPSC: Portuguese version of Hospital Survey on Patient Safety Culture; RMSEA: Root Mean Square Error of Approximation; SPSS: Statistical Package for the Social Sciences; TLI: Tucker-Lewis Index; VIF: Variance Inflation factor; X^2:Chi-Square.

Declarations

Ethics approval and consent to participate

This study was approved by the Ethics Committee of the School of Health Technologies of Lisbon, Polytechnic Institute of Lisbon, and all participating hospitals. All methods were performed in accordance with the relevant guidelines and regulations.

Consent of publication

All authors consent to the publication of this work.

Availability of data and materials

The datasets used and/or analyzed during the current study are available from the corresponding author upon reasonable request.

Competing interests

The authors declare that there are no competing interests.

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Author Contributions

The authors contributed equally to this work and have read and approved the final manuscript.

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Figures

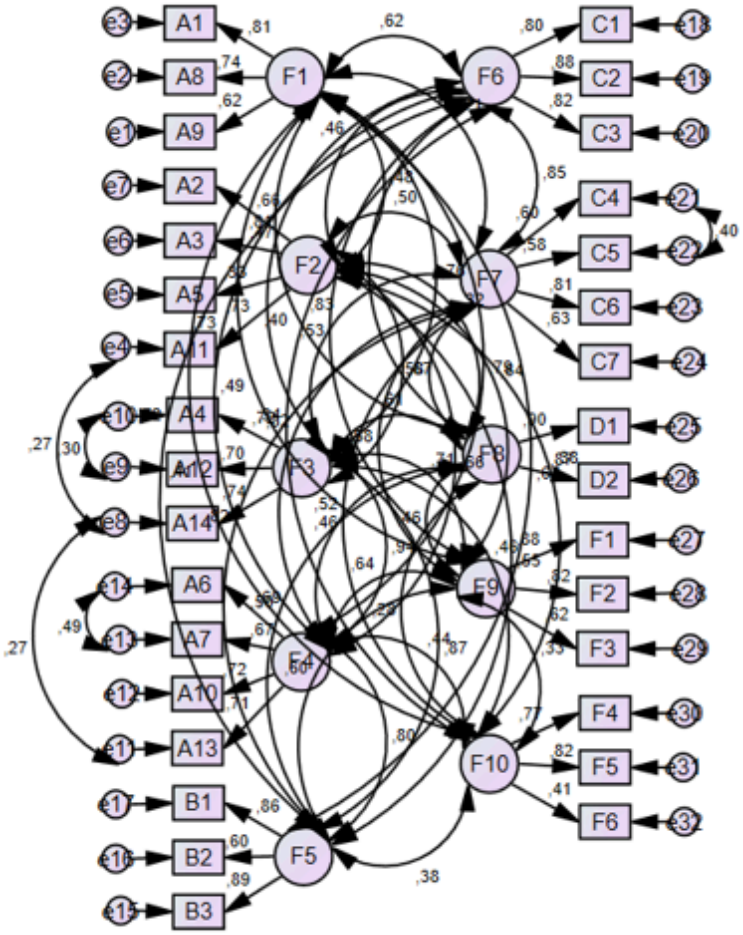

Figure 1

PT-HSOPSC 2.0: Confirmatory factor analysis model