Development and Validation of SafeHIT: An Instrument to Assess the Self-Reported Safe Use of Health Information Technology

Lizawati Salahuddin[1] Zuraini Ismail[2] Fiza Abdul Rahim[3] Syarulnaziah Anawar[1] Ummi Rabaah Hashim[1]

[1] Center for Advanced Computing Technology (C-ACT) Fakulti Teknologi Maklumat dan Komunikasi, Universiti Teknikal Malaysia Melaka (UTeM), Durian Tunggal, Melaka, Malaysia
[2] Kuala Lumpur, Malaysia
[3] Advanced Informatics Department Razak Faculty of Technology and Informatics, Universiti Teknologi Malaysia (UTM), Kuala Lumpur, Malaysia

Address for correspondence Lizawati Salahuddin, PhD, Fakulti Teknologi Maklumat dan Komunikasi, Universiti Teknikal Malaysia Melaka (UTeM), 76100 Durian Tunggal, Melaka, Malaysia (e-mail: lizawati@utem.edu.my).

Appl Clin Inform 2023;14:693–704.

Abstract

Background Implementing health information technology (HIT) may cause unintended consequences and safety risks when incorrectly designed and used. Yet, the tools to assess self-reported safe use of HIT are not well established.

Objective This study aims to develop and validate SafeHIT, an instrument to assess self-reported safe use of HIT among health care practitioners.

Methods Systematic literature review and a semistructured interview with 31 experts were adopted to generate SafeHIT instrument items. In total, 450 physicians from various departments at three Malaysian public hospitals participated in the questionnaire survey to validate SafeHIT. Exploratory factor analysis and confirmatory factor analysis (CFA) were undertaken to explore the items that best represent a specific construct and to confirm the reliability and validity of the SafeHIT, respectively.

Results The final SafeHIT consisted of 14 constructs and 58 items in total. The result of the CFA confirmed that all constructs demonstrated adequate convergent and discriminant validity.

Conclusion A reliable and valid theoretically underpinned measure of determinants of safe HIT use behavior has been developed. Understanding external factors that influence safe HIT use is useful for developing targeted interventions that favor the quality and safety of health care.

Keywords

- health information technology
- safety
- adoption
- questionnaire survey
- quantitative instrument

Background and Significance

Health information technology (HIT) involves processing, storing, retrieving, sharing, and using health information in an electronic environment. HIT includes electronic health records (EHRs) or electronic medical records (EMRs), personal health records, electronic prescribing (E-prescribing), computerized provider order entry (CPOE), telehealth, clinical decision support system, and hospital information systems (HIS). HIT aims to enhance the quality and safety of health care, medical outcomes, financial performance, and administrative efficiencies.[1–3] Nevertheless, there is substantial evidence of unintended consequences and patient safety risks of HIT globally. A retrospective analysis of all safety events between September 2005 and November 2011 revealed that software use errors associated with human factors

received
December 6, 2023
accepted after revision
June 5, 2023

Georg Thieme Verlag KG, Rüdigerstraße 14, 70469 Stuttgart, Germany

DOI https://doi.org/10.1055/s-0043-1771394.
ISSN 1869-0327.

problems resulted in three deaths.[4] Human factors issues were four times more likely to harm patients than technical issues.[4] Moreover, an analysis of EHR-related patient safety incidents in fully digital Finnish hospitals revealed that problems with human–computer interaction were the most often reported in HIT-related incidents.[5] HIT safety events arise in a complex health care environment due to several reasons, including hardware and software failure, poor usability or functionality, user behaviors, disruptions in workflow, and organizational characteristics.[6–8] Understanding the contributing factors is an important first step to minimizing the risks of HIT.

A sociotechnical approach is frequently recommended for patient safety improvement efforts.[9–11] Sociotechnical refers to the interconnection between social structure and technology. The concept of the human–machine system will not be accomplished if the system focuses primarily either on the human or machine. Safety incidents emerge from the interactions between people and the elements of technology, tasks, environment, and organization in which they work.[11,12]

HIT use behavior refers to the manner in which health care practitioners utilize the capabilities of HIT.[13] The manner in which HIT has been used can be described in several ways, namely workarounds, vigilance, and procedure compliance. The HIT use behavior has implications on the perceived quality and safety of HIT use. Safe HIT use is defined as the prevention of adverse events or outcomes arising from leveraging HIT in the health care process. It aims to avoid and lessen risks, mistakes, and injuries to patients during the delivery of medical care. To date, research on HIT use has profoundly relied on qualitative interviews to understand the factors influencing health care practitioners' HIT use behavior. Although interviews are convenient for gaining an in-depth understanding, they require a lot of time and resources and frequently permit a small sample size. A quantitative instrument, on the contrary, might be a quicker method to gain information among a larger sample.

To the best of our knowledge, the instruments to assess self-reported safe use of HIT among health care practitioners do not exist in the literature. Although there are validated patient safety instruments,[14,15] these instruments tend to measure general attitudes, culture, and climate rather than assess social–technical antecedents to safe HIT use behavior. A survey was administered to measure the attitudes of health professionals toward EHRs in primary health care settings.[16] The survey focuses on the attitude about benefits, barriers, and user satisfaction of EHRs, which influence the health care professional's acceptance, adoption, and use of an EHR rather than the safe HIT use behavior. Besides, the Safety Assurance Factors for EHR Resilience (SAFER) guides are designed to aid health care organizations in conducting self-assessments to optimize the safety and use of EHRs by identifying and addressing potential safety hazards related to technology, workflow, and organizational policies and culture.[17] The guides focus on the areas of foundational guides (high-priority practices and organizational responsibilities), contingency planning guides (contingency planning, system configuration planning, and system interfaces), and clinical process guides (patient identification, CPOE with decision support, test results reporting and follow-up, and clinician communication). Each of the guides contains a checklist of recommended practices for EHR safety. The SAFER guides do not focus solely on safe EHR use behavior but instead provide recommendations for improving the safety and reliability of EHR systems. Moreover, the SOPS Health Information Technology (Health IT) Patient Safety survey assesses health care organizations' safety culture related to HIT use.[15] The survey addresses EHR patient safety and quality issues, EHR system training, EHR and workflow/work process, EHR system support and communication, and overall EHR system rating. On the contrary, SafeHIT covers a broader aspect of social-technical antecedents to safe HIT use behavior, including person, organization, technology, and task dimensions. In addition, the safe HIT use behavior items in SafeHIT focus on vigilance, workarounds, and procedure compliance in using HIT. Therefore, this study developed and validated SafeHIT, a measurement tool to assess self-reported safe use of HIT among health care practitioners. The instrument contains three components: (1) antecedents of the safe use of HIT, (2) HIT use behavior, and (3) perceived quality and safety of HIT use. The safe use of HIT antecedents was considered by considering the socio-technical viewpoint: person, organization, technology, and task dimensions.

