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Scale for assessing the quality of life of women with Human Papillomavirus infection

Escala para avaliação da qualidade de vida de mulheres com infecção pelo Papilomavírus Humano

Escala para evaluar la calidad de vida de las mujeres con infección por Papiloma virus Humano

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ABSTRACT

Objectives: to develop and validate a scale for assessing the quality of life of women with Human Papillomavirus infection. **Methods:** a methodological study to develop the stages of item elaboration, apparent and content validation, semantic validation, pre-test, item allocation in domains, and reliability. **Results:** 98 items were elaborated and submitted to apparent and content validation (version 2; n=05). In semantic validation, 90.9% of women considered all items clear and understandable (version 3; n=11). In pre-test, the best applicability was in the form of a self-administered questionnaire in relation to the interview (version 4; n=38). The Exploratory Factor Analysis allocated 58 items in 6 domains; (version 5; n=351). For reliability, the general Cronbach's alpha value was 0.883. **Conclusions:** the instrument proved to be valid and reliable for assessing the quality of life of women with Human Papillomavirus infection, consisting of 54 items allocated in 6 domains.

Descriptors: Papillomavirus Infections; Quality of Life; Psychometrics; Validation Study; Women's Health.

RESUMO

Objetivos: elaborar e validar uma escala para avaliação da qualidade de vida de mulheres com infecção pelo Papilomavírus Humano. **Métodos:** estudo metodológico para desenvolvimento das etapas de elaboração dos itens, validação aparente e de conteúdo, validação semântica, pré-teste, alocação dos itens em domínios e fidedignidade. **Resultados:** foram elaborados 98 itens, os quais foram submetidos à validação aparente e de conteúdo (versão 2; n=05). Na validação semântica, 90,9% das mulheres consideraram os itens claros e compreensíveis (versão 3; n=11). No pré-teste, a melhor aplicabilidade foi no formato de questionário autopreenchido em relação à entrevista (versão 4; n=38). A Análise Fatorial Exploratória alocou 58 itens em 6 domínios; (versão 5; n=351). Para a fidedignidade, o valor do alfa de Cronbach geral foi de 0,883. **Conclusões:** o instrumento mostrou-se válido e confiável para avaliação da qualidade de vida de mulheres com infecção pelo Papilomavírus Humano, constituindo-se por 54 itens alocados em 6 domínios.

Descritores: Infecções por Papilomavírus; Qualidade de Vida; Psicometria; Estudo de Validação; Saúde da Mulher.

RESUMEN

Objetivos: desarrollar y validar una escala para evaluar la calidad de vida de mujeres con infección por virus del papiloma humano. **Métodos**: estudio metodológico para el desarrollo de las etapas de elaboración de los *ítems*, validación aparente y de contenido, validación semántica, pre-test, asignación de *ítems* en dominios y confiabilidad. **Resultados**: se elaboraron 98 *ítems*, los cuales fueron sometidos a validación aparente y de contenido (versión 2; n=05). En la validación semántica, el 90,9% de las mujeres consideró los *ítems* claros y comprensibles (versión 3; n=11). En el pretest, la mejor aplicabilidad fue en forma de cuestionario autoadministrado en relación a la entrevista (versión 4; n=38). El Análisis Factorial Exploratorio asignó 58 *ítems* en 6 dominios; (versión 5; n=351). Para la confiabilidad, el valor alfa de Cronbach general fue 0,883. **Conclusiones**: el instrumento demostró ser válido y confiable para evaluar la calidad de vida de mujeres con infección por virus del papiloma humano, compuesto por 54 *ítems* distribuidos en 6 dominios

Descriptores: Infecciones por Papillomavirus; Calidad de Vida; Psicometría; Estudio de Validación; Salud de la Mujer.

INTRODUCTION

Human Papillomaviruses (HPV) is a group that aggregates more than 200 virus subtypes, in which each subtype of this large group is called a number. Only 13 types are considered oncogenic, offering a higher probability or risk of causing persistent infections and precursor lesions. In most cases, viruses remain latent, have no symptoms and are spontaneously eliminated by the body[1-2].

