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**Review Article**

# VALIDATION STUDIES IN NURSING: INTEGRATIVE REVIEW

*ESTUDOS DE VALIDAÇÃO NA ENFERMAGEM: REVISÃO INTEGRATIVA*

*ESTUDIOS DE VALIDACIÓN DE ENFERMERÍA REVISION INTEGRADORA*

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The aim of this study was to analyze the methods used for validation studies in nursing research considering the clinical investigation as phenomenon. We carried out literature at BIREME, CINAHL, PUBMED which contain the terms 'validation studies', 'nursing' and 'clinical' and 21 articles were included in the review. The majority of the studies were conducted in 2008; in North America (USA) and European Community (62%) in the area of adult health. Most of the phenomena investigated were related to nursing care involving physical and emotional aspects. The content validity has been cited in 71.4% of the articles, criterion validity in 28.5% and construct validity in 23.8%. The reliability by means of Cronbach's alpha was used in the majority of the studies. It was found a knowledge gap concerning the validation estudies in the area of public health, child health and the social phenomena related to nursing care.
**Descriptors:** Validation Studies; Clinical Nursing Research; Nursing.

O objetivo desse estudo foi analisar os métodos de validação usados na pesquisa de enfermagem em que houve investigação clínica do fenômeno em estudo. Realizou-se levantamento bibliográfico na BIREME, PUBMED, CINAHL, com os termos 'estudos de validação', 'enfermagem' e 'clínica' e foram identificados 21 artigos que compuseram a revisão. A maior parte dos estudos foi efetuada em 2008, na América do Norte (EUA), e Comunidade Europeia (62%) na especialidade saúde do adulto. Os fenômenos investigados foram, na maioria, relacionados à assistência de enfermagem envolvendo aspectos físicos e emocionais. A validação de conteúdo foi citada em 71,4% dos artigos, validação de critério em 28,5%, de construto em 23,8%. Quanto à confiabilidade, a maioria utilizou o coeficiente alfa de Cronbach. Evidenciou-se lacuna de conhecimento ligada a estudos de validação na área de saúde coletiva, saúde da criança e os fenômenos sociais pertinentes à assistência de enfermagem.
**Descritores:** Estudos de Validação; Pesquisa em Enfermagem Clínica; Enfermagem.

El objetivo fue analizar los métodos de validación utilizados en investigación de enfermería en que hubo investigación clínica del fenómeno estudiado. Fue utilizada las bases de datos BIREME, CINAHL, PUBMED, con los términos "estudios de validación", "enfermería" y "clínica", fueron utilizados 21 artículos que compusieron la revisión. La mayoría de los estudios fue realizada en 2008, en América del Norte y Comunidad Europea (62%), en la especialidad de salud del adulto. Los fenómenos investigados estaban, en la mayoría, asociados con la atención de enfermería que involucran aspectos físicos y emocionales. La validación de contenido fue citada en 71,4% de los artículos, validación de criterio en 28,5%, y de constructo en 23,8%. Con relación a la confiabilidad, la mayoría utilizó el coeficiente alfa de Cronbach. Hay laguna de conocimientos acerca de estudios de validación en salud colectiva, salud del niño y los fenómenos sociales relacionados con la atención de enfermería.
**Descriptores:** Estudios de validación; Investigación en Enfermería Clínica; Enfermería.

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## INTRODUCTION

A current concern of nursing researchers is related to the evaluation of its phenomena, as research carried out with new tools or instruments used by other researchers must be validated[1]. If the validity and reliability of evaluation tools do not reflect the theoretical concepts being tested, the conclusions drawn from the empiric phase shall be invalid, thus failing to promote development[1].

The term validity is also defined as the degree to which it is adequate to measure the true value of what it is intended to evaluate, enabling to infer the extent to which results obtained with the applied instrument represent the true or are opposed to it[2]. There are three main validity principles that change according to the information offered and the goal of the researcher: content validity, construct validity and criterion validity[1].

The content validity represents the content universe or the control of constructed data that provides the structure and the base for the formulation of questions that shall adequately represent the contents. In this type of validity, the researcher must define the concept and identify the dimensions of the concept components[1,2].