Objectives

The objectives of this study are as follows.

- To develop SafeHIT, an instrument that assesses self-reported safe use of HIT among health care practitioners.
- To validate the reliability and validity of the SafeHIT instrument.

Methods

The SafeHIT items were developed and validated based on three stages which involved (1) item generation, (2) scale development, and (3) scale evaluation.[18]

Stage 1: Item Generation

A systematic literature review (SLR) and semistructured interviews with experts were conducted to identify the appropriate constructs for the instrument items generation. An SLR was conducted on relevant databases, including Science Direct, Medline, EMBASE, and CINAHL. The terms electronic medical record, health information system, health information technology, medical mistake, and safety were all included as keywords in the search.[19] The semistructured interview involved 31 physicians from three government hospitals in Malaysia. They have used HIS for patient care for 1.5 to 10 years.[20,21]

SafeHIT items were informed by the work system in the Systems Engineering Initiative for Patient Safety model and the extended DeLone and McLean information system (IS) success model. Content analysis and thematic analysis of the SLR and semistructured interview allow for articulation of the four key determinants of safe HIT use behavior: (1) person, (2) technology, (3) organization, and (4) tasks. Both SLR and semistructured interviews revealed that knowledge for the person component;

system quality for the technology component; organization resources and teamwork for the organization component; and task-related stressors for the task component emerged as the contributing factors.[19,20] In addition, it is discovered from the SLR that information quality and service quality for the technology component and training from the organization component contribute to the safe HIT use.[13] Contrary to the SLR findings, it was discovered from the semistructured interview that physical layout and noise does not influence the safe HIT use.[14] Moreover, the interview results revealed that (1) vigilance, (2) workarounds, (3) procedure compliance, and (4) copy and paste habits emerged as the attributes for safe HIT use behavior.[15] In terms of HIT use outcomes, the findings show that the implementation of HIT leads to positive and negative impacts on patient safety and quality of patient care.

Next, the content for the SafeHIT instrument is developed. The instrument is structured into 11 main sections with a total of 70 items that utilize a seven-point Likert scale ranging from 1 (strongly disagree) to 7 (strongly agree). ►Table 1 presents the meaning of each construct in SafeHIT, its items resources, and the number of items.

Stage 2: Scale Development

Pretesting questions, pilot tests, survey administration, and factor extraction were conducted in the scale development phase.

Pretesting Instrument

A pretest was performed to test the face and content validity of the SafeHIT. A group of four experts of lecturers and three physicians from a teaching university hospital and a government hospital was chosen to pretest the SafeHIT. The lecturers are involved in teaching and research in the field of health care and ISs. All the physicians have experience in using HIT. Once respondents were briefed about the research, a set of hardcopy SafeHIT was given to them for review in 1 week.

In terms of face validity, all experts indicated that the appearance and layout of SafeHIT were acceptable. Additionally, they indicated that the questions were easy to understand and answer. Concerning the content validity, five questions with codes C1, C2, TS2, TS4, and OR1 had to be rephrased to ensure clarity and similar meaning. One item with code ServQ4 was revised and broken down into two items due to double meanings. The panel of experts confirmed that the SafeHIT was a valid and effective measurement. The items did measure the theoretical construct.

Pilot Test

A pilot study was performed in this research to ensure the reliability and validity of the constructs of interest.[22] The final draft of the SafeHIT with modifications from the pretest and the instrument evaluation form was given to 37 physicians for pilot testing. The number of participants was small because each hospital's Clinical Research Centre (CRC) was restricted from accepting a certain number of SafeHIT for the pilot study.

Thirty-one SafeHIT were returned over a period of 2 weeks. However, five copies were excluded as there were some items that were not answered and suspicious response patterns or straight lining. Reliability analysis showed that all Cronbach's alpha values for each construct were more than 0.7, except for competence (0.650) and organization resources (0.685). A Cronbach's alpha ranging from 0.6 to 0.7 is considered 'acceptable', 0.7 to 0.9 'good', and above 0.90 is considered 'excellent' internal consistency.[23] Therefore, the internal consistency reliability of the majority of the constructs is considered good. ►Table 2 presents the results of the reliability analysis for each construct in the SafeHIT.

Half of the respondents remarked that the length of the SafeHIT was just right, while 45.83% indicated it was too long. The remaining 4.17% of the respondent did not comment on the length of the SafeHIT. More than half of the respondents (58.33%) indicated the overall usability of SafeHIT was good, very good, and excellent. Slightly over two-third of the respondents (70.83%) rated the questions were clear, and they are able to understand the questions. Three-quarters of the respondents (75%) indicated that SafeHIT provided answer choices that reflected their true thoughts, opinions, or experiences.

Questionnaire Survey Administration

It is most plausible for physicians to disregard the mail questionnaires due to their hectic schedules. Hence, self-administered survey research, as suggested by,[24] was adopted for this research. After obtaining ethics approval from the Medical Research and Ethics Committee and access approval from each hospital director of the selected hospitals, questionnaire survey requests were sent to each head of department (HOD). The improved SafeHIT based on the pretest and pilot test results was distributed to 450 physicians. Finally, a total of 346 responses were collected.