According to the Information Center on HPV and Cervical Cancer (ICO), in 2019, there were 5,880,000 people infected with HPV worldwide. Of these, 2,784,000 were women over 15 years of age, among whom cervical cancer emerges as the fourth most frequent type of cancer[3]. In Brazil, in 2018, it was estimated that 54.6% of young people aged between 16 and 25 years were infected with HPV. Also, in 2020, 16,590 new cases of cervical cancer should appear, which corresponds to 16.59 cases per 100 thousand women[1,4].

HPV infects the epithelium of both sexes, but among women it causes greater and more frequent damage. According to the Centers for Disease Control and Prevention (CDC), although HPV infection is the most common Sexually Transmitted Infection (STI), cancers related to this pathogen are uncommon in men[3].

At the moment when women face being infected with HPV, several feelings arise, of which suffering, guilt, despair, worry, frustration, fear and shame stand out. Thus, assessing the quality of life (QoL) in women with HPV is an important strategy to promote interventions that contribute to improving physical, psychosocial aspects, and even that can motivate the decision to implement an effective immunization program[5].

The WHOQOL Group conceptualizes QoL as "individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns"[6]. Although there are several types of instruments in the literature for assessing general QoL, there is an insufficiency or absence of tools that measure certain variables, which underlies the construction of new instruments[7].

Therefore, developing a specific tool capable of supporting the assessment of the QoL of women with HPV is justified due to the lack of this type of instrument aimed at this clientele in Brazil.

OBJECTIVES

To develop and validate a scale for assessing the quality of life of women with Human Papillomavirus infection (EQUALI-HPV).

METHODS

Ethical aspects

The research project was approved by the Research Ethics Committee of *Escola de Enfermagem Ribeirão Preto* at *Universidade de São Paulo*. The recommendations of Resolution 466/12 of the Brazilian National Health Council (*Conselho Nacional de Saúde*) were respected.

Study design, period and location

This is a methodological study developed in a reference service for diagnosis and treatment of HPV infection and lesions induced by this virus in a teaching hospital in the state of São Paulo from November 2015 to June 2019. STROBE was used as an instrument to guide the study methodology.

Sample; inclusion and exclusion criteria

Study participants comprised experts in the theme and method of the study (n=04) and women with HPV-induced lesions in different proportions for each stage, namely: item elaboration (n=20); apparent and content assessment (n=01); semantic validation (n=11); pre-test (n=38); item allocation in domains; reliability (n=351).

Women with HPV-induced lesions who attended elective medical schedules during the data collection period with a minimum age of 18 years were included. Women with concomitant HIV/AIDS infection diagnosis were excluded from the study because it is a confounding factor due to semantics similar to the HPV name.

The diagnosis was confirmed by accessing information from medical records and with the health staff. Based on the inclusion and exclusion criteria, the sample consisted of simple convenience sampling, and women were invited to participate in the study before the previously scheduled medical consultation.

From the order of arrival at the service, on the day of the previously scheduled return, women were invited to participate in the study by researchers, oriented to the research. After signing the Informed Consent Form (ICF), the interviews were conducted. The interviews were individual, in a private environment and lasted an average of 30 minutes.

Study protocol - Construction and validation process stages

The methodological framework that motivated the instrument elaboration and validation was based on Pasquali, Fayers, Machin, Hair, and collaborators[8-13]. These authors propose sequential steps, as shown in Figure 1.

Item elaboration: item elaboration was subsidized by integrative literature review and interviews with the study population[14-15]. Then, version 1 was forwarded to five judges who were experts on the subject, who assessed the instrument for apparent and content validation. Twenty women diagnosed with HPV infection were interviewed using a semi-structured questionnaire with five questions based on the World Health Organization's QoL concept[6]. At this stage, the interviews aim to ask people who represent the population for which they want to elaborate the instrument to express their opinion about the behaviors that the construct manifests[8]. This number was reached based on the answer saturation criterion as interviews presented recurrent ideas to the object of study.

