

# Accreditation and ISO certification: do they explain differences in quality management in European hospitals?

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## Abstract

**Background.** Hospital accreditation and International Standardisation Organisation (ISO) certification offer alternative mechanisms for improving safety and quality, or as a mark of achievement. There is little published evidence on their relative merits.

**Objective.** To identify systematic differences in quality management between hospitals that were accredited, or certified, or neither.

**Research design.** Analysis of compliance with measures of quality in 89 hospitals in six countries, as assessed by external auditors using a standardized tool, as part of the EC-funded Methods of Assessing Response to Quality Improvement Strategies project.

**Main outcome measures.** Compliance scores in six dimensions of each hospital—grouped according to the achievement of accreditation, certification or neither.

**Results.** Of the 89 hospitals selected for external audit, 34 were accredited (without ISO certification), 10 were certified under ISO 9001 (without accreditation) and 27 had neither accreditation nor certification. Overall percentage scores for 229 criteria of quality and safety were 66.9, 60.0 and 51.2, respectively. Analysis confirmed statistically significant differences comparing mean scores by the type of external assessment (accreditation, certification or neither); however, it did not substantially differentiate between accreditation and certification only. Some of these associations with external assessments were confounded by the country in which the sample hospitals were located.

**Conclusions.** It appears that quality and safety structures and procedures are more evident in hospitals with either the type of external assessment and suggest that some differences exist between accredited versus certified hospitals. Interpretation of these results, however, is limited by the sample size and confounded by variations in the application of accreditation and certification within and between countries.

**Keywords:** accreditation, certification, ISO, external assessment, quality and safety, MARQuIS, DUQuE

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## Introduction

Hospitals are subject to a number of external assessments for different purposes, by various statutory and voluntary agencies, using a range of approaches. The principal ‘peer review techniques’ in Europe, which focus on whole hospitals or services, were identified by the External Peer Review Techniques project [1] as certification according to International Standardisation Organisation (ISO) standards, professional peer review, health service accreditation and assessment against the European Framework for Quality

Management. These standards-based programmes were generally voluntary, independent and aimed at internal organizational development, self-regulation and marketing. In the past 10 years, health service accreditation programmes in Europe have become increasingly regulatory, transparent and governed by a range of stakeholders, including government [2].

There is generally little consistency or reciprocity between the several approaches either within or between countries, and most are adopted by only a minority of hospitals, unless they are mandatory. Their impact on health systems could be much greater if there were a clearer business case for the

investment, or more robust evidence for their benefit on structure, process or outcome of hospital care. ‘Considering the amount of time and money spent on organisational assessment, and the significance of the issue to governments, it is surprising that there is no research into the cost-effectiveness of these schemes’ [3].

Existing published literature shows increasing attention to these issues, but still no clear answers. A systematic review by Greenfield and Braithwaite in 2007 [4] of accreditation research classified possible impacts in 10 categories: professions’ attitudes to accreditation, promoting change, organizational impact, financial impact, quality measures, programme assessment, consumer views or patient satisfaction, public disclosure, professional development and surveyor issues. Of these, only promoting change and professional development showed consistent positive association with accreditation; three categories (consumer views or patient satisfaction, public disclosure and surveyor issues) did not have sufficient studies to draw any conclusion, and the remaining categories showed inconsistent conclusions.

An early study in Australia, tracking 23 hospitals over 2 years, reported that accreditation had led to changes in six areas: administration and management, medical staff organization, review systems, organization of nursing services, physical facility and safety, and hospital role definition and planning [5]. Hospitals participating in the accreditation programme in KwaZulu-Natal, South Africa, improved their compliance with accreditation standards; non-participating hospitals did not. However, there was no observed improvement on the defined quality indicators [6]. Recent studies in France include a description of changes in one university hospital centre after the introduction of mandatory accreditation in 1996 [7] and an analysis of the findings and recommendations of the first 100 hospital reports of the same national programme [8].