Factor Extraction

Exploratory factor analysis (EFA) was conducted in this research to identify items that best represent a specific construct. All 346 usable responses were randomly split into two equal sample sizes for EFA and confirmatory factor analysis (CFA).[25] A sample size of 173 was considered to be acceptable to perform an appropriate EFA.[26]

EFA was conducted according to the five steps in the EFA protocol as suggested.[27] This research applied the Kaiser–Meyer–Olkin (KMO) Measure of Sampling Adequacy and Bartlett's Test of Sphericity to assess the suitability of the data for factor analysis. Principal axis factoring was selected as the factor extraction method because it is appropriate for this research to identify the underlying constructs that reflect what the items share in common.[28] Next, parallel analysis was used in this research to determine the number of factors to be extracted or retained. Consequently, Promax was used to assist in the interpretation of the extracted factor because it permits factors to correlate.[28] Items with a factor loading of 0.45 and above were considered significant as the sample size of this research is 173.[28]

Stage 3: Scale Evaluation

CFA was conducted by using SmartPLS 4 software to confirm the reliability and validity of the refined SafeHIT. Composite

Table 1 Constructs in SafeHIT

Component	Construct	Definition	Items resources	Initial number of items
Person	Competence	The extent to which users know how to use HIT.[37] Competence is measured according to the knowledge of HIT and typing skills.	• Semistructured interview and findings of previous studies[38,39]	5
Technology	System quality	The degree of quality performance of information system.[40] SafeHIT focuses on four system quality factors which are usability, compatibility, reliability, and response time.	• Instruments[41] • Semistructured interview and findings of previous studies[42,43]	11
	Information quality	The degree of quality information provided by the information system.[40] The SafeHIT focuses on completeness, relevancy, and timeliness dimensions of information quality.	• Instruments validated[44]	7
	Service quality	The degree of quality service delivered by the IT department to users.[40] The SafeHIT focuses on responsiveness, assurance, and tangible dimensions of service quality.	• SERVQUAL instrument tested[45]	5
Organization	Organization resources	The extent to which organizational resources are available to support safe patient care.[46] The organization resources include staff, computer equipment, time, and policies or procedures associated with the safe HIT use.	• Instruments developed and validated[14,46] • Semistructured interviews and findings of previous study[47]	5
	Training	The extent to which training related to HIT is given to HIT users.[48]	• Instruments developed and validated[49–51]	5
	Teamwork	The extent to which health care practitioners work together to achieve a specific and shared goal.[52]	• Instruments developed and validated[14,53] • Semistructured interviews and findings from previous study[54]	5
Task	Task-related stressor	The extent to which task-related factors affect an individual and require extra coping strategies which are present during a job.[55] The SafeHIT focuses on four types of task-related stressors, namely time pressure, workload, cognitive load, and interruptions.	• Instruments validated[55,56]	5
HIT use	Workarounds	Alternative procedures are employed by health care practitioners to accomplish a task in response to a misfit between HIT and existing work processes.[57,58]	• Semistructured interviews and findings from previous studies[58–60]	5
	Vigilance	Careful action or attention to avoid potential errors or risks.	• Semistructured interviews and findings from previous studies[61,62]	4
	Copy and paste	To copy patient-related information from the previous entry and put it in the new entry of HIT.	• Semistructured interviews and findings from previous studies[63,64]	3
	Procedure compliance	The act of complying with a procedure of HIT usage.	• Semistructured interviews and findings from previous studies[36,65]	5
HIT use outcomes		The extent of belief of HIT users that using HIT contributes to the quality of care and the safety of the patient.[13,66]	• Instruments developed and validated[14,49] • Semistructured interviews and findings from previous study[67]	5

Abbreviation: HIT, health information technology.

Table 2 Reliability of each construct in the SafeHIT

Construct	Cronbach's alpha
Competence	0.650
System quality	0.865
Information quality	0.803
Service quality	0.914
Organization resources	0.685
Teamwork	0.783
Training	0.897
Task-related stressor	0.764
HIT use	0.783
HIT use outcomes	0.732

Abbreviation: HIT, health information technology.

reliability is applied as the measure of internal consistency reliability. Composite reliability values of 0.60 to 0.70 is considered acceptable in exploratory research; however, they should be more than 0.708 in more advanced stages of research.[29] Convergent validity and discriminant validity are important measures of construct validity. Outer loadings of the indicators and average variance extracted (AVE) are employed to judge convergent validity. On the contrary, discriminant validity is accessed by using the Fornell–Lacker criterion.

Results

Descriptive Analysis of Demographics

Of the 450 SafeHIT distributed to three hospitals, 364 were returned over a period of two and half months. In total, 346 SafeHIT were usable for further analysis. A total of 17 SafeHIT were found to be unusable due to suspicious response patterns or straight lining, missing answers, and more than one answer for an item. ►Table 3 presents the details of the demographic profile of the respondents.

The survey result demonstrates that a majority of the respondents were female respondents (61.56%). Most of the respondents were below 35 years of age (88.73%), and only 0.29% of respondents were between 45 and 54 years of age. The result indicates that respondents were generally from the young generation. Thus, technology should not be an unfamiliar topic for them. Interestingly, more than two-third (76.88%) of the respondents had experience using HIT within the range of 1 to 5 years. Only 12.14% of the respondents had experience using HIT for less than a year. The result implies that the respondents had adequate experience to undertake the specific tasks available in the HIT. Regarding the department attached by the respondents, it was observed that respondents attached to the emergency and trauma department were the largest groups (21.10%), followed by pediatric (14.74%), next, the medical department (11.27%), followed closely by obstetrics and gynecology (10.69%). The result typically suggests that a majority of the respondents are attached to the departments that are commonly available in most hospitals.

Exploratory Factor Analysis

The KMO measure of each component was between 0.651 and 0.914, and Bartlett's test is significant ($p < 0.001$), indicating that the data are adequate for factor analysis. All the items below the cut-off loading of 0.45 were removed. ►Supplementary Appendix A (available in the online version) presents the results of EFA.

