

Attachment D1

National Health and Nutrition Examination Survey (NHANES) Vaccination Provider Record Check Pilot Description

Vaccination Provider Verification Pilot

Eligibility: All NHANES participants 14 to 29 years old are eligible. The maximum number of respondents would be 275. The maximum number of respondents' providers would be 550.

Informed Consent: Standard NHANES consenting and assenting procedures performed as part of the NHANES household interview will be followed. For the provider record check, participants will be given two handouts (Appendix I and J) describing the provider record check. Verbal permission to obtain vaccination records from health care providers will be obtained (Attachment D1, Question PRQ.001) in addition to written authorization. Additionally, participants will be asked to give permission to link the vaccination records obtained from health care providers to NHANES data (Attachment D1, Question PRQ.002).

Authorization

HIPAA compliant authorization will be obtained from participants providing the individual's signed permission to allow the identified providers to disclose the individual's protected health information (PHI) to NHANES (Appendix B). The authorization will be obtained during the time of the NHANES household interview.

Exclusion Criteria: There are no exclusion criteria other than target group age.

Justification for Using Vulnerable Populations

Minors are included in the study because children as young as 9 years old are approved for HPV vaccination and HPV vaccination is routinely recommended for girls and boys aged 11 or 12 years. There is no reason to exclude mentally impaired persons, handicapped individuals or pregnant women from participation, if eligible.

Data Collection: The methods proposed for this pilot study are based on those that are used by National Immunization Survey (NIS)/ NIS-Teen. The steps are described below.

1. Questions will be added to the NHANES household survey immunization section to obtain contact information for participant's health care providers.

2. Participants (or parents and guardians) must provide authorization to access vaccination records from providers.
3. Vaccination providers, including, but not limited to hospitals, clinics, and medical offices shall be contacted to obtain vaccination status and detailed vaccination history for those who were vaccinated.
4. Provider Record Check (PRC) will be performed by a contractor. Providers will first be asked to complete a questionnaire by mail. If necessary, providers may receive a reminder postcard, a follow-up letter, and/or a telephone call. Completed questionnaires will be entered into a database. At the end of the data collection process, the contractor will provide all provider data files to NCHS.

Report of Findings: There are no findings to report.

Appendices

[Appendix A: Existing HPV questions in the vaccination questionnaire](#)

Appendix A

Existing HPV questions in the vaccination questionnaire

BOX 3

CHECK ITEM IMQ.050:

IF SP = FEMALE AND AGE IS >= 9 AND <= 59, CONTINUE.

IF SP = MALE AND AGE IS >= 9 AND <= 59, GO TO IMQ.070.

OTHERWISE, GO TO END OF SECTION.

IMQ.060 Human Papillomavirus (HPV) vaccine is given to prevent cervical cancer in girls and women. The HPV vaccines available are called Cervarix, Gardasil or Gardasil 9. It is given in 3 separate doses over a 6 month period. {Have you/Has SP} **ever** received one or more doses of the HPV vaccine?

- YES..... 1 (IMQ.080)
- NO..... 2 (END OF SECTION)
- REFUSED..... 7 (END OF SECTION)
- DON'T KNOW..... 9 (END OF SECTION)

IMQ.070 Human Papillomavirus (HPV) vaccine is given to prevent HPV infection and genital warts in boys and men. It is given in 3 separate doses over a 6 month period. {Have you/Has SP} **ever** received one or more doses of the HPV vaccine? (The brand name for the vaccine is Gardasil or Gardasil 9)

- YES..... 1 (IMQ.090)
- NO..... 2 (END OF SECTION)
- REFUSED..... 7 (END OF SECTION)
- DON'T KNOW..... 9 (END OF SECTION)

IMQ.080 Which of the HPV vaccines did {you/SP} receive, Cervarix, Gardasil or Gardasil 9?
INTERVIEWER INSTRUCTION: DO NOT READ. CODE ALL THAT APPLY.

- CERVARIX..... 1
- GARDASIL 2
- GARDASIL 9.....3
- GARDASIL (NOT SURE WHICH ONE)..... 4
- REFUSED..... 7
- DON'T KNOW WHICH VACCINE..... 9

IMQ.090 How old {were you/was SP} when {you/SP} received your first dose of {Cervarix/Gardasil/Gardasil 9/Gardasil or Gardasil 9/the vaccine}?

HARD EDIT: IF AGE SP RECEIVED FIRST DOSE IS GREATER THAN SP'S CURRENT AGE, DISPLAY "AGE SP RECEIVED FIRST DOSE CANNOT EXCEED SP'S CURRENT AGE."

SOFT EDIT: IF DIFFERENCE BETWEEN SP'S CURRENT AGE AND AGE SP RECEIVED FIRST DOSE IS MORE THAN TEN YEARS, DISPLAY "UNLIKELY RESPONSE AS HPV VACCINES WERE NOT AVAILABLE AT THAT TIME. PLEASE CONFIRM AGE SP RECEIVED FIRST DOSE."

ENTER AGE IN YEARS

REFUSED..... 7
DON'T KNOW..... 9

CAPI INSTRUCTION:

IF SP = MALE, THEN FILL GARDASIL OR GARDASIL 9

IF IMQ.080 = 1, DISPLAY "Cervarix"; IF IMQ.080 = 2 , DISPLAY "Gardasil"; IF IMQ.080 = 3, DISPLAY "Gardasil 9"; IF IMQ.080 = 4, DISPLAY "GARDASIL OR GARDASIL 9";; ELSE DISPLAY "the vaccine".

IF MORE THAN ONE VACCINE WAS SELECTED, THEN DISPLAY "the vaccine".

IF MORE THAN ONE VACCINE WAS REPORTED AND SP ASKS WHICH VACCINE SHOULD THE AGE BE REPORTED FOR, INSTRUCT SP TO PROVIDE AGE OF FIRST VACCINE GIVEN

IMQ.100 How many doses of {Cervarix/Gardasil/Gardasil 9/Gardasil or Gardasil 9/the vaccine} {have you/has SP} received?

