

*Full Length Research Paper*

# The evaluation of implementing the international organization for standardization (ISO) 9000 quality management system in medical setting: A study from a teaching hospital

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**International organization for standardization (ISO) published 9000 series of standards for quality management. This study aims to evaluate the effects of implementing ISO quality management system in hospitals. The sample hospital was a teaching hospital in central Taiwan. To investigate the nurses' experiences in establishing ISO system, the questionnaires using 5-point Likert scales were designed according to ISO's four quality management policies and were answered by the nurse directors and nurses in the sample hospital. The results analyzed with paired-t test, analysis of variance, and factor analysis showed the satisfaction score given to ISO from senior nurses were higher than that from junior ones. Hospital workers identified benefits resulting from the practice of ISO system. Therefore, ISO system benefits hospitals and healthcare centers without taking operating costs into consideration. Contrary to ISO's intention, statistically ISO only has three significant dimensions as opposed to the four designed into the system.**

**Key words:** Quality management, International organization for standardization (ISO) 9000 family of standards, hospital quality.

## INTRODUCTION

The International organization for standardization (ISO), the world's largest developer of standards (International organization of standard) released its 9000 series of standards for quality management. The ISO 9000 series of standards for international quality control and quality assurance was first released in 1984 and the third edition of ISO 9000 standards was further revised and released on December 15, 2000. The fourth edition was released on November 13, 2008.

ISO 9000 is a standard that developed from eight management principles (ISO) and contains 20 (Northern Ireland Executive) requirements or "clauses" concerning quality management and quality assurance (Pölluste et al.,2006). It is a product of the international organization for standardization, which comprises the adoption of these standards by more than 149 countries (International Organization for Standardization), with over 230,000 certificates awarded (ISO; Sweeney and Heaton, 2000). The ISO has been recognized to accredit the quality of care for hospitals internationally (Milstein and Smith, 2006). To become certified or "registered," an organization must be audited by an official ISO registrar (Moore, 1999

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Pandey et al., 2006). If a health care organization cooperates with ISO quality management approaches to process control and self-audit, then it contributes to reducing errors and adverse events (Schryve, 2000; Ternov and Akselsson, 2005). Both the health accreditation of the health quality service in the UK and the European foundation for quality management (EFQM) award, are based on ISO 9000 criteria (Counte and Meurer, 2001). The ISO series has been applied to hospitals worldwide.

In 2005, there were more than 150 hospitals that had ISO 9000 certification in the USA (Thomas, 2006). In Spain, 83% of hospitals had some ISO-certified areas of activity (Sánchez, Letona et al., 2006). Also, a hospital in Rome revealed the benefits of implementing ISO in quality assurance (Ruscitti et al., 2000). The ISO 17025 and ISO 15189 are also used for clinical and medical laboratories in hospitals (ISO15189; ISO/IEC 17025; Oja et al., 2006). The most frequently occurring benefits of implementing ISO 9000 were "fewer customer complaints" (46%) followed by increased productivity (37%), reduced costs (23%), and greater degree of quality control (14%). In addition, 77% of the businesses studied were pleased or very pleased with the ISO 9000 quality management system (Mcadam and Mckeown, 1999; Briscoe et al., 2005). Also, ISO has been demonstrated to reduce medical errors (van den Heuvel et al., 2005) and iatrogenic injuries (Allabaugh).

Although, there are also many tools and techniques for total quality management (TQM) (Lee, 2004) applied in the health care field (Baresi et al., 1997; Unruh and Wan, 2004), the healthcare organizations in Taiwan have not been very cognizant of the ISO series. In Taiwan, the comprehensive national health insurance which has been put into practice for twelve years since March 1995, has forced healthcare organizations into fierce competition. Hospitals take client-satisfaction very seriously as it is imperative to ongoing management and survival by providing higher quality of medical services (de Jager et al., 2010).

This study investigates a hospital experience in implementing an international quality management system, which accessed four of ISO's quality management policies on management responsibility, resource management, product realization, measurement, analysis and improvement. Furthermore, a detailed interview was given following a literature review in order to explore the fullness of the case hospital's experience. Through surveys and interviews, practical knowledge and applicable experience was identified. It is firmly believed more hospitals and healthcare facilities should adopt ISO and reap the benefits (Van den Heuvel et al., 2005).

### Sample institution

The sample hospital was a teaching hospital, located in

central Taiwan, with 1000 general beds and 250 special beds, serving approximately 60,000 inpatients and 1,000,000 outpatients annually. The ISO 9001 system was implemented and been certificated in 2008 in the whole hospital system (Haron et al., 2009). This study's aim is to evaluate the effects of implementing ISO quality management system in healthcare settings.