For the structuring of all items and their respective response options, the Likert scale technique was used.

Apparent and content validation: a consensual meeting was held with five expert judges on the subject and the study method being: a doctor nurse with experience in the scale method; a master nurse with experience in the QoL theme; two physicians who work in the service where data were collected, one being an infectious disease and the other a gynecologist, in addition to a representative of the population. Item analysis was performed

regarding clarity, representativeness and understanding. Content validity was quantified by content validity index (CVI). This method employs a Likert-type scale, with scores ranging from one to four, in order to verify the proportion or percentage of expert judges who have agreement on certain aspects of the instrument[16]. The alternatives were adopted: 1. item not clear; 2. unclear item; 3. clear item; 4. very clear item. At the end of this phase, EQUALI-HPV version 2 was obtained, which was subjected to semantic validation.

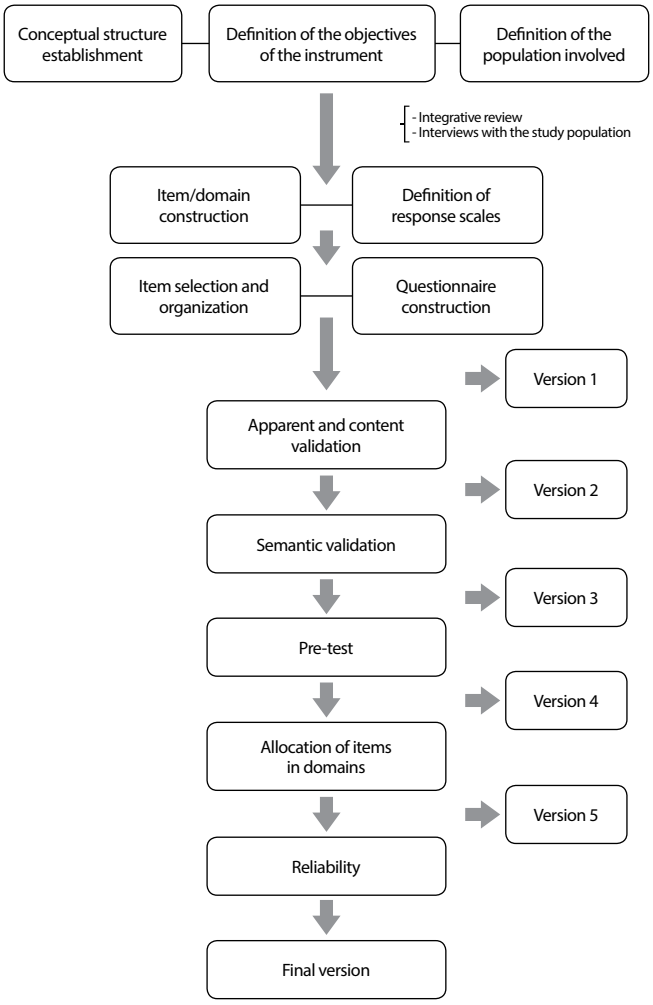

Figure 1 – Stages of instrument preparation, adapted according to Pasquali, Fayers and Machin and Hair and collaborators[8-13]

Semantic validation: this step included verifying the understanding and relevance of the instrument's items to the population for which the instrument is intended. Eleven women diagnosed with HPV infection participated in this stage. Each woman received a form to assess each item regarding the clarity of the wording and the response options, and they were asked to provide suggestions in case of change. After this stage, a pre-test was performed with version 3 of EQUALI-HPV, in order to verify the characteristics of the field of study.

Pre-test: pre-testing is an important tool to assess the feasibility, usefulness of data collection methods and carry out necessary reviews[17]. In order to verify the applicability of the instrument, at this time, EQUALI-HPV was administered in self-administered questionnaires and interviews. This phase originated EQUALI-HPV version 4, which was submitted to item allocation in their respective domains.

