

## Sample taking for identification of papillomavirus DNA: skills and knowledge

Coleta de amostra para identificação de DNA do papilomavírus: conhecimento e habilidades

Toma de muestra para identificación de ADN del papilomavirus: conocimiento y habilidades

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Health personnel; Health Knowledge, attitudes, practice; Uterine cervical neoplasms; Papillomavirus infections; Health evaluation

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### Abstract

**Objective:** To establish the relationship between the knowledge and skills of health personnel in taking samples for the identification of papillomavirus DNA.

**Methods:** Cross-sectional study, conducted between March and June of 2017. Population of 313 people, the probabilistic sample was calculated considering a  $r = 0.306$  expected, 95% confidence, and power of 90%, which equated to 90 workers from 23 health centers. A knowledge test and checklist were administered to evaluate sampling skills, with the hybrid capture method (HPV-CH2 test). For data analysis, Pearson's and the ANOVA correlation were used. Results: A correlation between knowledge and skills was found ( $r=0.438$ ) ( $p<0.001$ ). Regarding knowledge, there was no significant difference in the means obtained from the three groups of participants (nurses vs. interns 3.27  $p=0.557$ , physicians vs. nurses 2.17  $p=0.852$ , physicians vs. interns 5.45  $p=0.441$ ). Regarding skills, there was no difference between the means obtained between physicians and nurses (4.27  $p=0.388$ ), nor between nurses and interns (4.54  $p=0.179$ ), but there was a difference between physicians and interns (8.81  $p=0.041$ ).

**Conclusion:** There was a correlation between the knowledge and skills in taking samples for the identification of papillomavirus DNA. There were no significant differences in knowledge between the groups studied; but a difference in means for skills was found between physicians and interns.

### Resumo

**Objetivo:** Estabelecer a relação entre o conhecimento e as habilidades dos profissionais da saúde em coletar amostras para a identificação do DNA do papilomavírus.

**Métodos:** Estudo transversal, realizado entre março e junho de 2017, com uma população de 313 pessoas. A amostra probabilística foi calculada considerando um  $r=0,306$ , 95% de confiança e poder de 90%, equivalente a 90 trabalhadores de 23 centros de saúde. Um teste de conhecimento e um *checklist* foram administrados para avaliar as habilidades na coleta de amostra utilizando o teste de Captura Híbrida 2 (teste HPV-CH2). Para análise dos dados, foi utilizada a correlação de Pearson e ANOVA.

**Resultados:** Foi encontrada uma correlação entre conhecimento e habilidades ( $r=0,438$ ) ( $p<0,001$ ). Quanto ao conhecimento, não houve diferença significativa nas médias obtidas nos três grupos de participantes (enfermeiros versus estagiários 3,27  $p=0,557$ , médicos versus enfermeiros 2,17  $p=0,852$ , e médicos versus estagiários 5,45  $p=0,441$ ). Quanto às habilidades, não houve diferença entre as médias obtidas entre médicos e enfermeiros (4,27  $p=0,388$ ), nem entre enfermeiros e estagiários (4,54  $p=0,179$ ), mas houve diferença entre médicos e estagiários (8,81  $p=0,041$ ).

**Conclusão:** Houve correlação entre o conhecimento e as habilidades em coletar amostras para a identificação do DNA do papilomavírus. Não houve diferenças significativas no conhecimento entre os grupos estudados, mas uma diferença em relação às habilidades foi encontrada entre médicos e estagiários.

### Resumen

**Objetivo:** establecer la relación entre el conocimiento y las habilidades de los profesionales de la salud para tomar muestras para identificación del ADN del papilomavirus.

**Métodos:** estudio transversal realizado entre marzo y junio de 2017, con una población de 313 personas. El muestreo probabilístico fue calculado considerando un  $r=0,306$ , 95% de confianza y poder de 90%, equivalente a 90 trabajadores de 23 centros de salud. Se aplicó una prueba de conocimiento y una *checklist* para evaluar las habilidades de toma de muestra utilizando la prueba de captura de híbridos 2 (prueba HPV-CH2). Para el análisis de datos se utilizó la correlación de Pearson y ANOVA.