1 DOSE..... 1
2 DOSES..... 2
3 DOSES..... 3
REFUSED..... 7
DON'T KNOW..... 9

CAPI INSTRUCTION:

IF SP = MALE, THEN FILL GARDASIL OR GARDASIL 9

IF IMQ.080 = 1, DISPLAY "Cervarix"; IF IMQ.080 = 2, DISPLAY "Gardasil"; IF IMQ.080 = 3, DISPLAY "Gardasil 9"; IF IMQ.080 = 4, DISPLAY "GARDASIL OR GARDASIL 9"; ELSE DISPLAY "the vaccine".

IF MORE THAN ONE VACCINE WAS SELECTED, THEN DISPLAY "the vaccine".

IF MORE THAN ONE VACCINE WAS REPORTED AND SP ASKS WHICH VACCINE SHOULD THE DOSES BE REPORTED FOR, INSTRUCT SP TO PROVIDE DOSES PROVIDED OF THE FIRST VACCINE GIVEN

Appendix B
HIPAA AUTHORIZATION FOR DISCLOSURE

NATIONAL HEALTH AND NUTRITION EXAMINATION SURVEY (NHANES)
HIPAA AUTHORIZATION FOR DISCLOSURE OF HEALTH INFORMATION
(for the pilot study, this will be printed on legal size paper)

If you sign this document, you give permission to your health care providers to release your health information that identifies you to the National Health and Nutrition Examination Survey (NHANES). NHANES is conducted by the National Center for Health Statistics (NCHS), which is part of the Centers for Disease Control and Prevention (CDC).

Under the Health Insurance Portability and Accountability Act of 1996 (HIPAA), with your permission, your health care provider can release your vaccination records to NCHS and/or its contractor. The purpose of collecting vaccination records from your health care providers is to help better understand illnesses that can be prevented by vaccinations. Your vaccination records will be used to supplement the interview and exam data obtained in NHANES.

Health care providers are required by law to protect your health information under HIPAA. By signing this document, you authorize your health care providers to release your vaccination records for this research. Once your information is released to the study, it is no longer covered by HIPAA but is covered by the Public Health Service Act, which prohibits the release of information that would identify you or your medical providers outside of NCHS and its contractors without your permission or that of your medical providers. By contacting the health care providers you tell us about, your health care providers will know you took part in NHANES. We will tell your health care providers that they should not use this knowledge to obtain additional information about you through the released NHANES data or by using the NHANES data to link to other databases. We will inform your health care providers that any effort to identify you in the NHANES data is prohibited by the Public Service Act.

Please note that you do not have to sign this Authorization. You will not lose any benefits if you say no. You may change your mind and revoke (take back) this Authorization at any time, except to the extent that your health care provider(s) have already acted based on this Authorization. To revoke this Authorization, you may call: Dr. Kathryn Porter at 1-800-452-6115 with the National Center for Health Statistics. Or you may contact her by mail at 3311 Toledo Rd., Hyattsville, MD 20782. This authorization expires 30 months from the date of signature.

PARENT OR GUARDIAN OF SURVEY PARTICIPANT WHO IS UNDER 18 YEARS OLD:

For the Parent or Guardian of the Survey Participant who is a minor (unless the participant is an emancipated minor

I authorize and request that my child's health care providers release my child's health information to the National Center for Health Statistics.

Signature of parent/guardian

Date

Appendix C

Provider Record Check Questionnaire

BOX 1

CHECK ITEM PRQ.005:

IF SP AGE IS >= 14 AND <= 29, CONTINUE.
OTHERWISE, GO TO END OF SECTION.

PRQ.001 Next, we would like to ask you for the name and contact information for all health care providers, including doctors, medical offices, health clinics, hospitals, and pharmacies or drug stores, where {you/SP} may have received vaccinations. We would also like to contact the health care providers you tell us about to ask them for {your/SP's} vaccination records. The purpose of collecting vaccination records from {your/his/her} health care providers is to help better understand illnesses that can be prevented by vaccinations.

Before we contact the health care providers you tell us about, we will ask you to sign a document giving authorization for {your/SP's} health care providers to give us {your/his/her} vaccination records. Your participation is voluntary.

INTERVIEWER: REVIEW HIPAA AUTHORIZATION FOR DISCLOSURE OF HEALTH INFORMATION FORM, ABOUT THE VACCINATION PROVIDER RECORD CHECK, AND QUESTIONS AND ANSWERS FOR THE VACCINATION PROVIDER RECORD CHECK.

Do we have your permission to obtain vaccination records from {your/SP's} health care providers?

- YES..... 1
- NO.....2 (END OF SECTION)
- DON'T KNOW.....9 (END OF SECTION)

PRQ.002 RESPONDENT MUST SIGN THE HIPAA AUTHORIZATION FOR DISCLOSURE OF HEALTH INFORMATION FORM BEFORE THE INTERVIEW CAN CONTINUE.

HAS RESPONDENT SIGNED THE AUTHORIZATION FORM?

- YES..... 1
- NO.....2 (END OF SECTION)

PRQ.003 To do additional health research, we would like to link the vaccination records we obtain from {your/SP's} health care providers to {your/his/her} other NHANES data. May we link {your/SP's} vaccination records we obtain from {your/his/her} health care providers to {your/his/her} other NHANES data?

- YES..... 1
- NO.....2 (END OF SECTION)
- DON'T KNOW.....9 (END OF SECTION)

PRQ.010 G/Q Since 2006, or since {you were/SP was} **X** years old (**calculate X as age in years in 2016 minus 10 years**), how many locations have provided vaccinations for {you/SP}? Please include hospitals, school and workplace clinics, juvenile detention centers, emergency rooms, pharmacies or drug stores, and any other clinics or doctor's offices that have provided vaccinations.

