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## **DEVELOPING AND VALIDATING A MODEL OF ISO 9001 EFFECTIVENESS GAP: EMPIRICAL EVIDENCE FROM CHINA**

**Xiaojing Sun<sup>(\*)</sup>, Decheng Wen, Dongwei Yan**

School of Management, Shandong University, Jinan, People's Republic of China

<sup>(\*)</sup>*Email: 13953153097@126.com*

### **ABSTRACT**

Based on reverse thinking, this paper put forward the concept of "Effectiveness gap". The purpose of the study is firstly, to determine the critical factors which have a significant impact on the ISO 9001 effectiveness gap, and secondly, to develop and validate a model of ISO 9001 effectiveness gap to illustrate the relationship between these factors and their impact on ISO 9001 effectiveness gap. The authors of this paper investigated 413 ISO 9001 certified companies in china and they found out that motivation barriers, top management barriers, employee barriers, resource barriers, certification organization barriers all have positive impact on ISO 9001 effectiveness gap. In addition, the research also found that top management barriers play a central role in the model of ISO 9001 effectiveness gap, and employee barriers are affected by some other factors. It is also important to note that the role of certification organization barriers cannot be ignored.

**Keywords:** ISO 9001, QMS, effectiveness gap, barriers.

### **INTRODUCTION**

Since the introduction of the ISO 9000 series in 1987, it has become a world-wide quality management norm for organizations, regardless of their size and what they produce (Tsim, Yeung and Leung, 2002). By the end of 2016, the number of valid ISO 9001 certificates in the world amounted to 1106,356 (ISO, 2017), an increase of 7,2176 over 2015. Since the implementation of the certification system, QMS has become the most widely used quality management practice in China. As of December 31, 2016, the number of ISO 9001 certificates in China was 350,631 (ISO, 2017), accounting for 31.69% of the world total, ranking the first with an increase of 58,072 as compared with 2015. The contribution rate of global certificate growth is 80.46%.

Judging from the number of ISO 9001 certificates, China has undoubtedly become a veritable "Big Country of certification". However, there is no direct relationship between the number of certificates and the effectiveness of ISO 9001. The fact shows that there is still a gap between the effectiveness and the intended results of enterprises on quality management system. To illustrate this issue, the paper cites the concept of "Effectiveness gap" proposed by Fisher *et al.* (2004) in the medical field. We define "Effectiveness gap" as the gap between the effectiveness and the intended results of enterprises on quality management system.

This paper mainly intends to solve the following two problems:

Q1: what are the critical failure factors/barriers which have a significant impact on the ISO 9001 effectiveness gap?

Q2: what is the relationship between these critical failure factors/barriers? Can we develop and validate a model of ISO 9001 effectiveness gap to illustrate the relationship between these factors and their impact on the ISO 9001 effectiveness gap?

In order to solve these problems, we put forward 11 hypotheses through literature review, and developed a conceptual model of ISO 9001 effectiveness gap (Figure 1).

