

# Did Quality Management System ISO 9001 Version 2015 Influence Business Performance? Evidence from Indonesian Hospitals

Rinto Noviantoro<sup>1</sup>, Nihayatul Maskuroh<sup>2</sup>, Budi Santoso<sup>3</sup>, Muhammad Nur abdi<sup>4</sup>, Mochammad Fahlevi<sup>5</sup>, Rudy Pramono<sup>6</sup>, Agus Purwanto<sup>7\*</sup>, John Tampil Purba<sup>8</sup>, Ashiong Parhehean Munthe<sup>9</sup>, Juliana<sup>10</sup>

<sup>1</sup>Accounting Department, Dehasen University, Indonesia

<sup>2</sup>Sharia Economic Department, Sultan Maulana Hasanuddin Islamic University, Indonesia

<sup>3</sup>Accounting Department, Kusuma Negara Business School, Indonesia

<sup>4</sup>Finance Department, Muhammadiyah Makassar University, Indonesia

<sup>5</sup>Management Department, BINUS Online Learning, Bina Nusantara University, Indonesia

<sup>6,7,8,9,10</sup>Pelita Harapan University, Indonesia

Corresponding email: [aguspurwanto.prof@gmail.com](mailto:aguspurwanto.prof@gmail.com)

## ABSTRACT

This study aims to analyze the effect of implementing the ISO 9001: 2015 Quality Management System on the performance of hospitals in Indonesia. This research method is quantitative, data collection through online questionnaires conducted by simple random sampling technique and respondents are managers as many as 180 people from 15 hospitals that have implemented the ISO 9001: 2015 quality management system for 5 years in Indonesia. Data processing using SEM method with SmartPLS 3.0 software. The results of this study concluded that customer focus ISO has a positive and significant effect on hospital performance, Leadership principle has a positive and significant effect on hospital performance, People Engagement has a positive and significant effect on hospital performance, process approach has a positive and significant effect on hospital performance, improvement principle has a positive and significant effect on hospital performance, evidence-based decision making has a positive and significant effect on hospital performance, relationship management has a positive effect and significant to hospital performance. The novelty of this research is a new model of the effect of implementing on hospital performance.

**Keywords:** ISO 9001: 2015, Quality Management System, Hospitals Performance

## Correspondence:

Agus Purwanto

Pelita Harapan University, Indonesia

[aguspurwanto.prof@gmail.com](mailto:aguspurwanto.prof@gmail.com)

## INTRODUCTION

Competition for hospital services is very high in the industrial era 4.0. Indonesia has a total of 2,831 hospitals in 2017 consisting of 2,267 general hospitals and 564 specialty hospitals. Each hospital is required to be able to compete both in terms of service and in terms of price. Therefore, hospitals must have the right business strategy to survive and be superior to its competitors. strategies to retain existing customers, expand cooperation with other companies, improve convenience in the payment system, collaborate with other hospitals, provide services at affordable rates for all levels of society, improve training and education for employees, provide funds for activities promotion and the last strategy to collaborate with health centers and medical centers. One of the strategies is to implement an ISO 9001: 2015 quality management system. Hospital competition which is getting tighter as a result of globalization has shifted the service paradigm from comparative advantage to competitive advantage. This shift requires service activities to be directed with the right strategy. Strategy will determine the strategic position of the organization and its ability to adapt to a changing environment. In this environmental hospital organization, among others, it is influenced by government policies, namely in regulations that are directly or indirectly related to hospital services including, among others, hospital accreditation, hospital service standards, hospital professional education, and so on. The growth of technology, especially the technology of supporting facilities for hospital services, the competition that comes from the emergence of various hospitals in the same area will provide more

services to patients. So that hospitals that can maintain excellent service quality and technology support will survive. The organization needs to gain and maintain a competitive advantage for the organization's long-term success. Achieving competitive advantage leads to organizational success or failure. An organization can maintain a competitive advantage over a period of time only because rival hospitals will quickly replicate and push for that advantage. An organization must strive for a sustainable competitive advantage. Basically, the strategy chosen by the hospital is to improve the performance of the hospital, the strategy chosen is to carry out technological innovation and implement the ISO 9001: 2015 quality management system.