### METHODS

In this research questionnaires were used to investigate one sample hospital's experience in establishing ISO international quality management system in the year of 2008. Since the ward stations, central supply room (CSR), operation rooms (ORs), and intensive care units (ICU) were major working departments inside hospital, therefore, been chosen to fulfill the questionnaires. The other reason to choose these nurse units was that these units incurred dramatically change when the ISO clause 6.3 infrastructure and ISO 6.4 work environment were applied into hospital; all the suspended particulate on CSR, ORs, ICUs and wards had been measured and analyzed and the air purify system had been redesigned to fit the ISO standards with the high efficiency particulate air (HEPA) and ultra low penetration air (ULPA) standards as well as on the new antistatic cleaning environment tools and procedures.

### Procedure

The questionnaires were put in sealed envelopes and directly given to the nurse stations by researchers. There were no marks on all the questionnaires in order to prevent the possibility of tracking any of the respondents. Three hundred eighty six questionnaires were released to the employees in the nursing unit with three shifts. (exclude baby delivering and long vacation). Three hundred and thirty eight completed and valid questionnaires were collected and analyzed (exclude nurses with less than two year working experience at the sample hospital).

The questionnaires used the Likert5 scale (Buciuniene et al., 2006; Timothy, 2008; Timothy et al., 2008). It included workers' opinions and suggestions about implementing ISO's four quality management systems; the results were analyzed with the t test, paired-t test (Hothi et al., 2006), analysis of variance (ANOVA), and factor analysis technique on STATISTICA® version 7.1 (Baresi et al., 1997) statistic software.

### Instrument

The process of the questionnaire design was conducted by the 6 members of ISO team work, three were SGS® certified leading auditors and the other three were SGS® certified internal auditors, after 5 times brainstorming in two months. The theory of design regarding the questionnaire model was based on the ISO clause 4 quality management system, clause 5 management responsibility, clause 6 resource management, clause 7 product realization, and clause 8 measurement, analysis and improvement. The clause 4 combined with clause 5 added a financial question in the beginning. The other three sections consisted of the ISO sub clause such as the 6.2 human resources and 6.4 work environments.

The structured questionnaire used the Likert 5 scale and the main section of the questionnaires contained three parts. The first part was the background data of the hospital nurses which included position, department, working year, and the professional degree. Second part was to ask their satisfaction scores about the twenty ISO quality management and control system clauses, which included four segments: management responsibility, resource

**Table 1.** Statistic of attributes of satisfaction.

<b>Director t test</b>							
	<b>Mean<sub>1</sub></b>	<b>Mean<sub>2</sub></b>	<b>SD<sub>1</sub></b>	<b>SD<sub>2</sub></b>	<b>df</b>	<b>t</b>	<b>p</b>
Before	2.41	3.00	0.31	0.28	336	8.4	0.0000*
After	3.08	3.47	0.25	0.20	336	7.3	0.0000*
<b>Working year and satisfaction score correlation test</b>							
	<b>r</b>						
Before	0.40*						
After	0.32*						
*p<0.05							
<b>Education degree ANOVA analysis</b>							
	<b>Sum of squares</b>	<b>df</b>	<b>Mean square</b>	<b>F</b>	<b>P</b>		
Before	347.18	1	347.18	76.0	0.0000*		
	12.39	2	6.19				
After	520.81	1	520.81	72	0.0000*		
	6.94	2	3.47				
*p<0.05							
<b>Department ANOVA analysis</b>							
	<b>Sum of squares</b>	<b>df</b>	<b>Mean square</b>	<b>F</b>	<b>P</b>		
Before	1689.97	1	1689.97	0.3	0.93		
	0.29	7	0.04				
After	2711.26	1	2711.26	0.7	0.68		
	0.33	7	0.05				
*p<0.05							

1 = staff, sample size 316. 2 = head and associate head nurse, sample size= 22. \*p<0.05.

management, product realization and measurement, analysis, and improvement. In each segment, twenty questions were asked to see their satisfaction scores in the "before" and "after" of implementing the ISO quality management system. The third segment was "comments or suggestions." The main portion of the questionnaires is provided in the additional file.

### Power analysis

For a statistical power of 0.99 in terms of t test, the required sample size is 188. According to the calculation of Get PS version 3.1, 2009, when  $\alpha$  equals 0.05 in a two-tailed test, and the sample size is 188, the power is 0.99. If the effect size on the relationship between variables (service quality, perceived value and satisfaction) is 0.3, we need to study 188 subjects to be able to reject the null hypothesis that the relationships were no significance with probability (power) 0.99.

### Ethics

Since this study was evaluating an ISO quality process applying in nurses, and therefore, it waves the ethics approval.