Analysis of state psychiatric hospitals in the USA [9] revealed a weak relationship between accreditation or certification status and indicators of quality of care (average cost per patient, per diem bed cost, total staff hours per patient, clinical staff hours per patient, per cent of staff hours provided by medical staff, bed turnover and per cent of beds occupied); accredited or certified hospitals were more likely to have higher values on specific indicators than hospitals without accreditation. A comparison of rural critical access hospitals in the USA [10] found that accredited hospitals showed significant advantage over non-accredited hospitals in 4 out of 16 clinical indicators but noted that, in a sector where only one-third of hospitals seek accreditation, self-selection and motivation could explain much of this advantage. A study of 115 general medical–surgical community hospitals in 20 states of the USA examined the association between hospital characteristics and the use of patient safety practices on patient outcomes, comparing with 995 hospitals in 35 states contributing data to the 2002 Nationwide Inpatient Sample. This found that certain hospital characteristics were significantly associated with some patient outcomes, but not others, and accreditation standards specific to patient safety practices did not appear related to all four clinical outcomes studied [11].

Most recently, Braithwaite *et al.* [12] have reported an independent blinded assessment of 19 organizations representing approximately 5% of the Australian acute care health system, concluding that, ‘accreditation results predict leadership behaviours and cultural characteristics of healthcare organisations but not organisational climate or consumer participation’. Finally, Groene *et al.* [13] found in a study of 38 hospitals from eight countries that had undergone any type of external assessment had a significantly higher compliance with the World Health Organization Standards for Health Promotion in Hospitals than hospitals without such assessment (63.9% vs. 47.3%;  $P = 0.012$ ). In summary, there is evidence from many countries and settings that organizations and systems change in preparation for hospital accreditation and that there is some consistency of findings and recommendations for improvement within and between countries. Until now there has been no published study to explore differences between various modes of external assessment with hospital organization and systems in several countries. Compared with the broad scope of impact evaluated in previous studies, in this article we focus on differences in quality management systems associated with the type of external assessment.

## Methods

### Hospital sampling and data capture

A detailed description of the study of 89 hospitals in seven countries was published [14] together with the analysis and results of the ‘Methods of Assessing Response to Quality Improvement Strategies’ (MARQuIS) project [15]. Site visits by trained teams collected verifiable data on how hospitals manage quality and safety in seven of the eight countries participating in the project (Belgium, Czech Republic, France, Ireland, Poland, Spain, the Netherlands and the UK). Initially, a purposive sample of 105 hospitals was selected for on-site visit from a total of 389 respondents to a questionnaire circulated a year earlier, in 2006. The distribution was not even among the participating countries and had to be adapted according to the preferences of hospitals’ characteristics and the capacities of the local visitors; for a variety of reasons, several hospitals withdrew, especially in Belgium and the Netherlands. Overall, of the 105 visits planned, 89 were completed; visits could not be realized in hospitals in the Netherlands.

A hospital assessment tool was designed to capture verifiable data within 6 h on site, with minimum disruption and no preparation required of the hospitals except to locate a list of source documents. Most of the assessment criteria were evidenced in specified documents, such as personnel files, committee minutes and formal routine reports; the remainder were directly observable. The assessment tool included questions regarding the hospital’s external evaluation. Questions included whether the hospital had been recognized (within the past 3 years) by, or was in preparation for an external assessment by an established programme for health service accreditation, or by certification under ISO 9001 for hospital-wide quality management systems. Hospitals were grouped according to their recognition by

external assessment as ‘accreditation only’, ‘ISO only’, or ‘neither ISO, nor accreditation’. The remainder of the hospitals, which represent various combinations of approaches or were ‘in preparation’, were excluded.