G/Q

ENTER NUMBER OF VACCINE PROVIDERS..... 1
 Zero (0)..... 0 (PRQ.020)
 REFUSED..... 77 (END OF SECTION)
 DON'T KNOW..... 99 (PRQ.020)

ENTER NUMBER OF VACCINE PROVIDERS (PRQ.030)

PRQ.020 G/Q Since 2006, or since {you were/SP was} **X** years old (**calculate X as age in years in 2016 minus 10 years**), how many locations have provided **primary health care** for {you/SP}? Please include the health care settings such as clinics or doctor's offices that have seen {you/him/her} for primary health care. Primary health care includes family practice doctors, internists, pediatricians, OB/GYNs, and general practitioners.

ENTER NUMBER OF PROVIDERS..... 1
 Zero (0)..... 0 (END OF SECTION)
 REFUSED..... 77 (END OF SECTION)
 DON'T KNOW..... 99 (END OF SECTION)

ENTER NUMBER OF PROVIDERS (PRQ.040)

PRQ.030 {Before getting started on reporting the names and contact information for locations that have provided vaccinations for {you/SP}, would you take a moment to find shot records, appointment cards, or other records you may have?

We will start with the most recent location.} What is the last name of the (first/next) doctor?

INTERVIEWER INSTRUCTION: VERIFY SPELLING.

ENTER PROVIDER NAME..... 1
 REFUSED..... 77
 DON'T KNOW..... 99 (PRQ.060)

PRQ.031 LAST NAME #1: _____

PRQ.032 LAST NAME #2: _____ (PRQ.050)

CAP I INSTRUCTION: ALLOW LAST NAME #2 TO BE BLANK/NULL
 IF REFUSED FIRST PROVIDER, GO TO END OF SECTION.
 IF REFUSED SUBSEQUENT PROVIDERS, GO TO PRQ.140.
 DISPLAY TEXT IN { } FOR FIRST PROVIDER. SUBSEQUENT PROVIDERS, DO NOT DISPLAY.

PRQ.040 {Before getting started on reporting the names and contact information for (your/SP's) primary health care providers, would you take a moment to find shot records, appointment cards, or other records you may have?

We will start with the most recent location. What is the last name of the (first/next) doctor?

INTERVIEWER INSTRUCTION: VERIFY SPELLING.

ENTER PROVIDER NAME..... 1
REFUSED..... 77 (END OF SECTION)
DON'T KNOW..... 99 (PRQ.060)

PRQ.041 LAST NAME #1: _____

PRQ.042 LAST NAME #2: _____ (PRQ.050)

CAPI INSTRUCTION: ALLOW LAST NAME #2 TO BE BLANK/NULL
IF REFUSED FIRST PROVIDER, GO TO END OF SECTION.
IF REFUSED SUBSEQUENT PROVIDERS, GO TO PRQ.140.
DISPLAY TEXT IN { } FOR FIRST PROVIDER. SUBSEQUENT PROVIDERS, DO NOT DISPLAY.

PRQ.050 What is the doctor's first name?

INTERVIEWER INSTRUCTION: VERIFY SPELLING.

ENTER DOCTOR'S FIRST NAME..... 1
REFUSED..... 77 (PRQ.060)
DON'T KNOW..... 99 (PRQ.060)

FIRST NAME: _____

PRQ.060 Please tell me the name of the office, clinic, or other location.

ENTER OFFICE OR CLINIC NAME
REFUSED..... 77 (PRQ.070)
DON'T KNOW..... 99 (PRQ.070)

PRQ.070 What is the street address of the office, clinic, or other location?

a. ENTER STREET NUMBER

b. ENTER STREET NAME

REFUSED..... 7
DON'T KNOW..... 9

REFUSED..... 7
DON'T KNOW..... 9

PRQ.080 Is there a suite, floor or room number?

ENTER SUITE, FLOOR OR ROOM NUMBER

REFUSED..... 77 (PRQ.090)
DON'T KNOW..... 99 (PRQ.090)

CAPI INSTRUCTION: ALLOW SUITE, FLOOR OR ROOM NUMBER TO BE BLANK.

PRQ.090 What is the zip code?

ENTER ZIP CODE

REFUSED..... 77 (PRQ.100)
DON'T KNOW..... 99 (PRQ.100)

PRQ.100 What city is that in?

ENTER CITY

REFUSED..... 77 (PRQ.110)
DON'T KNOW..... 99 (PRQ.110)

PRQ.110 What state is that in?

|_|_|

ENTER TWO LETTER STATE ABBREVIATION TO START THE LOOKUP.
SELECT STATE FROM CAPI STATE LIST. PRESS ENTER TO ACCEPT
THE SELECTION.

SELECTION REFUSED..... 77 (PRQ.120)
DON'T KNOW..... 99 (PRQ.120)

CAPI INSTRUCTION:

DISPLAY FIPS STATE LIST. INTERVIEWER SHOULD ONLY BE ABLE TO SELECT 1 STATE FROM THE LIST. DON'T KNOW AND REFUSED SHOULD BE VALID OPTIONS. THE STATE LOOKUP IN THE SP AND FAMILY QUESTIONNAIRES SHOULD WORK EXACTLY THE SAME. SAVE STATE LOOKUP NAME AS PRQ.112 AND STATE FIPS LOOKUP CODE AS PRQ.115.

PRQ.120 What is their telephone number?

_	_ _ _ - _ _ _ _	_ _ _ _
PRQ.120	PRQ.121	PRQ.122
ENTER AREA CODE	ENTER TELEPHONE NUMBER	ENTER EXTENSION

REFUSED..... 777 (PRQ.130)	REFUSED.....7777777	REFUSED..... 7777
DON'T KNOW..... 999 (PRQ.130)	DON'T KNOW..... 9999	DON'T KNOW..... 9999

PRQ.130 ARE THERE ANY OTHER HEALTH CARE PROVIDERS?

