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ORIGINALES

Validation of the instrument: knowledge, beliefs and acceptance of the human papillomavirus vaccine

Validación del instrumento: conocimientos, creencias y aceptación de la vacuna del virus del papiloma humano

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ABSTRACT:

Introduction: The human papilloma virus (HPV) is the leading cause of cervical cancer. Having an instrument that measures the acceptance of the HPV vaccine, as well as the factors involved in the acceptance process, is an urgent need for HPV prevention. The objective was to validate the knowledge, beliefs, and acceptance of the human papillomavirus vaccine instrument.

Materials and Methods:

The validation process was carried out through a descriptive, cross-sectional study and a two-phase process. The population consisted of 393 mothers of girls between the ages of 9 and 11 years, belonging to the State of Puebla, with a non-probabilistic sampling for convenience; the sample was considered at a ratio of 10: 1.

Results: A valid and reliable instrument was obtained with a Cronbach's Alpha of .70, a value of p <.000 for Bartlett's sphericity test, and .82 for the KMO test. In this sense, the factor analysis resulted in a total of 40 items divided into six dimensions.

Discussion: The methodological process allowed to have an empirical indicator adapted and validated for the Mexican context, since it is the only one within the context that measures the factors related to the acceptance of the HPV vaccine.

Conclusion: We conclude that having an empirical indicator adapted to the Spanish language, which measures acceptance and related factors, is a contribution of great importance to society and an advance in nursing science.

Key Words: Validation, knowledge, beliefs, acceptance, Human papillomavirus, vaccine.

RESUMEN:

Introducción: El virus del papiloma humano es la primera causa de cáncer cervicouterino, contar con un instrumento que mida la aceptación de la vacuna del VPH, así como los factores que intervienen, es una necesidad para la prevención del VPH. El objetivo fue realizar la validación del instrumento conocimientos, creencias y aceptación de la vacuna del virus del papiloma humano.

Materiales y Métodos:

El proceso de validación se realizó a traves de un estudio descriptivo, transversal y de proceso de dos fases. La población fue de 393 madres de niñas de 9 a 11 años, pertenecientes al Estado de Puebla, con un muestreo no probabilístico por conveniencia, la muestra se consideró por razón de 10:1.

Resultados: Se obtuvo un instrumento válido y confiable con un coeficiente de Alfa de Cronbach de .70, un valor de p<.000 para la prueba de esfericidad de Bartlett y la prueba de Kaiser-Meyer Olkin obtuvo un resultado de .82, en este sentido el análisis factorial dio como resultado un total de 40 ítems divididos en seis dimensiones.

Discusión: El proceso metodológico permitió contar con un indicador empírico adaptado y valido al contexto mexicano, debido a que es el único dentro del contexto que mide los factores relacionados con la aceptación de la vacuna del virus del papiloma humano.

Conclusión: Se concluye que tener un indicador empírico adaptado al idioma español, que mida la aceptación y los factores relacionados, es un aporte de gran importancia para la sociedad y un avance para la ciencia en enfermería.

Palabras clave: Validación, Conocimientos, Creencias, Aceptación, Virus del Papiloma Humano, Vacuna.

INTRODUCTION

The World Health Organization ⁽¹⁾ reported that the prevalence of human papillomavirus (HPV) in women is 11.7%. More than 100 types are derived from this Sexually Transmitted Infection (STI), of which, 14 have an oncogenic load and have been classified into high-risk genotypes (16 and 18), responsible for 70% of cervical cancer (CC), and low-risk genotypes (6 and 11), responsible for anogenital warts ⁽²⁾. In Latin America, HPV prevalence is 16.1%, and the situation is no different in Mexico, with a prevalence in women of 14.4%, where the highest peaks occur between 25 and 65 years of age and the genotypes found are of high risk and the leading cause of $CC^{(3,4)}$.

As a result, in Mexico, the vaccine for the prevention of HPV (bivalent and quadrivalent) has been administered free of charge since 2008 to girls between 9 and 11 years old $^{(5,6)}$; however, the coverage was of 16% $^{(7)}$. Different studies identify a lack of acceptance of the HPV vaccine by mothers of girls due to social, economic, cultural, and educational aspects $^{(8-10)}$.

In this sense, it is fundamental to have evaluation instruments that allow to measure the acceptance of the HPV vaccine ⁽¹¹⁾. After a literature review, we identified some empirical indicators in the Mexican context that measure the general knowledge about the HPV vaccine but which do not consider the variables that affect the acceptance process; for example, the questionnaire "HPV and your health" by Medina-Fernández et al.⁽¹²⁾, which consists of 40 items, of which, 8 consider general information about the vaccine. We also identified the one proposed by Xolocotzi-Morales, Marín-Laredo, Gómez-Alonso and Valenzuela-Gandarilla⁽¹³⁾, "Knowledge about prevention of the human papillomavirus infection", with 38 items, of which, 8 evaluate the knowledge about the HPV vaccine, and the questionnaire "Of vulnerability to the human papillomavirus" by Sepúlveda, Meneses and Goldenberg⁽¹⁴⁾, with 36 items, of which, only two address the acceptance of the vaccine.

