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Validation of a proposal for evaluating hospital infection control programs

ABSTRACT

OBJECTIVE: To validate the construct and discriminant properties of a hospital infection prevention and control program.

METHODS: The program consists of four indicators: technical-operational structure; operational prevention and control guidelines; epidemiological surveillance system; and prevention and control activities. These indicators, with previously validated content, were applied to 50 healthcare institutions in the city of São Paulo, Southeastern Brazil, in 2009. Descriptive statistics were used to characterize the hospitals and indicator scores, and Cronbach's α coefficient was used to evaluate the internal consistency. The discriminant validity was analyzed by comparing indicator scores between groups of hospitals: with versus without quality certification. The construct validity analysis was based on exploratory factor analysis with a tetrachoric correlation matrix.

RESULTS: The indicators for the technical-operational structure and epidemiological surveillance presented almost 100% conformity in the whole sample. The indicators for the operational prevention and control guidelines and the prevention and control activities presented internal consistency ranging from 0.67 to 0.80. The discriminant validity of these indicators indicated higher and statistically significant mean conformity scores among the group of institutions with healthcare certification or accreditation processes. In the construct validation, two dimensions were identified for the operational prevention and control guidelines: recommendations for preventing hospital infection and recommendations for standardizing prophylaxis procedures, with good correlation between the analysis units that formed the guidelines. The same was found for the prevention and control activities: interfaces with treatment units and support units were identified.

CONCLUSIONS: Validation of the measurement properties of the hospital infection prevention and control program indicators made it possible to develop a tool for evaluating these programs in an ethical and scientific manner in order to obtain a quality diagnosis in this field.

DESCRIPTORS: Cross Infection, prevention & control. Infection Control. Indicators of Health Services. Program Evaluation. Validation Studies as Topic.

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INTRODUCTION

There is a growing demand for systems to assess the quality of care practices and services relating to hospital infection control.^{7,8} Such assessments can be made by means of indicators that are defined as quantitative measurements of variables, characteristics or attributes relating to a given process or system that make it possible to recognize its results, whether desirable or undesirable.^{2,3,9,10,12,14}

These indicators are ratios or quotients in which the numerator corresponds to the event that has been measured or recognized, which needs to have a clear and objective definition and be readily applicable and rapidly identifiable. The denominator is the population at risk of the event defined in the numerator.

These indicators take into consideration assessments of structures, results and processes. Structural assessments reflect the capacity of the service to provide quality care, through the existence of human resources, care systems, financial support, physical area and equipment, accessibility, protocols, physical plans and equipment, among others. The second assessment measures how frequently an event occurs, and thus makes it possible to estimate risk factors by identifying effects from the treatment, symptom relevance and other effects, along with establishing maximum and minimum acceptable limits for such events. The third assessment measures how the activities of a service or a given type of care are performed, this making it possible to analyze their quality in accordance with previously defined standards.³ Hence, assessments on specific practices require a set of indicators.

The validity of an assessment starts from prior recognition of the best practice available, based on: studies on the scientific evidence; guidelines or protocols available; controlled and preferably randomized clinical trials; case studies; consensus among specialists; and the relationship with results from assessments made using scientific methodological resources.^{2-4,9,10,12,14}

Hospital infection control programs (HICP) make assessments on results in order to identify the prevalence and incidence of cases of hospital infection. They classify cases according to topography, specialty, location and other characteristics, so that risk factors can be established. However, such assessments are not enough to recognize or determine the quality of the care practices effected, or to act preventively. The particular quality of the HICP also needs to be recognized, so that the quality of the care practices can be assessed and interventions can be made.

The present study aimed to validate the construct and discriminant properties of measurements on HICP.

METHODS

This study developed methodology for devising and validating health assessment measurements at 50 healthcare services in the municipality of São Paulo, Southeastern Brazil, in 2009. One hundred and sixty-two healthcare services were contacted by letter and in person. These were selected from the Datasus database in accordance with the following inclusion

criteria: attendance structures of greater complexity and hospital beds, respecting the hospital size classification. i.e. general or specialized and public or private in nature; and the following exclusion criteria: treatment of mental diseases, healthcare centers, care provided in patients' homes, solely outpatient services and non-surgical delivery.