For the person component, the EFA produced two distinct factors. Three items (C1, C2, and C3) with loadings of 0.821, 0.974, and 0.719 were loaded onto Factor 1. It was also observed that items C3 and C4 possessed moderately high loadings of 0.598 and 0.883, respectively, which were cleanly loaded onto Factor 2. Factor 1 was redefined appropriately as knowledge since the items best reflect more knowledge of HIT. On the contrary, two items in Factor 2 were identified as typing skills as the items were clearly identifiable with typing skills. This is in line with the definition of competence, which builds on a foundation of basic skills and knowledge.[30]

The generated factor analysis from the technology component consists of three distinct factors. Nine items from the "system quality" scale were cleanly loaded onto Factor 1 with loadings ranging from 0.554 to 0.882. However, SQ10 (HIT of this hospital is able to integrate with other in-house systems and medical machines) and SQ11 (HIT of this hospital occasionally system down occurs when I use the HIT) were dropped because they did not meet the cut-off point of 0.45. Factor 1 remains to be labeled as system quality. Factor 2 comprises all seven items from the "information quality" scale, with loadings ranging from 0.637 to 0.962. Similarly, all five items from the "service quality" scale were loaded clearly onto Factor 3. The loading results read from 0.631 to 0.919. Therefore, Factor 2 and Factor 3 remain to be labeled as information quality and service quality, respectively.

The results of the factor analysis for the organization component found three distinct factors. All five items from the "training" scale were loaded clearly onto Factor 1 with loading between 0.5360 and 0.995. Factor 1 remains to be labeled as training. All items that measure "teamwork" were loaded onto Factor 2 except for TW5. The four items have loadings between 0.568 and 0.896. Item TW5 (as an employee of this hospital, I am always aware on new orders requested through the HIT) did not meet the cut-off point. Thus, it was removed from further analysis. Adequately, Factor 2 is denoted as teamwork. Likewise, Factor 3 comprises four items from the "organization resources" scale with loadings between 0.504 and 0.980. OR5 (This hospital has specific written policies or procedures to prevent me from making errors when using the HIT) was dropped due to a loading value below the 0.45 threshold. Therefore, Factor 3 remains to be labeled as organization resources.

The results of the factor analysis for the tasks component found one factor. All five items from the "task-related stressor" scale were cleanly loaded onto Factor 1, with loading ranging between 0.720 and 0.825. Factor 1 remains to be labeled as a task-related stressor.

Three distinct factors were generated from HIT use. Five items (W1: I coordinate patient care activity by using the HIT

Table 3 Demographic details of the respondents

Characteristic	Item	Frequency	Percent (%)
Gender	Female	213	61.56
	Male	130	37.57
	Nil	3	0.87
Age	≤24 y	1	0.29
	25–34	306	88.44
	35–44	27	7.80
	45–54	1	0.29
	Nil	11	3.18
HIT experience	<1 y	42	12.14
	1–5	266	76.88
	6–10	22	6.36
	>10	0	0.00
	Nil	16	4.62
Department	Emergency and trauma	73	21.10
	Pediatric	51	14.74
	Medical	39	11.27
	Obstetrics and gynecology	37	10.69
	Surgery	28	8.09
	Orthopaedic	25	7.23
	Otorhinolaryngology	25	7.23
	Ophthalmology	14	4.05
	Hematology	9	2.60
	Psychiatric	8	2.31
	Nephrology	8	2.31
	Cardiology	7	2.02
	Cardiothoracic	5	1.45
	Oral and maxillofacial surgery	5	1.45
	Rehabilitation	5	1.45
	Neurosurgery and neurology	4	1.16
	Urology	3	0.87

Abbreviation: HIT, health information technology.

rather than through verbal, W2: I write notes on the paper containing information printed from the HIT, W3: I immediately transcribe patients' written progress notes to the HIT afterward rounds, V4: I sometimes forget to key in a patient's notes to the HIT, and WP4: I always log off from HIT after each usage) were dropped from further analysis due to loadings below the threshold of 0.45. Three items (V1, V2, and V3) from the "vigilance," and two items (CP2 and CP3 and WP1 and WP2) from "copy and paste" and "procedure compliance," respectively, were loaded onto Factor 1. Most of the items loaded on Factor 1 comprised of terms such as attention, double check, or carefully which were deemed to reflect vigilance. Hence, Factor 1 is denoted as vigilance. Factor 2 comprises two items (WP3 and WP5) from "procedure compliance," and one item (CP1) from "copy and paste." Since items from the "procedure compliance" scale had higher loadings, Factor 2 is appropriately labeled as procedure compliance. This is in line with the recommendation[28] that variables with higher loadings influence a great extent in naming to represent a factor. The remaining two items (W4 and W5) were loaded onto Factor 3 and remained as workarounds as the items were clearly identifiable with workarounds.

The results of the factor analysis for HIT use outcomes demonstrate two distinct factors. NB1 and NB2 were loaded onto Factor 1 with loadings of 0.718 and 0.791, respectively. It was also observed that items NB3, NB4, and NB5 possessed moderately high loadings of 0.698, 0.780, and 0.926, respectively. These items were loaded onto Factor 2. Factor 1 is relabeled appropriately as patient safety since the items best reflect errors and mistakes. On the contrary, NB5, which is concerned with patient-care quality, records higher loadings (0.926) as compared to the other two items (NB3 and NB4). Therefore, Factor 2 is labeled as patient-care quality. This is in line with the recommendation[28] that variables with higher loadings influence a great extent in naming to represent a factor.