The instruments mentioned above do not consider a measurement of the acceptance of the HPV vaccine. According to Galbraith et al.⁽¹⁵⁾ and Grandahl et al.⁽¹⁶⁾, apart from

knowledge about the vaccine, it is also necessary to integrate the interpersonal influences, beliefs, benefits of preventing HPV infection, and barriers that arise from concerns about events supposedly attributable to vaccination and immunization (ESAVI), which are factors that influence the acceptance process of the HPV vaccine.

Considering this, it is necessary to have an empirical indicator that allows to measure the factors mentioned above within the Mexican context and for it to be valid and reliable in order to be used in the target population, which will have an impact on social welfare and an advance in nursing science. Thus, the objective of the present study was to culturally adapt and validate the instrument proposed by Grandahl et al.⁽¹⁷⁾ called "Parents' knowledge, beliefs, and acceptance of the HPV vaccination for their daughters in Thailand".

MATERIALS AND METHODS

We carried out the Translation, Cultural Adaptation, and Validation (TCAV) process proposed by Ramada-Rodilla, Serra-Pujadas, and Delclós-Clanchet⁽¹⁸⁾, which is necessary in order to use measuring instruments developed in other countries.

The process was carried out in two phases. The first one (translation and cultural adaptation) consisted of 5 steps. For the first step, a translation from English to Spanish was done in order to maintain the structure of the instrument (semantic and conceptual equivalence). Two translators (A and B) participated in this step: translator A was Hispanic, their second language was English, was familiar with the objectives and concepts of the instrument, and had experience translating technical texts; and translator B was Anglo-Saxon, their mother tongue was English, and did not have knowledge about the concepts and objectives of the instrument.

In the second step, we analyzed the translations made by translators A and B and decided to make a summary and integrate a first Spanish version of the instrument. In the third step, a reverse or back-translation was performed by two translators (C and D), who were bilingual professionals with expertise in text translation, their mother tongue was Spanish, and were unfamiliar with the concepts and objectives of the questionnaire or the first version. We did not find any conceptual or semantic differences between the original and first version of the questionnaire.

The fourth step consisted in integrating a committee of seven experts on sexual health and human papillomavirus and one linguist, who received via email the instrument and an evaluation form to determine the content validity. The form consisted of a Likerttype response scale with a five-point scoring system (0 = Definitely not related, 1 = Not related, 2 = Not sure of its relationship, the item requires further review, 3 = Related, but minor modifications are necessary, 4 = Extremely related, no alteration). When contrasting, performing, and analyzing the scores and contributions by each expert, we obtained a pre-final version adapted to Spanish which was easy to understand and use.

In the fifth step, we conducted a pilot test with 40 mothers from the state of Puebla, which allowed to evaluate the equivalence, applicability, and comprehension of the items. We then conducted a final test with a descriptive, cross-sectional design with 393 mothers of girls between 9 and 11 years old from the state of Puebla, where we

considered a ratio of 10:1 for sample size, that is, 10 participants per question ⁽¹⁹⁾, and used non-probabilistic sampling for convenience. The data were collected virtually using the platform Google Forms. We obtained the authorization of the participants through an informed consent form which explained the purpose of the study, stating that participation was voluntary and confidential. The research project was approved by the Research and Graduate Studies Committee of the Facultad de Enfermería-BUAP, registration number SIEP/035/2021. The study complied with the Regulations of the General Health Law on Research ⁽²⁰⁾.

The second phase consisted in the validation of the instrument using Cronbach's alpha coefficient test in SPSS version 24, which allowed to evaluate the internal consistency of the instrument. We also performed a factor analysis for data reduction and to find homogeneous groups of variables (See Figure 1).



Figure 1: Cultural adaptation and validation of the instrument

Source: Created by the authors

RESULTS

We obtained a sample of 393 mothers of girls between 9 and 11 years old from the state of Puebla, where the mean age was 36.39 years (SD 6.903), 34.1% had a bachelor's degree, 38.1% declared to be employed, more than half of the participants were married (53.7%), and 53.2% had a daughter with a mean age of 11 years (SD 6.13). The main religion was Catholicism with 84.2% of participants, which was very important to 51.4%, and 46.8% had a monthly family income between MXN\$3,000 and MXN\$10,999. With respect to the health behavior of the mothers, 61.3% consumed alcohol from time to time and 19.4% smoked (Table 1).

