

CONSTRUCTION, VALIDATION AND RELIABILITY OF AN INSTRUMENT FOR EVALUATION AND EVOLUTION OF CHRONIC WOUNDS

CONSTRUÇÃO, VALIDAÇÃO E CONFIABILIDADE DE UM INSTRUMENTO PARA AVALIAÇÃO E EVOLUÇÃO DE FERIDAS CRÔNICAS

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ABSTRACT: construct and validate an instrument for evaluation and evolution of chronic wounds. The content and apparent validities were appreciated by experts, the reliability by the analysis of concordance between evaluators using the interclass correlation coefficient and to verify the construct validity was used the instrument *Pressure Ulcer Scale for Healing*. the analysis of the scores of the instrument by the ICC showed an excellent and significant correlation ($K = 0.914$) and to verify the construct validity of the instrument, the Pearson correlation coefficient, whose result was 0.573, showed a statistically significant and strong correlation between the scores instrument and the *Pressure Ulcer Scale for Healing*. Most of the concordances of the items were classified as moderate or substantial. The instrument is valid and reliable. It is suggest longitudinal studies in larger populations, semantic validation in a sample of nurses, and an illustrative guide to standardize concepts in order to improve the evaluation of metric properties.

KEYWORDS: Nursing. Wound Healing. Validation Studies. Nursing Records.

INTRODUCTION

Chronic wounds are complex and require individualized evaluation by a multi-professional team, often associated with systemic diseases, which makes the healing process long, requiring frequent evaluations and interventions (HEERSHARP; NICHOLAS; WHITEHEAD, 2019; BENBOW, 2016).

Changes in clinical practice such as methods of evaluation, diagnosis, prevention and diversified treatment can be used to meet the clinical needs of patients with chronic wounds. Thus, based on these innovative practices, nurses should keep their knowledge and skills updated to conduct evidence-based conducts, plan care, implement and reassess care, and contribute to improved care quality (TIMMS, 2011).

The assessment of the patient's general health, and wound examination should occur at the admission of the patient or at the beginning of the consultation. The evaluation should be comprehensive and document a minimal set of data. This attitude will provide the minimal information necessary to act as a baseline to monitor the success

or failure of chronic wound (SCOTT-THOMAS et al., 2017).

In this sense, data recording is of paramount importance, but it requires systematization of them, allowing to accompany the wound healing process, the standardization of language and verifiable items and forms of measurement will allow clarity and objectivity Health professionals and especially nursing professionals (THOMPSON et al., 2013).

There are several instruments described for evaluation and evolution of wounds, but most were developed to specifically evaluate a type of chronic wound (RESTREPO- MEDRANO; SORIANO, 2012). There are still other instruments in the literature that evaluate a type of wound characteristic (VESTJENS et al., 2017). It was chosen in this study by the elaboration of an instrument that is applied in several types of chronic wounds with important characteristics for evaluation and space for treatment orientation, a form not observed in other instruments.

For the elaboration of the instrument, it was considered for the management of chronic wounds the TIME strategy (non-viable or deficient tissue; infection/inflammation; moisture imbalance; margin of the wound does not advance), to systematize the

evaluation, preparation and treatment of wounds (MUNRO, 2017).

In view of the above, this study intended to construct an instrument capable of evaluating chronic wounds addressing more characteristics that are relevant for the evaluation of lesions that may aid in the treatment. Thus, the aim of this study was to construct and validate an instrument of evaluation and evolution of chronic wounds.

MATERIAL AND METHODS

It was a methodological research with the elaboration and validation of the metric properties of the "Chronic Wound Record Instrument -IRFC" developed in three stages: 1) Construction of the instrument, denominated in this study of Chronic Wound Record Instrument (IRFC); 2) Apparent and content of the instrument validation; and 3) verification of the validity and reliability of the instrument.

The items included in the instrument were determined from an integrative literature review, carried out according to the stages for the selection of the thematic question, establishments of inclusion and exclusion criteria and selection of articles, categorization of the studies and presentation of the results (WHITTEMORE; KNAFL, 2005).

Subsequently, the instrument was submitted to an evaluation by a committee composed of five PhD judges with experience in chronic wounds. The judges analyzed the apparent and content validity of the instrument through a questionnaire elaborated with questions related to format and content.

