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ORIGINAL ARTICLE

Validation of Questionnaire for Assessing Patient Safety Culture: Knowledge, Awareness, Attitudes and Practice among Medical Doctors

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ABSTRAK

Budaya keselamatan pesakit merupakan elemen penting dalam kualiti penjagaan kesihatan kerana ia mempengaruhi hasil klinikal dan kesejahteraan pesakit. Penilaian tahap amalan, kesedaran, pengetahuan dan sikap anggota kesihatan terhadap keselamatan pesakit adalah penting untuk memupuk budaya keselamatan yang kukuh. Memastikan instrumen pengukuran adalah sah dan boleh dipercayai adalah penting untuk mendapatkan data yang tepat dan berguna. Kajian ini memberi tumpuan kepada pengesahan soal selidik baru yang dibangunkan untuk menilai budaya keselamatan pesakit merentasi dimensi utama ini dan menyediakan alat piawai bagi menilai dan menambah baik amalan keselamatan dalam persekitaran penjagaan kesihatan. Pembangunan domain dan item telah dikenal pasti dan dirumuskan melalui kajian literatur secara sistematik. Pengesahan kandungan dilakukan oleh pakar-pakar, yang mendapati indeks kesahan kandungan (CVI) yang baik ialah relevan (0.988), kesederhanaan (1.000), kejelasan (0.914) dan kekaburan (0.901). Indeks kesahan muka (FVI) ialah 0.802 berdasarakan maklum balas pegawai perubatan. Nilai kappa yang diubahsuai menunjukkan julat nilai dari 0.52 hingga 1. Soal selidik yang dimuktamadkan telah diedarkan kepada 124 pegawai perubatan . Ujian sfera Bartlett menunjukkan keputusan yang sangat signifikan ($p < 0.001$), mengesahkan kesesuaian data untuk analisis faktor, manakal ukuran kecukupan sampel untuk semua konstruk yang diukur melebihi 0.6, memenuhi ambang yang diperlukan. Analisis faktor penerokaan (EFA) menunjukkan item yang dikekalkan mempunyai muatan faktor melebihi 0.6, menunjukkan kesesuaian mereka untuk mengukur konstruk. Instrumen ini juga mencapai nilai alpha Cronbach yang lebih besar daripada 0.8, menunjukkan konsistensi dalaman yang sangat baik. Secara keseluruhannya, penilaian EFA dan kebolehpercayaan mengesahkan keteguhan soal selidik yang dibangunkan. Keputusan ini memberikan gambaran baik tentang kebolehpercayaan dan keberkesanan instrumen untuk menilai budaya keselamatan pesakit merangkumi amalan, kesedaran, pengetahuan dan sikap dalam kalangan anggota penjagaan kesihatan. Soal selidik yang telah disahkan boleh digunakan sebagai piawai untuk menilai dan meningkatkan budaya keselamatan pesakit dalam persekitaran penjagaan kesihatan, seterusnya menyumbang kepada peningkatan kualiti penjagaan dan keselamatan pesakit.

Kata kunci*: Analisis faktor; budaya keselamatan pesakit; kesedaran keselamatan pesakit; pengetahuan keselamatan pesakit; sikap keselamatan pesakit*

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ABSTRACT

Patient safety culture is an essential element of healthcare quality, influencing clinical outcomes and patient well-being. Assessing healthcare professionals' practice, awareness, knowledge and attitudes toward patient safety are crucial for cultivating a culture of safety. This study focuses on validating a newly developed instrument designed to evaluate patient safety culture across these dimensions, providing a standardised tool for evaluating and improving safety practices in healthcare settings. A systematic literature review informed the development of the instrument's domains and items. Content validity was performed by subject matter experts, yielding good content validity index (CVI) values: relevance (0.988), simplicity (1.000), clarity (0.914) and ambiguity (0.901). Face validity index (FVI) was 0.802, based on feedback from medical officers. Modified kappa values ranged from 0.52 to 1.00, indicating fair to excellent agreement beyond chance. The finalised questionnaire was administered to 124 medical officers. The sphericity test by Bartlett was highly significant ($p < 0.001$), confirming the data's appropriateness for factor analysis, and sampling adequacy measures exceeded the 0.6 threshold. Exploratory factor analysis (EFA) showed that retained items had factor loadings above 0.6, affirming construct validity. The instrument demonstrated excellent internal consistency, with Cronbach's alpha exceeding 0.8 across constructs. Overall, the EFA and reliability assessment confirmed the robustness of the developed questionnaire. This result provides a good indication of reliability and the effectiveness of the instrument for assessing patient safety culture includes practices, awareness, knowledge and attitudes among healthcare professionals. This validated tool offers significant utility for assessing and improving patient safety culture among healthcare professionals, ultimately contributing to better patient care and safety outcomes in healthcare environments.

Keywords: Factor analysis; patient safety attitude; patient safety awareness; patient safety culture; patient safety knowledge

INTRODUCTION

Patient safety has emerged as a paramount concern in the global healthcare sector, since it influences patient outcomes, medical efficiency and the quality of service. The notion of patient safety pertains to the avoidance of harm to individuals receiving healthcare services (Mistri et al. 2023; Mitchell 2008; World Health Organisation 2009). Patient safety culture refers to the collective ideals, attitudes, perceptions and behaviours of healthcare personnel concerning safety matters inside their institutions and organisations (Ismail & Khalid 2022; Flin 2007; Weaver et al. 2013). This culture is important for minimising errors and enhancing the quality of care. Strong patient safety culture in health care institutions promotes open and honest communication, facilitates the reporting of safety risks, as well as the empowerment of healthcare providers to put patient safety above all else. A robust culture of patient safety within healthcare organisations promotes personnel to voice concerns, report safety issues and prioritise the patient's best interests (Brasaite et al. 2016a; Brasaite et al. 2016b; Mistri et al. 2023).

The foundation of strong patient safety culture lies in the awareness, knowledge, attitudes and practices of healthcare professionals (Ayyad et al. 2024). These elements shape how individuals perceive safety risks, adhere to safety protocols and participate in institutional initiatives to enhance patient safety (Institute of Medicine (US) Committee on Quality of Health Care in America 2000). Medical doctors, in particular, provide a vital function in this dynamic due to their direct interaction with patients, their involvement in decision-making, and their influence on organisational culture. Therefore, assessing and understanding their level of awareness, knowledge, attitudes and practices toward patient safety, which are essential for enhancing safety culture at both individual and organisational levels (Ismail & Khalid 2022).

To effectively assess and improve patient safety culture, institutions require reliable tools to measure the awareness, knowledge, attitudes and practices of healthcare professionals (Mistri et al. 2023; Sok May et al. 2024). Validated instruments are critical to gather objective information that can direct decision-making, pinpoint areas for improvement and monitor progress over time. These tools generally consist of structured questionnaires or surveys that evaluate multiple facets of patient safety culture, including adherence to safety protocols, communication practices, attitudes toward reporting errors and perceptions of leadership support for safety initiatives (Braun et al. 2020; Deilkas & Hofoss 2008; El-Jardali et al. 2011; Sexton et al. 2006).

The validation process of such instruments is crucial to ensure their reliability, validity and applicability to the specific healthcare context. A well-validated tool allows researchers and healthcare organisations to assess the true nature of patient safety culture within their institution, offering insights into strengths and weaknesses that may otherwise go undetected (Abd Hamid et al. 2016; Profit et al. 2012; Sexton et al. 2006; Singla et al. 2006). The process of validation involves several steps, including literature review, expert review, face validation, content validation and statistical analysis to confirm that the tool accurately measures the intended constructs. Through these steps, researchers ensure that the instrument is comprehensive, clear and culturally relevant for the intended demographic, and that it yields meaningful and actionable data (Singla et al. 2006; Taherdoost 2016).

Without reliable assessment tools, healthcare institutions may struggle to gauge their current safety culture, which hinders their ability to identify problem areas, evaluate interventions and track changes over time (Sok May et al. 2024). Tools that have undergone rigorous validation processes provide the data needed to inform patient safety improvement efforts, guide training programs and shape policy decisions that foster a better and safer healthcare atmosphere for both patients and healthcare practitioners (Hughes 2008; Mitchell 2008).

