

Indicators for evaluation of processing dental-medical-hospital supplies: elaboration and validation

INDICADORES DE AVALIAÇÃO DO PROCESSAMENTO DE ARTIGOS ODONTO-MÉDICO-HOSPITALARES: ELABORAÇÃO E VALIDAÇÃO

INDICADORES PARA LA EVALUACIÓN DEL REPROCESAMIENTO DEL PRODUCTOS MEDICOS DEL HOSPITAL: CONSTRUCCIÓN Y VALIDACIÓN

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ABSTRACT

Methodological study to elaborate and validate measures of evaluation in health contributing to an evaluation system of practices related to the control and prevention of hospital infection. It was elaborated eight dental-medical-hospital supply reprocessing conformity indicators. Indicators are described using items of the structure, process and outcomes that permitted the elaboration of conformity indicators related to the best practices (gold pattern). It was performed the content validity of the attributes of applicability and representativeness by a consensus expert judgment process using a psychometric scale. All the indicators showed to have content validity. Expert judgments, including comments and suggestions, evidenced the importance of perform validity of the evaluation processes, independently of the existence of golden pattern criteria and/or relevancies to the nursing practice.

KEY WORDS

Health evaluation.
Central Supply, Hospital.
Infection control.

RESUMO

Estudo de desenvolvimento metodológico de elaboração e validação de medidas de avaliação em saúde, com a finalidade de contribuir com sistemas de avaliação de práticas de controle e prevenção de infecção hospitalar, pela elaboração e validação de oito indicadores para avaliação do processamento de artigos odonto-médico-hospitalares. A partir de fundamentação teórico-científica e contemplando avaliações de estrutura, processo e resultado, tais indicadores permitem elaboração de índices de conformidade com relação às melhores práticas esperadas (padrão-ouro). A validação referiu-se à validade de conteúdo, pela técnica de consenso de especialistas para julgamento de representatividade e aplicabilidade. Todos os indicadores foram aprovados. Os julgamentos efetuados, incluindo comentários e sugestões, demonstraram a importância de se realizar validação de processos de avaliação, independentemente da existência de critérios padrão-ouro e/ou relevância na prática assistencial.

DESCRITORES

Avaliação em saúde.
Almoxarifado Central Hospitalar.
Controle de infecção.

RESUMEN

Estudio de desenvolvimiento metodológico para la elaboración y validación de medidas de evaluación en salud, con la finalidad de contribuir con los sistemas de evaluación de prácticas para el control y prevención de las infecciones hospitalarias, por la elaboración y validación de ocho indicadores de evaluación del procesamiento de instrumentos odonto-médico-hospitalarios. A partir de la fundamentación teórico científico, tales indicadores contemplan evaluaciones de estructura, proceso y resultado así como permiten la elaboración de índices de conformidad con relación a las mejores prácticas esperadas (padrón-oro). La evaluación se refirió a la validez del contenido, por la técnica de consenso de especialistas para el juzgamiento de representatividad y aplicabilidad. Todos los indicadores fueron aprobados. Los juzgamientos efectuados, incluyendo comentarios y sugerencias, demostraron la importancia de realizar la validación de procesos de evaluación, independiente da existencia de criterios padrón-oro y/o a la relevancia de su repercusión en la práctica asistencial.

DESCRIPTORES

Evaluación en salud.
Central de Suministros en Hospital.
Control de infecciones.

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INTRODUCTION

State health agencies have recognized the problem of infections acquired in health services (IASS) and have been developing policies either to orientate or to supervise its control and prevention⁽¹⁾. The increasing demand for evaluation systems of control and prevention practices of IASS requires the use of indicators, defined as measures of variables or attributes, which identify desirable or non-desirable results of a certain practice and establish conformity indexes⁽²⁻⁶⁾. They can incorporate three dimensions of quality evaluation⁽⁷⁾: structure, process and results, and the advantage of one evaluation over the other is in the appropriation of use.

Structure refers to the capacity of human and material resources to render assistance to health care quality. The processes refer to the way the practice is performed, and how it objectifies its dynamics. Results show how frequently an event happens, identifying desirable or non-desirable effects resultant from actions, efficiency and efficacy within acceptable limits, risk factors that determine good or bad quality, among others⁽⁷⁾.