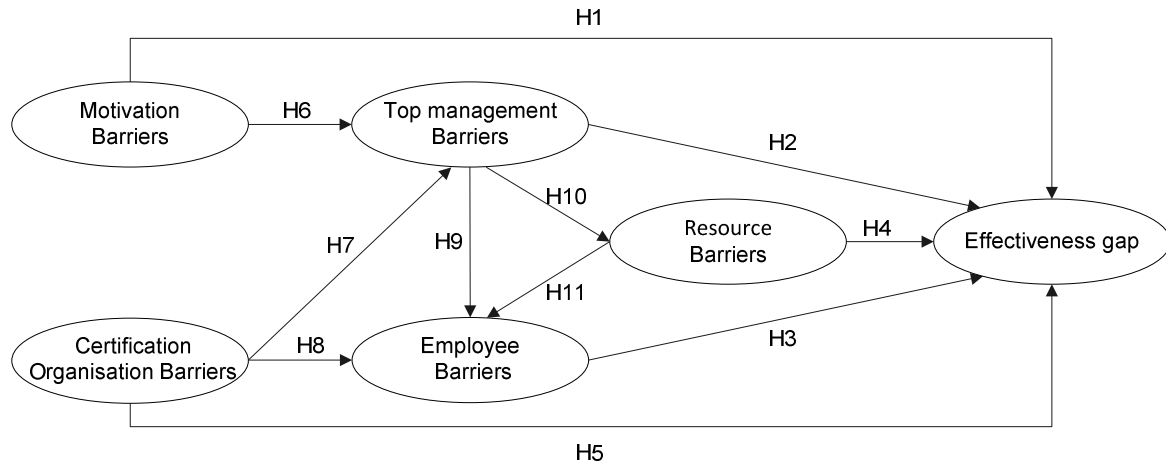


Fig. 1 - Conceptual model

## RESULTS AND CONCLUSIONS

This paper conducted a survey in Beijing City, Shandong Province, Anhui Province and Guangxi Province, which are representative in China, and recovered 413 valid questionnaires. We adopt SmartPLS 3 (Ringle, Wende, and Becker, 2015) for analysis, and use Bootstrap algorithm (N = 5000) to conduct significance test on the path coefficient of the conceptual model (Wakeling and Morris, 1993; Chin, 2010). The test results are presented in Table 1, which support all the hypotheses that we have proposed.

Table 1 - Path Coefficients

	Hypothesis	Original Sample (O)	Sample Mean (M)	Standard Deviation (STDEV)	T Statistics ((O/STDEV))	P Values
Motivation Barriers → Effectiveness gap	H1	0.179***	0.179	0.037	4.839	0.000
Top management Barriers → Effectiveness gap	H2	0.253***	0.260	0.046	5.496	0.000
Employee Barriers → Effectiveness gap	H3	0.238***	0.236	0.047	5.077	0.000
Resource Barriers → Effectiveness gap	H4	0.145***	0.146	0.038	3.779	0.000
Certification Organization Barriers → Effectiveness gap	H5	0.240***	0.236	0.052	4.660	0.000
Motivation Barriers → Top management Barriers	H6	0.345***	0.344	0.045	7.668	0.000
Certification Organization Barriers →	H7	0.428***	0.428	0.046	9.236	0.000

Top management Barriers						
Certification Organization Barriers → Employee Barriers	H8	0.382***	0.383	0.049	7.823	0.000
Top management Barriers → Employee Barriers	H9	0.366***	0.365	0.052	7.066	0.000
Top management Barriers → Resource Barriers	H10	0.489***	0.488	0.036	13.696	0.000
Resource Barriers → Employee Barriers	H11	0.172***	0.173	0.040	4.239	0.000

\*\*\*p<0.001.

The major conclusions of this paper are as follows:

- (1) Motivation barriers, top management barriers, employee barriers, resource barriers, certification organization barriers all have positive impact on ISO 9001 effectiveness gap.
- (2) Top management barriers play a central role in the model of ISO 9001 effectiveness gap. Top management barriers have the greatest impact on ISO 9001 effectiveness gap (path coefficient=0.253, p<0.001, higher than the other barriers to the effectiveness gap). Both the motivation barriers and the certification organization barriers have a positive effect on the top management barriers (path coefficients are 0.345 and 0.428, p<0.001), while top management barriers play a positive role in promoting employee barriers and resource barriers (path coefficients are 0.366 and 0.489, p<0.001).
- (3) The role of certification organization barriers cannot be ignored, in line with the findings of Luo (1999), Poksinska, Eklund and Dahlgard (2006). This research found that certification organization barriers not only have a positive impact on ISO 9001 effectiveness gap (path coefficient=0.240, p<0.001), but also have a positive impact on top management barriers and employee barriers (path coefficients are 0.428 and 0.382, p<0.001).
- (4) Employee barriers are affected by some other factors. Top management barriers, resource barriers, certification organization barriers all have positive impact on employee barriers (path coefficients are 0.366, 0.172, 0.382 respectively, p<0.001).
- (5) In addition, the research also found that there are significant differences in ISO 9001 effectiveness gap of the sample groups with different size and years of certification. The smaller the company size, the shorter the years of certification, the greater the ISO 9001 effectiveness gap will be. However, there is not much difference in the perception of ISO 9001 effectiveness gap between different positions.

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