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A structural model of total quality management, work values, job satisfaction and patient-safety-culture attitude among nurses

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Abstract

Aim: This study explores the impact of total quality management on patient-safetyculture attitudes among clinical nurses, focusing on the correlations between total quality management, work values, employee satisfaction, and patient-safety-culture attitudes.

Background: Implementing total quality management can improve nurses' attitudes towards patient-safety culture.

Method: This hospital-based, cross-sectional survey used a convenience sample of 30 inpatient units and 12 intensive care units at five Taiwanese regional teaching hospitals with over 500 beds. Seven hundred questionnaires were distributed (140 to each hospital) during 25 June-5 July 2015. Data were collected using an anonymous, self-administered, and structured questionnaire. The model was tested using structural equation modelling and serial mediation analysis.

Results: Of 515 completed questionnaires (73.6% response rate), 23 were invalid and 492 were used (70.3% retrieved rate). The total effect of total quality management on patient-safety-culture attitudes was significant via work values, which had a direct influence on patient-safety-culture attitude. Total quality management affected employee satisfaction, which directly influenced patient-safety-culture attitudes.

Conclusion: Total quality management creates a beneficial working environment and improves patient-safety culture. Total quality management, work values, and employee satisfaction orientation are important predictors of nurses' attitudes toward patient-safety-culture attitudes.

Implications for nursing management: Health care managers should cultivate nursing performance to achieve continuous quality improvement in nursing care.

KEYWORDS

job satisfaction, patient-safety-culture attitude, total quality management, work values

| INTRODUCTION

The issues of primary medical negligence, medication safety, and personnel education and training are critical for health care institutions in Taiwan and worldwide (Chen, Chang, & Pan, 2009). Total quality management (TQM) is a concept used by organisations to

maintain a competitive advantage and to ensure overall effective performance (Chang, Chiu, & Chen, 2010; Nasser, Yusoff, & Islam, 2013). Several studies have reported that total quality management has a positive effect on hospital performance, showing that accredited hospitals are more likely than unaccredited hospitals to engage in total quality management practices (Alaraki, 2014). Total quality management is characterized by the design and implementation of organisation-wide quality improvement programmes centred on core principles of customer focus, employee participation, reduced variability, and the continuous improvement of systems and processes (Rennie et al., 2007). Total quality management can simply be defined as an element of overall management, required of every organisational employee engaged in the daily management of an organisation. Total quality management can help an organisation to achieve its quality goals and satisfy customer demand by enhancing company performance (Lam, Lee, Ooi, & Lin, 2011). Adjusting a hospital's existing training system and workflow can enhance the mental health and job satisfaction of nurses (Gountas, Gountas, Soutar, & Mavondo, 2014). Although some organisations within the health care industry do not have total quality management programmes, the TQM concept is an important tool for assessing health care providers in health care settings.

Work values, employee satisfaction, and PSCA play an important role in TQM practices. The literature shows a close association between value orientation and positive work performance (Froese & Xiao, 2012). Work value has been classified into intrinsic and extrinsic values. An intrinsic value is an immaterial aspect, which includes self-realization and self-expression. Examples include autonomy, creativity, and initiative. By contrast, safety measures and significant acquisitions are examples of extrinsic values (Malka & Chatman, 2003; Vansteenkiste et al., 2007). Intrinsically motivated employees are more likely to exhibit higher levels of job performance and work effort than those who are less motivated. Extrinsic work values are positively associated with job performance (Dysvik & Kuvaas, 2011; Hammond, Neff, Farr, Schwall, & Zhao, 2011). Nurses and the guality of the health care environment are significantly associated with nurse-workforce outcomes, care quality and safety, and patient satisfaction (Aiken et al., 2012). Previous research has shown that nurses with a positive attitude toward fostering a culture of patient safety generally receive higher assessments in patient health care. The improvement of a patient-safety culture is related to nursing experiences (Sorra, Khanna, Dyer, Mardon, & Famolaro, 2012). Safety culture, defined as an organisation's approach to health and safety management, incorporates the values, attitudes, views, and competent behaviour of individuals and groups (Carney, West, Neily, Mills, & Bagian, 2010).