The construct validity is based on the extent to which a test measures a feature or theoretical construct and seeks to validate a theoretical body subjacent to the testing of hypothetical relations[1].

However, validity related to a criterion demonstrates the level at which the performance of the researched subject and its real behavior are related when using the evaluation tool. Therefore, criterion is the second measure that evaluates the same studied concept[1].

For example, when comparing the oxygen saturation level in newborns by applying fetal hemoglobin and the oxygen saturation level obtained through a pulse oxymeter device, both results should be equivalent[3]. This study serves as an example of criterion validity.

The correlation level of the evaluation with a criterion that is external to the measured phenomenon seeks to evaluate the degree to which the instrument discriminates among persons who differ in a certain feature in agreement with a standard criterion[4].

Validation studies are widely used in several research areas both in national and international literature. In nursing, in particular, these types of studies are not recent. Examples are the patient classification system created in 1960[5] or nursing diagnosis validation studies, which began in 1979[6]. Translation and adaptation of scales such as pain[7], pressure ulcer prevention[8], infant anxiety[9] and a questionnaire of drugs use[10] are other examples of validation studies.

International literature includes many nursing diagnosis validation studies[6] such as Gordon and Sweeny, the Fehring and Hoskin models, being the Fehring one the most accepted in Brazil[11].

Considering this context, the goal of this study is to analyze validation methods used in clinical nursing research, as we consider that there is a scarcity of works of this nature in literature. Due to their importance for nursing practices, it is necessary to evaluate the advances and gaps of this knowledge.

## METHODS

This research is based on the integrative review, which consists of the elaboration of a wide literature analysis, promoting discussions on research methods and results, as well as reflections on the materialization of future studies[12].

The integrative review study is performed in seven stages: hypothesis selection or questions for review; selection of the research that shall be included in the review sample; definition of primary research features that compose the review sample; analysis of findings from articles included in the review; interpretation of results; review narration and findings critical analysis[12]. In this review we opted for following these stages.

The questions formulated for the research were: which are the most used validation methods in which clinical practice phenomena investigation occurred? Which were the phenomena studied? In which nursing areas? And which were the statistics methods used?

After that, goals were set and the inclusion criteria were determined. Inclusion criteria considered validation studies carried out in the nursing area with a study of clinical phenomena. Articles written in Portuguese, Spanish or English and articles with abstracts available in the databases selected from January 1, 2004 to April 30, 2009 were considered.

*Online* search was performed for national and international literature databases. Consultation was carried out through BIREME (Online Health Library) bibliography, PUBMED (*National Library of Medicine and the National Institutes of Health*) and CINAHL (*Cumulative Index to Nursing Allied Health Literature*). At BIREME, all available databases in this library were included by entering Health Science keywords (DeCS/MeSH), the keywords "validations studies", "nursing" and "clinic and the Boolean Operator AND.

The search strategy was built in agreement with the specificities of each database. In order to grant database search uniformity, a question and the inclusion criteria were used as guidelines. Two researches performed the investigation independently, being initially selected those articles that had abstracts chosen by both of them in accordance with the set criteria.

In order to collect article data, a review protocol instrument was elaborated [2] containing the following items: database, publication year, publication journal, authors, article title, validation type, phenomenon studied, validation method used and nursing specialty.

The search was started with BIREME through the *validation studies* descriptor. Due to the wide variety of publications available, it was necessary to cross terms with the Boolean logic operator And. Applying the terms *validation studies* and *nursing* and *clinical,* 149 articles were found. After reading the titles and quickly checking the abstracts, 29 articles were selected.

After a second and careful abstract reading, only five articles were independently selected by the two researchers. After a complete reading of these five articles, only two articles qualified for selection by the researchers, meeting the criterion of being validation studies with clinical phenomenon study.

At PUBMED, the same keywords were used, together with the Boolean logic operator: *validation studies* and *nursing* and *clinical*. In this database, the same search limits were stipulated: publications from the last five years, studies in humans, English and Spanish language and *Nursing Journals*, being located 312 articles. Selecting per title and a quick abstract reading, 123 articles were selected. After abstract analysis, researchers independently selected 21 articles. After a complete reading, 15 articles were selected in agreement by the researchers.