## RESULTS

In order to analyze whether the background attributes

affected the satisfaction score, three t tests were conducted and were shown in Table 1. In Table 1, part A, nurse directors have significantly higher scores than their peers of lower rank both before ( $p = 0.0000$ ) and after ( $p = 0.0000$ ) implementing the ISO system. In Table 1, part B, the senior workers also have higher scores than junior workers ( $r = 0.40$  and  $r = 0.32$ ). In Table 1, part C, an ANOVA analysis shows the nurses with graduate degree and 4 year degree also have higher satisfaction scores than those with a 2 year degree ( $p = 0.0000$  on both).

In Table 1, part D, an ANOVA analysis of department satisfaction scores shows there are no differences between the departments before and after satisfaction scores ( $p = 0.93$  and  $p = 0.68$ ). Also, Figure 1 indicated that there is no difference in the director number for each unit, yet the number of workers in OR and ICU are obviously more than other units.

In Table 2, a paired t test was conducted to see whether implementing the ISO system could increase the workers satisfaction scores, and the results revealed that satisfaction scores significantly increased ( $p = 0.000$ ).

In Table 3, item 12 (customer procedure) reaped the highest score from ISO (3.78) and also had the higher gap in scores (1.23); this shows that ISO had great impact on ISO 7.2 customer procedure. Also, from item 13 to 20, the

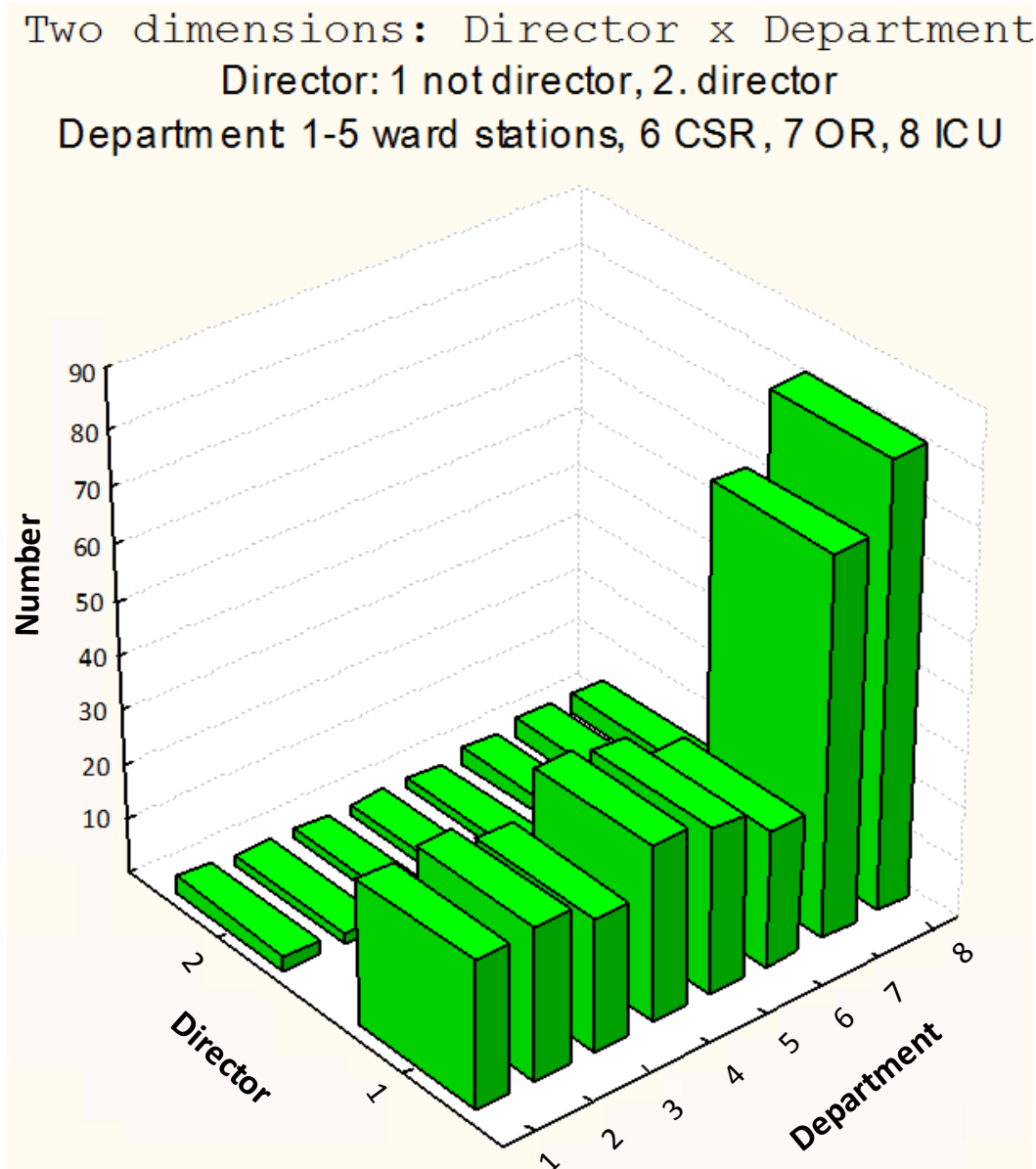


Figure 1. Two dimensions on director vs department.