The categories of responses for each item were evaluated according to criteria for the elaboration of instruments according to the referential of Pasquali (1988), which addresses objectivity, simplicity, clarity, relevance and accuracy. Of the 12 criteria pointed out by the author, five were selected because they better expressed the objectives and purposes of the evaluation. All the judges' adjustments were accepted and after the apparent and content validation, the first version was submitted to an experimental test, then the necessary were made for refinement of the instrument.

The IRFC is composed of ten items and 55 sub-items to evaluate the evolution of the wound. The items adopted were: a) amount of granulation tissue / six sub-items; b) amount of necrotic tissue / five sub-items; c) necrotic tissue type / five sub-items; d) type of exudate / five sub-items; e) exudate quantity / four sub-items; f) tissue impairment / five sub-items; g) borders/ four sub-items; h) perilesional

skin six sub-items; i) signs of infection/nine sub-items; j) wound area /six sub-items.

The sum of the items of the instrument, obtained by the sub-items score, generates a final score that varies from 2 to 49 points, where the higher the score, the worse the evolution of the wound.

In the last step, the validity and reliability of the IRFC were verified. To verify the construct validity of the IRFC, it was evaluated at the time of data collection with the use of another instrument of assessment and evolution of wounds: the *Pressure Ulcer Scale for Healing* (PUSH), which evaluates by means of three parameters with their sub-scores: 1) Area (0 to 10), 2) type of tissue (0 to 4) and 3) amount of exudate (0 to 3), where the total score varies from 0 to 17. This instrument was validated for the Brazilian language by Santos, Sellmer e Massulo (2007). The choice of PUSH was to attend IRFC-like characteristics and made it possible to validate the construct.

In order to verify the reliability, the inter-rater strategy was used by two nurses, who used the instrument simultaneously and independently.

In relation to the subjects the sampling was carried out by convenience, when All patients who were admitted to the medical and surgical wards of a public hospital, who met the inclusion criteria, who were presenting chronic wounds, Pressure Injury (LPP) and/or leg or foot ulcers and wounds originating from lower limb amputation attributed to Diabetes Mellitus (DM) and patients aged 18 years or over. We excluded those with LPP classified in category I and lesions resulting from sickle cell anemia and/or vasculitides.

To perform the data collection, the following sequence was followed: a) Initial evaluation, with a record of the socio-demographic data, history and characteristics of the wound; b) Afterwards the dressing was removed and the exudate of the covers and the wound bed were evaluated; After cleaning, the bed and perilesional skin were evaluated and a score of each item was selected to establish the total score; c) data were collected by two care nurses, who received a training performed by the research team; d) only the responsible researcher applied the PUSH instrument in order to establish a score for each item; e) When the patient had more than one ulcer, all of them were evaluated and subsequently performed a draw by using the program *Statistical Package for the Social Sciences* (SPSS) version 20.0, for selection and inclusion in the study.

The data was entered into an electronic data spreadsheet of the Microsoft Excel XP[®] program,

validated by double typing and exported to two programs: SPSS version 16.0, for descriptive analysis, calculation of Interclass Correlation Coefficient (ICC) and Pearson Correlation Coefficient (r); and MedCacl version 15.2, for calculation of simple Kappa for nominal variables and weighted for ordinal variables.

To express the concordance strength of the Kappa coefficient, the following classification was considered: a) 0.01-0.2: mild/low; b) 0.21-0.40: regular; c) 0.41-0.60: moderate; D) 0.61-0.80: substantial; e) 0.81-0.99: almost perfect (LANDIS; KOCH, 1997).

To express the correlation of the Pearson coefficient (r), the following classification was considered: a) $0 < |r| < 0.3$ weak; b) $0.3 \leq |r| < 0.5$ moderate; c) $0.5 \leq |r|$ strong ≤ 1 (COEHN, 1988).

The classification for ICC reliability followed the following categorization: a) of < 0.4 as low; b) between 0.4 and 0, 74 moderate to good; c) excellent ≥ 0.75 (FLEISS, 1986).

The study was approved in its ethical and methodological aspects by the Research Ethics Committee under opinion number 2602 regarding the resolution CNS/MS number 466/12 on research involving human beings.

RESULTS

The integrative literature review study presented a final sample of 61 primary studies and five reverse search studies. After analysis, 11 thematic categories were established regarding the evaluation of chronic wounds (Table 1).