With regards to the CINAHL database, the same keywords and words crossings were applied. In this database, some limitations were also applied, such as publications during the last five years, studies in humans, English and Spanish language and N*ursing Journals*, seeking to limit results. 247 articles were found, out of which 33 were selected per title and quick summary check. After verifying agreement between researchers, eight abstracts were selected. After a

complete article reading, a new concordance evaluation was carried out, finally selecting four articles.

Next, a flowchart synthesizes the search for the 21 articles that composed the final review sample (Figure 1).

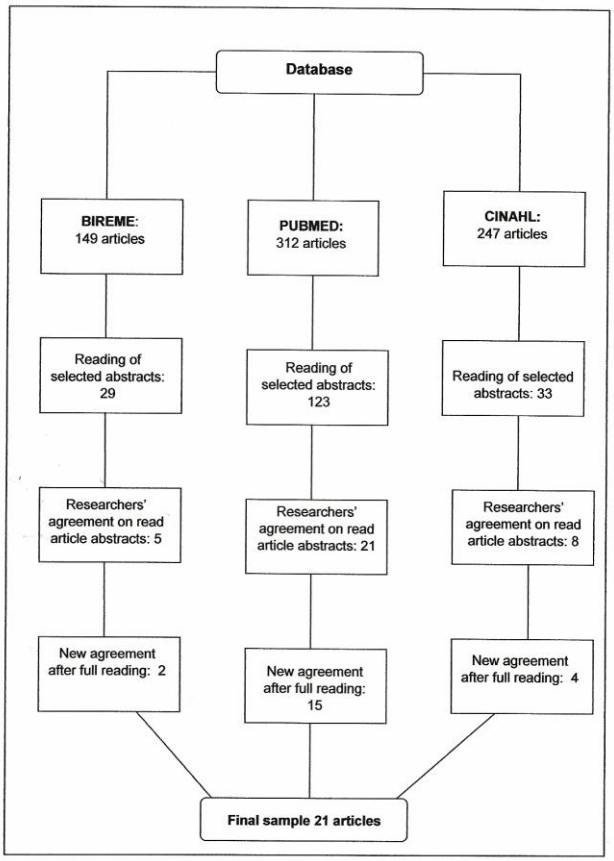


**Figure 1** - Article selection process flowchart according to the databases.

## RESULTS

Amongst the 21 articles analyzed, two were published in 2005, six in 2006, four in 2007 and nine in 2008. From the articles included for analysis, 42.9% were produced in North America (USA), 28.6% in Asia (China, Korea and Taiwan), 19.1% in Europe (Belgium, United Kingdom, Italy and Sweden) and 9.5% in South America (Brazil). Seven out of the 21 articles were written by one nurse[10,13-18] while in the others, authorship varied from two[3,7-9,19-25] to three[26-27] or four[28].

In relation to the kind of validation described in the analyzed articles, content validation was mentioned in 71.4% of cases, followed by criterion validation (28.5%) and construct validation (23.8%). Content validation only was used in 52.4% of studies, criterion validation in 14% and construct validation in just 9.5% of cases.

In studies that used more than one validation type, content and criterion validation were used together in 9.5% of studies, content and construction in 9.5 % and construct and criterion in 4.8% of cases, being that there was clinical application of the studied phenomenon in all cases, which means that the evaluation instrument developed was applied or tested in persons.

Regarding to the phenomena validation in the articles herein analyzed, it was observed that care aspects were considered: quality of services offered, degree of dependency of nursing care services rendered, specialized hospital discharge planning,

classification system for patients with severe brain trauma, modified comma scale, neurological deficit in stroke patients, dementia scale and ulcer prevention through pressure control. Besides, the same was criteria were applied for the use of IV drugs, perinatal clinical research, life scale programming for life control and oxygen saturation levels in newborns.