Table 2. Paired-t test of satisfaction between before and after implementing ISO system.

	Mean	SD	N	t	df	P.
Before	2.45	0.34	338	0	0	0
After	3.11	0.26	338	27.82	674	0.0000*

\*p<0.05

“after” scores are also very high (3.23 to 3.56), which means the ISO system contributed to product realization and measurement, analysis, and improvement.

In Table 3, the results of paired-t tests show that nineteen items had a positive and significant effect on the

four management systems. This means that the ISO system contributed to all four of the management systems. Among the significant questions, we can figure out that these units had positive impression on the ISO 6.3 infrastructures, and ISO 6.4 work environment, which

**Table 3.** Satisfaction of ISO quality management system (N= 338) (Cronbach's  $\alpha = 0.92$ ).

Items in each dimension	Before		After		Gaps		Paired-t
	Mean	SD	Mean	SD	Mean	SD	
<b>Management responsibility (Cronbach's <math>\alpha = 0.86</math>)</b>							
1. Quality commitment	2.62	0.75	3.07	0.76	0.44	0.66	13.42*
2. Quality policy	2.73	0.73	3.39	0.92	0.67	1.00	12.20*
3. Quality planning	2.72	0.73	3.34	0.89	0.62	0.89	12.69 *
4. Organization temperament	2.52	0.65	2.88	0.67	0.36	0.81	8.05 *
5. Financial reward	2.51	0.50	2.45	0.64	-0.07	0.58	-2.07*
<b>Resource management (Cronbach's <math>\alpha = 0.83</math>)</b>							
6. Human resource	2.44	0.68	2.27	0.59	-0.18	0.60	5.44*
7. Resource provided	2.44	0.54	2.81	0.63	0.37	0.48	13.97*
8. Facility	2.53	0.54	3.06	0.63	0.53	0.67	14.57*
9. Working environment	2.32	0.62	2.75	0.60	0.43	0.60	13.15*
10. Document standardization	2.35	0.58	3.34	0.53	0.99	0.53	34.61*
<b>Product realization (Cronbach's <math>\alpha = 0.86</math>)</b>							
11. Procedure planning	2.50	0.72	2.88	0.53	0.38	0.73	9.60*
12. Customer procedure	2.55	0.75	3.78	0.87	1.23	0.93	24.51*
13. Purchase procedure	2.32	0.58	3.40	0.60	1.09	0.58	34.31*
14. Service activity	2.42	0.62	3.43	0.70	1.01	0.71	26.20*
15. Equipment maintain and management	2.45	0.66	3.34	0.59	0.89	0.76	21.64*
<b>Measurement analysis and improvement (Cronbach's <math>\alpha = 0.80</math>)</b>							
16. Quality control plan	2.47	0.68	3.23	0.67	0.85	0.78	20.00*
17. Quality measure	2.69	0.68	3.33	0.59	0.85	0.78	20.20*
18. Control of non conformance	2.65	0.55	3.53	0.83	0.86	0.71	22.74*
19. Quality data analysis	2.51	0.52	3.44	0.63	0.93	0.60	28.35*
20. Quality improvement	2.57	0.57	3.56	0.63	0.99	0.72	25.29*

\*p&lt;0.05

were applied into hospital; all the suspended particulate on ORs, ICUs and wards were tested, and the air purify system had been redesigned to fit the new ISO standard for the high efficiency particulate air (HEPA) and ultra low penetration air (ULPA) standards as well as on the new antistatic cleaning environment tools and procedures.

The class 1000 ORs have been used for coronary artery bypass graft surgery (CABG) and open heart surgery. After the ORs and ICUs having been checked and improved by ISO system, the rate of infection and the rate of antibiotic use have been reduced significantly and the quality results on the international quality indicator project® (IQIP) have reached the international average level.

Only one item, financial rewards, did not get positive results. Instead of did not reaping a significant contribution, it showed a significant negative score. Due to the results of this research we were prudent to review whether there were any changes in the hospital management system, payment system, or hospital's

human resource policy during the implementation of the ISO management system.