## Data analysis

Dependent variables were established based on hospital compliance with 229 criteria, which were assessed and rated according to a grading scale as follows: exceptional compliance (indicative range >90%), extensive compliance (66–90%), broad compliance (41–65%), minor compliance (15–40%) and negligible compliance (<15%). This assessment was converted for each criterion into a score from 4 to 0; no weighting was applied. Invalid or null responses were excluded from calculations. Questions used to verify responses to the initial questionnaire were excluded from the scoring. The results were clustered under six dimensions in line with common chapters of accreditation standards: management, patients’ rights, patient safety, clinical organization, clinical practice and environmental safety.

Using the grading scheme described above, we created dimension and total scores by counting the value observed for each item of the dimension across all hospitals and dividing the mean score by the maximum theoretical value, multiplied by 100, in order to express the percentage compliance by dimension. The maximum theoretical value is the value that would be obtained if all hospitals complied fully with all items. After assessing normal distribution of the scores using the Kolmogorov–Smirnov test, we carried out an analysis of variance (ANOVA) in order to identify statistical significance for the differences observed in mean scores by mode of assessment. We repeated this test for three different possible combinations of the ‘external assessment’ grouping variable:

- comparison between all groups (accreditation vs. certification vs. neither),
- comparison between external assessment and no external assessment (accreditation or certification vs. neither and
- comparison between accreditation and certification.

In order to assess the effect of the country variable as a possible confounding factor and a potential interaction between country and the mode of external assessment, we carried out a two-factorial ANOVA for these three modes of external assessment.

## Results

Overall, site visits were carried out in 89 hospitals. Of these, 71 hospitals that complied with the inclusion criteria (accredited, certified or neither form of external assessment) were included in the analysis. Hospitals in preparation for accreditation or with combination of external assessment strategies were excluded from further analysis (Table 1).

In Table 2, we present the aggregate and total scores and standard deviations for the six quality dimensions by the type of external assessment. The overall percentage scores for all groups indicate that mean compliance is far from ‘exceptional’ irrespective of external assessment. Nevertheless, a pattern emerges suggesting that accredited hospitals, except for the dimension ‘patients’ rights’, consistently appear to score higher on measures of quality and safety than hospitals with ISO certification or hospitals which have passed no external assessment. Overall and dimension-specific scores by the mode of external assessment are also represented in Fig. 1.

In order to assess whether the dependent variables demonstrated statistically different values for the different groups of external assessment, we carried out a one-way ANOVA. This analysis was repeated for the three different grouping combinations of external assessment described in the methods section (Table 3).

When comparing differences in mean scores across all three modes of external assessment (accreditation, certification and none; column one), four of the dimensions (management, patient safety, clinical organization and clinical practice) and the overall score showed statistically significant differences at a level of  $P < 0.05$ . For the remaining dimensions (patients’ rights and environmental safety) we did not detect statistically significant differences. When comparing either form of external assessment

**Table 1** Distribution of site visits by country

Country	Total	Accreditation only	ISO certification only	Neither	Other <sup>a</sup>
Belgium	1	0	0	1	0
Czech Republic	15	2	4	7	2
France	18	16	0	0	2
Ireland	6	3	0	1	2
Poland	15	0	3	6	6
Spain	29	10	3	11	5
UK	5	3	0	1	1
Total	89	34	10	27	18

<sup>a</sup>In preparation, combination of external assessment or combination of external assessment with other quality management models (excluded from the analysis).

