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Developing a model for hospital inherent safety assessment: Conceptualization and validation

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Abstract.
BACKGROUND: Paying attention to the safety of hospitals, as the most crucial institute for providing medical and health services wherein a bundle of facilities, equipment, and human resource exist, is of significant importance.
OBJECTIVE: The present research aims at developing a model for assessing hospitals' safety based on principles of inherent safety design.
METHODS: Face validity (30 experts), content validity (20 experts), construct validity (268 examples), convergent validity, and divergent validity have been employed to validate the prepared questionnaire; and the items analysis, the Cronbach's alpha test, ICC test (to measure reliability of the test), composite reliability coefficient have been used to measure primary reliability. The relationship between variables and factors has been confirmed at 0.05 significance level by conducting confirmatory factor analysis (CFA) and structural equations modeling (SEM) technique with the use of Smart-PLS.
RESULTS: R-square and load factors values, which were higher than 0.67 and 0.300 respectively, indicated the strong fit. Moderation (0.970), simplification (0.959), substitution (0.943), and minimization (0.5008) have had the most weights in determining the inherent safety of hospital respectively.
CONCLUSIONS: Moderation, simplification, and substitution, among the other dimensions, have more weight on the inherent safety, while minimization has the less weight, which could be due do its definition as to minimize the risk.

Keywords: Inherent safety, hospital, model

1. Introduction

All organization, and especially those offering community instant services, should be provided with an environment where employees and customers are exposed to no harm. In this regard, paying attention to the hospitals' safety, as the most important institute providing community with medical

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health services, wherein combination of facilities and equipment, human resources, students, patients, disables and their companions gather together is of particular significance [1]. It is crucial for hospitals to be able to perform well under the most adverse condition and maintain their safety at any cost [2, 3]. The motto chosen by the World Health Organization in 2009 for the world health day as "making hospitals safe in the state of emergency" was to emphasize on this issue. The safety of hospitals is important to us owing to three reasons: a) social [4], b) hygienic [5], and economic [6]. Hospitals are in continuing circle of altering and developing their current model and facilities to adjust to changes and requirements [7]. Hospitals are growing bigger as the result of growth in population and an increased need for services and it makes enormous problems regarding excavating them from people in times of catastrophic disasters like fire [8]. In December 15th, 2005, 39 patients died in a fire sparked in Liu-Yan Central Hospital, Jilin Province. At midnight of December 9, 2006, a fire caused in a drug rehab center in Moscow led to the death of 45 people as they found no way out of the building due to closed doors and windows. In another incident in December 9th, 2011 more than 90 were killed in a fire in one of Indian hospital. Jung in his research put emphasis on developing safe deign for hospitals' buildings [9]. The direct relationship between hospital design and safety has been shown in many studies [10]. The building design is effective on not only the energy consumption of the hospital but also the people's performance as well as patients' recovery [11]. On the other hand, sustainable development could be defined as meeting the perceived needs without risking the future generations' capacity to respond to the need; and inherent safety is one of the most crucial criteria to achieve sustainable development [12]. The inherent safety, which was first introduced by Kletz in 1970, claims that it is possible to identify hazards in a process and to minimize them by early elimination, even before the process is went through [12, 13]. Kletz was among the first who outlined all activities done in the field of inherent safety design (ISD) of manufacturing workshops in 4 famous catch-phrases, namely minimization, substitution, moderation, and simplification, which then inspired Hassim to represent his inherent occupational hygiene [14, 15]. Inherent safety is a flexible concept, which can be used during either designing or operational phases [16]. The theory of inherent design has been specifically formulated by a number of authors [17]. ISD provides the opportunity to minimize the dangers considerably. Rather than adding the external safety equipment, this method of risk analysis avoids dangers in the work place by minimizing the hazardous materials or wrong operations [18]. The idea here is that the improvement of inherent safety is done through elimination or minimization (internal strategy) instead of controlling or managing (external strategy) the dangers [12]. As stated by Shariff, this approach can be used as a scientific tool [19]. Additionally, Abidin recognizes the inherent safety strategy as an integral part of all engineering activities, pursuing a sort of design that is easier, cheaper, and safer [20]. Furthermore, Aven defines risk as a two-dimensional concept consisting of disasters and their consequences as well as uncertain possibilities associated with them [13, 21, 22]. Risk and safety are in the guide book and the strategy is required to carry out safety and risk management processes in organizations thoroughly [23]. Economy was used to be considered the most important factor in choosing the best process pass but, given the results obtained from risk management, has been replaced by safety, environment, and hygiene and safety issues nowadays [24]. Safety assessment difficulties have been studies by many researchers through employing a wide array of methods [25]. However, there is arguably yet to be a specific and precise method to assess and manage risk in hospitals. Consequently, the present study is to develop a model for assessing inherent safety in the Iranian hospital by using structural equation models (SEM). SEM is a strong, general multi-variable analysis technique rooted in multi-variable regression or, to put it more precisely, developed from general linear model, which allows researchers to test a series of regression equations simultaneously and study the relationship between different variables concurrently [26–28].