We discovered the following changes are the reasons for the surprising disparity:

1. The reform of the reimbursement system of National Health Insurance system in Taiwan. In 2004, the bureau of national health insurance (BNHI) launched the implementation of individual hospital-based global budget plans in third quarter and fourth quarter in 2004. Without appropriate coordinating measures, the current global budget payment system caught hospitals up in a catch-22 (Danishevski et al., 2006) which resulted in a continuously lowering reimbursement conversion factor from 1.0 to 0.83. It means hospitals only get 83% of their original income and this, of course, had serious impact on the hospital's financial situation. To make up this deficit and help control costs, the hospital was forced to cut workers' fringe benefits. It is estimated that 10% of personal annual income was cut for workers in the sample hospital. Since the workers' salaries were reduced during the period of

ISO implementation, it is no wonder hospital workers had negative impressions on ISO and recorded drawbacks to the “financial reward” items.

2. During implementation of the ISO management system, the sample hospital did not provide any financial incentives to departments or individuals. Therefore, there is no wonder that hospital workers did not feel there were any financial rewards to implementing the ISO system.

3. The sample hospital's current policy is not to replace personnel as openings come up in order to cut costs but simply to request the remaining personnel in the department to fulfill the work load. Since all of Taiwan's hospitals are stuck in the mire of individual hospital-based global budgets, hospitals have to find ways to control costs. Personnel costs, in general, occupied 55 to 60% of total hospital expense; it is obvious that hospitals need to develop a policy to control escalating costs.

This study also found that the total service quantity of the sample hospital went up 4% during that fiscal year, and no additional labor was added, therefore, the workers are likely to have had a false impression and think ISO was responsible for the negative contributions to human resource management. The questionnaires were also analyzed in relation to reliability and underlying dimensionality.

## Reliability

### *Internal consistency reliability*

Item-total correlation and Cronbach's alpha was used as a reliability check for internal consistency of the survey instrument. The item-total correlation was expected to exceed 0.4 and the results were more than that (Garratt et al., 2005; Yaacob, 2010; Kroz et al., 2009).

Also, in Table 3, the results of the reliability test on all questionnaires yielded an alpha of 0.92 and four quality management dimensions are between 0.80 and 0.86 respectively, which is above the 0.70 minimum recommended by Nunnally 1978 and has acceptable level of reliability (Guey et al., 2008; Härdén et al., 2009).

## Validity

### *Content validity*

Content validity of the questionnaires was further confirmed by 3 SGS® certified ISO leading auditors and 3 healthcare management specialists.

### *Construct validity*

On the basis of a review of the literature, the ISO quality measurement was theorized to be multidimensional. The

factor analysis (Table 4) identified three dimensions of quality.

## Dimensionality

To examine the dimensionality of the scale, an exploratory factor analysis was conducted on the “before” and “after” data and on the gap scores (the “after” scores subtracted from the “before” scores). Factor analysis results for before, after, and the gap scores are listed in Table 4.

Factor analyses were conducted by the maximum likelihood method and goodness-of-fit test to determine the optimum factor number (Hairs et al., 1998; Ohaeri et al., 2007; Erhart et al., 2009; Lin et al., 2009). When subjected to oblique rotation and combined with the Scree plot of the Eigen value, the loading provides a three factor structure of “before” items and “after” items. The “gap” did not provide a meaningful structure, however.

The results of the third part of the questionnaires: “comments or suggestions.” Of the 54 valid questionnaires, 12 copies had comments and suggestions as the following:

1. The ISO system helped in establishing standardized administrative procedures; therefore, it was much easier to train new workers and to familiarize them with the department as well as with the entire hospital.
2. There will be fewer lag time (Lawton and Parker, 2002; Hirose et al., 2007) to make quality report to the TQIP (the IQIP system (Lim, 2004) in Taiwan, which direct report date to the Maryland) could be quicker.
3. Employees benefit from ISO most in on-job training courses and the related presentations. Before implementing ISO, the training programs only focused on the medically related training, but now there are presentations and courses in biostatistics, experimental design, as well as humanities and the arts.
4. The hospital provided no financial incentive or reward for establishing the ISO system. If proper incentives were provided, the results could be better.
5. The policy of the hospital has been to buy state-of-art medical instruments, and not focus on personnel recruitment and training. The ISO quality control system could make up for this shortcoming.