OR ASK RESPONDENT:
(Are there any other health care providers?)

YES.....	1
NO.....	2
REFUSED.....	77
DON'T KNOW.....	99

CAPI INSTRUCTION:
SOFT EDIT: IF NUMBER OF PROVIDERS ENTERED DOES NOT EQUAL PRQ.010 OR PRQ.020, DISPLAY "Earlier you said you had seen {x} providers but we have entered information for {x}. Is that correct?"

BOX 2

CHECK ITEM PRQ.135:
ASK PRQ.030 – PRQ.120 FOR NEXT PROVIDER (CODE 1 IN PRQ.130). IF NO, DK OR RF NEXT PROVIDER (CODE 2, DK, RF IN PRQ.130), CONTINUE WITH PRQ.140.

PRQ.140 REVIEW TOTAL NUMBER OF PROVIDERS AND THEIR CONTACT INFORMATION WITH RESPONDENT.

I have listed {TOTAL NUMBER} health care provider{s} for {you/SP}: {PROVIDER(S) NAME AND ADDRESS}

PRESS ENTER TO CONTINUE.

CAPI INSTRUCTION:
DISPLAY NUMBER OF PROVIDERS FROM PRQ.010 OR PRQ.020. DISPLAY NUMBER ON SCREEN.
DISPLAY LIST OF PROVIDER NAMES AND CONTACT INFORMATION FROM PRQ.030-PRQ.120.
DISPLAY PROVIDER NAMES AND CONTACT INFORMATION ON SCREEN.

Appendix D

Cover Letter

SAMPLE LETTER FROM DIRECTOR, NATIONAL CENTER FOR HEALTH STATISTICS

The National Center for Health Statistics, a part of the Centers for Disease Control and Prevention, conducts the National Health and Nutrition Examination Survey (NHANES) to measure progress towards meeting health and nutrition goals in the United States. This survey collects and reports on a variety of health topics, including obesity, exposure to second hand smoke, diabetes, and seroprevalence of infectious diseases.

Human Papillomavirus (HPV) vaginal, oral, and penile specimens and self-reported history of HPV vaccination are also collected in the survey. To supplement the self-reported reports of vaccination collected by in-person interviews, we are requesting information on HPV vaccinations given by medical providers, as part of a special study. The HPV vaccine data will be used in conjunction with HPV specimens to estimate vaccine effectiveness and also to identify populations that may be inadequately protected from HPV. For some persons, meningococcal and tetanus, diphtheria, and pertussis (Tdap) vaccines may be given at approximately the same time as HPV vaccine, therefore, we are also asking for information on these vaccines. The protected health information requested is the minimum necessary to accomplish the objectives of the study.

The named person(s) agreed to participate in this study. HIPAA Authorization for disclosure of vaccination histories was obtained. Enclosed is a copy of the form(s) used to document authorization to disclose information from their vaccination record(s). We would appreciate the completion of the enclosed Vaccination History Questionnaire(s) for the named person(s) whether or not you were the provider of the vaccinations.

This study is authorized by the Public Health Service Act. The information you supply will be treated confidentially, as specified by law. The information will be used for statistical purposes only; no information that could identify you, your practice, your facility, the participant, or the participant's family will be released. By completing the requested vaccination form, you will have received knowledge of the participant's enrollment in the NHANES study, which was done with the participant's consent. You should not use this knowledge to obtain additional information about the participant through the released NHANES data or by using the NHANES data to link to other databases. Any effort to determine the identity of any reported case is prohibited by this law. If you inadvertently discover the identify of a participant in the NHANES data files, please advise the Director, NCHS, of any such discovery (301-458-4500). Although your participation is voluntary, we hope that you will choose to participate.

You may participate by completing the enclosed questionnaire(s) and faxing or mailing it in the enclosed prepaid envelope with the vaccination information. As these medical documents are confidential, if sending a fax please take extra care to dial the correct toll-free fax number. Mail or fax to:

National Health and Nutrition Examination Survey
c/o Westat
1600 Research Blvd. Room RA 1116
Rockville, MD 20850
FAX: (XXX) XXX-XXXX

You may also provide the vaccination information using an on-line questionnaire, available at: <http://www.cdc.gov/nchs/nhanes/hlthprofess.htm>. Click on the picture that looks like a vaccine. You will be connected to another site where you will enter your login and password before you answer the questions. To complete the questions by on-line questionnaire, you will use your unique Login and Password.

Your Login is: xxxxxx

Your Password is: xxxxxx

In developing this package, efforts have been made to consolidate multiple requests for vaccination records for persons in your practice. However, as the survey collects information continuously, you may receive additional requests for vaccination information on other persons for whom you provide medical care.

If you have any questions or comments about the enclosed material, or the records being requested, please call 1-888-458-4762. If you would like additional information about the National Health and Nutrition Examination Survey, please call Dr. Kathryn Porter at 1-800-452-6115. You can also contact her by mail at: 3311 Toledo Rd., Hyattsville, MD 20782. Your participation in the study is greatly appreciated.

Sincerely yours,

Charles J. Rothwell, MBA, MS
Director, National Center for Health Statistics

Enclosures:

Roster of Vaccination History Questionnaires and issued Vaccination History Questionnaire(s)
(for each participant)

Documentation of authorization to disclose health information (for each participant)

Frequently asked questions about vaccination surveys

NHANES Brochure

Business Reply Envelope

Appendix E

Vaccination history questionnaire (for providers)

NEW1 Which of the following best describes your immunization records for this individual?