**Resultados:** se encontró una correlación entre conocimiento y habilidades ( $r=0,438$ ) ( $p<0,001$ ). Con relación al conocimiento, no hubo diferencia significativa en los promedios obtenidos en los tres grupos de participantes (enfermeros versus practicantes 3,27  $p=0,557$ , médicos versus enfermeros 2,17  $p=0,852$  y médicos versus practicantes 5,45  $p=0,441$ ). Respecto a las habilidades, no hubo diferencia en los promedios obtenidos entre médicos y enfermeros (4,27  $p=0,388$ ), ni entre enfermeros y practicantes (4,54  $p=0,179$ ), pero hubo diferencia entre médicos y practicantes (8,81  $p=0,041$ ).

**Conclusión:** hubo correlación entre el conocimiento y las habilidades para tomar muestras para identificar el ADN del papilomavirus. No hubo diferencias significativas en el conocimiento entre los grupos estudiados, pero se encontró una diferencia con relación a las habilidades entre médicos y practicantes.

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## Introduction

Cervical cancer (CC) is the fourth neoplasia worldwide; the highest incidence rate is found in regions of East Africa (42.7%). In Latin America there is an incidence of 21.2 %. In Mexico, during 2014, 4,056 women died of CC, representing a mortality rate of 11.9%.<sup>(1)</sup> In the State of San Luis Potosí (SLP), Mexico, 78 cases of death were reported in the same year, representing a rate of 10.6 %. In the first four months of 2016, 21 new cases and 25 deaths were reported in SLP, which affects mainly the poorest and most vulnerable women, with a negative impact on their families and communities.<sup>(1,2)</sup> The Human Papilloma Virus (HPV) is associated as an etiologic agent in almost 100% of cases of CC.<sup>(3-6)</sup> This condition is considered a priority health problem, since the possibilities of cure are directly proportional to the precocity of the diagnosis, and the initiation of appropriate treatment.<sup>(7)</sup>

The development of molecular tests represents a tool of great value, given that its contribution in primary screening has been proven, which is why its incorporation is part of current international guidelines.<sup>(3,8)</sup> In the Mexican Ministry of Health, the hybrid capture test was implemented to identify the deoxyribonucleic acid (DNA) of HPV as of 2009, which modified the protocol to a combined screening model (HPV, or papillomavirus test and cervical cytology, or Papanicolaou).<sup>(9)</sup> Quality control in conducting these tests is very important, because in Mexico most detections are performed by nurses; therefore, performance evaluation of the service provider is essential to increase the quality of processes. It has been documented that two-thirds of diagnostic errors in gynecologic cytology are due to problems in obtaining the specimen, with the remaining third occurring in the microscopic interpretation.<sup>(10)</sup>

Regarding the quality of screening for early detection of cervical cancer, SLP in Mexico has reported findings related to training service providers. One example is that health personnel do not always have the knowledge and skills necessary for the sampling procedure to be efficient, leading to failures that affect the entire care system and thus, a delay

in early detection of precancerous lesions.<sup>(11,12)</sup> The objective of this study is to establish the relationship between the knowledge and skills of health personnel in obtaining samples for the identification of papillomavirus DNA in Sanitary Jurisdiction Number 1 of the Health Services of SLP, Mexico.

## Methods

This was a cross-sectional, correlational study conducted between March and June of 2017, in a health jurisdiction that groups 23 health centers belonging to the Sanitary Jurisdiction Number 1 of the Health Department of San Luis Potosí (SSSLP), Mexico. The population consisted of 313 people whose function is to obtain samples for the detection of papillomavirus DNA through the molecular biology method: capture of hybrids (Hibryd Capture® 2 or HC2). The sample was calculated using the Epidat program, to estimate the correlation coefficient,  $r = 0.306$ , 95% confidence, and power of the test was considered 90%. The sample size was 88, and 2 more people were added. The group studied was composed of 90 people (57 nurses, 25 nursing interns, and 13 physicians). The participants were chosen through simple random sampling, stratified by health center.