Table 1. Thematic categories related to evaluation of chronic wounds resulting from an integrative review of literature.

Categorization of articles related to wound assessment	Publications	
	n	%
Evaluation of the area and/or depth of the lesion	10	15.5
Non-invasive objective methods of clinical and/or microbiological investigation	07	10.6
Assessment instruments and wounds evolution	14	21.2
Data and wound characteristics important to follow the evolution of the wound	12	18.2
Use of the photograph for evaluation and documentation of the wound	04	6.0
Electronic wound assessment and documentation systems	03	4.5
Assessment of granulation tissue	02	3.0
Assessment of signs of infection	08	12.0
Assessment of exudate	04	6.0
Assessment of pain	01	1.5
Assessment of necrotic tissue	01	1.5
Total	66	100

The evaluation of the first version generated the final version, obtained by agreement of at least 50 to 80% of the members of the judges' committee. All observations and suggestions were considered relevant, so the appropriate alterations were made in the instrument that aimed to make it more suitable for the assessment of the wound. The final version

of the instrument contains ten items that compose the part of evaluation and evolution of wounds.

For the evaluation of the psychometric properties of the IRFC, the sample consisted of 71 patients, when 43 of them were hospitalized and 28 in outpatient care. Men corresponded to 31 (43.7%) sample subjects and women to 40 (56.3%). The age

of the patients in the final sample ranged from 19 to 96 years, with an average of 65.6 years.

Regarding the etiology of the chronic wounds evaluated, 32 (45.1%) were LPP, 14 (19.7%) lesions resulting from DM actions, 15 (21.1%) lesions due to venous insufficiency, three (4.2%) due to arterial insufficiency, one (1.4%) mixed lesion (arterial / venous) and six (8.5%) lesions of unreported or unknown etiology.

The data below refer to the crosses between evaluators 1 and 2 responses, with the respective

weighted Kappa coefficients for ordinal variables, simple for dichotomous, ICC for the total IRFC scores, in order to determine the intensity of the agreement of the items and the score and Pearson correlation coefficient to verify the correlation of the IRFC and PUSH scores.

In the reliability analysis of the ordinal variables, the items were observed and the results are described in Table 2.

Table 2. Inter-evaluators agreement who applied the record chronic wounds instrument in relation to the general items.

Instrument items	Kappa (<i>p</i>)
Amount of granulation tissue	0.598 [0.454-0.742]
Amount of necrotic tissue	0.675 [0.556-0.795]
Type of necrotic tissue	0.754 [0.623-0.886]
Type of exudate	0.630 [0.474-0.787]
Amount of exudate	0.632 [0.482-0.782]
Tissue impairment	0.470 [0.316-0.625]
Wound area	0.807 [0.732-0.883]

The level of inter-evaluators agreement for the item Amount of granulation tissue was moderate and the item Amount of substantial necrotic tissue. Among the evaluations, there was a greater dispersion in the concordance in the classification of the percentage of Type of necrotic tissue.

The concordance intensity of the item type of necrotic tissue is substantial and the lowest concordance intensity occurred in the sub-item superficial gray/white tissue.

The results of the item type of type of exudate and Amount of exudate showed that the agreement was substantial among the nurses' assessment, when a similar proportion of agreement was found between the items. There was a moderate agreement between the two evaluators of the item Tissue Commitment, which was the item that presented the greatest dispersion in the concordance of responses. The inter-evaluator correlation coefficient of the Wound area item obtained substantial agreement.

In the reliability analysis of the dichotomous variables, the reliability of the items Edge of the wound, Perilesional skin and Signs of infection were analyzed according to the table below.

The results presented in Table 3 showed that the agreement of the sub-items of the Wound edge was perfect for the thick or fibrotic border sub-items, almost perfect for the sub-items Hyperkeratosis in the border and Detachment, and regular for the Damaged border.

The level of concordance for the sub-items of the Perilesional skin item were moderate to Macerated, Dried, Erythema and Flaking; almost perfect for Pruritus and perfect for Vesicles/blisters.

In the reliability analysis of the item Signs and symptoms of infection, the sub-items: Crispy granulation tissue, Cracking in the perilesional skin and Wound breakdown, concordance was perfect. During the evaluation of the wounds, none of the evaluators observed the presence of these signs; therefore, they did not select positive responses of the item.