YOU HAVE ALL OR PARTIAL IMMUNIZATION RECORDS FOR THIS INDIVIDUAL FOR VACCINES GIVEN BY YOUR PRACTICE OR OTHER PRACTICES..... 1 (NEW2)

YOU HAVE PROVIDED CARE TO THIS INDIVIDUAL, BUT DO NOT HAVE IMMUNIZATION RECORDS 2 (NEW21)

YOU HAVE NO RECORD OF PROVIDING CARE TO THIS INDIVIDUAL..... 3 (NEW21)

NEW2 Was any of the immunization information for this individual obtained from your community or state registry?

YES..... 1
NO 2
DON'T KNOW 3

NEW3 According to your records, what is this individual's date of birth?

ENTER BIRTHDATE (MM/DD/YYYY)

DON'T KNOW999

NEW4 What was the date of this individual's first visit, for any reason, to this place of practice?

ENTER DATE (MM/DD/YYYY)

DON'T KNOW999

NEW5 What was the date of this individual's most recent visit, for any reason, to this place of practice?

ENTER DATE (MM/DD/YYYY)

DON'T KNOW999

NEW6 Enter date of the Tdap vaccine received at age 11 years or older

ENTER DATE (MM/DD/YYYY)

NEW7 Was this Tdap vaccine given by another practice?

YES..... 1
NO 2

NEW8 Enter date of the first meningococcal conjugate vaccine (serogroups ACWY: Menactra® or Menveo®)

ENTER DATE (MM/DD/YYYY)

NEW9 Was the first meningococcal conjugate vaccine given by another practice?

YES..... 1
NO 2

NEW10 Enter date of the second meningococcal conjugate vaccine (serogroups ACWY: Menactra® or Menveo®)

ENTER DATE (MM/DD/YYYY)

NEW11 Was the second meningococcal conjugate vaccine given by another practice?

YES..... 1
NO 2

NEW12 Enter date of the first human papillomavirus (HPV) vaccine

ENTER DATE (MM/DD/YYYY)

NEW13 Was the first HPV vaccine given by another practice?

YES..... 1
NO 2

NEW14 Was this vaccine Gardasil® (4vHPV), Gardasil® 9 (9vHPV), or Cervarix® (2vHPV)?

Gardasil® (4vHPV)..... 1
Gardasil® 9 (9vHPV) 2
Cervarix® (2vHPV)..... 3

NEW15 Enter date of the second human papillomavirus (HPV) vaccine

ENTER DATE (MM/DD/YYYY)

NEW16 Was the second HPV vaccine given by another practice?

YES..... 1
NO 2

NEW17 Was this vaccine Gardasil® (4vHPV), Gardasil® 9 (9vHPV), or Cervarix® (2vHPV)?

Gardasil® (4vHPV)..... 1
Gardasil® 9 (9vHPV) 2
Cervarix® (2vHPV)..... 3

NEW18 Enter date of the third human papillomavirus (HPV) vaccine

ENTER DATE (MM/DD/YYYY)

NEW19 Was the third HPV vaccine given by another practice?

YES..... 1
NO 2

NEW20 Was this vaccine Gardasil® (4vHPV), Gardasil® 9 (9vHPV), or Cervarix® (2vHPV)?

Gardasil® (4vHPV)..... 1 (END)
Gardasil® 9 (9vHPV)..... 2 (END)
Cervarix® (2vHPV)..... 3 (END)

NEW21 Which of the following describes this facility?

- PRIVATE PRACTICE, SOLO..... 1
- PRIVATE PRACTICE, GROUP..... 2
- PRIVATE PRACTICE, HEALTH MAINTANCE ORGANIZATION (HMO)..... 3
- HOSPITAL-BASED CLINIC, INCLUDING UNIVERSITY CLINIC, OR RESIDENCY TEACHING PRACTICE..... 4
- PUBLIC HEALTH DEPARTMENT-OPERATED CLINIC..... 5
- COMMUNITY HEALTH CENTER..... 6
- RURAL HEALTH CLINIC..... 7
- MIGRANT HEALTH CENTER..... 8
- INDIAN HEALTH SERVICE (IHS)-OPERATED CENTER, TRIBAL HEALTH FACILITY, OR URBAN INDIAN HEALTH CARE FACILITY... 9
- MILITARY HEALTH CARE FACILITY (ARMY, NAVY, AIR FORCE, MARINES, COASTGUARD)..... 10
- WIC CLINIC..... 11
- SCHOOL BASED HEALTH CENTER..... 12
- PHARMACY..... 13
- NON-MEDICAL FACILITY THAT HOSTED A VACCINATION CLINIC RUN BY THE HEALTH DEPARTMENT OR OTHER SPONSOR..... 14
- OTHER 15

NEW22 Which of the following best describe the main specialties of this facility?

(MAY CHOOSE MORE THAN ONE)

- PEDIATRICS..... 1
- FAMILY PRACTICE..... 2
- GENERAL PRACTICE..... 3
- INTERNAL MEDICINE..... 4
- OB/GYN..... 5
- OTHER..... 6

NEW23 Enter contact name for the person returning this form

ENTER NAME

NEW24 Title for the person returning this form

- PHYSICIAN..... 1
- NURSE..... 2
- OFFICE MANAGER/RECEPTIONIST..... 3
- MEDICAL RECORDS ADMINISTRATOR/
TECHNICIAN..... 4
- OTHER..... 5

NEW25 Enter contact phone number for the person returning this form

ENTER PHONE NUMBER (XXX/XXX/XXXX)

NEW26 Enter contact fax number for the person returning this form

ENTER FAX NUMBER (XXX/XXX/XXXX)

Appendix F

Frequently asked questions about vaccination surveys

Frequently Asked Questions about Surveys of Vaccination Providers

Q: Why does the NHANES request information from vaccination providers?

A: Sources of vaccination information from doctors and clinics are the most up-to-date and comprehensive, and more importantly, the quality of the study's results is much improved by combining the information given by participants with that given by the vaccination providers. It is important that we obtain the most reliable information possible about vaccinations so that we can provide the public with reliable information.

Q: Is it necessary to fill out the entire questionnaire?