Employee empowerment, cooperation and coordination, employee salaries, and management leadership are positively associated with employee satisfaction (Chang et al., 2010). Job satisfaction among nurses has been shown to be a crucial indicator of nursing performance. One study has argued that nurses who perceive a supportive working environment generally display high levels of commitment to the organisation and deliver good-quality nursing care (Tanaka, Maruyama, Ooshima, & Ito, 2011). The literature shows that work climate, professional commitment, and work values can help to predict job satisfaction (Caricati et al., 2014). The five aspects of job satisfaction in nursing include professional dedication, relationships with colleagues, management strength, manpower and resource allocation, and ward management (Choi, Cheung, & Pang,

2013). High-reliability organisation theory argues that high reliability requires a safe culture, which includes both safety-related attitudes and experience. In general, the team atmosphere, level of job satisfaction, level of work stress, and improvements in safety are all highly relevant (Chaboyer, Mills, Roberts, & Latimer, 2015).

Health care institutions maintain that focusing on the issues of service quality and patient-safety brings obvious management improvement. However, few studies have addressed this issue, particularly in developing countries (Alaraki, 2014).

Total quality management includes employee training, employee empowerment, teamwork, management leadership, and employee compensation. As the literature has recognized, the use of TQM greatly enhances health care quality and patient safety, as well as having a significant positive effect on hospital performance. Work values and employee satisfaction are important factors for nurses; nursing management research has not yet explored the extent to which they play an important role in mediating between total quality management and patient safety.

The present study aims to discover whether hospital quality management and patient safety (as an aspect of hospital management) are critical factors in nurses' positive work values. Organisations that implement total quality management can improve staff job satisfaction. When employees have higher levels of job satisfaction, they are more likely to support the organisational culture, including the patient-safety culture. Nurses will be more attentive to the needs and safety concerns of patients. This study explores the impact of total quality management on PSCA among clinical nurses in Taiwan. Based on the scientific literature discussed above, we have focused on the following nine hypotheses, to find correlations between total quality management, work values, employee satisfaction, and patient-safety-culture attitude (Figure 1).

H1: TQM has a direct and positive effect on nurses' PSCA.

H2: TQM positively affects nurses' work values.

H3: Work values have a direct and positive effect on nurses' PSCA.

H4: TQM has an indirect effect on PSCA via work values.

H5: TQM enhances nurses' job satisfaction.

H6: Job satisfaction has a direct and positive effect on nurses' PSCA.

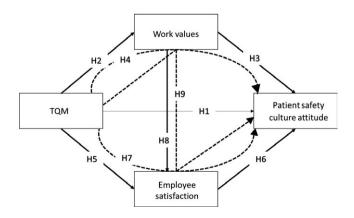


FIGURE 1 Proposed model of predictors of patient safety culture attitude and related hypotheses

H7: TQM has an indirect effect on PSCA via nurses' job satisfaction.

H8: Work values positively affect nurses' job satisfaction.

H9: Nurses' job satisfaction mediates the relationship between work values and nurses' PSCA.

2 | METHOD

2.1 | Study design and data collection procedures

We conducted a hospital-based, cross-sectional survey based on a convenience sample of 30 inpatient units and 12 intensive care units in five regional teaching hospitals in Taiwan, with over 500 beds each. A total of 700 questionnaires were sent to participating hospitals (140 to each hospital) between 25 June and 5 July 2015. All study participants were nursing staff members with more than half a year's work experience; all were directly involved in patient care. Nursing staff members included registered nurses, nurse practitioners, and head nurses. The study protocol was approved by the Institutional Review Board at MacKay Memorial Hospital in Taiwan (IRB No: 15MMHISO43).

A questionnaire, consent form, and two self-addressed reply envelopes were presented to participating hospitals. Data were collected using an anonymous, self-administered, and structured questionnaire. Completed questionnaires and consent forms were sealed and returned in self-addressed reply envelopes. All completed questionnaires were secured confidentially, with no identifiable labels or specific personal information.

2.2 | Measurements

The questionnaire content consisted of basic personal data, a total-quality-management scale, a work-value scale, a job-satisfaction scale, and a patient-safety-culture scale. An expert content validity test was adopted to confirm topic importance, suitability, and definition. The study included five health care experts (a management science professor, nurse professor, hospital president, and nurse director with more than 10 years administrative experience).

The questionnaire consisted of several measures, corresponding to the constructs described in the model (Figure 1). All responses used a five-point Likert type scale (1 = strongly disagree, 5 = strongly agree). The indicated lower levels of the measured construct and five indicated higher levels of PSCA and TQM; these were developed on the basis of items drawn from the literature.