The development and validation of instruments to assess patient safety culture, particularly focusing on knowledge, awareness, attitudes and practices among medical doctors, is an essential step in improving healthcare safety. Through rigorous validation processes, such tools enable healthcare organisations to gain valuable insights into their safety culture, pinpoint areas for improvement and create strategies that align with best practices for patient safety (Bashir et al. 2024; Mistri et al. 2023). By accurately assessing and addressing the knowledge, awareness, attitudes and practices of medical professionals, healthcare institutions can foster a culture of safety that ultimately leads to greater patient outcomes and a more effective healthcare system (Lu et al. 2022). This study sought to explore and create a reliable tool for assessing patient safety awareness, knowledge, attitudes and practices among healthcare professionals utilising exploratory factor analysis (EFA). This involved testing the construct validity and internal reliability of the measuring instrument.

Existing instruments such as the Hospital Survey of Patient Safety Culture (HSOPSC) and Safety Attitude Questionnaire (SAQ) have been extensively used to assess patient safety culture and attitudes. However, these tools were developed in Western healthcare settings and may not fully address the contextual nuances of Malaysian public hospitals. Although the language of instruction in both cases is English, differences remain in policy emphasis, organisational structure, professional hierarchy and implementation of safety initiatives, such as the Malaysian Patient Safety Goals (MPSG). Moreover, few existing tools directly integrate all four components; knowledge, awareness, attitude, and practice within a single instrument. Thus, there is a need to develop a locally relevant, policy-aligned tool that reflects the realities of the Malaysian healthcare system.

Patient Safety Awareness, Knowledge and Attitudes

Patient safety awareness encompasses the extent to which healthcare professionals understand the risks associated with healthcare delivery, the principles underlying patient safety and the specific safety protocols implemented within their practice environment (Emanuel et al. 2008; World Health Organisation 2011). Awareness refers to the recognition of potential hazards, such as medication errors, infections, surgical complications or miscommunication and the understanding of the need to address these risks proactively. However, simply recognising safety risks is insufficient to foster a culture of safety; healthcare professionals must also possess the knowledge and skills required to mitigate these risks effectively (Rodziewicz et al. 2024).

Patient safety knowledge extends beyond mere awareness and involves understanding the clinical guidelines, protocols and best practices that reduce the likelihood of patient harm. This knowledge is typically acquired through education, training and continuous professional development (Kinnunen-Luovi et al. 2013; Madigosky et al. 2006). For example, medical doctors must understand the importance of hand hygiene, medication reconciliation, surgical safety checklists and other evidence-based practised aimed at mitigating errors and improving patient care. Other evidence-based practices are designed to prevent errors and enhance patient care. Knowledge empowers healthcare professionals to make informed decisions, manage risks and contribute to a safety-conscious work environment (Brasaite et al. 2016a; Wakefield et al. 2010).

Attitudes toward patient safety are another critical element of patient safety culture. Attitudes shape how healthcare professionals approach safety challenges, report incidents and collaborate with others to address safety issues (Sexton et al. 2006; Thomas et al. 2005). A positive attitude toward patient safety includes the belief that patient safety is a collective obligation encompassing everyone within a healthcare setting regardless of their role contributes to the overall safety of patients (Cabrera 1998; Siu et al. 2003; Rundmo 2000). A strong safety culture is fostered when medical staff have a proactive attitude, feel comfortable reporting safety concerns and are committed to learning from mistakes without fear of punitive consequences. However, negative attitudes, such as a reluctance to report errors or a belief that safety is solely the responsibility of management, can undermine safety efforts and contribute to a culture of silence, making it difficult to address safety risks effectively (Huang et al. 2007; Lee et al. 2010; Modak et al. 2007).

The Role of Practices in Patient Safety Culture

In addition to awareness, knowledge and attitudes, the actual practices of healthcare professionals are indispensable for ensuring patient safety (Ayyad et al. 2024; Zhang et al. 2022). Adherence to safety protocols, active participation in safety audits and involvement in quality improvement initiatives are vital practices that directly influence patient safety outcomes. For instance, routine safety checks, structured communication strategies (such as handoff protocols) and team-based decision-making can significantly reduce errors and enhance safety outcomes (Cho et al. 2022; Leape et al. 2002; Modak et al. 2007). Healthcare professionals' engagement in these practices not only reflects their commitment to patient safety but also aids in the continuous advancement of a safety-oriented environment (Agbar et al. 2023; Cho et al. 2022; Herrington & Hand 2019; Mohammed et al. 2022).

Furthermore, the frequency with which safety events are reported whether adverse events, near misses, or unsafe conditions reflects the level of practice within an institution. Reporting these events is critical for identifying systemic problems and initiating corrective actions (Lee & Harrison 2000; Woolever 2005). When healthcare professionals actively report and discuss safety incidents, it creates an opportunity for learning and system improvement, rather than placing blame on individuals. Thus, practices like reporting errors and participating in safety audits are key components of a safety culture that prioritises continuous improvement (Agbar et al. 2023; Shojania et al. 2001).

METERIALS AND METHODS

This research was undertaken to develop and explore the study tool, focusing on patient safety knowledge, awareness, attitudes and practices among medical doctors. The research employed a cross-sectional design to gather quantitative data via a self-administered online questionnaire. A systematic literature review was carried out to refine and validate the items used to measure the constructs. Content validation was performed by subject matter experts, with the content validity index (CVI) computed. Face validity index (FVI) was determined following face validation by medical officers. The finalised items was distributed to randomly selected 124 medical officers through online questionnaire. Spielberger and Gorsuch (1983) recommended a minimum sample size of 100 to obtain meaningful findings for EFA. Kaiser-Meyer-Olkin (KMO) test was utilised to evaluate the appropriateness of the sample size for analysis, with a KMO value approaching unity being preferable (Awang 2012; Al-Khamaiseh et al. 2020). The data were subsequently analysed using EFA with IBM-SPSS version 28.0 (IBM Corp., Armonk, NY, USA).

Hospital Selection and Participants

First of all, hospital sampling was done randomly from each zone in Malaysia, namely the northern, southern, eastern, western and Sabah/Sarawak zones. Out of the 45 Ministry of Health (MOH) hospitals that were running the patient safety awareness program, one hospital from each zone was randomly selected, thus 5 hospitals were involved in this study. The 5 hospitals were Hospital V, Hospital W, Hospital X, Hospital Y and Hospital Z.

Sampling Unit

All medical officers working in selected public hospitals of the Ministry of Health and fulfilled the criteria. The inclusion criterias included (i) fully registered under the Malaysian Medical Council at least 6 months before the study period began; (ii) had undergone the patient safety awareness course program; and (iii) clinical staff. The exclusion criterias were (i) not working full-time (attachments and practical staff); (ii) not a Malaysian citizen; (iii) officers on long leave (maternity leave) – 90 days; and (iv) did not agree to participate in the study

Patient safety awareness course mentioned in inclusion criteris referred to the official program implemented under the Malaysian Patient Safety Goals (MPSG) initiative by the Ministry of Health. This program comprised structured learning sessions covering key domains such as medication safety, infection prevention, effective communication, adverse event reporting and building a positive safety culture. The course was typically delivered via lectures, workshops, or e-learning modules and was mandatory for junior medical doctors in selected MOH hospitals.

The sample frame for this study was the list of the doctors who fulfilled the inclusion criteria above. All of them was listed and computed in the Excel by Human Resource Department at each hospital. From the sample frame, the respondents from each hospital had been selected using proportionate stratified sampling method. To ensure that the sample size chosen from each hospital was proportional to the total number of medical officers meeting the criteria within that institution across the study population, a total of 124 medical officers who fulfilled these criteria were identified and randomly selected from list. To maintain the integrity and representativeness of the primary research, these participants were excluded from the main study sample. The respondents had access to the survey between Jul 2024 to August 2024.

