

## THE IMPACT OF AN EXTERNAL QUALITY MECHANISM IN HOSPITAL STAFF: DOES THE ISO9000 MAKES OUR DREAMS COME TRUE?

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**Abstract:** External quality mechanisms such as ISO9000 certification have been adopted by hospitals to increase trust of patients, financiers and government as well as to improve quality of health care. However, there is a lack of studies describing its impact on all hospital actors. This work studied the staff's opinion about the changes provoked by the ISO9000 certification on a 150 bed hospital by means of homogeneity analysis (HOMALS). The staff's opinions were acquired using a questionnaire about their background, working activities, professional experience, work shift and changes in the hospital after ISO9000 certification. The questionnaires were distributed to all hospital staff (958 employees) and 517 were returned. In the analysis we considered only the respondents who were working in the hospital before the certification and this yield to 387 subjects. The HOMALS pointed out that 26% of respondents had a negative and slight negative impression of ISO9000, 25% showed indifferent, 34% had a slight positive impression and 15% a positive opinion. In addition the clinical staff, who works directly with patient, had a more negative opinion on ISO9000 impact than the non-clinical staff, 33% versus 21%, and a less positive opinion, 38% versus 57%.

### Introduction

Quality has always been chased by everyone and, although it is not so hard to perceive, its definition is not trivial [1,2]. Nowadays quality has become an object of desire by both producers and consumers. However, the difficulty to establish a definition for quality has leading to confusion both to its interpretation and measurement. Somebody could interpret quality as the beauty of a jewels, others the low price of a product, they are right depending on the context and their expectation. Quality in health care has the same problem of definition and contextualization, in spite of this, there is an increasing pressure on health care providers to formally demonstrate the quality of their services.

External quality assessment mechanisms have been adopted by many health care services in order to increase the trust of external parties such as patients, financiers and government as well as to improve the quality of health care [3,4]. They are large scale

interventions with focus on the operationalization of control mechanisms, e.g. Accreditation, International Organization for Standardization (ISO) certification, European Foundation for Quality Management (EFQM) assessment and *visitatie* [4,5].

In spite of the dissemination of these mechanisms in health care, there is a lack of studies devoted to the evaluation of their effectiveness and long term results. Also, little research is available on the conditions needed to implement these mechanisms successfully [5,6].

Attention must be taken to the fact that the quality of services depends heavily on staff's background and motivation. Patients can be seen as co-producers of health care as could be seen elsewhere [7] but hospital staff have a more direct and decisive participation in the results of health care. They should act in a leading role instead of a supporting role and this is sometimes forgotten in these external assessment mechanisms.

The ISO9000 model claims to be a generic mechanism capable to be applied to manufacturing and service companies, including health care services, in order to improve the quality of products and services. The ISO9000 deals with quality system requirements that can be used for external quality assurance purposes by the specification of requirements which determine what elements quality systems have to encompass [8].

The aim of this work is to study the impact of the ISO9000 in hospital staff by means of a multivariate approach (homogeneity analysis – HOMALS) based on their opinions about the changes introduced by this external quality assessment mechanism.

### Materials and Methods

This work was developed in a 150 bed philanthropic general hospital with high complexity services available like hemodynamics, magnetic resonance imaging, x-ray computerized tomography, nuclear medicine and radiotherapy. The entire hospital received its initial ISO9000 certification on 1998 after four years of gradual adequation to the standards clauses. The hospital had a desirable feature of having a low turn over of employees so that it was possible to acquire the opinions of employees that had passed through the transition period before and after the certification. Another feature was that the hospital had minimal third parties services so that the majority of employees were involved in the certification process. Table 1 shows the

distribution of the hospital staff into six professional categories.

Table 1: Hospital staff distribution by professional categories

Professional Category	Number of employees
Physicians	258
Nursing Staff	227
Administrative Staff	105
Engineering Staff	59
Supporting Services	288
Council	20

The staff's opinion about the changes in the hospital after the ISO9000 were obtained by means of a questionnaire distributed between March and June of 2002.

This instrument was developed based on the information obtained by a non-participant observation, interviews, quality system documentation and ISO9000 standards. The questions were formulated in order to gather information about important items identified as key points in the certification. It consisted of 23 questions divided in 6 blocks: identification, scholarship, working activities, professional experience, work shift and the ISO9000. The ISO9000 block was composed of questions to collect the opinions of the staff about the changes in hospital due to the certification regarding infrastructure, medical devices, medical articles, drugs, organizational aspects, valorization of their work and satisfaction on performing their job. The questions were developed using simple and direct wording to make easy its understanding once the questionnaire was self-responded. Additionally, the questions were prepared as general as possible so that the questionnaire could be applied to all hospital staff without further modifications.