On the other hand, aspects related to physical conditions such as allergic rhinitis symptoms, collaborative management for asthma treatment, nursing diagnosis for ineffective peripheral tissue perfusion, nursing diagnosis related to mechanical ventilation patients and pain intensity scale for the elderly were included, as well as psychological factors such as: infant fatigue in oncology children, attitude scale related to cancer treatment and prevention, spiritual needs of terminal patients and anxiety levels for hospitalized children.

With regard to the adopted methods, it was observed that more than half of the articles (66.7%) used degree levels as the instrument to measure or evaluate the phenomenon under study. Other types of instruments used were questionnaires, forms and list of defining features in the case of nursing diagnosis validations for a given clinical situation.

As for the use of instruments, in 14 articles was observed that they were applied to inpatients, out of which 35.7% were critical patients in intensive care and emergency units. In six articles, evaluations were applied to ambulatory patients.

The nursing area in which more validation studies were performed was adult health care (42.9%) followed by critical patients care (14.3%). In the charts 1a, 1b, 1c and 1d a general outlook of analyzed articles is introduced.

| Year and reference | Validation type | Studied phenomenon | Method | Specialty |
|---|---|---|---|---|
| 2008 [20] | Content | Classification system for patients with severe brain trauma | **Instrument:** CPSCS - Critical Patients Severity Classification System. **Sample:** 190 patients with brain lesion in ICU-A. **Statistical test:** multiple regression analysis. | Critical patients care |
| 2008 [14] | Content | Patient collaborative management in asthma treatment | **Instruments:** CMS - Collaborative Management Scale; PABS - Patient Attitude and Belief Scale; ACT - Asthma Control Test e AQLQ - Asthma Quality of Life Questionnaire. **Sample:** 13 patients. **Statistical tests:** Cronbach's alpha and Chi-square test. | Adult health |
| 2008 [10] | Content | IV drugs use records | **Instrument:** development of LIH - Lifetime Injection History Questionnaire. **Sample:** 104 people under chemical dependency treatment. **Statistical test:** Analysis of Covariance (ANCOVA). | Mental health |
| 2008 [15] | Content | Attitudes related to cancer treatment and prevention | **Instrument:** ACTS - The Attitudes Towards Cancer Trials Scales. **Sample:** 312 people from different ethnics in a city in southern USA. **Statistical tests:** Cronbach's alpha. | Adult health |
| 2008 [26] | Content | Alzheimer disease | **Instrument:** discomfort scale. Alzheimer disease validation for Italian. **Sample:** 21 nurses and 71 patients. **Statistical tests:** Kruskal-Wallis, test, Kappa test and Cronbach's alpha. | Mental health |

**Figure 2a** - Description of selected articles per year and reference, content validation, studied phenomenon, method and nursing specialty.

| Year and reference | Validation type | Studied phenomenon | Method | Specialty |
|---|---|---|---|---|
| 2007 [28] | Content | Nursing diagnosis related to mechanical ventilation patients | **Instrument:** nursing diagnosis validation through the Fehring method. **Sample:** 38 patients. **Statistical tests:** Mann-Whitney test, U, Chi-Square, Kappa and, Fischer tests. | Critical patients care |
| 2007 [9] | Content | Anxiety level for children | **Instrument:** CSAS-C - State Anxiety Scale for Children Chinese version (developed for the Chinese version). **Sample:** 1st phase-112 children in pre-surgery stage. 2nd phase - 82 children in pre and post-surgery stages. **Statistical test:** Cronbach's reliability test. | Child health |
| 2006 [18] | Content | Spiritual needs | **Instrument:** SNI - Spiritual Needs Inventory, development and test. **Sample:** 100 terminal cancer patients. **Statistical tests:** Cronbach's alpha and factorial analysis. | Adult health |
| 2006 [25] | Content | Specialized planning for hospital discharge services | **Instrument:** hospital discharge protocol. **Sample:** 991 patients in 1998 and 3003 patients in 2002. **Statistical tests:** Chi-square, Odds-Ratio, univariate logistic regression and multivariate analysis. | Adult health |
| 2006 [27] | Content | Nursing diagnosis for ineffective peripheral tissue perfusion | **Instrument:** List of ineffective peripheral tissue perfusion defining features. **Sample:** 24 patients. **Statistical tests:** Student t test and Kruskall-Wallis. | Adult health |