One of the most popular standards is ISO 9001 for a Quality Management System. Since it was first published in 1987, ISO 9001 has undergone three revisions, namely in 1994, 2000 and 2008. Then in mid-2013 under the ISO technical committee, ISO / TC 176 for Quality Management and Quality Assurance, has published a draft revision of quality management standards for the 2015 version. This last revision was published and ratified in September 2015 and is expected to become a stable standard, at least for the next 10 years. ISO 9001: 2015 has started to be published in mid-2015 in the form of DIS and FDIS ISO 9001: 2015. Inputs from all stakeholders were perfected to include FDIS and the final product of ISO 9001: 2015. Some requirements were added in the 2015 version, this further enhances ISO 9001: 2015 that has been published by IOS (International Organization for Standardization) to replace the previous version. The

requirements added to the 2015 version further refine the system owned by ISO 9001 version 2008. ISO 9001: 2015 contains several main things such as Leadership, where later the role of company leaders is expected to be more active in taking responsibility for implementing the management system. Also, the application of Risk Management in every line of business enables the company to always calculate the risk to be faced from every action or decision it takes. The implementation of the High-Level Structure makes it easy to integrate between one management system and another. It is hoped that ISO 9001: 2015 will encourage the implementation of other management systems in the company. Quality Management System or ISO 9001: 2015 Quality Management System is a tool for companies to significantly improve operational performance. ISO 9001: 2015 contains requirements that have been agreed upon through international consensus as good business practice in implementing a quality management system. The ISO 9001: 2015 system is expected to help management in running the business more systematically so that products and service quality can satisfy all company stakeholders. ISO 9001: 2015 contains several main things such as Leadership, where later the role of company leaders is expected to be more active in taking responsibility for implementing the quality management system. Process approach (process approach), which is the application of risk management in each line of business, enabling the company to always calculate the risks to be faced from every action or decision it takes. Relationships management, namely the application of a high-level structure that will facilitate the skait house in integrating one management system with another. It is hoped that ISO 9001: 2015 can encourage the application of other management systems in the company or organization. The ISO 9001: 2015 quality management system is a tool for companies to significantly improve hospital operational performance. In addition, the requirements that the company has met can also be used as good business practice in implementing a quality management system. The ISO 9001: 2015 system will later be able to assist company management in running the business more systematically so that products and service quality can satisfy all hospital stakeholders.

Currently, some hospitals cannot only provide mediocre services because services in the health sector involve the life and death of a person. It is time for every health institution to have clear and definite standards so that people who use services can be calmer and more relieved when receiving treatment. One way to improve the quality of services within health institutions is to implement ISO 9001 - a quality management standard that has been recognized internationally. The application of ISO 9001 is one way for various parties involved in health services, such as doctors, nurses, employees and others to meet the requirements so that services can run effectively and efficiently. In addition, the application of ISO 9001 will also increase the image and trust of the public towards the hospital or health agency concerned. In principle, ISO 9001 provides directions and rules related to the planning, implementation, inspection, and preventive and corrective actions of problems that occur - even from problems that haven't happened yet but have the potential to occur. If all the directions and rules in ISO 9001 are applied, then community satisfaction can be achieved. By having a standard, agencies can

minimize existing errors or problems. The application of ISO 9001 is intended to reduce the risk of errors in health services in hospitals. Some of the obstacles for hospitals in implementing the ISO 9001: 2015 Quality Management System are limited human resources, the organizational structure is clear, but there is too much work in one division so that employee focus is easily divided, there is no outreach to external parties from the company. Lack of employee knowledge Regarding the new system, employees do not carry out the given procedures consistently, they do not even carry out these procedures at all, the implementation of procedures is unclear and not detailed. ISO 9001 has a broad coverage in all aspects in various fields, including also for health agencies such as hospitals and health centers. This means that through the application of ISO 9001, quality, effective and efficient service can certainly be achieved. The application in several hospitals has proven results that are able to boost the image of the health agency, and most importantly the increase in the quality of services to the community. If quality is boosted, the public will be increasingly convinced that health agencies in this country are the only destination when people need health services.

The purpose of this study was to analyze the effect of implementing the ISO 9001: 2015 quality management system on hospital performance with the details of the research questions as follows

- 1) Do the principles of Customer Focus ISO 9001: 2015 affect hospital performance?
- 2) Do the ISO 9001: 2015 Leadership principle affect hospital performance?
- 3) Do the principle of People Engagement ISO 9001: 2015 affect hospital performance?
- 4) Do the principles of the ISO 9001: 2015 Process Approach affect hospital performance?
- 5) Do the ISO 9001: 2015 improvement principle affect hospital performance?
- 6) Do the principle of Evidence-Based Decision-Making ISO 9001: 2015 affect hospital performance?
- 7) Do the principles of Relationship Management ISO 9001: 2015 affect hospital performance?

## LITERATURE REVIEW AND HYPOTHESIS DEVELOPMENT

### LITERATURE REVIEW

#### Quality Management System

According to Purwanto (2019), the purpose of a quality management system is to convince consumers that the products produced by the company are able to meet the requirements of the buyers. According to the International Organization for Standardization, a quality management system is a way for a company to control related activities (either directly or indirectly) to achieve the desired results. According to Santoso (2019) companies that run a quality management system tend to show the characteristics of a philosophy that prevention is better than detecting, correcting, and as a result, consistent communication in the process and between production, suppliers and buyers, Maintenance of documents careful and critical control efficiently, quality awareness of all employees Management trust is very high.