For data collection, two instruments were used: a test administered as a structured survey to measure knowledge, and a checklist to measure the skills of the staff.

The knowledge test contained 30; it was designed especially for the study and was directly applied by the researcher to the staff in each health center; questions and was applied deliberately, based on the guidelines of the Official Mexican Standard (Norma Oficial Mexicana-NOM-014-SSA2-1994, for the prevention, detection, diagnosis, treatment, control and epidemiological surveillance of cervical cancer) and the procedure manuals for obtaining HPV or papillomavirus samples.<sup>(13,14)</sup> This knowledge test had four sections: 1) general information of the participant, 2) knowledge about the Official Mexican Standard (Norma Oficial Mexicana-

NOM), 3) knowledge about cervical anatomy, 4) fundamental aspects of HPV and basic knowledge about obtaining samples.

The health personnel whose function was to obtain samples for the identification of papillomavirus DNA, and who signed the informed consent, were included in the study. We excluded people who did not agree to participate, and those who were absent when the instruments were administered. The criterion for elimination was an omission of >10% of the answers. No instrument was removed.

Knowledge was rated in a quantitative way according to the number of correct and incorrect answers. An evaluation code was assigned: 1 = correct answer, and 0 = incorrect answer; with this, the total score was obtained and the average knowledge of each group studied was calculated. The test was validated by experts in the field (pathologists and cytologists). Statistical reliability was determined by means of Cronbach's Alpha (0.78).

To evaluate the skills of the personnel in the sample collection, a validated instrument was administered, which is a checklist to evaluate the skills for obtaining the original cervical cytologies of Gutiérrez-Enríquez, designed in 2009, (Cronbach's Alpha of 0.83).<sup>(12)</sup> For the present study, the validated instrument was adapted with specific questions for the sampling of HPV DNA, since the sample for the identification of papillomavirus was obtained with the technique called "directed", which is very similar to the sample taken for conventional cervical cytology; this adaptation was again validated by experts in molecular biology, cytology, and pathology. It included 5 sections and 43 items. We considered the 5 steps that must be executed in chronological order for sample taking: 1) receiving the user, 2) making of records, 3) preparation of material, 4) user preparation, 5) conducting the technique. The evaluation code was as follows: procedure not performed = 0, procedure performed partially = 1, and procedure performed completely = 2; total possible points was 86.

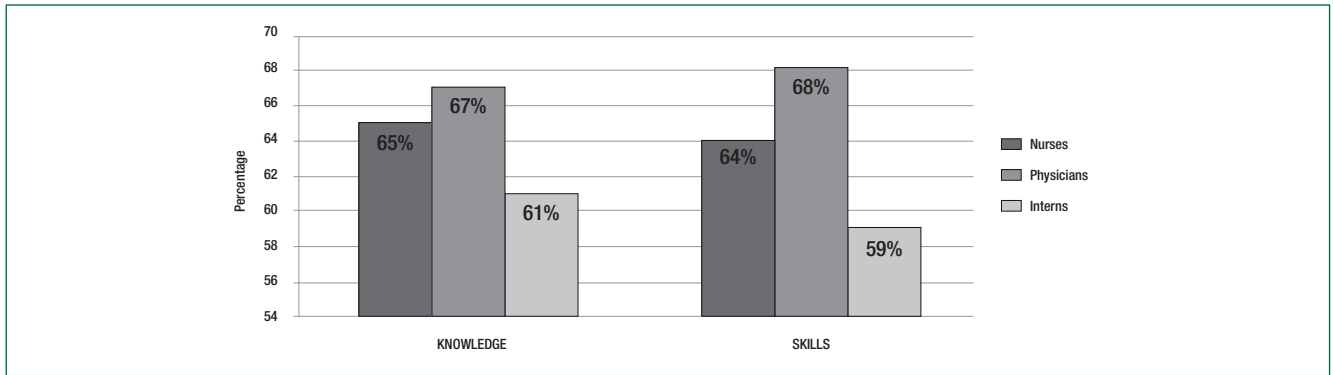
The data was processed using the statistical program, IBM SPSS Statistics, v.24. Descriptive sta-