Table 3. Inter-evaluators agreement who applied the record chronic wounds instrument in relation to the dichotomous variables.

Items and sub-items of dichotomous variables	Kappa (<i>p</i>)
Wound edge	
Thick or fibrotic edge	1.000 [1.000-1.000]
Detachment	0.915 [0.751-1.000]
Damaged Edge	0.235 [0.007-0.478]
Hyperkeratosis on the edge	0.933 [0.804-1.000]
Perilesional Skin	
Macerated	0.496 [0.288-0.703]
Dry	0.540 [0.316-0.765]
Flaking	0.505 [0.287-0.723]
Itching	0.948 [0.847-1.000]
Vesicles / Blisters	1.000 [1.000-1.000]
Erythema	0.447 [0.235-0.641]
Signs of infection	
Exacerbation of previous pain, report of pain not previously reported	0.683 [0.392-0.974]
Fetid odor	0.800 [0.581-1.000]
Wound bed Discoloration	0.024 [0.064-0.015]
Hardening	0.618 [0.339-0.897]
Edema	0.613 [0.387-0.839]
Increased temperature	0.525 [0.191-0.858]
Crispy granulation tissue	1.000 [1.000-1.000]
Cracking in the perilesional skin	1.000 [1.000-1.000]
Wound breakdown	1.000 [1.000-1.000]

The level of inter-evaluator agreement for sub-items Pain, Edema, Fetid odor, Hardening was substantial, moderate to increased temperature and insignificant for Discoloration of the wound bed.

The concordance scores and the Interclass Correlation Coefficient of the overall score of the instrument are described in Table 4.

Table 4. Interclass Correlation Coefficient for the total scores of the instrument of registry of wounds for verification of the inter-evaluator reliability.

Calculated values	Total Scores	
	Evaluator 1	Evaluator 2
Minimum	5.0	6.0
Maximum	30.0	31.0
Mean	19.6	19.9
Median	21.0	20.0
Standard Deviation	6.1	5.5
ICC	0.914	
P	< 0.001	

From the inter-evaluator reliability, the results evidenced a high ICC of 0.914, for the total points of the IRFC, in addition to an excellent and statistically significant correlation ($p < 0.001$).

The scores on the wound recording instrument range from 2 to 49. In the inter-evaluator evaluation, the total scores ranged from 5 to 30 for the evaluator 1 and from 6 to 31 for the evaluator 2,

to averages of 19.6 and 19.9, respectively, in order to characterize an excellent concordance among the evaluators.

In this stage of construct validation, the PUSH instrument was used to verify the relationship between this instrument and the IRFC. The results are described in Table 5.

Table 5. Pearson's correlation for total scores of the chronic wounds registry instrument and the PUSH.

Calculated values	Total Scores	
	IRFC	PUSH
Minimum	5.0	5.0
Maximum	30.0	17.0
Mean	19.6	12.9
Median	21.0	13.0
Standard Deviation	6.1	2.6
Pearson	r=0.573 p<0.001	

The correlation coefficients showed a strong relationship (0.573) and a statistical significance ($p < 0.001$) between the IRFC and PUSH scores. The PUSH instrument scores ranged from 0 to 17, and the IRFC from 2 to 49 by the assessment of evaluator one. When using the IRFC, the total scores ranged from 5 to 30, while the PUSH instrument from 5 to 17, with a mean of 19.6 and 12.9, respectively.

DISCUSSION

The content and apparent validations were performed with relevant results suggesting that the items were included in the evaluation of the judges, in total were requested six adjustments and all suggestions were accepted and the modifications made to the New version of IRFC. The final preparation of the instrument was performed according to the evaluation of the judges, based on the integrative review and the experimental study, which allowed considering the main aspects for evaluation of chronic wounds.

The results of the present study indicated that the developed instrument is a reliable and valid tool for evaluation of chronic wounds. It was demonstrated in the inter-evaluators reliability of the general IRFC score that reliability was excellent and significant. The analysis of some items of the instrument was observed lower agreement. Most of the concordances of the instrument items were classified as moderate or substantial.