### ISO 9001: 2015 Quality Management System

Asbari (2020) said that the ISO 9000 series is a quality management system first and foremost, a global system to optimize the quality effectiveness of an organization or company, by creating a framework for continuous improvement". ISO 9000 series includes several standards, namely ISO 9001, ISO 9004, and ISO 19011. Since it was first published in 1987, this standard has undergone four changes. All ISO standards are regularly reviewed and revised to ensure that the requirements in them remain relevant to market conditions. The latest version of ISO that is currently in effect is ISO 9001: 2015, replacing the previous version, namely ISO 9001: 2008. This revision aims to make the ISO 9001: 2015 standard applicable to all types of companies. The changes seen in ISO 9001: 2015 compared to the previous version are that the structure is adjusted to the structure in Annex SL, namely the High-Level Structure (HSL) which is the basic reference for all system structures. Quality management issued by ISO, making it easier for companies to use other management systems. In addition, the articles contained in ISO 9001: 2015 focus on risk based thinking, where companies are expected to be able to understand risk-based thinking in more detail and be able to make it happen in the implementation and improvement of quality management systems and business processes. . The ISO 9001: 2015 Quality Management System contains an emphasis on leadership involvement, directing company risks and opportunities in a structured manner, using common and simple language, structure and terms, making it easier for organizations that use multiple management systems, directing supply chain management more effectively, easier to use for service companies and knowledge-based companies, the International Organization for Standardization states that there are 7 principles that underlie the ISO 9001: 2015 Quality Management System, namely customer focus, leadership, people involvement, process approach, improvement, evidence-based decision making, and relationship management (Purwanto, 2020).

### Organization Performance

Performance is the behavior of how the target is achieved (Armstrong & Taylor, 2014). Performance is a goal-oriented process that is directed to ensure that organizational processes are in place to maximize the productivity of members. Another opinion, performance is what members do or don't do (Luthans, 2005). To be able to find out the performance in an organization, certain aspects are needed. Performance is influenced by work-related variables including role-stress and work / non-work conflicts (Babin & Boles, 1998). There are several criteria for measuring performance, namely: Quality, quantity, timeliness, cost effectiveness and interpersonal relationships (Bernardin & Russel, 1993). Meanwhile (Mathis & Jackson, 2002) states that performance has several elements, namely: quantity, quality, accuracy, presence, cooperation ability, and loyalty.

### ISO 9001: 2015 Quality Management System Principles

**Customer Focus**, the main focus of quality management is to meet customer requirements and to strive to exceed customer expectations. Continuous success is achieved when the organization attracts and maintains the trust

of customers and other stakeholders. Every aspect of customer interaction provides an opportunity to create more value for customers. Understanding the current and future needs of the customer contributes to the continued success of the organization. ISO 9001 principles, identify direct and indirect customers, understand the current and future needs and expectations of each customer, link organizational goals with customer needs and expectations, communicate customer needs and expectations throughout the organization, Plan, design, develop, produce, provide, and support products and services to meet customer needs and expectations, Measure and monitor customer satisfaction and take appropriate action, Determine and respond to the needs and expectations of relevant stakeholders, which can affect customer satisfaction, Manage customer relationships to achieve success continuous.

**Leadership**, leaders at all levels establish a unity of goals and direction and create conditions that make everyone involved in achieving the quality objectives of the organization. The creation of this unified goal, direction, and engagement enables the organization to align strategies, policies, processes and resources to achieve organizational goals. Principles of ISO 9001 Actions that can be taken to enhance leadership: Communicate mission, vision, strategy, policies and processes throughout the organization, Create and maintain shared values, fairness, and ethical models of behavior at all levels of the organization, Implement a culture of trust and integrity, Encourage overall commitment to quality, Ensure all leaders at all levels can be good examples, Provide resources, training and authority so that everyone can act responsibly, Inspire, encourage, and acknowledge contributions of organizational members

**Engagement of People**, Organizations need to make sure everyone is competent, empowered, and involved in providing organizational values. Competent, empowered and engaged people throughout the organization will increase the organization's capacity to create value. To manage an organization effectively and efficiently, everyone, everyone needs to be involved and respected as individuals. Recognition, empowerment, and improvement of skills and knowledge facilitate the involvement of people in achieving organizational goals. Actions that can be taken to increase people engagement: Encourage understanding of the importance of individual contributions, Promote collaboration throughout the organization, Facilitate open discussions and knowledge and experience sharing, Empower people to determine barriers to performance and not to be afraid to take initiative, Acknowledge and reward contributions, learn, and individual improvement, Apply self-evaluation of performance against individual goals, Conduct individual satisfaction surveys, communicate results, and take appropriate action.