The reprocessing quality of dental-medical-hospital (DMH) supplies represents one of the pillars of the control and prevention of IASS and is related either to guarantee its submission to processes of microbial reduction or destruction, or to its functionality and integrity, in order to prevent damages to the organism while using it. The concern with appropriate practices is the research theme, scientific events, as well as public consultations and legislation by the Brazilian National Agency for Sanitary Surveillance⁽⁸⁾.

Since the end of the 20th century, evaluations of structure, process and results have been developed in the health care area, however incipient regarding both in controlling and preventing IASS and in methods for its validation. The system developed and validated in this study is unprecedented, not being found, even in the scientific literature, national and international production that favors similar comparison of results, as well as its discussion.

OBJECTIVE

Elaboration and validation of indicators for assessing the processing of articles DMH.

METHOD

It is a methodological study of construction and validation of measures for health evaluation⁽⁹⁾ by indicators. Considering the theoretical-scientific fundaments, eight indicators were constructed which consider the DMH supply processing stages (cleaning, preparation/packing, sterilization/storage/distribution) and encom-

pass evaluations of structure, processing and results. Each indicator presents compounds to be evaluated, a way of obtaining information and a calculation formula for conformity measures. Validation refers to content validity⁽¹⁰⁾, by judging attributes of representativeness (capacity to access the phenomenon) and applicability (if it is applicable and measurable). The consensual technique⁽¹⁰⁻¹¹⁾ used the psychometric scale: (1) attribute not considered; (2) incapable of considering attribute without review; (3) attribute considered, but with minimal alteration; (4) attribute considered. The instrument also took into account comments and suggestions. To reach a consensus, it was taken into consideration minimal average for Content Validity Index (CVI) of 0.75 of scale-values 3 and or 4, similar to the Index verified in literature which ranges from 0.5 to 0.8 0^(10,11,12). In accordance with literature for specialist composition⁽¹⁰⁻¹²⁾, six nurses with experience in the Material and Sterilization Center (MSC) area judged the instrument.

The formula to indicate the conformity of each processing stage is:

$$\frac{\text{Number compounds of conformity and applicable indicators}}{\text{Total compounds of applicable indicators at MSC under evaluation}} \times 100$$

RESULTS

The following bibliography was used for a theoretical-scientific fundament of compounds: (1) Brazilian National Agency for Sanitary Surveillance. Public Consultation number 34, June 3rd 2009. Technical regulation establishing requirements for processing health products, including surgery instruments. D.O.U. – Official Daily Government Newspaper; 2009. Available at: <http://www4.anvisa.gov.br/base/visadoc/CP/CP%5B26720-1-0%5D.PDF>; (2) Brazilian National Agency for Sanitary Surveillance. Resolution RDC 50 online. Available at Internet site : <http://www.anvisa.gov.br/legis/resol200250-02rdc.pdf>; (3) *American National Standard. Sterilization of health care products – chemical indicators. Part 1: general requirements. Arlington(US): Association for the Advancement of Medical Instrumentation (AAMI); 2005*; (4) *Association of Operating Room Nurses. Standards, Recommended Practices, and Guidelines. AORN Inc, Denver, 2004*; (5) Graziano KU et al. Cleaning, disinfection, sterilization of supplies and antisepsis. In: Fernandes AT. Hospital Infection and interfaces in the health area. São Paulo: Atheneu, 2000; (6) Rutala WA et al. *Guideline for Disinfection and Sterilization in Healthcare Facilities. CDC/HICPAC. 2008*. Available: www.cdc.gov/ncidod/hip/dsguide.htm; (7) Guide elaborated by Brazilian nurses. Practical advice for sterilization process in Health Establishments – part 1: Health Sterilization. Campinas: Komedi, 2000; (8) Rodrigues E. Reutilization of cotton double-woven surgical drapes standardized by ABNT (Brazilian Association

of Technical Standards) used to pack medical-hospital supplies at humid heat sterilization. [Essay] São Paulo: Nursing School/USP; 2000; (9) Brazilian Association of Technical Standards. NBR 14028: Hospital apparel – double drape confection. Rio de Janeiro; 1997; (10) Brazilian Association for Technical Standards. NBR ISO 11134: Sterilization of hospital supplies for validity and control of humid heat sterilization routine. Rio de Janeiro;2001.