Trained professionals gathered data to characterize the health service and the hospital infection control service (HICS) and hospital infection control commission (HICC): the location, type of care, health certification or accreditation, size, maintaining entity, specialized services, length of time for which the HICS/HICC had existed, nature of the HICS/HICC and linkage of the professionals at the HICS/HICC. An instrument for assessing HICP was applied, consisting of four indicators: technical-operational structure of the HICP ("structure"); operational prevention and control guidelines for hospital infection ("guidelines"); epidemiological surveillance system for hospital infection ("epidemiology"); and prevention and control activities against hospital infection ("activities").³

Characteristics relating to the hospital's profile and indicator scores were described by means of descriptive statistics, means (with standard deviations), medians, minimum and maximum values, and percentages. The internal consistency was assessed by means of Cronbach's α . This could range from 0.00 to 1.00 and the higher the coefficient was, the more exact (internally consistent) the measurement would be.¹³ This coefficient estimated the mean correlation of each item with the total score. When the values of Cronbach's α were greater than 0.70, it was considered that the instrument had good internal consistency. To analyze the discriminant validity, the indicator scores were compared between hospitals with some type of quality certification and those without certification. In this, higher scores were expected for the hospitals with certification. The nonparametric Mann-Whitney statistical test was used.

To analyze the construct validity, exploratory factor analysis with a tetrachoric correlation matrix was used, which is indicated for variables with dichotomous responses.⁵ The method used for factor extraction was the iterative principal factor method, and the orthogonal rotation used was *Varimax*. The items that present loading greater than 0.30 were considered to be important in the factor composition. This technique made it possible to identify the least possible number of factors (or dimensions/constructs) that would best explain the correlations between the indicator items. The statistical packages used were SPSS version 14.0 (calculation of descriptive statistics, internal consistency and

³ Silva CPR. Indicadores para Avaliação de Programas de Controle de Infecção Hospitalar: construção e validação [master's dissertation]. São Paulo: Escola de Enfermagem da USP; 2005.

comparisons between groups) and SAS version 10.0 for the factor analysis. The significance level was taken to be 0.05 for all the statistical tests.

The study was approved by the Research Ethics Committee of the Escola de Enfermagem da Universidade de São Paulo, (Process 800/2009) on April 8, 2009. The participants signed commitment and informed consent statements.

RESULTS

Fifty hospitals participated in applying the HICP indicators (31%), while 16 (10%) formally refused to

participate (non-approval by the management or no return from the local Research Ethics Committee) and 96 did not give any response (59%). The envelopes sent through the post were not returned.

The care provision consisted predominantly of general hospitals (80%); 50% did not have quality certification or accreditation. The majority with certification (68%) had obtained it from the National Accreditation Organization, while 20% had certification of Commitment to Hospital Quality, 8% from the Joint Commission International and 4% from the International Organization for Standardization.

Table 1. Internal consistency of the indicators for assessing hospital infection control programs. São Paulo, Southeastern Brazil, 2009.