The questionnaire survey was administered digitally using Google Forms. Participants were provided with individualised QR codes printed on to access the survey. This QR code was printed on paper-based handouts and physically distributed by the research assistants during departmental briefings and shift handovers. These handouts also contained a brief introduction to the study. Upon scanning the QR codes with their smartphones or mobile devices, respondents were directed to an online platform where they could complete the survey. The Google Form questionnaire contained an information sheet outlining the study overview and instructions for completing the survey. Participants were also assured of the confidentiality of their data and the anonymity of their responses prior to starting the survey. To ensure the privacy of participants, personal data was anonymised by removing identifiable information such as names and contact details. The survey may only be submitted by participants who answered every question in each form section. Additionally, participants were permitted to exit their involvement in the study at any moment while filling out the questionnaires until they clicked the "submit" button. The system automatically discarded incomplete questionnaires at the time of withdrawal. The data collected was strictly used for research purposes. This method streamlined the data collection, reduced paper usage and enabled efficient response tracking and analysis.

Instrument

Existing research instruments were adapted for this study, with certain items revised to better align with the specific research context. The methodologies demonstrated that validating the modified instrument was crucial, notably when the instrument was initially tailored for a population with cultural and industrial backgrounds that differed from those in the current study (Bahkia et al. 2019; Bahkia et al. 2020; Hoque et al. 2018; Rahlin et al. 2019; Shkeer & Awang 2019). Furthermore, re-evaluating items through EFA was essential when adopting existing instruments with modifications in a new setting (Awang 2010; Awang 2015; Awang 2018; Mohamad et al. 2018). This step was necessary as certain items may not be applicable or relevant in the new setting and current scenario.

To address these concerns, we conducted a pre-test followed by a pilot study and employed EFA on the items to confirm their validity and reliability. The items were developed, modified and operationalised based on the Behavioural Model: The Impact of Safety Training on Safety Culture Practices (Tharenou et al. 2007). It was also in line with the Safety Reciprocity Model which used social cognitive theory (SCT) (Bandura 1977; Bandura 1986; Bandura 1991)and theory of planned behaviour (TPB) (Ajzen 1991) to measure medical officers' practice, awareness, knowledge and attitudes toward patient safety.

Item Generation

A systematic literature search was performed to develop the items used in the instrument. Previous studies were searched via Scopus, PubMed and Web of Science for articles published from 2005 to 2025. The keywords used were "patient safety culture", "patient safety awareness", "attitude", "knowledge", and "healthcare professionals." A total of 247 relevant articles were reviewed. Existing instruments including the Hospital Survey on Patient Safety Culture (HSOPSC), WHO Patient Safety Awareness Tool and Safety Attitudes Questionnaire (SAQ) were critically examined. Relevant constructs and items were then adapted and refined to suit the Malaysian healthcare context, ensuring both theoretical grounding and contextual relevance.

All items utilised to measure the construct of the present study were adopted and adapted from questionnaires of previous studies on patient safety culture practices and the impact of patient safety awareness programs with modifications and revisions to fit the context of the current study. This was to ensure the validity of the questions measuring each construct that was used in this study. The original authors of the questionnaires had given permission for their questionnaires to be used in the current study. As stated above, the survey questionnaires were adapted and modified to achieve better fit with the context of this study. In this study, the instrument structure was divided into five main sections and was developed in English language.

The first section (Section A) of the instrument consisted of questions based on the respondents demographic profile such as age, gender, race, length of work experience and area of work. The second section (Section B) consisted of 44 items which related to patient safety culture practices. This section was adapted from the HSOPSC questionnaire issued by Agency for Healthcare Research and Quality (AHRQ). This instrument had strong construct validity and internal consistency, possessed favourable psychometric properties, correlated with clinical and patient outcomes (AHRQ 2003; AHRQ 2015) and had been adapted by many other studies measuring patient safety culture (Ali et al. 2018; Brborović et al. 2014; Chen & Li 2010; El-Jardali et al. 2010; Ramos & Calidgid 2018). This Part B contained 44 items. Respondents needed to answer these 44 items based on a 5-point Likert scale.

For Section C, it concerned the impact of the program, namely the level of awareness of patient safety, where this item was adapted from a questionnaire issued by the World Health Organisation (2011) through the Patient Safety Curriculum Guidelines. This section contained 15 items on patient safety awareness. Next, for Section D contained of 7 items measuring the level of knowledge about patient safety, and Section E contained of 15 items to measure patient safety attitudes. Section D and E were adapted from a questionnaire conducted at the Asella Referral and Learning Hospital, Utopia (Wake et al. 2021). Section C, D and E also used 5-point Likert scale. As stated above, the questionnaire instrument was based on constructs that had been validated in previous studies that had been standardised, adapted and modified according to the context of this study. A comprehensive literature review was conducted to identify constructs that were suitable for adaptation and reference. A summary of item generation process was shown in the flow chart (Figure 1).

Content Validity and Face Validity

The pre-test was essential in research utilising survey questionnaires as a data collection method (Hashim et al. 2022; Ikart 2019). Expert input, clarification and verification were sought to assess content and criterion validity, followed by pre-testing among the potential population for face validity. Pre-testing aimed to proactively identify and resolve concerns or issues related to the questionnaire, ensuring the detection and correction of instrument or design flaws (Fernández-Gómez 2020).

Three experts, including representatives from the Patient Safety Unit, Quality Healthcare Division, Ministry of Health representatives and Public Health specialists, were recruited to validate the instrument's content and criterion validity stated that content validation through expert judgment involved seeking the opinions of

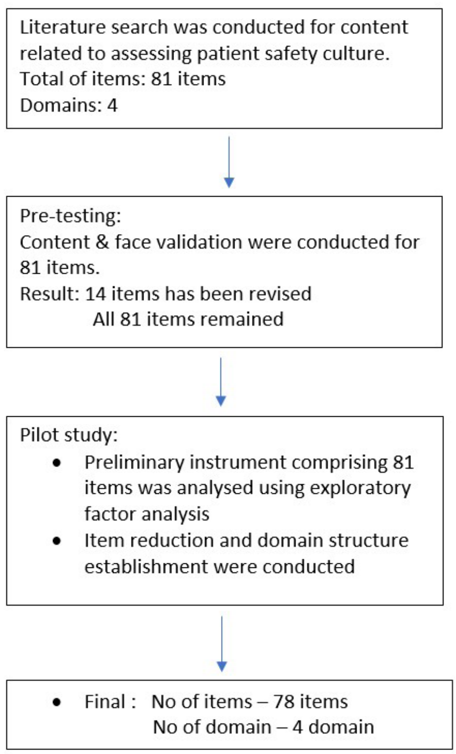

FIGURE 1: Item generation process flow chart

individuals with substantial expertise in a specific field (Fernández-Gómez 2020). These recognised experts provided invaluable insights, evidence and evaluations, enriching the questionnaire's credibility and relevance in line with their competencies.

The instruments' content validity was established using the CVI method, whereby the first version of the instrument was emailed to the panel experts to determine the relevance, simplicity, clarity and ambiguity of patient safety knowledge, awareness, attitude and practice domain items (Emmanuel & Clow 2017; Yusoff 2019). To prevent a neutral point, a 4-point scale was employed (Yusoff 2019). By completing the questionnaire's remark area, the experts were also asked to provide their opinions on the items. The pivotal role of these experts involved elucidating, clarifying, augmenting, supplementing and modifying essential aspects, as emphasised by Zun et al. (2019) and Fernández-Gómez (2020), and ensuring that the instrument was both relevant and easy to comprehend.

Based on the experts opinion and recommendations, the requisite modification was made. As suggested by experts, items with an I-CVI of ≥ 0.78 retained and those with I-CVI ≤ 0.70 were revised or removed (Yusoff 2019). The scale-level CVI based on average methods (S-CVI/Ave), scale-level CVI based on universal agreement method (S-CVI/UA), probability of change agreement (Pc) and modified kappa (K) were computed (Yusoff 2019). The preliminary form of the instrument was created and tested for face validity.

Following the content validation, face validation was performed to evaluate the clarity and comprehensibility of the instructions by calculating the FVI (Yusoff 2019). The face validation process involved 26 respondents, specifically medical officers who fulfilled the criteria mentioned before. The researcher personally distributed the second version of the instrument with a face validation form at the hospitals. The clarity of each item was rated by respondents using a 4-point scale: 1-meaning not clear, 2-meaning somewhat clear, 3-meaning quite clear and 4-meaning highly clear (Yusoff 2019). Additionally, the respondents could approach the researcher or provide written comments on items they found challenging to comprehend or that necessitated modifications.