Item allocation in domains: this step was performed using exploratory factor analysis (EFA). This type of analysis is related to data reduction, i.e., the identification of dimensions that an instrument is measuring[11]. This step culminated with EQUALI-HPV version 5.

Reliability: reliability was verified by analyzing the internal consistency using Cronbach's alpha. This analysis is expressed in correlation of items, assessing how much the items collaborate and qualify the instrument[18]. This phase gave rise to the final version of EQUALI-HPV.

Analysis of results, and statistics

In item elaboration, the interviews were submitted to content analysis. For data analysis, full transcription was performed, which generated a textual corpus. After exhaustive reading of all reports, thematic analysis was carried out[19].

To determine the agreement of judges in content validation, the Content Validity Index for Items (CVI-I) and Average Content Validity Index for Scales (CVI-S/Ave) were assessed. CVI-I is calculated based on the number of expert judges who rated all items with answers of 3 or 4 (clear item, very clear item), divided by the total number of expert judges. CVI-S/Ave is the average of the results of I-CVIs in relation to the total number of items in the instrument[20].

The best applicability of the format if a questionnaire or interview was determined by observing the researcher regarding the difficulties in filling it out.

For the sample characterization data, descriptive statistics with measures of central tendency and dispersion were used.

For factor extraction, Unweighted Least Squares were used. As for the number of factors to be extracted, some criteria were used, such as the percentage of the explained variance, eigenvalues ≥ 1 and tests with different numbers of factors aiming at a better distribution of items. Still, items with a factor load ≤ 0.30 were excluded from the model[11,13].

For the verification of reliability, Cronbach's alpha ranges from zero to one. The closer the value is to one, the greater the consistency, i.e., the greater the reliability of the assessed instrument[18].

The data obtained were inserted and organized in Microsoft Excel® 2016 spreadsheets. IBM® SPSS software, version 20.0 was adopted for statistical analysis.

RESULTS

During the stages developed, 420 women with HPV infection were interviewed. Regarding age, the median was 36.9 (SD=11.9), with a minimum of 18 years and a maximum of 79 years. The current diagnoses of women are described in Table 1.

As for vaccination, the majority, 382 (91.0%), reported not having received a vaccination schedule against HPV. With regard to knowledge about the forms of HPV transmission, 266 (63.3%) women were unaware and 115 (32.8%) indicated the sexual route as the source of transmission.

Table 1 – Characterization of women with lesions induced by Human Papillomavirus according to the current diagnosis, Ribeirão Preto, São Paulo, Brazil, 2015-2020, (N=420)

Variables	f	%
High-grade squamous intraepithelial lesion - Cervical	307	73.1
CIN III*	200	47.6
CIN II	91	21.7
ASCH**	11	2.6
Adenocarcinoma	03	0.7
Carcinoma	02	0.5
High-grade squamous intraepithelial lesion-Vulva and Vagina	10	2.3
VIN III***	06	1.4
VAIN II****	01	0.2
VAIN III	03	0.7
Low-grade squamous intraepithelial lesion	103	24.5
Condyloma	53	12.4
CIN I	37	9.0
Atypical squamous cells of undetermined significance	08	2.0
VAIN I	05	1.1

**CIN - cervical intraepithelial neoplasm; ** ASCH - atypical squamous cells that cannot exclude a high-grade lesion; ***VIN - vulvar intraepithelial neoplasia; ****VAIN - vaginal intraepithelial neoplasia.*

Item elaboration

In the integrative review, 416 articles were found. 13 different types of instruments were identified to assess the QoL of people with HPV, nine generic and four specific, none of which were of Brazilian origin.

After conducting the integrative review, 20 women with a HPV diagnosis were interviewed. From the statements of all experiences lived by women with HPV infection, it was possible to verify situations and feelings of concern, pain during intercourse, itchy genitals, decreased pleasure, fear, ignorance, pain when performing daily activities, absenteeism from work, among others. EQUALI-HPV version 1 comprised 98 items.