**Table 2** Aggregate scores in six dimensions by the mode of external assessment

Dimension	Content		Accredited	Certified	Neither	Total
Management (28 criteria)	1.1 Governing body	Mean (SD)	80.7 (16.7)	59.8 (15.7)	48.9 (19.8)	65.6 (23.0)
	1.2 Quality management	Max value	112	112	112	112
	1.3 Safety management					
	1.4 Infection control	% Score	72.0	53.4	43.7	58.6
	1.5 Medication management					
Patients rights (53 criteria)	2.1 Publication	Mean (SD)	148.5 (27.8)	153.5 (31.4)	135.0 (28.6)	144.1 (33.1)
	2.2 Patient records	Max value	212	212	212	212
	2.3 information					
	2.4 Consent to treatment	% Score	70.0	72.4	63.7	68.0
	2.5 Privacy					
Patient safety (41 criteria)	2.6 Patient feedback					
	3.1 Adverse events	Mean (SD)	117.9 (26.6)	91.6 (35.4)	81.1 (30.4)	100.2 (33.8)
	3.2 Infection control	Max value	164	164	164	164
	3.3 Medication safety	% Score	71.9	55.9	49.4	61.1
Clinical organization (55 criteria)	3.4 Security					
	4.1 Clinical responsibility	Mean (SD)	139.3 (36.9)	138.1 (39.3)	105.2 (33.2)	126.2 (39.0)
	4.2 Resuscitation	Max value	220	220	220	220
	4.3 External review					
	4.4 Internal review	% Score	63.3	62.8	47.8	57.4
Clinical practice (32 criteria)	4.4 Clinical records					
	4.5 Professional development					
	5.1 Surgery	Mean (SD)	65.7 (23.7)	47.9 (26.3)	44.3 (25.9)	55.0 (26.7)
Environment (20 criteria)	5.2 Obstetrics	Max value	128	128	128	128
	5.3 Medicine	% Score	51.3	37.4	34.6	43.0
	6.1 Fire safety	Mean (SD)	60.9 (12.1)	59.0 (12.6)	54.4 (11.3)	58.2 (12.1)
Overall (229 criteria)	6.2 Waste management	Max value	80	80	80	80
	6.3 Mechanical safety	% Score	76.1	73.8	68.0	72.7
		Mean (SD)	612.9 (117.9)	549.9 (140.4)	468.9 (135.2)	549.3 (142.6)
		Max value	916	916	916	916
		% Score	66.9	60.0	51.2	59.9

(accreditation or certification) with no external assessment at all (column 2), differences were statistically significant for all groups and for the overall score—except for the dimension patients' rights. The lack of statistical significance (close to borderline) in this case may be influenced by the small sample size. Less statistically significant difference was evident when comparing accreditation and certification (in the last column). Nevertheless, significant differences remain for the scores for management, patient safety and clinical practice.

In order to assess the effect of the country grouping variable as a possible confounding factor we performed a two-factorial ANOVA. In Table 4, we report on the amount of variation in the scores attributable to the mode of external

assessment (accreditation, certification, neither) and the variation attributable to the country effect.

For example, for the dimension 'management', external assessment is significantly associated with the variability in the management score (mean square, 1113;  $P = 0.002$ ); however, country accounts for an even higher variability in management scores (mean square, 1580;  $P < 0.001$ ). There appears to be interaction between external assessment and country; the effect is not simply additive but country to some extent overlaps with the mode of external assessment. Similar results for the effect of external assessment and country can be observed in the remaining dimensions and for the total score. From this analysis, it appears that the effect of the country on the mean scores is substantial and