The CVI and FVI were computed adhering to the proposed guidelines and parameters (Polit & Beck 2006; Yusoff 2019). Subsequently, the instrument was modified in response to the reviewers' feedback and comments, resulting in its final refinement. After the validation testing, the questionnaire was distributed among the study population in the study. The data collected during this phase were analysed using EFA, which provided insights into the validity and reliability of the survey items, thereby informing necessary adjustments and improvements.

Exploratory Factor Analysis Procedure

This study adapted instruments from prior research, making necessary adjustments to certain items in order to meet the requirements of the current study. To examine the dimensionality of potentially modified items, EFA was performed for all constructs. Using pilot data, the EFA was employed to identify and evaluate the usefulness and dimensionality of each item in relation to its construct. The analysis involved calculating the mean score, standard deviation and factor loadings for each item, as well as determining the total variance explained for each individual construct. Additionally, the dimensionality of items within their respective components was also examined through EFA, and Cronbach's alpha was computed to assess the internal consistency of each construct (Baistaman et al. 2020; Rahlin et al. 2019).

Bartlett's test of sphericity (BTS) and the KMO measure of sample adequacy were utilised to evaluate the data's appropriateness for factor analysis. A significant BTS result and a KMO value greater than 0.60 indicated that the data was appropriate for factor analysis (Al-Khamaiseh et al. 2019; Awang 2010; Hair et al. 2019; Hoque et al. 2018).

Internal Reliability

Reliability analysis was a method employed to examine the measurement items associated with each construct and determine the degree to which they were devoid of errors. To assess the internal reliability of each construct, Cronbach's alpha was employed. This metric assessed the efficacy of a collection of items in evaluating the corresponding construct. Internal reliability was achieved when Cronbach's alpha was greater than 0.7, as recommended by Awang (2010) and Awang (2015). A summary of the validation process was shown in the flow chart (Figure 2).

RESULTS

Demographic Characteristic

Table 1 showed the the characteristics of the respondents who participated in the study. Majority of the respondents aged below 41 years old. Half of them were female (51.6%), malay (52.4%), with working experience of 1-5 years (63%). Nearly half of the respondents were employed in the surgical area (49.2%) while the remainder were in medical area (50.8%).

Item Generation

A systematic literature search revealed 247 papers utilising the pertinent keywords, of which 32 were relevant to our research. After analysing the relevant articles, 112 items were created for the instrument based on four domains: practice, awareness, knowledge and attitude. Following discussion with the panelists resulted in the removal of 31 items due to confusion and overlapping questions. The instrument draft comprised 81 items: 44 items in the patient safety culture practice domain, 15 items in the patient safety awareness domain, 7 items in the patient

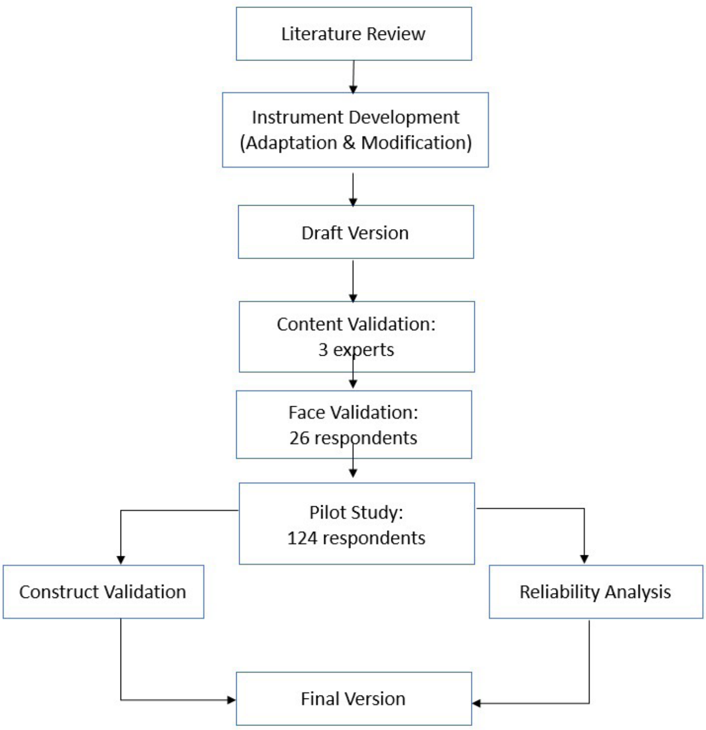

FIGURE 2: Validation process flow chart

TABLE 1: Demographic characteristics of respondents

Characteristics	Respondents (n= 124)	
	n	Frequency (%)
Age (years)		
Age group		
Below 31	62	50.0
31-40	60	48.4
41-50	2	1.6
More than 50	0	0
Gender		
Male	60	48.4
Female	64	51.6
Race		
Malay	65	52.4
Chinese	28	22.6
Indian	27	21.8
Others	4	3.2
Length of working		
Less than 1 year	0	0
1-5 years	78	63.0
6-10 years	46	37.0
Field of working area	63	50.8
Medical based	61	49.2
Surgical based		

safety knowledge domain and 15 items in the patient safety attitude domain.

Content Validation and Face Validation Result

Three experts assessed the content validity of the preliminary instrument for the domains of practise, awareness, knowledge and attitude. The content validity index (I-CVI), scale-level CVI based on average methods (S-CVI/Ave), scale-level CVI based on universal agreement method (S-CVI/UA), probability of change agreement (Pc), and Modified kappa (K) was computed for every domain based on relevance, simplicity, clarity and ambiguity (Table 2 & 3). Seven items were revised based on the results as their I-CVI values were below 0.78. Seven other items were revised in response to the experts' commentss and suggestions. The final draft of the instrument remain 81 items. Subsequently, 26 medical officials completed the draft instrument within 15-20 minutes, with no items left unanswered. Table 2 showed that S-FVI/AVE value was 0.967 and S-FVI/ UA value was 0.802. Based on the values, it can be concluded that S-FVI/Ave and S-FVI/ UA met satisfactory level. The findings indicated that the tool was deemed clear and easy to understand. All 81 items stayed unchanged and no modification has been done, as there were no comments or suggestions from the participants.

Factor Analysis

The items were developed, modified and operationalised based on the Behavioural Model: The Impact of Safety Training on Safety Culture Practices (Tharenou et al. 2007). The constructs were patient safety knowledge, patient safety awareness, patient safety attitude and patient

TABLE 2: Content validity and face validity

Construct	Items	S-CVI/AVE S-CVI/UA	S-FVI/AVE S-FVI/ UA
Patient safety culture practice	44	S-CVI/AVE Relevant (0.996) Simplicity (1.000)	
Patient safety awareness	15	Clarity (0.971) Ambiguity (0.968)	0.967 0.802
Patient safety knowledge	7	S-CVI/UA Relevant (0.988) Simplicity (1.000)	(n = 26)
Patient safety attitude	15	Clarity (0.914) Ambiguity (0.901)	

TABLE 3: Content validity index, Pc and Modified Kappa of each item for relevance, clarity, simplicity and ambiguity