The questionnaire provide a multidimensional nominal data set on the staff's opinion about the changes due to certification. HOMALS [9,10] was applied to map the opinion of the group by means of the principal variables in the data set and identify subgroups with similar opinion. The HOMALS can be seen as a principal components analysis applied to nominal data [11]. A typical output of the HOMALS consists of an object score and a category quantification plots in two or three dimensions, in which the object corresponds to each respondent and the categories corresponds to the answers options. These graphical output often were more effective to interpret data than mathematical models, numbers could give details but rarely permits a global view of the data [12]. Some basic properties of a HOMALS solution are: the category quantification and object scores are represented in a joint space; the object scores represent the co-ordinates of the cases in n-dimensions; the category quantification represents the

centroid co-ordinates of the categories in n-dimensions; the objects with the same response pattern receive identical object scores; the distance between two object points is related to the similarity between their profiles; the variable discriminates better to the extent that its category points are further apart; and the category points with low marginal frequencies will be located further away from the origin of the joint space, whereas categories with high marginal frequencies will be located closer to the origin [10].

In this analysis, we considered only respondents that were working in the hospital before the certification. The HOMALS was applied to the group of questions on the opinion of respondents to the modifications in the hospital due to ISO9000 certification, resulting in 12 variable from which one was binary and 11 had five categories. The scale adopted for the five categories goes from a positive opinion about the ISO9000 impact (category 1) to a negative opinion (category 5), passing through a slight positive opinion (category 2), indifferent opinion (category 3) and slight negative opinion (category 4).

## Results

A total of 517 questionnaires were returned that comprised a response rate of 54%. Taking into account only the respondents that were working in the hospital in the occasion of the ISO9000 certification, we had 387 questionnaires that was 75% of the returned questionnaires. Table 2 presents the percentage of respondents that were working in the hospital before the certification considering the respondents of each professional category. The high percentage for the council was due to the fact that only one questionnaire was returned and it was from a member that has worked in hospital during the certification. The response rate for this professional category was 5%. The Engineering Staff had a response rate of 75% but showed a low percentage on Table 2, this could be explained by its growth after the certification so that many new employees were hired.

Table 2: Percentage of respondents that were working in the hospital before the ISO9000 certification considering the respondents of each professional category

Professional Category	Percentage
Physicians	77
Nursing Staff	85
Administrative Staff	78
Engineering Staff	36
Supporting Services	76
Council	100

The data of the 387 questionnaires were used in the HOMALS analysis. A two dimensional plot of the category quantification is presented in Figure 1. The

plot was divided into four quadrants (Q1, Q2, Q3, Q4) where the first quadrant is on the upper-right side and others follow the clockwise sequentially. It could be observed a clustering of similar categories in some regions of the plot, suggesting an establishment of groups. Some of these groups were well defined like the cases of category “1” other were not so obvious as categories “3” and “4”. It could also be observed that there is a transition of the answer categories from “1” to “5” following a U-shape. The presence of this pattern indicated that there is an unidimensional structure represented by dimension “1” [13]. The quadrant Q4 was dominated by category “1” related to a positive opinion of ISO9000 impact. On the other extremity, categories “5” and “4”, associated to a negative and a slight negative opinion, rule over Q1. In the middle of dimension “1” scale, we had category “2” in Q3 associated to a slight positive opinion and category “3” in Q2 related to a indifferent opinion.

The Figure 2 shows the object scores (respondent opinion) on a two dimension plot coded by professional category. The “clinical staff” were the physicians and nursing; and the remaining professional categories (administrative staff, engineering, support services and council) were aggregated in “non-clinical staff”. It could be observed that the clinical staff were more concentrated in Q2 and Q3.

The analysis of the quadrants revealed that 26% of the objects (all respondents) in Q1 had a negative to a slight negative impression of the ISO9000 impact , 25% are indifferent (Q2), 34% perceived a slight positive impression (Q3) and 15% have a positive opinion (Q4).