**Process Approach**, consistent and predictable results can be achieved more effectively and efficiently when activities are understood and managed as an interrelated process that functions as an integrated system. The quality management system consists of interrelated processes. Understanding how an output is produced by this system, including all processes, resources, controls, and interactions, enables optimization of organizational performance Actions that

can be taken to improve the process approach, Determine the system goals and processes needed to achieve these goals, Exercise authority, responsibility, and process management accountability, Understand organizational capabilities and determine resource limitations before taking action, Determine inter-process dependencies, and analyze the effects of modifications to a process on the whole system, Manage processes and inter-process relationships as a system to achieve organizational quality objectives effectively and efficient, Ensure the availability of information needed to run and improve the process, as well as to monitor, analyze and evaluate the overall system performance, Manage risks that can affect process output and the overall results of the quality management system.

**Improvement**, a successful organization constantly emphasizes improvement. Improvements are important for organizations to maintain current levels of performance, to respond to changing internal and external conditions, and to create new opportunities. Actions that can be taken to increase improvement, Encourage the setting of improvement goals at all levels of the organization, Educate and train people at all levels on how to apply basic tools and methodologies to achieve improvement goals, Ensure HR competency to carry out improvement projects, Develop processes for implementing improvement projects throughout the organization, Track, review, and audit planning, implementation, completion, and improvement project results, Integrate improvement considerations in the development of new or modified products, services, and processes, Acknowledge and reward improvements

**Evidence-Based Decision Making**, Decisions based on analysis and evaluation of data and information are more likely to achieve the desired results. Decision making can be a complex process and always involves uncertainty. This process sometimes involves different types and sources of input, as well as interpretations of these inputs, which can be subjective. An understanding of the cause and effect relationship and the potential for unwanted effects is required. Facts, evidence, and data analysis increase objectivity and confidence in decision making. Principles of ISO 9001 Actions that can be taken to improve evidence-based decision making, Determine, measure and monitor key indicators of organizational performance, Provide necessary data to relevant people, Ensure that data and information are sufficiently precise, reliable and safe, Analyze and evaluate data and information with appropriate methods, Ensure competence of HR to analyze and evaluate data as needed, Take decisions and action based on evidence balanced with experience and intuition

**Relationship Management**, In order to achieve sustainable success, the organization manages its relationships with stakeholders, such as suppliers. Stakeholders influence organizational performance. This management of relationships with stakeholders optimizes their influence on organizational performance. Relationship management with suppliers and partner networks often has a particular interest. Actions that can be taken to improve relationship management, Determine relevant stakeholders (suppliers, partners, customers, investors, employees, or communities) and their relationships with the organization, Define and prioritize relationships with stakeholders who need to be managed, Create relationships that balance short-term with long-term benefits, Collect and share

information, skills and resources with relevant stakeholders, Measure performance and provide performance feedback to stakeholders as needed to enhance improvement initiatives , Run collaborative development and improvement activities with suppliers, partners and other stakeholders, Encourage and reward improvements and achievements from suppliers and partners.

#### HYPOTHESIS DEVELOPMENT

According to Hen and Cheng (2010) proposed a "Process Approach" and "Service Blueprint" as a means to increase the effectiveness of the quality management system implementation while increasing customer satisfaction. According to Hen and Cheng (2010), ISO 9001 emphasizes a process approach when developing, implementing and increasing the effectiveness of a quality management system. In general, the process approach can be divided into three parts, namely the customer-oriented process, the support process, and the management process. Meanwhile, regarding the concept of "Blueprint Services", According to Hen and Cheng (2003) concluded that the process approach in implementing ISO 9001 provides the advantage of easier control over individual processes and a service blueprint. In the health industry, Hen and Cheng (2003) emphasize the importance of the human resource aspect, especially in relation to employee behavior in supporting customer-oriented strategies. In the hospital business, customers tend to tell what makes the hospital service different from its competitors. Thus, the hospital must be as careful as possible to analyze customer needs so that it can be translated as customer requirements properly. According to Staines (2000) concluded that implementing ISO 9001 can provide many benefits for hospitals, namely encouraging organizations to understand the philosophy of quality as well as studying various problems related to quality, encouraging better compliance with laws and regulations, better document traceability, build better pride and motivation among employees, ensure global level competitiveness, ensure quality continuously, facilitate training for new employees, provide understanding of the goals for each activity carried out by employees, provide a better understanding to each employee about operations hospital, as a step for the application of Total Quality Management. According to research conducted by van den Heuvel *et al* (2005) in hospitals the benefits of implementing ISO 9001 are making the hospital more focused on understanding patient needs and satisfaction, better monitoring of performance by the owner. pro ses through the application of certain indicators. improvement of the documentation system, better patient safety. That the implementation of the ISO 9001 management system has a positive impact on the hospital. The Indonesian government can recommend that ISO 9001 be implemented in hospitals, especially government-owned hospitals that are considered to need service improvement.