Items	**Relevancy**			**Simplicity**			**Clarity**			**Ambiguity**		
	I-CVI	**Pc**	**K**	**I-CVI**	**Pc**	**K**	**I-CVI**	**Pc**	**K**	**I-CVI**	**Pc**	**K**
1	1.0	0.125	1.00	1.0	0.125	1.00	1.0	0.125	1.00	1.0	0.125	1.00
2	1.0	0.125	1.00	1.0	0.125	1.00	1.0	0.125	1.00	1.0	0.125	1.00
3	1.0	0.125	1.00	1.0	0.125	1.00	1.0	0.125	1.00	1.0	0.125	1.00
4	1.0	0.125	1.00	1.0	0.125	1.00	1.0	0.125	1.00	1.0	0.125	1.00
5	1.0	0.125	1.00	1.0	0.125	1.00	1.0	0.125	1.00	1.0	0.125	1.00
6	1.0	0.125	1.00	1.0	0.125	1.00	1.0	0.125	1.00	1.0	0.125	1.00
7	1.0	0.125	1.00	1.0	0.125	1.00	1.0	0.125	1.00	1.0	0.125	1.00
8	1.0	0.125	1.00	1.0	0.125	1.00	1.0	0.125	1.00	1.0	0.125	1.00
9	1.0	0.125	1.00	1.0	0.125	1.00	1.0	0.125	1.00	1.0	0.125	1.00
10	1.0	0.125	1.00	1.0	0.125	1.00	0.7	0.375	1.00	0.7	0.375	1.00
11	1.0	0.125	1.00	1.0	0.125	1.00	1.0	0.125	1.00	1.0	0.125	1.00
12	1.0	0.125	1.00	1.0	0.125	1.00	1.0	0.125	1.00	1.0	0.125	1.00
13	1.0	0.125	1.00	1.0	0.125	1.00	1.0	0.125	1.00	1.0	0.125	1.00
14	1.0	0.125	1.00	1.0	0.125	1.00	1.0	0.125	1.00	1.0	0.125	1.00
15	1.0	0.125	1.00	1.0	0.125	1.00	1.0	0.125	1.00	1.0	0.125	1.00
16	1.0	0.125	1.00	1.0	0.125	1.00	1.0	0.125	1.00	1.0	0.125	1.00
17	1.0	0.125	1.00	1.0	0.125	1.00	1.0	0.125	1.00	1.0	0.125	1.00
18	1.0	0.125	1.00	1.0	0.125	1.00	1.0	0.125	1.00	1.0	0.125	1.00
19	1.0	0.125	1.00	1.0	0.125	1.00	1.0	0.125	1.00	1.0	0.125	1.00
20	1.0	0.125	1.00	1.0	0.125	1.00	1.0	0.125	1.00	1.0	0.125	1.00
21	1.0	0.125	1.00	1.0	0.125	1.00	1.0	0.125	1.00	1.0	0.125	1.00
22	1.0	0.125	1.00	1.0	0.125	1.00	1.0	0.125	1.00	1.0	0.125	1.00
23	1.0	0.125	1.00	1.0	0.125	1.00	1.0	0.125	1.00	1.0	0.125	1.00

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Items	Relevancy			Simplicity			Clarity			Ambiguity		
	I-CVI	Pc	K	I-CVI	Pc	K	I-CVI	Pc	K	I-CVI	Pc	K
24	1.0	0.125	1.00	1	0.125	1.00	1.0	0.125	1.00	1.0	0.125	1.00
25	1.0	0.125	1.00	1	0.125	1.00	1.0	0.125	1.00	1.0	0.125	1.00
26	1.0	0.125	1.00	1	0.125	1.00	1.0	0.125	1.00	1.0	0.125	1.00
27	1.0	0.125	1.00	1	0.125	1.00	1.0	0.125	1.00	1.0	0.125	1.00
28	1.0	0.125	1.00	1	0.125	1.00	1.0	0.125	1.00	1.0	0.125	1.00
29	1.0	0.125	1.00	1	0.125	1.00	1.0	0.125	1.00	1.0	0.125	1.00
30	1.0	0.125	1.00	1	0.125	1.00	1.0	0.125	1.00	1.0	0.125	1.00
31	1.0	0.125	1.00	1	0.125	1.00	1.0	0.125	1.00	1.0	0.125	1.00
32	1.0	0.125	1.00	1	0.125	1.00	1.0	0.125	1.00	1.0	0.125	1.00
33	1.0	0.125	1.00	1	0.125	1.00	0.7	0.375	0.52	0.7	0.375	0.52
34	1.0	0.125	1.00	1	0.125	1.00	0.3	0.375	-0.12	0.3	0.375	-0.12
35	1.0	0.125	1.00	1	0.125	1.00	0.7	0.375	0.52	0.7	0.375	0.52
36	0.7	0.375	0.52	1	0.125	1.00	0.3	0.375	-0.12	0.3	0.375	-0.12
37	1.0	0.125	1.00	1	0.125	1.00	1.0	0.125	1.00	1.0	0.125	1.00
38	1.0	0.125	1.00	1	0.125	1.00	1.0	0.125	1.00	1.0	0.125	1.00
39	1.0	0.125	1.00	1	0.125	1.00	1.0	0.125	1.00	1.0	0.125	1.00
40	1.0	0.125	1.00	1	0.125	1.00	1.0	0.125	1.00	1.0	0.125	1.00
41	1.0	0.125	1.00	1	0.125	1.00	1.0	0.125	1.00	1.0	0.125	1.00
42	1.0	0.125	1.00	1	0.125	1.00	1.0	0.125	1.00	1.0	0.125	1.00
43	1.0	0.125	1.00	1	0.125	1.00	1.0	0.125	1.00	1.0	0.125	1.00
44	1.0	0.125	1.00	1	0.125	1.00	1.0	0.125	1.00	1.0	0.125	1.00
45	1.0	0.125	1.00	1	0.125	1.00	1.0	0.125	1.00	1.0	0.125	1.00
46	1.0	0.125	1.00	1	0.125	1.00	1.0	0.125	1.00	1.0	0.125	1.00

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Items	Relevancy			Simplicity			Clarity			Ambiguity		
	I-CVI	Pc	K	I-CVI	Pc	K	I-CVI	Pc	K	I-CVI	Pc	K
47	1.0	0.125	1.00	1.0	0.125	1.00	1.0	0.125	1	1.0	0.125	1.00
48	1.0	0.125	1.00	1.0	0.125	1.00	1.0	0.125	1	1.0	0.125	1.00
49	1.0	0.125	1.00	1.0	0.125	1.00	1.0	0.125	1	1.0	0.125	1.00
50	1.0	0.125	1.00	1.0	0.125	1.00	1.0	0.125	1	1.0	0.125	1.00
51	1.0	0.125	1.00	1.0	0.125	1.00	1.0	0.125	1	1.0	0.125	1.00
52	1.0	0.125	1.00	1.0	0.125	1.00	1.0	0.125	1	0.7	0.375	0.52
53	1.0	0.125	1.00	1.0	0.125	1.00	1.0	0.125	1	1.0	0.125	1.00
54	1.0	0.125	1.00	1.0	0.125	1.00	1.0	0.125	1	1.0	0.125	1.00
55	1.0	0.125	1.00	1.0	0.125	1.00	1.0	0.125	1	1.0	0.125	1.00
56	1.0	0.125	1.00	1.0	0.125	1.00	1.0	0.125	1	1.0	0.125	1.00
57	1.0	0.125	1.00	1.0	0.125	1.00	1.0	0.125	1	1.0	0.125	1.00
58	1.0	0.125	1.00	1.0	0.125	1.00	1.0	0.125	1	1.0	0.125	1.00
59	1.0	0.125	1.00	1.0	0.125	1.00	1.0	0.125	1	1.0	0.125	1.00
60	1.0	0.125	1.00	1.0	0.125	1.00	1.0	0.125	1	1.0	0.125	1.00
61	1.0	0.125	1.00	1.0	0.125	1.00	1.0	0.125	1	1.0	0.125	1.00
62	1.0	0.125	1.00	1.0	0.125	1.00	1.0	0.125	1	1.0	0.125	1.00
63	1.0	0.125	1.00	1.0	0.125	1.00	1.0	0.125	1	1.0	0.125	1.00
64	1.0	0.125	1.00	1.0	0.125	1.00	1.0	0.125	1	1.0	0.125	1.00
65	1.0	0.125	1.00	1.0	0.125	1.00	1.0	0.125	1	1.0	0.125	1.00
66	1.0	0.125	1.00	1.0	0.125	1.00	1.0	0.125	1	1.0	0.125	1.00
67	1.0	0.125	1.00	1.0	0.125	1.00	1.0	0.125	1	1.0	0.125	1.00
68	1.0	0.125	1.00	1.0	0.125	1.00	1.0	0.125	1	1.0	0.125	1.00
69	1.0	0.125	1.00	1.0	0.125	1.00	1.0	0.125	1	1.0	0.125	1.00