**Figure 2b** - Description of selected articles per year and reference, content validation, studied phenomenon, method and nursing specialty.

| Year and reference | Validation type | Studied phenomenon | Method | Specialty |
|---|---|---|---|---|
| 2005 [8] | Construct | Pressure ulcers | **Instrument:** Braden and Norton's pressure ulcer risk scale evaluation and comparison. **Sample:** 1772 patients. **Statistical tests:** Pearson's correlation and Student t test. | Adult health |
| 2008 [21] | Construct | Fatigue in children with oncology conditions | **Instrument:** children fatigue scale. **Sample:** 108 Chinese children under cancer treatment. **Statistical tests:** Spearman, Mann-Whitney, Cronbach's alpha coefficient. | Infant health |
| 2008 [22] | Content and Construct | Self-control programming (C-SCS) | **Instrument:** C-SCS - Self-Control Schedule in Chinese childbearing women (Chinese translation and validation). **Sample:** 360 pregnant women. **Statistical tests:** Cronbach's alpha and intra-class correlation coefficient. | Women health |
| 2006 [16] | Content and Construct | Dependency level of nursing care for emergency unit patients | **Instrument:** JTD - Jones Dependency Tool and its evaluation. **Sample:** 840 patients from six hospitals in emergency situation in the United Kingdom. **Statistical tests**: reliability and Kappa tests in random sample of 38 patients and testing and retesting in another sample with 26 patients. | Emergency care |

**Figure 3** - Description of selected articles per year and reference, construct and construct/content validation type, studied phenomenon, method and nursing specialty.

| Year and reference | Validation type | Studied phenomenon | Method | Specialty |
|---|---|---|---|---|
| 2008 [19] | Content and criterion | Health care quality | **Instruments:** Karen-patient and Karen-personnel. **Sample:** 64 patients and 42 nursing professionals. **Statistical test:** Cronbach's alpha coefficient. | Adult health |
| 2006 [24] | Content and criterion | Neurological deficit in patients with acute stroke | **Instruments:** C-NIHSS - The National of Health Stroke Scale compared to GCS - Glasgow Coma Scale and the Barthel Index (Chinese development and validation). **Sample:** 48 persons with ischemic strok. **Statistical tests:** Kappa test, Cronbach's alpha and Pearson's test. | Adult health |
| 2005 [13] | Content and criterion | Allergic rhinitis symptoms | **Instrument:** SSQ - Sinus Symptom Questionnaire, compared to blood samples from patients. **Sample:** 24 patients. **Statistical tests:** Cronbach's alpha, Pearson's correlation coefficient and Chi-Square. | Adult health |

**Figure 4** - Description of selected articles per year and reference, content/criterion validation type, studied phenomenon, method and nursing specialty.

| Year and reference | Validation type | Studied phenomenon | Method | Specialty |
|---|---|---|---|---|
| 2007 [3] | Criterion | Oxygen saturation levels in newborns with respiratory discomfort | **Instrument:** Comparison of 771 fetal hemoglobin blood samples with O2 saturation obtained by oxymeter. **Sample:** 78 newborns between 25 and 38 weeks old and weight from 660g to 3,800g. **Statistical tests:** multivariate analysis, multiple regression and Chi-Square test. | Newborn health |
| 2007 [17] | Criterion | Comparison between the FOUR and GCS scales | **Instrument:** evaluation and comparison between FOUR - Full Outline of Unresponsiveness and GCS - Glasgow Coma Scale. **Sample:** 80 patients in intensive care (ICU- Adult). **Statistical test:** Cronbach's alpha. | Critical patient care |
| 2006 [23] | Criterion | Comparison between OI-US points instruments | **Instrument**: OI-US - Optimality Índex-United States: evaluation and comparison of OI-US points methods. **Sample:** 3,425 women in obstetric nursing care between 1987 and 1999. | Women health |
| 2006 [7] | Construct and Criterion | Pain intensity | **Instrument:** FPS - Faces Pain Scale with a NRS - Numerical Rating Scale (0-10) development and comparison between the two scales. **Sample:** 31 painless Korean elderly people evaluated faces that suggested pain, sadness, sleepiness, anguish, happiness, etc.) FPS was immediately applied in a sample of 85 elderly persons with chronic pain. **Statistical test:** Kappa test. | Elderly health care |

**Figure 5** - Description of selected articles per year and reference, criterion and content/criterion validation type, studied phenomenon, method and nursing specialty.