Indicator/item	n	α	α^{k-1}	% ^a
Technical-operational structure	50			
Professionals with university-level education/ nurses		0.58	0.57	-1.00
Nurses with exclusive dedication			-0.04	-93.00
Physicians with exclusive dedication			0.57	-1.00
Operational prevention and control guidelines	50			
Sharps and biological risk		0.80	0.75	-6.00
Health service waste			0.75	-6.00
Respiratory infections			0.74	-7.00
Urinary infections			0.76	-5.00
Bloodstream infections			0.75	-6.00
Surgical site infections			0.75	-6.00
Surgical antibiotic prophylaxis			0.75	-6.00
Standardization of germicides and antiseptics			0.74	-7.00
Cleaning, disinfection and sterilization of materials			0.72	-10.00
Cleaning and disinfection of surfaces			0.74	-7.00
Washing of clothes			0.79	-1.00
Collection of material for culturing			0.72	-10.00
Dressings			0.75	-6.00
Epidemiological surveillance system	50			
Monitoring of microbiological results		0.58	-	-
Analysis of epidemiological reports			-0.04	-92.70
Correlation with prevention and control strategies			-0.04	-92.70
Prevention and control activities	6			
Blood bank		0.67	0.50	-25.00
Clinical analysis laboratory			0.52	-22.40
Pathological anatomy laboratory			0.53	-21.00
Nursery			0.58	-13.43
Emergency department			0.66	-1.49
Pharmacy service			0.68	1.49
Nutrition and diet service			0.69	3.00
Technical decisions for standardization of materials			0.76	13.43

α : Cronbach's α coefficient for the indicators.

α^{k-1} : Cronbach's α coefficient, excluding the item.

^a Percentage change when the item $[-(\alpha - \alpha_{(k-1)})/\alpha]$ is excluded. The sign indicated the direction of the change (positive = increase; negative = decrease).

Table 2. Comparison of the means for the assessment indicators for hospital infection control programs, between hospital groups. São Paulo, Southeastern Brazil, 2009.

Indicators	Groups	n	Mean (SD) ^a	Median	Minimum - maximum	p ^b
Technical-operational structure	With certification ^c	25				
	Without certification	25	97.6 (5.9)	100.0	80.0;100.0	
Operational prevention and control guidelines	With certification	25	96.8 (4.8)	100.0	86.7;100.0	0.001
	Without certification	25	85.9 (15.9)	93.3	46.7;100.0	
Epidemiological surveillance system	With certification ^c	25				
	Without certification	25	98.8 (4.4)	100.0	80.0;100.0	
Prevention and control activities	With certification	25	94.5 (10.6)	100.0	61.8;100.0	
	Without certification	25	72.4 (28.8)	84.6	9.5;100.0	0.001

^a Standard deviation.

^b Mann-Whitney test for comparison between means.

^c The values for this group were constant and equal to 100.0.

With regard to hospital size, 80% were of medium or large size (38% and 42%, respectively). The complexity was classified according to the structure: 100% had intensive care beds, an emergency department and a surgical center, and 98% had a sterilized material center. All the hospitals had their own HICS and HICC, which were not part of consortiums, and these had been in operation for six to 20 years (median = 14 years).

The analysis on the internal consistency (Table 1) showed that the α coefficients ranged from 0.58 to 0.80. However, for the “structure” and 3 “epidemiology” indicators, the coefficients could only be calculated using three items, since the others did not present any variability, i.e., they were constant and invariable.

The “guidelines” and “activities” indicators were the ones that presented the best internal consistency results: 0.80 and 0.67 respectively (0.76 without the participation and technical decisions).

Discriminant validity analysis was possible for the “guidelines” and “activities” indicators, because the other two indicators were constant and equal to 100.0% in the group with certification. This in itself shows that the “structure” and “epidemiology” indicators in the group of qualified hospitals presented better total conformity (Table 2).

The “guidelines” and “activities” indicators presented better mean values in the group with certification and with statistically significant difference (Table 2).

Table 3. Factor analysis for the indicator of operational prevention and control guidelines for hospital infection. São Paulo, Southeastern Brazil, 2009.

Operational prevention and control guidelines	Factor 1	Factor 2
Are there any recommendations for health service waste disposal?	0.31	0.22
Are there any recommendations for prevention and control of respiratory infections?	0.75	0.18
Are there any recommendations for prevention and control of urinary infections?	0.86	-0.12
Are there any recommendations for prevention and control of bloodstream infections?	0.88	-0.04
Are there any recommendations for prevention and control of surgical site infections?	0.52	-0.04
Are there any recommendations for assessment and referral of accidents with sharps and other exposures to biological material?	-0.01	0.68
Are there any recommendations for the use of prophylactic antibiotics for preventing surgical site infections?	0.03	0.47
Is there any standardization of germicide and antiseptic solutions?	0.04	0.72
Are there any recommendations for techniques for cleaning, disinfection and sterilization of materials and equipment?	0.47	0.65
Are there any recommendations for routines for cleaning and disinfection of surfaces	0.01	0.70
Are there any recommendations for washing and cleaning of clothes used at the institution?	-0.09	0.33
Are there any recommendations for techniques for collecting material for performing cultures?	0.36	0.61
Variance explained by the factor	2.82	2.70
Percentage of the total variance explained by the factor	23.52	22.52