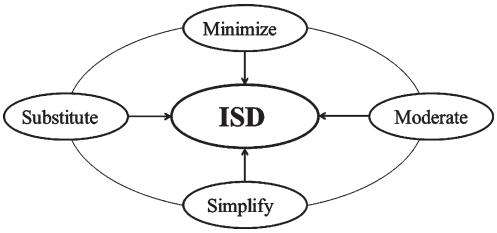

Fig. 1. Primary conceptual model for inherent safety.

2. Methods

2.1. Designing the dimensions and components

The present paper is classified as an applied study employing analytical research method to study the status-quo. The structure proposed by kletz regarding ISD, including four major aspects of minimization, substitution, moderation, and simplification, has provided the basis for conducting this study. Having taken into account the previously conducted researches on principles of ISD, conceptual model of the research was developed according to the Fig. 1, consisting of variables like minimization, substitution, moderation, and simplification. This model is a combination of variables obtained in previous studies. Afterwards, a series of questions and items (relating to the issue of safety) was extracted through studying existing standards associated with safety of patients and hospitals. On the next step, measuring scales (designing the answer choices) for each question were specified. The initial questionnaire was prepared at the end of this phase. Group of question designers included 5 seasoned experts with the experience of performing related researched in the context of hospital's safety.

2.2. Evaluating validity and reliability of the research instrument

The face validity, content validity, construct validity, convergent, and divergent validity were used to evaluate the validity of prepared questionnaire and, item analysis, Cronbach's alpha test, intra-class correlation (ICC) test (to measure the reliability of the test), and composite reliability coefficient (CR) were performed to evaluate the primary reliability. To study the face validity of the initial questionnaire, an expert panel, composing of 30 M.A and PhD students as well as experts in the hospitals, was selected and invited to cooperate in the study. Then, based on the panel's opinion, those questions needed correction were written. By conducting convenience sampling method, a group of 20 safety experts including faculty members and PhD students with at least five years of working, researching, and educational experience in the context of safety in hospitals was selected to measure the content validity– this group voluntarily chose to participate in this phase of the study [29, 30]. Content validity ration (CVR) and content validity index (CVI) were used to study the content validity. Given the number of participant in the content validity, which were 20, the least acceptable value for CVR and CVI were 0.42 and 0.79 respectively [31]. Having confirmed the face and content validity of the extracted questionnaire, which was prepared in five Likert scales, it was completed by 268 randomly-chosen, veteran experts in the field of hospital safety. The sample size was determined to be the four times as big as the number of items in questionnaire [32]. The construct validity, items classification, and questionnaire reliability were all done through performing the exploratory factor analysis (EFA) and data analysis was carried out by using the SPSS.