During the judgment process, all indicators had favorable consensus (IVC minimal \geq a 0,75) for representativeness and applicability (Table 1). The most problematic indicator was the Result for Cleaning Dental-Medical-Hospital Supplies (7L); the judges only disagreed with instrumental evaluation, considering that other supplies are equally important or even more important. The average of IVC values obtained at judgment is present on Table 1.

Table 1 - Average of IVC values at representativeness and applicability judgments of Processing Indicators of DMH supplies - São Paulo - 2006

Indicator/IVC	1L	2L	7L	3P	4P	5E	6E	8P
IVC Average	IVC	IVC	IVC	IVC	IVC	IVC	IVC	IVC
Attribute								
Representativeness								
(1)	-	-	0.04	-	-	-	-	-
(2)	0.04	0.04	0.17	0.08	0.04	-	-	-
(3)	0.22	0.12	0.12	0.21	0.04	0.29	0.33	0.21
(4)	0.73	0.83	0.66	0.70	0.91	0.70	0.66	0.78
Total IVC (3) + (4)	0.95	0.95	0.78	0.91	0.95	0.99	0.99	0.99
Applicability								
(1)	-	-	-	-	-	-	-	-
(2)	0.08	0.04	0.12	-	-	0.08	-	-
(3)	0.17	0.12	0.16	0.04	0.08	0.04	0.37	0.25
(4)	0.74	0.83	0.70	0.95	0.91	0.87	0.62	0.74
Total IVC (3) + (4)	0.91	0.95	0.86	0.99	0.99	0.91	0.99	0.99

Indicators approved and revised according to the judges' suggestion are presented herein. The information obtained for each compound was described as (E) interview, (I) inspection e (R) register. They were also

numbered as follows: 1L, 2L and 7L for supply cleaning indicators; 3P, 4P and 8P for supply preparation and packing indicators; 5E and 6E for sterilization process indicators.

Chart 1 - Compounds of Indicators for evaluation of processing dental-medical-hospital supplies: elaboration and validation

1L: Indicator for evaluation of technical-operational resources for cleaning DHM supplies
Compounds
(I) Liquid toilet soap dispenser and paper towel and 70% alcohol gel dispenser for hand sanitation. Reason: hand sanitation due to frequent manipulation of contaminated material.
(I) Racks or tables with wheels, recipients for perforating-cutting instruments and for residues of biological materials. Reason: worker safety and comfort.
(I) Area large enough to locate washbasin(s) with cabinet, equipment thermo-disinfecting/ultra-sonic washer(s), area to circulate materials and specific places for keeping PPE and cleaning inputs. Reason: cleaning requires proper area and equipment infrastructure.
(I) Area physically isolated from other areas. Reason: prevents cross-contamination and free-transit of people providing one-direction flow from contaminated area to cleaning area.
(I) Good lighting, resistant and washable construction finishing material. Reason: provide inspection of material cleaning. Area requires frequent competitive and terminal cleaning.
(I) Deep washbasin(s) with cabinets and hot and cold taps. Reason: deep washbasin decreases sparkling water to environment. Warm water help removing greasy residue from materials.
(I) Taps with special spout for cannulated articles. Reason: help to remove dirt and rinsing.
(I) Water/air guns for cleaning and drying cannulated and complex configuration articles. Reason: help removing dirty and effective drying.
(I) Soft bristle brush for manual cleaning. Reason: indispensable for effective cleaning and better than using sponges.
(I) Brushes with proper diameter for cannulated materials. Reason: indispensable for effective cleaning of material to remove dirt and biofilm.

