National Health and Nutrition Examination Survey

2015-2016 Data Documentation, Codebook, and Frequencies

Human Papillomavirus (HPV) DNA - Vaginal Swab: Roche Cobas High-Risk (HPVSWC_I)

Data File: HPVSWC_I.xpt

First Published: November 2018

Last Revised: NA

Component Description

Human papillomavirus (HPV) infection is one of the most common sexually transmitted infections in the United States. Cervical infection with certain types of HPV is a major risk factor for cervical cancer in women. The “high-risk” types of HPV (e.g., HPV 16, 18) are associated with cervical cancer as well as other anogenital cancers, and the “low-risk” types of HPV (e.g., HPV 6, 11) with genital warts. No national surveillance system exists to measure the full burden of HPV infection, and no reliable national population estimate of HPV exists. NHANES offers a unique opportunity to assess the prevalence of HPV infection in the general population.

Reducing the prevalence of HPV infection is a Developmental Healthy People 2010 objective: “Reducing the number of new HPV cases can help minimize the overall number of cases of high risk subtypes associated with cervical cancer in females...” Detection and typing of HPV DNA in vaginal swabs will allow evaluation of trends in prevalence of type-specific HPV infection by age, sexual behavior, and race/ethnicity. Three HPV vaccines (Gardasil, Gardasil 9, and Cervarix) are licensed and recommended for use in females. Two vaccines are licensed and recommended for use in males (Gardasil and Gardasil 9). In mid-2006, the Advisory Committee on Immunizations (ACIP) recommended routine vaccination of females aged 11 or 12 years and for those 13-26 years not previously vaccinated. In December 2011, ACIP recommended routine vaccination of males aged 11 or 12 years and for those aged 13 through 21 years not previously vaccinated. As a vaccine becomes more widely used, the national prevalence of HPV infection will be critical for evaluating vaccination strategies in the United States.

Eligible Sample

Examined female participants aged 14-59 years were eligible. This public data file includes data for examined participants aged 18 to 59 years. Please see *Analytic Notes* about the release of data for adolescents aged 14-17 years.

Description of Laboratory Methodology

DNA extraction was performed with a modified protocol and the commercial QIAamp kit (Qiagen, 2003). Presence of high-risk HPV in the extracted participant DNA is determined with the Cobas Human Papillomavirus (HPV) test. This qualitative in-vitro diagnostics test uses oligonucleotide probes labeled with four different fluorescent dyes. The primers target a DNA region of approximately 200 nucleotides within the polymorphic L1 region of the HPV genome to detect 14 high-risk HPV types (16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66 and 68) in a single analysis. The test reported concurrently the presence of one or more of these types at clinically relevant infection levels, however the test was modified from the FDA approved format (sample type and extraction) and results cannot be used clinically. Refer to the

Laboratory Method Files section for a detailed description of the laboratory methods used.

Laboratory Method Files

HPV Vaginal Swab Cobas High Risk Laboratory Procedure Manual (November 2018)

Laboratory Quality Assurance and Monitoring

Vaginal swab samples were processed, stored, and shipped to the Chronic Viral Diseases Branch, Division of High-Consequence Pathogens and Pathology, National Center for Emerging and Zoonotic Infectious Diseases, Centers for Disease Control and Prevention, Atlanta, GA for analysis.

Detailed instructions on specimen collection and processing are discussed in the NHANES Laboratory Procedures Manual (LPM). Swabs were stored at room temperature until they were shipped to the National Center for Emerging and Zoonotic Infectious Diseases for testing.

Detailed QA/QC instructions are discussed in the NHANES LPM.

Mobile Examination Centers (MECs)

Laboratory team performance is monitored using several techniques. NCHS and contract consultants use a structured competency assessment evaluation during visits to evaluate both the quality of the laboratory work and the quality-control procedures. Each laboratory staff member is observed for equipment operation, specimen collection and preparation; testing procedures and constructive feedback are given to each staff member. Formal retraining sessions are conducted annually to ensure that required skill levels were maintained.