## DISCUSSION

In recent years in North America, there was a steady growth in the number of validations in nursing studies that included clinical research of the phenomenon under study, which suggests the interest that the matter has attracted, confirming that nursing as a science has taken into account the evaluation and measurement of its results[1].

Therefore, scientific production in the nursing area has increased in the last decade both in the national and international scenarios, including those

studies that use integrative reviews as a research methodology[29].

In Brazil, the growth in the number of scientific research in the area consolidates post-graduate teaching, masters and doctorate courses, dramatically contributing to the development of Brazilian nursing[30], even if in this review there were only 9.5% of Brazilian studies.

A remarkable aspect of this research is the validation type: 71.4% of studies used content validity[9,10,14-15,18,20,25-28]. The explanation lies in the need for nursing to develop measurement instruments that contemplate all aspects of the researched phenomenon, once this validation is applied to cases in which a universal behavior can be clearly defined[31].

Although most studies are content validation ones, in this review, only two nursing diagnosis validation studies were identified[27-28], even knowing that nowadays this kind of research is considerably large. This is possibly due to the fact that these studies do not involve phenomenon analysis in clinical practice.

As for the phenomena studied, results enabled to identify that most of them were linked to assistance aspects such as care quality[19], brain trauma[20], newborns with respiratory discomfort saturation levels[3], nursing diagnosis related to mechanical ventilation patients[28] among others, confirming that today's nursing is seeking to qualify the assistance.

Nursing requires conceptualization of the phenomena that it treats and/or it takes care/of. Consequently, validation studies are still fundamental for the practice to be scientifically based and to overcome the elaboration of inductive/deductive nursing care or diagnosis, seeking to enable a quality improvement and better visibility of professional practices and as a consequence, achieve the long desired autonomy[32].

In this integrative review, it was observed that more than half (66.7%) of instruments started from the measure scale, confirming the nursing concern about using an instrument that can offer more precision to identify the phenomenon under study.

It was also verified that a large majority (66.7%) of populations studied was composed of inpatients. They were in critical areas such as intensive care units (21.4%) [17,20,28] and the emergency care sector (7.1%)[16]; which demonstrates that this kind of study has been limited to the hospital environment and to critical patients who require qualified and specialized assistance.

Another interesting aspect is the statistical analysis. In more than half (52.4%) of studies, the C*ronbach's,* alpha coefficient was applied, which is used when the item may have more than two alternatives. The result of this coefficient suggests an internal consistence indicator related to the researched scale and consequently, to the items that compose it. The advantage of its use lies in its capacity to obtain a very valid and reliable measure employing the smaller number of items possible. In other words, selecting items that contribute to achieve maximum reliability and validity[33].

Through the analysis of this study, it can be affirmed that there is a certain similarity in the ways content, criterion and construct validation studies are carried out. However, one of the limitations is the fact that validation studies that may bring some contribution might have been excluded during the first stage, when researchers often read only titles and abstracts, as only well-structured summaries that met inclusion criteria were selected. Another limitation is that articles written in other languages other than Portuguese, Spanish and English were not included.

## CONCLUSION

Despite the significant number of articles found, the selected sample size was reasonably sufficient. However, the number of publications on the topic has

grown in recent years, demonstrating the interest of nurses on the subject.

Most studies in this review aimed at content validation with phenomena analysis in clinical practice.

It was observed that the most studied phenomenon was related to the assistance to patients/clients with regards to physical and emotional aspects. The most frequently used instrument was the measurement scale. In more than half of articles, *Cronbach's* alpha was used for statistical analysis and the most studied area was adult health in the hospital environment.

There is a clear knowledge gap related to the validation of instruments that aim at evaluating public health, child health and social phenomena related to nursing care.

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