Table 4. Factor analysis for the indicator of prevention and control activities against hospital infection. São Paulo, Southeastern Brazil, 2009.

Prevention and control activities	Factor 1	Factor 2
Dialysis unit	0.63	0.15
Blood bank	0.70	0.04
Hospitalization unit	0.35	-0.11
Intensive care unit	0.55	0.43
Material sterilization center	0.66	0.48
Surgical center	0.94	0.32
Emergency department	0.43	0.17
Clinical analysis laboratory	-0.29	0.86
Pathological anatomy laboratory	0.31	0.52
Nursery	-0.17	0.93
Outpatient service	0.01	0.04
Variance explained by the factor	3.06	2.46
Percentage of the total variance of the data explained by the factor	27.8	22.42

It was not possible to perform a construct validity analysis for the “structure” and “epidemiology” indicators because these indicators varied very little, with 100% conformity in almost all the assessments.

Table 3 presents the factor analysis for the “guidelines” indicator, in terms of two factors: factor 1, recommendations for preventing infections; and factor 2, recommendations for standardizing the prophylaxis procedures.

Factor 1 had Cronbach’s α of 0.73 (five items), but if the item “Are there any recommendations for health service waste disposal?” were to be removed, Cronbach’s α would increase to 0.80. For factor 2, if this same question were to be included, Cronbach’s α would remain 0.79 (seven items).

Table 4 presents the results from the factor analysis on the “activities” indicator, in terms of two factors. In the first factor, Cronbach’s α was 0.88 (seven items), and this factor included items relating to the treatment units (dialysis, blood bank, hospital admission, intensive care, surgical center and emergency department). The second factor ($\alpha = 0.72$, three items) assessed support units (laboratories). The item “outpatient service” did not present any important loadings in either of the two factors extracted.

DISCUSSION

The system for HICP assessment was validated in the present study and applied to a sample that was epidemiologically similar to two previous investigations aimed at more specific assessment of HICPs. In one of these studies, conducted by the Brazilian National Health Surveillance Agency in 2004, 6,714 questionnaires were sent out, with a general return rate of 61.8%, of which 35.1% was from the southeastern region.^b In this first case, it was not stated whether the instrument used had previously been validated. In 2009, the Regional Medical Council of the State of São Paulo carried out and published a HICP diagnosis based on 158 visits to hospitals in the State of São Paulo, of which 56 were in the state capital and its metropolitan region (35%). However, the investigative method was not disclosed.^c

In the institutions evaluated here, the wide variation in the length of time for which the HICS/HICC had existed (six to 20 years) can be explained by the length of time for which the national legislation in this field has been in force. Brazil’s first regulations on hospital infection control were published in 1983, and these determined that HICCs were mandatory throughout the national territory. This was followed by Ordinance 930, in 1993.^d This platform defined models for HICCs based on formation of state and municipal commissions. This was followed by Law 9341 of 1997^e and RDC Resolution 2616 of 1998,^f which dealt with HICP.

Analysis on the internal consistency showed that the HICP indicators ranged from 0.58 to 0.80. The “guidelines” and “activities” indicators were the ones that presented the best results, even though the “activities” indicator had been applied in six hospitals. This was because some items presented unknown responses, since they were not applicable in the other hospitals. Although the item “participation in technical decisions” interfered with the final result, it was kept because of the importance of this activity developed by HICS, as support for healthcare managers.