2.3. Model representation and validation

The following equation was used to gather the required data for evaluating the convergent and divergent validity and doing the modeling and size of second sample was calculated to be 384 (at 95% confidence level, 0.5 SD, and ± 0.5 MOE). Eventually, 390 questionnaires was collected through simple random sampling method.

$$\frac{(U_1 - \alpha/2)^2 \times 0.25}{\varepsilon^2}$$

$\alpha = 0.5$ (*estimation error*)

$\varepsilon = 0.5$ (*possible error rate*)

The relationship between variables and factors was confirmed through confirmatory factor analysis (CFA) and SEM technique. The research employed Smart-PLS software for this analysis. It analyzes structural equation models, with multiple variables which have direct, indirect, and interactive effects on each other. In addition, it is a suitable program for testing moderating effects. As stated by Esposito and Vinzi, the PLS path models are calculated in two phases. In the first phase, it estimated latent variables' scores for each latent variable and, in the second phase, it analyses the moderating role of latent variables on the ground of their status on the model path [33]. Given the nature of second phase, it is recommended to test moderating effect of multiple regressions through Smart-PLS.

3. Results

3.1. Face validity

In line with the research's objective, all existing standards connected to the safety of patient as well as of hospital were placed under careful scrutiny. Accordingly, hospital-related safety issues were identified as 177 some of which were common between other standards and regulations. Therefore, the repetitive issues were removed and an aggregation of 109 remained, based on which a 109-item questionnaire was developed initially. All questionnaires were returned (100 percent response rate) in the face validity phase; however, they were returned on average of 45.23 days. The median age of panel members was 27.9 years and they had working experience of 5.6 years on average. Judgements made by members of face validation panel were investigated and applied in the initial questionnaire. Having done the face validity of questionnaire and made grammatical and scientific modifications into it, the questionnaire's items were reduced from 109 to 77.

3.2. Content validity

To do content validity, we made face-to-face, phone, and email contact with the panel members. 22 nodded their consent to take part in the study among the chosen ones. Consequently, a group of experts, including 13 faculty members holding doctoral degree in occupational health engineering, 4 faculty members with doctoral degree in medical and health services management, and 5 doctoral students in occupational health engineering with minimum experience of 5 years in respected fields, was brought together among which 11 were females and the rest was males. The median age of the group members was 42.86 years and they had working experience of 9 years on average. The questionnaire's response rate was 90.9% and, therefore, only 20 participated in validation of the questionnaire. The questionnaire was returned on average of 41 days. Judgments made by the panel members were inserted

Table 1
CVI average for questionnaire items

Variable	Mean	S.D	Max	Min
Simple	0.95	0.08	1	0.7
Quite simple	17.73	2.93	20	12
Simple	1.26	1.65	6	0
Relatively simple	0.86	1.37	5	0
Complicated	0.17	0.53	3	0
Clarity	0.92	0.11	1	0.6
Quite clear	17.05	3.47	20	7
Clear	1.32	1.67	6	0
Relatively clear	1.13	1.37	5	0
Unclear	0.53	1.07	5	0
Relevant	0.94	0.09	1	0.5
Quite relevant	17.48	3.02	20	8
Relevant	1.28	1.42	5	0
Relatively relevant	0.9	1.31	5	0
Irrelevant	0.31	0.95	5	0

into the Excel (2000) and SPSS (2000) to statistically calculate the data. Given the number of content validation panel members [20], the questions CVR and CVI values of which were less than 0.42 and 0.79, respectively, were rejected and removed from the questionnaire. Therefore, 19 items were removed from the questionnaire, after the content validity, and just 58 remained out of 109 items in initial questionnaire. In addition to the CVI and CVR, considering the definition put forward for each inherent safety aspect, each expert was asked on classification of questions, and then they were put into four general groups of ISD principles including substitution (9 questions), minimization (14 questions), simplification [18], and moderation (17 questions).

The most and least items removed from the questionnaire belonged to the simplification (35%) and substitution (15%) groups respectively. In general, CVI score for questionnaire was calculated to be 0.93 on average with the SD of 2.91. Moreover, the number of unaccepted questions for this index was 10 (11.49%), details of which are illustrated in the Table 1. Generally, the CVR score for questionnaire was 0.79 on average with the SD of 0.29 and the number of unaccepted questions, removed from the questionnaire, for this index was 13. The average of "necessary" component was 17.94 with SD of 2.91, the average of "useful but unnecessary" component was 1.59 with SD of 2.21, and the average of "unnecessary" component was 0.44 with SD of 0.94.