tistics were applied to the sociodemographic data of the participants. To establish the correlation between the variables studied (knowledge and skills), Pearson's linear correlation was used. A confidence level of 95% was used. To compare the means obtained by each subgroup (physicians, nurses, and nursing interns), the one-way ANOVA test was used.

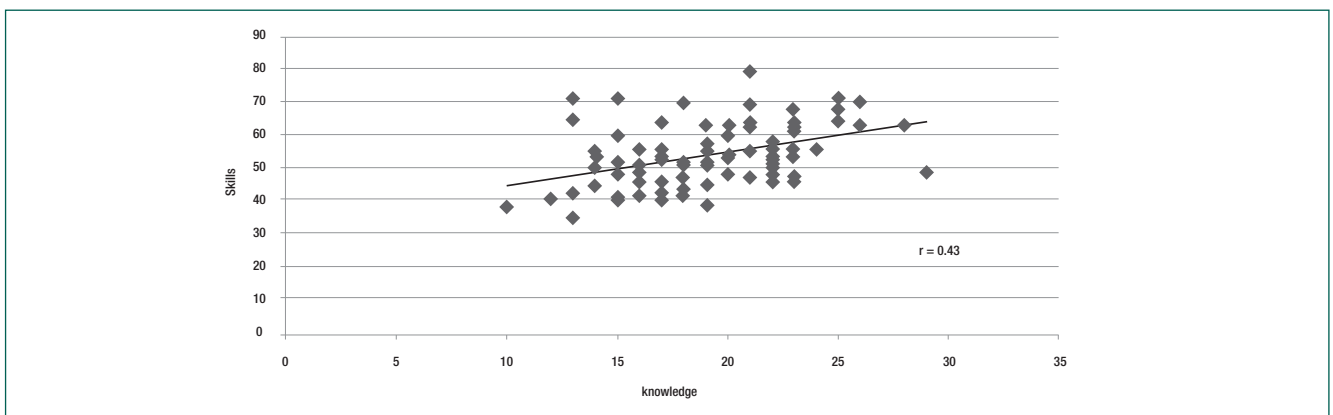
For the execution of this study, the legal dispositions in matter of investigation promulgated by the General Law of Investigation in Health of Mexico were considered, along with the ethical principles stipulated in the Declaration of Helsinki.<sup>(15,16)</sup> All participants signed the Terms of Free & Informed Consent. The Project was approved by the Ethics and Research Committee of the Faculty of Nursing and Nutrition of Autonomic University of de San Luis Potosí, with registration number: CEIFE 2016-189, and by the Ethics and Research Committee of the Health Jurisdiction No 1 of the Health Services of San Luis Potosí, with State registration number: SLP/008-2017.

## Results

Regarding sociodemographic characteristics, most of the participants were in the age group of 21 to 40 years, with a minimum value of 18 and a maximum of 60. The largest percentage was female. The average age was 35.3 years. The predominant participants were nurses with 58%; interns accounted for 28%, and physicians for 14%. Seventy-six percent held a bachelor's degree, and 6% held a graduate degree. In the working characteristics, we found that the majority held the position of general nurse; 48% were working between 1 and 10 years, while 31% had worked less than one year. Figure 1 shows a comparison between knowledge and skills. The medical staff obtained the highest average in knowledge (67%), and the interns obtained the lowest (61%). In the skills of performing the sampling technique, the medical staff again obtained the highest percentage (68%), in comparison to the other two groups.