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Items	Relevancy			Simplicity			Clarity			Ambiguity		
	I-CVI	Pc	K	I-CVI	Pc	K	I-CVI	Pc	K	I-CVI	Pc	K
70	1.0	0.125	1.00	1.0	0.125	1.00	1.0	0.125	1.00	1.0	0.125	1.00
71	1.0	0.125	1.00	1.0	0.125	1.00	1.0	0.125	1.00	1.0	0.125	1.00
72	1.0	0.125	1.00	1.0	0.125	1.00	1.0	0.125	1.00	1.0	0.125	1.00
73	1.0	0.125	1.00	1.0	0.125	1.00	1.0	0.125	1.00	1.0	0.125	1.00
74	1.0	0.125	1.00	1.0	0.125	1.00	1.0	0.125	1.00	1.0	0.125	1.00
75	1.0	0.125	1.00	1.0	0.125	1.00	1.0	0.125	1.00	1.0	0.125	1.00
76	1.0	0.125	1.00	1.0	0.125	1.00	1.0	0.125	1.00	1.0	0.125	1.00
77	1.0	0.125	1.00	1.0	0.125	1.00	1.0	0.125	1.00	1.0	0.125	1.00
78	1.0	0.125	1.00	1.0	0.125	1.00	1.0	0.125	1.00	1.0	0.125	1.00
79	1.0	0.125	1.00	1.0	0.125	1.00	1.0	0.125	1.00	1.0	0.125	1.00
80	1.0	0.125	1.00	1.0	0.125	1.00	1.0	0.125	1.00	1.0	0.125	1.00
81	1.0	0.125	1.00	1.0	0.125	1.00	1.0	0.125	1.00	1.0	0.125	1.00

I-CVI: Item-level content validity index; Pc: Probability of chance agreement; K: Modified kappa statistic (or kappa coefficient) safety culture practise. Table 4 displayed the mean response, standard deviation and item statement for every item of each construct.

The EFA used principal component analysis (PCA) for these items to examine the constructs adapted from the Behavioural Model. Table 5 demonstrates that the BTS results were significant ($p < 0.05$). In addition, the KMO measure of sampling adequacy surpassed the minimum requirement of 0.6 suggested by Awang (2010) and Bahkia et al. (2019), indicating that the sample size was adequate (Bahkia et al. 2019; Hoque et al. 2018; Noor et al. 2015; Shkeer & Awang 2019). The combined evidence from the significant BTS and the KMO measure > 0.6 strongly supported the suitability and adequacy of the dataset for factor analysis.

Exploratory Factor Analysis for Patient Safety Culture Practice Construct

The first construct was patient safety culture practice (AB) construct which was measured using 44 items (AB1-AB44). The mean scores and standard deviations of each item demonstrated a consistent score distribution, as the standard deviation for each item was < 1.5. EFA was conducted using the PCA extraction method with varimax (variation maximisation) rotation for the five items to assess the AB construct. Table 5 showed that the BTS was significant ($p < 0.05$), and the KMO measure of sampling adequacy was 0.921, surpassing the lower threshold of 0.6. This result suggested that the sample size was adequate, as indicated by Awang (2010), Awang (2015), Rahlin et al. (2019) and Shkeer and Awang (2019).

The significant BTS result and KMO above 0.6 confirmed the adequacy of the dataset (Baistaman et al. 2020; Yahaya et al. 2018). The EFA had retrieved five dimensions or components of the AB construct, with eigenvalues of 13.059 for component 1, 2.121 for component 2, 1.308 for component 3, 1.136 for component 4 and 1.076 for component 5, as presented in Table 6. This indicated that the items were categorised into five components for subsequent analysis. The total variation explained was 71.920%, as demonstrated in Table 6.

Table 7 demonstrated that the EFA procedure had identified five components. Every component contained specific quantity of items together with their corresponding factor loading. In current study, items with a factor loading exceeding 0.6 were maintained, as this signified their efficacy in measuring the specific construct (Awang 2010; Bahkia et al. 2019; Hoque et al. 2018). The aforementioned rotated component matrix indicated that only 26 items possessed a factor loading exceeding 0.6; items with a factor loading below 0.6 were eliminated. Consequently, only 26 items were included for subsequent research across five dimensions or components of the AB construct.

Exploratory Factor Analysis for Patient Safety Awareness Construct

For the second construct, patient safety awareness (TK) construct was measured using fifteen items (TK1–TK15), as detailed in Table 4, which also displayed the mean response, standard deviation and item statement of each item. The mean scores and standard deviations for each item exhibited a consistent score distribution, with the standard deviation for each item being less than 1.5. To evaluate the TK construct, EFA was performed using the PCA extraction method with varimax (variation maximisation) rotation for the fifteen items. Table 5 showed that the BTS was significant ($p < 0.05$), and the KMO measure of sampling adequacy was 0.827, surpassing the lower threshold of 0.6. This result suggested that the sample size was adequate, as indicated by Rahlin et al. (2019) and Shkeer & Awang (2019). The significant BTS result and KMO above 0.6 confirmed the adequacy of the dataset. Result revealed the emergence of two components from the EFA, identifying the respective items within this component (Baistaman et al. 2020).

The total variance explained (TVE) for the TK construct was 63.15%, as shown in Table 8, which was well above the minimum acceptable threshold of 60% (Hoque & Zainudin 2016;

TABLE 4: Mean and standard deviation for every item

Construct	Items	Summary of item statement	Mean	Std. Deviation[a]
Patiet safety knowledge	TP1	I know different types of human error.	3.65	0.998
	TP2	I know the factors contributing to human error.	3.63	0.801
	TP3	I know the factors influencing patient safety.	3.61	0.793
	TP4	I know the ways of speaking up about error.	3.57	0.876
	TP5	I know what should happen if an error is made.	3.66	0.864
	TP6	I know how to report an error.	3.81	1.026
	TP7	I know the role of healthcare organisations (e.g. hospitals, 1 2 general practitioners) in error reporting.	3.56	0.922
Patient safety awareness	TK1	Errors are common among healthcare workers	4.10	0.801
	TK2	In my country there is a safe system of healthcare for patients.	4.15	0.762
	TK3	Medical error can occur in daily practice.	3.72	0.976
	TK4			
	TK5	I am confident about speaking to someone who is showing a lack of concern for a patient's safety.	3.71	0.872
	TK9	If I keep learning from my mistakes, I can prevent incidents.	4.04	0.859
	TK10	Acknowledging and dealing with my errors will be an important part of my job.	3.91	0.937
	TK11	Errors are common among healthcare workers.	4.24	0.726
	TK12	In my country there is a safe system of healthcare for patients.	4.31	0.640
	TK14	Healthcare staff receive training in patient safety.	3.84	0.940
	TK15	I am confident about speaking to someone who is showing a lack of concern for a patient's safety.	3.80	1.067
Patient safety attitude	SK1	Nurse input is well received in this clinical area.	4.05	0.731
	SK2	In this clinical area, it is easy to speak up if I perceive a problem with patient care.	3.89	0.857
	SK3	Disagreements in this clinical area are resolved appropriately..	3.80	0.892
	SK4	I have the support I need from other personnel to care for patients.	3.98	0.770
	SK5	It is easy for personnel here to ask questions when there is something that they do not understand.	3.98	0.775
	SK6	The health care workers here work together as a well-coordinated team.	3.91	0.807
	SK7	I would feel safe being treated here as a patient.	3.91	0.865
	SK8	Medical errors are handled appropriately in this clinical area.	4.02	0.801
	SK9	I receive appropriate feedback about my performance.	3.84	0.887
	SK10	I know the proper channels to direct questions regarding patient safety.	3.89	0.778

Continued...