The present study has adopted the total quality management scales compiled by Jun, Cai, and Shin (2006). The scale is composed of 20 items and measures five factors (employee empowerment, employee training, teamwork, the appraisal system, and employee compensation). The following item is an example: "I received training on quality improvement skills". Higher scores indicate a more positive view of overall quality management. The reliability of the scale was very satisfactory (α = 0.73).

The work value scale, adopted from Wang, Chou, and Huang (2010), consists of 26 items and measures five factors (altruism,

fulfilment, professional autonomy, professional development, achievement, and reputation). The following item is an example: "I am sure of myself in the field of nursing". Higher scores indicate more positive work values. The scale reliability was good ($\alpha = 0.96$).

The job satisfaction scale, developed by Jun et al. (2006), consists of four items; this is an example: "for me, this is a great organisation and I am willing to work here". Higher scores indicate higher levels of job satisfaction. The reliability of the scale was satisfactory (α = 0.73).

To arrive at a "patient-safety-culture attitude", the present study assessed 42 items and measured 10 factors developed by Perneger, Staines and Kundig (2014): supervisor expectations and actions, organisational learning, teamwork within hospital units, communication openness, feedback and communication of error, non-punitive response to error, staffing, hospital management support, teamwork across hospital units, hospital handoffs, and transitions. The following item is an example: "When an abnormal event occurs, it is reported immediately". The Cronbach's alpha was 0.6.

2.3 | Statistical analysis

The mean (standard deviations) and proportion (%) were presented for the continuous variables and categorical variables, respectively. A value of p less than 0.05 was considered statistically significant. All descriptive statistics and correlations were computed using the SPSS Statistics software package for Windows (release version R22) (SPSS Inc., Chicago, IL, USA). The model was tested with structural equation modelling (SEM), calculating the maximum likelihood estimate by using a bootstrapping (n = 1,000) procedure to obtain a standard error estimate for the indirect (mediation) analysis test (Muthen & Muthen, 2006). The SEM and confirmatory factorial analysis were carried out using Mplus software (Version 5.21) (Muthen & Muthen, 2006). Participants who missed certain scales entirely were excluded from the analysis. The serial mediation analysis was performed using PROCESS, model 6 (Hayes, 2012).

3 | RESULTS

3.1 | Levels of social capital in relation to participant demographics

Table 1 presents the baseline participant characteristics, employment positions, and experience with current work. Of the 515 completed questionnaires (a response rate of 73.6%), 23 invalid questionnaires were excluded, leaving a total of 492 valid questionnaires, for a retrieved rate of 70.3%. Most of the nurses were between 31–40 years old (45%), held a university or postgraduate degree (67.6%), were married (53.3%) and had no children (52%) (see Table 1).

The means, standard deviations, and bivariate correlation of the measured variables are shown in Table 2. All candidate variables were correlated to allow for a mediation analysis (Baron & Kenny, 1986). Most of the nurses exhibited a positive and relatively strong TQM with a mean score of 3.73 (SD = 0.439); the mean score for employee satisfaction was 3.85 (SD = 0.590) and the mean score for

TABLE 1 Demographics of the study participants (n = 492)

Profiles	Category	n	Proportion (%)
Age	21-25	73	14.8
	26-30	73	14.8
	31-35	113	23.0
	36-40	108	22.0
	41-45	73	14.8
	46-50	39	7.9
	51	13	2.6
Education	High school	16	3.3
	Junior college	143	29.1
	University	322	65.4
	Master and above	11	2.2
Marital status	Married	262	53.3
	Single	230	46.7
Number of	None	256	52
children	One	59	12
	Two	130	26.4
	Three or more	47	9.6
Experience with	1-4	182	37
current type of	4-8	73	14.8
work (years) (including previous employer)	8-12	99	20.2
	12-16	43	8.7
	16 or more	95	19.3
Employment	Nurse	356	72.4
position	In charge	63	12.8
	Head nurse	73	14.8

PSCA was 3.39 (SD = 0.262). The mean score for the nurses' work values was 3.96 (SD = 0.362) (see Table 2).