Apparent and content validation

For 66 items of the instrument, changes in the wording of items were suggested by the majority of expert judges, which were accepted. In addition to the changes, 19 items were excluded and four were included. Thus, version 2 of EQUALI-HPV was composed of 83 items.

The results of CVI-Is ranged from 0.2 (item 18), 0.4 (items 11, 12, 81 and 82), 0.6 (item 14), 0.8 (items 3, 21, 52, and 92) to 1.0 (other items). Therefore, proceeding with the CVI-Ave calculation (Average CVI-I/total number of items), there is 91.6/98=0.93.

Semantic validation

For semantic validation, version 2 was applied to 11 women. At this stage, 10 (90.9%) considered the items "quite clear" and "quite understandable". Only one participant (9.1%) suggested altering the wording of item "I share my doubts, anxieties or fears that I feel regarding my HPV diagnosis with my partner (s)", becoming "I share my doubts, anxieties or fears that I feel when I am diagnosed with HPV with my partner (s)". Then, version 3, with 83 items, was submitted to pre-test.

Pre-test

In pre-test, 38 women with HPV infection diagnosis were interviewed. At the time of application of the instrument, with a view to exploring the field, 19 (50%) questionnaires and 19 (50%) interviews were applied. The average time taken to complete the questionnaires was 14.8 (SD=5.7) minutes, and in the interviews, 16.1 (SD=6.7) minutes.

Item allocation in domains – exploratory factor analysis (EFA)

Before proceeding to EFA, items 08 exclusively destined to women diagnosed with condylomatosis were excluded from the model, since the sample collected was composed of only 43 women, thus making it impossible to carry out the analyzes. Still, the 12 items related to women's knowledge regarding HPV interfered negatively with the instrument validation and were excluded. Therefore, the model submitted to EFA was composed of 63 items.

Before starting EFA, Kaiser-Meyer-Olkin (KMO) and Bartlett's Sphericity (AIC) tests were performed, obtaining, respectively, the values of 0.829 and 0.000, indicating a matrix capable of factorization. In EFA, by the eigenvalue criterion ≥ 1.00, it would be possible to extract up to 17 factors from the model. However, considering the percentage of the explained variance of 46.91% and eigenvalues ≥ 1, it was verified, by item distribution, that the model's best structure was with six factors, since, from seven factors, the items are dispersed excessively (Table 2).

Table 2 – Distribution of items according to their factor loadings with six factors, Ribeirão Preto, São Paulo, Brazil, 2015-2020, (n=351)

	Rotating factor matrix*					
	Factor					
	1	2	3	4	5	6
ITEM01	0.697					
ITEM02	0.673					
ITEM03	0.655					
ITEM04	0.653					
ITEM05	0.648					
ITEM06	0.641			0.301		
ITEM07	0.600					
ITEM08	0.589					
ITEM09	0.573					
ITEM10	0.570					
ITEM11	0.519					
ITEM12	0.510					
ITEM13	0.500					
ITEM14	0.464					
ITEM15	0.444					
ITEM16	0.346				0.328	
ITEM17	0.305					
ITEM18		0.926				
ITEM19		0.912				
ITEM20		0.909				
ITEM21		0.887				
ITEM22		0.864				
ITEM23		0.852				
ITEM24		0.583				
ITEM25		0.575				
ITEM26		0.515				
ITEM27		0.461				
ITEM28		0.418				0.320
ITEM29		0.342				
ITEM30			0.828			
ITEM31			0.775			

To be continued

Table 2 (concluded)