**Figure 1.** Percentages obtained by health personnel regarding knowledge and skills in obtaining samples for identification of papillomavirus DNA. S.L.P (n=90)



**Figure 2.** Relationship between knowledge and skills in sample taking for identification of papillomavirus DNA by health personnel. S.L.P (n=90)

**Table 1.** Comparison of means obtained in knowledge and technical skills in obtaining samples for identification of papillomavirus DNA, according to the profession of health personnel, S.L.P

Topical	Groups	Mean	Standard deviation	Comparison between groups	Difference in means	p-value*
Skills	Nurses	63.7	11.3	Nurses vs Interns	4.5	0.179
	Physicians	68.0	11.4	Physicians vs Nurses	4.3	0.388
	Interns	59.2	7.6	Physicians vs Interns	8.8	0.041**
Knowledge	Nurses	64.7	14.5	Nurses vs Interns	3.3	0.557
	Physicians	66.9	12.9	Physicians vs Nurses	2.2	0.852
	Interns	61.5	9.2	Physicians vs Interns	5.5	0.441

\* ANOVA; \*\* Difference significant

When making an inter-group comparison between knowledge and the practical skills needed to perform the HPV test, it is observed that there were no significant differences in knowledge between the three groups; however, in skills, differences were

identified between the physicians and interns (8.81,  $p=0.041$ ) (Table 1).

Figure 2 shows the correlation between the level of knowledge and skills in the sampling technique for the identification of papillomavirus DNA ( $r=0.438$ ,  $p<0.001$ ). The type of correlation is positive, which indicates that when the score for the skills increases, it does for knowledge, as well.

## Discussion

The Food and Drug Administration of the United States of America (FDA) approved, in 1999, the use of a test to identify HPV DNA, called Digene Hybrid Capture 2 (HC2). It is used for CC screening, and is effective in identifying women who are at risk for developing the disease more accurately. This test has important advantages, such as the ease of taking the sample, as well as greater sensitivity



to identify precursor lesions; in addition, coverage can be improved in areas of difficult access to health services. Thus, the use of new technologies for detection, such as the HPV test, needs to be implemented within the framework of an effective organization of the health services that offer it. A fundamental pillar is the education and adequate training of the health personnel that executes these technologies, where the central axis of the training is the standardization of sampling, and the adherence to official norms of each institution to achieve a successful implementation.<sup>(14)</sup>

In this study, the personnel that most frequently obtains the HPV samples is the nurse; according to Pulido et al., there are many barriers to the prevention and early detection of the CC, but it is identified that the educational activities conducted by professional nurses play a decisive role in identifying and meeting the needs of women.<sup>(17)</sup> Similar results were observed in a study conducted in Ecuador, in 2016, where it was mentioned that in health organizations, this function is delegated to the nursing staff which represents the highest percentage of human resources in these institutions, and which is closer to the users of the program. It is also said that their performance influences the participation of women in screening strategies.<sup>(18)</sup> It is for this reason that the exercise of the nursing profession is fundamental in health services throughout the world.

In the present study, the percentages obtained in knowledge and skills were between 59% and 68%, which indicates that more training is needed for the implementation of this type of screening. A study conducted by Deaza et al., in 2017, indicates that it is essential to incorporate teaching strategies in educational institutions that train human resources for health, so that they incorporate into their curricula the specific competencies for the prevention and early detection of cancer, seeking to have the knowledge and skills required to respond to the needs of users of health services.<sup>(19)</sup> Other authors, such as Machado and Santamarina, also mention the importance of the activities of physicians and nurses in primary care, since by achieving high coverage and ensuring a quality sample, we can aspire to reduce the mortality rate by 20% for this disease.<sup>(20,21)</sup>

In this study, the main deficiencies that were identified in the studied knowledge variable were the following: ignoring basic aspects of Mexican official standards, the usefulness of the HPV test, indications or requirements for performing the test on women, type of users to which it is directed, difficulty in recognizing the main genotypes of HPV associated with precancerous lesions, and the post-test orientation that health personnel should give to women; these results support the findings of some studies related to the performance of students or health service providers, where it is mentioned that in order to perform early detection of cancer, the following aspects should be reinforced: improving the skills of conducting the Papanicolaou tests, training on clinical guidelines, management of care protocols, as well as the adoption of applied methodologies from higher education, such as using problem-solving and problem-based learning as learning strategies.<sup>(22,23)</sup>