Confirmatory Factor Analysis

The primary objective of CFA is to confirm the reliability and validity of the refined SafeHIT derived from the EFA. Construct validity was assessed in terms of convergent validity and discriminant validity. ►Table 4 indicates the results of convergent validity. All indicators loading was above the 0.7 standards except for SQ7 (0.625) and CP1 (0.577) that fell

Table 4 CFA results of convergent validity

Construct	Indicators	Loading	Composite reliability	AVE
Knowledge	C1	0.891	0.937	0.832
	C2	0.927		
	C3	0.918		
Typing skill	C4	0.866	0.889	0.800
	C5	0.922		
System quality	SQ1	0.849	0.937	0.651
	SQ3	0.841		
	SQ4	0.864		
	SQ5	0.879		
	SQ6	0.828		
	SQ7	0.625		
	SQ8	0.792		
	SQ9	0.720		
Information quality	IQ1	0.880	0.945	0.742
	IQ2	0.873		
	IQ3	0.833		
	IQ5	0.848		
	IQ6	0.856		
	IQ7	0.856		
Service quality	ServQ1	0.856	0.921	0.701
	ServQ2	0.889		
	ServQ3	0.851		
	ServQ4	0.813		
	ServQ5	0.771		
Organization resources	OR1	0.827	0.871	0.629
	OR2	0.736		
	OR3	0.730		
	OR4	0.871		
Training	T1	0.819	0.926	0.715
	T2	0.872		
	T3	0.864		
	T4	0.884		
	T5	0.785		
Teamwork	TW1	0.838	0.910	0.717
	TW2	0.867		
	TW3	0.850		
	TW4	0.832		

(*Continued*)

Table 4 (*Continued*)

Construct	Indicators	Loading	Composite reliability	AVE
Task-related stressor	TS1	0.768	0.906	0.660
	TS2	0.787		
	TS3	0.859		
	TS4	0.864		
	TS5	0.779		
Vigilance	CP2	0.841	0.929	0.653
	CP3	0.811		
	V1	0.793		
	V2	0.820		
	V3	0.754		
	WP1	0.783		
	WP2	0.851		
Workarounds	W4	0.725	0.759	0.613
	W5	0.837		
Procedure compliance	CP1	0.577	0.769	0.530
	WP3	0.790		
	WP5	0.796		
Patient safety	NB1	0.824	0.858	0.751
	NB2	0.907		
Patient-care quality	NB3	0.875	0.941	0.888
	NB5	0.960		

Abbreviations: AVE, average variance extracted; CFA, confirmatory factor analysis.

below the less conservative 0.5 cut-offs. Hence, all indicators established indicator reliability. Moreover, the composite reliability of all constructs exceeded the recommended threshold of 0.7, which suggested high levels of internal consistency reliability. All constructs' AVE ranged from 0.53 to 0.888, which exceeded the 0.5 rule of thumb. Therefore, the results demonstrate that the measures of the 14 reflective constructs have satisfactory levels of convergent validity.

In terms of discriminant validity testing, the Fornell–Larcker criterion assessment was applied. ►Table 5 exhibits the results of the Fornell–Larcker criterion assessment. The square root of each construct's AVE is on the diagonal (bold). The nondiagonal elements represent the correlations between the constructs. It was found that the square roots of the AVE for each construct were all higher than the correlations of these constructs with other constructs. Hence, the discriminant validity of all constructs is supported. Altogether, the measurement constructs demonstrated adequate convergent validity and discriminant validity. This further suggests that the measurement items used for each construct are reliable and valid. All constructs are theoretically and empirically distinct.

Discussion

SafeHIT is developed and validated in this study to extend the current approach to assess self-reported safe use of HIT among health care practitioners. Specifically, SafeHIT is developed to capture social-technical elements of the people, technology, organization, and task components as well as HIT use behavior that potentially contributes to the safety and quality of patient care. The final SafeHIT comprising 58 items is presented in ►Supplementary Appendix B (available in the online version) The measure of safe HIT use determinants consisted of nine constructs: knowledge and skills from the person component; system quality, information quality, and service quality from the technology component; organization resources, training, and teamwork from the organization component; and task-related stressor from the task component. Moreover, safe HIT use behavior consisted of three constructs: vigilance, procedure compliance, and workarounds. HIT use outcomes consisted of two constructs, namely, patient safety and patient-care quality. Consistent with the safe HIT use literature contributing factors of safe HIT use are multidimensional[31] and safe HIT use behavior corresponds to vigilance, procedure compliance, and workarounds.[32,33]

As argued,[34] it is critical to examine the complex interplay between sociotechnical elements involved in the patient care to prevent or lessen the chances of safety incidents from happening. The SafeHIT can be used to quantitatively examine the key determinants of safe HIT use behavior from a wide range of sociotechnical factors such as user characteristics

Table 5 CFA results of discriminant validity

	Information quality	Knowledge	Organization resources	Patient safety	Patient-care quality	Procedure compliance	Service quality	System quality	Task-related stressor	Teamwork	Training	Typing skill	Vigilance	Work arounds
Information quality	**0.862**													
Knowledge	0.862	**0.912**												
Organization resources	0.526	0.292	**0.793**											
Patient safety	0.416	0.075	0.022	**0.867**										
Patient-care quality	0.242	0.365	0.411	0.233	**0.942**									
Procedure compliance	0.507	−0.056	−0.104	0.348	−0.054	**0.728**								
Service quality	−0.026	0.336	0.364	0.129	0.323	−0.117	**0.837**							
System quality	0.468	0.605	0.439	0.145	0.558	−0.112	0.418	**0.807**						
Task-related stressor	0.674	0.104	−0.113	−0.120	−0.026	−0.202	0.073	−0.012	**0.812**					
Teamwork	0.110	0.341	0.432	0.238	0.440	−0.058	0.592	0.408	0.025	**0.847**				
Training	0.590	0.372	0.430	−0.090	0.252	−0.107	0.329	0.455	−0.038	0.269	**0.845**			
Typing skill	0.328	0.337	0.207	0.010	0.201	−0.005	0.139	0.328	−0.016	0.133	0.244	**0.895**		
Vigilance	0.171	0.405	0.108	0.149	0.427	0.029	0.262	0.404	0.185	0.447	0.113	0.224	**0.808**	
Work arounds	0.420	−0.115	−0.124	0.106	−0.065	0.240	−0.239	−0.189	−0.399	−0.200	-0.295	-0.102	-0.117	**0.783**

Abbreviation: CFA, confirmatory factor analysis.