The total effect of total quality management on PSCA was significant (effect = 0.259, SE = 0.024, t = 10.61, p < 0.001). Three path effects were significant. In the first pathway, the effect of TQM on PSCA was mediated through work values (WV), a finding that supports Hypothesis 4 (TQM → WV → PSCA). Boot LLCI 0.097 and Boot ULCI 0.222 shared the same "+", presenting a significant mediation effect in WV. In the second pathway, the effect of TQM on PSCA was mediated by both WV and employee satisfaction (ES) (TQM \rightarrow WV \rightarrow ES \rightarrow PSCA). This shows that work values and employee satisfaction have an important effect on serial mediation. Boot LLCI 0.001 and Boot ULCI 0.026 shared the same "+", presenting the significant mediation effect in WV and ES; this finding supported Hypothesis 9. In the third pathway, the effect of TQM on PSCA was mediated by ES, supporting Hypothesis 7 $(TQM \rightarrow ES \rightarrow PSCA)$. Boot LLCI 0.002 and Boot ULCI 0.058 shared the same "+", presenting a significant mediation effect in ES (Table 3). The total percentages of the three path effects came to 76.6% of the model. WV and ES mediated completely. The first pathway accounted for 61.7% (TQM \rightarrow WV \rightarrow PSCA); the second pathway

accounted for 4.2% (TQM \rightarrow WV \rightarrow ES \rightarrow PSCA); the third pathway accounted for 10.6% (TQM \rightarrow ES \rightarrow PSCA) (Table 4).

3.2 | Summary of the hypothesis test

Based on the research framework used in this study, the results of the hypothesis test are summarized in Table 5. In relation to the links between TOM practices and PSCA, the results supported Hypothesis 1. The total effect of TQM on PSCA was significant. In addition, Hypothesis 2 (path coefficients 0.555, p < 0.001) predicted that TOM would have a positive impact on work values. Hypothesis 3 predicted that work values would have a strong and positive effect on PSCA in hospitals (path coefficients 0.288, p < 0.001). Hypothesis 4 predicted that TQM would have a positive effect on PSCA through work values. Hypothesis 5 predicted that there would be an association between TQM practices and employee satisfaction (path coefficients 0.563, p < 0.001). Hypothesis 6 predicted an association between employee satisfaction and PSCA (path coefficients 0.049, p < 0.001). Hypothesis 7 predicted that TQM would have a positive effect on PSCA through employee satisfaction. Hypothesis 8 predicted that work values would have a positive effect on employee satisfaction (path coefficients 0.403, p < 0.001). Hypothesis 9 predicted that TQM would have a positive effect on PSCA, which was mediated first by work values and then by employee satisfaction. The study predicted that work values and employee satisfaction would play an important role in serial mediation (Figure 1).

4 | DISCUSSION

This study explored the impact of total quality management on patient-safety-culture attitude among clinical nurses in Taiwan and assessed the correlations between TQM, work values, employee satisfaction, and PSCA.

Hypothesis 1 confirmed that the total effect of TQM on PSCA was significant, in line with other studies on this subject (Elsous et al., 2016; Kristensen et al., 2015; Singer & Vogus, 2013). Leaders perceived the teamwork culture and the safety climate more positively than did frontline staff. The leaders achieved their objectives during daily work tasks, implementing patient-safety measures and TQM methods to provide a safety culture (Kristensen et al., 2015). This study confirms the promising role of an existing management system that enhances a culture of patient safety. The findings show that the hospital quality management system is an important resource, which can improve teamwork and the safety climate (Singer & Vogus, 2013).

Hypothesis 2 was partially confirmed: TQM has a positive impact on work value. This finding suggests that the Confucian-derived work values of indigenous Chinese teams influence contemporary organisational management (Huang, Liang, & Hsin, 2012). Humans are the core element in implementing TQM and the values of individuals are the core of TQM effectiveness. It is essential to explore values in real situations, as they do not exist in isolation (Malik & Yusof, 2014).

TABLE 2 Means, standard deviations and correlation among variables (n = 492)

	Mean	SD	TQM	Satisfaction	PSCA	WV
TQM						
Pearson correlation			1	0.583**	0.433**	0.671**
Significance	74.60	8.777		0.000	0.000	0.000
Satisfaction						
Pearson correlation			0.583**	1	0.380**	0.526**
Significance	15.39	2.361	0.000		0.000	0.000
PSCA						
Pearson correlation			0.433**	0.380**	1	0.524**
Significance	142.58	11.019	0.000	0.000		0.000
WV						
Pearson correlation			0.671**	0.526**	0.524**	1
Significance	103.03	9.419	0.000	0.000	0.000	0.000

Note.