A: If you prefer, you may attach a photocopy of the participant's vaccination history to the questionnaire and just complete the items on the first page.

Q: Am I required to provide the NHANES with this participant's vaccination history?

A: Your participation is voluntary. We hope that you will choose to participate.

Q: What do I do if this participant is not my patient or if I have no vaccination records for this child?

A: The first item on the front page of the questionnaire (see below) allows you to indicate this. Please check the appropriate option and return the questionnaire so that we do not send you a second request for the information.

Which of the following best describes your vaccination records for this participant?

- You have all or partial vaccination records for this participant.
- You have provided care to this participant, but do not have vaccination records.
- You have no record of providing care to this participant.

Q: How do I return the Vaccination History Questionnaire?

A: A pre-paid, addressed envelope was included in the packet of materials along with the request for information about the participant's vaccinations. If you do not have the envelope, the address is:

National Health and Nutrition Examination Survey
c/o Westat
1600 Research Blvd. Room RA 1116
Rockville, MD 20850

If it is more convenient, you may fax the information to our toll-free number: 1-800-XXX-XXXX. Or you may respond via internet at

<http://www.cdc.gov/nchs/nhanes/hlthprofess.htm> and choose the picture of a vaccine.

To complete the questionnaire using the web-based option, you will need your unique login and password, which was mailed to you with the initial mailing.

Q: Is there someone I can talk with about the NHANES Vaccination Provider Record Check Study?

A: If you have any questions or comments about the materials being requested, please call Westat at: 1-888-458-4762. Someone will be available to answer the call from 9 AM to 4:30 PM Eastern Standard Time.

Q: Under what legal authority do you collect this information?

A: This study is authorized under Section 306 and 308 of the Public Health Service Act (42 USC Secs.242k and 242m). The National Center for Health Statistics and the contractor must treat the information you supply confidentially and can only use the information for statistical purposes, as specified by law in the Public Health Service Act. Information that could identify you, your practice, your facility, the participant, or the participant's family will not be released.

Q: What is the HIPAA Privacy Rule?

A: The HIPAA Privacy Rule establishes national standards to protect individuals' protected health information. Additional sources of information about the HIPAA Privacy Rule is available at <http://www.hhs.gov/ocr/hipaa/> and <http://www.cdc.gov/mmwr/preview/mmwrhtml/m2e411a1.htm>.

Q: What is protected health information?

A: Protected health information includes all medical records and other individually identifiable information used or disclosed by an entity subject to the HIPAA Privacy Rule. This would include directly identifiable information such as patient names or social security numbers.

Q: Is my participation in this study permitted by the HIPAA Privacy Rule?

A: The Privacy Rule permits covered entities, including health care providers, to use or disclose protected health information for research purposes when a research participant authorizes the use or disclosure of information about him or herself. For this study, we asked participants to sign a written authorization allowing for their health care providers to use or disclose their vaccination records.

Q: What does the HIPAA Privacy Rule require me to do if I participate?

A: Health care providers must ensure they have a copy of the written authorization signed by each participant. By law (45 CFR 164.508), all authorizations must be in plain language and must contain specific elements, including specific information regarding the information to be disclosed or used; the person(s) or classes of persons disclosing and receiving the information; expiration and right to revoke in writing. Written authorization meeting the requirement was sent to health care providers in the original

mailing and the document is entitled “HIPAA Authorization for Disclosure of Health Information.”

Q: Are there additional participant (patient) confidentiality considerations?

When asking permission from NHANES participants to contact vaccination providers, the participants were told that this would inform their vaccination providers that they had participated in NHANES. Some of the providers contacted to provide vaccination records for this study may also be users of the NHANES data files. Users of the NHANES data files, including health care providers asked to provide vaccination records, are instructed to: 1) Use the data in these data files for statistical reporting and analysis only; 2) Not link these data files with individually identifiable data from other NCHS or non-NCHS data files; and 3) Make no use of the identity of any person or establishment discovered inadvertently and advise the Director, NCHS, of any such discovery (301-458-4500). Any effort to determine the identity of any reported case in the NHANES study is prohibited by the Public Health Service Act (Section 308 (d)).

Q: Do I have to have an Institutional Review Board (IRB) review this research project?

A: No. For research projects, only one IRB must review the project. The NCHS Ethics Review Board, or ERB, has the authority to review such projects under the Regulations for the Protection of Human Subjects and has done so. Your IRB may review the project as well and may also verify that the documentation we have provided adheres to the requirements of the Regulations for the Protection of Human Subjects and the HIPAA Privacy Rule. Please feel free to call the NCHS Ethics Review Board at the toll-free number 1-800-223-8118 if you have any questions.

Q: Where do I get more information?

A: For information about the Vaccination History Questionnaire: Call our survey contractor, Westat, toll -free at 1-888-458-4762.

For NHANES information:

See “About NHANES” at: http://www.cdc.gov/nchs/nhanes/about_nhanes.htm

For information about NHANES human subjects and confidentiality protection: Call the Research Ethics Review Board at the toll-free number 1-800-223-8118.

For information on vaccinations: Visit CDC’s vaccine website at:

<http://www.cdc.gov/vaccines/default.htm>.

Your participation in the National Health and Nutrition Examination Survey is greatly appreciated.

Appendix G

NHANES Brochure



National Health and Nutrition Examination Survey, 2015–2016

Overview



Introduction

The National Health and Nutrition Examination Survey (NHANES) is a program of studies designed to assess the health and nutritional status of adults and children in the United States. The survey is unique in that it combines interviews and physical examinations. NHANES is a major program of the National Center for Health Statistics (NCHS). NCHS is part of the Centers for Disease Control and Prevention (CDC) and has the responsibility for producing vital and health statistics for the Nation.