## DISCUSSION

The results of this study show that the ISO quality system has a positive effect on the hospital quality management system, especially in relation to customer procedures. Also, the results showed the ISO clause 6.3 infrastructures, and ISO 6.4 work environment did help a lot on the suspended particulate that should be checked regularly and followed the ISO standard on the HEPA and ULPA standard. The rate of infection and the antibiotic use have also been improved and corresponded to the

**Table 4.** Exploratory factor analysis (N= 338).

Before scale items	Loadings			After scale items	Loadings		
	Factor 1	Factor 2	Factor 3		Factor 1	Factor 2	Factor 3
B1			0.92	A1		0.59	
B2			0.79	A2		0.66	
B3			0.66	A3	0.59		
B4			0.93	A4		0.52	
B5		0.88		A5			
B6		0.71		A6			0.47
B7		0.69		A7			0.74
B8		0.86		A8			0.76
B9	0.68			A9	0.60		
B10	0.75			A10	0.66		
B11	0.56			A11			
B12	0.71			A12	0.77		
B13	0.85			A13	0.43		
B14	0.65			A14	0.48		
B15	0.54			A15	0.49		
B16	0.74			A16			
B17	0.80			A17			0.52
B18	0.73			A18	0.45		
B19				A19	0.44		
B20	0.69			A20	0.45		
Eigen value	7.76	2.72	2.00	Eigen value	3.80	2.43	1.76
Variance explained (%)	38.81	13.62	10.01	Variance explained (%)	19.01	12.64	8.84
Total variance (%)			62.44				40.19

request of IQIP. The hospital nurses felt the benefits of implementing ISO are in ISO 7 product realization, ISO 8, ISO 8.2, ISO 8.3, ISO 8.4 measurement, analysis, and improvement. However, the ISO system itself does not provide a method of financial and economic analysis, different from Six Sigma (iSixSigma).

Although, ISO helped standardize the accounting system, the financial situation of the institution was not monitored on the ISO system. If implementing the ISO system combined with proper financial incentives, the results would likely be better. Results of this research show that the ISO quality management system has three dimensions instead of four dimensions designed originally.

## Conclusions

As other quality improvement program, the international organization for standardization (ISO) have been proven useful in this study as well as in Varkey's study in job satisfaction and overall satisfaction (Varkey et al., 2008). Also, ISO quality management system been proved to be benefit for organization (Okay and Semiz, 2010). The results of this study could serve as example for business to implement the ISO quality management system.

## LIMITATIONS

The sample hospital in this research is located in the metropolitan area and the employees' quality could be better than others (countryside hospital is not easy to recruit good quality employee in Taiwan); therefore, the concept and understanding of ISO could be better than other hospitals in the other area.

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## REFERENCES

- Allabaugh D ISO 9000 Enters Health Care. Retrieved Sep 1, 2011, from <http://www.citizensvoice.com/site/news.cfm?newsid=13057596>.
- Baresi L, Consorti F, Di Paola M, Gargiulo A, Pezze M (1997). LEMMA: a language for easy medical models analysis. *J. Med. Syst.*, 21(6): 369-388.
- Briscoe JA, Fawcett SE, Todd RH (2005). The Implementation and Impact of ISO 9000 among Small Manufacturing Enterprises. *J. Small Anim. Bus. Manag.*, 43(3): 309-330.
- Buciuniene I, Malciankina S, Lydeka Z, Kazlauskaitė R (2006).