3.3. Construct validity

The KMO test was performed before conducting factor analysis to do the construct validity and measure the sampling adequacy; and Bartlett's test of sphericity was carried out to ensure correlation matrix, as the basis of factor analysis, was not zero in the community under study. Given the value of KMO (0.854), the sampling adequacy for factor analysis was excellent in this research. Furthermore, the Bartlett's test of sphericity was estimated to be 5.313 with DOF equal to 1653 and 0.0000 confidence level. Therefore, the sampling was adequate and the data obtained from the sample could be used in the factor analysis. As the results, we could conduct other factor analysis indices. Results of the EFA showed that 4 factors were able to determine 51.733% of changes on aggregate; so that the first and

Table 2
Sample's demographic characteristics

Variable	Group	Frequency	Percentage	Variable	Group	Frequency	Percentage
Sex	Male	213	54.6	Work experience	Less than 10	250	64.1
	Female	177	45.4		Between 11 and 20	94	24.1
Age	Under 25	53	13.6		Between 21 and 30	35	9
	Between 26 and 35	159	40.8		Above 30	11	2.8
	Between 36 and 45	93	23.8	Education	BSc	221	54.6
	Between 46 and 55	50	12.8		MSc	136	34.9
	Above 56	35	9		PhD	33	8.5

fourth factors could determine the total variance by 22.377% and 5.027% respectively. Each variable is connected to the factor with which has significantly high correlation. To find what variable (sub-index) is connected to which component (factor), we only chose indices the factor loading of which on a component was at least 0.300, while had not high factor loading on the other factors. Of the 58 primary indices, 51 had factor loading on 4 factors.

3.4. Primary reliability

The Cronbach's alpha test was conducted to calculate the internal consistency. In the test, the values of SD, variance, and median were equal to 26.833, 720.034, and 2.32 respectively and the result of standardized test was 0.920 for 59 items of questionnaire, which was acceptable for the questions – given the 0.7 confidence level. To measure the reliability of test, the ICC was carried out, based on which the agreement between respondents was calculated to be 0.930 at 95% confidence interval (F-test = 10.274, p-value = 0.000 in the range of –0.919 and 0.885), which indicated the excellent agreement between respondents.

3.5. Model validation

390 questionnaires have been collected in the model validation phase. Table 2 illustrates demographic information of the participants. The convergent validity points to the principle that there should be intermediate correlation between indices in every construct.

AS stated by Larcker and Fornell, the square root of AVE for each reflective constructs should be greater than the correlation of that construct with other constructs in the model [34]. The Table 4 shows the correlation matrix between the dimensions of ISD. Additionally, the questionnaire's reliability has been determined by using two criteria, namely Cronbach's alpha and CR coefficients. The Cronbach's alpha coefficients for all variables were greater than the minimum value, i.e. 0.7. Likewise, the CR should be greater than 0.7 to indicate the construct's internal consistency [35]. R square is a criterion, used to link measuring phase to structural phase in SEM, and indicative of the effect produced by an exogenous variable on an endogenous one. Values, greater than 0.67, indicate the strong fit. In the present study, the questions' factor loading coefficients were greater than 0.300, which was the representative of the suitability of this criterion. The t-value in Smart-PLS shows the significance of effects of variables on each other. Since the t-values for all variables were greater than 1.96, the effect of variable on each other was positive and significant (see Table 3). In addition, the path coefficients are illustrated in the Fig. 2, based on which it can be concluded that there is a strong connection between two variables, since this coefficient for all aspects of ISD is greater than 0.6.