Based on previous research studies, the following hypothesis (H) is obtained

- 1) H1: Customer focus has a positive and significant effect on hospital performance
- 2) H2: Leadership principle has a positive and significant effect on hospital performance
- 3) H3: People Engagement has a positive and significant effect on hospital performance



- 4) H4: Process Approach has a positive and significant effect on hospital performance
- 5) H5: Improvement Principle has a positive and significant effect on hospital performance
- 6) H6: Evidence-Based Decision Making has a positive and significant effect on hospital performance
- 7) H7: Relationship Management has a positive and significant effect on hospital performance

**METHODS**

This research method is quantitative, data collection through online questionnaires conducted by simple random sampling technique and respondents are managers as many as 180 people from 15 hospitals that have implemented the ISO 9001: 2015 quality management system for 5 years in Indonesia. Data processing using SEM method with SmartPLS 3.0 software. Each closed question / statement item is given five answer options, namely: strongly agree (SS) score 5, agree (S) score 4, neutral / doubtful (N) score 3, disagree (TS) score 2, and strongly disagree. agree (STS) score 1. The method for data processing is by PLS and using the SmartPLS software.

Table 1. Respondent Profile

Criteria		Total	%
Age	< 30 Years	75	41.67 %
	30 - 40 Years	68	37.78 %
	> 40 Years	37	20.56 %
Work Periode	< 5 Years	28	15.56 %
	5-10 Years	93	51.67 %
	> 10 Years	59	32.78 %
Job Title	Manager	76	42.22 %
	Senior Manager	71	39.44 %
	Director	33	18.33 %
Gender	Female	76	42.22 %
	Male	104	57.78 %

Based on table 1, it is obtained the profile data of respondents aged 30 years and under 41.67%, ages between 30-40 years 37.78% and ages 40 years and over 20.56%. Work period of 5 years and under 15.56%, work period between 5-10 years 51.67% and work period of 10 years and above 32.78%. Job title senior manager 42.22 %%, job title manager 39.44%, job title director 18.33%. Gender for female 42.22% and male 57.78%. Based on previous research studies and literature reviews, the following hypothesis is obtained

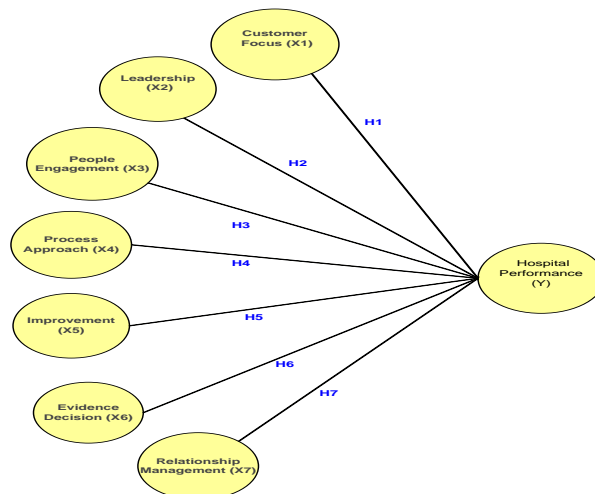


Fig 1. Research Framework

Based on previous research studies could be developed the following hypothesis (H) :

- Hypothesis 1 (H1): Customer focus (X1) has a positive and significant effect on hospital performance (Y)
- Hypothesis 2 (H2): Leadership principle (X2) has a positive and significant effect on hospital performance (Y)
- Hypothesis 3 (H3): People Engagement (X3) has a positive and significant effect on hospital performance (Y)
- Hypothesis 4 (H4): Process Approach (X4) has a positive and significant effect on hospital performance (Y)
- Hypothesis 5 (H5): Improvement Principle (X5) has a positive and significant effect on hospital performance (Y)
- Hypothesis 6 (H6): Evidence-Based Decision Making (X6) has a positive and significant effect on hospital performance (Y)
- Hypothesis 7 (H7): Relationship Management (X7) has a positive and significant effect on hospital performance (Y)

**RESULTS AND DISCUSSION**

**Convergent Validity Testing**

Convergent validity test is conduct by looking at the loading factor value of each indicator against the construct. Factor weights of 0.5 or more are considered to have sufficiently strong validation to explain latent constructs (Chin, 1998; Ghazali, 2014; Hair et al., 2010).