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(I) a) Natural ventilation: window screens. Reason: avoid insects from entering.
(I) b) Artificial ventilation: air conditioned environment. Reason: comfort for workers who use PPE. There are no scientific evidences of the negative pressure impact in this environment once cross-contamination occurs primarily by contact and not by air.
(I) Water treatment for removal of microorganisms, heavy metals and chlorine. Reason: microorganisms Gram (-) at material can be a source of endotoxins. Surgical instruments are affected for deposition and reaction with chemical pollutants, which cause stains, oxidation and make the material more friable.
(I) Obligatory PPE: coverall, impermeable long gloves or forearm protectors, safety glasses, mask, long impermeable surgical gown, cap, impermeable shoe cover. Reason: control/prevention of occupational accidents through contact with organic contaminated or toxic substances.
(R) Follow-up polices for perforating-cutting accidents. Reason: legal requirements.
(R) Easy-accessible and annually revised norms and routines. Reason: revised document-material is source of consulting and guarantees qualified standardization of procedures.
(R) Description of nursing professionals' qualification. Reason: MSC must count on qualified professionals to guarantee service excellence
2L: Indicator for evaluation of DHM supply cleaning process
Compounds
(I, E) Use of neutral/enzymatic/alkaline detergents or incrustation removal solutions with defined criteria, according to manufacturer instructions, for hospital and officially authorized use. Reason: cleaning input must be adequate to dirty levels in order to optimize removal.
(I, E) Replacements of enzymatic detergent solution meet defined criteria for solution saturation. Reason: efficiency of enzymatic detergent depends on quantity of organic material submerge in solution.
(I, E) There is no previous submersion of dirty materials in disinfecting chemical solution. Reason: disinfecting chemical solutions do not guarantee decontamination and eventually the result can be organic material fixation on article.
(I) Dry the articles manually processed piece by piece Reason: complete removal of all dirt.
(I) Use of complete PPE. Reason: evidence of highly transmissible occupational diseases (HIV, HBV e HCV) through contact with biological material.
(I) Do not use abrasive materials such as steel-sponges for manual cleaning of supplies. Reason: medium and long-term damage to instrument surface.
(I,E) Supply disassembling according to manufacturers' protocols and instructions. Reason: Do not sterilize dirty material with low-temperature method.
(I, E) Cleaning of complex and cannulated articles with brushes of proper diameter, swabs and complementary with ultra-sonic washer. Reason: Biofilms and accumulation of organic material over surfaces with no mechanical action, constituting a mechanical barrier to action of chemical disinfectants and low-temperature sterilization methods.
(I) Loading automatic washers at standardized and validated quantity and disposition. Reason: efficiency at article mechanical cleaning depends on contact pressure of a gush of water over the material.
(E) MSC nurse participate in the decision to buy cleaning equipment, products and used inputs. Reason: direct users select with more objectiveness and with defined criteria.
(I,E) Materials washed and dried with thermal fount, airflow and clean absorbing woven fabric. Reason: humid material propitiates bacteria and fungus growth in addition to interfering in the sterilization process through ethylene oxide and hydrogen peroxide plasma.
(R) Preventive maintenance of equipment used for documented automatic cleaning. Reason: preventive maintenance guarantees equipment functioning and production continuation.
(R) Periodic evaluation of automatic equipment for cleaning with specific tests and evidential reports. Reason: guarantees previous detection of water flows and leaks.
(R) Thermal-disinfection periodic validation. Reason: control of disinfection efficacy.
(R) Program of permanent education for MSC employees. Reason: education is essential for a qualified work.
3P: Indicator of technical-operational evaluation for DMH supplies preparation and packing
Compounds
(I) Located between expurgation and sterilization area, large enough to hold furniture related to these activities. Reason: area properly dimensioned optimizes time and movement for employees to perform their tasks.
(I) Well-lighted area. Reason: material inspection and preparation requires good illumination.
(I) Lenses for image intensification and compressed air guns. Reason: better quality evaluation of material cleaning. Air under pressure can reveal residue dirty not identified in cannulated and complex articles.
(R) Maintenance of package sealing equipment. Reason: guaranty of material sealing quality, which interferes in sterility maintenance during transportation and storage.
(I) Resources for hand hygiene with alcohol-gel 70%. Reason: materials must be manipulated with cleaned hands so they are not re-contaminated.
(I) Description of professional qualification of the nursing team. Reason: MSC must account with qualified professionals to guarantee service excellence.