Difficulties can be obtained in the evaluation of the wound, when it is not properly performed. Thus, the basic information related to the patient and his/her wound requires a critical care plan so that the effects of treatment can be monitored effectively (SCOTT-THOMAS et al., 2017).

The granulation tissue can be checked by staining, appearance, and how much it has filled the wound bed. The disagreement in this study in the item "Amount of granulation tissue" was higher in the category Superficial or non-visible wound, and

difficulties were observed in the percentage ranges between 25% and 75%. The training of the professionals may be necessary to assist in the evaluation and quantification of the granulation tissue and when the tissue is not visible or superficial.

A study evaluated the validity and reliability of the *Photographic wound assessment* (PWAT) instrument by photographic images of various types of chronic wounds, whose variables that had lower concordance between the evaluators were Type of granulation tissue, due to the difficulty of correlating red tones with healthy tissue, Adjacent skin and wound edge (THOMPSON et al., 2013).

Most evaluations of granulation tissue are subjective, based on observation of tissue staining and lesion area. A colorimetric instrument, called "*tristimulus*", was developed as a more objective evaluation method to analyze the color of the granulation tissue. Its analysis through digital photography differentiates the intensity and area of tissue color. A study that evaluated the predictive validity of this instrument demonstrated adequate results for the indicators of red staining index of the granulation tissue and indicated to be a useful monitoring tool to evaluate and monitor the development of granulation tissue (LIZAKA et al., 2013). However, research that used this instrument to evaluate LPP showed low reliability because it presented difficulty in interpreting the color of the evaluated tissue (LIZAKA et al., 2013).

In another study, an instrument developed for the evaluation of LPP, the "*Design*", was used to verify its reliability and validity by the photographic image. The results showed that the scores were lower when the professionals had no experience in the treatment of wounds, in the evaluation of the items of tissue impairment, inflammation, infection and granulation. Difficulties presented by the professionals have been attributed in the evaluation that were related to the lack of knowledge in assessing temperature, odor, hardening and wound bed. The study concluded that other additional clinical instruments can be used to assist in the

evaluation of these items to improve reliability (ZHONG et al., 2013).

The type and amount of necrotic tissue showed substantial agreement in this study. Similar to the amount of granulation tissue, there was greater agreement dispersion in the intervals between 25% and 75%, when it was necessary to train the professional or reformulate the interval in the two items. The identification of the type of necrotic tissue was easier even when observed in photographs, by having different colors and appearances (JESADA et al., 2013).

Regarding the evaluation of the amount and type of exudate, both presented substantial agreement; the evaluation of the amount of exudates is subjective, in the evaluation it is important to analyze whether the wound is dry, moist or with exudate extravasation, as well as look for signs and symptoms of excess such as maceration of the perilesional skin (BENBOW, 2016)

A study comparing macerated or non-macerated perilesional skin has shown that maceration evaluation was a significant predictor of wound healing and that when present it negatively affects wound area (HARYANTO et al., 2016).

In this study, besides the difficulty of evaluating the discoloration of the bed of the item "Signs of infection", the increased temperature presented a moderate reliability among the evaluators.

Studies with more objective measures that used the infrared thermometer, evaluated the perilesional skin temperature to assist in the evaluation and diagnosis of inflammation/infection of chronic wounds, the use of the thermometer does not exempt the clinical evaluation of signs of infection and the judgment of experienced professionals, because there is a possibility of differences in skin temperatures in individuals with vascular alteration and acute inflammatory process, which may confuse the evaluators (FIERHELLER; SIBBALD, 2010; BENBOW, 2016).

The evaluation of signs of local infection remains a priority for diagnosis and early intervention in the treatment of wounds, and that items such as odor and pain can only be clinically evaluated (VESTJENS et al., 2017).

One study compared the concordance of nursing examiners using a checklist of the *World Union of Wound Healing Societies*, 2008, criteria and did not obtain agreement at *wound breakdown* and slight concordance for discoloration of the bed, *bridging*, heat, malaise and lymphangitis. *Pocketing* and erythema marked fair agreement. Induration and perilesional edema presented moderate agreement.