The NHANES program began in the early 1960s and has been conducted as a series of surveys focusing on different population groups or health topics. In 1999, the survey became a continuous program that has a changing focus on a variety of health and nutrition measurements to meet emerging needs. The survey examines a nationally representative sample of about 5,000 persons each year. These persons are located in counties across the country, 15 of which are visited each year.

The NHANES interview includes demographic, socioeconomic, dietary, and health-related questions. The examination component consists of medical, dental, and physiological measurements, as well as laboratory tests administered by highly trained medical personnel.

Findings from this survey will be used to determine the prevalence of major diseases and risk factors for diseases. Information will be used to assess nutritional status and its association with health promotion and disease prevention. NHANES findings are also the basis for national standards for such measurements as height, weight, and blood pressure. Data from this survey will be used in epidemiological studies and health sciences

research, which help develop sound public health policy, direct and design health programs and services, and expand the health knowledge for the Nation.

Survey Content

As in past health examination surveys, data will be collected on the prevalence of chronic conditions in the population. Estimates for previously undiagnosed conditions, as well as those known to and reported by respondents, are produced through the survey. Such information is a particular strength of the NHANES program.

Risk factors, those aspects of a person's lifestyle, constitution, heredity, or environment that may increase the chances of developing a certain disease or condition, will be examined. Smoking, alcohol consumption, sexual practices, drug use, physical fitness and activity, weight, and dietary intake will be studied. Data on certain aspects of reproductive health, such as use of oral contraceptives and breastfeeding practices, will also be collected.

The diseases, medical conditions, and health indicators to be studied include:

- Anemia
- Body composition
- Cardiovascular disease
- Diabetes
- Environmental exposures
- Infectious diseases
- Kidney disease
- Nutrition
- Obesity
- Oral health
- Physical activity and physical functioning

- Reproductive history and sexual behavior
- Respiratory disease (asthma, chronic bronchitis, emphysema)
- Sexually transmitted diseases

The sample for the survey is selected to represent the U.S. population of all ages. To produce reliable statistics, NHANES over-samples persons 60 and over, African Americans, Asians, and Hispanics.

Since the United States has experienced dramatic growth in the number of older people during this century, the aging population has major implications for health care needs, public policy, and research priorities. NCHS is working with public health agencies to increase the knowledge of the health status of older Americans. NHANES has a primary role in this endeavor.

All participants visit the physician. Dietary interviews and body measurements are included for everyone. All but the very young have a blood sample taken and will see the dentist. Depending upon the age of the participant, the rest of the examination includes tests and procedures to assess the various aspects of health listed above. In general, the older the individual, the more extensive the examination.

Survey Operations

Health interviews are conducted in respondents' homes. Health measurements are performed in specially designed and equipped mobile centers, which travel to locations throughout the country. The study team consists of a physician, a dentist, medical and health technicians, as well as dietary and health interviewers. Many of the study staff are bilingual (English/Spanish).

An advanced computer system using high-end servers, desktop PCs, and wide-area networking collect and process all of the NHANES data,

nearly eliminating the need for paper forms and manual coding operations. This system allows interviewers to use notebook computers with electronic pens. The staff at the mobile center can automatically transmit data into databases through such devices as digital scales and stadiometers. Touch-sensitive computer screens let respondents enter their own responses to certain sensitive questions in complete privacy. Survey information is available to NCHS staff within 24 hours of collection, which enhances the capability of collecting quality data and increases the speed with which results are released to the public.

In each location, local health and government officials are notified of the upcoming survey. Households in the study area receive a letter from the NCHS Director to introduce the survey. Local media may feature stories about the survey.

NHANES is designed to facilitate and encourage participation. Transportation is provided to and from the mobile center if necessary. Participants receive compensation and a report of medical findings is given to each participant. All information collected in the survey is kept strictly confidential. Privacy is protected by public laws.



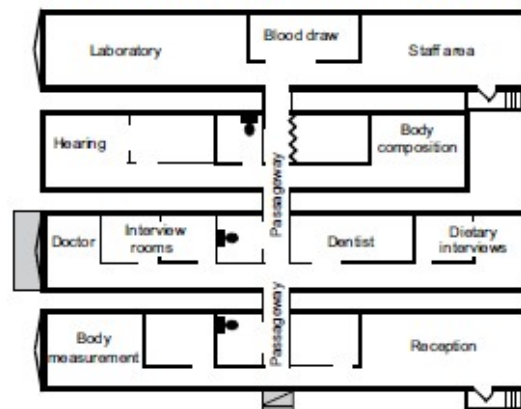
Uses of the Data

Information from NHANES is made available through an extensive series of publications and articles in scientific and technical journals. For data users and researchers throughout the world, survey data are available on the internet.

Research organizations, universities, health care providers, and educators benefit from survey information. Primary data users are federal agencies that collaborated in the design and development of the survey. The National Institutes of Health, the Food and Drug Administration, and CDC are among the agencies that rely upon NHANES to provide data essential for the implementation and evaluation of program activities. The U.S. Department of Agriculture and NCHS cooperate in planning and reporting dietary and nutrition information from the survey. NHANES' partnership with the U.S.

Environmental Protection Agency allows continued study of the many important environmental influences on our health.

Mobile examination center diagram



NHANES' record of important accomplishments is made possible by the thousands of Americans who have participated.

- Past surveys have provided data to create the growth charts used nationally by pediatricians to evaluate children's growth. The charts have been adapted and adopted worldwide as a reference standard—and have recently been updated using the latest NHANES figures.
- Blood lead data were instrumental in developing policy to eliminate lead from gasoline and in food and soft drink cans. Recent survey data indicate the policy has been even more effective than originally envisioned, with a decline in elevated blood lead levels of more than 70% since the 1970s.
- Overweight prevalence figures have led to the proliferation of programs emphasizing diet and exercise, stimulated additional research, and provided a means to track trends in obesity.
- Data have continued to indicate that undiagnosed diabetes is a significant problem in the United States. Efforts by government and private agencies to increase public awareness, especially among minority populations, have been intensified.