(e.g., knowledge and skill), technology context (e.g., system quality, information quality, and service quality), organization context (organization resources, training, and teamwork), and task-related stressor over a large sample size. Besides, the current study has made a theoretical contribution by conceptualizing the SafeHIT instrument as having 14 constructs and by empirically testing the instrument. The SafeHIT could potentially be a tool for developing theoretically underpinned large-scale interventions to develop feasible strategies to address key contributing factors or barriers to safe HIT use behavior.

The research findings have several implications for hospital management who adopt HIT for patient care. SafeHIT provides a multidimensional aspect of a sociotechnical perspective to identify determinants of safe HIT use behavior across a large sample. The SafeHIT could be used as a diagnostic tool to provide feedback to facilitate hospital management in addressing safe HIT adoption strategies and to plan the policies to establish safe HIT adoption and implementation. Furthermore, it might be beneficial to identify the potential risks of HIT adoption for the purposes of redesigning HIT and the organization. Interventions can be considered for HIT users with patterns of lower scores in specific HIT use dimensions. For example, if a majority of HIT users exhibit a high level of vigilance but a low level of knowledge of HIT, an educational intervention could be designed and put into action to deal with the potential issue. Additionally, HIT providers and developers could adopt and adapt the SafeHIT to examine whether HIT business model modifications impact user behavior.

Although our results indicate that SafeHIT is a valid measure to assess self-reported safe use of HIT among health care practitioners, the current study had several limitations. First, the evaluation was done by health care practitioners in Malaysian hospitals. Hence, this study cannot be generalized to other cultural contexts. Future research may be needed to test SafeHIT among health care practitioners in other countries. A larger sample from different countries and the use of probability sampling would permit increased confidence in the reliability and external validity of the measure. Second, the number of measures for typing skills, workarounds, patient safety, and patient-care quality was reduced to two items per construct. However, the measures have proved valid and reliable properties. The AVE of all constructs exceeded the 0.5 rule of thumb to establish convergent validity.[28] In addition, the square roots of the AVE for each construct were all higher than the correlations of these constructs with other constructs. Hence, the discriminant validity of all constructs is supported. Third, SafeHIT does not include workflow measures that may force a workaround. In the context of health IT use, workflow interruption or disruption happens when the health IT does not fit into their clinical workflow, poor usability, insufficient computers, and insufficient training.[35,36] All these measures that may force workarounds are included in SafeHIT, although a specific construct on workflow is absent. Nevertheless, the SafeHIT can be extended in the future to include workflow measures to evaluate workflow's causal effect on workarounds.

Conclusion

This study employed a rigorous scale development procedure to establish reliable and valid properties for assessing the psychosocial factors affecting practitioner HIT use behavior. The SafeHIT can be a useful diagnostic tool to identify the contributing factors to safe HIT use and, subsequently, develop effective intervention strategies. Furthermore, the 14 constructs measurement scale adds to the extant literature by establishing a basis for further theoretical advances on safe HIT use. Further research should be carried out to fully understand the SafeHIT measure's use and limitations.

Clinical Relevance Statement

The SafeHIT can be used to quantitatively examine the key determinants of safe HIT use behavior from a wide range of sociotechnical factors over a large sample size. Besides, SafeHIT could be used as a diagnostic tool to provide feedback to facilitate hospital management in addressing safe HIT adoption strategies and to plan the policies to establish safe HIT adoption and implementation. Furthermore, it might be beneficial to identify the potential risks and consequences of HIT adoption for the purposes of redesigning HIT and the organization.

Multiple-Choice Questions

1. SafeHIT is a measurement tool to assess safe HIT use behavior of which of the following social-technical dimensions:
   a. Vigilance, procedure compliance, and workarounds
   b. System quality, information quality, and service quality
   c. People, technology, organization, and tasks
   d. Patient safety and patient-care quality

   Correct Answer: The correct answer is option c. SafeHIT assesses safe HIT use behavior across the social-technical dimensions of people, technology, organization, and tasks.

2. The benefits of using SafeHIT include all the following except:
   a. SafeHIT provides a multidimensional aspect of a sociotechnical perspective to measure the patterns of safe HIT use behavior.
   b. SafeHIT is beneficial to qualitatively identify the complex interplay between sociotechnical elements involved in the patient care.
   c. SafeHIT provides feedback to facilitate hospital management in addressing safe HIT adoption strategies and to plan the policies to establish safe HIT adoption and implementation.
   d. SafeHIT is beneficial to identify the potential risks and the consequences of HIT adoption for the purposes of redesigning HIT and organization.

   Correct Answer: The correct answer is option b. There are many benefits of using SafeHIT: (1) providing a multidimensional aspect of sociotechnical perspective to measure the patterns of safe HIT use behavior, (2) providing feedback to facilitate hospital management in addressing safe HIT adoption strategies and planning the policies to establish safe HIT adoption and implementation, and (3) beneficial to identify the potential risks and the consequences of HIT adoption for the purposes of redesigning HIT and organization. SafeHIT is beneficial to qualitatively identify the complex interplay between sociotechnical elements involved in the patient care is not the benefit of using SafeHIT.

Protection of Human and Animal Subjects

The study was performed in compliance with the Ethical Principles for Medical Research Involving Human Subjects and received ethics approval from Malaysia's Ministry of Health Medical Review and Ethics Committee.

Funding

This work was supported by Universiti Teknikal Malaysia Melaka (UTeM) research grant (grant number: JURNAL/2020/FTMK/Q00055) and the Ministry of Higher Education (MOHE) Malaysia.

Conflict of Interest

None declared.