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Construct	Items	Summary of item statement	Mean	Std. Deviation[a]
	SK11	In this clinical area it is easy to discuss errors.	3.90	0.873
	SK12	I am encouraged by my colleagues to report any patient safety concerns.	3.96	0.840
	SK13	This clinical area makes it easy to learn from the errors of others.	3.97	0.785
	SK14	Management does not knowingly compromise patient safety.	3.75	0.942
Patient safety culture practise	AB1	People support one another in this unit.	4.33	0.608
	AB2	When a lot of work needs to be done quickly, we work together as a team to get the work done.	4.34	0.685
	AB3	In this unit, people treat each other with respect.	4.23	0.652
	AB4	When one area in this unit gets really busy, others help out.	4.20	0.710
	AB7	Whenever pressure builds up, my supervisor/manager wants us to work faster, even if it means taking shortcuts.	3.85	1.075
	AB8	My supervisor/manager overlooks patient safety problems that happen repeatedly.	4.09	0.012
	AB10	Mistakes have contributed to positive changes in our organisation.	4.09	0.765
	AB12	Hospital management provides a work climate that promotes patient safety.	4.02	0.738
	AB13	The actions of hospital management show that patient safety is a top priority	4.14	0.714
	AB17	It is just by chance that more serious mistakes don’t happen around here.	3.82	1.052
	AB18	We have patient safety problems in this unit.	3.90	1.035
	AB20	We are informed about errors that happen in this unit.	4.10	0.784
	AB21	In this unit, we discuss ways to prevent errors from happening again.	4.22	0.750
	AB25	Mistakes that are caught and corrected before reaching the patient are consistently reported.	3.84	0.983
	AB26	Mistakes with no potential to harm the patient are routinely reported.	3.77	1.068
	AB27	Mistakes that could have harmed the patient but did not are usually reported	4.03	0.995
	AB33	Staff in this unit work longer hours than is best for patient care.	3.14	1.472
	AB34	This unit relies too much on temporary staff than is best for patient care.	3.37	1.291
	AB35	We often operate under high pressure condition, attempting to accomplish too much too quickly.	2.98	1.440
	AB36	Things get overlook in regards to patient safety when transferring patients from one unit to another.	3.54	1.206

Continued...

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Construct	Items	Summary of item statement	Mean	Std. Deviation[a]
	AB37	Important patient care information is often lost during shift changes.	3.75	1.079
	AB38	Problems often occur in the exchange of information across hospital units.	3.53	1.165
	AB39	Shift changes are problematic for patients in this hospital .	3.75	1.056
	AB40	Staff feel like their mistakes are held against them (negatively worded).	3.35	1.211
	AB41	When an event is reported, it feels like the person is being targeted, not the problem.	3.17	1.286
	AB42	Staff worry that mistakes they make are kept in their personnel file.	3.00	1.243

TABLE 5: The value for KMO and Bartlett's test

Construct (Shkeer 2019)	Kaiser-Meyer-Olkin Measure of Sampling Adequacy	Bartlett's Test of Sphericity		
		Approx. Chi-Square	df	Sig.
Patient safety culture practise (AB)	0.921	2540.265	325	<0.001
Patient safety awareness (TK)	0.827	651.968	45	<0.001
Patient safety knowledge (TP)	0.890	731.378	21	<0.001
Patient safety attitude (SK)	0.958	1380.211	91	<0.001

TABLE 6: Total variance explained for AB construct

Component	Initial Eigenvalues			Extraction Sums of Squared Loadings		
	Total	% of Variance	Cumulative %	Total	% of Variance	Cumulative %
1	13.059	50.225	50.225	13.059	50.225	50.225
2	2.121	8.160	58.385	2.121	8.160	58.385
3	1.308	5.030	63.415	1.308	5.030	63.415
4	1.136	4.368	67.782	1.136	4.368	67.782
5	1.076	4.138	71.920	1.076	4.138	71.920
6	0.855	3.289	75.209			
7	0.734	2.823	78.032			
8	0.684	2.629	80.661			
9	0.560	2.152	82.813			
10	0.517	1.990	84.803			
11	0.451	1.733	86.536			
12	0.419	1.612	88.148			
13	0.370	1.423	89.571			
14	0.353	1.359	90.930			
15	0.303	1.166	92.096			
16	0.288	1.109	93.205			
17	0.279	1.073	94.278			

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Component	Initial Eigenvalues			Extraction Sums of Squared Loadings		
	Total	% of Variance	Cumulative %	Total	% of Variance	Cumulative %
18	0.237	0.912	95.189			
19	0.220	0.847	96.036			
20	0.202	0.777	96.813			
21	0.188	0.724	97.538			
22	0.160	0.617	98.155			
23	0.152	0.585	98.740			
24	0.142	0.546	99.286			
25	0.108	0.417	99.704			
26	0.077	0.296	100.000			

Extraction method: Principal component analysis.

TABLE 7: Rotated component matrix of AB construct

Construct	Items	Factor Loading (FL)				
Patient safety culture practise (Amalan budaya)	AB1		0.776			
	AB2		0.750			
	AB3		0.651			
	AB4		0.709			
	AB7	0.752				
	AB8	0.686				
	AB10			0.667		
	AB12			0.739		
	AB13			0.706		
	AB17	0.712				
	AB18	0.666				
	AB20					0.691
	AB21					0.745
	AB25				0.804	
	AB26				0.750	
	AB27				0.768	
	AB33	0.665				
	AB34	0.775				
	AB35	0.749				
	AB36	0.816				
	AB37	0.759				
	AB38	0.692				
	AB39	0.622				
	AB40	0.660				
	AB41	0.675				
	AB42	0.724				

Extraction bethod: Principal component analysis. Rotation bethod: Varimax with Kaiser normalisation

Hoque et al. 2018; Rahlin et al. 2019). Table 9 provided the results for the components and dimensions of individual items for TK, indicating that all items were grouped two components. To ensure retention, the loading factor of each item should be >0.6, as recommended by Mohamad et al. (2018) and Yahaya et al. (2018). Consequently, only ten items met this criterion and were retained. Other five items have been removed and only ten items were considered for further analysis under two components of TK construct.

Exploratory Factor Analysis for Patient Safety Knowledge Construct

Seven items were employed to measure the patient safety knowledge (TP) construct (TP1-TP7), as detailed in Table 4, which also presented the mean response, standard deviation and item statement of each item. The mean scores and standard deviations of every item demonstrated a consistent score distribution, as the standard deviation for each item was < 1.5. EFA was conducted using the PCA extraction method with varimax (variation maximisation) rotation for the seven items to assess the TP construct. Table 5 showed BTS was significant ($p < 0.05$), and the KMO measure of sampling adequacy was 0.890, surpassing the lower threshold of 0.6. This result suggested that the sample size was adequate, as indicated by Rahlin et al. (2019). The significant BTS result and KMO above 0.6 confirmed the adequacy of the dataset. Result revealed the emergence of a single distinct component from the EFA, identifying the respective items within this component (Baistaman et al. 2020; Yahaya et al. 2018).

Total variance explained was an extraction method that condensed items into a manageable quantity prior to further analysis. During this process, components with eigenvalues greater than 1.0 were separated into distinct components (Awang 2012; Hoque & Zainudin 2016; Pallant 2020). Table 10 indicated that the EFA had extracted only a single component for the TP construct, with an eigenvalue of 5.176 for

TABLE 8: Total variance explained for TK construct

Component	Initial Eigenvalues			Extraction Sums of Squared Loadings			Rotation Sums of Squared Loadings		
	Total	% of Variance	Cumulative %	Total	% of Variance	Cumulative %	Total	% of Variance	Cumulative %
1	4.942	49.416	49.416	4.942	49.416	49.416	3.658	36.581	36.581
2	1.374	13.738	63.154	1.374	13.738	63.154	2.657	26.573	63.154
3	1.024	10.238	73.392						
4	0.623	6.232	79.625						
5	0.542	5.417	85.042						
6	0.482	4.822	89.863						
7	0.352	3.522	93.385						
8	0.265	2.654	96.039						
9	0.205	2.048	98.087						
10	0.191	1.913	100.000						

Extraction method: Principal component analysis

TABLE 9: Rotated component matrix of TK construct

Construct	Items	Factor Loading	
Patient safety awareness	TK1		0.813
	TK3		0.768
	TK14		0.713
	TK15		0.708
	TK2	0.617	
	TK5	0.751	
	TK9	0.803	
	TK10	0.813	
	TK11	0.710	
	TK12	0.805	

Extraction method: Principal component analysis. Rotation method: Varimax with Kaiser normalisation.

component number 1. Table 10 indicated that the total variation explained was 73.946%. The TVE values were deemed acceptable, as they surpassed the commonly recognised threshold of 60% (Bahkia et al. 2019; Baistaman et al. 2020; Noor et al. 2015; Samsiah et al. 2016).

Table 11 showed that the EFA technique had isolated solely individual components. This study remained only items with a factor loading exceeding 0.6, as this signified their efficacy in measuring the specific construct (Awang et al. 2018; Bahkia et al. 2019; Hoque et al. 2018). The rotated component matrix indicates that all seven items possessed a factor loading over 0.6; hence, all seven items were included in the single components of the TP construct.