	Rotating factor matrix*					
	Factor					
	1	2	3	4	5	6
ITEM32	0.326		0.747			
ITEM33	0.341		0.720			
ITEM34				0.609		
ITEM35				0.576		
ITEM36				0.564		
ITEM37				0.545		
ITEM38				-0.478		
ITEM39	0.368			0.430		
ITEM40				0.422		
ITEM41				-0.405		
ITEM42**						
ITEM43**						
ITEM44**						
ITEM45					0.593	
ITEM46					0.524	
ITEM47					0.503	
ITEM48					0.472	
ITEM49					0.452	
ITEM50					0.431	
ITEM51					0.424	
ITEM52				0.305	0.414	
ITEM53	0.321				0.403	
ITEM54					-0.348	
ITEM55					0.326	
ITEM56						0.751
ITEM57						0.694
ITEM58						0.639
ITEM59						0.423
ITEM60						0.367
ITEM61						0.366
ITEM62**						
ITEM63**						

**Extraction Method: unweighted least squares; Rotation Method: Varimax with Kaiser Normalization; Converged rotation in 9 iterations; **Item excluded according to the factorial load criterion ≤ 0.30.*

All items were allocated to their respective factors and named after their contents: Factor 1: Reactions and feelings towards the diagnosis; Factor 2: Information by the Health Staff; Factor 3: Reactions to clinical examination; Factor 4: Social, family and work relationships; Factor 5: Coping with "living with HPV"; Factor 6: Social Support.

Reliability

When verifying the reliability of the 58 items through internal consistency analysis, it was observed that items 17, 36, 37 and 44 considerably compromised the scale values, therefore, choosing to exclude them. The value of EQUALI-HPV's Cronbach's alpha after excluding the items was 0.883 and the values for factors and items are shown in Chart 1. At the end of this step, the final version was composed of 54 items.

Chart 1 – Distribution of Cronbach's alpha values by factors and items and the instrument, Ribeirão Preto, São Paulo, Brazil, 2015-2020, (n=351)

Factor	Items	Cronbach's alpha if an item is deleted
Factor 1 0.903	1- I have a lack of appetite after being diagnosed with HPV	0.889
	2- I have trouble sleeping after being diagnosed with HPV	0.889
	3- I have negative feelings, such as anxiety and/or depression due to HPV	0.895
	4- I am afraid of not curing myself from HPV	0.898
	5- I feel judged for having HPV	0.902
	6- I am afraid of dying as a result of HPV diagnosis	0.897
	7- I feel less pleasure in sex after HPV diagnosis	0.893
	8- Concern with HPV diagnosis deconcentrates me from activities at work (be it formal or informal work)	0.899
	9- I feel pain related to HPV infection when performing daily activities	0.897
	10- I feel physical discomfort related to HPV infection	0.898
	11- I feel an itchy anus and/or vagina related to HPV infection	0.898
	12- HPV infection changes my way of living	0.899
	13- I feel disinterested in maintaining an emotional relationship after HPV diagnosis	0.894
	14- I feel worried during intercourse	0.893
	15- I avoid having sex due to my HPV diagnosis	0.893
	16- The frequency of my sexual relations changed after HPV diagnosis	0.894
	17- I receive information about condom use during sexual intercourse after HPV diagnosis	0.903
Factor 2: 0.924	18- I receive information about the risks of being a carrier and of worsening HPV	0.926
	19- I receive information from the physician about my diagnosis	0.911
	20- I receive information from the nurse about my diagnosis	0.912
	21- I receive information from the medical staff about my diagnosis	0.909
	22- I receive information from the physician about my treatment	0.910
	23- I receive information from the nurse about my treatment	0.912
	24- I receive information from the medical staff about my treatment	0.910
	25- I am open to clarify doubts with the physician who assists me	0.921
	26- I am open to clarify doubts with the nursing staff that assists me	0.921
	27- I clarify the doubts I have about HPV with the physician who assists me	0.927
	28- I feel satisfied with my medical treatment	0.926
	29- I feel welcomed by the health staff that assists me	0.929