References

1 Feldman SS, Buchalter S, Hayes LW. Health information technology in healthcare quality and patient safety: literature review. JMIR Med Inform 2018;6(02):e10264
2 Kruse CS, Beane A. Health information technology continues to show positive effect on medical outcomes: systematic review. J Med Internet Res 2018;20(02):e41
3 Wang T, Wang Y, McLeod A. Do health information technology investments impact hospital financial performance and productivity? Int J Account Inf Syst 2017;2018(28):1–13
4 Magrabi F, Baker M, Sinha I, et al. Clinical safety of England's national programme for IT: a retrospective analysis of all reported safety events 2005 to 2011. Int J Med Inform 2015;84(03):198–206
5 Palojoki S, Mäkelä M, Lehtonen L, Saranto K. An analysis of electronic health record-related patient safety incidents. Health Informatics J 2017;23(02):134–145
6 Martin G, Ghafur S, Cingolani I, et al. The effects and preventability of 2627 patient safety incidents related to health information technology failures: a retrospective analysis of 10 years of incident reporting in England and Wales. Lancet Digit Health 2019;1(03):e127–e135
7 Kim MO, Coiera E, Magrabi F. Problems with health information technology and their effects on care delivery and patient outcomes: a systematic review. J Am Med Inform Assoc 2017;24(02):246–250
8 Carayon P, Hoonakker P. Human factors and usability for health information technology: old and new challenges. Yearb Med Inform 2019;28(01):71–77
9 Singh H, Sittig DF. Measuring and improving patient safety through health information technology: The Health IT Safety Framework. BMJ Qual Saf 2016;25(04):1–7
10 Middleton B, Bloomrosen M, Dente MA, et al; American Medical Informatics Association. Enhancing patient safety and quality of care by improving the usability of electronic health record systems: recommendations from AMIA. J Am Med Inform Assoc 2013;20(e1)e2–e8
11 Committee on Patient Safety and Health Information Technology; Institute of Medicine. Health IT and Patient Safety: Building Safer Systems for Better Care. Washington (DC): National Academies Press (US); 2011
12 Carayon P, Wetterneck TB, Rivera-Rodriguez AJ, et al. Human factors systems approach to healthcare quality and patient safety. Appl Ergon 2014;45(01):14–25
13 Petter S, DeLone W, McLean E. Measuring information systems success: models, dimensions, measures, and interrelationships. Eur J Inf Syst 2008;17(03):236–263
14 Sorra JS, Dyer N. Multilevel psychometric properties of the AHRQ hospital survey on patient safety culture. BMC Health Serv Res 2010;10(01):199
15 Quality A for HR and Hospital Survey on Patient Safety Culture. https://www.ahrq.gov/sops/surveys/hospital/index.html
16 Secginli S, Erdogan S, Monsen KA. Attitudes of health professionals towards electronic health records in primary health care settings: a questionnaire survey. Inform Health Soc Care 2014;39(01):15–32
17 Sittig DF, Ash JS, Singh H. The SAFER guides: empowering organizations to improve the safety and effectiveness of electronic health records. Am J Manag Care 2014;20(05):418–423
18 Hinkin TR. A review of scale development practices in the study of organization. J Manage 1995;21(05):967–988
19 Salahuddin L, Ismail Z. Classification of antecedents towards safety use of health information technology: a systematic review. Int J Med Inform 2015;84(11):877–891
20 Salahuddin L, Ismail Z, Hashim UR, Raja Ikram RR, Ismail NH, Naim Mohayat MH. Sociotechnical factors influencing unsafe use of hospital information systems: a qualitative study in Malaysian government hospitals. Health Informatics J 2019;25(04):1358–1372
21 Salahuddin L, Ismail Z, Hashim UR, et al. Healthcare practitioner behaviours that influence unsafe use of hospital information systems. Health Informatics J 2020;26(01):420–434
22 Bhattacherjee A. Social Science Research: Principles, Methods, and Practices. 2nd ed. Scotts Valley, CA: Createspace Independent Pub; 2012
23 George D, Mallery P. SPSS for Windows Step by Step: A Simple Guide and Reference. 4th ed. Allyn & Bacon: The University of Michigan;2003
24 Zikmund WG. Business Research Methods. 7th ed. Thomson South-Western; Indiana University;2003
25 Fabrigar LR, Wegener DT, MacCallum RC, Strahan EJ. Evaluating the use of exploratory factor analysis in psychological research. Psychol Methods 1999;4(03):272–299
26 Hair JF, Anderson R, Tatham R, Black W. Multivariate Data Analysis. 4th ed. Englewood Cliffs: Prentice-Hall Inc.; 1995
27 Williams B, Onsman A, Brown T. Exploratory factor analysis: a five-step guide for novices. J Emerg Prim Health Care 2010;8(03):1–13
28 Hair J, Black W, Babin B, Anderson R, Tatham R. Multivariate Data Analysis. 7th ed. Prentice Hall; 2010
29 Hair JF, Hult GTM, Ringle CM, Sarstedt M. A primer on partial least squares structural equation modeling (PLS-SEM). Sage 2014
30 Epstein RM, Hundert EM. Defining and assessing professional competence. JAMA 2002;287(02):226–235
31 Palojoki S, Saranto K, Reponen E, Skants N, Vakkuri A, Vuokko R. Classification of electronic health record–related patient safety incidents: development and validation study. JMIR Med Inform 2021;9(08):e30470
32 Davy A, Borycki EM. Copy and paste in the electronic medical record: a scoping review. Knowl Manag E-Learning 2021;13(04):522–535
33 Kinlay M, Zheng WY, Burke R, Juraskova I, Moles R, Baysari M. Medication errors related to computerized provider order entry