There was variation in three items of the “structure” and “epidemiology” indicators. The other items had constant values of 100.0% for the conformity scores, which reflected the homogeneity of the sample, but interfered with the internal reliability. These indicators probably do not need to go through validation scrutiny, given

^b Santos AM. O modelo brasileiro para o controle das infecções hospitalares: após vinte anos de legislação, onde estamos e para onde vamos? [master’s dissertation]. Belo Horizonte: Faculdade de Medicina da UFMG; 2006.

^c Ministério Público do Estado de São Paulo. Conselho Regional de Medicina do Estado de São Paulo. Controle da Infecção Hospitalar é deficiente em mais de 90% dos hospitais de São Paulo. São Paulo; 2009[cited 2009 Aug 21]. Available from: http://www.cremesp.org.br/library/modulos/centro_de_dados/arquivos/infeccao_hospitalar_abril09.pdf

^d Ministério da Saúde. Portaria Nº 930, de 27 de agosto de 1992. Expede na forma de anexos, normas para o controle das infecções hospitalares. *Diário Oficial Uniao*. 25 set. 1992;Seção1:1000-2.

^e Brasil. Lei nº 9.431, de 6 de janeiro de 1997. Dispõe sobre a obrigatoriedade de manutenção de Programas de Controle de Infecção Hospitalar pelos hospitais do País. *Diário Oficial Uniao*. 7 jan 1997;Seção1:265.

^f Ministério da Saúde. Portaria 2616, de 12 de maio de 1998. Dispõe sobre a obrigatoriedade de Programas de Controle de Infecção Hospitalar e sua Estrutura e Atividades. *Diário Oficial Uniao*. 13 maio 1998;Seção1:133-5.

that hospitals have already incorporated them into their routine, in compliance with the legislation in force.

The reliability of an instrument is related to the heterogeneity of the sample, i.e. the more homogeneous the sample is, the more similar the scores will be and the lower the reliability coefficient will be. This does not necessarily mean that the instrument is unreliable, given that if an instrument is designed to measure differences and the members of the sample are similar to each other, it is more difficult to discriminate the reliability.¹¹

A measurement instrument should not be correlated with variables that have nothing to do with it (false attributes). This characteristic is known as discriminant validity and was used in the present study to test the hypothesis that the indicators selected would be sufficient to “measure” the quality of a HICP distinctly in institutions with and without qualification processes.⁶

In the analysis on the discriminant validity, there was a statistical difference in the group of institutions with quality accreditation/certification processes, for the “guidelines” and “activities” indicators. These indicators reflected actions of documentation, guidance, recommendation and interface with other services within the healthcare institution.

The results found showed that these indicators were sufficiently sensitive to detect the hospitals that had gone through healthcare quality processes and consequently had better HICPs.

The Joint Commission International recommends that effective programs should be wide-ranging, provide attendance beyond the minimum required by legislation and contain within their scope actions such as systems for data gathering, administration, analysis and communication, with a plan for continuous improvement; formal policies and procedures; study, education and training programs; and collaboration and interfaces with all departments in the institution.¹ Such actions are included in the set of HICP indicators, especially in the “guidelines” and “activities” indicators.

For the dimensions of a measurement instrument to be consistently determined, along with its correlations with other similar measurements within the same theory or concept, the construct validity is used. This is known to be difficult and challenging.^{6,11}

Five items correlated best with the factor “recommendations for prevention of infections” (respiratory, urinary, bloodstream and surgical site) in the “guidelines” indicator, with variance of 23.5%. The item “Are there any recommendations for health service waste disposal?” had the lowest correlation with factor 1 (0.30) and

mainly encompassed aspects of recommendations or standardization of procedures. It was observed that this was one of the items in which the HICS had least direct or separate influence. The recommendations and decisions are made jointly with other professionals, thereby contributing towards devising and implementing health service waste management programs.⁸

In the other factor of the “guidelines” indicator, seven items were correlated with the recommendations for prophylaxis procedures. The item “Is there any standardization of germicide and antiseptic solutions?” was the one with the highest loading in factor 2 (0.72). On the other hand, the item “Are there any recommendations for washing and cleaning of clothes used at the institution?” was the one with the lowest correlation with this factor (0.33), responsible for 22.5% of the total variance of the data. This item was also little influenced by the HICS. This may have resulted from the fact that laundry services were outsourced in most of the institutions visited, even though there was joint responsibility for the processes.