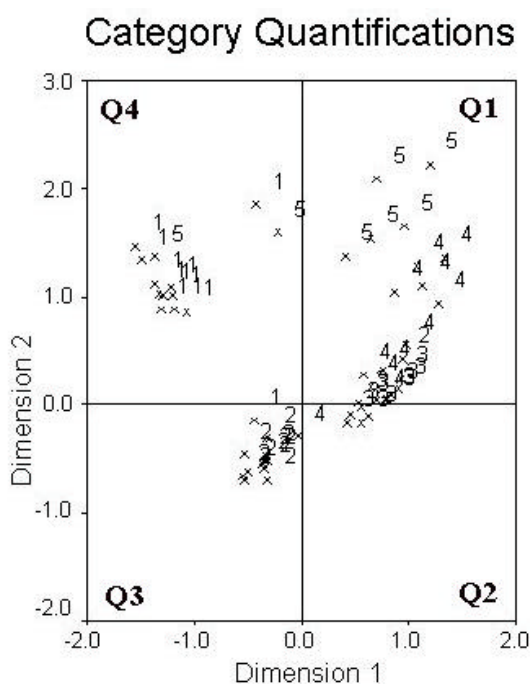


Figure 1: Plot of the category quantification of the 12 variables considering two dimensions

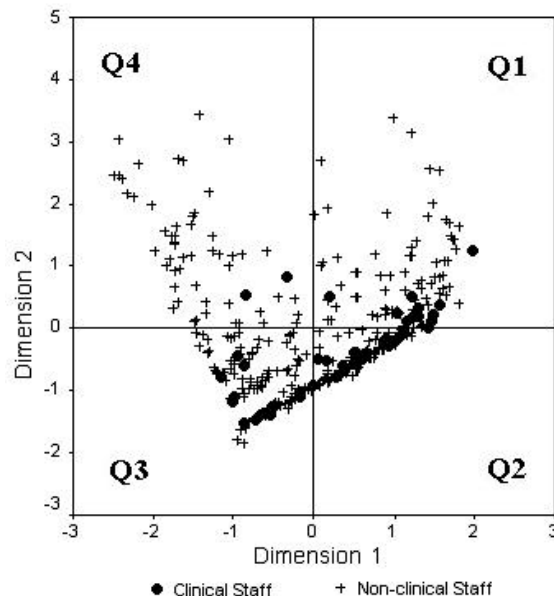


Figure 2: Plot of object score (respondent opinion) of the 12 variables considering two dimensions

Table 3 shows the distribution of the clinical and non-clinical staff opinion considering the quadrants of the plot in Figure 2. The clinical staff was more concentrated in Q1 (33%) and less concentrated in Q4 (9%) and the non-clinical staff was more concentrated in Q3 (38%) and less concentrated in Q4 (19%).

Table 3: Distribution of professional categories among the four quadrants

Quadrant	Clinical Staff	Non-clinical Staff
Q1	33%	21%
Q2	29%	22%
Q3	29%	38%
Q4	9%	19%

### Discussion

The findings show that, merging Q1 and Q2, we obtain 51% of the total respondents indifferent or with negative impression of ISO9000. The indifference is not a good result considering the effort to implement an ISO9000 quality system.

According to professional categories, the clinical staff, that usually works directly with patient, was more indifferent or had a more negative opinion on ISO9000 than the non-clinical ones, 33% versus 21%, and a less positive opinion, 38% versus 57%. This maybe due to the fact that the main focus of ISO9000 is the organizational practice rather than the clinical practice. The clinical staff’s expectation on ISO9000 certification benefits were probably not met. In part because they do not know what a ISO9000 certification really means and they were expecting an direct impact on their clinical practice. On the other hand, the non-clinical staff maybe

were more contemplated by ISO9000, specially those people in administrative functions.

The results of this work could be diverse in others scenarios as a successful ISO9000 certification depends on a variety of items like cultural aspects, interpretation of ISO9000 clauses, ways of implementation etc. but little research is available with respect to the impact of certification on hospital staff and this problem is worth to be addressed as it is not possible to improve health service adequately without hospital staff support and motivation.

### Conclusions

Considering the global result, only a minor group had a clear positive impression about the certification, this shows that the adoption of an external quality mechanism as a way to motivate the hospital staff should be carefully considered by the administration.

This work shows a distinction between the clinical and non-clinical staff opinions regarding the impact of the ISO9000 certification in the examined. The clinical staff had a more pessimistic impression about the benefits of the certification than the non-clinical staff. This result reflects that the ISO9000 standards might be more adequate to technical and administrative activities than the ones more related to patient care.

The hospital staff in this work indicates that probably their “dreams” did not have turned to reality. This fact was less related to ISO9000 fault but maybe more about the expectations generated in peoples’ mind based on different interpretation of the word “quality”.

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