Table 3
Convergent validity and reliability of the measuring instrument

Variable	Average Variance Extracted Factor (AVE)	Composite Reliability Factor (CR)	Cronbach's alpha Reliability Factor	R square Factor
Substitution	0.506	0.891	0.859	0.896
Minimization	0.517	0.884	0.795	0.851
Simplification	0.507	0.873	0.846	0.920
Moderation	0.502	0.933	0.923	0.941

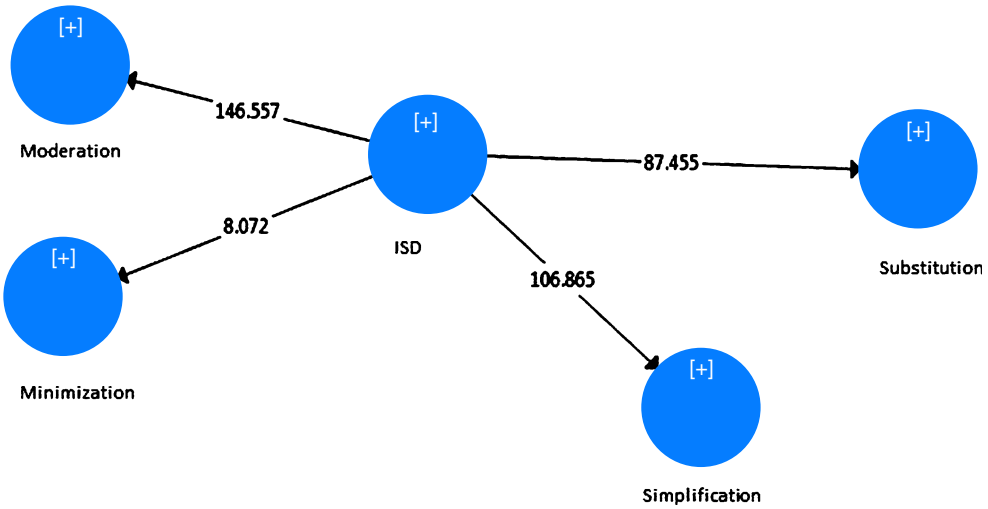

Fig. 2. Results of *t*-test.

Table 4
Correlation matrix and studying the divergent validity

Variable	Substitution	Minimization	Simplification	Moderation	Root of AVE
Substitution	1				0.711
Minimization	0.680	1			0.719
Simplification	0.658	0.686	1		0.712
Moderation	0.361	0.448	0.388	1	0.709

Table 5 shows the level of effect of "substitution", "minimization", "moderation", and "simplification" factors on status of ISD in hospitals. According to the results obtained front the table, all variables are significant at confidence level of 0.5% [36]. "Moderation" and "minimization" were the variables having the highest and lowest weights in defining the status of inherent safety in hospital with 0.970 and 0.5008 coefficients. Eventually, the final research model has been presented with 4 dimensions and 51 components, the result of path analysis of which is depicted in Fig. 3.

4. Discussion

In line with the research findings, all safety dimensions were embodied in the prepared questionnaire and, when its validation was confirmed in terms of measuring ISD aspects, it has been recognized as