Analytical Laboratories

NHANES uses several methods to monitor the quality of the analyses performed by the contract laboratories. In the MEC, these methods include performing blind split samples collected on “dry run” sessions. In addition, contract laboratories randomly perform repeat testing on 2% of all specimens.

Progress reports containing any problems encountered during shipping or receipt of specimens, summary statistics for each control pool, QC graphs, instrument calibration, reagents, and any special considerations are submitted to NCHS quarterly. The reports are reviewed for trends or shifts in the data. The laboratories are required to explain any identified areas of concern.

Data Processing and Editing

The data were reviewed. Incomplete data or improbable values were sent to the performing laboratory for confirmation.

Analytic Notes

Refer to the 2015-2016 Laboratory Data Overview for general information on NHANES laboratory data.

Sample Weights

MEC exam sample weights should be used for analyses.

Demographic and Other Related Variables

The analysis of NHANES laboratory data must be conducted using the appropriate survey design and demographic variables. The NHANES 2015-2016 Demographics File contains demographic data, health indicators, and other related information collected during household interviews as well as the sample design variables. The recommended procedure for variance

estimation requires use of stratum and PSU variables (SDMVSTRA and SDMVPSU, respectively) in the demographic data file.

This laboratory data file can be linked to the other NHANES data files using the unique survey participant identifier (i.e., SEQN).

The Questionnaire data files contain socio-economic data, health indicators, and other related information collected during household interviews. Certain sensitive data on participants under 18 years of age (e.g., HPV typing results, sexual behavior variables) are not included in the public use files. These data may be requested as described in the NHANES guidelines.

The public release data file includes HPV vaginal swab data for participants aged 18-59. HPV vaginal swab data for youth aged 14-17 years are available through the NCHS Research Data Center (RDC).

Roche Cobas HPV DNA Test

The Roche Cobas HPV test is qualitative and only determines the presence or absence of high-risk HPV. If any analyte (HPV 16, HPV 18, or Other High-risk HPV) is indicated as positive (POS) in the Cobas result file, the result for the sample ID will be recorded as positive. If all of the HPV analytes are negative (NEG) in the Cobas result file the result for the sample ID will be recorded as negative. If any of the analytes are indicated as invalid in the Cobas result file, the DNA from that sample will be re-tested one time to obtain valid results. If the repeated result is still invalid, the final result will be recorded as inadequate (Cobas Operator's Manual, 2009).

Detection Limits

If data is qualitative, the use of lower limits of detection (LLODs) is not applicable.

Please refer to the NHANES Analytic Guidelines and the on-line NHANES Tutorial for further details on the use of sample weights and other analytic issues.

References

- Centers for Disease Control and Prevention. FDA licensure of quadrivalent human papillomavirus vaccine (HPV4, Gardasil) for use in males and guidance from the Advisory Committee on Immunization Practices (ACIP). MMWR 2010; 59:630–2.
- Centers for Disease Control and Prevention. (2018). Healthy People 2010. Retrieved from https://www.cdc.gov/nchs/healthy_people/hp2010.htm
- Cobas 4800 system Operator's Manual Software Version 1.0, 2009, Roche Diagnostics Ltd.
- QIAamp DNA Mini Kit Handbook, Version Date February 2003. QIAGEN Corp.

Codebook and Frequencies

SEQN - Respondent sequence number

Variable Name:	SEQN
SAS Label:	Respondent sequence number
English Text:	Respondent sequence number.
Target:	Females only 18 YEARS - 59 YEARS

LBXHP2C - Cobas HPV Swab High Risk

Variable Name: LBXHP2C

SAS Label: Cobas HPV Swab High Risk

English Text: Cobas HPV Swab High Risk

Target: Females only 18 YEARS - 59 YEARS

binary

Code or Value	Value Description	Count	Cumulative	Skip to Item
1	Positive	359	359	
2	Negative	1475	1834	
3	Inadequate	38	1872	
.	Missing	192	2064	