Table 1						
Distribution of the h	ealth behavi	or of the mothers.				
Variable	Frequency					
	Yes, all	Only some	No	Not sure		
Vaccination schedule	72.5%	16.8%	7.9%	2.8%		
	Frequency					
	Yes	Νο	l do not know	Not applicable		
Abnormal Pap smear result	22.1%	60.8%	5.6%	11.5%		
		Frequency				
	Yes, mother	Yes,	Yes,			
		maternal/paternal	maternal/paternal	No		
		grandmother	aunt			
History of CC	2.8%	6.6%	4.1%	85.8%		
	Frequency					
	Every	Every 2 to 4	Every 5 years	Never		
	year	years				
Doctor visit	72%	17.8%	2.5%	7.6%		
Pap smear test	43.5%	23.9%	11.2%	21.4%		

Source: Created by the authors

According to the content validation of the instrument, once we obtained the first Spanish version of the questionnaire from the translation and back-translation, which had a total of 47 questions divided into 6 dimensions, we sent it for review by expert judges in topics of sexuality and sexual health and a linguist. The judges answered a Likert-type scale instrument that allowed to evaluate the consistency of each item. We also applied the content validity ratio proposed by Lawshe (1975), which allows to obtain a score for each question, as well as the index proposed by Davis (1992), where a value higher than .80 indicates that the items are adequate within the instrument ⁽²¹⁾; we obtained a value of .89, which is an acceptable score for internal validity, and also obtained a score for each dimension, shown in Table 2.

Table 2	
Content validity of items for each dimension	
Dimension	Score
Dimension 1. General information about HPV	.90
Dimension 2. Beliefs about HPV and the vaccine	.89
Dimension 3. Information mechanisms of HPV vaccine	.92

Dimension 4. Benefits of HPV vaccine	.85
Dimension 5. Barriers of HPV vaccine	.92
Dimension 6. Acceptance of HPV vaccine	.86
Source: Created by the authors	

Once we obtained the content validity, we made the changes proposed by the experts. We changed the writing of item 27, where we replaced the word "condyloma" with "genital warts", which allowed a better understanding of the item. In addition, the writing by the linguist was adapted to the target population. This is how we obtained the second version of the instrument, which was subjected to a piloting process with 40 mothers. The obtained data showed that seven items in dimension two of "knowledge about HPV and the vaccine" were confusing, did not provide a statistical contribution to the scale, and reduced the internal consistency of the items; thus, these items were removed. We also changed the writing of the items of the dimension "benefits of the HPV vaccine" because they showed inconsistency with respect to the evaluation of the scale and were not understood by the participants.

After making the changes derived from the pilot test, we obtained an instrument that consisted of 40 questions divided into six dimensions. For the factor analysis ⁽²²⁾ of the data obtained from the final test, we used Bartlett's sphericity test and the Kaiser-Meyer-Olkin (KMO) test for sampling adequacy; the results show a significant correlation between the items and the instrument (X^2 = 7346.71; *g*|= 10; *p*=.000).

The results of the factor analysis show six factors (dimensions) that explain 64.87% of the total variance.

The first dimension corresponds to general information about HPV (items: 9, 10, 11, 12, 13, 14, and 15), considers attributes about ways of transmission and HPV signs and symptoms, and the results of Bartlett's sphericity test and the KMO test were significant (X^2 = 177.37; *gl*= 21; *p*=.000), with a total explained variance of 45.3%.

The second identified dimension corresponds to beliefs about HPV and the vaccine (items: 16, 17, 18, 19, 27, 28, 29, 30, and 31) and the results of Bartlett's sphericity test and the KMO test were significant (X^2 = 947.70; g/= 36; p=.000), with 64.1% of the total variance explained.

The third integrated dimension corresponds to information mechanisms of the HPV vaccine (items: 1, 2, 3, 4, 5, 6, 7, and 8) and considers attributes about receiving information from friends, family, school staff, doctor/nurse, and the media. In this case, Bartlett's sphericity test and the KMO test were also significant (X^2 = 1842.96; *g*/= 91; *p*=.000), with 61.5% of the total variance explained.

The next dimension refers to benefits of the HPV vaccine (items: 20, 21, and 22) and showed significant results for Bartlett's sphericity test and the KMO test (X^2 = 310.83; g/= 3; p=.000), with 66.6% of the total variance explained.

The dimension of barriers of the HPV vaccine (items: 23, 24, 25, 26, 39, and 40) considers attributes about lack of information and effects of the vaccine, and the results of Bartlett's sphericity test and the KMO test were significant (X^2 = 516.28; *g*|= 15; *p*=.000), with 61.4% of the total variance explained.

Finally, the dimension of acceptance of the HPV vaccine (items: 32, 33, 34, 35, 36, 37, and 38) considers attributes about the cost of the vaccine and the results of Bartlett's sphericity test and the KMO test were significant (X^2 = 2187.10; *gl*= 21; *p*=.000), with 81.6% of the total variance explained.