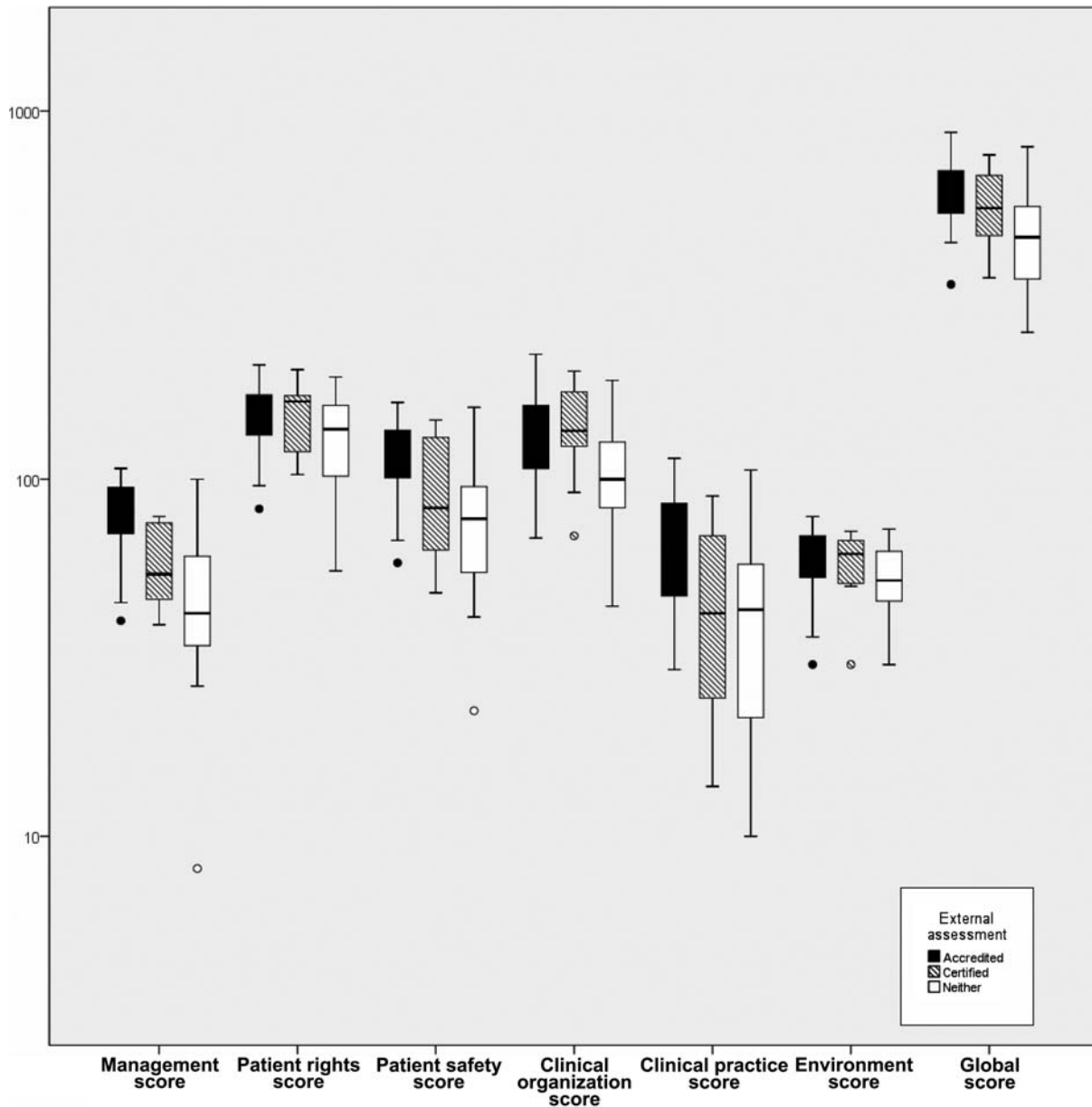


Figure 1 Clustered box-and-whisker diagrams of dimension-specific and overall scores by the mode of external assessment.

higher than the contribution of the mode of external assessment alone.

## Discussion

These findings suggest that in this group of hospitals, those that have either ISO certification or accreditation are safer and better than those which have neither—and that accreditation has more impact than ISO certification on hospital management, patient safety and clinical practice. If this were found to be true of European hospitals in general, this by-product of the MARQuIS project would offer evidence for demanding all EC member states to define, assess and improve compliance with published standards, as originally

drafted into the cross-border directive. No previous studies have compared the relative impact of ISO certification and hospital accreditation; if, again, this difference is found to be consistent with a larger sample of hospitals (such as in the successor project ‘Deepening our understanding of quality improvement (DUQuE) [16]) then organizational development may be more effectively based on the model of health-care accreditation rather than ISO certification.