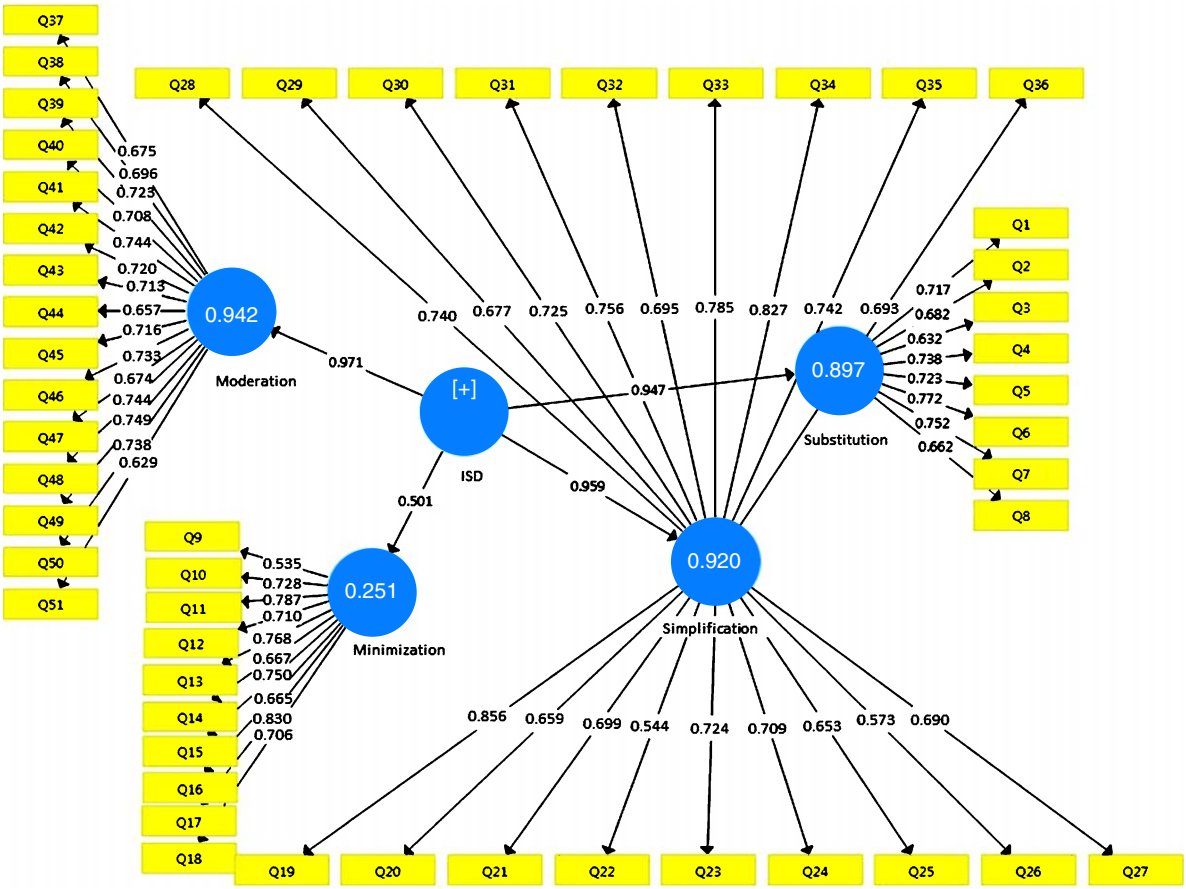

Fig. 3. Results of path analysis.

Table 5
Summary of results of testing model coefficients

Variable	Coefficient	Test statistic	Significant level	Effect level
Substitution	0.943	87.455	0.000	Very high
Minimization	0.5008	8.072	0.000	Medium
Simplification	0.970	146.56	0.000	Very high
Moderation	0.959	106.86	0.000	Very high

an acceptable and comprehensive questionnaire. In the study conducted by Varsha, the reliability of inherent safety intervention was enhanced with the help of process design simulator [18]. Tremblay, in his study "safety of machinery in hospitals", used a questionnaire to gather opinions and perceptions of non-medical managers and staff and found that machinery-related risks were a fact in the hospital environment that were usually either hard to be controlled or managed ineffectively [37]. It was found, in the study performed by Yari, that the community under study was more disposed to inactive, less costly safety measures [38]. Jafari and colleagues carried out a study in which they divided 5 major groups of barriers to adopt ISD philosophy in Iran into 21 sub-groups (organization-related barriers including 8 factors, inherent-safety-related barriers including 3 factors, barriers regarding rules and