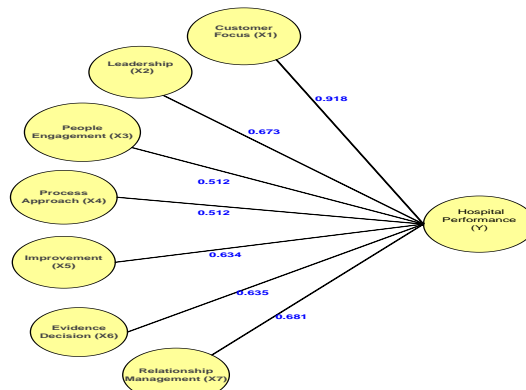


Fig 2. Research Model Framework Result

In this study, the minimum limit for the accepted loading factor is 0.5, provided that the AVE value of each construct is > 0.5 (Ghozali, 2014). All indicators have a loading factor value above 0.5 or provided that the AVE value is above 0.5. The fit or valid model of this study can

be seen in Figure 2. Thus, the convergent validity of this research model has met the requirements. The value of loadings, cronbach's alpha, composite reliability and AVE for each complete construct can be seen in Table 2 below:

**Table 2.** Loadings, Cronbach's Alpha, Composite Reliability, and Average Variance Extracted (AVE)

Variables	Items	Loadings	Cronbach's Alpha	Composite Reliability	AVE
Customer Focus (X1)	X11	0.654	0.867	0.904	0.653
	X12	0.542			
	X13	0.721			
Leadership (X2)	X21	0.567	0.919	0.935	0.673
	X22	0.612			
	X23	0.641			
People Engagement (X3)	X31	0.611	0.846	0.891	0.680
	X32	0.578			
	X33	0.653			
Process Approach (X4)	X41	0.641	0.867	0.904	0.653
	X42	0.531			
	X43	0.531			
Improvement (X5)	X51	0.612	0.919	0.935	0.673
	X52	0.564			
	X53	0.642			
Evidence-Based (X6)	X61	0.642	0.846	0.891	0.680
	X62	0.551			
	X63	0.612			
Relationship (X7)	X71	0.513	0.846	0.891	0.680
	X72	0.623			
	X73	0.612			

Construct reliability can be assessed from the Cronbach's alpha value and the composite reliability of each construct. The recommended composite reliability and cronbach's alpha value is more than 0.7 (Ghozali, 2014). The results of the reliability test in Table 2 above show that all constructs have composite reliability and Cronbach's alpha values are greater than 0.7 (> 0.7). In conclusion, all constructs have met the required reliability.

**Desriminant Validity Testing**

Discriminant validity was conducted to ensure that each concept of each latent variable is different from other latent variables. The model has good discriminant validity if the AVE squared value of each exogenous construct (the value on the diagonal) exceeds the correlation between this construct and other constructs (values below the diagonal) (Ghozali, 2014). The results of discriminant validity testing are by using the AVE square value, by looking at the Fornell-Larcker Criterion Value obtained as shown in Table 3.

**Table 3.** Discriminant Validity

Variables	Y	X1	X2	X3	X4	X5	X6	X7
Performance (Y)	<b>0.931</b>							
Customer Focus (X1)	0.567	<b>0.912</b>						
Leadership (X2)	0.685	0.656	<b>0.891</b>					
Engagement (X3)	0.634	0.612	<b>0.572</b>	<b>0.932</b>				
Approach (X4)	0.612	0.621	<b>0.621</b>	<b>0.521</b>	<b>0.821</b>			
Improvement (X5)	0.521	0.634	<b>0.523</b>	<b>0.631</b>	<b>0.732</b>	<b>0.982</b>		
Evidence (X6)	0.621	0.721	<b>0.532</b>	<b>0.532</b>	<b>0.632</b>	<b>0.621</b>	<b>0.821</b>	
Relationship (X7)	0.562	0.623	<b>0.521</b>	<b>0.562</b>	<b>0.562</b>	<b>0.634</b>	<b>0.621</b>	<b>0.982</b>

The results of the discriminant validity test in Table 3 above indicate that all constructs have a square root value of AVE above the correlation value with other latent constructs (through the Fornell-Larcker criteria). Likewise, the cross-loading value of all items from an indicator is greater than the other indicator items as mentioned in Table 4, so it can be concluded that the

model has met discriminant validity (Fornell & Larcker, 1981).