To be continued

Chart 1

Factor	Items	Cronbach's alpha if an item is deleted
Factor 3: 0.904	30- I feel afraid when being examined by the physician	0.889
	31- I feel afraid when being examined by the nurse	0.869
	32- I feel ashamed when I am examined by the physician	0.869
	33- I feel ashamed when I am examined by the nurse	0.877
Factor 4: 0.776	34- I feel isolated by other people due to HPV diagnosis	0.785
	35- I stop being with the people I like because of HPV diagnosis	0.743
	36- I am assisted by the psychologist	0.637
	37- I am assisted by the social worker	0.669
	38- I fail to perform leisure/recreation activities (walks, church, gym) due to HPV diagnosis	0.748
	39- My daily work has changed due to HPV diagnosis	0.725
	40- The relationship with my co-worker (s) changed after the discovery of my HPV diagnosis	0.740
	41- The relationship with family members changed after the discovery of my HPV diagnosis	0.716
Factor 5: 0.772	42- I'm ashamed to say that I have HPV	0.761
	43- I am afraid that HPV will interfere with my ability to have children	0.768
	44- Absence from work due to HPV treatment	0.773
	45- I am afraid that my partner will break the affective relationship due to my HPV diagnosis	0.746
	46- I feel less desired by my partner (s) due to my HPV diagnosis	0.759
	47- I am concerned about the risk of transmitting HPV to my partner (s)	0.761
	48- I think I was deceived by my partner (s) for acquiring HPV	0.746
	49- I feel angry towards my partner because of the possibility that he transmitted HPV to me	0.746
	50- I consider myself guilty for having acquired the HPV virus	0.751
	51- I feel uncomfortable with my image	0.752
	52- I feel insecure in my affective relationship with my partner after HPV diagnosis	0.740
Factor 6: 0.764	53- I have support from my family members regarding HPV diagnosis	0.735
	54- I get all the support I need from my friends in the face of HPV diagnosis	0.766
	55- I share the HPV diagnosis with a member of my family	0.752

To be continued

Chart 1 (concluded)

Factor	Items	Cronbach's alpha if an item is deleted
Factor 6: 0.764	56- I receive from my partner (s) all the support I need when diagnosing HPV	0.711
	57- I share my doubts, anxieties or fears I feel about my HPV diagnosis with my partner (s)	0.695
	58- I share information about HPV diagnosis with my partner (s)	0.712

T.N. - as this instrument was not validated for English, a free translation of all items was performed.

DISCUSSION

This study presented the process of preparing and validating EQUALI-HPV. Regarding the characterization of the women involved in this study, similar characteristics were observed in another instrument validation survey to measure QoL in patients with genital warts[21]. As for vaccination, most women reported not having received an HPV vaccination schedule. This is probably related to the fact that free HPV vaccination in Brazil started in 2014, and, by age, according to the Brazilian National Immunization Program (*Programa Nacional de Imunização*), these women were not eligible[22].

Concerning diagnosis, most women had a high-grade squamous intraepithelial lesion (HSIL) (cervical, vulva and vagina) and a small portion had a low-grade squamous intraepithelial lesion (LSIL). A similar result was observed in an American study that developed an instrument to determine the psychosocial impact of HPV infection and related interventions[23]. With regard to knowledge about the forms of HPV transmission, most participants reported not knowing and a part of them indicated the sexual route as the source of transmission. In contrast to this finding, an investigation carried out in Ipatinga, MG with 591 individuals found that the vast majority of respondents 93.2% said they knew how the virus is transmitted[24].

Measurement instruments are essential for clinical practice with regard to the health assessment process and research. However, only if they are developed reliably and with satisfactory psychometric criteria can they perform their functions in providing concrete scientific results. In addition, different resources can be used in item preparation of an instrument, such as basing existing questionnaires, research in the scientific literature, experience of the study population, prior knowledge of specialists, research and theories developed, among others[25].

In agreement with the described aspects, elaborating EQUALI-HPV items followed a systematic process using an integrative literature review, in addition to interviews with the study population. Conducting an integrative review has been presented as one of the main scientific strategies for developing measurement instruments, with the purpose of explaining to the researcher about the characteristics of the existing instruments[26]. Interviews aim to ask people representing the population for which it is desired to develop the instrument to express their opinion about the behaviors that the construct manifests. From the interviews, a great wealth of reactions can emerge that manifest assertiveness, which can be used as instrument items[8].