- Managerial attitude to the implementation of quality management systems in Lithuanian support treatment and nursing hospitals. *BMC Health Serv. Res.*, 6: 120.
- Counte M, Meurer S (2001). Issues in the assessment of continuous quality improvement implementation in health care organizations. *Int. J. Qual. Health Care*, 13: 197-207.
- Danishevski K, Balabanova D, McKee M, Atkinson S (2006). The fragmentary federation: experiences with the decentralized health system in Russia. *Health Pol. Plan.*, 21(3): 183-194.
- Erhart M, Ellert U, Kurth B-M, Ravens-Sieberer U (2009). Measuring adolescents' HRQoL via self reports and parent proxy reports: an evaluation of the psychometric properties of both versions of the KINDL-R instrument. *Health Qual. Life Outcome*, 7: 77.
- Garratt AM, Bjærtnes ØA, Krogstad U, Gulbrandsen P (2005). The OutPatient Experiences Questionnaire (OPEQ): data quality, reliability, and validity in patients attending 52 Norwegian hospitals. *Qual. Saf. Health Care*, 14: 433-437.
- Guey LT, Bromet EJ, Gluzman SF, Zakhozha V, Paniotto V (2008). Determinants of participation in a longitudinal two-stage study of the health consequences of the Chernobyl nuclear power plant accident. *BMC Med. Res. Meth.*, 8: 27.
- Hårdén M, Nyström B, Kulich K, Carlsson J, Bengtson A, Edvardsson N (2009). Validity and reliability of a new, short symptom rating scale in patients with persistent atrial fibrillation. *Health Qual. Life Outcome*, 7: 65.
- Hairs JF, Anderson RE, Tatham RL, Black WC (1998). *Multivariate data analysis*. New York, NY, Macmillan.
- Haron Y, Segal Z, Barhoum M (2009). Achieving quality in a government hospital: departmental responsibility. *Qual. Manag. Health Care*, 18(2): 141-145.
- Hirose M, Regenbogen S, Lipsitz S, Imanaka Y, Ishizaki T, Sekimoto M, Oh E, Gawande A (2007). Lag time in an incident reporting system at a university hospital in Japan. *Qual. Saf. Health Care*, 16: 101-104.
- Hothi DK, Geary DF, Fisher L, Chan CT (2006). Short-term effects of nocturnal haemodialysis on carnitine metabolism. *Nephrol. Dial. Transplant*, 21: 2637-2641.
- International Organization for Standard. ISO in Brief. Retrieved June 28, 2011, from [http://www.iso.org/iso/en/prods-services/otherpubs/pdf/isoibrief\\_2005-en.pdf](http://www.iso.org/iso/en/prods-services/otherpubs/pdf/isoibrief_2005-en.pdf).
- International Organization for Standard. Overview of the ISO System. Retrieved Sep 12, 2011, from <http://www.iso.org/iso/en/aboutiso/introduction/index.html>.
- iSixSigma. New Six Sigma Standard for Sustainable Financial Benefit. Retrieved Sep 14, 2011, from <http://www.isixsigma.com/library/content/n070119b.asp>.
- ISO15189. Medical laboratories- particular requirement for quality and competence. Retrieved June 20, 2011, from <http://www.iso-15189.blogspot.com/>.
- ISO. Certification, Registration, Accreditation. Retrieved Sep 20, 2011, from [http://www.iso.org/iso/en/iso9000-14000/understand/basics/general/basic\\_s\\_5.html](http://www.iso.org/iso/en/iso9000-14000/understand/basics/general/basic_s_5.html).
- ISO. Quality Management Principles. Retrieved Aug 10, 2011, from <http://www.iso.org/iso/en/iso9000-14000/understand/qmp.html>.
- ISO/IEC 17025. General requirement for the competence of testing and calibration laboratories. Retrieved June 20, 2011, from <http://www.17025.homestead.com>.
- de Jager JW, du Plooy AT, Femi AM (2010). Delivering quality service to in- and out-patients in a South African public hospital. *Afr. J. Aquat. Bus. Manag.*, 4(2): 133-139.
- Kroz M, Büssing A, von Laue HB, Reif M, Feder G, Schad F, Girke M, Matthes H (2009). Reliability and validity of a new scale on internal coherence (ICS) of cancer patients. *Health Qual. Life Outcome*, 7: 59.
- Lawton R, Parker D (2002). Barriers to incident reporting in a healthcare system. *Qual. Saf. Health Care*, 11: 15-18.
- Lee CY (2004). Perception and Development of Total Quality Management in Small Manufacturers: An Exploratory Study in China. *J. Small Anim. Bus. Manag.*, 42(1): 102-115.
- Lim MK (2004). Quest for quality care and patient safety: the case of Singapore. *Qual. Saf. Health Care*, 13: 71-75.
- Lin DJ, Sheu IC, Pai JY, Bair A, Hung CY, Yeh YH, Chou MJ (2009). Measuring Patient's Expectation and the Perception of Quality in LASIK Services. *Health Qual. Life Outcome*, 7: 63-70.
- Mcadam R, Mckeown M (1999). Life after ISO 9000: An analysis of the impact of ISO 9000 and total quality management on small businesses in Northern Ireland. *Total Qual. Manag.*, 10(2): 229-241.
- Milstein A, Smith M (2006). America's New Refugees - Seeking Affordable Surgery Offshore. *New Engl. J. Med.*, 355: 1637-1640.
- Moore LM (1999). High standards: ISO 9000 comes to health care. *Trustee*, 52: 10-14.
- Northern Ireland Executive. Briefing Paper-Quality of Service. Retrieved May 12, 2011, from <http://www.rpani.gov.uk/quality/approaches.htm>.
- Nunnally J (1978). *Psychometric Theory*. New York, NY, McGraw-Hill.
- Ohaeri JU, Awadalla AW, El-Abassi AHM, Jacob A (2007). Confirmatory factor analytical study of the WHOQOL-Bref: experience with Sudanese general population and psychiatric samples. *BMC Med. Res. Meth.*, 7: 37.
- Oja PI, Kouri TT, Pakarinen AJ (2006). From customer satisfaction survey to corrective actions in laboratory services in a university hospital. *Int. J. Qual. Health Care*, 18: 422-428.
- Okay Ş, Semiz S (2010). The effects of ISO 9000 quality management system implementation in small and medium-sized textile enterprises: Turkish experience. *Afr. J. Aquat. Bus. Manag.*, 4(14): 2921-2933.
- Pölluste K, Habicht J, Kalda R, Lember M (2006). Quality improvement in the Estonian health system--assessment of progress using an international tool. *Int. J. Qual. Health Care*, 18: 403-413.
- Pandey M, Thomas BC, Ramdas K, Ratheesan K (2006). Early effect of surgery on quality of life in women with operable breast cancer. *Jpn. J. Clin. Oncol.*, 36(7): 468-472.
- Ruscitti G, Palchetti G, Ciccarone L, Bernaschi P (2000). The ISO 9000 quality assurance projects of Paediatric Hospital Bambino Gesù. *Total Qual. Manag.*, 11(4-6): 393-398.
- Sánchez E, Letona J, González R, García M, Darpón J, Garay J (2006). A descriptive study of the implementation of the EFQM excellence model and underlying tools in the Basque Health Service. *Int. J. Qual. Health Care*, 18: 58-65.
- Schryve P (2000). The evolution of external quality evaluation: observations from the joint commission on accreditation of healthcare organizations. *Int. J. Qual. Health Care*, 12: 255-258.
- Sweeney J, Heaton C (2000). Interpretations and variations of ISO 9000 in acute health care. *Int. J. Qual. Health Care*, 12: 203-209.
- Ternov S, Akselsson R (2005). System weaknesses as contributing causes of accidents in health care. *Int. J. Qual. Health Care*, 17: 5-13.
- Thomas R (2006). ISO 9000 Is Coming: The Use and Discoverability of Hospital TQM Documents. *JCMC*, 13: 14-19.
- Timothy AD, Graham MJB, Andre WK, Brian RH, Brian HR (2008). Assessing the Sensibility of Two Clinical Decision Support Systems. *J. Med. Syst.*, 32(5): 8.
- Unruh L, Wan TT (2004). A systems framework for evaluating nursing care quality in nursing homes. *J. Med. Syst.*, 28(2): 197-214.
- van den Heuvel J, Koning L, Bogers AJ, Berg M, van Dijen ME (2005). An ISO 9001 quality management system in a hospital: bureaucracy or just benefits? *Int. J. Health Care Qual. Assur. Inc. Leadersh. Health Serv.*, 18(4-5): 361-369.
- van den Heuvel J, Koning L, Bogers AJJC, Berg M, van Dijen MEM (2005). An ISO 9001 quality management system in a hospital: Bureaucracy or just benefits? *Int. J. Health Care Qual. Assur.*, 18(4-5): 361-369.
- Varkey P, Karlapudi SP, Hensrud DD (2008). The Impact of a Quality Improvement Program on Employee Satisfaction in an Academic Microsystem. *Am. J. Med. Qual.*, 23: 215-221.
- Yaacob Z (2010). Quality management as an effective strategy of cost savings. *Afr. J. Aquat. Bus. Manag.*, 4(9): 1844-1855.