It was concluded that the structure of the “guidelines” indicator could be maintained as it was (i.e. only one dimension), on the basis of the results relating to internal consistency, factor analysis and internal consistency of the factors. This structure could also be stratified into two dimensions: recommendations for preventing infections and recommendations for standardizing prophylaxis procedures.

For the “activities” indicator, the results from the factor analysis showed two factors or dimensions: factor 1, treatment units; and factor 2, support units.

Factor 1 consisted of seven items: the best correlated item (0.94) was “surgical center”, while the least correlated item (0.35) was “hospitalization units”. The items “material sterilization center”, “intensive care unit” and “surgical center” were the most important items in factor 2 and, among these three, only the last of them seems to be more appropriate to this factor, which reflects support units. Factor 1 was responsible for 27.8% of the total variance of the data.

The items best correlated with factor 2 were the ones that reflected the support units, such as clinical analysis laboratories and pathological anatomy laboratories, and the nursery, which was the item with the highest correlation (0.93). This factor explained 22.4% of the total variance of the data.

The structure of the “activities” indicator was best represented in two dimensions, according to the results obtained. The results relating to Cronbach’s

⁸ Ministério de Saúde. RDC nº 306, de 07 de setembro de 2004. Dispõe sobre o regulamento técnico para o gerenciamento dos resíduos de serviços de saúde. *Diário Oficial Uniao*. 10 set. 2004;Seção1:40.

α were better with the stratification than without it ($\alpha = 0.67$). Application of the indicator was focused on specific actions for improving the treatment and support sectors.

We did not find any similar studies for validating HICP assessment instruments in either the Brazilian or worldwide literature. The closest was the study by Prade,^h carried out in 2002, in which a process for validating an information instrument for aiding in HICPs was developed. The instrument was capable of evaluating different dimensions of the systemic scope of hospital care, for its management, with a view to making managerial decisions.^h However, several indicators did not achieve validation, and the validity of the criteria and reliability of form B (the dimension of the hospital's care provision and its structure) was low. It was concluded that the group of examiners was unable to apply this type of assessment, or had had little practice in doing this. Prade considered that the internal validity was compromised by the unsatisfactory result from one of the studies, which would be redone after changes to examiner preparation had been made. It was concluded that the concordance between the examiners was not good and that the study would have to undergo the modifications suggested, and would have to be expanded in order to ensure external validity for the system.²

The individuals who applied the instrument in the present study had undergone prior training. Specific manuals were drawn up to guide the data gathering and systematize the data obtained.

The assessment proposal, with a small number of indicators and seeking only to evaluate the HICP, did not intend to correlate it directly with the hospitals' overall care provision and structures, or with the professionals' technical capacity. Although the conformity obtained may make it possible to make suggestions or reach conclusions in this regard, other assessment systems that are more specific can and should be added, given that a HICP in itself does not allow inferences to be made regarding the quality of the care provided.

Application of this proposal for assessment of HICPs to health services in the municipality of São Paulo enabled full validation of its measurement properties. The indicators that assess operational guidelines and prevention and control activities against hospital infection were the ones that presented the best internal consistency, discriminant validity and construct validity results.

In conclusion, the validity of the instrument for assessing HICPs, with the possibility of application with a scientific basis, will allow a diagnosis of the real situation of these programs throughout the national territory.

^h Prade SS. Desenvolvimento e validação de um instrumento de informação para a assessoria do programa de controle de infecção às decisões do dirigente hospitalar [Doctoral thesis]. Rio de Janeiro: Escola Nacional de Saúde Pública da Fiocruz; 2002.

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