TQM: total quality management; PSCA: patient safety culture attitude; WV: work value. p < .01

TABLE 3 Indirect effect(s) of TQM on PSCA

	Effect	Boot SE	BootLLCI	BootULCI
Ind1	0.160	0.032	0.097	0.222
Ind2	0.011	0.006	0.001	0.026
Ind3	0.028	0.014	0.002	0.058

Note.

Ind1: TQM \rightarrow WV \rightarrow PSCA; Ind2: TQM \rightarrow WV \rightarrow ES \rightarrow PSCA; Ind3: TQM \rightarrow ES \rightarrow PSCA.

TABLE 4 Ratio of indirect to total effect of TOM on PSCA

	Effect	Boot SE	BootLLCI	BootULCI
Total	0.766	0.142	0.517	1.045
Ind1	0.617	0.131	0.390	0.886
Ind2	0.042	0.026	0.005	0.109
Ind3	0.106	0.056	0.013	0.231

Note.

Ind1: TQM \rightarrow WV \rightarrow PSCA; Ind2: TQM \rightarrow WV \rightarrow ES \rightarrow PSCA; Ind3: TQM \rightarrow ES \rightarrow PSCA.

Hypothesis 3 was confirmed: work values have a positive impact on PSCA. Although the TQM was generally evaluated as moderately good, the hospital nurses saw a need to improve and adjust their work environment. Safety culture is considered a fundamental element in improving health care quality. It can be viewed as a set of shared values, collective attitudes, or group perceptions of safety, focused on reducing harm to patients within a medical institution (Vogus & Sutcliffe, 2007).

Hypothesis 5 confirmed that TQM has a positive impact on job satisfaction, which confirms the findings of Javalgi, Whipple, Ghosh, and Young (2005). Total quality management practices, such as employee empowerment, appraisal systems, and compensation have a significant positive impact on employee satisfaction. Another definite finding of this study was the importance of

understanding the influence of human and other factors on quality and TQM practices when implementing quality management (Ali Malik, Malik, & Zia-ur-Rehman, 2013; Jun et al., 2006). Various techniques and approaches, including TQM-related practices that incorporate trust-based relationships, problem solving, and cooperation within various departments, have been used to satisfy employees in the workplace (Kaynak, 2003). Quality management emphasizes teamwork, continuous quality improvement, and systematic process management. Contemporary concept in quality management is a continuous process that involves all employees in quality improvement. The present study details how implementing a management model can affect employees. The improvement of employees' job satisfaction benefits from a well-defined TQM model (Mosadeghrad, 2014). These results show that practising TQM has a significant positive effect on employee satisfaction, leading to higher levels of job satisfaction within organisations that have implemented TQM practices. In other words, the utilization of a TQM programme not only has a positive effect on employee satisfaction, but also suffices the need of human resource management (Alsughayir, 2014; Caricati et al., 2014).

Hypothesis 6 confirmed that job satisfaction had a positive impact on PSCA; this finding is similar to those reported by other researchers (Elsous et al., 2016; Rathert & May, 2007). Despite some variation between nurses and physicians, those with positive attitudes collaborate better with co-workers. At the same time, job satisfaction is regarded as the factor that most affects patient-safety, followed by the "Teamwork Climate" (Elsous et al., 2016). Other patient-safety factors include teamwork climate, safety climate, job satisfaction, and working conditions. Employees who are satisfied with their work performance tend to emphasize the patient-safety culture (Bondevik, Hofoss, Husebo, & Deilkas, 2017).

Better working environments for health care generated positive indicators related to institutions, such as the retention of qualified professionals and high job satisfaction (Aiken et al., 2012); they also

TABLE 5 Summary of the hypothesis test result based on research framework

Association	Hypothesis	Causal path	Path coefficients	t-Value	р	Hypothesis supported
TQM and work values	H2	$TQM \rightarrow WV$	0.555	20.083	<0.001	Yes
Work values and patient safety culture attitude	H3	$WV \rightarrow PSCA$	0.288	7.506	<0.001	Yes
TQM and employee satisfaction	H5	$TQM \to ES$	0.563	8.647	<0.001	Yes
Employee satisfac- tion and patient safety culture attitude	Н6	ES → PSCA	0.049	2.278	<0.001	Yes
Work values and employee satisfaction	Н8	$WV \rightarrow ES$	0.403	5.095	<0.001	Yes

favoured the improvement of health care quality (Ausserhofer et al., 2013).