Regarding the skills or abilities of the health personnel, the majority performed the procedure in an appropriate manner; however, it was observed that non-standardized techniques were used for sampling, different from what was indicated in the technical standards and procedure manuals by the Mexican Health Services.<sup>(13,14)</sup> The central technique, or the fundamental step for the collection of the HPV sample, is the rotation of the cervical brush (360° to the right and 360° to the left), in order to collect the largest amount of cells in the transformation zone (the junctional location between the endocervical and exocervical epithelium, where neoplastic lesions develop most frequently), and thus ensure that the sample collected is considered quality for further analysis in the laboratory. Other failures identified were that not all service providers perform gynecological assessment completely before sampling, (exploration of the particular characteristics of patients, such as age and gynecological-obstetric history), as well as adequate therapeutic communication, specifically in the instructions that are given to the user before, during and after the HPV test; therefore, it is necessary to provide women with more information about the importance of the following aspects: early detec-

tion, risk factors, forms of prevention, monitoring of their detection in the time determined by health professionals, attending to their results in a timely manner, guiding the meaning of possible outcomes, as well as mechanisms of medical reference if the test is positive.

The proposed hypothesis was verified by determining that there is a correlation between knowledge and the sampling skills for the identification of HPV DNA, since the result indicates that if the level of knowledge that the staff member has regarding the theory increases, the level of technical skills when performing the procedure will increase. This means that if the staff is properly trained on specific topics (such as technical standards, adherence to procedural manuals, knowledge about the anatomy of the female genital tract, epidemiology aspects of HPV, interpretation of results to provide guidance to users) and are also trained in the practice of a standardized technique for sample collection, it is expected that the performance will be optimal.

The nursing staff has contributed significantly to the well-being of the population in all areas of work; success lies in the adequate transfer of theoretical knowledge learned to a practical execution.<sup>(24,25)</sup> Supervision and evaluation are also fundamental aspects to ensuring quality in the provision of health services; organizations have the responsibility of having strategic plans to increase the performance of their workers, so that the dissatisfaction of the patients is diminished. Cardenas et al., in their study on the satisfaction of health services and impact on the quality of life of adult patients, state that the main complaints occurred where: they were not given their diagnostic test results in a timely manner, the treatment received from the staff due to lack of communication skills, as well as the insecurity and uncertainty they felt about the resolution of their condition. Therefore, it is important to follow a plan for continuous improvement for the implementation of these priority programs in health, and mainly for the timely detection of cancer in women.<sup>(26)</sup>

The main limitations of this study were the following: provision of time by health personnel to answer the survey due to saturation of activities, as

well as the low level of awareness among managers of health institutions to evaluate their workers. For future studies we suggest increasing the sample size and conducting educational interventions to evaluate the skills and knowledge with study and control groups, as well as design training programs with “*blended learning*” or “*online learning*” methodologies or by means of “*Problem Based Learning*” in such a way that an increase in the performance of the participants is possible to be observed.

## Conclusion

There is a correlation between the knowledge and skills of the health personnel regarding sampling for the identification of papillomavirus DNA. There were no significant differences in the knowledge of physicians, nurses, and interns complying with the Early Detection of Cervical Cancer program, but a difference was found in the skills between physicians and interns. The skills in sampling in general are not standardized, so it is important to improve adherence to official standards and technical manuals authorized by health institutions.

## Collaborations

Terán-Figueroa Y, Gutiérrez-Enríquez SO, Jiménez-Bolaños S and Gaytán-Hernández D contributed with the project and data interpretation, the writing of the article, the critical review of the intellectual content, and with the final approval of the version to be published.

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