Exploratory Factor Analysis for Patient Safety Attitude Construct

The patient safety attitude (SK) construct was measured using 15 items (SK1-SK15). The mean score and standard deviation of each item demonstrated a consistent score distribution, as the standard deviation for each item was <1. The EFA used PCA to extract the fourteen items to measure the SK construct. Table 5 revealed a significant outcome for the BTS, with $p < 0.05$. Furthermore, the KMO measure of sampling adequacy yielded a value of 0.958, higher than the 0.6 minimum threshold and thus suggesting the adequacy of the sample size (Yahaya et al. 2018).

The significant BTS and KMO values exceeding 0.6 underscored the adequacy of the dataset for analysis. The EFA for the SK construct revealed that only a single component emerged from the EFA with eigenvalue 9.009 for component number 1. As noted in Table 12, 14 items had factor loading above 0.6, meeting the recommended criterion for item retention. The TVE for this construct was 64.35%, as shown in Table 13, which was acceptable as it surpassed the minimum threshold of 60% (Bahkia et al. 2019; Hoque et al. 2018; Yahaya et al. 2018).

This study maintained only items with a factor loading exceeding 0.6, as this signified their efficacy in measuring the specific construct (Awang et al. 2018; Bahkia et al. 2019; Hoque et al. 2018). The rotated component matrix indicated

TABLE 10: Total variance explained for TP construct

Component	Initial Eigenvalues			Extraction Sums of Squared Loadings		
	Total	% of Variance	Cumulative %	Total	% of Variance	Cumulative %
1	5.176	73.946	73.946	5.176	73.946	73.946
2	0.544	7.778	81.724			
3	0.361	5.161	86.885			
4	0.314	4.487	91.372			
5	0.294	4.194	95.565			
6	0.172	2.455	98.020			
7	0.139	1.980	100.000			

Extraction method: Principal component analysis

TABLE 11: Rotated component matrix of TP construct

Construct	Items	Factor Loading
Patient safety knowledge	TP1	0.829
	TP2	0.877
	TP3	0.886
	TP4	0.867
	TP5	0.868
	TP6	0.885
	TP7	0.803

Extraction method: Principal component analysis.
Rotation method: Varimax with Kaiser normalisation

TABLE 12: Rotated component matrix of SK construct

Construct	Items	Factor Loading
Patient safety attitude	SK 1	0.736
	SK 2	0.810
	SK 3	0.805
	SK 4	0.864
	SK 5	0.859
	SK 6	0.848
	SK 7	0.841
	SK 8	0.871
	SK 9	0.776
	SK 10	0.736
	SK 11	0.829
	SK 12	0.788
	SK 13	0.792
	SK 14	0.645

Extraction method: Principal component analysis
Rotation method: Varimax with Kaiser normalisation

only 14 items possessed a factor loading over 0.6; hence, one item had been eliminated, and the remaining 14 items were included in single components of the SK construct.

Internal Reliability

As shown in Table 14, Cronbach's alpha values for all measuring constructs exceeded 0.7, thereby verifying the reliability of these items. The instrument achieved a Cronbach's alpha value greater than 0.8, indicating excellent internal consistency (Awang 2010; Awang 2012). The EFA and reliability assessment validated the robustness of the developed questionnaire.

DISCUSSION

The results of this study yield conclusive evidence for the validity and reliability of the adapted patient safety constructs within the context of healthcare setting. The newly developed and revised items underwent pre-testing, which involved obtaining expert verification and pilot testing, where the items were filtered using EFA.

Pre-testing ensured the instrument's content validity and face validity requirements were fulfilled. Based on the result and comments of the experts, seven items were revised due to I-CVI value less than 0.78. Another seven items

TABLE 13: Total variance explained for SK construct

Component	Initial Eigenvalues			Extraction Sums of Squared Loadings		
	Total	% of Variance	Cumulative %	Total	% of Variance	Cumulative %
1	9.009	64.350	64.350	9.009	64.350	64.35
2	0.746	5.326	69.676			
3	0.668	4.769	74.444			
4	0.576	4.118	78.562			
5	0.488	3.485	82.047			
6	0.437	3.118	85.165			
7	0.390	2.787	87.952			
8	0.339	2.421	90.374			
9	0.324	2.314	92.687			
10	0.249	1.777	94.465			
11	0.231	1.651	96.115			
12	0.209	1.493	97.608			
13	0.178	1.271	98.878			
14	0.157	1.122	100.000			

Extraction method: Principal component analysis

TABLE 14: The internal reliability value for each construct

Construct	Number of items	Cronbach's alpha
Patient safety knowledge (TP)	7	0.939
Patient safety awareness (TK)	10	0.879
Patient safety attitude (SK)	14	0.956
Patient safety culture practise	26	0.958

were revised due to comments and suggestions by the experts (Emmanuel & Clow 2017; Yusoff 2019). The face validity assessment indicates that the instrument is clear and easy to understand, reflecting a robust structure for the instrument (Yusoff 2019).

The EFA confirmed the fulfilment of the requirements for the KMO measure of sampling adequacy (> 0.6), significant BTS, and factor loading exceeding the baseline limit of 0.6, with a high Cronbach alpha score for internal reliability. The constructs TP, TK, SK and AB were thoroughly examined through EFA using the PCA method. The dataset's suitability for factor analysis and the adequacy of the sample size was confirmed by the significant results of BTS and the high values of the KMO measure of sampling adequacy across all constructs.

The results consistently demonstrated the emergence of every components for each construct, indicating a clear and distinct factor structure. This finding is further supported by the high total variance explained for each construct, which exceeded the acceptable minimum threshold of 60%. Specifically, the variance explained for the constructs ranged from 60% to as high as 73.95% for the TP construct, affirming the constructs' robustness and the overall quality of the data.

Additionally, several items were removed during EFA to enhance the structural validity of the instrument. Specifically, items with low factor loadings (<0.60), items that cross-loaded significantly on multiple factors, or those that demonstrated weak conceptual fit with their respective domains were excluded. This finding aligns with the recommendations of Al-Khamaiseh et al. (2019), Mohamad et al. (2018) and Yahaya et al. (2018), ensuring the retention of all items and confirming their relevance and significance within the constructs. The findings are further reinforced by the internal reliability of each construct, which was evaluated using Cronbach's alpha. The alpha values for all constructs were above 0.7, reflecting high internal consistency and reliability, as recommended by Awang (2010) and Awang (2015). This consistency highlights the effectiveness of the items in accurately assessing their respective constructs, ensuring the reliability of the data obtained through these measures.

Contribution

This study contributes to the existing body of patient safety research by providing a contextually relevant, empirically tested instrument tailored to Malaysia's healthcare environment. It not only fills a gap in local tools for safety culture assessment but also supports future benchmarking, training needs analysis and quality improvement initiatives. By enabling healthcare institutions to systematically identify strengths and areas for improvement, this instrument offers a practical and strategic contribution to advancing a culture of safety at both organisational and national levels.

Limitation

This study has several limitations that should be considered. First, as the instrument was developed within the Malaysian healthcare context, its relevance and applicability to other cultural or healthcare settings may be limited. Although the sample size met the requirements for factor analysis, the study's cross-sectional design provides a snapshot of perceptions at a single point in time, without capturing possible changes or trends over a longer period. Lastly, as with many survey-based studies, we relied on self-reported data, which may be influenced by response bias or social desirability, where participants respond in a way they think is expected rather than their true beliefs or behaviours.

CONCLUSION

The development and validation of this instrument mark a significant advancement towards a more structured and evidence-based approach in assessing patient safety culture among medical doctors. By encompassing the key dimensions of knowledge, awareness, attitude and practice, the tool provides a comprehensive measure of how safety principles are understood, valued and implemented in clinical settings. These findings provide significant insights into the instrument's reliability and validity in evaluating patient safety culture, encompassing practice, awareness, knowledge and attitudes among healthcare professionals. The rigorous validation process including literature review, expert input, face and content validation, and EFA ensured the instrument's clarity, consistency and contextual relevance. The validated questionnaire can now serve as a standardised tool for evaluating and improving patient safety culture within healthcare settings, ultimately contributing to enhanced patient care and safety outcomes. As healthcare systems strive to strengthen safety performance, the use of a robust, locally validated instrument will be essential in guiding quality improvement initiatives and fostering a culture of safety.

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