Considering this order of ideas and once the changes were made, we determined the reliability of the instrument using Cronbach's alpha coefficient, which indicates the level of correlation between the variables as well as the internal consistency of the scale. This measure uses values between 0 and 1, where values closer to 1 indicate higher consistency and the minimum accepted value is $.70^{(24)}$. Thus, after analyzing the questionnaire by dimensions and as a whole, we obtained a Cronbach's alpha coefficient of .70, indicating an acceptable internal consistency (Table 3).

Table 3

Cronbach's alpha coefficient by dimension

Dimension	Score
Dimension 1. General information about HPV	.60
Dimension 2. Beliefs about HPV and the vaccine	.58
Dimension 3. Information mechanisms of HPV vaccine	.80
Dimension 4. Benefits of HPV vaccine	.74
Dimension 5. Barriers of HPV vaccine	.74
Dimension 6. Acceptance of HPV vaccine	.90
Total	.70

Source: Created by the authors

DISCUSSION

The purpose of the present study was to carry out a cultural adaptation and validation of the instrument mentioned in the previous sections, since we did not identify any instrument measuring the factors associated with the acceptance of the HPV vaccine within the Mexican context ^(16,17). In this sense, the objective was met using the methodology proposed by Ramada-Rodilla et al.⁽¹⁸⁾. Four experts carried out the translation and back-translation of the instrument, which agrees with the work by Viera, Ching and Gir⁽²⁵⁾, who mention that using four experts increases the validation and semantic consistency of the questions in the target language.

Similarly, the evaluation by the committee of seven experts allowed to obtain a better analysis and understanding of the items. This agrees with Viera et al.⁽²⁵⁾ and Guimarães, Haas, Spadoti, Dos santos and Galvao⁽²⁶⁾, who show that using committees of judges of five or seven experts allows to evaluate the cultural, semantic, and conceptual equivalence of the instrument and its content validity. Díaz, Durán and López⁽²⁷⁾ obtained values of .56 in their first evaluation, compared to the results of the present study with values higher than .85 for each dimension and the whole instrument, which indicates a valid and easy-to-use instrument in the target language.

We also found that the use of a pilot test allows to evaluate the comprehension of the questions and identify errors, as mentioned by López-Ramírez et al.⁽²⁸⁾, since this process allowed to improve the items that were not understood by the population and there were areas of opportunity that allowed to improve the internal consistency of the questionnaire. It is important to note that the piloting process should involve

participants with similar characteristics to those of the target population. Thus, performing the test with 40 mothers allowed to restructure, change, and eliminate the items that were confusing to the participants. The results of the pilot test allowed to carry out the final test, where a number of participants higher than 200 (393 mothers) resulted in a favorable and accurate factor analysis, as mentioned by Guimarães et al.⁽²⁶⁾.

In this sense, the results of Bartlett's test and the KMO test agree with that found by Guimarães et al.⁽²⁶⁾, who report values of *p*<.05 and KMO values higher than .80. Furthermore, the factor analysis by Fraguas, Vietto, Arceo, Vázquez and Durante⁽²⁹⁾ showed results similar to those in the present study, since these authors originally considered 5 factors that were reduced to 3 after the factor analysis, and in the present study, the author ⁽¹⁷⁾ considered six dimensions that were confirmed when ordering the questions according to the identified factors. Finally, the reliability analysis using Cronbach's alpha coefficient agrees with that reported by López-Ramírez et al.⁽²⁸⁾, who mention that a value of .70 indicates an acceptable instrument that can be applied to a population in a Mexican context.

CONCLUSIONS

The cultural adaptation and validation of the instrument of knowledge, beliefs, and acceptance of the HPV vaccine is aimed at mothers in the Mexican context, since they are the main decision-makers regarding their family's health and influence the health behavior of their daughters. Having a valid and reliable instrument is a necessary and useful tool for the nursing staff, since it allows to evaluate the factors that influence the acceptance of the HPV vaccine, such as beliefs, interpersonal influences, benefits, and perceived barriers. The use of this tool along with nursing theory ⁽³⁰⁾ allows to propose reference points in order to address these issues with the target population and to propose behavioral changes for mothers that will have an impact on family health. In this sense, having an instrument allows nursing science to continue to expand and take into account factors that involve mothers' acceptance behavior regarding vaccination. This also allows the nursing staff to take the lead in the prevention of STIs, which are a serious health problem at a global and national level and will have a positive impact on the health of girls in Mexico.

Finally, the limitations of this study are that we used a non-probabilistic sampling for convenience, since we used a sample with a ratio of 10:1, that is, 10 participants per question, and thus the conclusions apply to similar populations. In addition, it was conducted at a particular point in time.

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