**Hypothesis test**

Hypothesis testing in PLS is also called the inner model test. This test includes the direct effect significance test carried out using the t-statistical test in the partial least

squared (PLS) analysis model using the SmartPLS 3.0 software. With the bootstrapping technique, the R

Square value and the significance test value are obtained below:

**Table 4.** R Square Value Result

	R Square	R Square Adjusted
Hospital Performance (Y)	0.786	0.682

Based on Table 5, the value of R Square for hospital performance is 0.786, which means that hospital performance can be explained by the variable implementation of ISO 9001: 2015 Customer Focus (X1), Leadership (X2), People Engagement (X3), Process Approach (X4), Improvement (X5), Evidence-Based Decision (X6), Relationship Management (X7) of 78.6%,

while the remaining 21.4% is explained by other variables not discussed in this study.

Table 6 shows t-statistics and p-values which show the influence between research variables on the application of ISO 9001: 2015 on the performance of hospital.

**Table 5.** Hypothesis Testing Result

Hypotheses	Relationship	Beta	SE	T Statistics	P-Values	Decision
H1	X1->Y	0.712	0.103	3.981	0.001	<i>supported</i>
H2	X2->Y	0.717	0.027	6.987	0.000	<i>supported</i>
H3	X3->Y	0.614	0.078	10.987	0.002	<i>supported</i>
H4	X4->Y	0.812	0.042	11.072	0.001	<i>supported</i>
H5	X5->Y	0.821	0.072	7.156	0.000	<i>supported</i>
H6	X6->Y	0.714	0.087	8.987	0.001	<i>supported</i>
H7	X7->Y	0.718	0.023	7.981	0.000	<i>supported</i>

## Discussion

### Relationship between Customer Focus (X1) and Hospital Performance (Y)

Based on statistical calculations in Table 5, it is concluded that the principle of customer focus (X1) in ISO 9001: 2015 positively and significantly affects hospital performance (Y). It is proven by the t-statistics value of 3.981 which is greater than 1.96 and the p-value of 0.001 is smaller than 0.05. That is, the first hypothesis (H1) is accepted. This finding is in line with the results of previous research from (Asbari, 2019; Purwanto, 2020; Santoso, et al., 2019;) that the implementation of the ISO 9001: 2015 quality management system principle of customer focus has a positive and significant effect on organizational performance, this means that the application ISO 9001: 2015, especially the principle of customer focus in organizations, especially in hospitals, will encourage increased hospital performance.

### Relationship between Leadership Principle (X2) and Hospital Performance (Y)

Based on the statistical calculations in Table 5, it is concluded that the Leadership principle (X2) in ISO 9001: 2015 positively and significantly affects hospital performance (Y). Evidenced by the t-statistics value of 10.987 is greater than 1.96 and a p-value of 0.002 is smaller than 0.05. That is, the second hypothesis (H2) is accepted. This finding is in line with the results of previous research from (Asbari, 2019; Purwanto, 2020; Santoso, et al., 2019;) that the implementation of the ISO 9001: 2015 quality management system has a positive and significant effect on organizational performance, this means that implementation ISO 9001: 2015, especially the principles of leadership in organizations, especially in hospitals, will encourage increased hospital performance.

### Relationship between People Engagement (X3) and Hospital Performance (Y)

Based on statistical calculations in Table 5, it is concluded

that the principles of People Engagement (X3) in ISO 9001: 2015 positively and significantly affect hospital performance (Y). Evidenced by the t-statistics value of 10.9872 is greater than 1.96 and the p-value of 0.002 is smaller than 0.05. That is, the third hypothesis (H3) is accepted. This finding is in line with the results of previous research from (Asbari, 2019; Purwanto, 2020; Santoso, et al., 2019;) that the implementation of the ISO 9001: 2015 quality management system principles of People Engagement has a positive and significant effect on organizational performance, this means that the application of ISO 9001: 2015, especially the principle of People Engagement (X3) in organizations, especially in hospitals, will encourage increased hospital performance.

### Relationship between Process Approach (X4) and Hospital Performance (Y)

Based on statistical calculations in Table 5, it is concluded that the Principle of Process Approach (X4) in ISO 9001: 2015 positively and significantly affects hospital performance (Y). Evidenced by the t-statistics value of 11.072 is greater than 1.96 and the p-value of 0.001 is smaller than 0.05. That is, the fourth hypothesis (H4) is accepted. This finding is in line with the results of previous research from (Asbari, 2019; Purwanto, 2020; Santoso, et al., 2019;) that the application of the ISO 9001: 2015 quality management system, the Process Approach principle has a positive and significant effect on organizational performance, this means that ISO 9001: 2015, especially the Process Approach principle in organizations, especially in hospitals, will encourage increased hospital performance.