regulations comprising 4 factors, technology-related barriers consisting of 3 factors, and science-related difficulties involving 3 factors) and placed them under careful scrutiny. At the end, all 5 major groups were identified as effective barriers to adopt ISD philosophy in Iran [39]. In Pinheiro's study, which was to examine safety climate in operating room through questionnaire validation, the internal consistency of 73 items in questionnaire was about 0.7 and, also, a significant correlation was found between the aspects of questionnaire [40]. Wang studied the relationship between patient safety culture and its adverse consequences and concluded that improving the safety culture would decrease the incidents of unfavorable events. Moreover, the ICC test performed in similar sections of different hospitals confirmed the agreement between reported rates [41]. In a study on linguistic barriers and safety risks concerning hospital-based treatment, Rosse and colleagues showed a broad spectrum of hazardous situations in hospital cares [42]. "Validation of a questionnaire measuring transitional patient safety climate indicated differences in transitional patient safety climate between primary and secondary care" was a study performed by Marije and colleague in which 162 questionnaires have been completed by 97 general practitioners and 65 hospital doctors but analyzing the answers provided by all respondents did not bring on an interpretable solution [43]. A questionnaire including Greek version of general approach to safety behaviors was used in all public ICUs across the Cyprus during Raflopoulos study, aiming at exploring the safety climate in 5 intensive care units, therein it was shown a significant relationship between age and group work. Indeed, the older the patients, the more inclined were they to do group work. Additionally, the study showed that age, infrastructure, severity of cases, and nursing skills were the variables affecting the patient safety culture in the ICU environment [44]. Likewise, lee and colleagues performed a study, aiming at safety culture of hospital, in Taiwan, therein a total number of 25242 questionnaires have been collected from 200 hospitals. The values of Cronbach's alpha for group work climate, safety climate, job satisfaction, understanding of management, and work condition were calculated to be 0.792, 0.816, 0.912, 0.874, and 0.785 respectively. In addition, the factor analysis showed a fit model for every aspect and the whole structure. Finally, it was revealed that the safety culture has not fully grown in most hospitals and there were still considerable room for improvement [45]. "Assessment of patient safety culture in Saudi Arabian hospitals" was the study conducted by Alahmadi and colleagues in which information obtained from a questionnaire survey, distributed to 223 personnel in 13 general hospitals, showed that overall patient safety grade was rated as excellent or very good by 60% of respondents, acceptable by 33% and failing or poor by 7%. Accordingly, they concluded that the leadership was a critical element in effectiveness of patient safety measures and that responding to error was a decisive factor in safety culture of healthcare organization [46]. Flin and colleagues examined 12 studies, on safety climate in healthcare systems, and found no clear theoretical principles for most standard, psychometric questionnaires and instruments therein. Accordingly, more attention should be focused on psychometric factors in healthcare safety design [47]. In his study, Mahdinia showed a statistically significant and reverse correlation between safety behavior score and incidents [48]. In Zimmermann and colleagues' study, on assessing safety attitude questionnaire (SAQ), a total of 319 questionnaires were completed, which was representing an overall response rate of 78.6%. Moreover, for three items, the item content validity index was <0.75. Confirmatory factor analysis also showed acceptable model fit and SAQ factor scores had positive correlations with the Safety Organizing Scale [49]. Based on 33 finished SAQs with Cronbach's alpha equal to 0.9, Devriendt conducted a study in which the questionnaire showed acceptable to good psychometric properties and could be an acceptable to adequate tool to evaluate the safety climate [50]. In addition to the face and content validity, the researcher also made use of convergent and divergent validity in the study. In the opinion of Denis, one of CVI weak points is its focus on consensus rather than consistency [51]. The content validity rate (CVR), which was originally proposed by Lawshe, is widely used for quantifying the content validity, though practical methods have not been proposed to measure the major, important values yet [52]. Results of ICC statistics show excellent agreement between respondents.

Eventually, the instrument's internal consistency was measured high, based on the Cronbach's alpha. Additionally, most questions belonged to the simplification dimension, according to the classification made by content validation panel, which was then confirmed by the results of CFA and EFA as well.

5. Conclusion

The bigger number of questions, classified by the content validity panel and according to the results of factor analysis, belonged to dimensions of simplification and moderation and a fewer number of indices were connected to more efficient dimensions of inherent safety (i.e. substitution, and minimization). Based on the CFA results, dimensions of moderation, simplification, and substitution have more weight on the inherent safety and the minimization has less weight, which could be associated to its definition as to minimize the risk.

6. Recommendations

According to the results obtained from this study, researchers are suggested to:

1. Do more studies on the dimensions of substitution and minimization as they are less fully implemented in the hospitals than that of simplification and moderation.
2. Use each one of the safety dimensions precisely and separately based on the proposed model to assess risks in hospitals.
3. Employ each ISD dimension's impact factor as a detection capability in FMEA risk assessment.
4. Perform more studies on the dimension of minimization as the impact factor of which was lower than that of the other dimensions.
5. Carry out more research on this field so that the impact factors can gain more reliability.

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Conflict of interest

There is no conflict of interest to be declared.

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