Hypothesis 8 confirmed that work values have a positive effect on job satisfaction, in line with other studies on this subject (Caricati et al., 2014; Jun et al., 2006). Prior studies (Froese & Xiao, 2012; Hegney, Plank, & Parker, 2006) have reported a strong relationship between positive job outcome and value orientation. A latest study also revealed an interaction between work values and work climate in nurse (Caricati et al., 2014). The efficient practice of these values requires nurses with stronger professional values and higher levels of job satisfaction (Bang et al., 2011).

Hypotheses H4, H7 and H9 were confirmed; the statistics showed that there were significant relationships between sub-dimensions of the Quality Management System and PSCA. The Quality Management System predicted 44% of variations in patient-safety culture (Taş, Akpinar, & Isci, 2016). Improving working conditions and levels of satisfaction can help patients reduce the risk of accidents (Bondevik et al., 2017).

Health care workers with a positive safety culture aim to engage in safety-related behaviours. In health care, safety culture has been associated with quality, safety performance, clinical practices, and outcomes that reduce incidents. Research has shown that nurses with positive attitudes collaborate better with other professionals than those with less positive attitudes (Neal & Griffin, 2006). Job satisfaction is perceived to be the most important factor influencing patient safety, resulting in a positive teamwork climate (Taylor, 2008).

Research has found that nurses with positive safety attitudes can increase staff enthusiasm and improve the quality of work, improving levels of job satisfaction (Elsous et al., 2016). When nurses accept and recognize the concept of patient safety, they become much more confident in confronting obstacles and difficulties related to safety issues. They also tend to be more positive about the dimensions of a patient-safety culture.

Durgun and Kaya have reported that the educational level of nurses influences the quality of patient care—and that reduced interventions endanger patient safety. Studies have recommended safety-related professional training programmes, suggesting that continuing education programmes should be developed and constantly updated (Durgun & Kaya, 2017).

5 | STRENGTHS AND LIMITATIONS

The present study has several strengths. First, most nursing studies have focused on issues related to patient safety; the effect of total quality management on patient safety has not been widely discussed, either in Taiwan or in other countries. Our study can therefore serve as a basis of comparison for future investigations. Second, the nurses who participated in this study were recruited from regional hospitals that shared a similar medical system. All the nurses took part in the same training programmes and shared similar hospital environments in different regions. There is therefore a high level of homogeneity in our study sample. However, the present study has the inherent limitations of a correlation study. Its cross-sectional study design made it impossible to determine the causal relationships between the study variables. Caution should be taken in assuming causality between a patient-safety-culture attitude and its predictors. Second, given social desirability, distortions, and common variances, self-reported measures using self-administered questionnaires may affect data results. Third, the external generalizability of the current results may be limited because the questionnaires were collected from hospital nurses. Different patterns could appear in job satisfaction research involving non-hospital-based nurses. Nevertheless, these findings warrant further investigation of job satisfaction in other types of nursing professions.

6 | CONCLUSION AND RECOMMENDATIONS

The study identified that variables such as total quality management, work values, patient safety culture, and employee satisfaction. We

observed significant effects of TQM on PSCA studied in the final model of this research. Implementing TQM improves nurses' attitudes towards the patient-safety culture. TQM creates a beneficial working environment and improves the patient-safety culture. Total quality management, work values, and employee-satisfaction orientation were shown to be important predictors of nurses' attitudes toward PSCA.

7 | IMPLICATIONS FOR NURSING MANAGEMENT

Positive work value is a key factor in creating a positive patient-safety-culture attitude. Nurse-managers should focus on cultivating and enforcing the work value of nurses to help them stay positive. The cultivation of positive work value among employees is important when new staff members join an organisation. We strongly advise health care managers to educate nurses to improve working communications, provide training to help them recognize safety programmes, and improve their perceptions of safety and the safety climate in health care settings. Nurses with positive PSCA can develop better operational standards and processes, allowing patients to receive the best quality care. Ultimately, work values influence nurses' attitudes toward the patient-safety culture. Our findings warrant future studies on the effect of positive work values on nurses.

ETHICAL APPROVAL

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