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4P: Indicator of process evaluation for DHM articles preparation and packing
Compounds
(I) Inspection with magnifying glasses of cleaning conditions and material conservation. Reason: Material cleaning, functionality and integrity must be assured in this stage of processing.
(I) Use of surgical/film non-woven wrapping paper or crepe paper registered at Ministry of Health as articles processed under steam or pressure, ETO, formaldehyde autoclave. Reason: verify microbial barrier. Woven fabric (controlled) can only be used for under-pressure steam.
(I) Use of Tyvek® wrap and polypropylene cover registered at the Ministry of Health as articles processed with hydrogen peroxide plasma. Reason: cellulose-free and microbial barrier guaranteed.
(E) Cotton-woven wrap must be of serge T1 or T2 for steam. Reason: NBR14028/1997
(I) Control of number of reutilizations of cotton-woven surgical wrappings. Reason: number of reutilization (washing and autoclaving) must be controlled, not exceeding 65 times. Cotton-woven surgical wrappings must not be repaired with patches or knitted up.
(I) Autoclave packages must not exceed 25 x 25 x 40 cm or 5 Kg weight. Reason: sterilization guaranty and package drying.
(I) Monitoring articles with exposition chemical indicator (class I). Reason: useful marker to distinguish processed and non-processed articles.
(I,E) Routine for rational use of chemical integrators or emulators/simulators (respectively class 5 and 6). Reason: immediate response of occasional failures in article sterilization process.
(R) Operational norms and routines of preparation and packaging sectors, which must be easily accessed and annually revised. Reason: qualified consultation and standardization of procedures guaranteed.
(I) Semi-critical thermal-disinfected material completely dried before packing in clean packaging. Reason: dampness propitiates growing of fungus and bacteria.
(I) Legible identification of articles with lot number, method and date of sterilization, as well as indication of storage time. Reason: Enables material tracking. Sterilization validity term depends on safety of microbiological barrier of packaging, sealing, and controlled keeping and handling. Control of storage time of material minimizes related events (package damaging, material palpating, keeping material in tight drawers, use of rubber bands and threads, etc.).
(I) Use of cap in preparation and keeping area for critical and semi-critical articles. Reason: prevent hair and annexes from falling over materials.
(E) MSC nurse participate in decision of buying packages, sealing machines, and performing chemical and biological tests. Reason: direct users select with more objectiveness and defined criteria products and inputs to their specific finality.
5E: Indicator of technical-operational structure evaluation for Sterilization, Keeping and Distribution of DMH Supplies
Compounds
(I) Dimensions compatible with number and size of equipment for sterilization. Reason: safety.
(I) Location between areas of preparation and of keeping and distribution. Reason: it prevents cross-contamination and provides one-direction flow of materials.
(I) Wired screens if natural ventilation. Reason: prevent insects from entering.
(I) Pre-vacuum steam autoclave. Reason: residual air removal from chamber and packages guaranteed.
(R) Evidential reports of thermal qualification of autoclave (s). Reason: all autoclaves require annual thermal qualification of performance according to norm ISO/NBR 11134.
(R) Evidential reports on effectiveness of water treatment system of steam autoclaves regarding heavy metal and chemical contaminants removal. Reason: packages and surgical instruments are negatively affected by deposition and reaction to chemical contaminants, resulting on stains and oxidations.
(R) Document preventive maintenance of equipment used for sterilization. Reason: preventive maintenance guarantees quality of equipment functioning.
(I) Room layout/architecture: (I) Limit transit; (I) Provide item identification; (I) Provide cleaning. Reason: provide control of related events to guarantee sterilization preservation.
(I) Shelves must present a minimum distance of 20 cm from the floor, 5 cm from the walls and 45 cm from the ceiling. They must be of stainless steel, treated formica, stainless steel wired baskets, or hard plastic. Wooden shelves are not advisable. Reason: Maximal protection of sterilized material.
(I) The place must not have water fountains, open windows, exposed tubulations, and siphoned and hidden drains. Reason: prevent dust deposition, dampness penetration and entrance of insects and rodents.
(I) No gross accumulation of dust, garbage, and presence of rodents or insects. Reason: risk of contamination.
(R) Permanent education for employees. Reason: education is essential for a qualified work.
6E: Evaluation indicator of sterilization, keeping and distribution process of DHM supplies
Compounds
(R) Bowie & Dick test at pre-vacuum autoclaves before the first cycle of the day. Reason: efficiency guarantee of vacuum bomb and sealing system and, consequently, no air bubbles at cycles.
(I,R) Parameters of temperature, pressure and time of all autoclave cycles must be registered and filed for 5 years. Reason: mechanical controls of each cycle are obligatory for certification achievement of the pre-established parameters.