The apparent and content validity was carried out with expert judges on the theme, with the participation of a representative of the study population. To compose the committee, the selection of judges must consider members' experience and qualification. The insertion of lay people gives the possibility to correct phrases and terms that are not very clear[27].

Regarding agreement among judges, the CVI-Ave result was 0.93. A similar result was demonstrated in a study on an instrument development and validation on the production of nursing care that obtained a CVI-Ave above 0.9[28].

There were minor changes in the wording of an item of semantic validation. Assessment by the target population is not intended to carry out statistical procedures, but rather to assess item adequacy and the instrument's structure. If items are clear according to reality, or are not well written, it should be suggested that participants provide synonyms for a better understanding of the vocabulary[29].

In relation to pre-test, with regard to using self-administered questionnaires and interviews, it was possible to verify situations of limitations as to their applicability, especially in relation to time, since the interviews have better applicability, but they consume more time on the part of the interviewer. Such a situation was also described in a study that pointed out as limitations, in addition to time, the influence that the researcher may have, consciously or unconsciously, on the interviewee, which may lead to the provision of false answers or obstruction of relevant data[30].

Right after pre-test, the instrument must be applied to a sample of adequate size to perform the EFA technique. At least 100 individuals are required to perform EFA. In this study, 351 women participated in this stage[9]. EFA was also used in a study that aimed to develop an instrument that addressed important aspects of female sexual function, the Sexual Function Questionnaire (SFQ)[31].

The reliability measured by Cronbach's alpha showed a satisfactory result. Values greater than 0.70 are expected, not to exceed 0.95[32]. The value of Cronbach's alpha for EQUALI-HPV domains ranged from 0.76 to 0.92. A similar result was found in a study, in which the Cronbach alpha of its seven domains ranged from 0.69 to 0.90[31].

Therefore, EQUALI-HPV is a valid and reliable instrument to assess QoL in women with HPV infection, considering aspects related to health, physical and psychosocial well-being, affective-sexual and environmental.

Study limitations

The limitation of this study is located in data collection performance in only one place that, despite being a reference center for several municipalities and even states, does not favor the heterogeneity of the sample.

Contributions to nursing, health, and public policies

It is believed that using this instrument will bring benefits to the health field, mainly to women with HPV, since it will make it possible to identify relevant characteristics of this population in terms of not only physical, but also psychological, environmental, social, sexual and affective, thus favoring greater interaction with multidisciplinary staff that assists them through access to this information.

CONCLUSIONS

This study made it possible to complete the stages of item elaboration, apparent and content validation, semantic validation, pre-test, item allocation in domains and reliability with satisfactory results from EQUALI-HPV.

EQUALI-HPV proved to be valid and reliable for assessing the QoL of women infected with HPV, consisting of 54 items allocated in 6 domains, namely: 1: Reactions and feelings towards diagnosis; 2: Information by the Health Staff; 3: Reactions to clinical examination; 4: Social, family and work relationships; 5: Coping with "living with HPV"; 6: Social Support.

It is worth mentioning that EQUALI-HPV consists of a tool built and validated in a specialized setting in the care of women with HPV infection, showing that it is a specific Brazilian scale to assess this construct. Future studies with other psychometric tests should be considered in order to proceed with the validation process of this instrument.

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ADDITIONAL MATERIAL

The data in this manuscript come from the Doctoral thesis of the author Natália Maria Vieira Pereira Caldeira available in the Data Repository through the link https://doi.org/10.11606/T.22.2020.tde-18032021-095614.

ERRATUM

Article "Scale for assessing the quality of life of women with Human Papillomavirus infection", with number of DOI: https://doi.org/10.1590/0034-7167-2020-0698, published in the journal Revista Brasileira de Enfermagem, 74(6): e20200698, on the front page:

Where to read:

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Read:

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