These are just a few examples of how survey findings have been used. The current program promises continuing contributions and some new initiatives.

- Information collected in this survey will help the Food and Drug Administration decide if there is a need to change vitamin and mineral fortification regulations for the Nation's food supply.
- National programs to reduce hypertension and cholesterol levels continue to depend on NHANES data to steer education and

prevention programs toward those at risk and to measure success in curtailing risk factors associated with heart disease, the Nation's number one cause of death.

Because NHANES is now an ongoing program, the information collected contributes to annual estimates in topic areas included in the survey. For small population groups and less prevalent conditions and diseases, data must be accumulated over several years to provide adequate estimates. The new continuous design also allows increased flexibility in survey content.

Results of NHANES benefit people in the United States in important ways. Facts about the distribution of health problems and risk factors in the population give researchers important clues to the causes of disease. Information collected from the current survey is compared with information collected in previous surveys. This allows health planners to detect the extent various health problems and risk factors have changed in the U.S. population over time. By identifying the health care needs of the population, government agencies and private sector organizations can establish policies and plan research, education, and health promotion programs that help improve present health status and will prevent future health problems.

For more information about the National Center for Health Statistics, contact:

National Center for Health Statistics
Information Dissemination Staff
3311 Toledo Road, Room 5412
Hyattsville, MD 20782

Telephone: 1-800-232-4636

E-mail: cdcinfo@cdc.gov

Internet: <http://www.cdc.gov/nchs>

For more information about the National Health and Nutrition Examination Survey you may visit the NHANES web site at: <http://www.cdc.gov/nhanes>.

Appendix H

Reminder postcard

Text:

Dear health care provider,

Two weeks ago, you should have received a request to participate in the National Health and Nutrition Examination Survey's provider record check of vaccinations. It was sent to your address as part of our effort to collect the most accurate vaccination data possible.

Although your participation is voluntary, we hope that you will choose to participate in the study. If you have already responded, please accept our sincere thanks. There is no need to provide your answers again. If you have not responded, please provide your information as soon as possible.

If you have any questions about completing your questionnaire, please call 1-888-458-4762.

Thank you.

Charles J. Rothwell, MBA, MS, Director, National Center for Health Statistics

Attachment I

ABOUT THE VACCINATION PROVIDER RECORD CHECK

ABOUT THE VACCINATION PROVIDER RECORD CHECK BACKGROUND

The National Health and Nutrition Examination Survey (NHANES) is conducting a provider record check to obtain more information about the vaccines you received from your health care providers. We hope to better understand illnesses that can be prevented by vaccines, such as human papillomavirus (HPV), a disease that can cause cancer.

INFORMATION COLLECTED FROM PARTICIPANTS

We will ask you for the name and contact information for all health care providers, including doctors, medical offices, health clinics, hospitals, and pharmacies or drug stores, where you may have received vaccines.

INFORMATION COLLECTED FROM HEALTH CARE PROVIDERS

We will ask health care providers about the following vaccines:

- Human papillomavirus (HPV)
- Meningococcal
- Tetanus, diphtheria, and pertussis (Tdap)

We will ask your health care provider to return a form telling us the type of vaccine, dates, and location the HPV vaccines were given. Information on the meningococcal and Tdap vaccines will be used to help us know that we have a complete vaccine record for you and we will only ask about dates and location these vaccines were given.

We will give your health care provider the option to return a printed copy of your vaccination record, which may include information about other vaccines we did not ask about.

We will also ask health care providers to tell us:

- Information about their facility, including the main specialty (for example, family practice, internal medicine, pediatrics, or OB/GYN).
- Dates of your first and last visit to the facility. This information will help us know if your vaccination record is complete by telling us if there are missing time periods.

INFORMATION WE WILL SHARE WITH YOUR HEALTH CARE PROVIDERS

By contacting the health care providers you tell us about, your health care providers will know you are a participant in NHANES. We will tell your health care providers that they should not use this knowledge to obtain additional information about you through the released NHANES data or by using the NHANES data to link to other databases. We will also inform your health care providers that any effort to determine your identity using the NHANES data is prohibited by the Public Health Service Act.

We will share your name, gender, and date of birth with your health care provider to help them complete the form we send. We will also ask them to confirm this information. We will not share other information from this survey with your health care provider.

Appendix I

**Questions and answers for the vaccination provider record
check**

QUESTIONS AND ANSWERS FOR THE VACCINATION PROVIDER RECORD CHECK

Q Why is the vaccination provider record check important?

A We will use the data gathered in the study to help us better understand illnesses that can be prevented by vaccinations. We will look at your vaccination history data and the other data you provide in the survey to help us learn how well vaccines work. NHANES data will also tell us about the number of people who have had vaccinations. Research from this study will provide valuable information for the public health community, health care providers, and doctors.

Q Why do you need to contact my health care providers?

A To have the same type of information for everyone, we need to contact health care providers directly. We also ask health care providers a few questions about their practice or clinic, so that we can accept only forms filled out by health care providers.

Q Will my information be kept private?

A We respect your privacy. We will contact only the health care providers you tell us about. As a result, the health care providers we contact will know you are a NHANES participant. We will give your health care providers your name, gender, and date of birth but no other information. We will ask your health care provider to return a form telling us the type of vaccine, dates, and location the vaccines were given.

Q What if I have more questions about the survey in the future?

A In the future, if you have questions about NHANES, the vaccination provider record check, or if you change your mind and want to take back permission, please call us toll-free at 1-800-452-6115. Dr. Kathryn Porter of the U.S. Public Health Service is available to discuss any aspect of the survey. She can be reached at 1-800-452-6115, Monday-Friday, 8:30 a.m.-6:00 p.m. EST. You can also get answers to your questions by mail (3311 Toledo Rd., Hyattsville, MD 20782).