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(I) Vertical material disposal in autoclave (not piled), with gaps (25 to 50 mm) between packages. Reason: to guarantee steam circulation. Use of wired baskets prevents excessive loading of autoclave, packages from touching walls of internal chamber, hot material handling, and unnecessary manipulation.
(I) Vertical or inclined disposal of concave-convex configuration articles; articles as jars, buckets and flasks disposed upside down; and packages disposed at inferior position. Reason: the suggested disposal guarantees drying of material; larger packages under smaller packages allow steam to circulate through materials.
(I) Packages leave autoclave dried. Reason: humid packages are vulnerable to environmental contamination.
(I) No transfer of hot packages to storage area, except when wired-basket sterilized. Reason: steam condensation humidifies packages through thermal shock and can compromise microbial barrier.
(I) Hand hygiene before unloading material from autoclave. Reason: good practices when handling recently sterilized material.
(I) At storage, earlier-dated packages are in front of later-dated packages. Reason: It decreases the possibility of long-term storage of sterilized packages, which increases the risk of related events.
(I,E,R) Frequent sterilization control of autoclaves performed by chemical indicator classes 5 or 6 and biological: weekly or daily minimal frequency, and always after preventive or corrective maintenance, and in situations suspicious of autoclave mal-functioning. Reason: consensually biological control is still indispensable to prove sterilization, despite AAMI, ANSI and ISO 2005 recognition of response equivalence of biological indicator and indicators classes 5 and 6.
(E,R) Sterilization control of autoclave performed by biological indicator whenever there is implant and/or prosthesis material, releasing them only after results. Reason: Implant and prosthesis material needs lower microbial inoculum to cause hospital infection.
(E,R) Results of biological indicators must be filed for 5 years. Reason: Document proof in case of audit.
(E) MSC nurse participate in decision of buying equipment and input with register at the Ministry of Health authorized by Brazilian National Agency for Sanitary Surveillance to use in sterilization and storage sector. Reason: direct users select with more objectiveness, safety and defined criteria products and inputs to their specific finality.
(I) Use of caps in environments for sterilization, storage and distribution of articles. Reason: prevents hair and annexes from falling over materials.
(R) Frequent material recall in cases of positive results of biological indicator, or when indicator class 5 or 6 presents failure. Reason: responsibility to control infection.
(R) Norms and routines of sterilization and storage sector are easy accessible and annually revised. Reason: revised document material is source of consult and enables qualified standardization of procedures.
7L: Indicator of result evaluation of cleaning condition of DMH
Sample of inspected articles: _____ Relation of inspected articles: _____ Indicator formula: $\frac{\text{Articles found dirty after cleaning (visual inspection + chemical tests)}}{\text{Total of articles evaluated}} \times 100$
8P: Indicator of result evaluation of DHM package conservation
Sample of evaluated packages: _____ Indicator formula: $\frac{\text{Total packages of sterilized articles with conservation problems}}{\text{Total of inspected packages}} \times 100$

DISCUSSION

Evaluation systems of nursing practices must consider: 1) previous existence of gold pattern; 2) relevance of its repercussion of assistance; 3) validity of its performance^(2-6,13). The first two items are considered in the herein study object; resultant scientific knowledge enables recognition of better practices and it is proved to be important for preventing and controlling IASS⁽⁸⁾.

Some authors⁽²⁾ believe gold standard practices already have validity, whereas others think there is a necessity of a process of scientific validity. This study made an option for the second opinion and submitted the indicators to a consensual technique in accordance with literature suggestion⁽¹⁰⁾. Despite the approval of all indicators and their ad-

justments according to judges' suggestions, some points were considered such as difficulty in applying an objective evaluation, impossibility to compare institutions, necessity to previously consider assistance characteristics and precision checking tests of indicators.

Nevertheless, it is an advantage of this system to establish conformity indexes in relation to the best expected practice, as well as to identify and define immediate policies of improvement specially designated to the most problematic aspects, aiming continually to achieve better conformity indexes. These indicators offer the advantage of attendance to the conformity evolution of each institution with the objective of a continuous improvement of quality. As soon as the acceptable conformity standard is achieved, it will be possible to perform inter-institutional comparative evaluations.

CONCLUSION

All elaborated indicators obtained content validity, regardless of the existence of the gold standard and rel-

evance of the impact of clinical practices in nursing. The validity process used in this study demonstrates the importance of conducting validity prior to evaluation procedures.

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