Given that many of the criteria reflect common elements of standards used by healthcare accreditation programmes, it is perhaps unsurprising that accredited hospitals appear advantaged. Comparable criteria are not explicit in ISO 9001 which is designed for quality management systems in general, rather than being specific to hospitals. This difference may be reduced with the development and application of an



**Table 3** Test for statistical significance for differences in dimension and total scores by the mode of external assessment

Dimension	Comparison		
	1. All groups (accreditation vs. certification vs. neither) ( <i>P</i> -value)	2. Either forms of external assessment vs. neither ( <i>P</i> -value)	3. Accreditation vs. certification ( <i>P</i> -value)
Management	<0.001*	<0.001*	0.001*
Patient's right	0.183	0.072	0.628
Patient safety	<0.001*	<0.001*	0.015*
Clinical organization	0.001*	<0.001*	0.930
Clinical practice	0.004*	0.007*	0.048*
Environmental safety	0.109	0.039*	0.665
Overall	<0.001*	<0.001*	0.162

\**P* < 0.05.**Table 4** Variation in dimension and total scores by external assessment (accredited–certified–neither) and country

Dimension	External assessment, mean square ( <i>P</i> )	Country, mean square ( <i>P</i> )	Interaction, mean square ( <i>P</i> )
Management	1113.5 (0.002)	1580.8 (<0.001)	1275.8 (0.069)
Patient rights	1010.3 (0.367)	1467.0 (0.201)	1054.8 (0.389)
Patient safety	428.2 (0.374)	5046.8 (<0.001)	1070.1 (0.041)
Clinical organization	428.1 (0.001)	6634.2 (<0.001)	1275.8 (0.069)
Clinical practice	127.9 (0.714)	2862.0 (<0.001)	246.0 (0.662)
Environmental safety	73.5 (0.584)	203.4 (0.194)	126.7 (0.465)
Overall score	24 271.9 (0.74)	80 148.4 (<0.001)	13 843.0 (0.188)

interpretation document for ISO 9001 in healthcare such as the CEN/TC 362 project of the Swedish Institute for Standards. This project set out to develop a health services guide for the use of EN ISO 9001:2000 as a European standard applicable to all EC member states [17].

In practice, many countries have no national accreditation programme; many hospitals in search of voluntary external assessment—whether for internal quality improvement or for external marketing and contracting—thus face uncertainty whether to contract accreditation services from another country, or ISO 9001 certification from registered auditors. Where a national accreditation programme is available, hospitals may take a decision based on what they aim to achieve from participation, what it would cost and what external pressures exist as incentives from regulators, contractors and patients. ISO certification is well recognized and accessible in many countries.

Although they share much in methodology, individual accreditation programmes in each country have much diversity in the content of standards, assessment procedures and thresholds for award. Likewise, although conceptually international, ISO certification relies heavily on consistency between individual registered auditors—especially in the interpretation of ISO 9001 in the healthcare setting [18].

This analysis of data from the MARQuIS study suggests that in the sample of hospitals the impact of ISO certification on quality and safety may be less than with hospital accreditation, but it appears that either system is better than no system. While this is in line with previous reports of the data [19], caution in the interpretation of the findings is required since statistical significance is limited by the small sample size and the selection of hospitals for external audit (from the upper and lower quartiles of respondents to the initial MARQuIS questionnaire survey). The effect of the country variable is clearly pronounced in this international study and needs to be considered in the interpretation of the results. Nevertheless, despite the many cautions, the results of this study clearly indicate potentially fruitful lines of further enquiry.

Given the need to advance the evidence base for external assessment in healthcare, the International Society for Quality in Healthcare has established a research website, hosted by Accreditation Canada, to gather published and unpublished evidence of the impact of various forms of external assessment [20]. In Europe, these will be further explored in the successor project to MARQuIS, DUQuE which will examine among other issues the effect of external pressure on the uptake of quality improvement by hospitals

and their impact on patient-level outcomes in a larger sample of hospitals [21].

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