### Relationship between Improvement (X5) and Hospital Performance (Y)

Based on the statistical calculations in Table 5, it is concluded that the principle of Improvement (X5) in ISO 9001: 2015 positively and significantly affects hospital performance (Y). Evidenced by the t-statistics value of

7.156 is greater than 1.96 and the p-value of 0.000 is smaller than 0.05. That is, the fifth hypothesis (H5) is accepted. This finding is in line with the results of previous research from (Asbari, 2019; Purwanto, 2020; Santoso, et al., 2019;) that the implementation of the ISO 9001: 2015 quality management system has a positive and significant effect on organizational performance, this means that the application of ISO 9001: 2015 especially the principles of improvement in organizations, especially in hospitals, will encourage increased hospital performance.

#### **Relationship between Evidence-Based Decision (X6) and Hospital Performance (Y)**

Based on the statistical calculations in Table 5, it is concluded that the principle of Evidence-Based Decision (X6) in ISO 9001: 2015 positively and significantly affects hospital performance (Y). Evidenced by the t-statistics value of 8,987 is greater than 1.96 and the p-value of 0.000 is smaller than 0.05. That is, the sixth hypothesis (H6) is accepted. This finding is in line with the results of previous research from (Asbari, 2019; Purwanto, 2020; Santoso, et al., 2019;) that the implementation of the ISO 9001: 2015 quality management system principle of Evidence-Based Decision has a positive and significant effect on organizational performance, this means that the implementation of ISO 9001: 2015, especially the principle of Evidence-Based Decision in organizations, especially in hospitals, will encourage increased hospital performance.

#### **Relationship between Relationship Management (X7) and Hospital Performance (Y)**

Based on statistical calculations in Table 6, it is concluded that the principles of Relationship Management (X7) in ISO 9001: 2015 positively and significantly affect hospital performance (Y). Evidenced by the value of t-statistics 7.981 is greater than 1.96 and the p-value of 0.000 is smaller than 0.05. That is, the seventh hypothesis (H7) is accepted. This finding is in line with the results of previous research from (Asbari, 2019; Purwanto, 2020; Santoso, et al., 2019;) that the implementation of the ISO 9001: 2015 quality management system principles of Relationship Management (X7) has a positive and significant effect on organizational performance. means that the application of ISO 9001: 2015, especially the principles of Relationship Management (X7) in organizations, especially in hospitals, will encourage increased hospital performance.

#### **CONCLUSION**

The results of this study concluded that customer focus ISO has a positive and significant effect on hospital performance, the Leadership principle has a positive and significant effect on hospital performance, People Engagement has a positive and significant effect on hospital performance, the process approach has a positive and significant effect on hospital performance, improvement principle has a positive and significant effect on hospital performance, evidence-based decision making has a positive and significant effect on hospital performance, relationship management has a positive effect and is significant to hospital performance. The implementation of the ISO 9001: 2015 Quality Management System is expected to help hospital management to be more structured and produce quality products that can satisfy stakeholder needs. It is recommended that the top management of the hospital increase their commitment and understanding of the

implementation of the ISO 9001: 2015 Quality Management System. Once fully understood, companies must create detailed procedures regarding a new management system that has adapted ISO 9001: 2015. More in-depth socialization needs to be given to all parties involved in hospital activities that currently the hospital has used a management system based on ISO 9001: 2015 and provides firm action so that its employees must follow these procedures. Customer focus is the top priority of the hospital's Quality Management System by providing all the needs that exceed stakeholder expectations for the achievement of stakeholder satisfaction. So that the survival of the company will be guaranteed in the long term. Each leader in the hospital has a role as a trainer who has targets according to the hospital's goals through employee empowerment, decision makers based on data and facts (decision makers) and making company management system standards inherited for the next generation. Creating and providing added value to stakeholders will be easier if supported by competent personal, able to be empowered and involved at all levels throughout the hospital. Its application is to promote a process approach and the importance of contributions at all levels in the organization.

The quality management system that has been established in the hospital is not based on a departmental approach but is based on a pure process in the hospital by involving all related parties. Hospitals that are successful and able to withstand competition are hospitals that focus on improvement, the application form is to always make changes through continuous improvement both internally and externally adapted to the latest hospital climate. So that the hospital will always be ready to face competition with competitors. Making decisions based on data and facts, the application form is that every time a conclusion of a problem is determined based on the analysis of facts and data obtained during the analysis. So that the decisions taken will produce productive and targeted decisions. To maintain the success of the hospital, it must manage its relationship with interested parties, including its suppliers, partners, employees, government, and the community. Based on the findings of this study, it is recommended that hospital management implement a quality management system consistently and thoroughly to increase stakeholder satisfaction and create competitiveness. This study has several limitations on the number of respondents and limited questionnaire variables. The author highly recommends finding, exploring, and analyzing them in future studies. this study was conducted in a hospital and may not be generalizable to other sectors. Therefore, it is highly recommended to conduct further research on this topic in other sectors. May be added to the entire region, or in another country.

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