systems in hospitals and how they change over time: a narrative review. Res Social Adm Pharm 2021;17(09):1546–1552
34 Joseph AL, Stringer E, Borycki EM, Kushniruk AW. Evaluative frameworks and models for health information systems (HIS) and health information technologies (HIT). Stud Health Technol Inform 2022;289:280–285
35 Zheng K, Ratwani RM, Adler-Milstein J. Studying workflow and workarounds in electronic health record-supported work to improve health system performance. Ann Intern Med 2020;172 (11):S116–S122
36 Redwood S, Rajakumar A, Hodson J, Coleman JJ. Does the implementation of an electronic prescribing system create unintended medication errors? A study of the sociotechnical context through the analysis of reported medication incidents. BMC Med Inform Decis Mak 2011;11:29
37 Miller GE. The assessment of clinical skills/competence/performance. Acad Med 1990;65(09):S63–S67
38 Sittig DF, Singh H. Eight rights of safe electronic health record use. JAMA 2009;302(10):1111–1113
39 Janols R, Lind T, Göransson B, Sandblad B. Evaluation of user adoption during three module deployments of region-wide electronic patient record systems. Int J Med Inform 2014;83(06):438–449
40 DeLone WH, McLean ER. The DeLone and McLean model of information systems success: a ten-year update. J Manage Inf Syst 2003;19(04):9–30
41 Viitanen J, Hyppönen H, Lääveri T, Vänskä J, Reponen J, Winblad I. National questionnaire study on clinical ICT systems proofs: physicians suffer from poor usability. Int J Med Inform 2011;80 (10):708–725
42 Yu P, Zhang Y, Gong Y, Zhang J. Unintended adverse consequences of introducing electronic health records in residential aged care homes. Int J Med Inform 2013;82(09):772–788
43 Walji MF, Kalenderian E, Tran D, et al. Detection and characterization of usability problems in structured data entry interfaces in dentistry. Int J Med Inform 2013;82(02):128–138
44 Seddon PB, Kiew MY. A partial test and development of Delone and Mclean's Model of IS success. AJIS Aust J Inf Syst 1996;4(01): 90–109
45 Pitt L, Watson R, Kavan C. Service quality: a measure of information systems effectiveness. Manage Inf Syst Q 1995;19(02):173–187
46 Singer S, Meterko M, Baker L, Gaba D, Falwell A, Rosen A. Workforce perceptions of hospital safety culture: development and validation of the patient safety climate in healthcare organizations survey. Health Serv Res 2007;42(05):1999–2021
47 Thompson D, Duling L. Computerized physician order entry, a factor in medication errors: descriptive analysis of events in the intensive care unit safety reporting system. J Clin Outcomes Manag 2005;12(08):407–412
48 Bradford M, Florin J. Examining the role of innovation diffusion factors on the implementation success of enterprise resource planning systems. Int J Account Inf Syst 2003;4(03):205–225
49 Lee F, Teich JM, Spurr CD, Bates DW. Implementation of physician order entry: user satisfaction and self-reported usage patterns. J Am Med Inform Assoc 1996;3(01):42–55
50 Evans B, Glendon AI, Creed PA. Development and initial validation of an Aviation Safety Climate Scale. J Safety Res 2007;38(06):675–682
51 Ostrom L, Wilhelmsen C, Kaplan B. Assessing safety culture. Nucl Saf 1993;34(02):163–172
52 Manser T. Teamwork and patient safety in dynamic domains of healthcare: a review of the literature. Acta Anaesthesiol Scand 2009;53(02):143–151
53 Sexton JB, Helmreich RL, Neilands TB, et al. The Safety Attitudes Questionnaire: psychometric properties, benchmarking data, and emerging research. BMC Health Serv Res 2006;6:44
54 Pirnejad H, Niazkhani Z, van der Sijs H, Berg M, Bal R. Evaluation of the impact of a CPOE system on nurse-physician communication—a mixed method study. Methods Inf Med 2009;48(04):350–360
55 Konradt U, Hertel G, Schmook R. Quality of management by objectives, task-related stressors, and non-task-related stressors as predictors of stress and job satisfaction among teleworkers. Eur J Work Organ Psychol 2003;12(01):61–79
56 Kinzl JF, Knotzer H, Traweger C, Lederer W, Heidegger T, Benzer A. Influence of working conditions on job satisfaction in anaesthetists. Br J Anaesth 2005;94(02):211–215
57 Beuscart-Zéphir MC, Borycki E, Carayon P, Jaspers MWM, Pelayo S. Evolution of human factors research and studies of health information technologies: the role of patient safety. Yearb Med Inform 2013;8(01):67–77
58 Saleem JJ, Russ AL, Neddo A, Blades PT, Doebbeling BN, Foresman BH. Paper persistence, workarounds, and communication breakdowns in computerized consultation management. Int J Med Inform 2011;80(07):466–479
59 Niazkhani Z, Pirnejad H, van der Sijs H, Aarts J. Evaluating the medication process in the context of CPOE use: the significance of working around the system. Int J Med Inform 2011;80(07): 490–506
60 Odukoya OK, Chui MA. e-Prescribing: characterisation of patient safety hazards in community pharmacies using a sociotechnical systems approach. BMJ Qual Saf 2013;22(10):816–825
61 Westbrook JI, Baysari MT, Li L, Burke R, Richardson KL, Day RO. The safety of electronic prescribing: manifestations, mechanisms, and rates of system-related errors associated with two commercial systems in hospitals. J Am Med Inform Assoc 2013;20(06): 1159–1167
62 Ash JS, Sittig DF, Dykstra RH, Guappone K, Carpenter JD, Seshadri V. Categorizing the unintended sociotechnical consequences of computerized provider order entry. Int J Med Inform 2007;76 (Suppl 1):S21–S27
63 Embi PJ, Yackel TR, Logan JR, Bowen JL, Cooney TG, Gorman PN. Impacts of computerized physician documentation in a teaching hospital: perceptions of faculty and resident physicians. J Am Med Inform Assoc 2004;11(04):300–309
64 Holden RJ. Cognitive performance-altering effects of electronic medical records: an application of the human factors paradigm for patient safety. Cogn Technol Work 2011;13(01):11–29
65 Santell JP, Kowiatek JG, Weber RJ, Hicks RW, Sirio CA. Medication errors resulting from computer entry by nonprescribers. Am J Health Syst Pharm 2009;66(09):843–853
66 Hoonakker PL, Cartmill RS, Carayon P, Walker JM. Development and psychometric qualities of the SEIPS survey to evaluate CPOE/EHR implementation in ICUs. Int J Healthc Inf Syst Inform 2011;6(01):51–69
67 Love JS, Wright A, Simon SR, et al. Are physicians' perceptions of healthcare quality and practice satisfaction affected by errors associated with electronic health record use? J Am Med Inform Assoc 2012;19(04):610–614