**Additional file: The questionnaire**

i. Please fill the following background data

- A. Director: Yes \_\_\_\_\_, No \_\_\_\_\_
- B. Department: \_\_\_\_\_
- C. Working year after getting registration nurse license \_\_\_\_\_
- D. Degree: \_\_\_\_\_

ii. Please fill your satisfaction on before and after hospital implement ISO system. Please give score from 1-not satisfy to 5-very satisfy.

iii. If you have any comments or suggestions to let us know, please write on the following space, thanks.

<b>S/N</b>	<b>Before implement</b>	<b>S/N</b>	<b>After implement</b>
1.	Quality commitment	1.	Quality commitment
2.	Quality policy	2.	Quality policy
3.	Quality planning	3.	Quality planning
4.	Organization temperament	4.	Organization temperament
5.	Financial reward	5.	Financial reward
6.	Human resource	6.	Human resource
7.	Resource provided	7.	Resource provided
8.	Facility	8.	Facility
9.	Working environment	9.	Working environment
10.	Document standardization	10.	Document standardization
11.	Procedure planning	11.	Procedure planning
12.	Customer procedure	12.	Customer procedure
13.	Purchase procedure	13.	Purchase procedure
14.	Service activity	14.	Service activity
15.	Equipment maintain and management	15.	Equipment maintain and management
16.	Quality control plan	16.	Quality control plan
17.	Quality measure	17.	Quality measure
18.	Control of non conformance	18.	Control of non conformance
19.	Quality data analysis	19.	Quality data analysis
20.	Quality improvement	20.	Quality improvement