Substantial concordance was reported in the crispy granulation tissue, delayed healing, and increased exudate. Erythema marked a statistically significant finding. Almost perfect and perfect agreement was scored for bad odor and pain. (VESTJENS et al., 2017)

The high percentage of concordance of wound breakdown, crispy granulation tissue and crackling can be explained by the consensus among the nurses or by the lack of variability of responses and knowledge of the evaluators who selected the "No" answer. Thick and fibrotic border, detachment and hyperkeratosis were more visible sub-items, which facilitated the evaluation. As for pruritus, the patient's experience was taken into consideration, because it deals with a symptom that interferes with the quality of life and can be associated with visualization of signs of skin excoriation.

The wound area also presented substantial concordance. In this study, the wound was measured with a ruler, which measured greater length by the greater width. Despite the good agreement among the nurses, it does not constitute the ideal method for evaluation. Reliability in this study may be related to the spacing of the response intervals.

In future studies, depth and area assessments may be considered, which presented moderate and substantial agreement by objective methods to improve the reliability and validity of the instrument, as well as the development of an explanatory guide with validated photographic images for evaluating instrument items before application in practice; except for items that cannot be evaluated by photographic images such as odor, adjacent skin texture, temperature increase, edema and pain dor (ZHONG et al., 2013; JESADA et al., 2013; LI; MATHEWS; ZHANG, 2018).

One study concluded that the identification of some characteristics of wounds in patients with diabetes as the presence of a devitalized tissue, depth and presence of biofilm are predictive factors of wound healing and when identified and treated early could mean fewer long-term complications such as amputations and reduction of expenses (VELLA; FORMOSA, 2017).

The agreement of some items as insignificant, regular and moderate can be justified by the variation of subjective perception. Even when evaluators have experience with wound evaluation, subjective perception can be described in other studies (LI; MATHEWS; ZHANG, 2018). The variation of the subjective perception can be improved with training of professionals before the application of the instrument.

The results of the construct validity showed a 0.573 correlation between IRFC and PUSH for evaluation of chronic wounds. The relationship analysis calculated by Pearson's correlation is sufficiently accurate to evaluate chronic wounds, with approximately the same level as PUSH.

As limitations of the study can be considered the cross-sectional design that does not allow the follow-up of patients over time, as well as the use of a convenience sample, with unequal distribution of the types of wounds.

CONCLUSIONS

The Chronic Wound Record Instrument (IRFC) is valid and reliable in relation to its content and appearance. However, further research is needed with larger samples, homogeneous distribution of lesions by different chronic etiologies, as well as longitudinal studies to evaluate the ability of the instrument to detect changes in the wound state over time and predict the necessary healing time.

In a future study, the validation of photographs can be performed, to be used as an illustrative guide to facilitate the educational process of nurses in the use of the instrument for evaluation and documentation in clinical practice, besides promoting improved reliability of some items such as damaged border, discoloration of the bed, granulation tissue and items that were not selected by the evaluators. Similarly, objective methods should be investigated to evaluate the temperature, area, depth and granulation tissue to be considered in wounds that are difficult to heal.

It is also necessary to perform the other methodological steps for semantic validation in a sample of nurses to verify the understanding, pertinence and approval of the IFRC, as well as to evaluate the need to define items of the instrument that were not chosen or insufficiently chosen. They are processes that may be necessary to consolidate the validation and reliability process of the instrument and prove its relevance in practice, research and teaching.

RESUMO: construir e validar um instrumento de avaliação e evolução de feridas crônicas. As validades de conteúdo e aparente foram apreciada por experts, a confiabilidade pela análise de concordância entre avaliadoras com uso do coeficiente de correlação intraclasse e para verificar a validade de construto foi utilizado o instrumento *Pressure Ulcer Scale for Healing*. A análise dos escores do instrumento pelo ICC apresentou correlação excelente e significativa ($K=0,914$) e para verificar a validade de construto do instrumento, o coeficiente de correlação de Pearson, cujo resultado foi de 0,573, apresentou correlação estatisticamente significativa e forte entre os escores do instrumento e o *Pressure Ulcer Scale for Healing*. A maioria das concordâncias dos itens foi classificada como moderada ou substancial. O instrumento é válido e confiável. Sugere-se estudos longitudinais em populações maiores, validação semântica em uma amostra de enfermeiros e um guia ilustrativo para padronizar conceitos afim de melhorar a avaliação das propriedades métricas.

PALAVRAS-CHAVE: Enfermagem. Cicatrização de Feridas. Estudos de Validação. Registros de Enfermagem.

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